The Only Planet Guide
to the Secrets of Chemicals Policy in the EU

# REACH

## What Happened and Why?

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## REACH - What Happened and Why?

When raindrops, breast milk and human blood as a rule contain hazardous chemicals, something has gone wrong. Since 1998 the EU has been developing a chemicals policy to increase the safety of human health and the environment. However, the new policy is increasingly focusing on protection of the chemicals industry. How did this happen? Who made it happen? And most of all, *why* did it happen?

The Only Planet Guide to the Secrets of Chemicals Policy in the EU is a guide to help politicians, media and citizens navigate in this complex world.

**REACH - The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why?**
Brussels, April 2004

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This book would not have been possible without the help of a few persons. First of all, Axel Singhofen, Joe DiGangi, Stefan Scheuer and Michael Warhurst who supplied endless flows of information. Miles Goldstick has been invaluable in providing technical support and linguistic guidance. The International Chemical Secretariat supplied crucial contacts, knowledge and electronics. Tor Hauksson and Jarkko Nordlund found the right pictures. Last but not least: Hanne and Filippa. Many thanks to all of you and to all the other persons who have contributed in different ways.

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Page 2, Ms Schörling: Joe Formgren
Page 4, Mr Lind: Filippa Adolfsson

This is an Internet-version of the original book. Some photos have been removed but the text is identical.

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Said about REACH:

*“The potential damage to the global economy, our employees and communities in which we operate, and yes, our shareholders, is enormous.”*

- Greg Lebedev, American
Chemistry Council, April 2003

*“It will create a win-win situation for industry, workers and citizens and our ecosy*

- Margot Wallström,
EU Commissioner, October 2003

*“The proposed REACH is a shadow of the original plans”*

- European Environment Bureau,
December 2003

# This Book

**The Only Planet**

Over the past years, the EU has been shaping a new chemicals policy: Registration, Evaluation and Authorisation of CHemicals (REACH). I became the Rapporteur for the "White Paper - Strategy for a future Chemicals Policy" of the European Parliament in 2001 and I have travelled with REACH since then. It has been an exciting journey, a new world in itself to discover. I have learned a lot, not only about chemicals, but also about power, money, and tactics. I have met nice and committed people in the Commission, Parliament and industry. I have met charming lobbyists but also not so nice dinosaurs from the chemicals industry. In October 2003, the Commission presented the proposal for a new regulation. The proposal will now be debated by the newly elected Parliament and then the Parliament and Council will jointly decide on the regulation. It is an important and huge task which covers a multitude of sectors and issues.

The things I experienced in the REACH process were so interesting, but also so upsetting, that I wanted to share them with others that have an interest in politics and health and environmental issues. Thus, I decided to publish the REACH story. With the input of others the project grew and developed into this book, "The Only Planet Guide to the Secrets of Chemicals Policy in the EU."

Earth is the only planet known to be suitable for human habitation. We share this home with other living creatures and it should be the home of countless generations to come. All of us, and those not yet born, are dependent on the global ecosystem to survive. It is a closed system, and if we risk disrupting or destroying it, we threaten ourselves.

Many chemicals greatly benefit our daily lives and our health. However, many are also extremely dangerous. Some man-made chemicals do not disappear once they are released. They circulate and sooner or later show up in the atmosphere, oceans, plants and in the bodies of humans and other animals. The long-term effects are uncertain, but there is damage and there is reason to believe that the damage is more far-reaching than we understand today. A great risk is being taken.

Commissioner Margot Wallström is one of those that has been fighting hard for the creation of a comprehensive and strong EU chemicals policy and regulation. In 2003, she participated in a bio-monitoring survey conducted by WWF. Scientists took samples of her blood and looked for some chemicals that shouldn't be there. Out of the 77 man-made chemicals analysed, the laboratory found 28 of them in her body, for example PCB and certain brominated flame-retardants. I have recently gone through a similar test and am waiting for the results. I expect to have the same chemicals in my blood, a result that most people in our generation would get.

Inger Schörling has been a Member of the European Parliament since 1995. Inger was one of the founders of the Green Party in Sweden and the first Green groupleader in the Swedish Parliament 1988-91. She was also Vice President for the Greens in the European Parliament 1997-99.

In March 2004, a Greenpeace study showed that ordinary house dust, collected from the European Parliament and from my own home in Brussels, contains phthalates, alkylphenols, brominated flame retardants, organotins and short-chain chlorinated paraffins. These are hazardous chemicals that can cause cancer, damage the immune system, and affect reproductive health and/or cause disruption to the endocrine system. Unfortunately, these chemicals may be found in every home as they appear in everyday consumer products. In my everyday life, I try to buy environmentally friendly products, but there is no way of knowing everything that is in the all products we buy.

The environment, and especially chemical threats, are important, and people are worried. According to the Eurobarometer survey from 2003, 93 percent of European citizens believed that chemicals have a negative impact on their health. Some severe accidents in the chemicals industry, as in Bhopal, Seveso and Toulouse, stay in peoples minds. People worry about the exposure to chemicals in their daily environment and life. People wonder what is in the water they drink, the food they eat, the air they breath, and the milk they give to children?

This means politicians in the EU have a special responsibility. Member State governments, the European Parliament and national parliaments must take peoples' concerns seriously, and not just to create public trust. They must also take the warnings by scientists seriously. It's real.

The only reasonable goal is to make the environment free from dangerous man-made chemicals and to try to keep the levels of metals close to natural levels. When there is risk, the precautionary principle should be used. This means that the chemicals industry also has a special responsibility. They should stop producing persistent and bioaccumulating chemicals and try to find alternatives.

Finally, I want to thank a few people. Gunnar Lind, the author, made this book possible. He applied his great knowledge and enthusiasm, and handled a lot of material within a tight time frame. Special thanks also to Axel Singhofen, the excellent and passionate adviser for the Green/EFA group on chemicals and my saviour and guide. I would also like to thank everyone in the Green/European Free Alliance group in the European Parliament for their support.

Brussels and Gävle
March 2004

Inger Schörling
Member of the European Parliament

# The Author

**Gunnar Lind**

Born in Sundsvall, a city in northern Sweden, at the time also known as the most polluted city north of Hamburg, Gunnar grew up in the USA, Mexico and Stockholm. After working with marketing for ten years, he grew sick of promoting and selling useless products and making a living on consumerism. He dropped out and joined the environmental movement in Sweden in 1993, initially working as a fundraiser. As he learned the issues, he became increasingly involved in campaigns and was soon a senior campaigner for Greenpeace. He spent the next ten years reading reports, writing press releases and background information sheets, chaining himself to suitable objects and speaking to industry, politicians and the media. He started out working with the nuclear power issue, the also worked on other issues: forests, ocean ecology, genetically manipulated organisms, climate change and toxics. After spending four months in Southeast Asia, he became addicted to Lonely Planet Guides. He is now a freelancer.

## How to use this Guide

Travelling in an unfamiliar environment can be difficult. A new culture and language can turn your world upside-down. To get properly oriented in a new context, there are numerous customs, places and faces to remember, and names and words that need to be learned. Without help, an exciting new experience may turn into a nightmare. Many people who travel to new places use guidebooks. They are indispensable for navigating in a new environment. Given the time, it is possible to prepare by reading them beforehand, avoiding unnecessary confusion or mishaps. On arrival in the new surroundings, they can be kept easy at hand, making it possible to quickly find facts or hints of interest in a specific situation. A good guidebook lets you find the facts with the flick of a finger.

Over the past five years, the EU has been working on a proposal for a new chemicals regulation, called REACH. It is an important and huge task which covers a multitude of sectors and issues. The proposed new regulation was presented in October 2003 and it will be debated and developed by the European Parliament and Council over the next years.

REACH concerns all of us, but to most people it is a new world. To help those interested in navigating this fascinating place we have produced a travel guide, *The Only Planet Guide to the Secrets of Chemicals Policy in the EU*. You can either read it in the same way as you read an ordinary book, starting at the beginning and reading to the end. Or you can use it like a traveller would use a guidebook, reading here and there, finding facts and background information when you need them or when you have the time to browse.

The guide consists of three parts. The first part, *Chemicals*, covers the background, facts about the chemicals industry, the occurrence of chemicals in the environment and finally what effects these chemicals have or what concerns are being voiced about them. The second part, *Politics*, describes international chemicals policies, the current EU regulations, the political intentions behind REACH and how the initial ideas and draft regulations were watered down. The third part, *Behind the Scenes,* is an inside view that describes the aggressive lobbying campaign against REACH conducted by the chemicals industry and some governments.

An attempt has been made to cover the most important parts of the REACH process in this book. However, it is not possible to cover everything. There are always streets, buildings and alleys that are not mentioned. This is also true for this guide.

The scope of the information covered for this guide is large. Hundreds of documents containing tens of thousands of pages and a myriad of details have been examined. Prior to publishing, the text has been reviewed by experts in different sectors. Nevertheless, there may still be inaccuracies. If any are found, please send them to the publisher.

# CONTENTS

## PART TWO: POLITICS

# Foreword

**By Joseph DiGangi**

For many of us, the words “synthetic chemicals” bring to mind far-off smokestacks or the smell of a pungent factory. They seem distant and not immediately threatening -- a nuisance or a bit of an eyesore. If synthetic chemicals seem remote, then policies that regulate them seem even more removed. Why should we be interested in either one? More to the point, why should we read a travel guide that takes us on a journey to this destination?

Actually, “The Only Planet Guide” takes us on a trip right into our homes and our bodies. Instead of far-away plumes of smoke, we can encounter synthetic chemicals when we rock our babies, relax on our sofas, watch TV, or enjoy a delicious dinner. All of us have an intimate relationship with synthetic chemicals, whether we want to or not – chemicals that invisibly surround us in our products, our air, our water, food and land – chemicals that are getting into our bodies, even if we try to avoid them.

Every day routines, even those that focus on clean living, bring the unexpected consequences of chemicals in our bodies. Some of these chemicals come from consumer products. Others linger from substances such as DDT and PCBs that seemed like great ideas decades ago. We didn’t intend to ingest them like medicine, and few of us would grant permission for them to be in our bodies, if we had the choice.

Once we acknowledge our proximity to synthetic chemicals, a common-sense assumption emerges: these things are safe, right? This question goes to the heart of policies that regulate chemicals. The “Only Planet Guide” explores this question on a European tour that draws us into a struggle with global implications.

This book tells the story of a landmark proposal to regulate synthetic chemicals, called Registration, Evaluation, and Authorization of Chemicals, or REACH for short. The story begins on a drizzly day in 1998 in Chester, UK, at a meeting of the Council of Environment Ministers. This gathering raised serious questions about the effectiveness of existing laws governing chemicals. Did the laws assure the safety of the public? How well did they work? The disappointing answers provoked an effort to improve the laws to match the expectations of the citizenry. REACH appeared on the horizon.

The ideas about reforming chemical policy were made concrete in the White Paper in 2001 and “The Only Planet Guide” offers a detailed account of its ideals and its fate. With sustainable development at its heart, REACH rested on the precautionary principle as a fundamental route to achieving its goal of responsible chemical management and control that protects public health. This placed it directly at odds with US-style regulation and incurred the wrath of the US chemical industry.

To respond to the White Paper, the US chemical industry has engaged four US government agencies to wage an aggressive campaign to weaken and defeat the proposal. Secretary of State, Colin Powell, sends cables to US embassies urging action on behalf of the industry. EPA officials fly to Europe with US chemical industry executives to lobby for US-style voluntary regulation. High-level Commerce Department officials plan outreach campaigns to sway opinion. The Office of the US Trade Representative tasks industry to develop themes to oppose REACH for use by the US government. The pressure has even extended beyond Europe to the world stage where the US government seeks to instigate opposition to the proposal from developing countries. The campaign has challenged the very notion that sovereign nations can protect their citizens by enacting better laws.

The runaway train of US government lobbying to weaken REACH has attracted repeated public condemnation from US public interest groups.

In 2002, more than 50 public interest NGOs signed a letter of protest to President Bush about the lobbying and asked the Administration to support REACH. Nearly a year later, more than 70 public interest NGOs, public health professionals, nurses, environmental and community groups wrote another letter requesting that federal funds not be used to undermine REACH and asking for Administration support in light of REACH's public health benefits. These efforts and new revelations from internal government documents attracted the attention of the US Congress. The House of Representatives Committee on Government Reform Minority Staff launched an investigation in April 2004 of the lobbying and criticized the Administration's misguided solitary reliance on the US chemical industry to determine US policy.

Ironically, while US government officials are flying off to Europe to weaken REACH, enthusiasm for it is building at home. Public interest NGOs, public health professionals, and community groups have translated the principles in the White Paper into tangible legislative proposals at the state and local levels. These policies restrict toxic chemicals, change government procurement policy, and even implement the precautionary principle as the guiding force of operation. Progressive members of the business community quietly recognize REACH as a way to reduce product liability. REACH has even drawn the attention of US Congressional Members who have begun analyzing how US laws could be updated, using the White Paper as a model.

The growing support for genuine chemical safety on both sides of the Atlantic should prompt greater international cooperation. Chemical substances easily cross borders and authentic solutions require multinational collaborative efforts. The profound economic significance of the chemical industry places it center stage on the sustainable development agenda. The serious concerns over public health and the dangerous ignorance of the chemical industry's products demand action.

The ensuing and continuing internal and external fights about REACH bring to mind unpredictable curves, deep potholes, and sudden steep hills.

In some ways the battle over REACH has divided along lines that define long- or short-term thinking. Immediate costs, the difficulties of change, and temporary uncertainties crowd the minds of the short-term thinkers. The sustainability of the chemical industry, preservation of public health, and commitment to innovation motivate the long-term thinkers.

"The Only Planet Guide" describes a serious journey toward a new European chemical policy that could pave the road toward smarter, safer chemical policy worldwide. The tug-of-war between the antiquated approaches of the past and REACH can be thought of as an upcoming fork in the road. The outmoded path is well worn and familiar. The new path is uncertain with exciting possibilities. One path rewards ignorance while the other prizes common sense. This high-stakes choice requires wisdom and thoughtfulness. "The Only Planet Guide" provides helpful hints, warnings, and knowledge to steer us in the right direction.

Joseph DiGangi, PhD
Environmental Health Fund
USA

# PART ONE: CHEMICALS

# Facts About the Chemicals Industry

## GLOBAL INDUSTRY

### Overview

The chemicals industry is the third largest industrial sector in the world. Global sales are estimated at €1,481 billion for 2002 and the industry employes some ten million people around the world. Most work in small or medium sized companies.

It is also one of the most diverse industries in the world. It covers production of innumerable substances and products, ranging from high-volume basic chemicals via pesticides, additives, sealants, coatings and pharmaceuticals to infinitely specialised products.

While almost all nations have their own chemicals industry, the bulk of chemicals are produced in OECD countries. As much as 80 percent of global production comes from only 16 countries. Europe is one of the key players in this field. With more than 30 percent of global sales, it is the largest chemicals producing region in the world.

### Production

Production of chemicals has soared over the past decades. Since 1970, global sales have increased from €155 billion to €1,481 billion in 2002, representing almost a ten-fold increase. Though the chemicals industry is very diverse and is comprised of tens of thousands of companies, a large portion of production is carried out by a small number of large corporations. In 2002, the top 30 companies had aggregated sales of €378 billion and made up nearly one-third of the total global sales. The top five companies alone had sales totalling a value of €130 billion.

In more physical terms, the global production of chemicals increased from one million tonnes in 1930 to over 400 million tonnes in the year 2000. In Western Germany, the production was 25 million tonnes in 1980, which is equivalent to 400 kilograms of synthetic chemicals per person. This is roughly the same amount as the entire per capita annual production of crops, forests, flowers and other natural green organisms in Western Germany.

**Global top 10 chemical companies 2002 by sales, € billion (Cefic, March 2004)**

| | |
|---|---|
| BASF (DE) | 30.5 |
| Bayer (DE) | 28.0 |
| Dow Chemical (US) | 27.5 |
| DuPont (US) | 24.0 |
| ExxonMobil (US) | 20.5 |
| Atofina (F) | 18.5 |
| Mitsubishi Chemical (J) | 15.0 |
| Akzo Nobel (NL) | 13.5 |
| BP (UK) | 12.5 |
| Shell (NL, UK) | 11.5 |

### Outlook

Based on past and current trends, it is predicted that the tremendous growth rate will continue. According to the UK Chemical Industries Association (CIA), global sales will reach €2,125 billion by 2010 and the OECD speculates there will be a staggering €4,500 billion in sales by 2020.

Most of the growth over the next decade is likely to happen in developing countries and countries in transition. Today, consumption of chemicals is far higher in OECD countries than in countries with less developed economies. A person living in Europe or the US consumes chemicals value at of over €1,500 per year, while a person living in India or Africa spends some €50 on chemicals annually. Thus, the chemicals industry sees an enormous potential in the developing world.

### Globalisation

Attempting to avoid fierce price competition from developing countries, the chemicals industry in the OECD is shifting production

from basic high-volume chemicals to more sophisticated and high value-added products. The chemicals industry in richer countries will become more high-tech while industry in developing countries will account for an increasing part of the production of basic high-volume chemicals.

In the period up to 2020, there will be a shift, where non-OECD countries will increase their share of global production, from 23 percent in 1995 to 33 percent. In physical terms, the increase will be from approximately 100 million to 260 million tonnes.

The growth of the chemicals industry in the developing world, and the shift of production of basic chemicals from OECD to non-OECD countries, does not mean that European and US chemical corporations are losing ground and that competition will increase. On the contrary, they are in the fore-front, already expanding into the developing countries.

Globalisation and deregulation of trade has made it possible for them to move into these new markets. According to a survey by the Chemical Manufacturers Association (CMA) among its member companies, the US industry intends to shift its investments from Europe, Canada and the US to Asia, Eastern Europe and Latin America.

### Mergers and Acquisitions

Another important trend in the chemicals industry over the past decade has been mergers and acquisitions. Large corporations merge and buy smaller companies in the quest for economies of scale and market domination.

In 1999, the value of mergers and acquisitions in the chemical industry hit a new record of €34.4 billion. An important part of this record was to advance global consolidation of the industries. In 2001, the top 50 chemical companies increased their sales by 14.3 percent in a market that grew by 2-3 percent the same year. Most of the growth was due to mergers and acquisitions of smaller businesses. Dow Chemicals increased its sales by 21 percent from 2000 to 2001, entirely through acquiring and merging with other companies such as Union Carbide.

Illustrating the frenzy for mergers and acquisitions in the business, the number of major agrochemical producers has gone from 28 to 12 since 1980. This development cuts through the entire industry and is also expected to continue, leading to fewer and larger multinational corporations dominating global production of chemicals.

### Organisation

As for any major industry, keeping abreast with political and social development is essential to the chemicals industry. The International Council of Chemical Associations (ICCA) is the world-wide voice, representing 80 percent of global manufacturing operations.

ICCA is also the main channel of communication between the industry and various international organisations that are concerned with health, environment and trade-related issues, including the United Nations Environment Programme (UNEP), the World Trade Organization (WTO) and the Organisation for Economic Co-operation & Development (OECD). Furthermore, ICCA is the entity that promotes and co-ordinates voluntary industrial agreements such as Responsible Care.

Slimming the organisation, the ICCA only has a few members, typically one or a few regional associations in each continent, e.g. the European Chemical Industry Council (Cefic) and the American Chemistry Council (ACC). These member associations in turn are organised in a multitude of regional and national federations, associations, trade organisations, sector groups, institutions, councils, NGOs, think-tanks, etc.

## EUROPEAN INDUSTRY

### Overview

Europe is the worlds biggest producer of chemicals, having a share of approximately 35 percent of global sales. Most of this pro-

duction, 30 percent, takes place in the EU. The top European chemicals producing nations are Germany, France, Italy and Great Britain. Production in Eastern and Central Europe fell dramatically after the collapse of the Soviet Union. In 1970 these countries had a global market share of 14 percent which had fallen to a mere 3 percent by 1998.

| Top chemical producing nations in the EU, percentage of total (Cefic, 2004) | |
|---|---|
| Germany | 25 |
| France | 16 |
| Italy | 12 |
| Great Britain | 10 |

The chemicals industry is the largest industrial sector in Europe. It employs 1.7 million people directly and up to 3 million jobs are dependent on it. As well as several leading multinationals, it also comprises some 25,000 small and medium-sized companies with less than 500 employees. These represent 98 percent of the total number of enterprises but only account for 28 percent of chemical production.

In 2002, the EU chemical industry exports outside the region were worth €155 billion. Imports from outside the region amounted to some €85 billion, creating a trade surplus of €70 billion, three-quarters of the total EU manufacturing trade surplus. Most of the exports went to the USA and Asia.

### Production

There are about 100,000 chemicals registered in the European Inventory of Existing Commercial Chemical Substances (EINECS) created in 1981. It is uncertain how many of these substances are actually in production. Estimates vary from 30,000 to 70,000. Additionally, there are 3,000 substances registered after 1981 in the European List of Notified Chemical Substances (ELINCS).

While some of these substances are produced in high volumes, often millions of tonnes per year, others are produced in low quantities. Approximately 10,000 of them are produced in volumes above 10 tonnes per producer and year, and a further 20,000 substances are marketed in volumes between one and ten tonnes annually per producer.

The bulk of the chemicals produced in Europe is manufactured by large corporations. Two percent of the companies produce approximately 70 percent of the volume. These companies have high-tech plants which are highly automated and can produce enormous quantities each year. Some plants are virtually self-contained cities with large numbers of workers and enormous amounts of equipment, including their own power plants, spread over huge areas. The chemical plant in Leverkusen, Germany, owned by Bayer, covers an area of 3.4 square kilometres and consists of 600 buildings.

### Outlook

As markets for basic high-volume chemicals in Europe and other OECD countries are becoming mature and saturated, the EU chemicals industry is looking into other fields.

One way of expanding is to enter new markets with high growth potential, such as in non-OECD countries, either through exports or by investing in production facilities in these countries (see *Outlook* and *Globalisation* in the previous section). Investments by chemical companies in facilities in foreign countries has been growing since the 1980s and is expected to continue.

Another route of expansion is to become more specialised. European companies, like their US competitors, are becoming more innovative and specialised in areas such as biotechnology, electronics and advanced materials.

Through technological developments they have also expanded into speciality chemicals, agrochemicals, pharmaceuticals and food production, where biotechnology is creating

new commercial opportunities. Increasingly, the EU chemicals industry is becoming an industry where agriculture, biotechnology, pharmaceuticals, chemicals and food are all part of the business.

**Mergers and Acquisitions**

As a result of the saturated markets in the OECD and the expansion into other regions as well as into new product areas, the chemicals industry in the EU is undergoing a major restructuring. Investments in foreign countries are often done by acquiring foreign companies or merging with them. Similarly, expansion into new product areas also demands new structures.

It is anticipated that the increasing scale and growth of the global chemicals industry, together with continuing globalisation, increased openness and competitiveness, are likely to intensify recent trends of companies forming alliances.

Steadily mounting cost pressures will provide further impetus. Research and development (R&D), bringing new products to the market, managing the safe production and distribution of chemical products from cradle to grave, and meeting pressures of environmental health and safety regulations entail costs that will escalate.

The trend towards fewer and larger multinational producers is expected to continue, with companies becoming knowledge-based (speciality chemicals and life sciences) rather than asset-based (basic chemicals).

**Organisation**

While the International Council of Chemical Associations (ICCA) is the world-wide voice of the chemicals industry, its counterpart in Europe is Cefic, the European Chemical Industry Council. The organisation consists of 25 national federations of chemicals producers, 30 corporate members and approximately 700 business members. Acting as an umbrella organisation, Cefic has also recognised about 100 sector groups and affiliated associations

such as Eurochlor and European Brominated Flame Retardant Industry Panel (EBFRIP). Within Cefic there are eight leadership teams dealing with specific issues of high concern to the industry, e.g. trust & reputation, international trade, chlorine etc.

Cefic represents the interests of the national federations and its other members, sector groups and affiliated associations toward international organisations and treaties. The stated mission of Cefic is *"To maintain and develop a prosperous chemical industry in Europe by promoting the best possible economic, social and environmental conditions to bring benefits to society with a commitment to the continuous improvement of all its activities including the safety, health and environmental performance"*.

On the tier below Cefic, the national federations, sector groups and affiliated associations are divided into countless groups representing specific interests. For example, the European paint industry is organised in an affiliated organisation: the European Council of the Paint, Printing Ink and Artists Colours Industry (CEPE). Similar to Cefic, CEPE has 18 federations on national levels as well as 14 company members and 12 affiliated organisations and company members. As an example of a sector group within Cefic, the European Flame Retardants Association, has 15 member companies, three associate member companies and five observer organisations, among them several other sector groups and

the international Fire Retardant Chemicals Association, with further members and affiliated members.

While simple and streamlined at the top, the chemicals industry is organised in hundreds or thousands of other organisations further down. Ultimately, the organisation is virtually impossible to overlook. Many of these organisations exist mainly or exclusively to influence politics. To this end they interact and network in different constellations depending on specific needs.

An example of this is the Downstream Users of Chemicals Co-ordination group (DUCC). The organisation was founded in 2001 with the specific purpose of influencing the development of REACH. It comprises seven organisations representing some 3,700 companies that use chemicals, such as paint and ink producers, perfume producers, chemicals distributors and producers of detergents. Several of the seven member organisations, as well as many of their member companies, are also members of Cefic directly or through other sector groups.

One of the main tasks for these organisations, federations and groups is to monitor and influence policy making in an advantageous direction. However, the chemical industry also has other means of exercising a powerful lobby. Most of the major chemical companies as well as Cefic and federations, are also members of influential think-tanks such as the European Policy Centre and the European Round Table of Industrialists. The major organisations and companies also consult well known marketing and lobby organisations such as Burson-Marsteller and the European Marketing Group.

## SUMMARY

The chemicals industry is one of the world's biggest and most powerful sectors, with global sales of approximately €1,500 billion. The growth rate has been high over the past decades. Within the next 20 years, sales are expected to continue growing, maybe even be tripled to €4,500 billion in todays prices. Most of the future growth is expected to take place in developing countries and countries in transition where production and consumption of chemicals has been low.

While there are tens of thousands of small companies in the industry, global production is almost entirely controlled by a few very large multinational corporations based in the OECD, primarily in the EU and US. With saturated markets in the OECD, these companies are moving into the non-OECD markets, where the future growth is expected, by investing in manufacturing facilities, mergers and acquisitions.

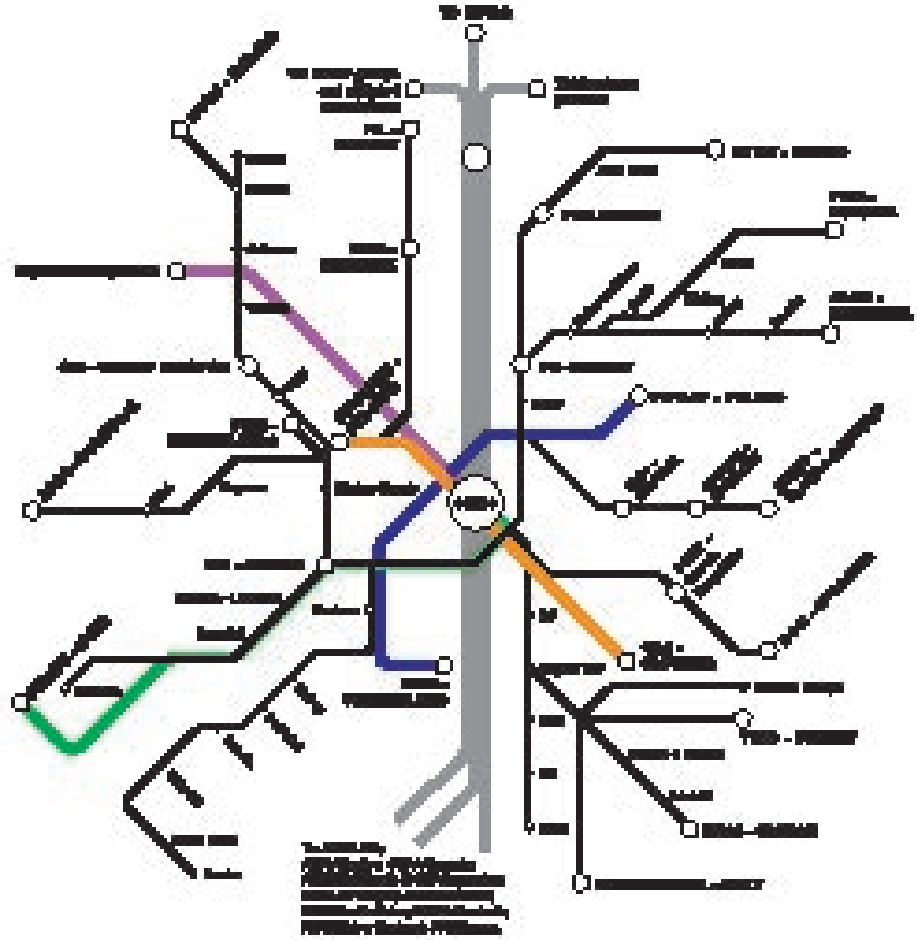
While shifting the production of basic high-volume chemicals to non-OECD countries, production of chemicals in Europe and the US is becoming more specialised. The large corporations, and the industry as a whole, are also moving into new product areas such as agriculture, pharmaceuticals and food by investing in biotechnology.

As a consequence the industry is undergoing dramatic restructuring. In the future there will be fewer but bigger companies. These are likely to also dominate the future chemicals production in non-OECD countries, and they will be active in a wider range of product areas.

Deregulation of trade barriers in non-OECD countries and globalisation of (OECD) trade is a prerequisite for the expansion of the dominating companies. In the ICCA (and Cefic in Europe) they have a powerful and efficient lobby that should be expected to protect and advance their interests. Considering the financial importance of the industry in several European countries, it is likely that governments will also protect and promote the interests of the industry in national as well as international contexts.

## Map of the Chemicals Industry in Europe

Below is an illustration of the organisation of the chemicals industry in Europe. The system is more complex in reality since there are links between many of the federations, members and companies. These are also likely to have connections to other groups which are not included in the map. Most of the corporate members of Cefic are also active members in many of the federations as well as in the sector groups, which also have federations at national levels. Federations and sector groups may also have non-chemical members, such as the CIA in the UK. Among it's members are some 20 solicitors, crisis managment consultants, marketing consultants, railway companies and accountants. Additionally, there are numerous institutes, think-tanks, non-profit organisations etc. with less official connections to the industry.



## Defining the Chemicals Industry

The chemicals industry covers a wide range of processes and products. However, defining the industry may be difficult and depends on who is doing it. According to Cefic, the chemicals industry consists of all the companies that use raw materials to produce chemical substances and all the companies down the line that alter or blend these substances.
Cefic defines the industry according to 11 different sectors (see below). Each sector may consist of several sector groups, of which Cefic has recognised approximately 100. Companies in these sectors are, according to Cefic, the chemicals industry and thus the basis for the figures presented by Cefic. Generally, any company which is active in at least one sector may become a member of sector groups or of a national federation and thus be a part of the chemicals industry. Some companies are only active within one sector, while others may be active in a range of sectors. Additionally, Cefic represents a number of sector groups which do not fit into the categories.
There are also other definitions of the chemicals industry. For example, the Swedish Chemical Industry Federation (Plast- och Kemiföretagen) divides the sectors differently, and also includes producers of pharmaceuticals, rubber, cement, hand-made glass, explosives as well as companies that distribute the products. This means that a national federation may have members which are not part of the industry according to Cefics definition of sectors. Nevertheless, they may be included in the statistics over the European chemicals industry if they are members of a federation or of a sector group recognised by a federation.

### Cefic Sectors

**Agriculture**
Producers of fertilisers, biocides, food additives, insecticides, pesticides, herbicides, etc.

**Biotechnology**
Companies that develop or use biotechnology, primarily in medicines, vaccines, diagnostics, gene therapy and in food and agriculture to develop herbicide and pest resistant plants.

**Chlorine and Other Halogens**
Producers of chlorine, bromine or fluoride, used for producing a variety of chemicals, plastics, pharmaceuticals, etc.

**Colorants**
Producers of pigments and substances used for colouring food, textiles, plastics, dyes, etc.

**Detergents**
Producers of substances containing soap or other surfactants intended for washing clothes and dishes as well as hard surfaces.

**Food and Feed**
Producers of food additives such as emulsifiers, food contact additives, processing aids and agents, etc.

**Oleochemicals**
Producers of fatty acids, glycerine, alcohols and metallic soaps, fatty nitriles and their derivatives, etc. Oleochemicals are used in lubricants, soaps and detergents, cosmetics, pharmaceuticals, food additives, leather, paints and coatings, printing inks, rubber, plastics, and in metal-working and many other industries.

**Paints, Coatings and Adhesives**
Producers of paints, inks, dyes, glue and many other kinds of surface coatings.

**Petrochemistry**
Companies that produce intermediate chemicals from fossil gas and oil. These are the main suppliers of raw materials and intermediates to most of the chemicals industry.

**Plastics**
Producers of all kinds of plastic such as polystyrene, acrylic polymers, PVC, nylon, polyethylene, polyurethane, polyester, epoxy resins, polycarbonates, silicones, polyamides and polyacetals.

**Others**
Manufacturers of activated carbon, sporting ammunition, cellulose ethers, lead oxide, photographic chemicals, titanium dioxide, etc.

## POLLUTION

### Overview

Naturally, the environment has always consisted of chemicals and always will. Some of them are hazardous, but these are mostly deposited in the ground where they are either not readily accessible to humans and most other organisms, or have only limited impact in the immediate vicinity. Since the beginning of civilisation mankind has extracted substances for specific purposes, such as mercury or lead. This created local pollution and health problems for those exposed.

With the advent of industrialisation, the extraction and dispersal increased. But additionally, mankind started producing synthetic substances. Most of these had never existed before. Today, the bulk of chemical production consists of synthetic chemicals that are primarily based on fossil oil.

Most of the substances produced by the chemicals industry eventually end up in the environment and, via the environment, in humans. Thus, the environment today contains a greater number of chemicals than before and many of them are synthetic.

Synthetic chemicals can be found in most places: water, soil, air, plants, humans and other animals. They are also found in remote areas such as the Arctic, deep seas and mountain tops.

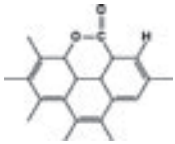
Chemicals found in such places are mostly persistent, which means that they do not degrade or break down easily. They may also be bioaccumulative, meaning that they accumulate in fatty tissue. Once released into the environment, such substances stay around for a long time.

In this section some examples are given of places where synthetic chemicals have recently been identified. In many of the studies scientists have identified more or less the same substances, often well known pollutants. This is no coincidence. When analysing something for the presence of pollutants, scientists have to know what they are looking for and they tend to look for substances which are considered hazardous. However, this does not mean that the substances identified are the only substances in the sample. On the contrary, it is very likely that the sample contains many more substances that have not been analysed.

While the findings below are disturbing in themselves, they should also be recognised as examples, indications of greater dispersal and widespread exposure which make them even more disturbing. They are warning signals of an even greater problem.

**Persistence**

A chemical substance consists of molecules, typically based on carbon. With time the bonds in the molecule break down and the substance decomposes. If a substance breaks down quickly, there is less time for it to cause harm, and vice versa. A substance that breaks down slowly is called persistent. Chemicals break down at different paces in different media and temperatures. A substance that breaks down in a few days in air may take months or years to decompose in water, sediment, soil or human tissue.



### Rainwater

Ordinary rainwater collected in Europe has proven to contain pesticides, brominated flame retardants and other synthetic chemicals. In 2002, the Dutch institute TNO presented the results from a two-year study of rainwater in the Netherlands. The presence of many pesticides was clearly shown.

In May 2003, Greenpeace presented the results of the analysis of 50 samples of rainwater collected in the Netherlands, Germany and Belgium. The samples had been analysed by TNO for a wider range of synthetic chemi-

cals, primarily xeno-estrogens, substances that are considered to have effect on the hormone system and belong to a group known as Endocrine Disrupting Chemicals (EDCs) or Endocrine Disrupters.

The results show that these substances were present in most samples. All the samples contained phthalates, used as softeners in PVC plastic. A total of 32 percent of the samples contained bisphenol A, 28 percent contained brominated flame retardants, and almost all samples contained musk compounds, used to produce scent in perfumes, detergents, etc. Alkylphenols and ethoxylates were also present in almost all the samples. The levels varied between different compounds but also between the locations where the samples had been taken.

**The Arctic**

Though the Arctic region is still clean compared to many other areas in the world, for a specific group of substances - Persistent Organic Pollutants (POPs) - there is reason for concern (see separate box). The Arctic Monitoring and Assessment Programme (AMAP) has been monitoring chemicals in the Arctic for many years and have found POPs in all compartments of the Arctic.

Most of the pollutants in the Arctic originate in warmer areas of the world, and are transported to the Arctic by a process known as *grasshopping* or *global distillation*. POPs travel to colder areas of the globe through a series of hops. Under warm conditions they evaporate to the air and are then deposited again to the surface, repeating the same process over and over again until they become trapped in cold areas. There are also sources of POPs in the Arctic, e.g. military installations and rivers depositing water in the Arctic.

Through bioaccumulation (see box on page 24), persistent chemicals may stay in the fatty tissues of humans and other animals. Over time the concentrations add up to high levels, even when the levels in the environment are low. A human or other animal living

**Persistent Organic Pollutants (POPs)**

Persistent organic pollutants (POPs) include a wide range of substances: industrial chemicals (such as PCBs) and by-products of industrial processes (e.g. HCB, and dioxins) whose toxic characteristics are unintentional, and others, such as pesticides (e.g., DDT) and herbicides (e.g., lindane – HCH), that are designed to have toxic properties.
Interest in the presence of POPs in the Arctic environment arises in particular because of the concern that Indigenous people and other northern residents depending on traditional food for all or part of their diet may be adversely affected by chronic exposure to these pollutants.
POPs are of special concern because:
1) They persist in the environment for long periods of time, which allows them to be transported large distances from their sources, are often toxic, and have a tendency to bioaccumulate; many POPs biomagnify in food chains;
2) Many Indigenous people in the Arctic depend on traditional diets that are both an important part of their cultural identity and a vital source of nourishment; alternative sources of food often do not exist; however, traditional diets are often high in fat and POPs tend to accumulate in fatty tissue of the animals that are eaten;
3) Most northern residents have not used nor directly benefited from the activities associated with the production and use of these chemicals; however, certain Indigenous populations in the Arctic have some of the highest known exposures to these chemicals.

*AMAP POPs fact sheet #1*

at the top of the food chain may have concentrations that are hundreds of thousands of times greater than in the surroundings.

AMAP studies have found POPs in Arctic air, water, snow, plankton, amphipods, cod, whales, seals and polar bears.

### Mountains

The same phenomena that brings POPs to such remote places as the Arctic, also disperse POPs in other remote places, for example the crystal clear lakes in the Alps. In 2001, studies on fish from lake Schwarzsee ob Soelden, which is located 2,800 metres high up in the Oeztal Alps in Austria, showed substantial pollution with industrial chemicals such as DDT and PCB.

Lake Schwarzsee is far away from local sources of pollutants and draws its water solely from the neighbouring mountain tops. The pollutants found in the water enter almost entirely from the atmosphere.

In the study, done by the Mountain Lake Research Project (MOLAR) in the EU, fish and sediments from a total of 19 mountain lakes in Europe were analysed. This research established an important connection: the concentrations of the persistent pollutants in the lakes clearly increased with height and as the temperature fell.

The following year, Greenpeace analysed fish from the same lake, but looked for six other substances. This time, analyses showed that the lake was also contaminated by brominated flame retardants, HBCDs, chloroparaffins, phthalates, toxaphenes, and chlorinated dioxins and furans. By analyses of snow, the presence of POPs has also been proven in the North American Rocky Mountains, another high remote area.

### Fish

Fish is one of the places where synthetic chemicals are most often analysed and found. As a rule, fish contain pollutants from industrial and civil discharges to water.

There are many studies showing synthetic chemicals in wild fish. However the variation in substances and levels is large and depends on where the fish lives and the fat content of the fish. A fatty fish, such as a salmon or herring, will accumulate more chemicals than a leaner fish, since many industrial chemicals accumulate in fatty tissue.

Today it is difficult to find fish which does not contain man-made chemicals. Among the most frequent pollutants found in fish are dioxins, PCBs, brominated flame retardants, plasticisers and organotins.

In some areas of the world, like the Baltic Sea and several rivers and lakes, fish are often so contaminated that they are not considered to be fit for human consumption. However, most of the fish being sold in supermarkets

### Dioxin in Fish

Dioxins are a group of extremely toxic POPs that are primarily unintentional by-products of industrial processes. The EU has adopted limits for permissible levels of dioxins in food for human consumption. The levels are set above safe levels to accommodate the food industry, but the aim is to lower them over time. As can be seen in the table below, fish is the only commodity regulated on picogram per gram of *freshweight* (the whole fish) while other foodstuffs are regulated on a *lipid* (fat) base. Since fat content is often only ten percent of the freshweight, a regulation permitting similar levels of toxins in freshweight will mean much higher permissible levels. Most of the fish sold in Europe contains levels of dioxins that are above the permissible levels for meat, eggs, milk, etc.

**Maximum allowed levels for dioxins, EU**

| | |
|---|---|
| Bovine and sheep meat | 3 pg/g lipid base |
| Poultry and farmed game | 2 pg/g lipid base |
| Pig meat | 1 pg/g lipid base |
| Liver and derived products | 6 pg/g lipid base |
| Fish and fishery products | 4 pg/g fresh weight |
| Milk and milk products | 3 pg/g lipid base |
| Hen eggs and egg products | 3 pg/g lipid base |
| Oils and fats (various) | 0.75-3 pg/g lipid |

across Europe would be banned from sale if fish had the same limits for dioxin as meat, eggs, milk or other regulated food. Nevertheless, eating fish is still recommended.

### Vegetables, Fruit and Oil

A total of 1,770 samples of fresh and frozen fruit and vegetables were examined for residues of pesticides by the National Food Administration in Sweden in 2002. The samples came from nations all over the world, though primarily from the EU, and had been collected from supermarkets and restaurants.

A total of 44 percent of the fruit and vegetables contained residues of at least one pesticide. At the same time, 19 samples of olive oil were analysed, of which 17 contained the pesticide endosufan. Out of 43 samples of fried potato products, such as chips, 15 contained the pesticide klorprofam.

### House Dust

In another study, in May 2003, Greenpeace presented the results of analysis of ordinary house dust taken from 100 volunteer homes across the UK.

The analyses focused on finding industrial chemicals from five different groups: phthalates, used as plasticisers in PVC plastic; alkylphenols, mostly used in cosmetics; organotins, used as stabilisers in PVC; brominated flame retardants from furniture and electronic equipment; and finally chlorinated parafins used in plastics, rubber and paint.

All the samples from the UK contained phthalates, brominated flame retardants and organotin compounds. More than 75 percent of the samples also contained chlorinated parafins and alkylphenols. With just one exception, all the samples contained a range of other industrial chemicals such as pesticides, solvents and plastic additives.

### Human Blood and Tissue

Considering the presence of industrial chemicals in water, air and food, it comes as no surprise that the human body also contains quite a few industrial chemicals.

**Bioaccumulation**

Many persistent chemicals are deposited in the fatty tissue of organisms. Since they do not break down quickly, the amount accumulated in the body increases even if the intake is low. Thus, a human or other predator accumulates chemicals from its prey and stores them in its own fat reserve. The only way the body can get rid of them is by disposing of the fat or through breast milk.

In a study from 2002 led by Mount Sinai School of Medicine in New York, USA, researchers found an average of 91 industrial chemicals and pollutants in the blood and urine of nine volunteers, with a total of 167 chemicals found in the group. Like most of us, the people tested do not work with chemicals nor live near industrial facilities. The substances found included PCBs, dioxins, DDT, insecticides, plasticisers, musk and volatile compounds. The scientists refer to this contamination as a person`s body burden.

In 2003, Greenpeace reviewed what studies had been made of certain industrial chemicals in human tissue with relevance to children before and slightly after birth. The review found that a number of man-made chemicals such as alkylphenols, bisphenol A, brominated flame retardants and plasticisers had been identified in umbilical cords, ovaries, placenta and blood.

In a study of blood samples from 155 volunteers from 13 locations in England, Northern Ireland, Scotland and Wales, WWF analysed the content of 78 different chemicals. All of the chemicals belonged to one of three groups: chlorinated pesticides, brominated flame retardants or PCBs.

The results showed that all the volunteers carried at least one substance from each chemical group. The highest number of chemicals found in a single person was 49. One volunteer carried 90 percent of the 78 substances.

**Human Breast Milk**

Since persistent industrial chemicals tend to deposit in fat, the pollutants found in human tissue (see above) are likely to also be present in human breast milk.

The 1999 report "Toxic Legacy" from WWF shows that more than 350 synthetic contaminants have been found in the breast milk of mothers, including dioxin, PCBs, DDT, flame retardants, plasticisers, musk compounds and pesticides. Moreover, even more contaminants are likely to be present according to WWF since the number of substances that these studies looked for was limited.

In another WWF study from 2003, the content of certain chemicals in the blood of 155 volunteers in the UK was analysed (see *Human Blood and Tissue* on previous page). One of the conclusions from this study was that women have significantly lower levels of PCBs in their blood than men. The levels also seem to fall with the number of children that the mother has given birth to. This implies that women may off-load PCBs to their babies, thereby reducing their own bodyburden.

**Summary**

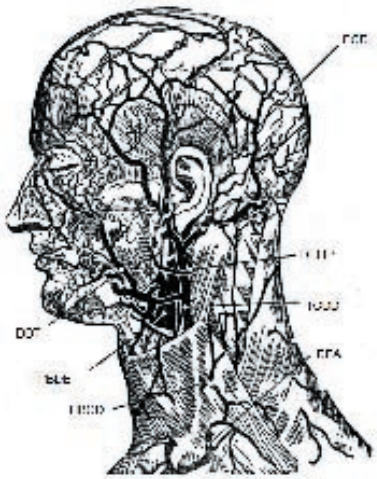
Annually, some 400 million tonnes of chemicals are produced in tens of thousands of varieties by mankind. Most of it is produced from natural resources such as fossil oil, salt, lime, minerals, etc. Most of it, if not all, re-enters the environment in its new form, interacting with humans, other animals, plants and other organisms.

Some of these substances may decompose quickly but little is known about the actual rate or the effects of the breakdown products. There are examples showing that the breakdown product from an industrial chemical can be very hazardous. DDT is one of the most familiar cases.

However, some of the chemicals break down slowly, stay in the environment for a long time and build up in soil and sediment, even in organisms through bioaccumulation. Other chemicals are so abundant that they are present everywhere all the time, even though they are not persistent.

Industrial chemicals therefore seem to be present in most places. Over the years, scientists have identified them in all of the environmental compartments they have looked in. Perhaps the most upsetting fact is that they seem to be present in all humans, flowing in our blood.

However, there is still a huge gap in knowledge. Since scientists always look for a limited number of specific chemicals, those are the only ones they find. What other substances are present in humans and the environment is largely unknown.



*Body burden:*
*All 155 volunteers in a WWF study had chlorinated pesticides, brominated flame retardants and PCB in their blood. A study on nine volunteers from the USA found an average of 91 industrial chemicals in their blood. Some 350 synthetic substances have been found in breast milk.*

## EFFECTS

### Overview

Humans and other organisms have always been exposed to chemicals that flow around on Earth. Over millions of years they have adapted and become more resistant in order to survive and multiply. However, the increased exposure to natural toxins such as metals, has caused problems. Organisms are not adapted to today's higher levels of lead, mercury and copper and have in many cases been damaged.

Another problem is the dispersal of new chemicals produced by mankind - synthetic chemicals - with the advent of industrialism and development of the chemicals industry. Organisms are now continuously exposed to low doses of chemicals that they have never been exposed to before and are not adapted to handle.

A third problem is that the releases of natural and synthetic chemicals to air, water and soil alters the chemical composition of the recipient. Such changes may have dramatic effects for life on Earth. The depletion of the stratospheric ozone-layer is one example. Global climate change is another.

Finally, chemicals may play an indirect but crucial role in other issues. For example, the increasing amounts of waste and the problems associated with the treatment of waste, would be less troublesome if the waste did not contain high levels of hazardous chemicals.

### Exposure Types

Chemical exposure to humans and other organisms can be characterised as being either acute or chronic. Acute exposure is by definition limited in time and duration but may cause severe effects for those exposed depending on the toxicity and exposure level in question. Chronic exposure is a prolonged - even life-long - exposure to low doses of one or many hazardous substances to individuals or a large population.

**Characteristics of Exposure Types**

| | Acute | Chronic |
|---|---|---|
| Exposure level | High | Low |
| Duration of exposure | Short | Long term |
| Size of exposed group | Limited | Unlimited |
| Size of exposure area | Local | Global |
| Composition | Simple | Complex |
| Effect development | Dramatic | Subtle |
| Effect assessment | Easier | Complex |

### Acute Exposure

Since acute exposure to hazardous substances may cause dramatic and visible damage in the short term, it is often easier to identify and monitor. The chemical and source in question may be simple to establish and its effects are often either well known or possible to assess. Exposure can also be prevented, minimised and controlled to a certain extent through technical measures. Today, acute exposure is predominantly caused by industrial accidents and spills that injure and kill large numbers of people.

### Chronic Exposure

Chronic exposure is more complex. It is caused by a number of sources and by pollution in the general environment, water, air, food, etc. It consists of an unknown - but large - number of identified and unidentified substances and their breakdown products. The effects are not as immediate as those caused by acute exposure. Instead the effects may take years or decades to develop. The damage may even turn up in the offspring of the exposed individual, making connections very difficult to prove.

### Causality

Since the number of substances that humans and the eco-system are continuously exposed

to is so large (see the previous section), it is virtually impossible to positively connect an observed effect with any particular substance. The effect may even be caused by the breakdown substances or by synergistic effects, where two or more substances interact causing damage which none of the substances causes alone.

Consequently, the full range of damage caused by chronic exposure to synthetic chemicals are presently not possible to quantify. However, according to many scientists there is an increasing amount of data and observations indicating that chronic exposure to synthetic chemicals has severe consequences for human health as well as for the environment.

As in the previous section, *Chemicals in the Environment*, examples which are causing concern among scientists and politicians around the world are presented. Again - however troubling these examples may be in themselves, they are mere examples and indicators of a larger problem. The greatest problem with chronic exposure is the time-frame and scope. Once damage has been identified, it is very difficult to reverse the situation. Persistent and bioaccumulative chemicals stay around for a long time, and when they are dispersed into every corner of the environment, there is no way to clean them up.

**Causality and Association**

It is sometimes fairly easy to show that a measure of ill-health (e.g. the number of admissions to hospital per day) is associated with a possible cause, such as the day-to-day variation in levels of air pollutants. However, to show that a causal relationship exists is more difficult. A number of guidelines or tests have been developed to help assess this. These include identifying whether there is a "dose-response relationship" between the proposed causal factor and the effect, whether the sequence of events makes sense (i.e. the cause always precedes the effect), checking the consistency of results between different studies, and the way in which the results of different studies fit together (coherence). Proof of causality is often very difficult but, by the application of these and other criteria, an expert judgement as to whether an association is likely to be causal can often be made. Where effects are likely to be serious and/or irreversible, then a low level of proof, as in the "precautionary principle", may be sufficient to justify actions to remove or reduce the probable causes.

*WHO & EEA, 1997*

## ENVIRONMENT AND WILDLIFE

### Overview

Chemicals play an important role in many environmental issues. It is a problem that cuts through many others, which normally are not conceived as associated with chemicals.

In its 1998 assessment of major environmental concerns in Europe, the European Environment Agency (EEA), identified 12 areas which need urgent attention and further measures. Although synthetic chemicals play a role in all of them, either directly or indirectly, defining the extent to which they contribute to the problems is difficult and can only be estimated. Any such estimation is bound to be debated, but is nevertheless presented for the sake of visualisation (see separate box on the next page). In nine of the areas of concern identified by the EEA, the role of synthetic chemicals may be considered significant or major.

### Climate Change

Emissions of $CO_2$ from fossil fuels are undoubtedly the main cause of climate change, representing some 80-90 percent of the effect. Industry is the second largest consumer of oil, at approximately 25 percent of the total. About one-fourth of industrial oil is consumed as chemical feedstocks, slightly over five percent of global fossil oil consumption. The oil is used to produce chemical substances, plas-

tics, etc., and is eventually released as $CO_2$ to the atmosphere. Fossil oil in chemicals makes a minor contribution to global $CO_2$ releases.

There are also other chemical substances that contribute to global warming. Three of the six greenhouse gases covered under the Kyoto protocol are synthetic substances that have powerful effects: HFC, PFC and $SF_6$. Releases of such substances are small, representing a few percent of the total effect.

### Ozone Depletion

Depletion of the stratospheric ozone-layer is caused entirely by synthetic substances known as chloro- and bromofluorocarbons used as refrigerants, industrial cleaners, foaming agents and fire extinguishers. International agreements have been reached to phase out ozone-depleting substances, but even if they are fully implemented, it will take 70 years before ozone depletion stops.

Concentrations of ozone at mid-latitudes over Europe have declined by 6-7 percent over the past decade and Europe contributes about one-third of global annual emissions of ozone-deleting substances.

Consequences of ozone depletion are possible changes in atmospheric circulation and increased UV-radiation. Skin cancer deaths in Europe due to increased radiation are expected to reach two per million by the year 2030. Effects on wildlife and the environment may also be severe.

### Loss of Biodiversity

The populations of more than one-third of the bird species in Europe are in decline, most severely in North-Western and Central Europe. This is mainly caused by damage to their habitats by land-use changes and logging.

However, synthetic chemicals are an additional burden making it even more difficult for species to survive. In numerous cases, severe damage to the reproduction of fish, birds, shellfish and mammals have been connected to exposure to persistent synthetic chemicals.

### Major Accidents

The chemicals industry produces and handles a great number of hazardous substances. These are often transported widely across the European continent and globally.

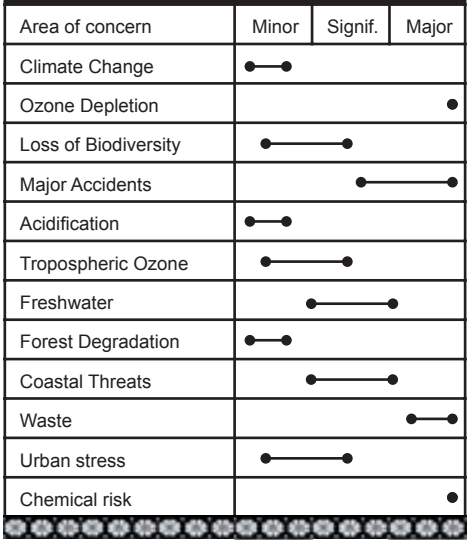
There have been many serious accidents in chemical plants and involving transports of hazardous substances globally and in Europe. The tragedies in Bhopal, Seveso and recently in Toulouse are the most known examples where chemical facilities have caused great havoc. The potential for major accidents with severe consequences for humans and the environment is large.

### Tropospheric Ozone

Levels of oxidants such as ozone are increasing in the lower atmosphere. WHO Air Quality Guidelines for ozone are frequently exceeded in most parts of Europe. The oxidants arise from the main precursors nitrogen oxides, volatile organic compounds, methane and carbon monoxide.

At ground level, photochemical oxidants including ozone, can cause premature ageing of the lungs, eye, nose and throat irritation,

**Indication of Role of Synthetic Chemicals in Areas of Concern**



chest discomfort, coughs and headaches. They can also affect crop and possibly forests.

In the northern hemisphere ozone concentrations are expected to keep rising at one percent per year. No goals for limits have yet been set and in Europe the actions already undertaken are not thought to be sufficient.

### Management of Freshwater

Consumption of water in Europe has increased from 100 to 650 $km^3$ per year from 1950 to 2000. In some countries, up to 30 percent of the water is lost in the distribution system. Agriculture is the dominant consumer of water, mainly for irrigation. Of all the manufacturing industries in Europe, the chemicals industry is the largest consumer of water, using approximately 45 percent of the total industrial consumption.

It should be noted that the impacts of using water is not limited to the amounts used. The quality in which it is returned to the environment is also crucial. In this respect, chemicals also play an important role. Waste water from agriculture, treatment plants, industries and other sectors are, as a rule, contaminated by synthetic chemicals.

Despite the introduction of water quality regulations in the EU and the attention to water quality in the Environmental Action Programme for Central and Eastern Europe, there has been no overall improvement of river quality since 1989/90.

Groundwater quality is affected by increasing concentrations of nitrate and pesticides from agriculture. Groundwater concentrations of certain pesticides frequently exceed EU maximum admissible concentrations. Significant pollution from heavy metals, hydrocarbons and chlorinated hydrocarbons has also been reported in many countries.

### Forest Degradation

A 1992 survey of 113 tree species in 34 European countries showed that in 24 percent of the trees, defoliation exceeded 25 percent and ten percent were suffering from discoloration. In certain areas as much as 54 percent of the forests may have suffered irreversible damage.

Although acidification is considered to be a major cause, the processes leading to this damage are not fully understood. There are several hypothesis including factors such as climate change, nutrification, insects and fungus. It seems likely that the damage is not due to a single problem. Instead, the damage may be caused by a wide range of interacting factors where air pollution plays an important role.

Some countries, such as former Czechoslovakia, Germany and Poland, where several thousands of hectares of forests have been severely degraded, consider air pollution with its associated atmospheric deposition of nutrient, growth-altering, or toxic substances, to be a factor leading to the weakening of forest ecosystems. The extent to which synthetic chemicals contribute to this problem is unknown.

### Coastal Threats

The European coastline, which is at least 148,000 km long, has great importance for biodiversity and as a buffer between land and sea. Human activities creating physical modifications of the coastline and emissions of contaminants have led to the deterioration of habitats and water quality.

Though only limited data is available, mainly covering Western and North-Western Europe, chemical pollution of the coastal zone is a serious problem in all of Europe's seas. Contamination of sediments, animals and plants by anthropogenic chemicals seems to be common in almost all European seas.

Elevated concentrations (above natural background) of heavy metals and PCBs have been found in fish and sediment, with high levels near point sources of emission. Bio-accumulation of these substances pose a threat to ecosystems and human health.

### Waste

Europe produces more than 250 million tonnes of municipal waste and more than 850 million

tonnes of industrial waste annually. In the OECD countries of Europe there are 10,000 annual transfrontier movements of hazardous waste, totalling two million tonnes.

More than 55,000 contaminated sites have been registered in just six European countries, and the total contaminated area in Europe is estimated to be between 47,000 and 95,000 $km^2$ including 1,000-3,000 $km^2$ of contamination from landfills.

A determining factor in the waste problem is the chemical content of the waste. Typically all kinds of waste contain a multitude of synthetic chemicals of which many may cause negative effects if released to the environment. If waste was free from hazardous substances, re-use, recycling and deposition would be a minor problem.

### Urban Stress

Urbanisation is continuing, despite the fact that around three-quarters of the population of Western Europe and the newly independent states (NIS), and slightly less than two-thirds of that in Central and Eastern Europe (CEE), already live in cities. The rapid increase in private transport and resource-intensive consumption are major threats to the urban environment and, consequently, to human health and welfare. Extensive car transports, noise levels, air pollution, waste generation and water consumption are all parts of urban stress. No doubt synthetic chemicals play a part in the increasing consumption and transports.

### Chemical Risk

As mentioned initially, most environmental problems in Europe and in the world can be traced back to some form of excessive chemical loading. Many of these problems have been covered in the above. The specific and direct influence of chemicals on human health is covered below.

A general indication of the the potential extent of the problem is given above. However, there are many other ways of categorising effects of chemicals that are not addressed here.

## HUMAN HEALTH

### Overview

Calculating damage to human health caused by exposure to synthetic chemicals involves many problems. Thus, any such calculation may only serve as a preliminary indication in the absence of better data and scientific knowledge.

First of all there is a great lack of data concerning health effects from synthetic chemicals. Some 85 percent of all the high production volume chemicals (HPVs) lack basic toxicity data (see separate box, page 52).

Second, there is the time problem: certain effects, such as damage to the reproductive function, appears after a very long time or even in the next generation.

Third, some effects are very subtle and difficult to assess, such as minor brain damage and developmental dysfunctions. Finally, there may be contributing and confounding factors: a specific effect may have multiple causes making it impossible to attribute it to a single source.

When attempting to assess whether a chemical may cause damage, the substance is tested on animals. If the substance in question has already been released to the environment, it is also possible to collect samples of exposed organisms from wildlife. When assessing possible effects on humans, scientists either have to rely on the observed effects on animals, or when possible, on observations and experiences from accidents, spills and work-places where humans have been exposed unintentionally.

The above uncertainties make it extremely difficult to prove causal connections between the exposure to a certain chemical and an observed effect (see page 27). Nevertheless, many scientists are convinced that there is a connection between a number of illnesses and disorders and long-term exposure to a large number of synthetic chemicals.

### Some Numbers

There is no doubt that man-made chemicals are having a large scale effect on human

**Human Health Effects from Certain Chemicals**

The below table summarises the main health effects of certain chemicals. The link with chemicals varies from wellknown causal relationships such as benzene and leukaemia, to suggestive associations, such as chemical sensitivity and pesticides. Most harmful effects are the result of many causes acting together, such as genetics, lifestyle, radiation, diet, pharmaceuticals, chemicals (manufactured and natural), smoking and air pollution, including indoor and outdoor exposures. It is also important to consider sensitive groups, such as the elderly, children, the embryo, the sick, and pregnant women, who may be affected at much lower doses than others.

*UNEP/EEA 1997*

| Health effect | Sensitive group | Some associated chemicals, examples |
|---|---|---|
| Cancer | All | Asbestos, Polycyclic aromatic hydrocarbons (PAHs), benzene, some metals, some pesticides, several hundred animal carcinogens, some solvents, natural toxins |
| Cardiovascular diseases | Especially elderly | Carbon monoxide, arsenic, lead, cadmium, cobalt, calcium, magnesium |
| Respiratory diseases | Children, especially asthmatics | Inhalable particles, sulphur dioxide, nitrogen dioxide, ozone, hydrocarbons, some solvents, terpenes |
| Allergies and hypersensitiv. | All, especially children | Particles, ozone, nickel, chromium |
| Reproduction | Adults of reproductive age | PCBs, DDT, phthalates |
| Developmental | Foetuses, children | Lead, mercury, other endocrine disruptors |
| Nervous system disorders | Foetuses, children | PCBs, methyl mercury, lead, manganese, aluminium, organic solvents |

health. According to the latest estimates from the International Labour Organization (ILO), a staggering 439,000 workers were killed by chemicals and other hazardous substances in 2003. Some 35 million persons are currently suffering from work-related diseases caused by hazardous substances.

But these figures give an incomplete and misleading picture. They refer to people damaged at work and exclude the persons who are subject to long-term exposure outside industrial facilities through their day-to-day life.

In an attempt to assess the human impact from long-term exposure to chemicals in Sweden, the National Chemicals Inspectorate (KemI) has estimated that five percent of the total burden of illnesses in the industrialised world, including cancers, may be attributed to chemical pollution, including air pollution and occupational exposure to chemicals. This would mean, for example, that chemical pollution in all its forms causes some 130,000 cases of cancer in Europe annually.

### Cancer

Cancer has been the predominant issue of concern for discussions about health effects from synthetic chemicals for decades. The reason is that cancer was one of the first potential health problems identified with chemicals. Although cancer is undoubtedly an issue of concern, the spectra of effects studied by scientists and authorities has grown and includes several other issues of similar concern.

Some chemicals clearly cause cancer within some exposed groups, but the overall causation is unclear. Any increased cancer incidence is likely to be limited to a certain group of people, and may not be clearly visible in the general statistics.

Particularly troubling is the dramatic increase in testicular cancer among young men in the last decades. Since the 1950s, the incidence has increased some 400 percent. Of similar concern, there is an increase in the incidence of breast cancer in women. Long-term exposure to synthetic chemicals are considered to play an important role through hormonal influence (see *Reproduction* below).

Annually there are approximately 10 million new cancer patients in the world. Europe has a disproportionately high share of the incidence: in 1995 the number of new cases was 2.6 million, more than one-quarter of the global burden. Out of these, 1.6 million were fatal.

Tobacco and diet are by far the major known causes of cancer in Europe, representing 65 percent of the cases. Long-term exposure to chemicals, including air pollution and workplace exposure, is considered to cause five percent of the cases, some 130,000 cases and 80,000 fatalities per year in Europe.

**Reproduction**

It is a known fact that some chemicals have negative effects on the reproductive systems of wildlife. Human reproduction has become a main area of concern.

Many of the effects observed in wildlife are considered to be caused by oestrogenic and anti-oestrogenic influence from chemicals. Malfunctioning or suppression of other natural hormones is another observed effect in wildlife. Chemicals which are considered to cause any of these effects are called *Endocrine Disrupters* or *Endocrine Disrupting Chemicals (EDCs)*.

Over the past decade, there has been an increasing concern that humans are also affected by EDCs. However, since tests can not be performed on humans, scientists have to rely on experiences from real life.

Clinical experience involving human exposure to a specific EDCs is very limited. The most important experience is the administration of the pharmaceutical DES in the 1940s to 1960s. DES, which has an oestrogenic effect, was given to women to prevent miscarriage. Eventually it has been proven that the daughters to these women have a significantly increased incidence of vaginal cancer and that sons and daughters have a higher rate of birth defects.

Three important lessons may be learned from this tragedy. The first is that the effects of DES on humans was very similar to those observed on animals in clinical studies. The second is that even minute amounts of a substance may cause serious effects on an offspring, especially if it occurs during a sensitive time during the development of the foetus. The third, and perhaps most troubling lesson, is the time it took for the effects to become apparent.

Another human experience of EDC concerns the production of the pesticide Kepone. A study on the male workers producing Kepone shows that their sperm production had been affected and some were even sterile.

There are a number of clinical effects that have been observed and documented in humans which could be caused by influence from such substances. The dramatic increases of testicular cancer in young men and breast cancer among women is one such area. Others are prostate cancer, kryptorkidism (when a testicle stays in the abdomen), defects on male genitalia and miscarriage.

One of the most hotly debated areas where EDCs may play an important role is declining sperm counts. It is a known fact that EDCs, such as Kepone, may impair sperm production in humans. According to several studies, the number of sperms in human semen, and their quality, has decreased dramatically over the past 50 years. This has given rise to the concern that human reproduction as such may be threatened by synthetic chemicals.

**Allergies and Asthma**

The immunological system is also highly dependent on hormonal balance and may be disturbed by EDCs, especially in the foetus

stage or in the early years of life. It is well known that the immunological systems of wildlife have been damaged by EDCs and there are concerns that they may have similar effects on humans.

This concern is fuelled by the fact that illnesses with an immunological background are increasing worldwide. For example, the incidence of asthma among school children in some European countries has increased from one percent in the 1950s to almost ten percent today. The fact that some 20 percent of the population in industrialised countries have some form of allergy is also troubling.

It is likely that there are several factors involved in this development. Outdoor air pollution, the quality of indoor air and sterile surroundings are considered to be major causes. However, the influence of EDCs may also be involved.

### Economic Costs

Assessing the economic costs incured on the global society by hazardous chemicals is impossible. Such an assessment would need to cover a multitude of issues. These would include, but not be limited to, the global costs from depletion of the stratospheric ozone layer and other environmental effects, loss of income for fishermen, farmers and forestry, costs for water treatment, health-care costs, clean-up costs for hundreds of thousands of acres of polluted soil and liability for the loss of tens of thousands of human lives.

However, it is possible to give some indications of the costs involved in some of these issues. For example, it has been estimated that chemical pollution causes some five percent of the health problems in the industrialised world and five percent of the health-care costs. The socio-economic costs for allergies alone in the EU have been estimated at €29 billion per year. Thus the costs for allergies induced by chemical pollution may be estimated at €1.4 billion annually in the EU.

In the US, the annual costs for morbidity, mortality. lead posioning, asthma, cancer and developmental disabilities caused by environmental pollution have been estimated to be €50-60 billion. The annual overall health costs caused by toxic substances in the US and Canada, have been estimated to be up to €320 billion. While these figures are huge, they are only fractions of the total costs created by chemical pollution.

## SUMMARY

The extensive production, use and dispersal into the environment of man-made chemicals, creates or contributes to a number of problems. While the direct effects of such chemicals on wildlife and humans is difficult to quantify, there is little or no doubt that the effects are vast and an issue of great concern. Hundreds of thousands of people die and millions are injured by hazardous chemicals every year.

Man-made chemicals are also responsible for other severe problems such as depletion of the stratospheric ozone layer and a major contributor to current problems with waste. Additionally, the chemicals industry and its products play a significant role in many other areas of concern, such as loss of biodiversity, water consumption and degradation of coastal areas. The total annual cost to society is immense.

# Summary of Part One

**Chemicals Industry**

The chemicals industry is the third largest industrial sector in the world. It employs some ten million persons and the global sales in 1998 were approximately €1,500 billion. Eighty percent of the production takes place in 16 countries, primarily in the OECD.

While the majority of workers are employed in small and medium-sized enterprises, sales are completely dominated by a few large multinational corporations. In Europe, the worlds largest chemicals producing region with some 35 percent of world production, two percent of the companies produce 72 percent of the volume.

The consumption of chemicals is also unevenly distributed around the world. Most of it takes place in OECD countries. A person living in Europe, USA or Japan consumes chemicals worth €1,500 per year, while an Indian or African only spends €50.

Markets in the OECD region are becoming mature and saturated with basic high-volume chemicals. Thus, the industry is looking at new market strategies. On the one hand, they are moving production and sales of basic chemicals to non-OECD countries, predicting that consumption will increase dramatically in these areas. On the other hand, they are using biotechnology and increased know-how to move into agriculture, food, pharmaceuticals and production of more specialised chemicals in Europe. This requires a dramatic restructuring of the industry.

Sales of chemicals are predicted to continue to grow. By 2020 the global sales, counted in today's prices, may have tripled. Most of this growth is likely to take place in non-OECD countries.

**Chemicals in the Environment**

Although most chemicals have not been assessed, sales are permitted until they have been proven hazardous or unacceptable. Such chemicals are widely used and dispersed, mainly through products, into the environment and eventually to humans. Low levels of synthetic chemicals have been found by scientists in every corner and environmental compartment of the world, from the high alpine lakes to ocean sediments. They are found around the globe in food, water, dust, human blood and human milk.

**Effects of Chemicals**

The full impact on the environment and human health cannot be assessed. But there are few environmental problems that cannot be traced back to chemical over-loading. There is no doubt that even low levels of certain - mostly still unidentified - synthetic chemicals are responsible or contributing to a multitude of serious effects on the environment and also on human health. While the full socio-economic costs of chemical pollution can not be assessed, they cover a wide range of issues and amount to enormous sums.

# PART TWO: POLITICS

# International Chemicals Policy

## BRIEF HISTORY

### Prehistoric

Since the beginning of civilisation, mankind has extracted, manufactured and used chemicals from the environment. Insects have been used as pigments, metals and minerals have been mined and wood has been fragmented and boiled to produce paper.

Many of the processes turned out to have certain disadvantages to human health and the environment. However, production was limited to small-scale operations causing effects that were mostly local and personal and there was little understanding of long-term effects.

### Early Industrialism (1700-)

With the advent of industrialism and large-scale operations, problems increased and authorities started to intervene on - as far as they could see - the most devastating operations.

The primary concern was the health of people living close to operations, and if an operation moved to another, less populated area, the problem of pollution was considered to be solved. Still, there was little understanding of long-term effects or the mobility of pollutants, and the practices continued as production increased.

### 1800-

With the increasing large-scale production, concern rose regarding the health of workers. Industrial facilities began to pop up in every small town of the industrialised parts of the world, creating discomforts to the neighbours and citizens. At this time, industrial smoke stacks were considered a sign of prosperity and wealth and a favourite motif of artists. Another issue of concern was the increasing use of chemicals in war.

Although the progress made possible through industrialisation was widely hailed, there were protests against the increased pollution and mass-production. The Arts & Crafts movement, which had a somewhat romantic ideal, was very active against industrialism in the United Kingdom and USA between the 1890s and 1920s.

### The First Conventions

The very first international convention considering chemicals was signed in 1868, the Saint Petersburgh Declaration. This convention covered the use of certain flammable chemicals in war.

In 1906, an international workers organisation organised a conference in Bern, Switzerland, to negotiate a convention regarding the use of phospor in the production of matches. After the first world war, in 1919, the International Labour Organisation was created and two of its first conventions concerned the use of chemicals: lead and phosphor.

### The Petro-Chemistry Boom

From the early 1900s, the arrival of petrochemistry dramatically changed society. For the first time, humans could produce new substances in a large scale. One of the end products was, of course, gasoline, or petrol. Other substances derived from the same process were benzene, toluene, xylene, ethylene and propylene. All of them could be processed into a number of new substances and were the building blocks for the emerging chemicals industry.

These building blocks were used to develop products that found great markets and

the industry started developing thousands of new substances for every possible use. Paints. plastics, pesticides, textiles, fuels and cosmetics are some examples where the new substances had created a revolution. Of course these substances were welcome by society and when the real boom came in the 1940s and 1950s, few persons voiced any concern, much less any ambition to regulate production and use.

Now we know that some of the new substances were not entirely positive. It was at this time that substances and products such as PCB, DDT, PVC, phthalates, chlordane and other notorious toxins were developed and put into large scale production and use. Simultaneously, there was a huge increase in the extraction and use of many toxic metals, such as lead, mercury and cadmium.

**Post WW II**

After the second World War, the United Nations World Health Organisation (WHO) and Food and Agriculture Organisation (FAO) were formed. Both of them were engaged in chemicals, predominantly pesticides, from the start. Ironically, their main ambition was to increase the use of pesticides such as DDT.

It took until the early 1960s before authorities started to react. By that time, concerned reports from scientists and protests from individuals and organisations were mounting and it was obvious that something needed to be done. DDT and mercury became the early focus after the publication of Rachel Carson's book "Silent Spring" in 1962. In 1966 the Danish scientist Sören Jensen presented evidence that PCB, a substance used in industrial oils, could be found in birds eggs.

Among the first to react were the authorities in the USA and in the Nordic countries (Denmark, Sweden, Norway and Finland) where environmental and health effects had become apparent. The production and use of certain substances was banned or regulated in some countries, starting in the early 1970s. DDT, mercury and PCB were among the first to be regulated. They were followed by lead, chlordane, dieldrin and others.

**Time for Treaties**

A political breakthrough was reached in 1972 at the United Nations Conference on the Human Environment in Stockholm, the first UN conference to focus on environmental issues. A declaration was adopted and it was agreed to establish a separate UN programme for the protection of the environment - the United Nations Environment Programme (UNEP).

After this point, numerous treaties, agreements, conventions, declarations and protocols for the protection of the environment - including measures against chemical pollution - were negotiated globally. Some of them are truly global, encompassing over one hundred nations, while others are regional.

Though the USA and the Nordic countries were the most active, authorities in some other countries started to react. From the late 1970s through the 1990s, several other nations, primarily in Europe, took an active role. However, the majority nations in the world still play a passive role, following the developments and implementing regulations when demanded.

**Loss of Leadership**

Since the 1970s it has become apparent that the problems are not limited to a small number of substances. Scientists and authorities eventually realised that it was impossible to protect the environment and human health by picking one substance at a time. New problems were identified continuously and the number of potentially problematic substances was too great. Additionally, new substances were being developed and marketed every day. A different approach was necessary.

Lately, the USA seems to have abandoned its ambition to be one of the global leaders in this area. Similarly, the Nordic countries have taken a more passive approach, possibly in order to adapt to the general policies of the EU. While working for stronger regulation

inside the EU, they are reluctant to implement stronger national regulations. Hopefully, the EU as a whole will now take on the task of being a global leader in the regulation of chemicals and protection of human health and the environment.

## GLOBAL INSTRUMENTS

### Some Definitions

Global instruments to protect the environment are negotiated in many different fora and have different status depending on which instrument has been chosen for the agreement. Most of the important instruments have been negotiated under the United Nations.

Over the past centuries, state practice has developed a variety of terms to refer to international instruments by which states establish rights and obligations among themselves. In spite of the diversity of terminology, no precise nomenclature exists. In fact, the meaning of the terms used is variable, changing from state to state, from region to region and instrument to instrument. Some of the terms can easily be interchanged: for example, an instrument that is designated "agreement" might also be called "treaty."

The title assigned to such international instruments thus has normally no overriding legal effects. The title may follow habitual uses or may relate to the particular character or importance sought to be attributed to the instrument by its parties. The degree of formality chosen will depend upon the gravity of the problems dealt with and upon the political implications and intent of the parties.

Although these instruments differ from each other by title, they all have common features and international law has applied basically the same rules to all of them. These rules are the result of long practice among the states, which have accepted them as binding norms in their mutual relations.

As a general rule, the title of an instrument serves as an indicator of its legal status, but there are many exceptions. Thus the status must be defined case by case.

#### Declaration

Although "declarations" are generally not legally binding, they are very important as indicators of the ambitions and directions of the global community. The term is often deliberately chosen to indicate that the parties do not intend to create binding obligations but merely want to declare certain aspirations which will later be laid out in other, legally binding, instruments. An example is the 1992 Rio Declaration. Declarations can however also be treaties in the generic sense intended to be binding by international law. It is therefore necessary to establish in each individual case whether the parties intended to create binding obligations.

#### Treaty

There are no consistent rules when state practice employs the terms "treaty" as a title for an international instrument. Usually the term is reserved for matters of some gravity that require more solemn agreements. The signatures of the parties are usually sealed and they normally require ratification.

#### Agreement

"Agreements" are usually less formal than treaties and deal with a narrower range of subject-matter. There is a general tendency to apply the term "agreement" to bilateral or restricted multilateral treaties. It is employed especially for instruments of a technical or administrative character, which are signed by the representatives of government departments, but are not subject to ratification.

#### Convention

The term "convention" is usually used for formal multilateral treaties with a broad number of parties. Conventions are normally open for participation by the international community as a whole, or by a large number of states. Usually the instruments negotiated under the auspices of an international organisation are

entitled conventions. Conventions are also considered binding, for example the Statute of the International Court of Justice refers to "international conventions, whether general or particular" as a source of law, apart from international customary rules and general principles of international law.

### Protocol

The term "protocol" is used for a variety of instruments. Typically, they are less formal than conventions and treaties or they may be subsidiary to framework conventions, defining what measures to implement, targets to reach or other technical matters. An example is the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer adopted on the basis of the 1985 Vienna Convention for the Protection of the Ozone Layer.

### Ratification

"Ratification" is when an international instrument is adopted on a national regulatory level, usually by parliaments of the contracting parties. Some instruments, especially treaties and conventions, require ratification of a certain number of governments before they enter into force internationally.

## UN Instruments Concerning Chemicals

The problems associated with chemicals are of concern to the global population. Thus the management of chemicals is addressed in a number of UN organisations, treaties, programmes and declarations. The main UN body dealing directly with chemicals is the United Nations Environment Programme (UNEP).

However, control of chemicals concerns many other UN bodies. Therefore,in 1995, the UN created the Interorganisation Programme for the Sound Management of Chemicals (IOMC). The programme consists of a cooperative agreement among UNEP, the International Labour Organisation (ILO), the Food and Agriculture Organisation (FAO), United Nations Industrial Development Organization (UNIDO), United Nations Institute for Training and Research (UNITAR) and the Organisation for Economic Co-operation and Development (OECD).

### The Stockholm Declaration

The first time long-term chemical pollution was officially addressed at a high level was during the 1972 United Nations Conference on the Human Environment (UNCHE) in Stockholm, where chemical pollution was recognised as an issue of global concern. At the conference, a number of guiding principles for the protection of the environment were adopted. These have been important in the successive development of other instruments.

Another important outcome of this conference was the agreement to create a new programme for global environmental protection under the United Nations: UNEP.

### The MARPOL Convention

The International Convention for the Prevention of Pollution from Ships (MARPOL) was first adopted in 1973, but was later modified in 1978. The aim of the convention is to minimise releases of oil, noxious liquids, harmful substances, sewage and garbage from ships. The convention stipulates certain criteria for ships travelling the seas and also designates some marine areas to be especially sensitive, thus requiring a higher level of protection and stricter rules. The convention had 118 contracting parties in 2001.

### The Vienna Convention

The evolving insight that certain man-made chemicals were destroying the stratospheric ozone layer finally triggered action. In 1985, the Vienna Convention was agreed upon. This is a framework convention which needs the development of measures in separate protocols (see also *the Montreal Protocol*). The convention had 176 parties in 2001.

### The Montreal Protocol

As a protocol under the framework of the Vienna Convention (see above), the Montreal

protocol was first adopted in 1985 and has been adjusted five times. It aims to reduce and eventually eliminate the emissions of man-made ozone depleting substances by ceasing its production and consumption. The protocol had 175 contracting parties in 2001.

### The Rio Declaration and Agenda 21

The second time chemicals were addressed broadly in a global effort was at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, Brazil, in 1992. At the conference, the signatories once again laid out important principles. The principles of greatest relevance to chemicals are number 8, which declares that states should reduce and eliminate unsustainable consumptions patterns, and principle 15 which declares the importance of using the precautionary principle.

Additionally, the states agreed on an action plan, that was named "Agenda 21," based on these principles. The agenda consists of 40 chapters which are intended to create a sustainable development for the 21st century.

Chemicals are widely covered in the agenda. The entire Chapter 19 concerns safe use of chemicals and chemicals are also covered in Chapter 6 (protection of human health), Chapter 9 (protection of the atmosphere), Chapter 14 (sustainable agriculture), Chapter 17 (protection of the seas), Chapter 18 (protection of fresh water) and Chapter 20 (treatment of hazardous waste).

### The Stockholm Convention

In the mid-1990s, negotiations to eliminate releases of persistent organic pollutants (POPs, see also box in *Chemicals in the Environment* in Part One) were initiated. The negotiations focused on the 12 most hazardous substances - the Dirty Dozen - and were finalised in 2001 in Stockholm, Sweden.

In a historic agreement in May 2001, the nations of the world for the first time agreed to eliminate all releases of certain chemical substances. The treaty is also known as the POPs Treaty. Eventually other POPs are likely to be added to the list and be banned globally.

### The Basel Convention

In order to control the transboundary movements of hazardous wastes, the Basel Convention was adopted in 1989. The convention lays out principles for avoiding damage to the environment from such transports. In 1995, an amendment to the convention was also adopted, banning the export of hazardous waste for final disposal, recovery or recycling from OECD countries to non-OECD countries. The convention had 148 contracting parties 2001.

### The London Convention

First adopted in 1972, the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, concerns dumping of wastes which contain hazardous chemicals or radioactivity as well as incineration of hazardous wastes at sea.

The convention was amended several times and was finally replaced in 1996 by a framework convention and protocols. While the original convention was permissive in the sense that it allowed dumping in general except for matters defined in the convention, the 1996 convention reverses the logic. It bans dumping in general, except for certain matters that are defined in the protocols, such as organic waste.

One of the most important innovations was the introduction of the "precautionary approach." This states that preventive measures should be taken when there is reason to believe that wastes or other matter introduced into the marine environment are likely to cause harm even when there is no conclusive evidence to prove a causal relation between inputs and their effects. The protocol also states that "the polluter should, in principle, bear the cost of pollution" and it emphasizes that contracting parties should ensure that the protocol should not simply result in pollution being transferred from one part of the environment to another.

### The Rotterdam Convention

Aiming to control trade of hazardous substances to countries with insufficient knowledge about chemicals and lax border control, an agreement to inform authorities in the receiving countries in advance was negotiated. Chemicals covered by this convention are pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by parties of the convention, and which have been notified by parties for inclusion in the Prior Informed Consent (PIC) procedure.

The agreement, called the Rotterdam Convention on Prior Informed Consent, was adopted in 1998 and also stipulates that the receiving country must give consent to the import before it may take place. In 2001, the convention had 14 parties.

### The Convention Concerning Safety in the Use of Chemicals at Work

The objective of the Convention is the enhancement of the existing legal framework for occupational safety, by regulating the management of chemicals in the workplace. It has the broad purpose of protecting the environment and the public, and the specific objective of protecting workers from harmful effects of chemicals. It applies to all branches of economic activity in which chemicals are used, and it covers all chemicals with particular measures concerning hazardous chemicals.

The preamble of the Convention notes that the protection of workers from harmful effects enhances the protection of the general public and the environment. In addition, workers have a need for, and a right to, information about the chemicals they use at work.

### UNFCCC

The United Nations Framework Convention on Climate Change (UNFCCC), which was adopted in 1992, aims to stabilise the releases of greenhouse gases. It establishes certain principles and provides a process for agreeing on action. The technical measures to be taken were defined in the Kyoto Protocol in 1997. The convention had 186 parties 2001.

### The Kyoto Protocol

Under the Framework Convention on Climate Change (see above) the Conference of the Parties in 1997 adopted the Kyoto Protocol containing stronger reduction commitments for developed countries in the post-2000 period. The convention covers six specific greenhouse gases, of which three are man-made chemicals, HFCs, PFCs and $SF_6$.

### The Convention on the Control of Harmful Anti-fouling Systems on Ships

Regulation of the use of tributyltin (TBT) and other hazardous substances as paint on ships (anti-fouling) was first addressed in Chapter 17 of Agenda 21 and has been negotiated in the IMO since 1999. In 2001 a convention was adopted.

Under the terms of the convention, parties to the Convention are required to prohibit and/or restrict the use of harmful anti-fouling systems on ships flying their flag, as well as ships not entitled to fly their flag but which operate under their authority and all ships that enter a port, shipyard or offshore terminal of a party.

Anti-fouling systems to be prohibited or controlled will be listed in an annex to the convention, which will be updated as and when necessary.

### World Summit on Sustainable Development (WSSD)

In September 2002, the World Summit on Sustainable Development (WSSD) in Johannesburg, South Africa, adopted a historic objective much similar to the generation goal set in the Esbjerg Declaration from 1995 and in the OSPAR convention from 1998 (see *Regional Instruments* below).

The WSSD goal is that, by the year 2020, chemicals will be used and produced in ways that *"lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk*

*assessment procedures and risk management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development".*

The Summit also endorsed the further development of a strategic approach to international chemicals management (SAICM), based on the IFCS Bahia documents, by 2005 and urged UNEP, IFCS, other international organizations dealing with chemical management and other relevant international organisations and actors to cooperate closely in that regard, as appropriate. The Plan of Implementation of the Johannesburg Summit also identified the need to increase efforts to achieve sustainable consumption and production, cleaner production processes and methods and prevention and/or minimisation of the generation of wastes

### Strategic Approach to International Chemicals Management (SAICM)

In February 2002, the United Nations General Assembly adopted a decision to develop a global strategy for chemical management. This was confirmed by the participating states at the World Summit of Sustainable Development (WSSD) in Johannesberg, South Africa, in September the same year. The first negotiations for a Strategic Approach to International Chemicals Management took place in Bangkok in November 2003. The intention is that negotiations will be finalised by 2005, resulting in a Ministerial declaration and global convention.

### Other UN Activities

UNEP is also a driving force in other areas concerning chemicals, such as the promotion of cleaner production, the phase-out of lead in petrol, global assessment of mercury pollution and enabling information sharing.

Beside the agreements made under UNEP, other UN bodies also address chemical control in specific sectors or indirectly. Such activities are conducted through a variety of programmes and have resulted in a large number of global instruments. Examples of such bodies are the United Nations Economic Commission for Europe (UNECE) which created the first international agreement on air pollution in 1979 and the Convention on Long-range Transboundary Air Pollution (CLRTAP), also known as the Geneva Convention.

The United Nations Food and Agriculture Organisation (FAO) covers some aspects of the use of pesticides, primarily through the Code of Conduct. The World Health Organisation (WHO) also addresses specific aspects of chemicals, such as establishing tolerable daily intakes (TDIs) of pesticides and other pollutants. The International Maritime Organisation (IMO) covers some aspects of chemical pollution at sea and operational regulations for ships. The International Labour Organization (ILO) covers work-related issues of chemical safety.

The International Programme on Chemical Safety (IPCS), a cooperative programme of the UNEP, WHO and ILO, was formed in 1980 to assist states in the evaluation of risks associated with chemicals and strengthening their capacity in preventing damage to human health and the environment.

## IFCS

At UNCED in Rio de Janeiro in 1992, some 100 nations and organisations formed the Intergovernmental Forum for Chemical Safety (IFCS). The forum is an independent organisation which is administered by WHO but funded by IFCS members.

The objective of IFCS is to help nations to implement the agreements concerning chemicals made in Rio de Janeiro. However, at the Forum III meeting in Salvador da Bahia, Brazil, in October 2000, the organisation adopted a new declaration, reviewed its objectives and adopted new priorities for global control of chemicals beyond the year 2000, thus making a commitment to achieving a number of key goals within a defined time frame and drawing the attention of governments and the

**The OECD High Production Volume (HPV) Programme and SIDS**

In 1990 the OECD established a programme on the co-operative investigation of existing chemicals. This programme focuses on chemicals produced in high volumes (i.e. produced in greater than 1000 tonnes in one OECD country or the European Union) of which there are about 5,000. Little is known about the toxicity for some 75-85 percent of these chemicals. A minimum set of data - the Screening Information Data Sets (SIDS) - upon which an initial hazard assessment can be based for HPV chemicals will be provided by OECD countries in co-operation with industry.
To this end, the OECD countries have identified a number of data elements needed for screening chemicals to determine whether further work is necessary. The SIDS is comprised of a limited number of data elements which can give information on certain characteristics - such as persistence and bioaccumulation - and effects of chemicals. Similar to the Minimum Pre-marketing Set of Data (MPD) for new chemicals, SIDS is used in the HPV Chemicals Programme by many countries and in voluntary industry programmes.

public to the need for action on chemicals issues. IFCS has also played an important role in the negotiations of many of the more recent agreements. In particular, it has been active in promoting the need for a global strategy (SAICM, see previous page).

## OECD

The Organisation for Economic Cooperation and Development (OECD) is an intergovernmental organisation with 30 member states. Its primary purpose is to achieve the highest possible sustainable economic growth, improve the economic and social well-being of its population and to contribute to global development in general.

The OECD has an extensive programme concerning chemicals. The focuses of the activities are to assist member states in risk management, promoting the public right to know, preventing disturbances in the trade of chemicals and to promote new technologies.

### The Chemicals Programme

Specifically, the OECD Chemicals Programme provides guidelines for the testing of chemicals, principles for good laboratory practices, a system for the mutual acceptance of data, harmonised methods of risk assessment, cooperative testing and assessment of high volume production chemicals, support for national activities regarding risk management and proposals for a harmonised classification system for chemical hazards. The Chemicals Programme is also developing a project to coordinate national and regional activities concerning endocrine disrupting chemicals (EDCs).

### The Chemical Accidents Programme

The OECD Chemicals Accidents Programme, which began in 1988, addresses prevention, preparedness and response related to accidents involving hazardous substances. Its activities focus on the development of common principles and policy guidance for public authorities, industry, labour, communities and others as well as the sharing of information and experience among OECD and non-member countries.

### The PRTR Programme

The OECD Work on Pollutant Release and Transfer Registers (PRTRs) was initiated in 1993, as a follow-up to UNCED in Rio de Janeiro 1992, with a project to prepare guidance for, and promote the development of, PRTRs. This work was undertaken in close cooperation with IPCS, WHO, UNEP, UNITAR and UNIDO. A 1996 OECD Council Recommendation calls on member countries to establish PRTR systems.

### The Pesticides Programme

The Pesticide and Biocides Programme was formally launched in 1994, after recognition by member countries of the pressing need to initiate new international work on pesticides and biocides. The goals of the project are to harmonise pesticide and biocide review procedures for registration and use, to share the work of evaluation of pesticides and biocides and to find new approaches to risk reduction.

### Other OECD Programmes

Beside the activities undertaken in the different programmes directly associated with chemicals, the OECD has many other activities that are indirectly connected. Examples are activities regarding climate change and an extensive programme on waste issues.

## The World Bank

In its own words, the UN World Bank assists countries in order to alleviate poverty and improve living standards. The Bank has been extensively criticised for investing into unsustainable and destructive technology and projects. Today the World Bank recognises that that its goals can only be achieved if they address local, regional and global environmental issues and sustainability.

The World Bank claims to take into account issues of sustainable development and protection of the environment in the development and review of lending projects. Guidance has been developed for use in Bank-funded projects to raise attention to pollution prevention, including issues related to chemical safety.

The World Bank is involved in a number of activities relating to global environmental agreements, including climate change, persistent organic pollutants (POPs), ozone depletion and the Global Environment Facility (GEF). The International Finance Corporation (IFC), the private sector part of the World Bank Group, helps the private sector develop projects that promote the objectives of the climate change and biodiversity conventions.

## World Trade Organisation (WTO)

The WTO is an international organisation overseeing the rules of international trade. Its purpose is to help trade flow smoothly, in a system based on rules, to settle trade disputes between governments, and to organise trade negotiations.

There is wide concern that the liberalisation of trade is allowed to over-ride measures to protect the environment and human health through multilateral environmental agreements (MEAs). This has two dimensions: firstly, multilateral and global agreements that have already been agreed may be difficult to implement, and secondly it may become more difficult to develop new instruments.

The WTO claims that a range of provisions in the WTO can accommodate the use of trade-related measures needed for environmental purposes, including measures taken pursuant to MEAs. Of key importance are the WTO provisions relating to non-discrimination and to transparency as well as the exceptions clauses allowing a WTO Member to legitimately place its public health and safety and national environmental goals ahead of its general obligation not to raise trade restrictions or apply discriminatory trade measures.

# REGIONAL INSTRUMENTS

## United Nations

In addition to the global instruments, the United Nations also negotiate regional and multilateral agreements for protection of the environment. Some of them are connected to global instruments, such as the Barcelona Convention, others are independent agreements. There are also a few conventions which have not been negotiated under the United Nations, such as the Helsinki and OSPAR conventions.

### CLRTAP

The Convention on Long Range Transboundary Air Pollution (CLRTAP), adopted in 1979, is a European instrument developed under

UNECE. The objective of this Convention is to protect man and the environment against air pollution and to endeavour to limit and gradually reduce and prevent air pollution including long-range transboundary air pollution.

The Convention sets up an institutional framework, bringing together policy and research components. It establishes a number of co-operative programmes for assessing and monitoring the effects of air pollution.

Since its entry into force, the convention has been extended by eight protocols regulating releases and transboundary movement of air pollution, among them sulphur, nitrogen oxide, volatile organic compounds (VOCs), some heavy metals and 16 POPs. The convention had 48 contracting parties in 2001.

### Regional Seas Programme

One of the first attempts at global instruments made by UNEP was the Regional Seas Programme, established in 1974. The programme aims to tie nations together in regional maritime fora in order to protect the marine and coastal environment. While the approach is regional, it has global reach.

In this programme, the world's seas are divided into 14 regions where each region has a specific programme to address the specific issues of concern. These regions remain the central UNEP initiative to implement Chapter 17 of Agenda 21 (see *Rio Declaration*). Thirteen of the regions have adopted individual action plans and nine have adopted regional conventions, such as the Barcelona Convention (see below).

The United Nations Regional Seas Programme does not include certain marine areas that are covered by other conventions, such as the North-East Atlantic and the Baltic Sea.

### The Barcelona Convention

The Mediterranean Sea is one of the regions that has adopted a convention under the UNEP Regional Seas Programme (see above). The Convention, which is called The Barcelona Convention (Barcon), was adopted already in 1976. In recent years the convention has been increasingly focusing on releases of hazardous substances to the marine environment from land-based sources.

In 1995, Barcon adopted the precautionary principle and also set the objective to eliminate all releases of hazardous substances to the Mediterranean, making its objective very similar to those of OSPAR and HELCOM.

## Other Instruments

### The Esbjerg Declaration

At the Ministerial Conference of the North Sea Ministers in Esbjerg, Denmark, in 1995, the Ministers adopted a declaration voicing concern regarding the state of the North Sea and - for the first time - defined an operational objective. The declaration concludes that the only acceptable level of hazardous substances - man-made and natural - are background levels. To achieve this, all releases of hazardous substances to the marine environment must cease within one generation, i.e. before the year 2020. This objective has later been called "the generation goal" (see separate box).

This declaration and the generation goal have come to set the agenda for several regional conventions, such as the OSPAR, Barcelona and Helsinki Conventions, and is now finding its way into global instruments as well. Similar wordings were adopted in June 2001 by the Council concerning the objectives of the new EU chemicals strategy (see *REACH*) and at the WSSD in 2002 (see above).

The Esbjerg Declaration is probably the first international political declaration explicitly seeking to eliminate the threats from chemicals at their source.

### The OSPAR Convention

The OSPAR Convention, or The Convention for the Protection of the Marine Environment of the North-East Atlantic, which is the full name, was adopted in 1992, replacing the previous Oslo-Paris Convention. The OSPAR convention seeks to protect the marine environment in a large area, from Gibraltar to northern Norway and Russia, by taking

**OSPAR and The Esbjerg Declaration**

At the North Sea Ministerial meeting in Esbjerg, Denmark in 1995, the Ministers adopted the following declaration. It has become the new standard for other regional instruments and is increasingly finding its way also into global policies.

"The Ministers AGREE that the objective is to ensure a sustainable, sound and healthy North Sea ecosystem. The guiding principle for achieving this objective is the precautionary principle.

This implies the prevention of the pollution of the North Sea by continuously reducing discharges, emissions and losses of hazardous substances thereby moving towards the target of their cessation within one generation (25 years) with the ultimate aim of concentrations in the environment near background values for naturally occurring substances and close to zero concentrations for man-made synthetic substances."


*Map of the OSPAR Convention area with 16 contracting parties.*

all possible steps to prevent and eliminate pollution and take the necessary measures to protect the sea area against the adverse effects of human activities. It also aims to safeguard human health and to conserve marine ecosystems and to restore marine areas which have been affected.

To this end, the Ministers in the contracting parties adopted the Esbjerg Declaration in 1998 in Sintra, Portugal (see above). The convention has 16 contracting parties. OSPAR now has an extensive programme to identify hazardous substances which will be phased out by the contracting parties in order to achieve the generation goal as defined in the Esbjerg Declaration.

### The Helsinki Convention

For the first time ever, all the sources of pollution around an entire sea were made subject to a single convention, signed in 1974 by all Baltic coastal states. The 1974 Convention entered into force on 3 May 1980.

In the light of political changes, and developments in international environmental and maritime law, a new convention was signed in 1992 by all the states bordering on the Baltic Sea, and the European Community. After ratification the Convention entered into force on 17 January 2000.

The Convention has ten contracting parties and covers the whole of the Baltic Sea area, including inland waters as well as the water of the sea itself and the sea bed. Measures are also taken in the whole catchment area of the Baltic Sea to reduce land-based pollution. In 1996 the Helsinki Commission adopted an objective similar to the Esbjerg Declaration and generation goal of OSPAR.

### The Rhine Convention

In what was to become possibly the first convention intended to protect the environment, the five states living along the Rhine River in Europe started discussing chemical pollution of the river in the 1950s. The negotiations led to the adoption of the Convention on the Protection of the Rhine Against Pollution (the Bern Convention) in 1963. The Convention was amended many times over the years and was finally replaced by the Rhine Convention in 1999.

The convention aims to protect the Rhine river, its catchment area, groundwater and ecosystem against chemical pollution. The convention largely focuses on restoration of the badly polluted river area, using the precautionary principle as well as the polluter pays principle. Five nations and the European Community are contracting parties.

## CORPORATE INITIATIVES

To address its own environmental and safety performance, improve public relations and/or avoid increased regulations (take your pick), the chemicals industry has launched numerous voluntary programmes and measures. Most of them are specific to certain sectors, but there are also more general initiatives of global character.

### Responsible Care

One of the largest such programmes is called Responsible Care and was established in 1985 by the chemicals industry. Today some 47 chemical industry associations around the world are partners of the programme. The industry associations in each country or region are responsible for the implementation in their countries.

Individual Responsible Care programmes are at different stages of development and have different emphasis. The programme, which is managed by the International Council of Chemical Associations (ICCA), consists of a set of rules and principles, information sharing schemes, checklists and verification procedures.

Responsible Care is the largest of many voluntary initiatives launched by the chemicals industry. Another example is Coatings Care, a similar initiative launched by the printing ink industry association CEPE and SunCare, a programme developed by the dominant company in the ink and coatings manufacturing industry, Sun Chemicals.

However, Responsible Care has very little relevance to risk management of chemicals and long-term exposure to low doses (see *Effects of Chemicals* in *Part One*).

Furthermore, it is uncertain to which extent such programmes have improved safety and health within the industry or has helped to avoid accidental releases of chemicals. While industry often presents figures pointing to the success of the programme, others have reported figures showing that Responsible Care has little or no positive effect.

In 1997, the International Federation of Chemical, Energy, Mine and General Workers' Union (ICEM) presented a survey showing that Responsible Care "had no impact on most of the world`s chemical workers" and ICEM concluded that "the voluntary nature of the RC programme may mean that it is more of a public relations exercise."

### The HPV Initiative

In October 1998, ICCA announced a global industrial initiative to speed up the process of data collection and hazard assessment of existing chemicals (see boxes on pages 52 and 55). According to the plans, the initiative will establish a priority list of 1,000 High Production Volume (HPV) chemicals.

These substances will then be screened for potential effects on human health or the environment according to the same procedure that is already used by the OECD in the Screening Information Datasets (SIDS).

The screening is intended as a first indicator of potential effects and should not be mistaken for a risk assessment. The screening of the 1,000 HPVs is intended to provide an improved basis for risk assessment in existing programmes, and is to be completed by the end of 2004.

The HPV Initiative is financed through industry who also state that the results of the screenings are made available to authorities and the general public. According to other sources, the industry only publishes summaries of what it wants to release.

### The Long-range Research Initiative

In October 1998, ICCA also launched the Long-range Research Initiative (LRI), financed by chemicals industries in the USA, EU and Japan. It provides support for research to focus on scientific understanding of the mechanisms via which chemicals have impact on human health and the environment. Subjects targeted are endocrine disrupters, exposure assessment, carcinogenesis, respiratory toxicity, immunotoxicity and allergies.

### HERA

Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products is the full name of a joint project between Cefic and the International Association for Soaps, Detergents and Maintenance Products (AISE). The aim is to provide a common risk assessment framework for the household cleaning products industry and show that this process will deliver evaluated safety information on the ingredients used in these products in a speedy, effective and transparent way. This process is intended to support a risk-based approach to chemicals legislation in the European Union, and may serve as a pilot for the application of the same process in other sectors and/or geographical areas.

## SUMMARY

Chemical pollution has a long history, beginning when mankind started extracting minerals. However, large-scale adverse effects did not arise until the advent of industrialisation in Western society. With the boom of the petro-chemical industry in the first half of the 1900s, production and dispersal of man-made substances was introduced and created a new dimension to the problem. Today, the long-term exposure to man and the environment by low levels of synthetic chemicals has become a pressing concern of global dimensions.

Regulation was all but non-existent until the late 1960s when some states and the United Nations started to act. From the 1980s, international and global cooperation also picked up speed and many multilateral instruments were negotiated.

However, political activities have been characterised by their inability to address the problems in a pre-emptive manner. Authorities and intergovernmental organisations have been chasing substance after substance, trying to catch up but lagging further behind every day.

There are numerous global and regional instruments as well as corporate initiatives addressing chemicals in different ways. Some of them focus on protecting a certain environmental compartment, while others focus on specific uses of chemicals. Some are legally binding and far-reaching, while others tend to have the character of management systems or window-dressing.

However, they are far from sufficient. Most of them are very general in their approach and unclear in the objectives. Others have limited scope, focus on end-of-pipe solutions and aim to control releases and effects of a limited number of substances. Others are of technical character, improving cooperation but having little progressive implication. Very few of the instruments come close to addressing the problem at the source, i.e. regulating the production and use of certain chemicals.

There are some exceptions. The adoption of the Esbjerg Declaration into the OSPAR Convention, and similar declarations in the Helsinki and Barcelona Conventions are positive examples, setting clear objectives that have the ability to protect human health and the environment when reached. Notably, the Stockholm Convention is the only global instrument taking a similar approach. SAICM, which is being negotiated currently, may also be pro-active in this sense.

Some of the nations that have been the global leaders regarding chemical safety seem to be abandoning their ambitions and roles. It is crucial for world development that they revitalise their efforts and that others now join in.

## RISK MANAGEMENT

### Overview

Chemicals have the ability to cause damage on the environment and human health. Thus, society needs to have a mechanism to minimise the risk of harm by establishing whether a chemical substance poses a threat and, if necessary, define what measures should be taken against it.

Developing such a mechanism - or regulation - is an extremely difficult task. Chemicals are very diverse to their nature and have different properties that may pose risks in a myriad of different ways. There are a multitude of different factors to consider and the amount of information and data needed is extensive. In most cases there are serious data gaps regarding effects on humans or the ecosystem.

The predominant way to deal with the problem hass been to use an approach based on Risk Assessment. Typically, the procedure consists of two different processes: an assessment of what risk the substance in question poses, based on scientific research, and in a second phase, a risk reduction strategy on regulatory action that needs to be taken, if any. The latter is based not only on the outcome of the risk assessment, but also weighs in social and economic factors and the consequences of a possible regulation.

### Existing and New Substances

The current situation in Europe is characterised by the fact that there are two groups of chemicals. By far the largest group are the 100,106 substances that were registered in the EU before 1981 - also known as *existing substances* and listed in the European Inventory of Existing Commercial Substances (EINECS). The second group only contains some 3,000 substances registered after 1981 - known as *new substances* - listed in the European List of Notified Chemical Substances (ELINCS).

While all the new substances have undergone a certain degree of testing, hardly any of the existing substances have been evaluated for possible effects on humans or the environment. When EINECS and ELINCS were established, the intention was that also the existing substances would be tested, but this has not happened. Only some 140 of the existing substances have been identified as priority substances and are subject to comprehensive assessments. To date, only 17 assessments have been published and only four of them have been implemented into community legislation.

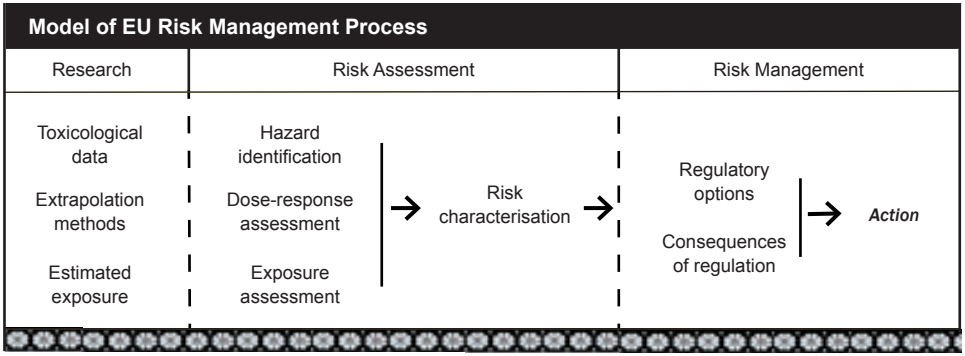
The reasons are debated: the enormous amount of information needed for a single risk assessment, delayed reporting by the industry, lack of resources by Member States, bureaucracy, etc. Some also point out that producers have little interest in speeding up the process as sales are permitted until risk reduction measures are adopted. Such measures can only be taken after a full-fledged risk assessment and an extensive regulatory process.

### The EU Model

Current regulation in the EU is based on ideas developed jointly by authorities in Europe and the USA in the late 1970s, almost 30 years ago (see the simplified model in the box on the next page). One of the main features of the EU model is that it prescribes that the risk assessment should be complete before any regulatory action is considered.

This model is considered to have certain advantages. Theoretically it enables a fully scientific approach to assessing the risk associated with a substance. The result of this scientific risk assessment can then be used to decide on any regulatory action. In theory, this should prevent political decisions based on assumptions and ignorance.

But it also has some serious disadvantages. In particular, it prescribes that a complete risk assessment should be made before any regu-




latory action may be taken. This requires obtaining a reasonably complete set of data, an extensive and extremely resource demanding process. Until the completion of such an assessment, any regulatory action is blocked.

A fundamental problem with this model - and risk assessments in general - is that it disregards that there are always data gaps in the scientific part of an assessment. It is simply impossible to determine all the relevant aspects that need to be covered. Instead, assumptions have to be made all the time. Decisions are taken on incomplete, sometimes even rudimentary, information. Yet, risk assessments are presented as a scientific and fully neutral process.

Such assumptions, also called *defaults*, are of different character depending on what purpose or use the substance is intended to have on the market and what kind of data are lacking. If the substance in question is a food additive lacking data about toxicity, the data gap will be considered serious. The following assumption will be that the substance should be regulated as being toxic. If, on the other hand, the substance in question is a basic industrial chemical it may be assumed to be non-toxic.

### Introducing Precaution

Since the current risk assessment model was developed and introduced in the late 1970s, there have been important discoveries resulting in a different way of looking at risk. Such discoveries are the effects of substances like PCB, DDT and CFCs. These substances had been risk assessed in much the same way as in the model above, and considered safe on scientific grounds. As is well known, this was proven wrong.

These discoveries led to the development of the precautionary principle, perhaps one of the most important policies for the protection of humans and the environment to date. But

**The Four Elements of Risk Assessment**

**Hazard identification:** The identification of the inherent capacity of a chemical to cause adverse effects, without regard to the likelihood or severity of such effects.
**Hazard characterisation** (dose-response assessment): Following exposure to the chemical, the quantitative evaluation of the nature of adverse effects, including assessment of toxic potency and, where possible, a dose-response assessment.
**Exposure assessment:** The quantitative evaluation of the likely exposure of the environment and, via the environment, humans to a chemical.
**Risk characterisation:** The quantitative estimation of the probability that an adverse effect will occur, and of its severity and duration in a given population under defined exposure conditions, based on the three previous elements.

*Royal Commission on Environmental Pollution, Chemicals in Products, 2003*

the risk assessment model used by the EU has no specific mechanism for precaution. Even if there is scientifically relevant suspicion of a substance causing harm, no action will be taken until completion of the risk assessment, which normally takes several years. Thus, harm may be done before the knowledge or suspicion reaches the eyes of the persons who should use the precautionary principle: the regulators.

### Liability

As a general principle in society, those who cause damage should pay compensation for the damage. But the current liability regimes in the EU are insufficient to uphold this principle regarding chemicals. For someone to be held liable, it is necessary to prove a causal connection between the damage and the source of the damage.

It is virtually impossible for victims of chemical pollution to prove such a causal connection. There is insufficient knowledge about the pathways and effects of most chemicals and there are many confounding factors.

### Responsibility

Performing a risk assessment is a lengthy and resource-demanding process where a multitude of testing and examinations need to be undertaken. The process takes many years and the costs are substantial. Under the current EU legislation, the responsibility for performing the assessment lies with the authorities, not with the companies that produce, import or use the substances.

Furthermore, while producers and importers are required to provide information for the assessment, there is no such requirement on the companies that buy the chemicals, the down-stream users. As a consequence, it is difficult to estimate the final destiny of the substances and exposure to the environment and humans, which is a vital part of a risk assessment (see previous page).

If authorities should want to perform further testing of substances, a decision to do so can only be taken via a lengthy committee procedure. During this procedure it is not only necessary to further examine the risks posed by the substance, but the authorities are also obliged to carry out an analysis of the benefits and costs prior to any proposal or adoption of a regulatory measure which effects the chemicals industry.

Here is the catch: initiating such a procedure can only be done if the authority can prove that the substance may present a serious risk. However, proving serious risk is impossible without test results.

### Summary

There is an urgent need to assess the approximately 30,000 existing substances in production that have not been assessed regarding their potential to cause damage to the environment and humans. However, the risk assessment process is limited to only a fraction of the total of existing substances, it is slow and resource demanding. Its current application, which assumes that all chemicals are "innocent" until harm is proven, also disregards the precautionary principle. Thus, only very few decisions to restrict the use of hazardous chemicals have been adopted on the basis of precaution.

Most of the responsibility for performing risk assessment lie with the authorities. However, the authorities lack the power that needs to go with such responsibility.

## CURRENT REGULATION

### Overview

"There is no elaborated overall policy for chemicals with short and long-term goals". These are the elucidating words used in March 1998 to describe the current EU chemicals policy in a paper from Austria, Denmark, Finland, The Netherlands and Sweden to the Council of Environment.

While the above statement would be equally valid for almost any nation in the world, it points at the basic problem: regulation of

**Data Gaps Regarding High Production Volume Chemicals (HPVs) in the EU**

Prior to the introduction of pre-market regulation in 1979, industrial chemicals could be put on the market with very little or no information concerning their potential risks to human health and the environment. The exact number of such "existing" substances still on the EU market is unknown. 100,106 were registered before the deadline 1981 but all of them are not in production. The current estimates for those actually on the market vary widely from 30,000 to 70,000 (EEA/UNEP, 1998). Given the large number it is considered unfeasible to conduct extensive testing on all of them within a reasonable timeframe.

The starting point for setting priorities for information gathering, testing and assessment among this large number of chemicals has generally been production volume, which is considered to reflect potential exposure. Thus, substances being produced in volumes above 1,000 tonnes per year, also called High Production Volume (HPV) chemicals, are prioritised for assessment. But also the number of HPVs is considered too great for immediate risk assessment. There are 2,465 HPVs in the EU and only a few of them have a “full” data set, including long-term eco-toxicity results, degradation behaviour in various environmental compartments and a complete mammalian toxicity profile. Thus another tier of prioritisation is used to identify which of the HPVs should be prioritised. To this end, the EU has identified a minimum package of information - known as a base set - needed to make an initial assessment. The data required to fulfil a base-set are similar to those required in the OECD SIDS (see separate box in the section *International Chemicals Policy*, page 43, and box on page 55).

But even data for prioritising is scarce:

- 3 percent of the HPVs in the EU have a full data set
- 14 percent have data at the level of the base-set (including the above)
- 86 percent have less than the base-set level (including the below), and
- 15 percent have no data at all.

chemicals in the EU is based on the objectives of free trade policies, not on protection of human health and the environment.

Protection of workers has been an issue in chemicals regulation for over 100 years. Initially the focus was on crude and dramatic risks such as explosions, fire and corrosion, but eventually other risks have also been addressed. Risks to the environment and human health in the general population was not introduced as an issue until 1979.

With time environmental and human health issues have however managed to influence the regulation. Complementary instruments have been adopted and amendments had been made when necessary to accommodate the most pressing needs. Unfortunately, these adjustments create confusion and cannot change the structure and underlying problems. For example, the precautionary principle has not been implemented into the regulations.

Today there are many different pieces of regulation concerning many different classes of chemicals in the EU, but concerning industrial chemicals the basis is laid out in a few key provisions (see below). These have all been amended and adapted numerous times, making the legislation difficult to understand and sometimes even incomprehensible.

### 1967: The Directive on Classification and Labelling of Chemicals

The first EU regulation on industrial chemicals was adopted in 1967 (Dir 67/548/EEC). At the time, the regulation of chemicals in the six Member States differed widely and were an obstacle for Community trade.

The Member States agreed to harmonise regulation and adopted a Directive with provisions on the classification and labelling of dangerous chemical substances in order to protect public health, in particular the health

of workers, against acute exposure. Protection of the environment and long-term chronic exposure were not addressed.

Notably, producers and importers were not required to do any testing, supply any data regarding their substances or classify them. The Directive only stipulated the requirement to classify and label a substance if the producer or importer knew or suspected that the substance may be dangerous.

Initially there were eight different classifications of dangerous substances. Examples are Flammable, Explosive, Toxic and Carcinogenic. Eventually the number of classifications grew and have come to include more than 15. Although amended numerous times since its adoption, and although other Directives have been adopted to complement it, this Directive is still the basis for EU regulation of industrial chemicals.

### 1976: The Directive on Restrictions of Certain Substances

The 1967 Directive was generally successful in enabling Community trade with chemicals. However, some problems remained. In the 1970s some Member States had started banning or otherwise restricting the production and use of certain chemicals or products while other chemicals were being restricted in other Member States. Again an obstacle against trade had been identified and again there was a decision to harmonise. In 1976 a complementary Directive was adopted, laying out how regulation should be implemented in the community and which substances to restrict (Dir 76/769/EEC).

Under this Directive the Commission has also committed itself to carry out risk assessments and adequate analyses of the costs and the benefits prior to any proposal or adoption of a regulatory measure affecting the chemical industry. Thus, the responsibility for identifying a dangerous substance and proving its guilt lies with the authorities. They must also prove that the benefits of restricting it outweigh the costs.

### 1979: Amendment Concerning Existing Substances

By the mid-1970s chemicals were flowing freely and in large numbers and quantities in the Community. Essentially there was very little, if any, control of what substances were being produced, in what quantities they were being released or what effects they could have on humans or the environment. But concerns were being voiced from different directions and in 1979 an amendment of the first directive from 1967 was adopted. This was the first time that concerns for the effects of chemicals on the environment were introduced into the regulatory system.

The amendment states that all substances being produced in, or imported to, the community must be registered before 18 September 1981. Future trade in these "existing" substances could continue, making this a business-as-usual situation. However, any introduction of a "new" substance after this date would only be accepted if the producer or importer could supply certain data about the substance.

This created a situation of reversed substitution. Tens of thousands of "existing" substances, many produced in huge volumes and almost all of them without even basic data or tests, were traded freely while "new" substances needed to be tested and risk assessed. Of course, industry continued producing and selling the existing substances and the development of new substances was made more difficult.

### 1988: Directive on Classification and Labelling of Preparations

Even though classification of substances had been harmonised since 1967, there was still friction in trade since Member States had different regulations concerning the classification and labelling of preparations (mixtures of substances). Most of the chemicals being sold on the common market were in the form of preparations, e.g. solvents, fuels, lubricants, pesticides, consumer products, etc.

Already in 1969 the Community addressed this in a programme dealing with the elimination of technical barriers against trade. By 1988 the Council had adopted another three Directives dealing with the classification of certain preparations such as solvents, prints, varnishes, glues, inks and pesticides.

In June 1988 they were all replaced by a Directive concerning the classification and labelling of all dangerous preparations, albeit there are exemptions such as pesticides (Dir 88/379/EEC). The Directive prescribes the same classification and labelling system irrespective of how the preparations were intended to be used. The objective was to eliminate trade barriers and to increase protection of human health and the environment.

### 1993: The Council Regulation on Evaluation of Existing Substances

Eventually it was widely acknowledged that the structure of the regulation was unacceptable. The existing substances posed a substantial threat to human health and the environment until they had been tested, risk assessed and approved.

In 1989 - some 25 years after the alarming discovery of the effects of DDT and PCB and four years after the adoption of the United Nations Vienna Convention to phase out ozone-depleting CFCs - the EU Council "recognises" that the control of chemical substances should be based on the evaluation of their risks to man and the environment.

Luckily, a general overview of the community situation at the same time showed that considerable disparities in the national legislations of the Member States concerning chemicals were (again) creating trade obstacles. It was time to re-establish uniformity for the purpose of trade while also increasing the level of protection for humans and the environment.

Another four years passed before a regulation was adopted in 1993 (Reg EEC 793/93). According to the Regulation, existing data about certain properties and uses of substances produced in more than 1,000 tonnes per year and manufacturer should be provided. For substances produced in volumes between 10 and 1,000 tonnes, only the name, the quantity produced, the classification and foreseeable uses were required.

On the basis of the information submitted by manufacturers and importers for all of these substances, the Commission, in consultation with Member States, should regularly draw up lists of priority substances or groups of substances requiring immediate attention because of their potential effects on man or the environment.

So far, out of the 100,106 existing chemicals registered in the EU, of which some ten percent are produced in volumes above ten tonnes per year, only 141 priority substances have been risk assessed.

As described in a previous section, (see *Risk Assessment*), risk assessment is a cumbersome and resource demanding process. A report from the Commission in 1998 showed that only four substances had been assessed so far. Progress was excruciatingly slow. But for the chemicals industry it was still business as usual; sales of an existing substance is - according to the 1979 amendment (see above) - permitted while a risk assessment is ongoing.

In the meantime, the authorities have limited possibilities of restricting or banning the use of an existing substance. Such restrictions can only be adopted if the authority can show strong evidence that the substance is in some way having adverse effects. Normally this requires testing, but without test results it is almost impossible to provide such evidence.

## INITIATIVES FOR INCREASED SAFETY

### Overview

By the mid-1990s it was apparent that the system was not working well. While most trade barriers had been eliminated or significantly reduced, the regulations were not able to protect human health and the environment.

**Existing and New Substances**

Before the late 1970s, regulation of chemicals was all but non-existent throughout the world. Chemicals were developed, produced and used with little or no consideration to long-term effects on the environment and human health. Producers in Europe and other Western countries were only required to classify a substance according to a crude system if they suspected or knew that a substance was dangerous. But there was no requirement to test the substance to find out.
When authorities became aware of the effects that chemicals could have on human health and the environment, there were so many substances being produced and used in large volumes that testing them all seemed impossible. Instead they decided that any new substance would need to be tested and risk assessed before being marketed, while the existing substances could stay in production without any testing. Thus, there was a line drawn regarding the safety requirements between old and new substances in most OECD countries in the late 1970s and early 1980s. In the EU, substances registered before September 1981 are called "existing" substances, while substances registered thereafter are called "new" substances.
There are 100,106 "existing" substances registered in the EU. However, all of them are not produced. It is estimated that between 30,000 and 70,000 are currently in production. More than 2,000 of them are produced in volumes above 1,000 tonnes per year and per producer. Existing substances represent some 95 percent of the chemicals produced in the EU.
By comparison, there are few "new" substances, i.e. substances registered after September 1981, in the EU. To date, some 3,700 substances have been registered.

Since the establishment of the existing regulation, there have been major developments, scientifically as well as politically, concerning chemicals and protection of human health and the environment. Increased knowledge about endocrine disrupters and political declarations to create a toxic-free environment, as in the Esbjerg declaration, are examples of developments that require a different approach.

Of special concern are the thousands of existing substances still being produced in vast quantities without even basic data or testing. The higher requirements for new substances were also stifling development of potentially safer substances.

Voices were raised for a complete review of the system. Many stakeholders were proposing a new regulation where the safety of existing substances was addressed. They made the claim that all substances need to be equally tested and assessed irrespective of when they were first produced. Thus existing substances should be assessed in the same way as new substances were already being treated and industry should pay for it.

The chemicals industry could see that the days of the existing substances loophole were being counted and they did not like what was being proposed. Nevertheless they held a low profile initially, promoting voluntary measures, such as the HPV-programme, as a solution and highlighting the need for industrial initiatives in general.

### March 1998: Proposal for a Policy

At an informal discussion meeting, representatives from Austria, Denmark, Finland, The Netherlands and Sweden met experts to discuss the situation and what should be done. The discussion resulted in a joint position by these Member States and a document laying out some ideas intended for discussion at an informal Council meeting in April.

The document identified several operational problems with the present regulation, but concluded that the main problem was the lack of an overall chemicals policy (as described in the beginning of this section). The five Member States therefore proposed that a chemicals policy be introduced in the EU and also iden-

tified some key components:
• Operative goals should be adopted, such as the ones set up in the Esbjerg Declaration (see pages 45-46).
• The responsibility of different stakeholders needed to be clarified. The burden of proof that a substance is harmless must lie with the producer or importer. The producer or supplier of a product must inform the consumers of the possible impact of the chemicals in products on man and the environment.
• General guidelines on precaution, substitution, minimisation and the safe management of chemicals need to be introduced.
• Substances that have irreversible toxic effects or are persistent and bioaccumulative should not be used in products.
• The precautionary principle should be applied
• Costs for risk assessment and similar work should be carried by industry - not as today by the Community.

**April 1998: Council Requests Review**

The lack of progress regarding risk assessments on the 110 priority substances (and the remaining 30,000 or so existing substances in production) and an increasing concern for endocrine disruption from substances that had been risk assessed already, forced the Council to act.

To this end, the Environment Ministers met at an informal meeting in Chester, UK, to discuss the Community approach to the safe management of chemicals. A number of factors and guiding principles were identified. These included:
• Protecting the environment and human health as an integral part of sustainable development.
• The principles established by the Rio Declaration and the treaties of the EU.
• The economic and social benefits that the use of chemicals bring to society and to the quality of life.
• The importance of maintaining an effective single market.
• The wide range of legal instruments associated with chemicals management.
• The need for international cooperation on the testing and assessment of chemicals.

Following discussions on existing substances, it was suggested that a wide review of the system as a whole was necessary. In this context, the paper tabled by Austria, Denmark, Finland, the Netherlands and Sweden (see above) was welcomed and it was proposed that the concept of a framework directive should be considered.

Concerning the assessment and management of risk in general there was a shared view that the principles of sustainable development should be included in chemicals management.

The meeting concluded in suggesting a number of ways in which the present Community framework could be improved. The Ministers welcomed the idea of the European Commission to take stock of existing legislative instruments dealing with chemicals, in particular the regulation of existing substances. This stocktaking exercise was expected to include a brain-storming exercise and should enable the Commission to identify the weaknesses of the instruments. The meeting welcomed the Commission´s proposal to report back on its findings by the end of 1998.

**October 1998: Call by Parliament for Action on Endocrine Disrupters**

See separate box on the next page.

**October 1998: Launches of Global Initiatives by Industry**

At their Board of Directors Meeting in Prague of early October, the ICCA established a framework for a series of global programmes to improve its cooperation with international authorities.

The first of the three programmes launched on 12 October, was an effort to speed up data collection and hazard assessment of existing substances globally. This programme, called the HPV Initiative, is based on the OECD

**Regulating Endocrine Disrupters**

Although observed already in the 1960s, the effects of long-term exposure to certain chemicals on the reproductory and hormonal system popped up as an issue of increasing concern during the 1990s. It had become known that a large number of substances had such effects but it was not being addressed in the risk assessments of any chemicals. Strangely it had become a forgotten issue in the wake of the increasing focus on the risk of cancer. Substances with such effects are called endocrine disrupters, and it is not known which substances affect the reproductory and hormonal systems or how to assess the risk they pose. They are simply not caught in the risk assessment procedures and authorities have initiated programmes to assess this "new" problem.

In October 1998, the European Parliament adopted a Resolution calling upon the Commission to take action in this area to improve the legislative framework, reinforce research efforts and to make information available to the public.

In March 1999, the Scientific Committee for Toxicity, Ecotoxicity and the Environment (SCTEE) issued a report, "Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with emphasis on Wildlife and on Ecotoxicology test methods." The report identified a "potential global problem" for wildlife. It also stated that "impaired reproduction and development causally linked to endocrine disrupting substances are well-documented in a number of wildlife species and have caused local and population changes."

Against this background, the Commission Communication, presented in June 2001, identified four key requirements to address the phenomenon of endocrine disruption: further research; international cooperation; communication to the public, and appropriate policy action. Short, medium and long term action was proposed to cover these requirements. According to the Commission Communication, it was clear that the strategy on endocrine disrupters would, in the longer-term, form an integral part of the overall strategy on chemicals being developed.

SIDS programme for High Production Volume chemicals and aimed to establish a priority list of 1,000 substances to be screened for hazardous properties before the end of the year 2004.

The second new programme, called the Long-range Research Initiative (LRI), aims to provide financial support for research on the mechanisms via which chemicals impact on the environment and human health. Special attention would be given to endocrine disrupters. The third initiative was to send representatives to the Sectoral ILO meeting in February 1999 where the ICCA would concentrate on its commitment to the Responsible Care programmes.

At the conclusion of the meeting, the Chairman of the Board of the Chemical Manufacturers Association concluded that the ICCA in the future would contribute better to the deliberations of various UN bodies since it had been accorded a formal NGO status there. (See also *Corporate Initiatives* on page 47 in the previous section.)

**November 1998: Commission Review**

As desired by the Ministers of Environment, the Commission initiated a review of the regulation concerning chemicals, in particular existing substances. In November the review was presented to the Council. The Commission evaluated the operation of four regulatory instruments: Council Directive 67/548/EEC, Directive 88/379/EEC, Council Regulation (EEC) 793/93 and Directive 76/769/EEC on restriction regarding certain substances.

The review identified a large number of weaknesses in all of the instruments but particularly in the two pieces of legislation that were meant to control and/or restrict the uses of existing chemicals, Council Directive 76/769 and Regulation 793/93. The review identifies 22 issues to be considered in the development of a new regulation (see summary in separate box on page 59).

Throughout the current regulation, the Commission identified the need to use the

regulation more effectively and to implement and enforce it rigorously and consistently, to develop the instruments further and the need to give full consideration to the precautionary principle. More specifically, the findings highlight the importance of:

• Using hazard identification as the initial key step in protecting human health and the environment from hazardous chemicals. A policy that makes it possible to regulate substances on the basis of their inherent properties, such as persistence, bioaccumulation and toxicity, would increase protection while reducing the need for completing risk assessments. In this context, the possibility to evaluate substances as groups, based on their properties, is also suggested.

• Reversing the burden of proof. Producers should be made responsible for collecting and submitting data on the substances they produce enabling risk assessments and evaluation of the need for regulatory measures.

• Creating a clear strategy for assessing the harmful effects of existing substances.

**December 1998: Council Feedback**

On 20 December, the Environment Council welcomed the review and adopted the following statement: "The Council welcomed the Commission document which revealed shortcomings in the application and efficiency of the Community instruments dealing with risk assessment and risk management for chemicals. It underlined the necessity to adopt a more coherent approach to the legislation on chemical products, notably on control procedures, in order to ensure a higher level of protection for public health and the environment and welcomed the Commission's intention to work on such an approach, in consultation with the Member States."

**February 1999: Stakeholder Brainstorm**

As requested by the Council, the Commission held a brain-storming meeting where all stakeholders were invited to attend. At the meeting, held on 24-25 February, it was agreed that process was too slow. The fundamental issue of relying on risk assessment was debated. Cefic reiterated the voluntary commitment made in October 1998 by the ICCA to provide toxicological and ecotoxicological data for 1,000 High Volume Production chemicals by the end of 2004 and investments in the LRI programme where the European industry contributed some €4.5 million in 1999.

**April 1999: Council asks for Precaution**

On 13 April the Council adopted a resolution urging the Commission inter alia "to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as priority clear and effective guidelines for the application of this principle."

**June 1999: Industry Increases Efforts to Create Confidence**

At the Cefic general assembly in Madrid on 11 June, president Bryan Sanderson said that as calls for restrictions and bans were becoming louder, industry has a responsibility to bring answers to the concerns being raised about chemicals. To this end Cefic would enhance "significantly and visibly its commitment to the responsible risk management of chemicals."

Among other things, this meant engaging in dialogue with green groups, governments, the Commission, consumer groups, academics and the scientific community. Cefic also pointed out that "a number of major industry initiatives at the European and international level have been launched with the ultimate aim of achieving a higher level of public confidence in chemicals".

A few days later, at the 3rd WHO Ministerial Conference on 16 June, Cefic announced that the European chemicals industry would increase its contribution to the LRI programme from some €4.5 million to €20 million a year.

### June 1999: Council Adopts Conclusions for a Future Strategy

At its meeting 24-25 June, the Council adopted a document outlining the background, components and objectives of a new chemicals strategy. The Council concluded that the EU needed a new integrated and coherent chemicals strategy to increase protection of humans and the environment. Such a strategy should make a major contribution towards enabling the Community and Member States to fulfil its international obligations, such as the generation goals of OSPAR and HELCOM.

While welcoming the initiatives of the industry to make initial assessments of 1,000 HPV chemicals by the end of 2004, the Council called on the Commission to base the new strategy on the principles of sustainability and precaution. Further, the Council inter alia concluded that the strategy should shift the burden of proof, giving industry the responsibility for risk assessments; require that industry provides adequate information and data to users and the public and encourage substitution of dangerous substances by less dangerous ones.

A proposal from the Commission was requested for the end of 2000.

### December 1999: Commission Presents Fundamental Elements

The Commission presented the progress in formulating a new chemicals policy to the Internal Market Council on 7 December and to the Environment Council on 13-14 December. The focus of the work was on existing substances, problematic chemicals such as persistent, bioaccumulative and toxic (PBT) substances, preparations and products and what resources and structures were needed to build a more successful system.

Redefinition of the responsibility of the industry and the public regulator, the burden of proof, risk assessment, the precautionary principle and endocrine disrupters were all described as aspects and principles which needed to be addressed.

#### Commission Review

On the request of the Council in April 1998, the Commission performed a review of the current chemicals regulation to identify what was causing the delay in assessing existing chemicals and to suggest a strategy for a future policy better equipped to protect humans and the environment. Below are some specific issues for consideration identified by the Commission review.

**Directive 67/548/EEC and Reg. 793/93:**

- Address operational weaknesses, specifically the risk assessment and risk reduction strategy procedures.
- Restructure, clarify and increase transparency.
- Clarify the roles of member states for completing work on existing substances.
- Review data on hazardous properties of existing substances and develop guidelines and criteria.
- Address the burden of proof issue.
- Ensure that member states consider liability as well as withdrawal of substances as a means to improve compliance.
- Ensure that instruments keep up with scientific development, such as the potential threat from endocrine disrupters.

**Directive 88/379/EEC:**

- Assess whether target groups understand the labelling of dangerous substances.
- Identify the causes of delays and non-compliance from member states, take appropriate measures and consider withdrawal of preparations as a means of increasing compliance.

**Directive 76/769/EEC:**

- Accelerate the adoption of new restrictions by giving preference to the Committee Procedure.
- Accelerate the adoption of restrictions characterised by scientific uncertainty or high economic costs by improving risk assessment procedures.
- Address the delays in the practical implementation of new restrictions.
- Ensure that the precautionary principle is given full consideration in the introduction of marketing and use restrictions of dangerous substances and preparations.

**The Precautionary Principle**

The development of a new chemicals strategy in the EU uses the precautionary principle as a basis for future regulation. The weight thus given to precaution has been one of the major issues of disagreement over REACH between the EU and the USA, where the precautionary principle does not have the same standing. The precautionary principle has been cited in 14 multilateral agreements over the past 15 years and was adopted by the EU in 2000. The most widely used definition of the precautionary principle is the one adopted at the UNCED in Rio de Janeiro 1992. It states:
"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."

The Commission's work was described as aiming at laying down the basis for an efficient, integrated and coherent EU system taking into account the interest of the environment and public health but also taking on board the industry. The Commission intended to present its White Paper on the issue by summer 2000.

**December 1999: Cefic Launch Stakeholder Dialogue Meetings**

Following its strategy to improve public perception of the chemicals industry by avoiding conflict and being seen as a partner in dialogue, Cefic invited stakeholders to discussions in a Stakeholders Dialogue Meeting. The intention was that such meetings would become routine over the coming years. The first meeting, in December 1999, showed very little result. In December 2000 the second meeting, with similar result, was organised. There have been no more meetings.

**February 2000: Communication on the Precautionary Principle**

Following the request from the Council in April 1999, the Commission presented its communication regarding the precautionary principle on 2 February. The communication proposed when, where and how the principle should be used.

**April 2000: Industry Calls for Partnership**

The academic and industrial communities concerned with chemicals issued a joint statement on 14 April under the banner of the AllChemE Alliance. In the statement, Europe´s chemical community was adamant that it could deliver the quality of life which is expected by the European citizens, but only if governments help by creating the necessary organisational and financial structures. It was stated that Europe needs a partnership for prosperity, bringing together the chemical industry, academics and governments.

**June 2000: Commission Presents Progress**

The Environment Council was informed by Commissioner Wallström of DG Environment on 22 June regarding the progress made with the future strategy. Commissioner Wallström described the strategy as "being based on the principle of sustainable development, the fundamental objective being to ensure a high level of protection of human health and the environment. At the same time, the efficient functioning of the internal market and the competitiveness of the industry will have to be preserved."

Other important principles pursued by the Commission in the development of its new strategy were the precautionary and the substitution principles as well as producer responsibility and the polluter pays principle.

The Commission intended to adopt a White Paper before the end of 2000 so that it could be presented to the Environment Council in December.

**October 2000: Industry and Commissioner Stress Growth and Innovation**

At a joint conference attended by chemicals industry, trade unions, representatives of member states and the Commission, Commissioner of Enterprise Erkki Liikanen and the Director General of Enterprise, Fabio Colasanti, discussed and reviewed the possible consequences of a new chemicals strategy. Commissioner Liikanen pointed out that a new strategy, besides looking at protection of human health and the environment, also needs to consider the importance of a favourable regulatory climate for the competitiveness of the European chemicals industry.

Eggert Voscherau, member of the Cefic board, pointed out that research and technical progress were indispensable drivers and thus a regulatory framework that promotes innovation rather than hindering it was needed.

The participants shared the view that the present review of the regulation was a good opportunity to improve the framework, that dialogue was needed, that the decision-making process must be based on science, that the single market be safeguarded to maintain free circulation of goods and that the situation of the candidate countries be considered.

**Highlights**

**1992:** Contracting parties at UNCED agree to address the threat from chemicals.

**1995:** OSPAR countries agree to phase out releases of hazardous substances to the marine environment within one generation (25 years.)

**1998:** Council asks Commission to review EU chemicals regulation.

**1999:** Council asks Commission to develop guidelines for using the precautionary principle.

**1999:** Council defines components and objectives of a new chemicals strategy for the EU in order to increase protection of human health and the environment.

**1999:** Commission presents fundamental elements of the Strategy for a Future Chemicals Policy in the EU.

## SUMMARY

The current EU regulation regarding industrial chemicals is mainly based on instruments that were drafted in the 1960s and 1970s to enable trade in the common market. Since the early and mid-1980s environmental and health issues have caused increasing concern, resulting in alterations and amendments of the instruments. However, these amendments had not given sufficient protection of human health nor the environment. They have also made the instruments unfocused and confusing.

Following UNCED in Rio in 1992 and the adoption of the generation goal in the OSPAR and HELCOM conventions, it became increasingly clear that the instruments needed to be reviewed. The Council and Commission had repeatedly during the later part of the 1990s declared that an integrated policy with the main objective to protect human health and the environment was needed. Such a policy needed to implement the precautionary and sustainability principles and make a major contribution to achieve the objectives defined in the Rio Declaration, OSPAR and HELCOM.

While the Council and Commission drafted elements and principles for such a regulation from summer 1998 to January 2001, other stakeholders were invited to participate. Initially industry reacted by highlighting the voluntary programmes being launched. Toward the end of 2000 it seemed industry would oppose the new regulation on grounds of competitiveness and trade.

## THE WHITE PAPER

### Overview

The Commission finally adopted the "White Paper on a Strategy for a Future Chemicals Policy" on 13 February 2001. The overriding goal of the strategy was sustainable development as described in the Rio Declaration. Additionally the strategy aimed to ensure a high level of protection of human health and the environment as enshrined in the Treaty, both for the present generation and future generations, while also ensuring the efficient functioning of the internal market and competitiveness of the chemicals industry.

The precautionary principle was considered fundamental to achieving the objective. Whenever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment, but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision making must be based on precaution. The reason for this was to prevent damage to human health and the environment. Another important objective was to encourage the substitution of dangerous by less dangerous substances where suitable alternatives were available.

The strategy also considered it essential to ensure the efficient functioning of the internal market and the competitiveness of the chemicals industry. The EU policy for chemicals should provide incentives for technical innovation and development of safer chemicals. According to the White Paper, recent experience has shown that innovation (e.g. in developing new and often safer chemicals) has been hindered by the burdens of the present notification system. Ecological, economic and social aspects of development had to be taken into account in an integrated and balanced manner in order to reach the goal of sustainability.

To protect human health and promote a non-toxic environment, the Commission proposed that existing and new substances should in the future be subject to the same procedure under a single system. The current new substances system should be revised to become more effective and efficient and the revised obligations be extended to also cover existing substances by 2012.

The proposed system was called REACH, an acronym for **R**egistration, **E**valuation and **A**uthorisation of **CH**emicals. The requirements, including the testing requirements, of the system depend on the proven or suspected hazardous properties, uses, exposure and volumes of chemicals produced or imported. According to the system, all chemicals produced in volumes over one tonne should be registered in a central database. At higher production volumes, special attention would be given to the long-term and chronic effects.

### Political Objectives

In order to achieve the overriding goal of sustainable development, the Commission identified a number of objectives that must be met within the framework of the Single Market. These were defined as:

- protection of human health and the environment,
- maintenance and enhancement of the competitiveness of the EU chemicals industry,
- prevention of fragmentation of the internal market,
- increased transparency,
- integration with international efforts,
- promotion of non-animal testing, and
- conformity with EU international obligations under the WTO.

### Elements

As indicated by the acronym, the proposed system consisted of three elements which stand at the heart of the regulation: registration, evaluation and authorisation. The elements represent three different tiers of safety requirements.

### Registration

All substances produced or imported in volumes above one tonne per year must be registered. Registration would require a manufacturer or importer to notify an authority of the intention to produce or import a substance and to submit a dossier containing the information required by the legislation. The authority puts this information into an electronic database, assigns a registration number and performs spot-checks and computerised screening of the registered substances for properties raising particular concern. The registration dossier should include the following information:

- data/information on the identity and properties of the substance including data on toxicological and ecotoxicological properties,
- intended uses, estimated human and environmental exposure,
- production quantity envisaged,
- proposal for the classification and labelling of the substance,
- a "Safety Data Sheet,"
- preliminary risk assessment covering the intended uses, and
- proposed risk management measures.

### Evaluation

This element would require authorities to carefully examine the data provided by industry. It also requires them to decide on substance-tailored testing programmes, following industry proposals.

- Substances above 100 tonnes per producer or importer: When the quantity produced or imported reaches the level of 100 tonnes, the manufacturer or importer would be required to submit to an authority all available information and to propose a strategy for further testing based on the general information requirements defined in the legislation, and additional information would be required if the quantity reached 1,000 tonnes. The authority would evaluate the information and the testing strategy submitted by industry and decide on the appropriate course of action. In essence, the current approach for new substances would be maintained for substances above 100 tonnes. The availability of a risk assessment drawn up by the manufacturer or importer would reduce the workload of the authorities. Testing programmes at Level 1 (100 tonnes) and Level 2 (1,000 tonnes) would be substance-tailored.
- Substances below 100 tonnes per manufacturer or importer: Substances which are suspected to be persistent and liable to bioaccumulation, substances with certain hazardous properties such as mutagenicity or high toxicity, or substances with molecular structures giving rise to concern would require an evaluation by the authorities at volume levels below 100 tonnes. Based on this evaluation, immediate safety measures and/or further testing may be needed. Thus, the authorities' right to request additional information for low volume substances on a case by case basis, as possible under the current notification system, would be retained. Furthermore, authorities should be empowered to require additional testing, when the aggregate volume produced

**REACH Presentations**

The Strategy for a new chemicals policy in response to the request by the Council to increase protection of human health and the environment, has been developed and presented by the Commission in three steps:
**1. The White Paper** (February 2001), laying out principals and main elements.
**2. The Draft Regulation** (May 2003), presenting the regulatory details of the strategy to the public and stakeholders for comments.
**3. The Proposal** (October 2003), the final regulatory proposal on REACH from the Commission.
During 2004 and 2005 the proposal will be debated and commented in a co-decision procedure by the European Parliament and Council. The role of the Commission in the continued process is to amend the Proposal according to the findings of Parliament and Council until there is agreement.

and/or imported by all manufacturers and/or importers exceeded to a considerable degree the next higher tonnage threshold for a single producer or importer.

### Authorisation

For the production and import of substances of very high concern, authorities would have to give specific permission before such a substance could be used for a particular purpose, marketed as such or as a component of a product. The scope would be clearly defined and strict deadlines be set for both industry and authorities.

New and existing substances, including those produced in volumes below 100 tonnes, which have hazardous properties giving rise to very high concern would be progressively subjected to an authorisation regime. These include substances that are carcinogenic, mutagenic or toxic to reproduction (CMR substances categories 1 and 2) and substances with POPs characteristics. However, uses that do not give rise to concern would generally be exempted.

### PBT, vPvB and Endocrine Disrupters

The White Paper was indecisive regarding substances that are persistent, bio-accumulative and toxic (PBT) and substances that are very persistent and very bio-accumulative (vPvB) other than those that fulfil POPs criteria. It was stated that further research is needed to develop criteria for the identification of such substances and the Commission would decide at a later stage how substances with these properties should be treated.

The majority of the endocrine disrupting chemicals would have to undergo authorisation in the REACH system. Serious human health effects which have so far been associated with endocrine disrupting chemicals are testicular cancer, breast cancer, prostate cancer, decrease in sperm concentration and semen volume, cryptorchidism, hypospadia and impaired development of the immune system and the nervous system. All these effects would qualify a substance either to be classified as carcinogenic or as toxic for reproduction and so would trigger its submission to authorisation. Furthermore, adverse effects on the endocrine system of wildlife species have been causally linked to certain POPs, which would be subject to authorisation.

### Scope

All existing and new chemicals produced or imported in volumes larger than one tonne per year and producer/importer would be covered by REACH. The Commission estimated that there are 30,000 such substances.

Most of these - about 80 percent - are produced or imported in volumes below 100 tonnes per year and are expected to be of little concern. Thus, they would only be required to undergo the first step of the system, registration.

The number of substances produced or imported in volumes above 100 tonnes, or being of concern and thus requiring evaluation in the second step of the system, was estimated to be 5,000.

Finally, about five percent, or 1,400 substances, are expected to have properties which would require authorisation in the third step or be taken off the market. However, uses which do not give rise to concern - such as well controlled industrial uses or uses in research laboratories - may be subject to general exemptions from the authorisation procedure.

### Accelerated Risk Assessment

Specific uses of substances which do not have one of the properties listed under the authorisation system but for which restrictions are needed, should be addressed in an improved and accelerated procedure. The following four elements are prescribed in REACH to bring about the necessary acceleration of risk assessments:

(1) Due to the registration requirement of all chemicals above one tonne there would be extensive data available on the health and safety properties of all substances marketed.

*Most of the fish being sold in supermarkets and restaurants in Europe would be banned for sale if fish had the same maximum permitted levels of toxins as meat, eggs, milk or chicken.* *See page 23.*

*Three Sages by Bente Christensen-Ernst.*

(2) The obligation of enterprises to submit a preliminary risk assessment would provide the authorities with comprehensive information on whether or not the chemical substance in question could be handled safely, avoiding unacceptable risks for workers, the population at large and the environment. Thus, for the large majority of substances (estimated at more than 80 percent), there would be no need for further assessment. In the minority of cases where there is need for further assessment, it would be clear where the further assessment should be focussed. The gain in time would be substantial compared to the present system.
(3) Under the new system, the industry would be responsible for preliminary risk assessments and assume responsibility for the safety of its products. It would be under an obligation to cooperate on the establishment of Community Risk Assessments where these were considered necessary. The delays encountered under the present system, where Member State authorities assume full responsibility for risk assessments without the necessary means at their disposal, would be eliminated.
(4) Targeted risk assessments would in most cases replace the comprehensive risk assessments of today. The latter are the main cause of delays under Regulation 793/93 as they require consideration of all dangerous effects, all exposed populations and all environmental compartments.

**Accelerated Risk Management**

According to the Commission, REACH also contains two factors that would contribute to an acceleration of the legislative process:
(1) The precautionary principle would be invoked whenever the risk assessment process is unduly delayed and where there is an indication of unacceptable risk. In particular, should a producer of a given substance delay the filing of information or test results, the authorities would be entitled to conclude the assessment. It would then pass the dossier to the Commission with a recommendation to apply the precautionary principle and to proceed to risk management measures to the possible extent of a total ban.
(2) A further acceleration is needed in order to proceed to risk management decisions for other substances in a reasonably short time frame. Thus, the Commission should be authorised to use the Committee procedure under Directive 76/769 more extensively than in the past. This approach would take account of the full range of implications of possible restrictions.

**Responsibility**

While industry has the formal responsibility for the safe use of chemicals in the current regulation, authorities have the responsibility for performing risk assessments of chemicals that the industry produce. This is very impractical and imposes considerable burden on the authorities, as well as high costs.

In the new strategy however, this responsibility is shifted to industry. Producers, importers and downstream users become responsible for carrying out risk assessments and providing data to the authorities as well as to users and consumers.

**Timetable for Existing Substances**

The testing and evaluation of the large number of existing substances on the market has a phased approach in REACH. Precise deadlines would be established for the submission of registration dossiers for existing substances. In general, substances produced in higher volumes would have to be registered first. However, the system is intended to be flexible enough to allow for earlier registration of substances of concern (e.g. intended for consumer use or having particular proven or suspected hazardous properties) produced in lower tonnage. Under these presumptions and given rapid progress in adoption of the revised legislation, the suggested deadlines for submission of registration dossiers were basically:

• substances exceeding a production volume

of 1,000 tonnes - at the latest by the end of 2015,
• substances exceeding a production volume of 100 tonnes - at the latest by the end of 2008, and
• substances exceeding a production volume of one tonne - at the latest by the end of 2012.

Dossiers drawn up in the context of the voluntary initiative on the part of the International Council of Chemicals Associations (ICCA) which comply with the OECD procedure would be valid for this purpose. However, the information contained in these dossiers would have to be supplemented in order to meet the requirements in REACH.

The strategy also included a tiered approach for the testing and evaluation of high production volume existing substances. Level 2 testing should be completed for substances above 1,000 tonnes by 2010 and Level 1 testing of substances above 100 tonnes should be completed by 2012.

**A Central Entity**

The Commission proposed to establish a central entity for the administration of the REACH system and the provision of technical and scientific support. Building on its existing experience, the entity would be the receiving body for the registration dossier, and forward the copies of the registration dossiers to the Member State authorities; establish and maintain a comprehensive central database on all registered chemicals and perform spot-checks and computerised screening of the registered substances for properties raising particular concern. It would also support Member State authorities in the evaluation of substances.

**Public Access to Information**

Today there is no central tracking system by which the public can determine whether regulatory measures are in place for individual chemicals. There is a lack of public awareness of the requirements of chemicals legislation. There is also little knowledge in the public sphere about the risks posed by chemicals.

The Commission acknowledged consumers' "right of choice." Information should enable the consumer to make a judgement on whether alternative products on the market are more favourable in terms of their intrinsic properties and risks.

The new strategy intended to increase the public understanding of the regulatory system and, furthermore, to give the public access to information about the chemicals being used. Better public access to information on chemicals would increase public awareness and lead to greater accountability on the part of industry and authorities.

The Commission believed that industry, including downstream users, should be responsible for providing this information to consumers. Information must be presented in such a way that it enables a person to understand the risks and to develop a sense of proportion in order to make a judgement on the acceptability of those risks.

**Other Issues**

The White Paper also touched briefly on other subjects:
• Stimulating Innovation: The Commission proposed to increase the current thresholds for notification and testing of new substances, to extend the conditions for derogation for research and development and enable test data to be used and submitted in a flexible way.
• Substitution: A key aim of the White Paper. The increased accountability of downstream users and better public information was expected to create a strong demand for substitute chemicals that have been sufficiently tested and that are safe for the envisaged use.
• Non-animal Testing: To maximise the use of non-animal test methods, testing requirements would be met as far as practicable through use of existing non-animal test methods. The development of new non-animal test methods would be encouraged. Measures to increase testing thresholds and more flexible test regimes would limit the need for testing.
• Trade Barriers: The new policy should not

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*Humans, birds, arctic mammals and other animals have persistent man-made chemicals in their blood and tissue. Scientists refer to it as our "body burden". See pages 21-25.*

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*Photo: Left, Robert Blombäck*

discriminate against imported products. In that respect, the EU should conform with Article 2.1 of the WTO's Technical Barriers to Trade, which sets out that imported products shall be accorded treatment no less favourable than that accorded to like products on national origin.

• Complying with OSPAR: The Convention for the Protection of the Marine Environment of the North East Atlantic aims to prevent and eliminate pollution and to protect the maritime area of the North East Atlantic against the harmful effects of human activities (e.g. land-based sources, off shore sources, dumping and incineration of wastes). The strategy supports this aim, in particular through the proposals for improved controls on downstream users of chemicals.

### Costs

The Commission pointed out that it is very difficult to give a reliable estimate of the "cost of action" implied, such as for the testing of existing substances where availability of test data generated earlier is largely unknown. However, a first estimate was given:

• Testing costs for existing substances: €2.1 billion over 11 years = €0.2 billion/year, to be borne by the chemicals industry.

• Human resources for a new entity: A staff of 190 people at the European Chemicals Bureau (ECB) to provide the technical and administrative framework.

• Public human resources in the Member States: Member States will relocate their current staff. Extra resources will be allocated to evaluation of existing substances. These resources will be freed from their current tasks by the following measures:

• Computerised screening and spot checks will replace the current general conformity check for new substances below 100 tonnes.

• Risk assessments will generally be carried out by industry rather than authorities.

• Industry human resources: an estimate is hardly possible because an increase can be expected for processes such as the authorisation process, but a reduction can be expected because of:

• notification of substances between ten kg and one tonne/year/manufacturer,

• less strict requirements for certain substances such as intermediates with low exposure,

• less strict requirements for R&D (research and development) substances.

### Benefits

According to the Commission, the main benefits of the proposal were:

• Better protection of the environment and human health through appropriate risk management based on adequate information about the dangerous properties of chemicals. This would reduce the incidence of certain diseases related to chemicals (such as cancer or allergies) and reduce the risks that chemicals can pose to the environment (such as through the accumulation of persistent chemicals in the food chain). The main difficulty is that neither the dangerous properties nor the uses of chemicals are sufficiently known. The influence on allergies is an example.

• Allergy treatment costs are estimated at €29 billion/year in Europe. Chemical substances are considered to play a major role in inducing allergies either directly or by increasing susceptibility to natural allergens (e.g. pollen). For example, a US study has shown that asthma cases have risen by 40 percent since the 1970s. If the new strategy makes even a small reduction in the €29 billion cost of allergies, this will outweigh the costs of the strategy.

• Improved framework for innovation in the chemicals sector which will contribute to the development of novel chemicals that may substitute current chemicals of concern thus decreasing the risks from chemicals.

• Strengthen the competitiveness of the EU chemicals industry.

• Increased transparency and better access of the public to information, thus enabling more informed choices.

### General Advantages

The REACH system was described by the Commission as having many advantages compared to the current regulation. The main issues were:

• A single coherent system for all chemical substances.
• All substances, existing and new, produced in volumes above one tonne per year would be covered.
• Acute and long-term toxicity would be tested.
• Waiving of testing on due justification, and all available test data used and registered.
• Reduced testing for low exposure substances and R&D (research and development) substances.
• Limited in vitro testing for substances between one and ten tonnes.

## REACTIONS ON THE WHITE PAPER

### Overview

The White Paper outlining the new strategy was sent to the Council and European Parliament (EP) for consideration. The Council reacts by adopting conclusions while the EP adopts a resolution. These are then sent back to the Commission for the drafting of a legislative proposal based on the opinions of the Council, EP and other stakeholders.

The Council adopted conclusions in June 2001 while the Parliament adopted its resolution in October the same year. Both were positive towards REACH but also asked for amendments, in general making the system stronger in protection of the environment and human health, animal protection, consumer protection, etc., but also requiring it to be simplified.

Simultaneously, the Commission held conferences and stakeholder meetings to get feedback from other stakeholders. The Commission also set up working groups consisting of experts to provide advice on specific areas, enabling the Commission to draft legislative proposals for the implementation of REACH.

Beside these formal channels, many stakeholders reacted through media and initiated lobbying campaigns. The chemicals industry and trade unions, as well as political, environmental, consumer and animal protection groups, increasingly made their voices heard in support or defiance of the REACH system. Eventually even government officials and Heads of State from major industrial (chemical) countries engaged in the debate.

The Commission was also divided internally between the interests of health and the environment on the one hand - represented by DG Environment - and the interests of the chemicals industry, represented by DG Enterprise, on the other. Both Directorates had been involved in the process of drafting the new chemicals policy.

With the call for a new chemicals strategy coming from the Environment Council to increase the protection of human health and the environment, DG Environment had the initiative through the initial stages of drafting the strategy. However, as critique against REACH from the chemicals industry and powerful industrial countries increased, DG Enterprise took the initiative, increasingly turning the focus of the strategy toward competitiveness, downplaying the reason for developing a new strategy in the first place: to increase protection of humans and the environment.

### Council

The European Council, consisting of the EU Heads of State, adopted conclusions on the White Paper at a meeting on 7 June 2001. The Council welcomed the White Paper and generally supported the REACH system as proposed. The Council also called on the Commission to present a proposal for a regulatory framework by the end of 2001.

However, the Council also had a number of concerns where they called for clarification and amendments, mostly with the aim of further increasing protection of human health and the environment. Thus the Council invited the Commission to:

• More deeply study the relationship to legislation in other areas and consider measures to avoid duplication of legislation work and to achieve coherence and the same level of protection in all fields of Community legislation.
• Study the case for introducing within the REACH system a simple register including substances produced in volumes below one tonne, with the aim of allowing, if possible, prioritisation of substances of concern.
• Study how to develop screening procedures to effectively identify chemicals with potentially harmful properties or uses of concern for the purposes of prioritising substances for which further information is urgently needed and those requiring accelerated risk management.
• Study how to develop criteria for classifying substances in categories of concern and explore the use of decision trees to apply consistent control measures, based on hazard criteria and use patterns, in line with a prudent and precautionary chemicals management.
• Further study the data requirements for substances produced in volumes below ten tonnes in order to ensure that the information provided will be sufficient for classification and labelling and to assess the need for risk reduction measures. The data sets must also provide appropriate information for handling cases of unintentional releases and to enable the protection of the health and safety of workers while ensuring a minimum of animal testing.
• Develop procedures that can be used both by authorities and the industry to simplify the identification of the relevant testing strategies and reduce the need for animal testing, including the use of decision trees and specific screening methods for all chemicals, such as validated computer modelling and testing to identify chemicals that are persistent and that bioaccumulate, taking into account the cost of testing requirements.
• Exploit, in order to limit the costs and efforts involved in the novel authorisation procedure, all realistic means of simplifying the procedure and of making use of available informa-

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tion; to this end authorisations that have an impact on the internal market should have general validity and be taken on the Community level.

• Add PBT (persistent, bioaccumulative and toxic chemicals) and VPVB substances (very persistent, very bioaccumulative chemicals) to the groups of substances of very high concern that will be subject to authorisation as soon as the necessary criteria for their identification are established.

• Envisage the addition of known endocrine disrupters to the authorisation system when agreed scientifically valid test methods and criteria are established, and study whether other substances with properties of concern, such as sensitizers and chronic toxic substances, need to be included in the authorisation system.

• Co-ordinate in co-operation with member states the input into the international work on the Globally Harmonised Classification and Labelling System (GHS) and also analyse its implications for the Community legislation and consider, as appropriate, the need to submit proposals for its implementation.

• Further investigate how a central entity such as an expanded ECB (European Chemicals Bureau) or other body should best be organised and financed to avoid duplication of tasks as well as how fees, funds and other means of financing can support the resources of such an entity as well as the tasks carried out by member states and to assess and minimise the overall costs for their public administrations, with the aim not to exceed, if possible, the costs implied by full implementation of the existing legislation.

• Develop mechanisms and define practical rules, to be operational when the system is implemented, through which the industry makes testing data and other information available in order to avoid duplication of tests and market distortions, while ensuring an equitable sharing of costs taking due account of the property rights of the party who generates the data.

• Investigate ways to ensure the effective implementation and study the adequacy of

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industry's data quality assurance system, and the enforcement of the new legislation, including provisions for a review of its implementation to allow for adjustments if the objectives are not being met.

### European Parliament

In the European Parliament, the White Paper was considered by the Environment Committee, based on the Schörling Report by the Rapporteur Ms. Inger Schörling. The Committee welcomed, as did the Council, the White Paper and agreed with the REACH system in general, but also called for changes to strengthen the proposal, in many cases on the same issues as the Council had called for changes.

On 17 October 2001, the Environment Committee motioned for the adoption by the Parliament of a resolution supporting the Commission's plan to establish a single system for the registration, evaluation and authorisation of both existing and new chemicals but called for a more proactive, preventive approach.

According to the motion, a key aim of the new policy must be to phase out substances as soon as they are shown to be of "very high concern" unless their use and their hazardous properties are shown to be essential and there is no safer alternative.

To this end, the Committee wanted the range of chemicals subject to authorisation to include persistent and bioaccumulative substances, endocrine disrupters and substances that are carcinogenic, mutagenic and toxic to reproduction.

The motion also called for the inclusion of imports into the EU and chemicals present in manufactured goods. Substances deemed to be of very high concern must, it said, be banned from consumer products by 2012 and products must be labelled to warn consumers of dangerous substances contained in them.

Chemicals in volumes of less than one tonne should also be included in the new regime and registered, under a simplified procedure, by 2012 unless they were shown, as a result of screening carried out before 2008, to be of potential concern in which case they must be subject to full registration.

The motion also set out that effects of chemicals on children's health must be taken into account and it also wanted animal testing banned where recognised alternative tests are available.

The motion was debated and adopted by the Parliament on 15 November, 2001. The Rapporteur had tried to find compromises for the amendments with her colleagues and shadow rapporteurs from the different party-groups. Although some successful compromises were achieved, the PPE voted against the Resolution in the final vote. The motion was adopted by 242 in favour, 169 against and 35 abstentions.

Most of the proposals from the motion remained, although some points were taken out or rephrased, while some additional points were inserted. In the end, the Parliament vote on the Resolution required the strengthening of REACH on many points. Among the key issues were:

**Objective:** The Parliament stressed that protection of human health and the environment must have priority, that the new policy must cover the entire life-cycle of chemicals, and aim to achieve the generation goal of the OSPAR Convention (see *Esbjerg Declaration* and *OSPAR Convention* on pages 45-46).

**Animal tests** should be reduced to a absolute minimum and prohibited where recognised alternatives are available.

**Duty of Care:** industry should have a Duty of Care for chemicals irrespective of the production volume.

**The Substitution Principle** and the promotion of safer practices and substances to replace hazardous practices and substances must be implemented as a key aim of the EU chemicals policy, and as primary risk reduction option. The substitution principle should apply to all chemicals of concern.

**Registration of substances below 1 tonne:** contradictory votes were adopted. A PPE amendment asking for the rejection of such a register was adopted narrowly with support from the UK Labour Party. At the same time, the original paragraph 17, that asked for comprehensive minimum information on all chemicals, irrespective of tonnage, was maintained.

**Scope of substances of very high concern:** (substances to be phased out, unless they are specifically authorised): Calls from the Rapporteurs for an extension of the scope was rejected with the adoption of amendment from PPE, again with the votes of UK Labour. The result was the same as the Commission proposed, substances that are carcinogenic, mutagenic and toxic to reproduction categories 1 and 2 and POPs to be included, inclusion of other substances that are of high concern, such as substances that are persistent, bioaccumulative and toxic to reproduction are to be considered.

**Authorisation:** Strong wording from paragraph 34 was adopted with a request that industry must prove that the use of the substance in question is really needed and that there are no alternatives, and that the hazardous properties of the substance are needed for the intended purpose.

**Public availability of data:** key information such as production volumes, use patterns and exposure sources were requested to be made publicly available in addition to information on the properties of chemicals, and requests for comprehensive labelling.

**Chemicals in consumer products:** Parliament asked that imported articles should be treated the same way as articles produced in the EU and for labelling provisions for substances of concern in consumers products.

### Cefic

While the Council and Parliament were supportive but asked for more, the chemicals industry opposed the new system on many grounds. On 13 February, Cefic issued a press release stating that the chemicals industry supported the objectives of the proposed new strategy. These are defined as to protect human health, safety and the environment, assuring coherence of the internal market, giving the public access to information and enhancing the competitiveness of the European chemicals industry.

However, Cefic did not believe that REACH would work in practice or that it would achieve the objectives. Furthermore, the association asserted that it may even damage the competitiveness of the European chemicals industry. The main critique from Cefic wa that chemicals regulation should be based on risk assessment. The requirement for authorisation of substances based on their intrinsic properties, such as persistence and bioaccumulation, was considered of particular concern, as it could lead to arbitrary restrictions and bans with potentially serious effects on the chemicals industry.

Cefic also pointed out that the proposed system would increase bureaucracy and result in more tests having to be performed on more chemicals, which would slow down progress. Instead Cefic wanted to see a streamlined testing programme, speeding up the risk assessment process.

The increased testing would also mean that more animal testing would have to be done by the chemicals industry. Cefic wanted the test programme to focus on the substances which give the greatest cause for concern.

The registration process for new substances was also considered inadequate. Cefic wanted it improved in order to regenerate innovation. Finally, Cefic said that it will continue its commitment to the voluntary HPV programme, which is scheduled to provide basic information on 1,000 HPV chemicals by the end of 2004.

#### Cefic Thought Starter

In September 2001 Cefic launched a "Thought Starter on REACH - an Initial Proposal for Translating the REACH System into

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*Forty-four percent of sampled vegetables and fruit contained at least one pesticide. One hundred percent of sampled rain contained phthalates, softeners used in PVC plastic. Alkylphenols, ethoxylates and synthetic musks were found in almost all samples. Brominated flame retardants were found in 30 percent.*

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Practice." In a 21-page paper, Cefic presented its own version of REACH where the requirements of the chemicals industry had been met. In summary Cefic proposed the following:

**Registration:** should only be required for non-polymer substances which are placed on the market in volumes exceeding one tonne per year. Cefic specified a "core information set" for necessary information as related to likely exposure and tonnage. Documentation of data should be the responsibility of industry and be accessible to authorities.

**Evaluation:** Cefic proposed that if the available data and information are insufficient for an appropriate risk assessment, the regulators have the ability to require the consortia or company concerned to provide the required information. If there are indications of unacceptable risks, regulatory action can be taken.

Evaluation must take place within a "reasonable" and definitive timeframe to enable the enterprises involved to plan for the future and for the system to work effectively.

**Authorisation:** Authorisation should apply only to those substances which match criteria, and which have been through the registration and evaluation procedure. Substances, which are controlled by other legislation, should not need authorisation under REACH.

It is the view of Cefic, that substances of "very high concern" should be very limited in scope, restricted to CMRs of Category 1 and 2, and POPs (characteristics laid down in the Stockholm Convention on POPs).

If the substance is not already "adequately controlled," industry should be required to provide further information within an agreed timeframe. Unless the substance gives rise to severe concern due to exposure, the enterprise may continue to market the substance in the interim.

Cefic wrote that all decisions on authorisation for specific uses should be based on:

- a risk assessment,
- a full socio-economic analysis,
- the availability and the impact of alternative substances (substitutes), and
- risk reduction measures to minimise exposure to acceptable levels.

Uses which do not give rise to concern or which are already controlled would be exempt from this procedure.

### Non-Government Organisations (NGOs)

Many NGOs, mostly environmental and consumer groups, had been watching what was going on since the Council had called on the Commission to draft a new strategy for a chemicals policy in 1998. They were also trying to have an influence in the debate, supporting a strong and pro-active legislation for the protection of human health and the environment. Since 2000, some of them had joined the statement in the Copenhagen Chemical Charter.

When the White Paper was presented, most of the international environmental groups, such as The European Environment Bureau, Friends of the Earth, Greenpeace and WWF, welcomed it as a step in the right direction. However, they had many reservations (see *Differing Views*).

## STAKEHOLDER'S CONFERENCE

In April 2001, the Commission organised a conference to launch the new chemicals strategy as introduced in the White Paper and to gather input from key stakeholders on its implementation. The Conference was opened by the Commissioner for the Environment, Margot Wallström and the Commissioner for Enterprise, Erkki Liikanen.

Stakeholders gave their input during two workshops. The first workshop addressed the process and how to implement the new policy in the most cost-effective way. The second concentrated on major stakeholder contributions.

Stakeholders agreed on a wide range of subjects, such as the objectives of the strategy, the need for a scientific approach, that a single system was preferred to the current regu-

lation, to increase efforts to communicate and that international cooperation is essential.

However, there was vast disagreement on many complex issues and basic principles. Some elements of the proposed strategy were judged inappropriate by certain stakeholders.

Industry and trade union representatives considered the authorisation process as unnecessary in view of the registration and evaluation steps, and would prefer a system that uses restrictions rather than authorisation. Moreover, the time schedule proposed in the White Paper was, according to industry, too tight, in particular for the in-depth testing requirements. Further, it was pointed out by some stakeholders that the White Paper did not take into account socio-economic consequences.

The trade union representatives disagreed with the fact that substances should be banned solely on the basis of intrinsic properties. They thought that the policy should include assessments of risks and benefits before bans are decided, and risks of alternative options must also be considered.

The environmental NGOs viewed the strategy developed in the White Paper as too narrow and as catering too much to industry self-interest. As it stands, they believed that it was not adequate to protect human health and the environment.

The consumer NGO representative requested downstream liability in industry - the new chemicals policy should set out the minimum requirements for all other sectors. Several member states expressed concerns about the resources that would be necessary to implement the new strategy. Representatives from small and medium-sized enterprises (SMEs) and some downstream users expressed similar concerns about the proportionately high costs that they might have to face.

Stakeholders also held diverging views on the scope for authorisation, some calling for inclusion of other categories than CMR and POPs. NGOs and some Member States called for a prudent approach, particularly concerning testing requirements in the one to ten tonne range because most of the in vitro tests have yet to be developed.

## TECHNICAL WORKING GROUPS

In order to assist the Commission in its development of legislation to implement REACH, a number of working groups of technical experts were convened from October 2001 to February 2002. The working groups were made up of stakeholder experts on particular topics covered by the White Paper, who came from authorities in the member states, industrial associations and NGOs.

Eight working groups were established assessing different aspects of REACH and the legislative context. During the first meeting, tasks were assigned to the members of the groups. The papers that were produced as a result of this assignment were presented and discussed during the second meeting. The working groups covered the following areas:

- testing, registration and evaluation,
- risk assessment,
- substances of very high concern,
- classification and labelling,
- risk management,
- substances in products, and
- information through the supply chain.

The final documents were presented to the Commission as stakeholder input to the initial drafting of a regulation.

## BUILDING BLOCKS

Based on the Council Conclusions, the EP Resolution, reports from the Technical Working Groups and input from various conferences and meetings with stakeholders, the Commission initiated the task of drafting legislation to implement REACH into EU regulation.

The work was organised under eight headings, similar to those of the Working Groups, which together would form the entire legislative proposal. Each heading was called

*Snow, ice and water from Alpine regions contain DDT, PCB, brominated flame retardants, HBCDs, chloroparaffins, phthalates, toxaphenes and chlorinated dioxins and furans.*

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a Building Block. These were drafted from June to October 2002.

The Building blocks were internal working documents which contained the detailed suggested wording of the proposal. In November 2002 an early draft of the authorisation block leaked from the Commission. This draft shows that there was considerable disagreement between DG Environment and DG Enterprise on many issues, e.g. regarding which substances would be banned and require authorisation for production. DG Environment wanted to include PBT and vPvB substances, required specification of which uses the authorisation would cover and time limits for the authorisation if granted. In the draft, this view was not shared by DG Enterprise. Drafting of the legislative proposal went on into spring 2003. In the meantime, a number of studies concerning specific aspects of the regulation were performed.

## THE DRAFT REGULATION

### Overview

Since the White Paper was presented in February 2001, there had been a major political, media and lobbying battle in the EU regarding the future chemicals regulation. Initially industry opposition came mainly from individual large chemicals industries, but when the presidency of Cefic went to the BASF top-gun Eggert Voscherau in summer 2002 things really started to heat up (see also *Behind the Scenes*).

The entire chemicals industry was mobilised and came out aggressively against the content of the White Paper. Moreover, the industry put pressure on DG Enterprise and created an increasing internal split within the Commission. They even managed to have Heads of State from Member States - who had recently requested stronger provisions in REACH - to come out against REACH. Furthermore, unions, employer organisations and animal welfare organisations were attacking different aspects of the strategy.

As if these forces were not sufficient, in March 2003 the European Council had expressed that "competitiveness must once again be centre stage" in the EU. To this end, the new Competitiveness Council was requested to be involved in the REACH process.

Also the US chemicals lobby ACC, the global chemicals federation ICCA and the US government joined the battle. The campaigns against REACH were among the most aggressive ever experienced in the EU.

The result of these campaigns was that the Commission backed down. The requests put forth by the European Council and European Parliament for strengthening the strategy were mostly left out. Instead the Commission began to water down the White Paper.

### The Internet Consultation

The Commission decided to present the Draft Regulation to stakeholders and the general public in a consultation, inviting comments on the content before finalising it and sending it to the European Parliament and Council for consideration. On 7 May 2003, the entire draft was presented on the Internet.

The purpose of the Internet consultation was to test the workability of the proposals with stakeholders. There were about 1,200 pages of legislative text, largely made up of technical annexes that were not new requirements, as well as a range of new procedures. The Commission wanted feedback on the drafts before finalising its` proposal.

### The Draft

The Draft Regulation, which would replace over 40 existing directives and regulations, intended to implement the proposals set out in the White Paper. The legislation aimed to place a duty on companies which produce, import and use chemicals to assess the risks arising from their use, requiring new test data to be generated and to take the necessary measures to manage any risks they identify. This would reverse the burden of proof from public authorities to industry for putting safe

chemicals on the market. Testing results had to be shared to reduce any likely animal testing. Registration of information on the properties, uses and safe use of chemical substances were also said to be an integral part of the new system.

**Main Features**

The main features of REACH in the Draft Regulation were similar to the White Paper:

Registration

A mandatory registration of existing and new chemicals produced in volumes above one tonne per year and producer. The registration procedure required that the producer or importer provide a technical dossier containing data and information about the substance in question to the authorities. A substance may not be marketed until it was registered.

Evaluation

The dossier and the substances that apply for registration would be evaluated by authorities in the Member States. The evaluation followed prioritisation criteria to be elaborated by the new agency (see below).

Authorisation

Substances of very high concern may only be produced and marketed if the Commission gave permission - authorisation. The authorisation must be granted if the applicants show that the risk generated from its use were "adequately controlled." If this was not shown, the authorities may grant an authorisation if it was shown that the socio-economic benefits outweighed the risk to human health and the environment and that there was no suitable alternative substance or technology. Such an authorisation would normally be time-limited.

**Scope**

The registration requirements varied depending on the volume in which a substance was produced, and on the likelihood of exposure to humans or the environment. A phased-in system lasting up to 11 years was foreseen. Higher tonnage substances would require the most data, and would have to be registered first. The latter provisions were intended to reduce the regulatory burden on small and medium sized enterprises.

Tighter controls would be introduced for the chemicals of highest concern. Thus, certain types of substances such as carcinogens, mutagens and reproductive toxicants (CMRs), persistent, bioaccumulative and toxic substances (PBTs) and very persistent and very bioaccumulative substances (vPvBs) would be subjected to the authorisation regime and would be registered early. In certain cases also other substances, for example with endocrine disruption effects, could be included on a case by case basis within the authorisation system where it was shown that they give rise to the same level of concern.

Each use of such substances would have to be authorised for a specific use. Decisions would be based on a risk assessment and consideration of other socio-economic factors.

Others, such as polymers (chemicals used as raw materials for plastics and detergents and a wide variety of other products), and substances used as intermediates would be subject to substantially lighter registration requirements. In many cases, where there is little risk of exposure, polymers and intermediates will be exempted from registration.

The Commission expected that around 80 percent of all substances would only have to be registered, the rest would have to undergo evaluations for safety and subsequent authorisation.

The member states would be responsible for the evaluation of substances by examining certain registration dossiers, as well as checking the application of REACH within their own territories. They would also be able to suggest restrictions on the use of substances based on a structured risk assessment - where they consider that EU legislative action is necessary, although the final decision on such restrictions would be taken by the Commission.

The Commission would grant authorisations after taking into account the views of the agency on the risk and on the socio-economic aspects. Authorisation decisions would take into account the guarantees provided by the applicant firms and available information on alternative substances and processes that may reduce the risk posed. To simplify the system and to reduce costs, an authorisation would be valid for enterprises further down the supply chain as long as they abide by the conditions for the intended use and inform the Agency.

### A New Agency

A new chemicals agency was also proposed to manage REACH. The agency would have the task of ensuring the efficient operation of the new system, including providing advice to the Commission, and guidance to Member States and to enterprises, including SMEs. Non-confidential data generated by REACH would be made available to downstream users of chemicals and to the general public in a publicly accessible database.

### Research and Innovation

Research and innovation would be encouraged by allowing research and development to take place without registration for five years, extendable to ten years, an extension of existing provisions. In order to keep the need for animal testing to a minimum and to keep costs down, a system of data sharing among companies was proposed. In addition, important elements of flexibility were proposed within the testing requirements, allowing industry to use alternative sources of information to fill data gaps, or to argue that certain tests were unnecessary because of a lack of exposure.

### Changes from the White Paper

Albeit the European Council and European Parliament had requested significant changes to the strategy as proposed in the White Paper, it was difficult to see that this had any major impact on the Commission. Instead the Draft Regulation became weaker than the White Paper in many details. But there were two severe cutbacks.

The first concerns the substitution of hazardous substances with less hazardous substances. This is one of main aims of the new strategy according to the White Paper and it had provisions calling for the substitution of hazardous substances when less hazardous alternatives exist. In the Draft Regulation, this had been reversed; the availability of safer alternatives was explicitly ruled out as reason enough to decline authorisation of a hazardous substance.

The second cutback concerns the ambition in the White Paper that producers or importers of products that can lead to significant exposure of humans and the environment to chemicals should provide relevant information about the chemicals released. In the Draft Regulation, the Commission abandoned this ambition and foresaw registration of substances released in volumes above one tonne and that are likely to cause harm.

## REACTIONS TO THE DRAFT

### Overview

The consultation went on from May to July 2003 and resulted in some 6,500 responses, mainly from the chemicals industry, its employees and associated organisations, but also from a wider group of stakeholders. All comments are available on the Commission Website. Below are some examples but all the comments may be downloaded or viewed on the Commission Website http://europa.eu.int/comm/environment/chemicals/whitepaper.htm.

In addition to the comments received via the Internet and e-mail, the Draft Regulation was widely commented on in media by politicians, academics, industrialists, activists and other stakeholders. Notably, even heads of Member States, the US government and governments in Asia voiced concern and critique against the Draft Regulation.

### Chemicals Industry

The chemicals industry was very critical of the Draft Regulation presented for consultation, even though they had won considerable alleviation on the issues of substitution and chemicals in products. The main issues of concern for the industry were:

**Scope:** Under the REACH system, chemicals may be regulated on their intrinsic properties, such as persistence, bioaccumulation and toxicity (PBT), or if they are very persistent and very bioaccumulative (vPvB) toxicity is not required for regulatory action to be taken. This approach is opposite to the current concept that exposure can be predicted and used as a determining factor. The chemicals industry also opposed required authorisation of endocrine disrupters and potentially carcinogenic substances.

Further, they stated that all substances already covered by other EU regulation should be excluded from the scope of the regulation.
Information and management: The proposal was considered too bureaucratic, demanding too much documentation and information. Industry also wanted to put more responsibility and decision-making power with the new central agency, avoiding individual member states starting substance evaluation on suspicion.

According to Cefic, the problems identified above would lead to serious effects for the European chemicals industry and ultimately the EU economy as a whole. The following effects were predicted:

**Workability:** The REACH system as proposed was not workable because of the high demands. It was considered unscientific, over bureaucratic and unmanageable and may collapse up front.

**Competitiveness:** The lack of workability and the restrictions regarding what substances would be allowed in production would put the European chemicals industry at a serious disadvantage compared to its main competitors in the US and Japan. Sales, especially outside the EU, were threatened. Since the chemicals industry is the largest industry in Europe, this would have repercussions throughout the whole European economy.

**Costs:** While the White Paper estimated that the increased costs to be borne by the EU chemicals industry would be about €2.1 billion over 11 years, other studies, commissioned by the chemicals industry, claimed that costs would be immensely higher. In France alone the costs, including loss of GDP growth, could be up to €88 billion.

**Jobs:** The ultimate consequence of the lack of workability, reduced competitiveness and high costs is, of course, jobs. The chemicals industry claimed that REACH would lead to massive unemployment across Europe, especially in countries with large chemicals industries such as Germany, France, Italy and the UK. In France, up to 670,000 jobs would be lost according to a report commissioned by the French chemicals industry. A report commissioned by the German industry had previously claimed that 1.8 million jobs could be lost in Germany.

In August, the European Federation of Chemical Distributors (FECC), an organisation very close to Cefic, let its` national federations in France, Germany, Italy and Ireland write letters to the Heads of State. The letters outlined the concerns for financial problems to the chemicals businesses throughout Europe and ensuing unemployment. FECC urged the governments to act against REACH.

### George W. Bush Administration

The US government ran an aggressive lobby campaign to influence the development of REACH since the White Paper was presented in February 2001 (see also *Behind the Scenes,* page 101). The campaign was mainly orchestrated by the American Chemistry Council (ACC) and its global counterpart ICCA where ACC held the rotating presidency. In fact, the US lobbying was so strong that it prompted a letter of protest from 68 medical, healthcare, academic, scientific and environment NGOs in the US.

The prime concerns of the US government were that the new approach to regulation of chemicals could:

• Disrupt US exports of chemicals and consumer products containing hazardous substances to the EU and distort global trade in tens of billons of dollars in chemicals and downstream products - from autos to textiles.

• Influence REACH-like policies to spread to other regions and be embraced by the United Nations for regional or global regulation and treaties (e.g. SAICM).

In April 2003, while the Commission was having internal negotiations regarding the Draft Regulation, US Foreign Secretary Colin Powell sent a cable to US embassies in the EU (see *US action Cable* in the Appendix.) Echoing the concerns voiced by the chemicals industry, the cable outlined the concerns of the Bush administration and requested that the embassies should act by presenting these concerns to all relevant Commission Directorates General (DGs), as well as all Ministries of Environment, Trade, Industry and Foreign Affairs in the EU member states. The talking points listed and ways of presenting them were inter alia:

**Workability:** The approach outlined in the White Paper raises questions about its workability and thus its ability to effectively achieve its health and environmental policy objectives. The focus on tens of thousands of chemicals is too broad and lacks prioritization. Implementation may prove problematic.

**Scope:** Regulatory resources should focus on chemicals posing the greatest risks. Certain low risk types of chemicals should be excluded - such as certain polymers and intermediates where exposure is negligible - and most constituents of articles. An additional benefit of a more focused approach would be reduced animal testing - an outcome which would be consistent with EU animal welfare objectives.

**Costs and Competitiveness:** The costs to implement REACH are substantial. The Commission's own cost estimates for REACH total €18-32 billion and do not take into account effects on prices, international competitiveness and employment. These costs of compliance may negatively impact innovation and development in the EU of new, more effective, and safer chemicals and downstream products.

**Trade:** The proposed approach would adversely impact production and transatlantic trade in tens of billions of dollars in chemicals and downstream products - from autos to textiles. There is concern that the economic implications are not adequately assessed.

Considering the content of the Draft Regulation presented one month later by the Commission, it seems that the Bush administration had some success on key issues, e.g. the exclusion of polymers and most constituents of articles. Nevertheless, the Bush administration was not pleased.

In May 2003 the Draft Regulation was criticized in an official comment from the US government. Key points were similar to the lines that had been communicated throughout

**Typical Industry Arguments**

A study of industrial argumentation made by The Stockholm Environment Institute in 1999 shows that there are four arguments that are typically raised by industry in opposition to new environmental regulation:

1. The proposed policy may be counterproductive, adding to costs as well as failing to yield environmental benefits, i.e. a lose-lose situation.
2. The environmental goal may be valid, but the proposed instrument is inefficient in that it imposes unnecessary costs.
3. The proposed instrument may lead to changes in competitive conditions which may disadvantage important sections of industry or place industry at a disadvantage compared to those in other countries or regions.
4. There is an irresolveable conflict between society's desire for higher environmental standards and a company's goal of adding to shareholder value.

the campaign. The Draft Regulation:
• may be unworkable,
• departs from ongoing international regulatory cooperation,
• imposes substantial costs while providing uncertain benefits,
• adversely impacts small and medium sized companies,
• disrupts global trade,
• adversely impacts innovation,
• creates market uncertainty,
• is unclear regarding administrative coordination and consistency, and
• raises concerns regarding consortia and data sharing.

In conclusion, the US government strongly encourages the Commission to:
1) Reduce the scope of aspects of the regulation to better focus EU resources on substances that are likely to pose the highest risks;
2) Develop an EU approach which supplements - and does not supplant - ongoing international cooperative efforts to effectively address the risks posed by existing chemicals;
3) Clarify and simplify the process by which regulatory decisions will be made; and
4) Ensure that the impacts of the EU regulation - both positive and negative - are fully and transparently assessed. The Commission should also ensure that its final proposal is fully consistent with the EU's international obligations.

### Blair, Chirac and Schroeder

The governments of the UK, France and Germany submitted comments on the Draft Regulation. The comments voiced concern regarding the same issues as the chemicals industry and the US government brought up: bureaucracy, lack of workability, loss of competitiveness for the EU, jobs, trade effects, etc., as has been previously described.

On 20 September 2003, as the Commission was again redrafting the regulation after the comments from the Internet consultation, the Heads of State of these nations went further. In a joint letter to Romano Prodi, the President of the Commission, Prime Minister Tony Blair, President Jaques Chirac and Chancellor Gerhard Schröder reiterated their concerns.

They pointed out that in March 2003, the European Council has sent out a clear signal for strengthening the competitiveness of the industries in the EU and to reduce the bureaucracy facing these companies in order to achieve economic growth and comply with the Lisbon Strategy.

They clearly state that "a future EU chemicals policy must be designed in such a way as to ensure environmental, health and consumer protection without endangering the international competitiveness of the European chemicals industry." The concerns of the three Heads of State can be summarised as:
• the Draft Regulation is too bureaucratic,
• it may be unworkable,
• it does not prioritise the substances of most concern, and
• it may have an impact on competitiveness.

The letter in itself, the context in which it was written and the specific demands was clearly a very strong statement from the three major chemical producing nations in the EU. The implicit meaning is that economy is the priority if protection of the environment, health and consumers is not compatible with international competitiveness.

### Environmental NGOs

The four largest environmental NGOs - the European Environment Bureau, Friends of the Earth, Greenpeace and WWF - submitted a joint document in the consultation. The groups welcomed REACH and wrote that the Draft Regulation goes part of the way towards phasing out the production and use of hazardous substances. The NGOs particularly welcomed that PBT and vPvB substances, as well as EDCs are covered by the scope of the authorisation stage and that substances will not be allowed to be marketed if there is insufficient data.

However, they also identified a number of crucial flaws in the Draft Regulation:

**Substitution:** Continued use of the worst chemicals, even when safer alternatives are available. The new system will identify the worst chemicals - those of very high concern - but, as currently designed, industry would be able to get permission to carry on using them, even if safer alternatives are readily available. In the view of the NGOs, the use of chemicals of very high concern (such as those that accumulate in breast milk) should only be allowed if industry demonstrates an overwhelming societal need, that no safer alternatives are available and that risk reduction measures will be put in place.

The NGOs stated that progressive, stepwise substitution of hazardous chemicals with safer alternatives is necessary to achieve the goal of phasing out use of the worst persistent, bioaccumulative and toxic chemicals. They also wrote that consideration of availability of alternatives as an integral part of an authorisation application is necessary to prevent the authorisation system from becoming bogged down with applications for unnecessary uses of chemicals of very high concern.

**Transparency:** Secrecy remains. The current proposals would allow industry to keep a large amount of information confidential regarding the production and use of chemicals. The NGOs wrote that this is against the interests of consumers, workers, downstream users and retailers.

**Untested chemicals in consumer products:** The current proposal would allow imported products to contain untested chemicals, presenting unknown hazards to Europe's consumers.

**Unclear definitions:** The NGOs point out that, a number of key concepts were not sufficiently defined and/or explained. This includes adequate control, socio-economic assessment and exposure scenarios. They noted that poor definition of such concepts leaves many aspects of the REACH system open to interpretation, particularly by the agency and its Committees. This would not prevent political horse-trading in controlling chemicals and continue the current cumbersome and ineffective decision making.

**Inconsistency** between treatment of different chemical properties of very high concern in authorisation and registration. The Commission's inclusion of substances with PBT, vPvB, CMR and endocrine disrupting properties in the authorisation scheme was welcomed. However, it was pointed out that in several places in the text relevant for the authorisation and registration procedure, CMRs are dealt with as a priority or specific arrangements have been provided, without considering the new scope of authorisation.

In addition, a number of specific comments were given by the NGOs in the order required in the Commission's guidance for the Internet consultation.

**The Lisbon Strategy for Economic, Social and Environmental Renewal**

The Lisbon Strategy is a commitment to bring about economic, social and environmental renewal in the EU. In March 2000, the European Council in Lisbon set out a ten-year strategy to make the EU the world's most dynamic and competitive economy. Under the strategy, a stronger economy will drive job creation alongside social and environmental policies that ensure sustainable development and social inclusion.

The Lisbon Strategy touches on almost all of the EU's economic, social and environmental activities. The European Commission's annual Spring Report examines the Strategy in detail. The Spring Report is the only document on the agenda of the Spring European Council, where EU Heads of State and Government assess the progress of the strategy and decide future priorities in order to realise the Lisbon targets.

### Consumer Organisations

The consumer organisations support the introduction of a more protective regulation on chemicals, especially concerning chemicals

## Letter from Blair, Chirac and Scröder to Romano Prodi

Berlin, 20 September 2003

Dear President,

On our initiative on 21 March 2003, the European Council sent out a clear signal for strengthening the industrial competitiveness of the EU. We agreed that we had to reduce the bureaucracy that European companies encounter and decisively improve the regulatory framework within which our companies, faced with strong competition, must manoeuvre.

To achieve this, we must ensure we do not place unnecessary burdens on industry. We continue to call on the Commission to conduct an analysis of current market and competitive conditions. We will therefore suggest to our partners that the Commission present a report to the European Council at its December meeting containing suggestions for the optimization of industrial framework conditions in order to avoid risks of de-industrialisation.

It is also essential to comprehensively assess all important Community projects with respect to their potential effects on industrial competitiveness.

The review of EU chemicals policy provides the first concrete opportunity to apply the described principles in a manner that could serve as an example for other areas of industry.

A future EU chemicals policy must be designed in such a way as to ensure environmental, health and consumer protection without endangering the international competitiveness of the European chemical industry. We would also want the new regulatory system to keep animal testing to an absolute minimum.

The Consultation Document published by the Commission in May 2003 contains certain positive elements in this regard. However, the ideas currently being considered give us cause for concern. In particular, we consider the envisaged registration procedure to be too bureaucratic and unnecessarily complicated. We are concerned in addition that the proposed regulatory system does not prioritise sufficiently between the handling of substances, that it will as a result not be workable in practice and that it will be difficult to convince stakeholders that we have created

an effective system for targeting and handling those substances which present real safety or environmental concerns. It is still a long way from being the fast, simple and cost-efficient procedure that was promised.

For this reason, France, Germany and the United Kingdom have brought forward comments on the workability and impact of proposals made in the consultation document. We made suggestions for substantial changes to the proposals so that they can be an effective approach for sustainable development.

We are also concerned about the potential impact of the new requirements on the competitiveness of EU businesses exporting to Third Country Markets, and about the position of EU businesses competing in the EU with Third Country suppliers able to avoid these requirements when sending products to our markets.

We must ensure that the proposals do not disadvantage legitimate EU business interests in the global market by imposing requirements which are not pertinent to protecting health and environment. With this in mind, the Commission should carry out a full evaluation of the concrete effects of the planned regulations on the European chemicals industry, as well as on the economy, taking account of the effects throughout the supply chain. The proposals presented to the European Parliament and the Council should create an effective framework which allows EU business to continue to thrive.

To this end, the Commission must work with the Presidency of the Council to ensure that the Competitiveness Council - in accordance with the European Council decision - plays an effective role in the handling of this legislation.

We would be grateful if you could take up these proposals and help contribute to making the planned new regulation of the chemicals regime a successful example of our joint efforts to strengthen the industrial competitiveness of the EU.

Yours sincerely

Tony Blair
Jacques Chirac
Gerhard Schröder

used as constituents of articles (the regulatory name for consumer products in the draft). The two largest organisations - The European Consumers Organisation (BEUC) and EuroCoop - strongly support the draft REACH regulation, but are very critical of some key aspects, as summarised below.

### The European Consumers Organisation (BEUC)

According to BEUC the EU needs to establish horizontal minimum requirements for all chemicals being produced and used in the EU, but it is unclear to which extent the Draft Regulation would effect sectorial directives concerning chemicals in paints, pharmaceuticals, cosmetics, toys and food. They want REACH to be clarified and strengthened in this respect.

BEUC is very critical of the lack of clear provisions concerning chemicals in consumer products. Chemicals in products will mainly be considered by the REACH system if they are registered and if they are released in "sufficiently high amounts to cause adverse effects on health and/or the environment." BEUC points out that this leaves an important question unanswered: how is substantial exposure to be defined and who will define it?

BEUC states another problem is that the provision only covers products containing substances which are already known to be hazardous. Substances which are produced in volumes below one tonne per year per producer within the EU will not need to be assessed even when used in consumer products and even if the total amount is substantially higher than one tonne per year. Chemicals in imported products will not be controlled at all unless there is substantial exposure due to chemicals released from these products.

According to BEUC the proposed system will not enable consumer organisations to provide meaningful information to consumers on the chemical content of everyday consumer products.

### EuroCoop

EuroCoop points out that REACH lacks a mechanism to deal with the potential of synergistic effects from a mix of chemicals. As a result there is a risk that chemicals will be authorised despite the fact that there may be a problem if a number of chemicals appear as a "cocktail" in the air, water or soil.

EuroCoop stresses the need to include the necessity for a simple, easy to understand labelling system. Their position is that consumers have a right to know the constituents of products in order to be able to make an informed choice.

They also believe that retailers will need the information in order to be able to advise their customers and consumers. In the Draft Regulation there is no system in place to secure the flow of information from producers to downstream users and consumers.

While EuroCoop demands labelling, they also stress that labelling must not be used by industry to put the responsibility on consumers. Industry must remain responsible for the content, and carry out correct use and disposal of their products.

EuroCoop also wants to strengthen the proposal in terms of how to deal with chemicals in imported goods. They state that as the proposal stands now it is too weak compared to the requirements for domestic products.

EuroCoop also believes that the precautionary principle and the principle of substituting for safer alternatives need to be further developed and more clearly expressed in the proposal. They do not want the system to act as a license to continue using risky chemicals. Their position is that the intention must be to ban risky chemicals except in those cases where it can be proven that there is a public need and no safer substitute.

## Animal Protection NGOs

One of the controversial issues regarding the REACH system - or any other strategy to assess the vast amount of untested chemicals being produced and used throughout the world

- is animal protection. By necessity these chemicals must be tested in different ways for their effects and the traditional way of testing often implies using animals. Thus, it has been widely discussed how many tests will be necessary, how many animals will need to be killed and how this can be avoided or at least minimised. Therefore animal protection groups have engaged in the discussions about the REACH proposal.

### European Coalition to End Animal Experiments (ECEAE)

The organisation represents animal rights organisations in 12 European countries and is the largest animal rights organisation in Europe campaigning solely on the issue of animal experiments. Established in the 1990s, initially to lobby the European Parliament over the issue of cosmetics testing, the ECEAE proved such a success that the campaigning alliance was continued.

While not taking any clear position on the REACH system, the ECEAE supports the aim of properly identifying and controlling chemicals that may be hazardous and have effects on humans and wildlife. However, the ECEAE opposes animal testing as part of the strategy and identifies seven steps to avoid or minimise such tests:

### Eurogroup for Animal Welfare

Eurogroup represents 20 animal protection and welfare groups in Europe. The group was set up in 1980 with the aim to influence and promote the introduction of EU animal protection legislation, with member organisations in all EU member states.

As ECEAE, Eurogroup for Animal Welfare shares the concern of environmental and consumer organisations about the effects of some widely used chemicals on the health of both human and wildlife populations and supports their call for tighter control of existing chemicals. However, Eurogroup is concerned that the existing testing strategy will still be the underlying principle of new Community chemicals legislation.

The proposal in the Draft Regulation that low production volume chemicals could be registered after in vitro testing only is very much welcomed. However, they want the EU to thoroughly review its risk management policy with greater emphasis on the use of non-animal tests in all testing strategies, together with more positive support for the development of non-animal tests. Eurogroup recommends:

Eurogroup points out that the White Paper gives little indication of how the development and validation of alternative methods is to be fostered. They believe immediate action is imperative if significant progress is to be made in time to impact the testing for chemical registration. They note that a substantial amount of funding will be required, and the work must be focused on tests with the greatest potential to save animals that might be used in the registration of existing chemicals. They want the Commission to make funding of development and validation of alternative methods a priority in the Sixth Framework Programme for Research.

## Other NGOs

A joint declaration from July 2003, signed by 429 organisations and over 22,000 individuals, was submitted as a comment to the Draft Regulation in the consultation. The signatories represent environment, consumer and health interests. Specifically, the call states:

"We, the undersigned, 429 organisations and 22,464 citizens around the world, from Australia to Zaire, wish to ensure that our health and that of the environment will be properly protected from hazardous chemicals.

We therefore ask the European Commission to ensure that the new chemicals legislation enforces:

• An obligation to phase out chemicals that accumulate in wildlife, humans or the environment, and those that disrupt hormones. Restricted uses of such chemicals should only be permitted temporarily, if safer alternatives

are not available, and the use is essential to society;
• A full right to know, for both consumers and businesses, including what chemicals are present in products; and
• A requirement that products imported into the EU have to conform to the same safety standards as those made in the EU.

The draft legislation does not implement these three points. We consider that the new system will not be workable, and will not effectively protect future generations, unless these measures are taken.

Please take this declaration as our submission to the Commission's consultation on the workability of the chemicals legislation."

**Non-chemicals Industry**

Unice

The European industries and employers are organised in national federations which are represented at the EU level by the Union of Industrial and Employers Confederations of Europe (Unice). Unice has 35 member federations and four observers from 28 countries in Europe.

Unice has a history of close connections to the chemicals industry. The fact that the chemicals industry is the single largest industry in Europe undoubtedly gives the chemicals sector a certain clout within Unice.

Mirroring and further enhancing the position of the chemicals sector as the prima donna of the European industry, Unice's current president, Jürgen Strube, is chairman of the board of the German chemistry giant BASF, the largest chemicals producer in the world (BASF also holds the presidency of Cefic through top executive Eggert Voscherau). Strube was quoted in the Los Angeles Times in March 2004 saying "What Europe needs i more entrepeneurship, less regulation". His predecessor as president of Unice, Georges Jacobs, was chairman of the executive committee of the Belgian giant chemicals group UCB. The chairman of Unice, Philippe de Buck, has a long history as a top executive in the Belgian industry federation Agoria where the chemicals industry also has a strong position.

Thus it comes as no surprise that Unice unreservedly takes the same position on REACH as the chemicals industry. In its position paper and press release from July 2003, Unice expresses concerns about bureaucracy, competitiveness, costs and trade, pointing out that these issues have not been sufficiently assessed and/or considered by the Commission. In short, Unice calls for:
• Prioritisation of the most problematic substances.
• Basing test requirements on the risks involved, not on hazardous properties; and clear and straightforward exposure categories.
• The scope to be limited to marketed substances, and exemptions given for products and substances regulated under other EU legislation, polymers and intermediate products.
• Simple and rapid procedures, safeguarding competitiveness and protection of confidential business information.
• Careful evaluation of all costs, pilot projects on the effects on SMEs, and benchmarking with USA/Japan.
• Consistency with other regulations - no duplication of requirements, e.g. in workplace health and safety.
• Centralised decision-making, enhanced legal certainty for registered uses of substances.

Other Non-chemicals Industries

Non-chemical industry have been represented by Unice and have mostly followed the official line. However, there are some companies that believe REACH could bring advantages to their business and hold a more radical position than Unice. Among them are producers and retailers that want to be able to supply their clients with information regarding the chemical contents of the products they are producing and/or selling. For example, the large retail chains Marks & Spencer and Booths supported the Draft Regulation.

Another industrial sector that sees ad-

vantages with the Draft Regulation is the construction sector. Many large construction companies had experienced PCBs and asbestos being built into buildings and other structures, putting them in a situation potentially leading to financial disaster. Many of them, such as the Swedish global construction company Skanska, welcomed the provisions of substitution, information and clear political objectives brought forward in the White Paper. In the Internet consultation, many of them were critical that these provisions had been weakened and requested that they be reinstituted.

**Unions**

Many trade and worker unions commented on the Draft Regulation in the Internet consultation. While the vast majority were represented by ETUC (see below) some organisations chose to make individual comments. Below are some examples.

The European Trade Union Confederation (ETUC)

The trade and worker unions of Europe are mainly represented by The European Trade Union Confederation (ETUC). The confederation consists of 77 member organisations from 35 counties in Europe. In total, ETUC represents some 50 million individual members across the continent.

ETUC called on the European Commission to hold on to a high level of ambition implementing REACH. In its contribution to the public Internet consultation procedure, ETUC pointed out that such a system must ensure a high level of protection of workers in all workplaces against dangerous substances.

The main objective of REACH is the protection of human health and the environment against adverse effects of chemicals., ETUC pointed out, and in their view the exposure of workers to chemical substances in a wide range of workplaces should be a priority for attention.

Important elements in the Draft Regulation were the general "Duty of Care," requiring producers of chemicals to ensure that they can be used safety; the obligation to make a chemical safety assessment for every chemical put on the market; and a central registration of safety data of all chemicals marketed in higher volumes (over one tonne/year). Thus the burden of proof would lie on the shoulders of industry, where it belongs, and a huge amount of safety information will become available that is essential for the proper functioning of existing legal instruments for Workers' protection.

The ETUC accepts that exemptions be made, particularly on intermediates and polymers. However, for those substances, they require some essential information on workers' safety in order to prevent existing legislation from being undermined. The ETUC calls on the Commission not to weaken the approach.

In the view of the ETUC, REACH has the potential to give a strong impulse to the protection of workers against dangerous substances and to sustainable development of the European chemical industry.

IG Metall, ver.di and IG Bau

The German unions IG Metall, ver.di and IG Bau jointly support the development of a more progressive chemicals policy. Therefore they demand that the new EU chemicals policy be urgently developed in order to put an end to the current organised lack of responsibility. The three unions see the need for manufacturers and suppliers to build up their knowledge on the effects of their chemicals, provide their customers with comprehensive information on the dangers and provide them with tailor-made safeguards.

According to the unions, the chemicals industry is not opposed to this reasoning and also accepts the essential features of the definitions given, as shown by their expert opinions. However, the chemicals industry tries to convey the opposite impression in its media campaigns against REACH.

The dual strategy is designed to cause the

European legislation on the new chemicals policy to fail. If the industry were serious about "responsible handling," which is often mentioned, it should help to quickly find solutions for the weak points still causing trouble from the first draft law, and implement the central elements of the new policy:

• General liability of the manufacturer and user for ensuring that all substances and preparations can be made and used safely so that there will be no negative effects on human health or the environment for foreseeable uses - such producer responsibility is par for the course in other areas of industry.

• The requirement that a risk assessment be carried out for all substances (regardless of the quantity produced) and that this be documented.

• Plugging gaps in knowledge of substances already on the market and registering them.

• Automatic ban on the use of particularly hazardous substances with the exception of uses which have been specifically approved (authorised).

• Public access to available data.

The unions also point out that the earlier the legislation enters into force, the quicker existing knowledge deficits can be systematically rectified and the sooner protection against undesirable effects of chemical substances can be improved. They believe that the result of these efforts, which will definitely take more than a decade to emerge, will benefit not only workers but also consumers and the environment in general.

### EMCEF

The European Mine, Chemical and Energy Workers' Federation (EMCEF) is a pan-European organisation representing hundreds of thousands of workers. The chemical workers are of course the most vulnerable group if the apocalyptic predictions made by some stakeholders about job losses would become reality.

Already in 2001 EMCEF had entered into dialogue with Cefic regarding REACH. In 2002 Cefic formed a European Chemical Industry Employers Group (ECEG) to accommodate talks about issues of mutual interest, such as the EU chemicals policy review, between industry and unions. The cooperation developed in a positive way, eventually culminating in joint statements and press releases.

The EMCEF comment to the Draft Regulation is remarkably neutral considering the issues at stake (health and jobs) and the cooperation with ECEG and Cefic. EMCEF points out that social issues are, beside ecological and economic aspects, the third vital leg for achieving sustainable development. Thus, the social conditions for the chemical workers need to be considered in the new regulation.

For EMCEF, main areas of social impact are not only the number of jobs, but also: quality of work, training and education, health, safety and workplace environment, motivation of employees, and reduction of existing research and development. They believe that these are commitments of the social partners that need support of the EU decision-making bodies to give social aspects a more important role in the Lisbon vision.

EMCEF welcomed the introduction of access to information for workers and the public and also the inclusion of PBT and vPvB substances into the authorisation scheme. However, they did not agree that such substances need to be phased out if they are adequately controlled, and they wanted a clearer definition of the substitution mechanism.

## THE ROYAL COMMISSION

Starting in 2000, the highly renowned Royal Commission on Environmental Pollution in the UK had carried out a wide-ranging study on the long-term effects of chemicals. The report was presented in June 2003 and gave echo throughout Europe.

The Royal Commission clearly recognised that there were problems with releases of persistent and bio-accumulating substances and

that the current system was not addressing these concerns. "Where synthetic chemicals are found in elevated concentrations in biological fluids... and the tissues of humans... regulatory steps should be taken to remove them from the market immediately."

The Royal Commission also thought that the new EU chemicals strategy REACH was insufficient in that the phase-out of persistent and bio-accumulating substances would take too long. It believed such substances should be substituted for safer substances within one decade. An important tool in this work would be the precautionary principle.

## THE CHANCELLOR'S SPEECH

In June 2003, in the middle of the ongoing Internet consultation, the German Chancellor Gerhard Schröder turned up and gave a supportive speech at the Cefic General Assembly in Hamburg.

In his speech, the Chancellor praised the successful lobby efforts made by Cefic and warned that "*other viewpoints are dominating industrial issues, which cannot and should not be the case.*" He also praised Commissioner Liikanen of DG Enterprise, who was also present at the Assembly, for raising the industrial thinking in the Commission and achieving positive changes to REACH.

"*We do of course agree in principle that the attempt to promote a new comprehensive body of legislation for chemical politics in the sense of health or environmental protection should not meet with any objections. But it is equally clear that the competitiveness of the European chemical industry should not be left behind in achieving this.*"

The Chancellor continued by identifying problems with the Draft Regulation and then asked Commissioner Liikanen and the Commission to review the Draft Regulation accordingly "*in the interest of innovation and employment in Europe.*"

This speech was remarkable in itself. However, the fact that the Chancellor had been one of the Heads of State requesting stricter provisions and a quick implementation of REACH at the European Council meeting in June 2001, made it astonishing.

## COSTS

The cost of implementing REACH has been an issue of discussion, and has been exaggerated since the White Paper was first introduced in February 2001. While the Commission then estimated that the costs for increased testing would be some 2.1 billion over 12 years, industry pointed out that the total costs would be much higher.

Several reports were commissioned during 2001-2003 by the Commission as well as by Member States and industry. However, it was clear that any estimate produced before the arrival of a more comprehensive proposal would be uncertain. The White Paper did not contain enough detail to perform any credible estimates of the total costs or benefits.

This created a situation where "anything goes" and parts of the anti-REACH lobby felt free to use their imagination and creativity. Some studies presented impact scenarios showing that the whole EU was threatened by mass-unemployment and financial recession.

The first studies with some relevance came shortly after the Draft Regulation had been presented, since this was the first time any credible assessment was possible. Nevertheless estimates of the associated costs continued to vary greatly, from some €3 billion to hundreds of billion (see *Costs: the Facts and the Figures*). All of the cost estimates, except those from the Commission, ignored the potential socio-economic benefits, estimated to be tens of billions.

## ANIMAL TESTS

REACH requires that substances produced in volumes above one tonne per year are registered and provided with data regarding toxicity and other properties. Over the years

the chemicals industry and scientific society by tradition have mainly used and developed test methods including animals. Thus, when authorities demand more data, there is considerable risk that this will mean an increase in the number of animals used for testing, regardless of what strategy is used.

One of the aims of REACH is to minimise the use of animal testing. To this end there are provisions requiring computerised test-schemes, development of non-animal testing methods etc. Nevertheless the concerns remain.

In April 2001, just two months after the White Paper had been presented, it was estimated by the Institute for Environment and Health (IEH) in the UK that as many as 12 million animals would be needed to test all of the existing substances in production. This estimate was widely criticised and in March 2002 the IEH presented a revised estimate saying that some six million animals would be required.

Also this lower figure has been criticised. Other stakeholders pointed out that these estimates were done on the basis of the White Paper which lacked details, making any estimate very difficult and uncertain.

Also the estimates did not fully consider the development of non-animal testing methods, the provision for industry to share data information, the alleviations concerning data requirements for substances produced in volumes below one tonne per year and underestimated the volume of data already available within the industry.

However, the main point from the pro-REACH stakeholders was that the current situation, with tens of thousands of untested chemicals being used and released to the environment, is a much larger test including enormous numbers of animals and humans which also includes future generations. Data are required promptly and it is not acceptable to wait for non-animal testing to become fully developed. In the meantime, it is imperative that authorities invest heavily in the development of non-animal testing to minimise the use of animals. Most animal welfare organisations agree with this position.

## THE PROPOSAL

### Overview

Based on the responses on the presentation of the Draft Regulation, the Commission began finalising the official Proposal for a new regulation. The proposal was adopted on 29 October by the Commission. The bulk of the proposal was similar to the Draft Regulation from May 2003.

Again, few of the requirements from the European Council and Parliament from 2001 were introduced. Moreover, none of the impairments introduced in the Draft Regulation had been restored. On the contrary, the Commission introduced some new changes making the regulation even weaker.

The chemicals industry and its allies reacted positively to the new provisions, although still complaining that all of their requirements had not been met, while environment, health and consumer NGOs were furious about the watering down.

### Changes from the Draft Regulation

While the Proposal outlined a regulation which is a vast improvement compared to current regulation, it is a watered down version of the Draft Regulation, which in turn was a watered down version of the White Paper. And even the White Paper was weak compared to what the European Council and Parliament requested in 2001. Moreover, in its present state, the Proposal also represents some serious impairments even when compared with current regulation. The main impairments in the Proposal were:

#### Registration (Scope)

The Draft Regulation required that data regarding the properties of substances produced or imported in volumes over one tonne per year per producer/importer be submitted to the authorities if industry wanted to continue

to put the substance on the market. In the Proposal, the data requirements for substances below ten tonnes per year had been reduced.

The Draft Regulation also required that a Chemical Safety Report (CSR) should be produced for all chemicals produced in volumes above one tonne per year and distributed to downstream users. In the Proposal, CSRs only had to be produced for substances above ten tonnes, and communication to downstream users became limited to the safety data sheet.

About 65 percent of all the existing substances on the market belong to the category 1-10 tonnes and would thus not be affected by the reduced Registration and reporting requirements.

Furthermore, some 90 percent of the new substances also belong to this category. In the current regulation, new substances produced in volumes over ten kilograms are required to submit such data. For new substances, REACH will actually mean lower requirements than today. It must also be pointed out that the Council in their Conclusions from June 2001, requested the Commission to consider registration of all substances, even those produced in volumes below one tonne.

The Draft Regulation had excluded certain kinds of polymers from the Registration process. In the Proposal, this exemption had been extended to include all polymers, representing many thousands of substances.

### Responsibility (Duty of Care)

The White Paper and the Draft Regulation contained an important general provision about the industry's responsibility, called Duty of Care. It was stated that all actors should have a basic responsibility for the safe management of chemicals, regardless of more specific requirements. These provisions on Duty of Care disappeared in the Proposal.

### Authorisation (Substitution)

The White Paper had provisions calling for the substitution of hazardous substances for less hazardous substances when such alternatives were available. This requirement had been reversed in the Draft Regulation presented in May - the availability of safer alternatives was explicitly ruled not to be reason enough to decline an authorisation. This caused an outcry from various stakeholders, notably the environment, consumer and health NGOs. Though this explicit clause had been removed in the Proposal, substitution remains subordinate to a vague concept of "adequate control", allowing the continued production and use of a very hazardous substance to be authorised, even if there are safer alternatives on the market.

### Consumer Products

As regards substances in products that can lead to significant exposure of humans and the environment, the White Paper proposed to set up a working group which would identify the product categories (e.g. toys and textiles) the relevant exposure situations and all other practical implications. On the basis of the findings of this working group, producers or importers should be requested to identify products containing such substances and provide any information as appropriate.

The Draft Regulation foresaw registration of hazardous substances in articles that may be released in volumes above one tonne and that are likely to cause harm. In the Proposal, registration was only required when hazardous substances are intended to be released from the products in quantities above one tonne. This clause is virtually empty since hardly any products would fall under this definition that would not already be covered by the requirements for preparations. If such substances may be released, all that is required is a notification in that respect.

### Transparency

An important principle introduced in the White Paper was the Right to Know. It was conceived that the general public had the right to know what chemicals were in the products they bought and consumed, and what the risks

with these substances were.

This general principle was translated into a general requirement for producers and users to provide such information to the public. The European Council and Parliament requested even more transparency than proposed in the White Paper. The chemicals industry objected and the provisions were reduced in the Proposal by introducing a list of information that should be confidential, such as the name of registrants.

## REACTIONS TO THE PROPOSAL

### Overview

The Draft Regulation had prompted some 6,500 comments and thus most stakeholders felt they had already expressed their view. However, the stakeholders mostly concerned, the chemicals industry and the environment and health NGOs, were still on top of the issue. The amendments on the Scope of REACH made to the Proposal were known by the chemicals industry and other stakeholders well before the presentation of the Proposal. On 16 October the Commission presented a revised impact assessment where most changes were discussed.

### Chemicals Industry

If Cefic and the rest of the chemicals industry allies were pleased with the watering down of the Proposal, they did not spill it. On 16 October, when the Commission presented the changes to the Scope of REACH at a presentation of the new Impact Assessment, Cefic commented by saying:

"Whilst an encouraging move on the Commission's part, this latest analysis, in Cefic's view, does not meet the request made by the three Heads of State and Government Chirac, Schröder and Blair, in their recent letter to Commission President Romano Prodi."

On 29 October, the same day the Proposal was adopted by the Commission, Cefic cautiously commented: "The challenge is always to strike a balance between protection of human health and environment, and the competitiveness of the European industry. Given our concerns about workability, we now have to analyse the final proposal to see whether it meets the objectives."

The UK chemicals federation CIA was unimpressed but more aggressive. On 8 October 2003, CIA Director General Judith Hackett acknowledged the improvements but wanted more: "The Commission have completed half the job in reducing the scope of the proposals. If REACH is to be workable the Agency has to be established and given the power to prioritise, make decisions and manage the system. Failure to do so will result in the REACH monster consuming us all."

The French chemicals federation UIC kept a similar tone: "If some lightening brought in the field of application and for some requirements of tests are noted, UIC nevertheless deplores that the proposed text remained bureaucratic and unnecessarily complicated, and that it presents serious threats on the competitiveness of the French chemical industry and downstream industries."

The US chemicals industry, represented by ACC, was even less enthusiastic about the Proposal as they "expressed disappointment that the proposed scheme remains unworkable and could lead to a new trade conflict."

ACC President and CEO Greg Lebedev said "a few tweaks do not change a fundamentally flawed proposal" and repeated his concern that the proposal also may be at odds with World Trade Organization (WTO) rules. He added: "Some Commissioners have said they want to sell the REACH scheme across the globe. The world doesn't want or need European regulatory colonialism, and the EU's trading partners won't buy a scheme that puts them at a competitive disadvantage and is more complicated than a Rubik's cube."

### Environment and Consumer NGOs

As the Proposal had been watered down further, the environment and consumer NGOs were furious. In December 2003 the Euro-

**Support for and Opposition against REACH and Tighter Regulation**

Since the first presentation of REACH in the White Paper in 2001, most stakeholders have declared that they agree with the main objectives of REACH, to increase the protection of human health and the environment. But agreeing with the objective is one thing, and agreeing with the details of the Proposal is another. Thus, the positions on the strategy differ dramatically. Many stakeholders promote tighter regulation on chemicals and support REACH, although most of them want the regulation to be tighter than proposed. Others believe REACH goes too far and want to streamline regulation and solve the problem through voluntary measures from the industry. The table below shows the positions of some stakeholders. See also *Differing Views*.

| Support REACH - Tighter Regulation | Oppose REACH - Voluntary Measures |
|---|---|
| The European Council | The Chemicals Industry |
| The European Parliament | The US Government |
| Some Member State Governments | Some Member State Governments |
| European Workers' Union | Industrial Federations |
| Some Industries | |
| Environment NGOs | |
| Consumer NGOs | |

pean Environment Bureau (EEB) published a review of the proposal. The report points to a number of impairments and in the summary EEB expressed its disappointment at how the initial aims of the White paper had been watered down:

"Unprecedented interference by the chemicals producers' in Europe and the US, has led the Commission to considerably weaken the proposal and to tip the balance away from environmental and public health protection towards the self-interests of business, which seems to fear public exposure and claims serious negative economic impacts.

As a result the proposed REACH is a shadow of the original plans, which were supported by the European Parliament and the EU Member States. Loopholes, flawed approaches and bureaucratic procedures have been introduced after the Commission's internet consultation before summer 2003, some of which are a reversal of standards already achieved. Instead of moving away from chemicals of very high concern their continued use is accepted under a toothless and flawed 'adequate control' obligation. Relevant safety information, like what chemicals are found in consumer products, will not be made available at all, or, as with company names and use categories, only after time-consuming administrative red tape. Above all, the scope of REACH has been reduced, which will only ensure an appropriate safety assessment for about 10% of existing chemicals, and leave most chemicals entering the EU via consumer products largely untouched.

Despite all these problems REACH still holds its position as the right framework, which the EEB supports. EU governments and parliaments now have the responsibility of closing those gaps and correcting flawed procedures to realise its benefits for society and the environment."

While these are the words of EEB, they are used in this book to summarize what other environment and consumer organisations said.

### ETUC

In a somewhat delayed response to the Proposal, the Executive Committee of the European Trade Union Confederation (ETUC) adopted a Declaration regarding the REACH proposal at its` meeting in Brussels on 17-18 March 2004. The Declaration represents a

similar position to that taken by ETUC in the Internet consultation in June 2003 (page 91).

In the Declaration, ETUC expresses the opinion that the proposed REACH system would constitute a significant contribution to sustainable development, improving protection of the environment and human health, and that it will foster innovation in Europe.

ETUC pointed out that the final regulation may be improved by re-instituting the Duty of Care for substances produced in volumes below 1 tonne per year, introducing certain tests and a requirement for a Chemical Safety Report for substances produced in volumes between one and ten tonnes per year and by including sensitising substances in the authorisation process. ETUC also suggests the creation of an "aid plan" from authorities to facilitate the implementation of REACH, especially for small and medium sized companies and downstream users.

## SHIFT OF COMPETENCY

### Overview

Since the first calls for a new strategy on chemicals came from the Council of Environment Ministers in 1998, they had the lead competency on the development of the new strategy. Other Councils were consulted but the responsibility was on the Ministers of Environment since it was an initiative to increase environmental and human safety. In Parliament, the lead on REACH was in the Committee on Environment. For those opposing REACH, it was of key importance to shift competency and have industry allies take the lead.

### Council

Following the adoption of the Lisbon Strategy (see box on page 85) the European Council decided to create a new "super-Council" to ensure that the objectives of the Strategy were met, the Competitiveness Council (CC). The CC, consisting mainly of Ministers of Industry and Energy, should inter alia have a horizontal role, examining the proposals of other Councils from an economic and competitiveness perspective.

Already at its spring meeting in March 2003, the European Council had requested that the CC become more involved in the drafting of the new chemicals regulation. This request was repeated by Schröder at the Cefic General Assembly in June 2003, and then jointly by Blair, Chirac and Schröder in their letter to President of the Commission, Romano Prodi in September 2003 (see page 86).

At a meeting of the European Council on 16-17 October 2003, it was decided that the CC would take over the lead responsibility for the REACH proposal, due to be adopted by the Commission within two weeks, from the Council of Environment. In its conclusions, the European Council wrote:

"The Council and the Commission must address the needs of specific industrial sectors, especially the manufacturing sector, in order for them to enhance their competitiveness, notably in view of their essential contribution to economic growth. EU legislation should not be a handicap to EU competitiveness compared to that of other major economic areas.

To this end the Commission is invited to take into account the consequences of proposed EU legislation on enterprises through providing a comprehensive impact assessment. The forthcoming proposal on chemicals, which will be examined by the Competitiveness Council in coordination with other Council configurations, will be the first case for implementing this approach, taking in particular into account its effects on SMEs."

From then on CC had the lead on REACH. The consequences remain to be seen. Though the CC meetings are usually attended by Ministers of Industry, Competitiveness, Energy etc, Member States are free to send whichever Minister they prefer. Thus they may, in theory, send their Ministers of Environment to discuss REACH at the CC meetings.

### The European Parliament

A similar takeover was also attempted in the European Parliament. REACH had been handled by the Committee on Environment since the White Paper was presented in 2001. In December 2003 the REACH Proposal was officially allocated to the Committee on Environment by the President of the Parliament, Pat Cox. However, the Committee on Industry and the Committee on Legal Affairs each claim they should have the lead competency since the competency had been moved in Council. Nevertheless, the Committee on Environment defended its lead on the issue in letters to the President.

The decision on which committee should have the lead was delayed since PPE and ELDR had not yet decided on their opinion. In January, the Chair of the Committee on Environment, Caroline Jackson, blocked the discussions of the draft report produced by the Rapporteur Guido Sacconi (see below). The reason for blocking the discussions was that there had been no decision regarding which Committee should have the lead. In effect, this stopped the adoption of the draft report until after summer 2004, when a new Parliament will start working on the issue again.

In February it was finally decided that the lead would stay with the Committee on Environment.

### The Sacconi Report

Although there was an on-going dispute regarding which committee should take the lead on REACH in Parliament, MEP Guido Sacconi had been appointed Rapporteur by the Environment Committee and he pursued the task.

The Sacconi Report was debated in the Environment Committee in Strasbourg on 29 of March and in Brussels 6 of April. It was clear from the beginning that it was a draft report without time for amendments from other Members. The draft report simply mirrored the view of Mr Sacconi. Mr Sacconi focused on certain priorities relating especially to the functioning and functionality of REACH.

On Registration he restricted himself to two types of amendments of the Commissions proposal: establishment of a single registration system for substances contained in articles, and the further relaxing of the obligations to be imposed on downstream users as regards the provision of indications to suppliers of chemical substances or preparation.

On the Evaluation Mr Sacconi stressed that The Agency should be given the job of drawing up the list of priority substances for evaluation and the simplification of the procedure.

On the Authorisation and Substitution the Rapporteur´s view was that the link between Authorisation and the Substitution Principle needed to be made clearer and more forceful. Overall, Sacconi asked for the New Chemical Agency's role to be strengthened.

## FURTHER DELAYS

During the lively debate in the Environment Committee, the timetable became more obvious. The Commission presented a draft proposal on further work regarding assessment of the impact from REACH on business throughout the supply chain, on innovation and on accession countries, as demanded by industry. Further delays were apparent. The working groups were scheduled to start their work in April and present results in November or December 2004. Further, a high level group consisting of principal stakeholders and representatives of Parliament, the Council, as well as the Commission, would oversee the work and give overall direction to the exercise. This group is scheduled to start work in autumn 2004.

Some members of the Committee voiced concern that the work would delay the process and questioned why the impact assessment only addressed potential impacts on business and not included impacts and benefits to the environment and on social issues.

# Summary of Part Two and Final Remarks

## SUMMARY OF PART TWO

The production and use of chemicals remained virtually unregulated throughout the world until only some forty years ago, when the petro-chemistry boom flooded society with new substances and articles used for a multitude of purposes and the negative consequences first became obvious. When regulations eventually started, it was limited and focused on acute exposure.

The current regulations in the EU were created with free trade and the internal market in mind. They provide insufficient protection for human health and the environment against the hazards of persistent and bio-accumulative substances.

The REACH Proposal, presented by the Commission in October 2003, was born as an initiative to increase the protection of human health and the environment. The strategy also aimed to achieve a sustainable European chemicals industry, living up to the commitments of the EU and all Member States according to the Rio Declaration, Agenda 21 as well as the obligations of OSPAR States to reach the generation goal.

The same governments that had supported REACH and requested even tighter provisions in the European Council meeting in 2001, were during 2002 and 2003 convinced to turn around and oppose the regulation. The US chemicals industry joined the battle, eagerly supported by the Bush administration.

Under the vicious attacks from one of the largest industrial sectors and four of the most powerful governments in the world, the Commission backed down. The Proposal is undoubtedly a watered down version of the initial ambitions and drafts.

## FINAL REMARKS

The Proposal is not perfect. It will not provide the level of protection it aimed for. Nevertheless it is still much better than current EU regulation and a great example for others to follow and to build on. This is also the main worry of the chemicals industry, especially in the US.

REACH has been the subject of an unprecedented aggressive and sustained attack from one of the largest industrial sectors in the world and it has been slashed and denounced by four of the most powerful governments.

However, REACH has also been supported by many politicians, agencies, scientists, NGOs, industries, down-stream users, unions and governments. Unfortunately these stakeholders have no-where near the same political power or the same resources as those allocated by the global chemicals industry and the governments of France, Germany, Great Britain and the USA.

The anti-REACH lobby have undoubtedly taken the initiative. In a “political coup”, the President of the European Council even handed over the responsibility for REACH, one of the most important environmental and health protection initiatives of our time, to the Ministers of Industry, Internal Market and Energy in the Comptetitiveness Council.

But the process is nowhere near its end. The fight over REACH will go on for years and once adopted it will be attacked over and over again. In this process it is crucial that people and organisations aiming to protect human health and the environment do not lose their perspective, that they do not get lost in the labyrinths of chemicals policy, drown in technical discussions or forget their priorities when mesmerised or scared by the anti-REACH lobby.

REACH must be seen for what it is: an initiative to protect human health and the environment against hazardous chemicals and a way of living up to the commitments made in Rio de Janeiro 1992, OSPAR 1998 and WSSD 2002. I must be safeguarded against the attacks of the chemicals industry as well as governments and politicians with short-term perspectives.

# PART THREE: BEHIND THE SCENES

# Deadlock

**A look at what has been going on behind the scenes is useful when trying to understand why a perfectly reasonable political objective, such as REACH, turned into a political deadlock. It may also explain why a regulation intended to increase protection of humans and the environment is being watered down in the name of competitiveness.**

It would prove to be the rainiest month of April in Chester, Great Britain since 1818 and the coldest for ten years. When the 15 Ministers of the European Council met for an informal two-day meeting on the 25th and 26th of April 1998, the temperature was only a few degrees above zero.

The Ministers had several important issues troubling them and creating friction. Climate change was at the top of everybody's minds after negotiations in Kyoto resulted in an emerging conflict between Europe and the United States. The European governments were now discussing transports and national reduction goals. There was also an evolving conflict with the US regarding the import and acceptance of genetically manipulated organisms. However, the conflicts in these areas would later be dwarfed by another issue on the agenda now: a review of the EU chemicals policy. Few, if any, of the Ministers present realised the magnitude of the conflict they were starting.

In preparing for the meeting, five of the governments present had adopted a paper setting out the need for a review of the chemicals policy. The paper had been developed after discussions with experts in the field and laid out the problems and effects of the current regulations. It also proposed some specific ways of addressing the problems. The paper was tabled and discussed. For decades the problems of the past had been haunting them and their predecessors. All the tens of thousands of chemicals that had been registered in the EU before 1981 were still not examined for their effects on human health and the environment. Further, about 95 percent of all the chemicals being produced and used were such "existing" substances. There was a process on how to assess some of them, but it had proved excruciatingly slow and inefficient. To date not one of the substances had gone through the process.

But there were additional problems. Even if authorities wanted to restrict or ban a substance because it was considered dangerous, their hands were tied. Restriction could only be taken after lengthy processes, often taking years, and the outcome was uncertain. In the meantime the substance could stay on the market. These problems had become evident over the past year, when the governments in the EU tried to ban the use of some toxic softeners in soft PVC toys.

The personal concerns of the Ministers were enough in themselves. But chemical security, in particular endocrine effects, had become an issue of broad public concern. Moreover, the crisis over mad cow disease had taught them the potential costs - economic as well as political - for not taking a precautionary approach. Finally, the Environment Ministers of the EU Member States party to OSPAR were committed to cease all releases of hazardous chemicals to the marine environment before 2020 as was to be agreed two months later in the OSPAR Convention. Since all pollution eventually ends up in the marine environment, this commitment had a greater meaning than the wording itself.

The time had come to address the problems. The Ministers agreed to request that the European Commission review EU chemicals regulation and propose a strategy that would be better equipped to protect human health and the environment.

There are many regulations concerning chemicals in the EU. Some lie under DG Environment and others under DG Enterprise. When Council requested a review of the chemicals regulation in 1998, and later provided fundamental guidelines in 1999, it became a joint task for these two DGs in the Commission to do the work. However, since the initiative came from the Council of Ministers of Environment and the objective was to increase security of human health and the environment, the main responsibility in the Commission was put on DG Environment. Once the Commission had presented a proposal, it would be handed over to Council and the European Parliament in a co-decision procedure.

Although the Commission was burdened by internal conflicts, accusations of corruption and even resignation in 1999, the need for the development of a new chemicals policy remained high on the agenda. In February 2001 the Commission delivered a proposal for a new chemicals strategy in the European Union in the form of a White Paper. The stage was set for what German media has called the greatest lobbying battle ever: REACH.

## The Prima Donna Awakens

In the modern corridors of the European Chemical Industry Council, Cefic, on 4 Avenue E. Van Nieuwenhuyse in Brussels, the representatives of the European chemicals industry are used to being listened to. They work hard to make things smooth for their members, creating streamlined regulations and, when necessary, going out of their way to fight regulation or costs that may stifle growth.

Few industrial sectors on Earth are as economically important as the chemicals industry. The size of their global annual sales are difficult to imagine, amounting to some €1,500 billion and growing quickly. While only a third of the size of global oil, sales of chemicals are bigger than those of automobiles, weapons, food, agriculture and most other industrial sectors in the world. Chemicals are big business and the chemicals industry is used to being treated accordingly. This is especially true in Europe where the chemicals industry has a stellar status. It is not only the biggest European industry, it is also the globally most expansive, out-competing US and

Asian companies and creating 75 percent of the European trade surplus. It is the crown jewel of European industry - the Prima Donna.

While the European Commission was busy drafting a new chemicals strategy in 2000, Cefic watched carefully. The then newly elected president of Cefic, Jean-Pierre Tirouflet, comes from the French speciality chemicals manufacturer Rhodia, a company that safeguards its reputation. He believed that improving the image of the chemicals industry was a priority for Cefic. Gaining public confidence was essential to the survival and development of the industry. In this sense, he has continued the tradition of his predecessor, Bryan Sanderson, who preferred openness, dialogue and cooperation with other stakeholders rather than being seen in an open conflict.

At an early stage, Mr. Tirouflet and his colleagues in Brussels were of course aware of the political movement to improve regulation and they realised that this could become a problem. However, they did not want to be associated with high-profile opposition to environmental regulation. Subtlety was of essence. The strategy they decided on was to let the Commission understand their opposition to any dramatic regulatory changes. Simultaneously, they would highlight all the positive things that the industry was doing and stress the need for a dialogue where Cefic and the industry would take a positive note. And to some extent it worked. The Commission was so divided on the issue that, even when the White Paper was presented in February 2001, the text was not available for several days and there were still uncertainties regarding for example which substances should be subject for authorisation.

Nevertheless, the arrival of the White Paper sent shivers through the entire chemicals industry. The principles of the new strategy would significantly alter the playing field, setting new and extended demands on industry. But Cefic was not taken aback. They had been consulted and informed by the Commission. Besides, being the largest industry in the EU gives certain clout and access to the political salons of Brussels. But they simply had not believed the Commission would pursue their task as requested by Council, once Cefic had let them know that industry preferred things just the way they were.

The White Paper was clear evidence that the Commission was not listening and Cefic raised its voice, but only slightly. As a reaction to the proposal, they assured the Commission that they supported the objectives but had doubts about practical issues. Of particular concern to Cefic at this point was the alleged proposal in the White Paper to ban or restrict substances based on their intrinsic properties. This could have severe consequences for the chemicals industry. Though concerns were raised, the tone was still civil and opposition subtle.

## Enter the Hood

But the splash created by the White Paper had also awakened others and subtlety has never been their hallmark. In the offices of the United States Mission to the European Union (USEU) on Rue Zinner in Brussels, Ambassador Rockwell Schnabel

**"We recognize and respect each nation's right to set legitimate public health and environmental standards and to take appropriate precautionary action."**

Al Gore, Vice President USA, 1998

and his staff were deeply worried about the development. For the United States the proposed new European chemicals regulation would be of great political and economic concern.

Firstly it threatened US exports of chemicals and products to the EU. The US chemicals industry was fighting an uneven battle with the European industry, losing ground day by day, but exports from the US to the EU were still worth billions of dollars. Not only could these exports be threatened, the EU chemicals industry could even enhance their competitive advantage if European chemicals were considered safer than US chemicals. Secondly the principles in the new strategy could spread to the US and other regions and find its way into international treaties, setting a new global agenda which the US industry would not be prepared for and was ill equipped to handle. The Commission had already stated that spreading the principles in REACH to other regions and global political fora was an ambition. Finally, there are many US-owned chemicals industries in the EU and most of them are low-tech production facilities, often in Eastern Europe, which could have great difficulties adapting to the new regulation.

The USEU reported back to Washington D.C. where the government put together a team of experts from the Environmental Protection Agency (EPA), State Department, Commerce Department and the Office of the Trade Representatives (USTR). The team had meetings with the American Chemistry Council, the American Plastics Council and individual companies to solicit their views on the EU strategy and the impact it could have on chemicals trade.

From the beginning the goal seems to have been to intervene and change the direction of the new regulation before it could be finalised. While the team was working in Washington D.C., the USEU met with a number of US chemical producers based in Europe. After these meetings the USEU reported back to the US government that it was imperative that they begin a dialogue with the EU as soon as possible with the hope of influencing the draft text.

This was not the first time the US government tried to intervene in European chemicals policies. In 1997 and 1998, the State and Commerce Departments mounted a sustained lobby effort on behalf of the US chemicals and toys industries to derail European efforts to limit the use of softeners in soft PVC toys. One year down the road, after right-to-know request in the US had revealed the extent of the lobbying by the US, the interventions provoked a letter from Congressional Representatives Waxman and Miller asking if it was administration policy to lobby against public health legislation in foreign countries. Their letter prompted Vice President Al Gore to ask the Commerce and State Departments to stop the lobbying. Gore

wrote: "We recognize and respect each nation's right to set legitimate public health and environmental standards and to take appropriate precautionary action."

Another stakeholder with a reputation of being somewhat unsophisticated in exercising its considerable power was also waking up. The German chemicals industry is by far the biggest in Europe and the two largest chemical producers in the world are German. They were now increasing pressure on the authorities on their own, using a more confrontational approach.

While the US government was once again building a strategy to interfere with European chemicals policy and the German industry began to act on its own, Cefic maintained its subtle tone. Concerns were raised that the subtle approach was not working and another major setback to the industry was soon to come. In June 2001 the European Council discussed the White Paper at its meeting in Gothenburg, Sweden. Industry was hoping that the Ministers would have a different, more industry-friendly, perspective than the Commission had shown so far. However, they were to be disappointed. In fact, the Council thought the provisions in the White Paper were too weak and demanded even more.

At the Cefic General Assembly one week later, on 15 June 2001, Jean-Pierre Tirouflet proclaimed that REACH had become the most important legislative issue facing the European chemicals industry. He was concerned that the new regulation focused too much on health and the environment and called on the Commission to improve the workability of the proposal. Cefic's main concern was still the element which made it possible to ban or restrict substances on the basis of their intrinsic properties, such as persistence or bio-accumulation. Cefic feared that decisions could be made to ban substances unnecessarily and arbitrarily.

But Tirouflet also criticised the chemicals industry and possibly the evolving US involvement: "It is not good enough for us to simply complain... We must take a more positive and creative approach. We must be more innovative in our thinking and come up with workable solutions... which are acceptable to everyone. It is in this spirit that Cefic is organising its response and involvement in this regulatory area."

## Time is Running out

Things were not going well for the chemicals industry. First the Commission had proposed a new strategy that was not to their liking. Then the European Council had adopted conclusions requesting stronger provisions, and soon the European Parliament was scheduled to comment by adopting a Resolution on REACH. All the signs showed that Parliament would follow the Council in its call for stronger provisions, or maybe go even further.

In the Parliament, the Committee on the Environment, Public Health and Consumer Policy was in charge of developing the position on the White Paper. Additionally, it was decided that the Committees on Industry and on Legal Affairs would provide opinions.

According to the procedure, the Committee appoints a political group responsible for producing a report on the issue at hand. The group which gets the responsibility then appoints a person to be Rapporteur. Since a rapporteur has considerable influence, there are often several groups who want the responsibility for important files. Thus there is a system where the political groups are given a certain amount of points each year according to their political strength. These points are used to "buy" the responsibility for a certain issue. Which group is given the responsibility for a report depends on who is next in line and has points left to pay with. The groups who do not become Rapporteur appoint a Shadow Rapporteur who follows the issue and co-operates with the Rapporteur.

When it was time to appoint a Rapporteur for the White Paper, the Conservatives and the Green group were particularly interested in handling the report. For a long time the Greens had saved points and abstained from seeking to become Rapporteur on other issues, and where next in line when the White Paper finally came and were thus given the responsibility to handle the issue.

The Green group appointed Ms Inger Schörling to be Rapporteur. She was to produce a report that would form the basis for the opinion of the Committee. After discussions and possible amendments, the report would be submitted to the rest of the Parliament as a draft resolution from the Committee. The draft resolution would then be discussed and possibly also amended by Parliament before being voted on in plenum.

## Changing the Tone

The chemicals industry was deeply worried. Ms Schörling represented the Greens and was not likely to promote the views of the chemicals industry on this issue. On the contrary, they assumed that her report would contain some very far-reaching provisions. But such a report would ultimately need the support of a majority in the Parliament. Thus, the German chemicals industry and Cefic intensified their lobbying and focused on the Members of Parliament, aiming to stop approval of further demands.

A campaign directed toward the parliamentarians was rolled out. It included seminars, workshops, meetings, lunches, dinners, letters, mailouts, phone-calls, visits to plants, media releases and any other component that could be used. The prime targets of the campaign were parliamentarians from Germany, UK, France and Italy - all big producers of chemicals. Especially German Social Democrats supporting REACH were targetted with allegations of being anti-industry and complementary arguments that easily find their way into the hearts of most politicians: costs and jobs.

As expected, the Schoerling Report, presented to the Committee in August 2001, had a number of recommendations which were even stronger than the requirements of the European Council in June. Reacting to the report, Cefic said that it would have serious effects on the European chemicals industry if implemented.

Again, the most serious problem according to Cefic was the use of intrinsic properties as a basis for decisions on restrictions. While the Schoerling Report argued that "full risk assessment has proved to cause paralysis by analysis" Cefic considered continued reliance on risk assessment to be key: "Risk assessment based on sound science is the corner stone to an acceptable and successful regulation."

On 16 October, while the chemicals lobby was mapping out the opinions of the German Social Democrat parliamentarians, sending concerned letters to their constituencies and publishing advertisements, the Environment Committee took a vote on the recommendations of the Schoerling Report. There were more lobbyists and stakeholders than Members of Parliament present, the room was filled with people who wanted to follow the debate and proceedings. Many of the large chemicals industries were present, particularly watching what the German parliamentarians were saying and how they were voting. There were more than 300 amendments to discuss and vote on. Finally, most of the recommendations from the Schoerling Report were endorsed for the draft Resolution.

Cefic was in shock, but the upcoming vote in Parliament was still an open affair and could be influenced. The campaign intensified as Cefic and environmental NGOs sent letters to parliamentarians asking them to vote in certain ways on specific parts of the Resolution. The German chemicals lobby VCI published a series of advertisements in The European Voice, Der Spiegel, Frankfurter Allgemeine and other prominent newspapers, requesting parliamentarians not to vote for the Schoerling Report. German media reports were filled with critiques against REACH, Commissioner Wallström and MEP Schörling.

Nevertheless the Greens managed to build political support by the majority of the European Parliament. But the United European Left/Nordic Green Left and The Greens/EFA were the only groups that were totaly united in voting for the resolution. While almost all of the Socialists and Liberals also supported the final resolution, they where split on several key issues. The Conservatives on the other hand were almost united in voting against the resolution in the final vote. One of the key points where the UK Labour members voted with the Conservatives was for example on the registration of substances below one tonne.

The rejection of such a register was adopted narrowly, 242/215 votes. Another key issue was the scope of substances of very high concern, were the same alliances of Conservatives and UK Labour managed to weaken the scope. After the final vote, 242/169 with 35 abstentions, the resolution still remained strong but not as strong as it could have been.

Not only industry was involved in the lobby before the EP vote. Also Governments and trade unions had sent their messages to the MEPs. When the vote in plenum finally came, on November 15, the chemicals industry was relieved. Though the Resolution was still unacceptable to them, some of the provisions from the original motion had been weakened. Maybe more important was the fact that it had only been adopted with a small majority, making it politically weaker.

Despite the intensive lobby from the chemicals industry, there was now a broad political unity. The Commission, the European Council and the European Parliament all requested stronger chemicals regulation to increase the protection of human health and the environment.

## How Swede it is...

At this point the chemicals industry must have realised that a substantial lobby- and media campaign was needed if they wanted to stop or soften the new chemicals regulation. The campaign had already started with the vote in Parliament and was now stepped up and directed with more long-term strategies.

One specific strategy was to be patronising and portray the White Paper as a somewhat naive proposal from people who did not really know what they were talking about. Sweden had played an important role throughout the process. It had been one of the five Member States initially requesting a review of chemicals regulation in the EU. The Commissioner of DG Environment was a Swede. The content of the White Paper was similar to a national Swedish regulation that had been developed over years in one of the most extensive committee investigations on chemicals ever. Sweden had prioritised the issue during its presidency in 2001, the green Rapporteur was Swedish and the Swedish Chemicals Inspectorate, KemI, had been involved in the preparations of the White Paper.

The anti-REACH lobby pointed out that Sweden did not have a chemicals industry of any real importance. "What do Swedes know about the importance of chemicals industry?" Additionally, many of the Swedish key persons in the issue were women. Commissioner Margot Wallström, MEP Inger Schörling and the DG Environment Head of Chemicals Unit Eva Hellsten were portrayed as a trio trying to demolish the chemicals industry and were even referred to as "The Swedish Witches" in Germany.

Right-wing and non-regulation think-tanks attacked one of the fundaments of REACH, the precautionary principle, and described it as a "good idea" that had been taken too far by the Swedes. For example, in an outrageous article under the headline "How Swede it is" in TechCentralStation, a free-market writer, Roger Bate, described the Swedish focus on environmental and health protection as being dangerous to innovation, jobs and progress: "Unless the Swedish folly with misuse of science and precaution is exposed, other countries may follow down its path."

## Finding Friends

Though reacting late, the anti-REACH lobby was taking form and gaining speed. At the center was Cefic with its nice manners and unwillingness to take a direct and open confrontation. On one side of them were a number of large chemicals producers, national federations and sector groups running their own race, often being more confrontational. On their other side they had the US government and chemicals industry as well as the global chemicals organisation ICCA. They were also

lobbying old friends to join the fight and finding new ones, from workers unions, academics and industry-funded "green" NGOs to governments in Southeast Asia and South America.

**"For many reasons, the future of the European chemical industry is at stake. It is time for us to move a step further to strengthen our cooperation with social partners."**

Eggert Voscherau, Vice President of Cefic, December 2001

Winning public and political support for global chemicals industries can be difficult. Huge chemical plants and transnational corporations are unsympathetic entities to many people. However, small and medium-sized companies are more personal and "cuddly". A lot of the REACH debate focused on the impact that the new regulation could have on smaller companies, the "downstream users", and this was a winning concept. In 2001, seven sector groups within the chemicals industry joined forces and formed the Downstream Users of Chemicals Co-ordination Group (DUCC). The only aim of this organisation was to influence the political REACH process. The seven member organisations of this group of "downstream users" were large associations representing producers of aerosols, detergents, paints, inks, photographic chemicals, cosmetics, etc as well as the chemical distributors FECC. The companies within the seven Member organisations have an annual turnover of €115 billion. From the outset, DUCC adopted a policy on REACH which was identical to that of Cefic, though not as elaborate. Cooperation and liaison with Cefic was also one of the three strategies of DUCC.

The influence of the UK unions on the vote of Labour MEPs showed that the unions and the workers in the plants were powerful and had political influence. Over one million people work in the European chemicals industry and they constitute a substantial force that Cefic wanted on their side. Talks about REACH had been going on between Cefic and the chemical workers union EMCEF for some time. In December 2001, these talks were intensified as Cefic announced that they had formed a new organisation - ECEG - to open dialogue with the trade unions of Europe. The aim was to facilitate talks on national levels between federations of chemical producers and workers unions.

## Impact Assessment - the Industry Way

On the other side of the Atlantic, things had been a bit tense. The US government was eager to start lobbying against the new EU proposal but needed the assistance and input of the US chemicals industry. The industry was also concerned, but acted slowly. Tired of waiting for industry to get their act together, the US government drafted a preliminary set of questions which they sent to the EU Commission in December.

In January 2002 the US government and the chemicals industry became closer as the American Chemistry Council, ACC, drafted a paper outlining the possible

impact on US exports of the proposed EU regulation. Details and conclusions from this impact study would later re-surface as official US policy in the infamous "non-paper" as well as in communication from Colin Powell to US embassies.

One of the most widely used figures from the ACC impact study is that "Examination of just four commercially important chemicals on the EU authorization list shows that $8.8 billion worth of U.S. exports are at risk." This figure is as un-scientific as it can get. Here is how the ACC reasoning goes:

1. Acrylonitrile is used in ABS plastic.
2. Acrylonitrile is carcinogenic and would require authorisation in the EU.
3. If there is no acrylonitrile due to authorization, then there will be no ABS plastic.
4. If there is no ABS plastic there will be no more computer sales to the EU.
5. Computer sales worth USD 7.5 billion are threatened. ACC used similar reasoning for the other three chemicals studied in the impact assessment.

The same month, the US government also attended a two-day meeting at the headquarters of the ACC in Arlington, Virginia. The government representatives were welcomed by CEO Fred Webber, who was also a "Pioneer" fundraiser for the George W Bush election campaign since he had raised more than US$ 100,000 to, as he said, "give industry access to a leader that's ready, willing and able to listen." The government and ACC agreed that the US should become more active and push for greater influence in the making of the new EU chemicals policy. The meeting was also attended by representatives of the EU, who responded positively to US "assistance to the initiative". In this time of building alliances and bonding, the US government also had meetings to discuss the EU proposal with other chemical producers and federations, such as DuPont, Dow Chemicals, The American Plastics Council and the Synthetic Organic Chemical Manufacturers Association.

### Colin Powell and the Non-paper

With the help of the US chemicals industry, the US government had reached a more detailed position regarding REACH and it was now possible to become more aggressive. On March 21, 2002, Secretary of State Colin Powell sent an "action request" cable to the US embassies in EU Member states and 35 other countries. The cable outlined the arguments against the EU proposal. It also called on the Embassies to distribute a paper outlining the US views to officials of the Ministries of Environment, Trade and Foreign Affairs, as well as local business communities. The cable refers to this paper as the "non-paper" indicating that no government agency wanted to take responsibility for it.

The non-paper effectively adopted the viewpoint of the US chemicals industry. For example it quotes the ACC impact study almost word for word, saying that "Examination of just four commercially important chemicals on the authorization list shows that $8.8 billion worth of downstream products are at risk for bans or severe restrictions under the new system." This figure would become frequently quoted by politicians and media in the US and elsewhere.

## US Government and Industry Take a Trip

A few weeks before the embassies in the EU member states began lobbying Ministries of Environment, Trade and Foreign Affairs on behalf of Colin Powell and the US chemicals industry, the German government received special treatment. Representatives from the US embassy, the Environmental Protection Agency (EPA) and ACC met with German government officials and industry representatives on 8 March. One objective of the meeting was to promote the US regulatory system as a better alternative to REACH. Ironically, the weak US system resembles the EU policy that REACH is designed to replace.

At the meeting, the US team attacked the substitution principle, argued for voluntary regulation of chemicals and claimed it was necessary to narrow down the scope of regulatory engagement.

Initially, the German Ministry of Environment's Deputy Assistant Secretary, Wilfried Mahlmann showed disbelief that voluntary regulation could work. But the US government and industry team was animated when he demonstrated an openness to US positions.

Apparently the US initiative was warmly received. A US report from the meeting states that the Ministry of Environment responded with interest to the US positions, while the Ministry of Economics took a decidedly pragmatic and pro-business stance. One heading of the report is entitled, "Little opposition from Ministry of Environment". The lobbying of Charlie Auer from the EPA received the gratitude of a chemical industry representative who "praised EPA's presentation and asks that EPA organise seminars to educate government officials in Germany and Europe on how the EPA review system works. To help clear up misconceptions about the efficacy and efficiency of the US approach."

In the opinion of the US State Department, the lobbying trip was successful. A German joint government, industry, and trade union position paper from 11 March echoed many of the US positions. The US was gratified to see the recognition of the need for a "workable, affordable, and not overly burdensome solution…" in accordance with chemical industry interests.

## US Speaks Out

Following up on the lobby activities, US Ambassador to the EU, Rockwell Schnabel, spoke out against REACH at a speech at the European Policy Centre in May 2002. He stated: "The implications of this for industry are massive. We warned businesses over a year ago that they needed to watch carefully how these rules develop…We are now working with industry to ensure that the EU

**"If we fail to get our needs accepted, the resulting conflicts can be protracted, sometimes politically nasty - and always economically costly for business."**

Rockwell Schnabel,
US Embassador to the EU, 2002

**United States Non-paper on REACH**

I. Background: The European Commission adopted a White Paper in February 2001, which outlines a new policy for chemicals regulation called "REACH": registration, evaluation, and authorization of chemicals. REACH seeks to close information gaps in both existing and new chemicals data (in total over 30,000 chemicals). It also extends data requirements to downstream users of chemicals. Virtually every industrial sector could be impacted by the new policy.

The European Council and the Parliament endorsed the White Paper, and Leaders requested implementation by 2004. The Commission is expected to propose draft legislation this Summer, which will be subject to co-decision. The Commission established working groups to advise on matters related to the legislation. While a diverse group of stakeholders participated, there is a perception that some views have not been heard by key policymakers.

II. U.S. Position: While the United States fully supports the EU's objective to protect human health and the environment, there are concerns that the new policy could have significant trade implications for U.S. chemicals and downstream products. The EU's White Paper outlines what appears to be a costly, burdensome, and complex regulatory system, which could prove unworkable in its implementation. The system could present obstacles to trade in chemicals - 9% of total world trade - possibly distorting global markets for thousands of products. The United States is also concerned that the White Paper approach represents a move by the EU away from greater coherence of chemical regulatory approaches among OECD countries.

III. Concerns with the EU policy include:

• Increased costs: Testing costs (average $250,000 per chemical) - which would apply to all chemicals, even those on the market for decades - will total Euro 9 billion, according to a UK Institute for Environment and Health study. Costs will increase not only for businesses, but also for government regulators.

• Unrealistic time lines for testing: The UK study estimates that the EU would need to extend its time line by 36 years, to 2048, to accomplish the minimum level of testing.

• Unwarranted increases in animal testing: The same UK study estimates that nearly 13 million animals will be required for testing under the proposed system.

• Adverse impacts on innovation and competitiveness: The EU's proposal would make Europe the most expensive place to bring a chemical to market - and keep it on the market - which could divert innovation offshore and further reduce the competitiveness of the EU industry. Four times as many new chemicals are brought to market in the United States as in the EU each year.

• Negative impact on jobs: Increased costs and administrative burdens for marketing chemicals in the EU could disrupt product lines and/or result in plant closures, endangering the millions of EU jobs in this sector.

• Reduced Consumer Choice: Authorization component could remove useful chemicals

from the market, which could in turn impact hundreds of products. Examination of just four commercially important chemicals on the authorization list shows that $8.8 billion worth of downstream products are at risk for bans or severe restrictions under the new system.
· WTO inconsistency: The EU approach, particularly the suggestion to regulate chemicals contained in products manufactured outside the EU (e.g., dyes used in manufacturing textiles), raises significant concern with regard to World Trade Organization (WTO) rules, and may prove more trade restrictive than necessary.
· Disproportionate impacts on small and medium businesses: SMEs, which account for 96% of the European chemical industry, generally produce specialty chemicals in smaller volumes. SMEs could end up paying more per ton produced to comply with the new system than large multinationals that sell in huge volumes. Increased administrative burdens are more difficult for SMEs to deal with as well.
· Arbitrary discrimination: Under the new policy, authorities may force substitution of certain chemicals for others that have been deemed "safer." It is unclear whether this could be implemented without resulting in arbitrary discrimination.
• Overly narrow exemptions: While the R & D exemption is improved over current EU practice, it could be expanded further to encourage innovation, particularly in more environmentally friendly products. It is unclear if provisions will be available to exempt polymers and other low-risk chemicals from the new requirements.
• Movement away from international regulatory harmonization: The EU proposal goes further than any other OECD country's chemical regime, and appears to require new and additional testing of chemicals beyond current OECD initiatives. This move could undermine efforts to create a coherent scheme for international chemicals management.
• "Precautionary principle:" Invocation of the "PP," particularly where data are unavailable or delayed, could provide cover for politically-motivated bans and other severe restrictions.
• Developing countries: While most developing countries are net importers of chemicals, many are major exporters of products that contain chemicals. Toys and textiles are two such products that the EU appears to be targeting under its new proposal. Developing country exporters may have difficulties complying with the complex new requirements.

IV. U.S.-EU Cooperation: The United States government and interested stakeholders are working closely with the European Commission to ensure transparency and to effect a balanced regulation that protects the environment and human health without unnecessary distortions to trade and competitiveness. We are also interested in engaging the EU member state authorities in discussion on the new chemicals policy, as member states will maintain regulatory authority. We seek increased coordination among U.S. and EU regulators and more coherent regulatory approaches. The United States is hopeful that increased cooperation and dialogue early on in the EU legislative process will lead to more effective, protective, and balanced regulation in the end.

doesn't reinvent the wheel and that the regulatory process follows those principles I laid out."

A month later in a speech at the Los Angeles World Affairs Council, Schnabel quoted the $ 8.8 billion figure from the ACC impact study and issued a threat; "If we fail to get our needs accepted, the resulting conflicts can be protracted, sometimes politically nasty - and always economically costly for business."

## Money Talks

While the US government and chemicals industry were using the $8.8 billion figure to legitimise their opposition to REACH, their European counterparts used the same tactics and arguments. Since there were few details in the White Paper, estimating the costs was not easy. This lack of detail was used by the chemicals industry who started making claims about the costs. In the absense of data, anything goes. Cefic estimated that the costs for testing substances would be some €8 billion over a ten-year period. However, an impact study commissioned by the EU, presented to industry at a workshop in May 2002, showed that the costs for testing would be between €1.4 and 7 billion with a best estimate around 3.6 billion over 11 years. Cefic reacted to this by saying that it showed their €8 billion estimate was correct. The chemicals industry also claimed that the costs for testing were not the only costs. In total, REACH would cost industry some €20-30 billion. The Commission responded by saying costs would probably be lower and moreover they would be dwarfed by the socio-economic benefits which would be much higher. Later, the chemicals industries in France and Germany would hit back with new studies showing impacts of apocalyptic dimensions.

## BASF Takes Over Cefic and Sets a New Agenda

Within Cefic, spring and summer 2002 was a time of change. Over the past two years, the presidency had been held by the French specialty chemicals producer Rhodia, but in June 2002 the German giant and world leader BASF would be taking over. Under the presidency of Rhodia, Cefic had prioritised image-building and avoiding open conflicts. However, BASF had other priorities and adopted a more confrontational style of doing business. Producers of high volume chemicals, like BASF, have more at stake. Thus Cefic´s opposition toward REACH would become more aggressive. The new president was the former Cefic vice president and BASF top-gun Eggert Voscherau.

Already in his opening speech on 14 June 2002, Voscherau started to set a new agenda. Gone were the phrases calling for cooperation and dialogue. Gone was also the self-criticising and calls on the chemicals industry to be more positive. Proclaiming that the creation of a level playing field for the chemicals industry, inside and outside Europe, was his priority, Voscherau attacked the EU authorities and demanded action.

Notably, he did not attack REACH, instead he sidetracked the issue by

demanding a coherent industrial policy for all sectors in the EU based on the Lisbon strategy to make the European economy the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion.

Doing this, he created a whole new playing field, lifting the issue to a higher level, and found many friends. While REACH was still an unacceptable proposal, it was now an example of a regulatory proposal that did not comply with the Lisbon strategy and needed to be stopped if the over-arching goals were to be reached. This also showed the need for industry-friendly policies in general in the EU, an issue that needed the attention of heads of state. Eventually, this was also what happened.

At the time, the German and French governments were under great pressure from the Commission because their public deficits were above the three percent agreed in the EU stability pact. Italy was also close to the limit. As a consequence, the governments risked paying fines as stipulated by the pact. The last thing the governments of these countries wanted to see was a new regulation that, according to the industry, threatened to increase the deficit.

### More Non-papers

Governments around Europe and elsewhere were now in the process of developing positions on REACH. In the US, the government had more or less adopted the position of the US chemicals industry into the "non-paper" which was not acknowledged as being an official position but nevertheless used as such. In the UK the government took a similar approach. But instead of adopting an industry paper, they borrowed Liz Surkovic from the UK Chemical Industry Association (CIA). In August 2002 Surkovic was given the task to help formulate the UK government position on REACH. Working in the Department of Environment, Food and Rural Affairs, she sought advice and proposals from the US government and EPA on how to adopt the US system in Europe. While drafting the UK position, Surkovic promised to send drafts to Charlie Auer, the US EPA representative who joined the lobby-trip to the German government in March 2002. She referred to these drafts as "non-papers". The UK position paper was presented in December 2002 and was an echo of the demands from Cefic and chemical industries, requiring inter alia REACH to become more streamlined and simple and take greater consideration to competitiveness. The position paper was hailed by the CIA although they pointed out that they were disappointed that the UK position was still more demanding than they wanted it to be.

### Competitiveness!

Following the adoption of the Lisbon Strategy, competitiveness became the word of the day. Everything was to be considered from a competitiveness perspective and anything that could threaten the competitiveness of the European industry

was evil. To ensure that political initiatives in the EU did not endanger the Lisbon Strategy, the European Council decided to create a new Competitiveness Council to work horizontally and oversee the activities and proposals being drafted by other Councils, such as the Council of Environment Ministers. Basically, the Competiviness Council consisted of Ministers of internal market, industry and research who were now given a control function over other Ministers. The new Council held its first meeting in September 2002.

### More Costs

Cost predictions are generally a favourite subject of the industry when opposing new environmental regulation. In mid November 2002, the first major study commissioned by industry of the costs of REACH arrived. The consultants Arthur D Little had been commissioned by the German industry federation BDI to estimate the impact of the proposed regulation on the German industry and economy. Since the White Paper was still the only basis for estimation the report gave a wide scope of results under three different scenarios, named "Clouds", "Storm" and "Hurricane" depending on the gravity of the outcome. The study shows that, in the best case scenario, REACH will mean a production loss of 1.4 percent for the German manufacturing industry and a loss of 150,000 jobs in Germany alone. The worst case scenario, "Hurricane", predicted a production loss of over 20 percent and that 2,350,000 jobs would be lost in Germany.

The report was widely criticised by independent economic experts for having fundamental methodological flaws. Even though the critique came from a panel brought together by the German Environment Protection Agency as well as from the top Environment Advisory Council appointed by the government, the report provided the chemicals industry lobbyists with exactly what they needed: figures of costs and unemployment. What´s more, the report predicted gargantuan impact not only on the industry but on the German economy as a whole. The report quickly became the favourite piece of reference and the figures were used widely. It was welcomed the Director General of the UK chemicals lobby Judith Hackitt with the words "When we talk about the threat to competitiveness, we mean the threat to the employment of 100s of 1000s people employed by the industry EU-wide – and the threat to the kind of innovation which has so enhanced people's standard of living and quality of life in recent decades."

### Industry Plays the Animal Card, the Costs Card, the Jobs Card...

In the past, Cefic and the US chemicals lobby ACC had not been close. However, over the past months they seem to have bonded. In November 2002 they participated at the Trans Atlantic Business Dialogue meeting in Chicago and issued joint statements against REACH. Mostly it was a repetition of the concerns for costs, loss of competitiveness, trade barriers, unemployment etc. However, Cefic also played a new card: animal tests. They claimed that the tests prescribed by the REACH

proposal would require some 12 million animals for testing. This figure was based on a report from the Institute of Environment and Health in the UK, dated April 2001. However, the report was so widely criticised for its` false base assumptions, that IEH was forced to review it. In March 2002, five months before the Trans Atlantic Business Dialogue meeting, IEH had published new estimates showing a need for less than half of the original figure. Many stakeholders claim that also this figure is far too high, but nevertheless, the figure 12 million was already in the air and raised an outcry from the animal protection NGOs, especially in the UK and Germany. Cefic had made some new, highly unexpected, friends. Over the coming year or two, the animal test issue would become a very important political aspect of the REACH proposal, and the figure 12 million is still used regularly by NGOs.

**" When we talk about the threat to competitiveness, we mean the threat to the employment of 100s of 1000s people employed by the industry EU-wide."**

Judith Hackitt,
Director General CIA, 2002

Continuing to use disproven figures, Cefic and ACC went on to say that the cost of testing was estimated at €7 billion, although the estimate in the impact assessment from May 2002 said that the cost would be between 1.4 and 7 billion, with a best estimate of 3.6 billion.

In December 2002, the Cefic initiative from 2001 to make friends with the chemical workers unions across Europe started to pay off. In a joint statement given at an annual conference organised by the Cefic group ECEG, the UK chemicals lobby, CIA, and four UK trade unions urged unions and industry in other European countries to step up their lobbying against REACH.

But more was to come. Another large group of friends had been approached and told of the evils of REACH: the downstream users representing all the companies that depend on chemicals in some form in their manufacturing process, i.e. all manufacturing industries. Most of them were organised under the European industry federation UNICE, which, incidentally, was led by another BASF top-gun: Jürgen Strube. UNICE was to come out hard against REACH.

## The Tide Turns

The tide had definitely turned for Cefic. The US government was lobbying heavily on their side together with the US and European chemicals producers, chemical workers unions and industry groups. Animal protection groups attacked REACH from another side. Reports predicting economic disaster were rolling in. The calls for industry-friendly policies and the portrayal of REACH as being incompatible with the Lisbon strategy had reached the ears of the European Ministers of Enterprise. Governments across Europe were questioning REACH and there was an increasing focus on competitiveness. There was an increasing split in the Commis-

sion between DG Environment and DG Enterprise.

On March 10, only little more than a week before the meeting of the EU Heads of State at the European Council spring meeting, Cefic and its new ally EMCEF, the European chemical workers union, held a joint press conference in Brussels. The topic of the press meeting was to announce that the two organisations called for a coherent industrial policy as recently proposed by Commissioner Likkanen of DG Enterprise. Cefic president Eggert Voscherau spoke of the need to meet the objectives of the Lisbon strategy, the importance of a competitive industry and the dangers of regulation overkill. Reinhard Reibsch of EMCEF warned that excessive regulation could threaten jobs and economy.

Whether the calls of Cefic and EMCEF were heard by the Heads of State is uncertain, but there was definitely movement in the political arena. On 20-21 March 2003, the EU Heads of State met in Brussels at the annual spring meeting of the European Council. On the initiative of Tony Blair, Jacques Chirac and Gerhard Schröder, reviewing progress and setting objectives to meet the Lisbon strategy was at the top of the agenda for the meeting. This must have been especially important to Chirac and Schröder who were under pressure from huge deficits in excess of the EU stability pact and desperate to increase economic growth in their countries, where chemical production was key. Indeed, the Council meeting concluded that economic growth was the main objective. To this end it was considered necessary to raise employment, promote innovation and entrepeneurship and strengthen the internal market. Echoing the calls from industry, the Ministers proclaimed that "Competitiveness must once again be placed centre stage".

Although the Council conclusions set the priorities for the EU as a whole, they were intended to be applied to all sectors, also to the regulation of chemicals. To this end, the Competitiveness Council - consisting mainly of Member State Ministers of Industry and Energy - should be consulted by the other Councils on all issues that could possibly have an impact on European Competitiveness. Soon the Blair-Chirac-Schröder trio would make this point very clear.

### Powell Sends Another Cable and Schnabel Goes into Denial

In the US, the government lobbying against EU policy making had created some turmoil. In December 2002, in a letter to President George W. Bush, some 70 US environmental, public health and labour organisations came together to denounce their governments efforts to derail the REACH proposal. However, this did not stop Colin Powell from continuing to lobby for the US chemicals industry. On 29 April, just days before the REACH proposal was due to be released for public comment, Powell sent another cable, this time to the governments of the EU Member States and EU Candidate States as well as to the US mission to the EU. The cable mainly repeated industry objections to REACH, including predicted costs, objections to the precautionary principle, the wide scope and the complexity of the regulation. Instead, Powell promoted a US-style regulation. The cable also complained about

the length of the proposed 5-week comment period and supported to have it extended as demanded by the chemicals industry.

**"ACC rallied opposition to the draft proposal, including a major intervention by the U.S. government."**

2003 in Review, ACC

Press reports in the US and EU described the US opposition against REACH and reported about the lobbying. In May, these reports prompted a letter from Rockwell Schnabel, US Ambassador to the EU and one of the most prominent US lobbyists against REACH, to the International Herald Tribune. Despite two years of lobbying, and numerous public appearances on the issue, Schnabel denied that the US had criticised REACH or identified it as a problem and added that the government had not yet had time to study the proposal. The denial from Schnabel prompted a response from MEP Schörling and the debate was heated.

However, only a few days later, William Lash, Assistant Secretary of Commerce, commented on REACH in media. He admitted that US officials had met with EU leaders on several occasions to express their concerns about the proposal. Lash described REACH as being a barrier based on un-sound science or non-existent risk analysis that would damage US exports. In addition, the Commerce Department announced their intention to hold a series of public town hall meetings to organise US opposition to REACH.

The ACC was even more outspoken about the US role in shaping European chemicals policy when they, almost a year later, in January 2004, presented their main achievements of 2003 in the report "2003 in Review." ACC not only confirms the extensive US involvement, they see it as one of their main achievements and consider themselves as being instrumental: "ACC rallied opposition to the draft proposal, including a major intervention by the U.S. government, and ACC actively supported the European industry's advocacy efforts with the leaders of Britain, France and Germany, and many Southeast Asian nations. These efforts helped to build an aggressive position worldwide, and brought about significant concessions in the draft now being considered by the European parliament."

### Waiting

Spring 2003 was a tense time for all stakeholders as they waited for the detailed REACH draft proposal from the Commission. It was five years since the first calls from the Council meeting in Chester, UK, to develop chemicals regulation that provided safety for humans and the environment. The REACH system, presented by the Commission in the White Paper 2001, had been approved by the European Heads of State in Council as well as by Parliament, with requests of further strengthening. But since then the chemicals industry had run an aggressive campaign directed against REACH, gaining support from high places and it was no secret that the issue had created a great split in the Commission. While DG

Environment wanted to strengthen the proposal in accordance to the requests from the European Council and Parliament, DG Enterprise saw it from the perspective of the chemicals industry.

In April the anti-REACH coalition presented another economic study of the effects of REACH. This time, the French chemicals industry and Ministries had commissioned Mercer Management Consultants to assess the costs to the French chemicals industry and society. The Mercer report, timely presented just as the Commission was laying the last hand on the REACH proposal, predicted enormous costs, unemployment and social problems if REACH - as presented in the White Paper - was implemented.

Needless to say, the Mercer study was welcomed by the chemicals industry and used extensively to discredit the upcoming proposal. The study prompted the French government to oppose strict chemicals regulation. Now the chemicals industry had the backing of four of the worlds` most powerful governments and their Heads of State in their fight against REACH: Tony Blair in the UK, George W Bush in the US, Jacques Chirac in France and Gerhard Schröder in Germany.

In May 2003 the Commission presented a Draft Regulation for Internet consultation and stakeholders, governments and citizens were invited to comment. The duration of the consultation was extended to eight weeks following requests for such extension by industry and the US. This meant that the timetable for final adoption of the proposal foreseen for July could not be met. This in turn had the knock-on effect that the time left for the European Parliament to do a first reading was so tight that it was close to impossible to be able to have a first reading.

Oddly, the entire Commission did not officially stand behind the document as would have been expected if it was a proposal from the Commission. Instead, it was presented as a document from DG Enterprise and DG Environment. Lacking the official support from the entire Commission signalled that the Commission had internal difficulties with the proposal and that there was considerable room for changes. The Commission said it would use the comments received in the consultation to finalise the proposal, which would be presented before the end of the year.

It was apparent that the anti-REACH campaign, orchestrated by the US and EU chemicals industry and the US government, had been successful. The Draft Regulation contained almost none of the improvements requested by the European Council and Parliament. Instead, several of the demands from the chemicals industry had been met and the Draft Regulation was a watered down version of the White Paper. The most obvious impairments were that the requirements for substitution of hazardous substances and the demand for assessment of all chemicals used in consumer products, also imported ones, had been effectively taken out or severly watered down.

Despite the alleviations presented in the Draft Regulation, the chemicals industry was not pleased and the internet consultation presented new possibilities

for lobbying activities. The chemicals industry mobilised its friends from around the world to send comments. Anti-REACH industry associations, governments, unions, downstream users, NGOs, academics and citizens sent thousands of comments. In the end, the Commission received some 6,500 comments, almost half of them from industry and many from citizens. Many referred to the enormous costs and high unemployment figures predicted by the chemicals industry, or the 12 million animals that they thought would be used for testing. The fact that over 90 percent of the citizens in the EU are concerned about chemicals was not reflected in the comments received by the Commission.

## The Letter

While the chemicals industry continued to oppose REACH on the grounds of high costs and lack of workability, non-compliance with the Lisbon Strategy was the main argument on the higher political level. Heads of State could hardly oppose a regulation on the grounds of alleged bureaucracy or uncertain financial predictions, especially not when they had themselves identifed it at the European Council in Gothenburg in June 2001 as a priority which should enter into force in 2004.

However, when the chemicals industry re-phrased their objections to REACH as it being a threat to the aims in the Lisbon Strategy, that was adifferent ball-game. Even the US government started talking about the threat REACH posed to the Lisbon Strategy. Why the US government should be concerned over the success of a strategy that aims to out-compete the US industry is a mystery.

On 20 September 2003, while the Commission was significantly re-drafting the Draft Regulation and making it into a Proposal, Tony Blair, Prime Minister of the UK, Jacques Chirac, President of France and Gerhard Schröder, Chancellor of Germany, sent a formal letter to Romano Prodi, President of the European Commission. In the letter they pointed out that the European Council, at its spring meeting in March 2003, had on their initiative discussed the progress in reaching the aims of the Lisbon Strategy. They had then agreed to increase the competitiveness of the European industry by reducing the bureaucracy that European companies encounter. The Heads of State went on, voicing their concern that the proposal for a new chemicals regulation would endanger this work and thus threaten the aims of the Lisbon Strategy. As if reading a script from the chemicals industry or the US government, they were particularly concerned about the registration procedure which was too bureaucratic and unnecessarily complicated. Also the scope was too wide and lacked prioritisation. Lastly they expressed concern that the new requirements would have unacceptable effects on the competitiveness of EU businesses and signed off by saying: “To this end, the Commission must work with the Presidency of the Council to ensure that the Competitiveness Council - in accordance with the European Council decision - plays an effective role in the handling of this legislation.”

All of their governments had two years earlier agreed that the White Paper

needed strengthening and wanted it to have a greater scope. But now the Heads of States of the three largest chemicals producing Member States was telling the President of the Commission that the Commission was out of line and that the proposed REACH system would not be accepted. The Commission needed to take greater consideration to the economy of the chemicals industry. They demanded that the Competitiveness Council be given greater influence in the issue. The Prime Minister of the fourth chemical giant nation in the EU - Italy - had not been asked to sign the letter. However, Silvio Berlusconi, President of the European Council at the time, would soon play an important role as well.

## The Move of Competency

The presidency of the European Council rotates every 6 months. When the EU Heads of State meet four times per year, the Head of State in the presiding Member State has great influence on the agenda. From 1 July to 31 December 2003, Italy was the President Member State and Silvio Berslusconi was consequently not only Prime Minister of Italy, but also President of the European Council. The first of the two European Council meetings to be held during the Italian presidency was on 16-17 October in Brussels. It would be two field-days for the chemicals industry

The focus of the meeting was "Relaunching the European Economy", how to create economic growth and a social and economic backdrop in accordance to the Lisbon Strategy. Under the heading "Creating Favourable Conditions for Growth and Employment - Enhancing the Competitiveness of the European Economy" the Council discussed REACH. If any of the Ministers present in Chester 1998 had been in the room they would probably have been astonished. Why was the European Council discussing a policy, intended to increase the safety of humans and the environment, under such a heading? They would probably have been taken even more aback as the Heads of State declared that "the Council and the Commission must address the needs of specific industrial sectors ... in order for them to enhance their competitiveness, notably in view of their essential contribution to economic growth. EU legislation should not be a handicap to EU competitiveness compared to that of other major economic areas."

Having set the priorities straight, the Heads of State continued: "The forthcoming proposal on chemicals, which will be examined by the Competitiveness Council in coordination with other Council configurations, will be the first case of implementing this approach, taking in particular into account its effects on small and medium sized enterprises." With these words, the European Council declared that the responsibility for the chemicals policy would be taken from the Ministers of Environment and was in the future going to be handled by the Competitiveness Council. No Head of State opposed the decision.

As far as the European Council was concerned, REACH was now a strategy to increase the competitiveness of the EU chemicals industry. As a result, REACH was presented by the Commissioner of DG Enterprise, Erki Liikanen, at the next Com-

petitiveness Council meeting in November 2003. Some of the Ministers expressed concern about the costs and the bureaucracy and they welcomed a decision to set up a Working Party to examine the proposal in all its aspects. They also reminded Liikanen about the words from the latest European Council: "EU legislation should not be a handicap to EU competitiveness compared to that of other major economic areas."

### At last: The Proposal

The letter from Blair, Chirac and Schröder to the Commission and the decision by the European Council to move the competency to the Competitiveness Council was undoubtedly a strong signal to the Commission as they were working on the Proposal, scheduled to be released at the end of October. The European Council would not be disappointed. When the Proposal was presented the scope of REACH had also been reduced, meaing less bureaucracy, less costs, less data requirements, less reporting and less protection. Polymers had been excluded and the data requirements for other substances produced under 10 tonnes per year had been reduced. Chemical Safety Reports were not required anymore for substances below 10 tonnes. The general "Duty of Care" had been taken out and transparency had decreased. The impairments from the Draft Regulation had not been restored. By most accounts, the Proposal was another great victory for the EU and US chemicals industry.

### The Block

The REACH Proposal was now scheduled to be commented on by Council and Parliament. The Anti-REACH lobby had turned the opinion of several Member States and the European Council, shifted the political responsibility from the Environment Council to the Competitiveness Council and put pressure on the Commission to give competitiveness greater importance. Thus, Council would be receptive to the arguments of the chemicals industry, making it possible to convince them to water down the Proposal further. However, since REACH was formally still an environmental issue, it is handled in a co-decision procedure, where Parliament and Council need to find an agreement. The Proposal had now been assigned to the Social Democrats by the Environment Committee and the Italian Member of Parliament Guido Sacconi was appointed to be Rapporteur. He was considered to start his work on the basis of the European Parliament`s resolution from 2001.

Parliament was scheduled to start working on the Proposal right away, hoping to adopt a first reading in May 2004, before the European elections so as to give timely input to the discussions in the Council for their adoption of a common position.

In December 2003, the President of the European Parliament, Mr Pat Cox, received a letter from Mr Berenguer Fuster, the chairperson of the Committee on Industry, External Trade, Research and Energy. The letter declares that following

the shift of competency in Council, the competency in Parliament should also be changed. Therefore REACH should be moved from the Committee on Environment, Public Health and Consumer Policy to the Committee on Industry etc. Shortly thereafter, another letter with similar content arrives, this time from the Committee on Legal Affairs who also want the lead competency. The chairperson of the Committee on Environment, Public Health and Consumer Policy, Caroline Jackson, reacted by strongly defending the lead responsibility of her committee.

However, the primary purpose of these letters however was of procedural nature: by creating a conflict of competence, the work of the lead committee was to be stalled to stop the Parliament from adopting a first reading in this legislature. The Conservatives in the Enviroment Committee and the chair of that committee had already stated that they thought more time was required, in line with demands from industry. A key motivation may also have been to keep the issue out of the elections. The strategy worked: The unresolved conflict of competence served as the necessary pretext for the chair of the Environment Committee to block the discussions as planned in January. As a consequence, it became impossible to complete a first reading.

Once REACH was off the agenda of this Parliament, it was a smooth decision with no objections that the Committee on Environment would keep the lead competency. The Committees on Industry and on Legal Affairs were given enhanced cooperation due to a majority by the Conservatives and the Liberals. Thus it will be up to the new Parliament to carry on the fight for a regulation to protect the health of humans and the environment agaisnt hazardous chemicals.

### Powell Sends a Third Cable and US Intervention is Unveiled

In March 2004 Colin Powell sent yet another cable to US embassies requesting them to act against REACH. The content of this new cable was similar to the first one.and critique against the intervention of the US government in European policy-making was growing in the USA. On 1st of April, the US House of Representatives Committee on Government Reform presented a report looking into the multi-year US lobby campaign against REACH. In the report, the Bush administration is accused of working with the US chemicals industry to influence the new EU chemicals strategy. The Bush administration is also accused of basing its opposition against REACH entirely on the American Chemistry Council`s assessments. The report, which was released by Henry A. Waxman, a democrat from California, found no evidence that the Bush administration had performed any own analysis of the impacts of REACH or sent the assessments of ACC for peer review.

The report contains details from e-mail correspondence between the US government, chemiclas industry and US embassies in Europe. In a letter to president George W. Bush, Mr Waxman says: “I request a clear statement from you that the United States will not work to undermine environmental protections

**"Who will take on Wallstrom? The answer is only other ministers or heads of state"**

US Trade Representative

in other nations." EU Commission spokesperson in the US, Anthony Gooch, commented the US lobby campaign "There would seem to be an inordinate weight given to only one side of a complex argument. Significant concerns about the environment and public health seem to be totally absent from their agenda." In an e-mail quoted in the report, an official of the US trade representative wrote: "But who will take on Wallstrom - the answer is only other ministers or heads of state. The US government plans to send in our ambassadors to member states and commission to make our case." Another e-mail from the US trade officials urged the chemicals industry to "get to the Swedes and Finns and neutralize their environmental arguments."

## REACH is Loose

While European leaders are caving in to the pressure from the chemicals industry and over-seas governments, REACH has embarked on a voyage of its own. Beyond the wide, but short-sighted, circles of the multinational chemical industries and their protectors, the interest for REACH is mounting. People around the world are inspired by the fact that politicians are trying to address something that concerns people in their everyday life.

While right-wing think-tanks are debating how to "confine" stricter chemicals regulation like REACH to Europe, many NGOs are studying REACH, trying to find ways of implementing it in their parts of the world.

Ironically, the aggressive lobby campaign mounted by the ACC, which was undoubtedly aimed at preventing regulation similar to REACH from spreading to the US and other regions of the world, has fuelled the interest for stronger regulation in the US. Politicians and the media are starting to question the safety of their own system, the Toxic Substances Control Act, which in many ways is similar to the current regulation in the EU.

US Democratic staff have met environmental groups to determine which parts of REACH could be incorporated into US law. On 19 March 2004, three key US senators called for investigations into whether the current US laws were enough to protect human health and the environment. The call was made in a letter to the congressional General Accounting Office, saying inter alia: "Concerns have been raised that existing statutes may not provide an effective means of responding to data indicating that substantial risk may exist."

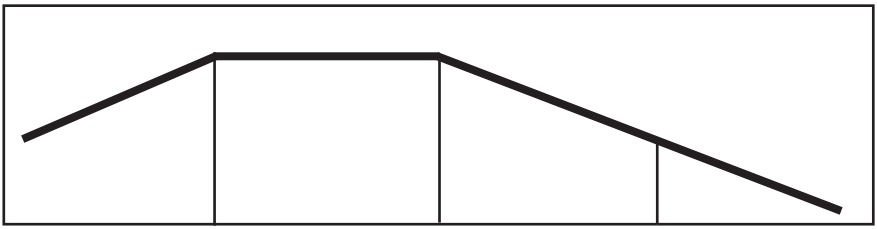
The words sound familiar. Perhaps the distance beween Chester and Washington D.C. isn't so big after all.

# ATTACHMENTS

## The Ups and Downs of REACH

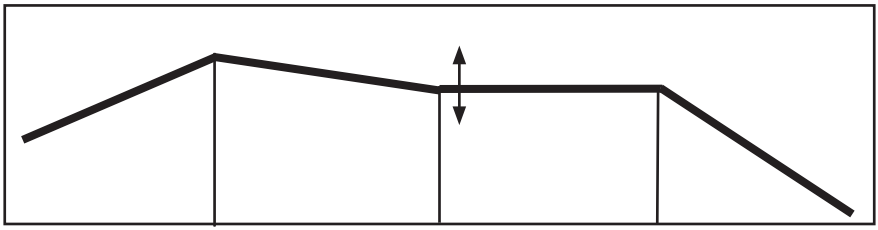
The strategy put forth in the White Paper meant substantial improvements in protecting human health and the environment against effects of industrial chemicals. However, the provisions were not enough to reach the objectives of the initial request of the Council or the European Parliament. Both of these institutions demanded changes, increasing protection further. Environmental and consumer groups were unimpressed by the proposal and requested stricter regulation. However, the Draft Regulation, presented in May 2003, contained impairments on some issues and very few improvements compared to the White Paper. The Proposal laid forth in October 2003 had even more reductions in the requirements, falling short even of the White Paper. While there are many details in the provisions, the general demise may be summarised in the following (graphs by EEB)

### Transparency




The White Paper instigates an improved transparency for the public, requiring the chemicals industry to provide information regarding chemicals. However, the White Paper does not extend this right-to-know to consumer products. The Council required the Commission to improve citizens' right-to-know and the European Parliament required increased burden of information on chemical producers, extending transparency also to the labelling of consumer products containing hazardous substances. In the Draft Regulation presented by the Commission in May 2003, there were no improvements from the White Paper. In the Proposal from the Commission in October 2003 the Commission had decreased transparency further by adding a new list of information that should always be confidential, such as the names of registrants.

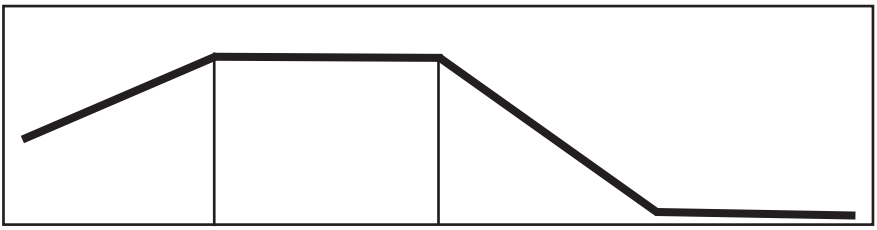
### Scope and Duty of Care




According to the White Paper all chemicals produced or imported in quantities above one tonne per year and producer/importer must be registered and required provision of certain data. The Council requested that the possibility to have a simple register also of chemicals produced or imported in volumes below one tonne per year be studied. The Parliament reacted in an unclear way. On one hand they said there should be no requirements for substances below one tonne, on the other

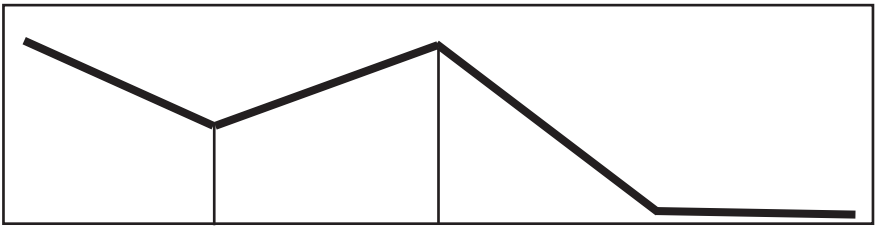
hand they also asked for a simple register for substances below one tonne. In the Draft Regulation presented in May 2003, the provisions were the same as in the White Paper. In the Proposal, the Commission introduced a severe decrease in the data requirements for substances produced in volumes from one to ten tonnes per year and also excluded polymers completly from the requirement. The White Paper also contained a general provision called “Duty of Care” which required that chemicals be produced and used in ways that would not have negative effects on human health or the environment. This duty was also disappeared in the Proposal.

**Substitution of Hazardous Substances**




The White Paper includes a principle aim to substitute hazardous substances with less hazardous. The Council required that this general aim be replaced by a clear duty on the downstream users to always substitute when possible. This requirement was echoed by the European Parliament. In the Draft Regulation the requirements from the Council and Parliament had not been introduced. Instead the Commission had softened the wording from the White Paper, now only requiring that hazardous substances should be substituted if they could not be “adequately controlled.” In the Proposal this remained.

**Chemicals in Consumer Products**




The White Paper states that all producers of consumer products have a duty to assess the safety of all chemicals used in their products and that this duty also applies to importers of consumer products. The Council softened the requirement by saying that this only applied to “substances of concern” while the Parliament agreed with the provisions from the White Paper. In the Draft Regulation the Commission had softened the provision to only apply when there are “significant releases” from the products. The Proposal has similar provisions.

## Differing Views

While there was broad agreement among the stakeholders on the need to achieve sustainable development within the chemicals industry and to create a single regulatory system aiming to increase protection of human health and the environment, there were many points of differing opinion regarding the details of the new strategy proposed in the White Paper. The main points were:

**Objective**

**Commission:** Promotion of a non-toxic environment and compliance with the OSPAR generation goal.
**Council:** Within one generation (2020), chemicals are only produced in ways that do not lead to a significant negative impact on human health and the environment.
**EP:** New policy to achieve the OSPAR generational goal. 2012: no authorisation for substances of very high concern in consumer products as soon as appropriate alternatives are available. 2020: zero discharges.
**Cefic:** 2012/2020 goals are unrealistic. Even the benefits of products that are essential to society such as important hygiene products and medicines could be jeopardised.
**NGOs:** Implementation of the OSPAR generation goal. A commitment to stop all releases to the environment of hazardous substances by 2020.

**Substitution**

**Commission:** The substitution of hazardous chemicals is an important objective.
**Council:** Chemicals that are dangerous should be substituted with safer chemicals or technologies.
**Parliament:** Substitution principle should be fully applied to all chemicals of concern. Broad concept of substitution (safer substances, materials or technologies).
**Cefic:** Concept of substitution would lead to significant implementation difficulties.
**NGOs:** A requirement to substitute less safe chemicals with safer alternatives. The substitution requirement should apply to all chemicals and should include substitution with non-chemical alternatives.

**Registration, Scope**

**Commission:** Substances and preparations.
**Council:** All uses of concern of chemicals in products must be covered by the new system.
**Parliament:** Chemicals produced in, or imported to, the EU as substances, preparations, or in products.
**Cefic:** Substances and preparations placed on the market .
**NGOs:** A full right to know, including what chemicals are present in products.

**Registration, Tonnage Threshold**

**Commission:** Greater than one tonne.
**Council:** Study the case for introducing within the REACH system a simple register including substances produced in volumes less than one tonne.
**Parliament:** Rejected calls for additional register for greater than one tonne but also calls for registration of all chemicals irrespective of production volume with comprehensive minimum data.
**Cefic:** appreciates .. that key concerns are shared ... to avoid unworkable scope for registration
**NGOs:** All uses of a chemical should be approved and should be demonstrated to be safe beyond reasonable doubt.

**Evaluation**

**Commission:** Supports research on improvement and simplification of risk assessment procedures.
**Council:** Develop procedures that can be used both by authorities and by the industry to simplify the identification of the relevant testing strategies.
**Parliament:** Simplified risk assessment: criteria to put substances in categories of concern based on hazard criteria and use pattern to trigger rapid risk reduction.

**Cefic:** Risk assessment of chemicals, where potential exposure and use are also taken into account; must form the basis for all regulatory decisions.
**NGOs:** Decisions need to be based on generic principles such as usage in consumer products and a simple check list of conditions.

**Authorisation, Scope**
**Commission:** CMR1+2 and POPS; decide later on PBT and VPVB.
**Council:** CMR1+2, POPs, PBT, VPVB; envisage addition of endocrine disruptors; and study inclusion of sensitizers and chronic toxic substances.
**Parliament:** CMR1+2, POPS, and study others e.g. PBT.
**Cefic and VCI:** Proposed extension of scope would lead to an unmanageable situation.
**NGOs:** CMR, PTB, vPvB, + equivalent level of concern, e.g. PT. Phase out of persistent or bioaccumulative chemicals (P or B).

**Authorisation, Conditions**
**Commission:** Risk assessment to show that use constitutes a negligible risk, conditional authorisation if justified by the overall socio-economic benefits of the use.
**Parliament:** Use must be essential to society. Hazardous properties essential for intended use, no safer alternative, alternatives are being developed, decisions by authorities as directly as possible on the information received from registration and evaluation steps.
**VCI:** Criticises that entire groups of substances of economic relevance are to be replaced merely on the basis of certain hazardous properties without considering their usefulness and their actual risks during use. Decisions by authorities as directly as possible on the information from registration and evaluation.
**The German Industry Federation BDI:** Criticises “societal needs” as incompatible with the objective of safe use.
**NGOs:** Authorisation only when there is an overwhelming societal need and no safer alternatives can be found.

**Public Availability of Data**
**Commission:** Industry list of dangerous substances to be made available on the Internet, and stakeholder access to non-confidential info in the database.
**Council:** Information relevant for the safe use of chemicals as well as products must be made available to all users. Stakeholder access to the non-confidential information is important but not sufficient. A general duty for manufacturers to provide comprehensive information on the content of chemicals in products and their hazard and risks and to label products appropriately.
**Parliament:** Data on properties of chemicals to be published, no confidentiality for production volumes, use patterns, sources of exposure. Duty of manufacturer to provide information on content and properties of chemicals in products. Toll free number for information on chemicals in products, and labelling of consumer products with regard to substances of concern.
**VCI:** Production volumes, and use patterns and sources of exposure should remain confidential.
**NGOs:** A full right to know, including what chemicals are present in products. Labeling of consumer products with information regarding the contents of hazardous substances.

## Costs: The Facts and the Figures

Estimating the costs of a proposed regulation can be done in a variety of ways and using many different definitions of cost. Studies can also be limited to specific parts of the regulation, for example costs for testing, or far-reaching in their scope such as trying to assess dynamic effects down the whole business chain. Most cost assessments only look at expenses and ignore benefits, thus not showing the real cost. Below are the most important assessments of the costs of REACH.

**The White Paper**

The first cost estimate relating to the new strategy was presented in the White Paper in 2001. According to the Commission, the direct costs of testing chemicals would be approximately €2.1 billion over 11 years, or €191 million per year, corresponding to 0.05 percent of annual sales. Other costs to the chemicals industry, downstream users or other parts of society were not considered. The Commission pointed out that there were also substantial benefits to society in terms of health effects which were difficult to asses, but may exceed the costs many times over.

**UK Impact Assessment**

In May 2001 Risk & Policy Analysts (RPA) in Loddon,UK presented a partial impact assessment with a cost/benefit analysis for the UK. The report, ordered by the Department of Environment, Transport and the Regions (DETR), was limited in that it was based on the White Paper, which did not give sufficient detail for a comprehensive assessment. The result showed that the total costs for UK society could be some £0.6-1 billion over 20 years while the socio-economic health benefits, in the form of prevention of asthma, cancer, dermatitis, injuries and fatalities, were estimated to be at least £1.5-2 billion over ten years.

**RPA Business Impact Assessment**

In June 2002 the Commission presented an impact assessment that had been done by RPA together with Statistics Sweden. As other impact assessments at the time, it was based on the White Paper which did not give sufficient detail for a comprehensive assessment. The assessment estimated the total costs for the chemicals industry to be between €1.4 and 7 billion with a best estimate around €3.6 billion over 11 years. This would mean an annual cost of approximately €327 million or 0.08 percent of annual sales.

**The Arthur D. Little Report**

To examine the economic effects of the new strategy, the German industry federation Bundesverband der Deutschen Industrie (BDI) commissioned the consultants Arthur D. Little (ADL). The report, which was presented in December 2002, based its assessments on the rough strategy presented in the White Paper and presented three scenarios depending on how the strategy was to be interpreted. The result showed that the German economy would suffer substantially from the new regulation. Estimates were presented in terms of “gross value added loss,” for all industrial sectors in Germany and showed that the loss would be between 0.4 and 6.4 percent and that between 150,000 and 2.3 million jobs would be lost in the German industry depending on which regulative scenario would be realised. The methodology of this report was widely criticised by economists as well as the German government.

**The Mercer Study**

In April 2003 Mercer Management Consultants presented a report supervised by the French chemicals industry federation Union des Industries Chimiques (UIC), several other French industrial federations as well as Ministries of the French government. The scope of the study was to assess the total costs to French society of implementing REACH. The methodology was basically the same as that of the Little report (see above). Since there was no detailed proposal at this time, the study worked with assumptions based on the strategy presented in the White Paper. The study showed that the main economic impact would be a domino effect, where non-chemical industrial sectors would be affected either by passing-on of the chemicals industry’s costs or by the need to replace substances that are no longer available.

It was concluded that the implementation of REACH would ultimately affect the whole French economy, due to reduced business activity and lower consumption. The impact on employment was estimated to be a loss of 360,000 - 670,000 jobs, or up to 2.8 percent of the working population. The economic costs in France were claimed to be between €29 and 54 billion, and the cumulative loss of investment was estimated at between €47 and 88 billion.

**RPA Combined Costs Assessment**

In February 2003 RPA presented another study including the costs for administration of the new agency. The report concluded that the costs for testing substances and administration were €3.8 - 4.1 billion.

**RPA Estimate of Benefits on Occupational Health**

Already with the presentation of the White Paper in 2001, the Commission claimed that the economic benefits of the new strategy would be substantial. In March 2003 RPA presented a report studying the economic benefits that REACH could bring to occupational health in Europe. The report estimated that the benefits would be between €27 to 54 billion over 30 years.

**RPA Revised Business Impact Assessment**

In connection to the presentation of the draft regulation in May 2003, the Commission asked RPA to undertake a new business impact assessment based on the details in the draft regulation. The study was presented in October 2003 and showed that the provisions in the draft regulation were much more costly than the assumptions that had been made in the first business impact study in 2002. The proposed inclusion of polymers and the requirement of separate Chemical Safety Reports (CSR) increased costs significantly. The total costs up to the year 2020 for the chemicals industry and downstream users to implement the draft regulation were estimated to be somewhere between €14 and 26 billion. The best estimate was €12.6 billion excluding costs for testing. The Commission stated it would present a final impact assessment once the final proposal was developed.

**Supplement by Arthur D. Little**

Following the presentation of the draft regulation, BDI commissioned ADL to follow up on the previous report from December 2002 by assessing the effects of the proposed regulation on the German industry. The report was published in August 2003 and claimed that the “gross value added loss” to the whole German industry could be 4.7 percent and that some 1.7 million jobs could be lost as a result of implementing the draft regulation.

**The Commission’s Extended Impact Assessment**

When the final Proposal from the Commission was presented in October 2003 it was accompanied by an extended impact assessment. The assessment states that the changes from the draft regulation to the final proposal brought dramatic cost reduction compared to the RPA Revised Business Impact Assessment (see above). The decision to drop the requirements for CSRs, exempt polymers, lower testing and registration requirements for substances produced under ten tonnes per year and the lighter requirements for intermediates meant that costs would be reduced by €10.6 billion. The remaining cost would be €2.3 billion. When costs were passed on to downstream users the final costs to industry would be €2.8-5.2 billion. The assessment also pointed to potential benefits of the new strategy. Concerning long-term health effects, REACH was expected to lead to economic benefits in the region of €50 billion over 30 years, although the Commission pointed out that this was not intended as an estimate. On the environmental side, benefits were stated to be even more difficult to assess, but an example given of the many economic benefits was the potential to avoid future contamination of land. As an example of the amplitude of such costs, the Commission pointed out that the costs of polluted land sites in the Netherlands alone were estimated to be €23 billion.

## The Codecision Procedure - Map of the Political Process

During 2004/2005, the European Parliament will have its first reading of the Proposal from the Commission. The process then follows the codecision procedure. This procedure puts the European Parliament and the Council on an equal footing, and together they adopt legislation proposed by the Commission. Parliament has to give its final agreement. Codecision is an essential power of the European Parliament, which enhances its ability to influence European legislation. Codecision applies, among other things, to the environment, consumer protection, education, culture and health. The codecision procedure involves one, two or three readings.

1. The Commission proposes a legislative text;

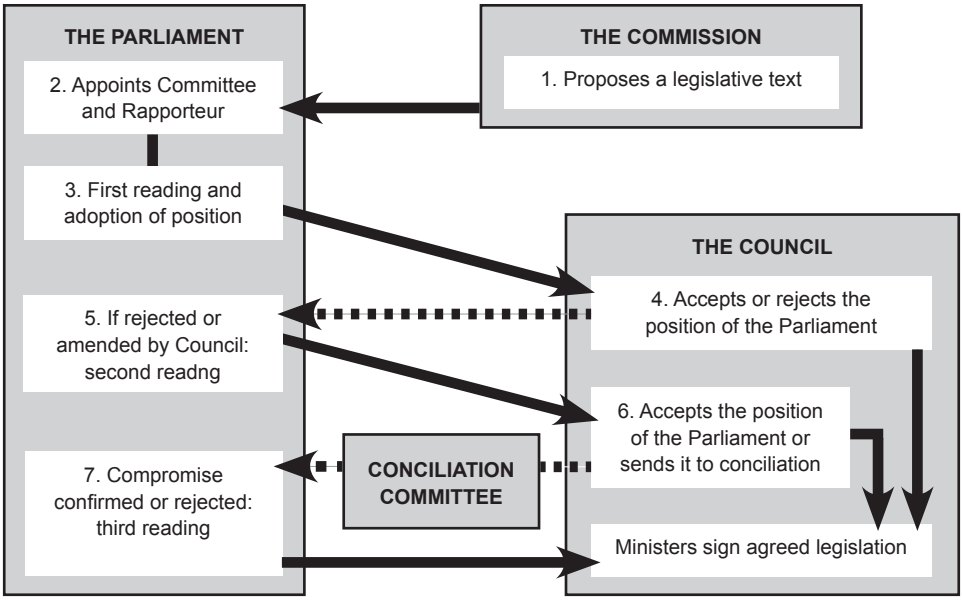
2-3. The European Parliament adopts a position on the basis of a report by its relevant standing committee and usually suggests changes to the Commission proposal in the form of amendments. This is the first reading;

4. The Council of Ministers either approves Parliament's amendments - in which case the legislative proposal is adopted - rejects or modifies them;

5. On the basis of a recommendation by the relevant standing committee, the European Parliament delivers a position at second reading: it approves, rejects or amends the Council position by an absolute majority of its Members (314 votes);

6. The Commission takes account of Parliament's amendments and forwards an amended proposal to the Council. The Council can adopt Parliament's amendments that have been accepted by the Commission by a qualified majority, or modify Parliament's amendments only by a unanimous vote. In the event of disagreement between Parliament and the Council, a conciliation committee made up of the members of the Council and a delegation from Parliament meet for a maximum of six weeks. In the vast majority of cases the two parties reach an agreement, in the form of a joint text;

7. Parliament is invited to confirm this agreement at the third reading. If no agreement is reached, the proposal for a Community "law" is deemed not to have been adopted (i.e. it lapses).



In preparing this guide a great number of documents have been used. For practical reasons, only the most important documents are listed below. However, most documets referring to the process of creating a new chemicals policy in the EU are available on the Internet. Below are some useful links with vast amounts of information and more links. See also the Contact List at the end of the guide.

## Links

European Commission websites on the Future Chemicals Policy:
http://europa.eu.int/comm/environment/chemicals/whitepaper.htm
http://europa.eu.int/comm/environment/chemicals/reach.htm
http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/whitepaper.htm
European Chemicals Bureau:
http://ecb.jrc.it
European Council Presidency Conclusions:
http://europa.eu.int/european_council/conclusions/index_en.htm
European Council Newsroom:
http://ue.eu.int/Newsroom/Contents.ASP?LANG=1
European Parliament Resolution on the White Paper:
http://www3.europarl.eu.int/omk/omisapir.so/pv2?PRG=QUERY&APP=PV2&LANGUE=EN&TYPEF=A5&FILE=BIBLIO01&NUMERO=0356&YEAR=01
The Swedish Chemicals Inspectorate (KemI) website on REACH:
http://www.kemi.se/default_eng.htm
Department for Environment, Food and Rural Affairs (UK) website on chemicals policy:
http://www.defra.gov.uk/environment/chemicals/eufuture.htm
Development Initiative for Chemical Industry Dependent Areas in the UK, website on chemicals policy:
http://www.teesvalley-jsu.gov.uk/dicidauk/keyissues/chemstrat/chemstratindex2.htm
EurActive, on-line media on European Union Policies - website on REACH:
http://www.euractiv.com/cgi-bin/cgint.exe/1043577-444?204&OIDN=1506288&-tt=en.
Report on US intervention from House of Representatives and internal US government documents:
http://www.house.gov/reform/min/inves_admin/admin_reach.htm
Cefic website on chemical policy review:
http://www.chemicalspolicyreview.org/

## Literature

### European Commission

Industrial Chemicals: Burden of the Past, Challenge for the Future, a Stakeholder Workshop, 24-25 February 1999.
White Paper - Strategy for a Future Chemicals Policy, 27 February 2001.
Communication from the Commission on Impact Assessment, May 2002.
Building Block on Authorisation of chemical substances, July 2002.
Stakeholder Reactions on the Internet Consultation, 24 July 2003.
Proposal for a Regulation of the European Parliament and of the Council etc (REACH Proposal), Volumes 1-6, 29 October 2003.
Commission Staff Working Paper - Extended Impact Assessment, COM (2003) 644 final, 29 October 2003.
Memorandum of Understanding between the European Commission side (DG Enterprise and DG Environment) and Industry (UNICE/CEFIC) to Undertake Further Work Concerning the Impact Assessment of REACH, April 2004.
Implications of the proposal for a new chemicals legislation - REACH system - for animal testing, undated.

## Useful Links and Literature

Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau: Public Availability of Data on EU High Production Volume Chemicals, undated.
White Paper - Strategy for a Future Chemicals Policy, 27 February 2001.

**European Parliament**
European Parliament Resolution on the Commission White Paper on a Strategy for a Future Chemicals Policy (The Schoerling Report), A5-0356/2001 - Final Edition, November 2001.
Letter from Ms Caroline Jackson to Mr Pat Cox, December 2003.
Draft Report on the Proposal for a regulation etc, Guido Sacconi, January 2004.
Letter from Ms Caroline Jackson to Ms Karamanou, February 2004.

**Council**
Chemicals Policy - Council Conclusions, 7 June 2001.
Presidency Conclusions, 20/21 March 2003.
Presidency Conclusions, 16/17 October 2003.
2539th Council Meeting, Competitiveness, 10 November 2003.+++++

**Industry**
Arthur D. Little: Economic Effects of the EU Substances Policy, 18 December 2002.
Arthur D. Little: Supplement to the Report on the BDI Research Project, 31 August 2003.
BDI: For a Competitive and Innovation-oriented Chemicals Policy, Position Paper, September 2001.
Cefic: Key Problems on the Schörling Report as Percieved by the European Chemicals Industry, Annex, August 2001
Cefic: Draft Schoerling Report on the Commission Paper on Strategy for a Future Chemicals Policy - an Appraisal by the European Chemicals Industry, August 2001
Cefic: EU Chemicals Policy Review - Plenary Session 12-15 November, A. Perroy, November 2001.
Cefic: EU Chemicals Policy Review, September 2002.
Cefic: Assembly of Business Members: EU Chemicals Policy Review - the View of European Mid-sized and SME Chemical Manufacturers, November 2002.
Cefic: Strategy for a future Chemicals Policy - Expectations of the European Chemicals Industry: Workability and Competitiveness, January 2003.
Cefic: Consultation Document Concerning Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), Appendix 4, Summary of Business Impact Assessments of new Chemicals Policy, July 2003.
Cefic: Consultation Document concerning Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), Executive Summary, July 2003.
Cefic: Annual Reports and Press Releases 1998-2004.
Cefic: Thought Starter on REACH - an Initial Proposal for Translating the REACH System into Practice, undated.
CEPE: Annual Reviews, newsletters and press releases 2000-2003.
CIA Press Releases 2000-2004.
DUCC: Position on Future Chemicals Policy, undated.
FECC: Letter to the German Chancellor Gerhard Schröder, August 2003.
FECC: EU new Chemicals Policy - Summary of the Official Submission to the Internet Consultation, 2003.
Mercer Management Consulting: Study of the Impact of the Future Chemicals Policy, Final Report, April 2003.
UIC: Press Releases 2000-2004.
Unice: Letter to President of the European Commission Romano Prodi, 11 September 2003.
Unice/Cefic Press Release, November 2003.
Unice: Press releases 2000-2004

## Useful Links and Literature

**NGOs**

BUAV-ECEAE: Report on “The Way Forward - Action to end Animal Toxicity Testing, January 2004.
BUAV: Response to the CSTEE criticism of the Way Forward, February 2004.+++
Copenhagen Chemicals Charter: 5 key demands for a better EU chemicals policy, 27/28 October 2000.
EEB, Eurogroup, Friends of the Earth and WWF: A New EU Chemicals Policy, Some Key Arguments, August 2001.
EEB: Position on Commission Proposal for a Regulation on REACH, December 2003.
EEB/WWF: A New Chemicals Policy in Europe, new Opportunities for Industry, January 2003.
Environmental Health Fund: US Intervention in EU Chemical Policy, September 2003.
Friends of the Earth, Safety Testing of Chemicals and the new EU Chemicals Policy, May 2003.
Greenpeace: Consuming Chemicals,2003.
Greenpeace: Chemical Legacy, 2003.
Vier Pfoten: Internet Comment on REACH Draft Regulation, 2003.
WWF: Toxic Legacy, 1999.
WWF: UK National Biomonitoring Survey 2003.

**Other**

AMAP: POPs Fact Sheet #1, Arctic Monitoring and Assessment Programme, 2000.
ECVAM, Alternative (non-animal) Methods for Chemicals Testing: Current Status and Future Prospects, draft, May 2002.
EEA: Low Doses, High Stakes? 1998.
EEA: Late Lessons from Early Warnings, 2001.
ETUC Declaration on the Proposed Reform of EU Policy on Chemicals (REACH), 17/18 March 2004.
House of Representatives (USA): A Special Interest Case Study: The Chemical Industry, the Bush Administration, and the European Efforts to Regulate Chemicals, April 2004.
IEH: Testing Requirements for Proposals under the EC White Paper “Strategy for a Future Chemicals Policy”, April 2001.
IEH: Testing requirements under the EC White Paper ‘Strategy for a future chemicals policy’ - an update, March 2002.
Royal Commission on Environmental Pollution, Chemicals in Products, 2003.
RPA and Statistics Sweden: Assessment of the Business Impact of New Regulations in the Chemicals Sector, Final Report, June 2002.
RPA: Regulatory Impact Assessment of the EU White paper; Strategy for a Future Chemicals Policy, May 2001.
RPA: Assessment of the Impact of the New Chemicals Policy on Occupational Health, March 2003.
Revised Business Impact Assessment for the Consultation Document, October 2003.
SCF: Opinion of the EU Scientific Committee on Food on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food, 22 November 2000, 5.2.1
Stockholm Environment Institute (SEI): Costs and Strategies Presented by Industry During the Negotiation of Environmental Regulations, April 1999.
TNO: report R2002/606, 2002 and R2003/198, 2003.
The Swedish Chemicals Inspectorate (KemI): Kemikalieutredningen (Assessment of Chemicals), ISBN 91-38-21380-X, 2001.
The Swedish Chemicals Inspectorate (KemI): Main Issues in the European Commission`s Proposal, 14 November 2003.
The Swedish Food Administration, the Swedish Monitoring of Pesticide Residues in Food of Plant Origin: 2002.
SRU: On the economic impactof the planned reform of European chemicals policy - Statement, July 2003.

## List of Acronyms

ACC - American Chemistry Council
ADL - Arthur D. Little
AMAP - Arctic Monitoring and Assessment Programme
Barcon - The Barcelona Convention
BDI - Bundesverband der Deutschen Industrie, German Industry Federation
BEUC - European Consumers Organisation
CEE - Central and Eastern Europe
Cefic - European Chemical Industry Council
CEPE - European Council of the Paint, Printing Ink and Artists' Colours Industry (Conseil Européen de l'industrie des peintures)
CFC - chlorofluorocarbon
CIA - Chemical Industries Association
CLRTAP - Convention on Long-range Transboundary Air Pollution, also called The Geneva Convention
CMA - Chemical Manufacturers Association
CMR - carcinogens, mutagens and reproductive toxicant
CSR - Chemical Safety Reports
DDT - dichlorodiphenyltrichloroethane
DES - diethylstilbestrol
DETR - Department of Environment, Transport and the Regions (UK)
DG - Directorate General (of the European Union)
EBFRIP - Eurochlor and European Brominated Flame Retardant Industry Panel
ECB - European Chemicals Bureau
ECEAE - European Coalition to End Animal Experiments
ECEG - European Chemical Industry Employers Group
EDC - endocrine disrupting chemicals
EEA - European Environment Agency
EEB - European Environment Bureau
EEC - European Economic Commission
EINECS - European Inventory of Existing Commercial Chemical Substances
ELINCS - European List of Notified Chemical Substances
EMCEF - European Mine, Chemical and Energy Workers' Federation
EP - European Parliament
EPA - Environmental Protection Administration (USA)
ETUC - The European Trade Union Confereration
EU - European Union
FAO - Food and Agriculture Organisation
GDP - Gross Domestic Product
GEF - Global Environment Facility
GHS - Globally Harmonised Classification and Labelling System
HBCD - hexabromocyclododecan
HCB - hexachlorobenzene
HELCOM - The Helsinki Commission, the governing body of the Convention on the Protection of the Marine Environment of the Baltic Sea Area
HPV - High Production Volume
ICCA - International Council of Chemicals Associations
IEH - Institute for Environment and Health (UK)
IFC - International Finance Corporation
IFCS - Intergovernmental Forum for Chemical Safety
ILO - Internationl Labour Organisation

IMO - International Maritime Organisation
IPCS - International Programme on Chemical Safety
KemI - National Chemicals Inspectorate (Sweden)
LRI - Long-range Research Initiative
MARPOL - International Convention for the Prevention of Pollution from Ships
MEA - multilateral environmental agreement
MOLAR - Mountain Lake Research Project
MPD - Minimum Pre-marketing Set of Data
NGO - non-governmental organisation
NIS - newly industrialized states
OECD - Organisation for Economic Co-operation & Development
OSPAR - The Convention for the Protection of the Marine Environment of the North-East Atlantic
PBT - persistent, bio-accumulative and toxic
PCB - polychlorinated biphenyl
PCT - polychlorinated terphenyl
PIC - Prior Informed Consent
POP - persistent organic pollutant
PRTR - Pollutant Release and Transfer Register
QSAR - Quantitative Structure Activity Relationship
R&D - Research and Development
REACH - Registration, Evaluation and Authorisation of CHemicals
RPA - Risk & Policy Analysts (UK)
SAICM - strategic approach to international chemicals management
SIDS - Screening Information Datasets
SMEs - small and medium sized enterprises
TBT - tributyltin
TDI - tolerable daily intake
UIC - Union des Industries Chimiques (France)
UK - United Kingdom
UN - United Nations
UNCED - United Nations Conference on Environment and Development
UNCHE - United Nations Conference on the Human Environment
UNECE - United Nations Economic Commission for Europe
UNEP - United Nations Environment Programme
UNFCCC - United Nations Framework Convention on Climate Change
Unice - Union of Industrial and Employers Confederations of Europe
UNIDO - United Nations Industrial Development Organisation
UNITAR - United Nations Institute for Training and Research
USA - United States of America
USEU - United States Mission to the European Union
USTR - United States Office of Trade Representatives
VCI - Verband der Chemischen Industrie eV
VOC - volatile organic compound
vPvB - very persistent and very bio-accumulative
WHO - World Health Organisation
WSSD - World Summit on Sustainable Development
WTO - World Trade Organisation

## Contact List

American Chemistry Council (ACC)
1300 Wilson Blvd., Arlington, VA 22209, USA
Tel. 703-741-5000, Fax: 703-741-6000
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Arctic Monitoring and Assessment Programme (AMAP), AMAP Secretariat
Strømsveien 96, P.O. Box 8100 Dep., N-0032 Oslo, Norway
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www.amap.no

Chemical Industries Association (CIA), UK
Kings Buildings, Smith Square, London SW1P 3JJ, UK
Tel. 020 7834 3399, fax: 020 7834 4469
E-mail: enquiries@cia.org.uk
www.cia.org.uk/

Chemical Reaction Website
A joint project of The European Environmental Bureau, Friends of the Earth and Greenpeace
E-mail: info@chemicalreaction.org
chemicalreaction.org/

European Chemical Industry Council (Cefic)
Avenue E. Van Nieuwenhuyse, 4 box 1
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www.cefic.be and www.chemicalpolicy.org

European Chemical Industry Employers' Group (ECEG)
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www.emcef.org

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16a Crane Grove, London N7 8NN, UK
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www.eurocoop.org

European Council of the Paint, Printing Ink and Artists Colours Industry (CEPE)
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www.eeb.org/activities/chemicals/main.htm

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www.theepc.net

Food and Agriculture Organisation (FAO)
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www.fao.org

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www.foei.org

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www.greenpeace.org

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www.chemsec.org

International Council of Chemical Associations (ICCA)
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www.icca-chem.org

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www.ilo.org

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www.slv.se/engdefault.asp

Organisation for Economic Co-operation & Development (OECD)
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The Swedish Chemicals Inspectorate (KemI)
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www.kemi.se/default_eng.htm

The European Consumers Organisation (BEUC)
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www.beuc.org and www.chemical-cocktail.org

The European Mine, Chemical and Energy Workers Federation (EMCEF)
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www.emcef.org and
www.emcef.org/Committees/Chemical/Chemical.asp

The European Trade Union Confederation (ETUC)
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www.etuc.org/en/

UN Interorganisation Programme for the Sound Management of Chemicals (IOMC)
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www.unep.org/themes/chemicals
www.chem.unep.ch/default.htm
www.chem.unep.ch/saicm

United Nations World Health Organisation (WHO)
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www.panda.org/epo/toxics