GMO-Regulation: Case Study for Switzerland

By Franz Xaver Perrez, Christoph Errass and Krisztina Bende[1]

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[1] *Franz Xaver Perrez*, head of section Global Affairs in the Swiss Agency for the Environment, Forests and Landscape; J.S.D. 1998 (N.Y.U.), LL.M. 1996 (N.Y.U.); Attorney at law 1992 (Bern); additional studies at University of Bern School of Law and Université de Paris II. *Christoph Errass*, deputy head of Legal Service Section 2, Legal Affairs Division of the Swiss Agency for the Environment, Forests and Landscape, Dr. iur. 1998 (University of Fribourg); Attorney at Law (Basel), Law Degree (University of Fribourg); additional legal studies at the ETHZ (Physics) and University of Basel (philosophy). *Krisztina Bende*, intern in the section International Environmental Affairs in the Federal Department for Foreign Affairs, Law Degree (2003) from the University of Bern School of Law.
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I. INTRODUCTION

The Swiss legislation on genetically modified organisms (GMOs) is interesting for several reasons: Switzerland that began in the early 1990s to address issues of genetic engineering has developed novel approaches and concepts for GMO-regulation such as the concept of "dignity of living beings" and the establishment of an Ethics Committee at an early stage. And not only was Switzerland a pioneer concerning labeling requirements for food products containing GMOs, it was also among the first states to introduce a threshold for such labeling. The Swiss regulation on GMOs is the product of a broad public debate within the Swiss population, which led to the emergence of a generally accepted approach to GMOs that was confirmed in two referenda in 1992 and 1998. The debates during the two referenda have revealed that all major concerns, interests and fears generally raised in the context of GMOs are present in Switzerland: Thus, while Switzerland shares on the one side European sensibilities with regard to environmental and social concerns, Switzerland has also a strong pharmaceutical and biotechnology industry. And while there is a powerful agriculture lobby, Switzerland has at the same time a major interest to avoid unilateral economic policy approaches and a strong commitment to the international trade regime established by WTO. In the light of its participatory system in which each major group can block political decisions, Switzerland had to develop an approach to genetic engineering that reflect all these seemingly conflicting concerns and interests.[2]

This study will explore the Swiss regulatory approach to genetic engineering in the non-human area and GMOs and the values, interests and objectives that have determined this approach. Because the Swiss legislation on GMOs can only be understood in the context in which it was developed, Part II will first provide a very short introduction to Switzerland and its political system. Part III will further address the political and social-economic environment of the Swiss GMO-legislation and present an overview of the main actors involved such as the political parties, the science and research sector, the private sector and the civil society, and then identify the different values and interests involved. After this introduction to the political and social economic context, Part IV will summarize the history of the Swiss GMO-legislation and then present the content of this legislation. Part V will address specific issues such as the Swiss approach how to deal with the risks of GMOs under uncertainty and precaution, and international aspects. Thereby, it will specifically focus on the WTO-compatibility of the Swiss GMO-regulation. Finally, Part VI will summarize the main elements that have shaped and that are reflected in the Swiss legislation on GMOs. It will conclude that Switzerland, forced by its participatory political system, has taken a constructive and flexible approach taking fully into account all the different values and interests. It might therefore provide useful insights and helpful guidance for others.

[2] See generally: Franz Xaver Perrez, *Taking Consumers Seriously: The Swiss Regulatory Approach to Genetically Modified Food*, 8 N.Y.U. ENVT. L.J. 585, 585-596 (2000) [hereinafter: *Taking Consumers Seriously*].

II. A BRIEF INTRODUCTION TO SWITZERLAND[3]

II.1 THE PHYSICAL, HUMAN AND ECONOMIC CONTEXT

Located in the middle of Western Europe, Switzerland is surrounded by Austria, France, Germany, Italy and Liechtenstein. Switzerland is a mountainous country with a peak elevation of 4 634 meters at the centre of the Alpine arc. About 25 per cent of its territory of 41 000 km^2 is intensively farmed, 14 per cent are Alpine pastures, forest cover 32 per cent of the country, and buildings and infrastructure 6,5 per cent. Switzerland is poor in mineral raw materials and in energy resources other than water.

The population of Switzerland is of about 7 million people, from which 4, 6 million are Swiss citizens. The population density in habitable areas is 350 inhabitants per km^2, comparable to that of the most densely populated OECD countries.

Switzerland belongs to the richest countries of the world. Services such as banking and insurance generate 63,5% of Gross Domestic Product (GDP). Industry accounts for 33.5% of GDP. Such sectors as chemicals, pharmaceuticals, watchmaking and machinery are of international importance. Primary activities, including agriculture, generate 3% of GDP. Tourism accounts for 7% of total revenue in the country's balance of payment. Switzerland has an open economy. The EU is Switzerland's main trading partner, both for imports (79% of total) and exports (61% of total).

II.2 THE INSTITUTIONAL CONTEXT

II.2.1 Federal system: competence of communities, cantons and federal state

Switzerland is a Confederation of 26 cantons (6 half-cantons). The federal constitution outlines the federal competencies. Genetic engineering clearly falls within the federal competence.[4]

Each canton has its own constitution, parliament, government and courts. Its sovereignty is limited by the federal constitution.[5] Cantonal law never takes precedence over federal law.[6] The municipalities at a third level are autonomous within the limits of the cantons and the federal law. They have competencies in areas such as education, energy supply, local road building, civil protection and rural planning.

II.2.2 Federal Parliament

The federal parliament is composed of 2 chambers, the National Council with 200 members representing the „population", and the Council of States with 46 members representing the „cantons". While the distribution of the National Council depends on the size and population of the cantons, each canton is represented by two and each half-canton by one representative in the Council of States. Together they are the legislative authority of the Confederation.

Both chambers have their parliamentary committees who prepare the debates. The committee for science, education and culture, as well as the committee for social security and health and

[3] See generally: THE SWISS CONFEDERATION, A BRIEF GUIDE, ed. by the Swiss chancellery, February 2003; OECD, *Environmental Performance Reviews: Switzerland*, 35-50 (1998).
[4] Art. 120 Bundesverfassung (Swiss Constitution, SR 101) *reprinted in*: BBl **1997** I 1 [hereinafter: BV].
[5] Art. 3 BV, supra note Error: Reference source not found.
[6] Art. 49 BV, supra note Error: Reference source not found.

the committee for the environment, spatial planning and energy had a leading role in the process for the elaboration of the new GMO-legislation.

II.2.3 Federal Government

The Swiss government, the Federal Council, is composed of 7 ministers, the Federal Councilors. Each minister leads one of the following seven ministries or departments: The Department of foreign affairs (DFA), the Department of Home Affairs (DHA), the Department of Justice and Police (FDJP), the Department of Defense, Civil Protection and Sports (DDPS), the Department of Finance (FDF), the Department of Economic Affairs (DEA), and the Department of Environment, Transport, Energy and Communications (DETEC), each of which is divided in offices or agencies. With regard to GMOs, the Swiss Agency for the Environment, Forests and Landscape of the DETEC is the lead agency. Other agencies with competencies in the area include the Federal Office of Public Health (part of the DHA), the Federal Veterinary office, the Federal Office of Agriculture, and the State Secretariat for Economic Affairs (all part of the DEA) and the Federal Institute of Intellectual Property (part of the FDJP).

II.2.4 Direct Participation of the Swiss Population

Switzerland's political system allows citizens to participate directly in the political decision making process. Switzerland is therefore often referred to as a "direct democracy". At the federal level, there are three instruments which enable the direct involvement of the Swiss population in the political decision-making process:[7] (i) the "constitutional initiative": Swiss citizens can propose amendments to the constitution by presenting a "constitutional initiative" signed by at least 100'000 voters, such proposals have then to be voted on by the whole population; (ii) the "facultative referendum": the adoption of a new law, the revision of an existing law or the adoption of certain international treaties can be challenged by 50'000 voters in which case the new law or treaty has to be voted on by the whole population; (iii) the "obligatory Referendum": each constitutional amendment and the adoption of certain international treaties have to be voted on by the whole population.[8]

[7] See also infra, subchapter IV.3.7.2.
[8] See generally ULRICH HÄFELIN and WALTER HALLER, SCHWEIZERISCHES BUNDESSTAATSRECHT, 281-297 and 320-321 (2nd ed. 1988).

III. THE POLITICAL AND SOCIAL CONTEXT

III.1 MAIN ACTORS INVOLVED

III.1.1 The Swiss Population

While it is generally assumed that the debate on GMOs divides the population more or less into two groups, the opponents and supporters, a recent survey has revealed a third group, the so-called "pragmatists".[9] Members of this third group appreciate the potential economic and medical benefits of genetic engineering but remain nevertheless concerned about potential negative effects. They therefore tend to oppose genetic engineering in other areas than the health sector. From an overall perspective, the majority of the Swiss has a very critical approach to genetic engineering. Thereby, it is interesting to see that the acceptance of GMOs in general is very low in rural areas and big cities and rises among the young population and the male population.[10] Moreover, the Swiss population makes a major distinction between the use of biotechnology in the health industry (including the pharmaceutical industry) on the one side and the use of biotechnology in agriculture and food processing on the other side. While medical applications are generally favored, the use for food production is rejected among all groups.[11]

The cultural disparities between German speaking and French and Italian speaking people have resulted in different perceptions of genetic engineering. The 1998 referendum showed that the debate on the benefits and risks of GMOs was not as fierce in the French speaking part of Switzerland.[12] Issues regarding ethics and the dignity of the living beings have not raised so many questions in the Latin parts of Switzerland.[13]

III.1.2 The Private Sector, Farmers and NGOs

The main private actors favoring genetic engineering include industry and research. Thereby, it is interesting to note that important parts of Switzerland's research activities are state funded.[14] The pharmaceutical, the biotechnology, and the seed industry clearly stand in favor of genetic engineering and its applications. *Interpharma*, an association funded by pharmaceutical industries dedicates itself to inform people and government about positive outcomes of biotechnology in the pharmaceutical developments.[15] *Internutrition*, a food research association funded by industries active in the biotechnological field regularly informs media and population about progresses and benefits of biotechnology.[16] The *Gensuisse* Foundation, born in 1991 as an alliance of university researchers with the pharmaceutical industry, aims at promoting biotechnology through dialogue and debate.[17]

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[9] Claude Longchamp, *Klare Präferenzen bei der Anwendung: Schlussbericht zum Gentechmonitor 2003 für die Interpharma*, 17 (2003), available at http://www.gfs.ch/publset.html [hereinafter: *Gentechmonitor 2003*].
[10] *Id*., at 9.
[11] *Id*., at 21; see also Nadine Sommer, *Perception du genie génétique sous l'angle d'une perspective genre*, Académie Suisse des sciences naturelles (2000).
[12] www.interpharma.ch/themen/biogen/archiv/index.html.
[13] Task Group on Public Perception of Biotechnology, European Federation of Biotechnology, Briefing paper 8, *Lessons from the Swiss biotechnology referendum*, August 1998, 8 [hereinafter: *Lessons*].
[14] Most Swiss research institutions that are not directly linked to a private company are government financed, and individual research projects are funded for an important part by the Swiss National Fund. However, applied research projects tend to be financed by the private sector. www.snf.ch/SPPBiotech/PMBICS_f.html.
[15] Official website: www.interpharma.ch, last visited October 8, 2003.
[16] Official website: www.internutrition.ch, last visited July 17, 2003. See e.g. POINT, a monthly internet newsletter published by Internutrition, available at www.internutrition.ch/in-news/point/index_f.html.
[17] www.gensuisse.ch. See also *Lessons*, supra note Error: Reference source not found, at 8.

The farmers approach genetic engineering generally with caution. There are approximately 76'000 farmers in Switzerland,[18] organized mainly in four associations, depending either on their production methods or on the size of their industry: the *Swiss Farmer's Association*;[19] the *Small and Middle Farmers' Association*;[20] *Uniterre*[21] and the *Organic Farmers' Association*[22]. All four groups take at least a critical if not negative approach to the use of GMOs in agriculture.[23]

Finally, the consumer groups and the environmental and development NGOs have similarly a very critical approach to GMOs. Consumer groups have built up a very strong position against food processing with GMOs. Moreover, they require strict labeling of any product that contains or has been processed with GMOs.[24] Environmental groups such as Pro Natura, Greenpeace Switzerland and the Swiss section of the WWF stand firmly against uses of biotechnology in Switzerland. Developmental NGOs also oppose GMOs and their introduction in the third world.

III.1.3 The Political Parties

Not all political parties take a clear position on GMOs. The five biggest parties in the Swiss parliament are the *Swiss People's Party* (26% of the seats in the national parliament) which is the strongest right wing party; the *Liberal Democratic Party* (22% of the seats in the national parliament) and the *Christian Popular Party* (17% of the seats in the national parliament) which defend a more flexible, economy oriented position; and the *Social-democratic Party* (25% of the seats in the national parliament) and the *Green Party* (6% of the seats in the national parliament), both defending generally social and environmental interests.

The *Swiss People's Party*[25] does not take a clear position in this debate. This party is in a difficult position as it is representing both the interests of the Swiss industry as well as of most farmers. A recent survey has shown that only 16% of its voters favor genetic engineering in general.[26]

The *Liberal Democratic Party*,[27] representing the economic sector, is the only political party fully supporting the development of gene technology.[28] But even this party recommends a careful and sustainable development of this new technology and calls for responsibility towards the environment by the actors involved. While strongly opposing any moratorium, the Liberal Democratic Party supports the consumer's right to free choice between GMO- and non-GMO-food. 52% of its voters favor genetic engineering.[29]

While the *Christian Popular Party*[30] has adopted a critical approach towards gene technology, it has nevertheless remained flexible to its uses. Thereby, it is important to note that the Christian

[18] See www.blw.admin.ch, the official website of the Swiss Federal Office for Agriculture; see also www.organic.europe.net/country, which provides an overview of organic farming in Switzerland, last visited July 20 2003.
[19] Official website: www.usp.ch.
[20] Also called "Swiss Farmer's Union"; official website: www.kleinbauern.ch, last visited July 20, 2003.
[21] Uniterre was originally called the "Union des producteurs suisses" (UPS) and has changed its name in 2001; official website: www.uniterre.ch.
[22] Official website: www.biosuisse.ch.
[23] See infra, subchapter III.2.2.2.
[24] Matthias Nast, *Gentech-Essen? Nein danke*, KONSUMENTENSCHUTZ AKTIV, Februar 20, 2002/4; for more information, see also www.sks.ch, last visited June 2003.
[25] Official website: www.udc.ch.
[26] Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 9.
[27] Official Website: www.prd.ch.
[28] See: *Génie génétique: Des contrôles sont préférables aux interdictions. La Suisse pays de recherche* (position paper adopted by the party on April 13, 2002, available at www.prd.ch/page/doc/search.asp_Q_ID_E_216_A_Menu_E_3_A_Item_E_3.1_A_section_E_183
[29] Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 9.
[30] Official website: www.pdc.ch.

Popular Party, as a party representing the Swiss middle-class, is often crucial for majority building. 34% of the voters of the Christian Popular Party favour genetic engineering.[31]

The *Social-democratic Party*[32] has a critical approach to biotechnology and opposes the use of GMOs in agriculture. The main reasons include the fear of potential risks posed to the environment and human health, the concern that the use of genetically modified crop in agriculture will make GMO-free and organic farming impossible, the desire to ensure that consumers have free and informed choice to buy the products they prefer, the concern that ethical values are not adequately respected, and the concern that genetic engineering in agriculture could increase the dependence of farmers from the agrochemical industry. Only 34% of the voters of the Social-democratic Party favour genetic engineering.[33]

Finally, the *Green Party*[34] rejects similarly the release of GMOs in the environment, primarily because of environmental and human health concerns.

III.2 VALUES AND INTERESTS INVOLVED

This subchapter will discuss the different interests and values involved in GMOs along the production line. It will then address other, more horizontal values and interests such as ethical values, developmental interests and the concern to be in conformity with the requirements of international trade and international environmental law.

III.2.1 Research and Science

Switzerland takes a leading role in GMO-related research.[35] While significant parts of research in this field are state sponsored through the financing of public research institutions and universities and through the sponsoring of concrete research projects by the Swiss National Fund,[36] the presence of a strong chemical, pharmaceutical and biotechnology industries and the presence of global food companies such as Nestlé entails important private research in the area. Directly linked to this research are benefits such as qualified jobs, a high level of expertise and know-how, the reputation of Switzerland as a leading country in the areas of medical, pharmaceutical and biotechnology research, and the attraction of Switzerland for international companies working in the field. Thus, the interests of science and research clearly favor an open approach to genetic engineering that promotes and stimulates research on this new technology and its use.

III.2.2 Production

III.2.2.1 Pharmaceutical, Medical, Chemical, and Agricultural Biotechnology Industries

Switzerland has acquired a strong advanced position in genetic engineering.[37] Swiss based multinationals such as Novartis and Roche in the pharmaceutical sector, Syngenta in the

[31] Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 9.
[32] Official website: www.sp-ps.ch. For the parties' position towards GMOs, see also: http://al.sp-ps.ch/data/Pospap-d/GentechnologieAusserhuman.pdf.
[33] Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 9.
[34] Official website: www.verts.ch.
[35] *La recherche en Suisse*, PHARMACH, 1 (1997/5), available at www.interpharma.ch/themen/biogen/index.html.
[36] See supra note Error: Reference source not found.
[37] See e.g. press release of the 11th European Congress on Biotechnology, available at http://www.ecb11.ch/pressinfo/Press_report_wednesday_longV2_fin_e.pdf.

agrochemical sector and Nestlé in the food processing industry are the biggest economic actors related to genetic engineering in Switzerland. They belong to the biggest players internationally. At present, the country has the largest number of biotech firms in Europe and Biotechnology companies provide employment for more than 7000 people in Switzerland.[38] Switzerland plays a dominant role in Europe since a few years despite its lack of public subsidies in the branch.[39] The private interests of the pharmaceutical and medical industry and the public interest to ensure an excellent environment for this industry and its jobs speak naturally in favour of genetic engineering and its application. A soft legislative answer to the issue of GMOs is favoured that does not establish unnecessary impediments and barriers but is generally positive and supportive to this work. However, they do not oppose such requirements as labeling and favour in general an internationally harmonized approach to GMOs.[40]

III.2.2.2 Farming Industry

Due to Switzerland's geographic characteristics, the small dimensions of the country, and the traditional social rural structures, no large-scale industrial farming takes place in Switzerland.[41] As GM seeds have mainly been developed for intensive large-scale farming, Swiss farmers do see no benefits in this method. Moreover, in the light of the consumers' clear rejection of GM food products, the fear that GM products cannot be sold or that they have to be sold at a lower price creates an important disincentive against the use of GMOs in agriculture. At the same time, Switzerland is a pioneer in organic farming. Farmers have grown organic food since the seventies. The increase of organic farms in Switzerland was a response to consumers' concerns about healthy food. It was also encouraged by the Swiss agri-environmental policy that promotes sustainable farming methods,[42] as well as because of the catering of organic food by the two dominant supermarket chains. Today, 90% of the Swiss farmers, which corresponds almost to the entire cultivation area, have chosen integrated or organic production methods.[43] Organic production does not allow any use of GMOs, neither as crops nor as pesticides or fertilizers.[44] Moreover, the use of genetically modified crops by others is seen as a threat to integrated or organic farming because of the risk of cross-contamination and because GM-technology might provoke resistances against traditionally used pesticides.[45] Additionally, it is argued that the use of GMOs in agriculture contradicts Switzerland's general efforts towards a sustainable agriculture, that it might involve risks for the environment, and that governmental compensation for environmental services of agriculture are therefore not available for GM farming.[46]

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[38] Armando Monbelli, *Switzerland banks on biotech*, NZZ-ONLINE, July 10, 2003, available at http://www.nzz.ch/2003/07/10/english/page-synd4017402.html.
[39] Swissinfo June 18, 2002, with reference to Ernst & Young industry survey, available at www.swissinfo.org, last visited July 3, 2003.
[40] See on this Willy De Greef, *Regulatory Conflicts and Trade*, 8 N.Y.U. ENVT. L.J. 579 (2000).
[41] In 1998 there were 76,000 farms. The average farm size was 14.2 hectares; see for a general introduction www.organic-europe.net.
[42] Art. 104.II and 104.III BV, supra note Error: Reference source not found, requires the promotion of sustainable and multifunctional agriculture in Switzerland. See also: http://www.umwelt-schweiz.ch/buwal/eng/fachgebiete/fg_landnutzung/landwirtschaft/index.html.
[43] See the Agriculture report 2003 by the Swiss Federal Office for Agriculture, available at http://www.blw.admin.ch/agrarberichte/index.html?lang=fr.
[44] Art. 104 BV, see supra note Error: Reference source not found; Art 3 of the Ordinance on organic farming and labeling of organic products and foodstuff of September 22, 1997 (Bio-Verordnung SR 910.18).
[45] On the possibility that the use of BT-crops such as BT-maize might promote the development of resistances of pests against the use of the bacterium *Bacillus thuringiensis*, a pesticide which is allowed and widely used in organic farming, see e.g. Hansjakob Baumartner, *Sabotieren Genpflanzen die biologische Schädlingsbekämpfung?*, Magazin UMWELT 4/2000, 12-16 (2000); Michael G. Koziel *et al*., *Transgenic Plants for the Control of Insect Pests*, in AGRICULTURAL BIOTECHNOLOGY 283, 291 (Arie Altman ed., 1998); Brian Tokar, *Monsanto: A Checkered History*, 28 THE ECOLOGIST 254, 259 (1998); Joshua M. Stone, *Restraints on Competition Through the Alternation of the Environment at the Genetic Level*, 8 N.Y.Y. Envtl. L.J. 704, 710-711 (2000) (discussing the phenomenon known as cross-tolerance, i.e. the possibility that pests become immune not only to Bt but to also to all similar chemicals); ISABELLE WILDHABER, PRODUKTEHAFTUNG IM GENTECHNIKRECHT: EINE RECHTSVERGLEICHENDE STUDIE (2000), 66-67.
[46] See supra, note Error: Reference source not found.

In the light of these interests, the Swiss farmers' organizations take all critical if not a negative stand towards the use of GMOs in agriculture. The *Swiss Farmer's Association*, the largest farmers' group, opposes introduction of GM agriculture because of the impossibility to separate traditional farming from GM fields without contaminating traditional cultures with GMOs.[47] However, the *Swiss Farmer's Association* is not totally opposed to genetic engineering as such and it remains open to its future use in agriculture if its consequences are better understood. The *Small and Middle Farmers' Association* and *Uniterre* are strictly opposed to genetic engineering in Swiss agriculture because of the conflict between genetic engineering on the one hand and sustainable agriculture and especially integrated and organic production methods on the other hand.[48] Moreover, while not seeing a need or a benefit for the use of GMOs in agriculture, the members of the *Small and Middle Farmers' Association* wish to respond to the consumer's preferences and therefore do not want to change to GM agriculture as long as consumers show no demand for it. And, *Uniterre* conceives the use of GMOs in agriculture as conflicting with the goals of sustainable development. Finally, the *Organic Farmers' Association* opposes GMOs in agriculture as being contrary to the basic principles of organic farming.[49] Organic farmers are especially concerned about risks that the cultivation of GMOs would entail, not only because the risk of cross-pollination would make organic production difficult if not impossible,[50] but also because the use of GMOs might lead to resistances against insecticides such as Bt-toxin that are used in organic farming.[51]

Interestingly, the opposition of Switzerland's farmers does not seem to be motivated by protectionist goals and farmers have so far not opposed the import of GM food products. Thus, the main interests and values involved can be summarized as relating to the perception of GM farming as non-sustainable and potentially harmful to the environment, to the interest in preventing the contamination of traditional, integrated and organic farming through cross-pollination, to the non-existence of benefits from using GMOs in small- and middle-scale agriculture, and to the desire to meet consumers' demands. All these interests and values favor a legislation that does not allow the use of GMOs in agriculture at least for a certain time to enable a better understanding of the risks involved and a better acceptance of GMO food products by the consumers.

III.2.2.3 Food Processing Industry

The food processing industry has for itself an interest in favor nor against the use of GMOs in food-products. Its main interest is to produce in a cost effective manner according to the consumers' taste and preferences. Given the very clear demand of Switzerland's consumers for GMO-free products, it has repeatedly assured in public that there is no intent to use GMOs in food processing. E.g., the baby food company Gerber, a subsidiary from Novartis, has publicly announced in September 1999 not to use any genetically modified soy or corn in its products.[52] It was Novartis itself that announced this measure publicly, stressing that it had taken this decision in response to consumers' clear preferences.[53] Most of the Swiss chocolate

[47] Swiss Farmers' Union, press communiqué, June 1, 2001, available at http://www.usp.ch/fr/medien/presse/2001/01-06.htm.
[48] See the different statements by members of the Small and Middle Farmers' Association, available at www.kleinbauern.ch, last visited July 20, 2003.
[49] Bio Inspecta (www.bioinspecta.ch) certifies all Swiss organic farms. The Research Institute of Organic Agriculture FiBL was founded in 1973 and has since become one of the biggest organic farming research centres worldwide. Official website: www.fibl.ch.
[50] Daniel Amman, *Gentechnik an Lebensmitteln*, STUDIENPAPIERE SCHWEIZERISCHE ARBEITSGRUPPE GENTECHNOLOGIE, 15, September 1999, with further references, available at www.gentechnologie.ch/papiere.
[51] See supra note Error: Reference source not found.
[52] See Florianne Koechlin, *Wer will gentechnisch veränderte Nahrungsmittel? Babys essen gentechfrei*, in: DIE WOCHENZEITUNG, August 18, 1999.
[53] Swiss Press Agency, *Gerber verzichtet auf Gentech-Zutaten*, ST GALLER TAGBLATT, August 8, 1999.

industry similarly assured not to use derivates from genetically modified soy in its chocolate production.[54]

Given the strong opposition of consumers against GM food products, the Swiss food processing industry has an interest in clear international standards for GMO-free production and in segregating supply channels that enable a cost effective supply of GMO-free ingredients and products.

III.2.2.4 Protection of the Environment, Ecosystems and Human Health

Environmental concerns are a priority of the Swiss population.[55] There is a general perception of a substantial risk that the release of GMOs in the environment will have negative impacts on the environment.[56] The Swiss population has therefore a very critical if not a plain negative approach to the release of GMOs in the environment.[57] In fact, the interactions between organisms and their impact on the ecosystem and the long-term or indirect effects of GMOs on human health and ecosystems are difficult to assess and not yet fully understood.[58] While most studies did not yet find any proof that GMOs harm the environment, some studies indicate however that such a possibility nevertheless exists.[59] Namely, the transfer of GMOs to other plants seems to be possible both horizontally, i.e. through the transfer of gene sequences from one organism to another, and vertically, i.e. through cross-pollination.[60] Cross-pollination may also result from alien species introduced in a new region. The new dimension of GMO-plants relates to the fact that non-vegetable genes might be introduced into the genetic pool of plants.[61] The use of certain transgenic crops could also promote the development of pest resistances.[62] Other risks concern secondary effects such as unintended reactions of a genetically modified organism. These concerns are not only expressed by environmental organizations but also by the insurance industry that is not willing to provide insurance against the risks of GMOs.[63]

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[54] Alain Zucker, *Fiasko Genfood*, DIE WELTWOCHE, 1, June 24, 1999.
[55] See e.g. Schweizerische Gesellschaft für praktische Sozialforschung Gfs, *Angstbarometer*, December 2002, available at http://www.gfs.ch/publset.html, indicating that the fear from ecologic threats belong to the most important concerns of the Swiss population. See also UNIVOX Umwelt 2003 Trendbericht, available at http://www.gfs.ch/publset.html.
[56] Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 11, indicating that 77% of the Swiss population link risks to GMOs.
[57] *Id.*, at 22, indicating that 67% of the Swiss population oppose the use of GMOs in agriculture.
[58] See e.g.: Gerd Neemann and Paul Braun, *Freisetzungspraxis und ökologische Begleitforschung*, in: ZUKUNFT DER GENTECHNIK (Peter Brandt, ed., 1997); HEINZ RUTTLOFF, JÜRGEN PROLL and ANDREAS LEUCHTENBERGER, LEBENSMITTEL-BIOTECHNOLOGIE UND ERNÄHUNG. PROBLEME UND LÖSUNGSANSÄTZE (1997), 124; Julian Kinderlerer, *Genetically Modified Organisms: A European Scientist's View*, 8 N.Y.U. ENVT'L L.J. 556, 558-560 (2000).
[59] See for example Wiebke Rögener, *Unkontrollierbar und umweltschädlich*, WOZ-ONLINE, 23d October 2003, with further references, available at http://www.woz.ch/wozhomepage/Gentech/freisetz_a43j03.htm; Beatrix Mühlethaler, *Begrenzte Lust auf Gentech-Nahrung*, MAGAZIN UMWELT 4/2000, 17, 17-19 (2000) (referring to studies with BT-maize, potatoes with an insecticide against aphids, and gentransfers from cultivated to wild plants); John E. Losey et al., *Scientifc Correspondence: Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999); Paul Raeburn, *Clamor Over Genetically Modified Foods Comes to the United States*, 8 N.Y.U. ENVTL. L.J. 610, 610-611 (2000) (discussing the monarch butterfly study of John E. Losey and how environmentalists and the biotech industry dealt with this study).
[60] BUNDESAMT FÜR STATISTIK, supra note Error: Reference source not found, at 15; Kirsten Schlüter and Ingo Potrykus, *Horizontaler Gentransfer von transgenen Pflanzen zu Mikroorganismen (Bakterien und Pilzen) und seine ökologische Relevanz*, in: GENTECHNISCH VERÄNDERTE KRANKHEITS- UND SCHÄDLINGSRESISTENTE NUTZPFLANZEN. EINE OPTION FÜR DIE LANDWIRTSCHAFT? (Elisabeth Schulte and Othmar Käppeli, eds, 1996), 160-199; Klaus Ammann, Jacot Yolande and Pia Rufener Al Mazyad, *Field release of transgenic crops in Switzerland – an ecological risk assessment of vertical gene flow*, in: GENTECHNISCH VERÄNDERTE KRANKHEITS- UND SCHÄDLINGSRESISTENTE NUTZPFLANZEN. EINE OPTION FÜR DIE LANDWIRTSCHAFT? (Elisabeth Schulte and Othmar Käppeli, eds, 1996), 193-252.
[61] Ammann *et al*., supra note Error: Reference source not found.
[62] See supra note Error: Reference source not found.
[63] Beatrix Mühlethaler, *Streit um eine griffige Haftpflicht*, MAGAZIN UMWELT 4/2000, 16-17 (2000) (Umweltfakten).

All these interest and values strongly favor a strict regulation of genetic engineering and GMOs and the prohibition of the release of GMOs in the environment until the potential environmental and health impacts are better understood.

III.2.3 Distribution and Sale

The actors involved in the distribution and sale of products pursue two main interests: to perform their activities in a cost-effective manner and to meet the consumers' demand. In order to reduce transportation and distribution costs, distributors and retailers in principle tend to be critical towards specific requirements such as compulsory labeling requirements or the requirement to segregate supply chains for GMO and non-GMO products.[64] However, the demand of consumers in Switzerland for GMO-free products is so strong, that distributors and retailers are supporting labeling requirements. Moreover, to ensure the consumer's trust in their products and to avoid negative campaigns against their shops, most have publicly announced that they will not sale food-products containing GMOs. Thus, Migros and Coop, Switzerland's two major food retailers have explicitly assured consumers not to sell any GM-food.[65] And, in order to reduce the costs for segregated supply chains, Migros and other distributors have created a consortium at the European level aimed at buying products only from GM free producers.[66]

The Swiss market has shown very clearly that no demand existed for genetically engineered food products. In Switzerland meeting the market demand means avoiding selling GM products. The distributors and retailers have therefore an interest in a regime that enables them to meet this demand in a cost-effective manner. Clear international standards on GMO-free production, internationally segregated supply channels and the GMO-free agricultural production in Switzerland would e.g. significantly reduce costs for ensuring GMO-free products.

III.2.4 Consumption

While Switzerland's consumers traditionally accepted new food products without hesitation, they recently began to oppose the introduction of new food like beef treated with growth hormones and food products containing GMOs.[67] This considerable shift in the attitude towards food was energized by several food scandals that have revealed the contamination of food products with harmful substances such as hormones or pesticides. The BSE scandal has further contributed to the consumers' skepticism.[68] Interestingly, the opposition to GM food has risen since 1998 when the Swiss population voted on the second constitutional amendment concerning genetic engineering. At the same time, consumers' interests and concerns are no longer limited to the products themselves and their direct health impacts, but extend also to the process of production. However, while opposing GMO-food and genetic engineering in general,[69] the Swiss citizens generally support the use of genetic engineering in the area of

[64] Concerning the costs of segragated supply chains, see the following study commissioned by the Swiss Federal Office of Public Health: prognos (European Centre for Economic Research and Strategy Consultation), *GMO Segregation wihin Food Supply Chains*, Feb. 2001, available at http://www.bag.admin.ch/verbrau/lebensmi/gvo/e/prognos_kurzf.pdf.
[65] *Keine GVO Produkte bei Coop*, in COOPZEITUNG, 24th March 1999; Christian Kaiser, *McDonald's: Nur noch gentechfreie Frites*, SALDO, May 10, 2000; Florianne Koechlin, *Wer will gentechnisch veränderte Nahrungsmittel? Babys essen gentechfrei, in* DIE WOCHENZEITUNG, August 18, 1999; Interview with Stefan Flückiger, *Migros dit non aux OGM*, in 42 ENGAGEMENT, October 15, 2002.
[66] Dieter Claassen, *Gentechfreies in Supermärkten*, TAGESANZEIGER, March 19, 1999.
[67] Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 586.
[68] See on this: James Meikle, *Genetic mutation in cattle may have caused BSE*, in: GUARDIAN WEEKLY, December 11-17, 2003, at 11.
[69] Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 9, 22 and 23, indicating that 53% of the Swiss population generally oppose genetic engineering, 67% oppose the use of GMO in agriculture and 65% would never consume GMO-food products.

medicine.[70] Thus, the following different interests and values of consumers – and thus the citizens and voters[71] – can be distinguished:

III.2.4.1 Interest in Effective Medicine

The Swiss have a great interest in effective medicine. Gene technology for medical research is well accepted. The positive approach to the use of gene technology in medical and pharmaceutical products can be explained by the perception of a clear benefit of using the technology in this area. Thus, 62% of the Swiss population is convinced that genetic engineering will help to find solutions to incurable diseases, 58% trust in the medical doctors who prescribe GMO-medicine, and 84% of the Swiss population support the use of genetic engineering if this helps curing serious diseases such as AIDS or cancer.[72] Moreover, it is generally believed that risks of GMOs can be assessed and better controlled in the area of medical uses. The major concerns with regard to GMOs in medicine relate to potential ethical concerns. And, the fear that gene technology could provoke a further increase in the public health costs could become over time another important concern in this field. Nevertheless, one can conclude that the Swiss, due to their interest in effective medicine, have a positive approach to the use of GMOs in this area.

III.2.4.2 Interest in Food Quality

Swiss consumers care about the quality of food-products. Thereby, most consumers see GMOs in food as potentially unsafe or unhealthy.[73] This fear relates not only to direct negative impacts of eating GM food but also to indirect risks such as the risk that the use of antibiotic resistance marker genes in crops may lead to microbial resistance to antibiotics, which would render the latter useless for medical purposes.[74] At the same time, they don't see a benefit of using GMOs in food products or in agriculture.[75] Thus, the Swiss see GM food as a secondary choice of lower quality. As a consequence, the Swiss consumers do not want to buy GM food.[76]

III.2.4.3 Interests in Process and Production Methods

While consumers have been traditionally interested only in the physical characteristics and composition and in the quality and health-impacts of the products themselves, they became increasingly concerned also about their process and production methods.[77] With regard to food products produced with GMOs, they are especially concerned that the production method may be harmful or dangerous to the balance of ecosystems, biodiversity and the environment in general.[78] Thus, consumers prefer organically grown products not only because they consider

[70] *Id*. at 19, indicating that 52% of the Swiss populations support the use of genetic engineering in the area of medicine.
[71] It is important to realize that citizens cannot be reduced to „consumers" who can merely pronounce their priorities in the market but that they are also voters who able to formulate their priorities in the political decision making process. See on this: SWISS ETHICS COMMITTEE ON NON-HUMAN GENE TECHNOLOGY (ECNH), GENE TECHNOLOGY FOR FOOD 18 (2003), available at http://www.umwelt-schweiz.ch/buwal/eng/fachgebiete/fg_ekah/stell/index.html.
[72] *Id*, at 15, 20, 55.
[73] *Id*, at 28.
[74] Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 587; Floriane Koechlin, *Antibotika-Resistanz und der Novartis Mais: Spiel mit gefährlichen Keimen*, DIE WOCHENZEITUNG, 3, November 7, 1997.
[75] *Id*. In fact, Swiss consumers even reject the use of GMOs in agriculture for enhancing the quality of products, see Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 30.
[76] Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 23.
[77] Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 586-589. See generally: Franz Xaver Perrez, *The Efficiency of Cooperation: A Functional Analysis of Sovereingty*, 15 ARIZ. J. INT'L & COMP. L. 515, 524-25, 527-48 (1998), noting several reasons for this interest in the process and production methods.
[78] Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 587; see also supra, subchapter III.2.2.4, with further references.

them to be healthier. The organic production method is also seen as more respective of the environment. Similarly, consumers oppose GM food not only because of the associated negative health impacts of the product as such but also because of the feared negative impacts of process and production methods involving gene technology. Consumers are also concerned about ethical questions. They have questioned the ethical adequacy of including "terminator" genes in crops that prevent harvested seeds from germinating and thus preclude farmers from reserving a certain amount of harvested seeds for the next planting.[79] And, consumers worry that biotechnology will increase income disparities between large- and small-scale farmers and that patenting transgenic seeds will create a new feudalism in which farmers, especially those in developing countries, will depend upon a few multinational companies.[80]

III.2.4.4 Interest in Information

The consumers' interests in the quality of the products and the way they were produced lead to a new concern, the concern to be informed whether a product is produced with or contains GMOs.[81] This concern relates not only to the physical characteristics of the end-product as such but also to its production and process method.[82] Thus, surveys highly important.[83]

III.2.4.5 Freedom of Choice

Another interest relates to the freedom of choice. Thus, while the minority that would prefer a general ban on GM food products seems to have doubled since 1998, a strong majority of 64% still wants to be able to take a free choice between GM and non-GM-products.[84] But, interestingly, there seems to be no concern that the freedom of choice could be limited by the fact that in the light of the lack of consumer demand no GM-food-products are put on the market.[85] Consumers seem to be worried only that no GMO-free food will be available in future if not action is undertaken to ensure GMO-free production.

III.2.4.6 Interest in Price

In principle, consumers are also interested in low prices. However, most Swiss consumers are generally more concerned about the quality than the price of the products they buy. Thus, the market demand for organic food has increased strongly over the last years despite the fact that organic food is generally more expensive than traditionally grown products. Therefore, the argument that GM food would be less expensive does not have great appeal to consumers who can afford to choose quality rather than something they consider as being of inferior quality or even unhealthy.[86]

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[79] Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 587 with further references; Adi Sollberger, *Das "Terminator"-Gen geht um*, WELTWOCHE, 46, February 4, 1999.
[80] Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 587 with further references.
[81] *Id*., at 587-588.
[82] *Id*., at 588.
[83] Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 23.
[84] *Id*., at 25. While in 1998 only 17% of the Swiss population favoured a general ban of GM food, 33% have done so in 2003.
[85] See on this also ECNH, supra note Error: Reference source not found, at 16-17, indicating that the freedom of choice can be seen as a *freedom right* indicating that nobody should be compelled to consume GM products or as a *claim right* indicating that every consumer should have the right to make a choice which would require that both GM and non-GM products are on the market. The ECNH unanimously rejects the interpretation of the freedom of choice as a claim right.
[86] *Id*., at 30, indicating that 64% of all consumers oppose the use of genetic engineering in order to reduce prices of products.

III.2.5. Crosscutting Interests and Values

III.2.5.1 Ethical Values

Gene technology enables for the first time to cross the natural genetic borders of species. This is generally seen as opening new dimensions for influencing and manipulating nature and thus raising important new ethical questions. It is feared that the new technology reduces the value of nature to its direct utility for humans, and subjects it to short-term human interests, thereby neglecting intrinsic values of nature, the dignity of living beings and the interests of future generations.[87] Some fear that genetic engineering gives mankind the means to "act like God".[88] In the light of this, 74% of Switzerland's population favour strict ethical rules for the use of genetic engineering.[89]

III.2.5.2 International Trade Interests

Switzerland's economy depends heavily on international trade. While larger states may be in a position to develop more autonomous approaches and to impose, if necessary, their rules and principles upon other trading partners, Switzerland has a natural interest in transparent and strong international rules that enhance and facilitate international trade.[90] Moreover, harmonized international regulations enable predictability and reduce the costs of international commerce.[91] Therefore, Switzerland has a strong interest to ensure conformity with international trade rules, especially with those established by the WTO.[92]

III.2.5.3 International Environmental Interests

The protection of the environment as the natural base of all living and human activity is a priority of Switzerland's policy.[93] In the light of the complex and far reaching international interdependencies, effective measures to solve environmental challenges and prevent environmental destruction require international cooperation and co-ordination.[94] Switzerland is therefore actively pursuing a policy to strengthen the international environmental regime, and it has a strong interest to respect and implement the rules and principles established by international environmental agreements.[95]

III.2.5.4 Developmental Interests

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[87] Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 587-588 and 591-94. Concerning the dignity of living beings, see Christoph Errass, *Zum Verhältnis von Recht und Ethik in der Verfassungsbestimmung über die Gentechnologie im Ausserhumanbereich*; ZSR 2002/I 313, 327-335 (2002) [hereinafter: *Recht und Ethik*]. See also infra, text accompanying notes Error: Reference source not found-Error: Reference source not found and subchapter IV.3.2, with further references.

[88] Häberle Irène, *Dem lieben Gott (nichts) ins Handwerk pfuschen*, WENDEKREIS 6/1997, 22-23 (1997); Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 591-593 with further references to Sloterdijk and Dworking.

[89] Longchamp, *Gentechmonitor 2003*, supra note Error: Reference source not found, at 20. The survey has shown that 74% of the Swiss population favour clear ethical rules for the use of gene technology in the area of medicine where ethical concerns seem to be most evident. In the light of the less positive approach to the use of gene technology in other areas, the desire for ethical rules and guidelines might be even stronger for the use of this technology in agriculture.

[90] Schweizerischer Bundesrat, *Bericht zur Aussenwirtschaftspolitik* 2002, BBl **2003** 826, 837-838 (2003).

[91] De Greef, supra note Error: Reference source not found.

[92] Luzius Wasescha, *Internationale Bezugspunkte im Gen-Lex-Prozess*, BIOWORLD 1999.

[93] Supra, note Error: Reference source not found. See also Art. 2.IV BV, supra note Error: Reference source not found.

[94] See generally: Franz Xaver Perrez, COOPERATIVE SOVEREIGNTY: FROM INDEPENDENCE TO INTERDEPENDENCE IN THE STRUCTURE OF INTERNATIONAL ENVIRONMENTAL LAW (2000) [hereinafter: COOPERATIVE SOVEREIGNTY].

[95] Philippe Roch and Franz Xaver Perrez, *International Environmental Governance: The Strive Towards a Comprehensive, Coherent, Effective and Efficient International Environmental Regime* (forthcoming, on file with the author); Schweizerischer Bundesrat, *Aussenpolitischer Bericht 2000*, BBl **2000** 261, 312-313 (2000).

While the goal to promote sustainable development especially in developing countries is generally agreed upon, the opinions differ what consequences have to be drawn with regard to genetic engineering. Some see this new technology as an effective solution to solve the developing countries' problems. Others fear that it will lead to a further increase of the developing countries' dependencies from the industrialized world. The Swiss Development and Cooperation Agency (SDC), while taking the view that every country should take its own decision whether it wants to introduce biotechnology or not, supports its applications in developing countries because of its potential to increase agricultural production, especially in areas of drought.[96] Thereby, the SDC relies on Agenda 21 that is seen as encouraging the use of biotechnologies.[97] The Swiss development and cooperation NGOs, however, have a more critical approach to the use of gene technology for developmental purposes: they consider the use of GMOs in agriculture not as sustainable because of possible negative environmental and negative socio-economic impacts. They fear that GM seeds are too expensive for developing countries' farmers and that they may establish new dependencies on a few multinational companies from the northern hemisphere. They argue that other technologies such as organic farming techniques better meet the needs of the small-scale subsistence farmers of developing countries.[98] It can be concluded that there is a tension between Switzerland's developmental interests and values with regard to genetic engineering as represented by the official governmental development and cooperation agency on the one side and by the relevant NGOs on the other side. This tension is fully reflected in the discussions of the Swiss Ethics Committee and by the two reports it has commissioned on this issue.[99]

[96] Interview of Paul Egger, *Biotechnologie et développement: L'engagement de la DDC*, Séance de réflexion: Biotechnologie et Coopération au Développement, September 27, 2002, GENSUISSE, available at www.gensuisse.ch/focus/entw/index_f.html.
[97] Agenda 21, chapter 16: *Environmentally sound management of biotechnology*, available at www.un.org/esa/sustdev/documents/agenda21/english/agenda21toc.htm.
[98] See e.g.: Miges Baumann, *Genmanipulierter Mais gegen den Welthunger?*, WENDEKREIS 6/97, 8-9 (1997); *Wirkungsvolle Rezepte gegen weltweiten Hunger*, NEUE ZÜRCHER ZEITUNG, February 18, 2000.
[99] See: Johann S. Ach, *Ethische Analyse und Auslegeordnung zum Thema "Auswirkkungen der Biotechnologie auf Entwicklungs- und Schwellenländer"* (report to the ECNH, 2003) available at http://www.umwelt-schweiz.ch/buwal/de/fachgebiete/fg_ekah/stell/index.html; Mirko Saam, Barbara Bordogna Petriccione and Antrás November, *Les impacts des plantes transgéniques dans les pays en voie de developpement et les pays en transitions* (report to the ECNH, 2003) available at http://www.umwelt-schweiz.ch/buwal/fr/fachgebiete/fg_ekah/stell/index.html.

IV. THE SWISS REGULATION OF GMO

IV.1 HISTORY OF SWISS GMO-REGULATION

Three major political events influenced the history of the Swiss legislation: Two popular referendums on constitutional amendments in 1992 and 1998, and the adoption by the parliament of the "Gen-Lex", a package of several amendments of laws relevant to genetic engineering, in March 2003.[100] In Switzerland, genetic engineering has become a major public and political topic in the early 1990s. The debate on genetic engineering in Switzerland since then has been focusing on the overarching themes of safety for the humans and the environment, medicine, research and ethical, social and economic questions.[101] Because of the many different aspects of genetic engineering which often involve very specific and technical questions in diverse areas such as liability, intellectual property rights, consumer information or prevention from major accidents, the Swiss government and the Swiss parliament have declined to regulate genetic engineering in a single horizontal regulation but adopted a "decentralized", "sectorial", or "vertical" approach according to which the different aspects are regulated in the specific laws, decrees and ordinances.[102] Thus, the first Swiss regulation addressing genetic engineering was the federal ordinance on the protection against major accidents of 1991 which aimed at protecting humans and the environment from major accidents during the use of GMOs in closed systems such as research laboratories or during their transportation.[103] While this ordinance dealt with a very specific risk of genetic engineering, a constitutional amendment of 1992 established the broader framework for the Swiss GMO-regulation. Since then, Parliament and government have amended existing or enacted new laws and regulations in the following sectors to reflect the specific needs and concerns of GMOs: the protection of the environment, the release of GMOs in the environment, plant protection, food products, feed for animals, seeds, fertilizer, the use of GMOs in contained systems, the protection of the workers, transportation, and epidemics.[104]

IV.1.1 First Constitutional Referendum: Approval, Labeling and "Respect for the Dignity of living beings"

[100] For an overview of the history of the Swiss legislation on GMOs, see generally: Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found at 590-596; Schweizerischer Bundesrat, Stand der Gesetzgebung über die ausserhumane Gentechnologe: Bericht des Bundesrates an die eidgenössischen Räte, BBl **1998** 1648, 1651ff (1999) [hereinafter: Stand Gesetzgebung], (indicating that the first regulation of genetic engineering took place on a private basis of science in the 1970s); Stefan Kohler, *Stand und Entwicklung im schweizerischen Gentechnikrecht für den Ausserhumanbereich*, in: ASPEKTE DER GENTECHNOLOGIE IM AUSSERHUMANBEREICH (Bernhard Schmithüsen and Jörg Zachariae eds., 2002), 3; Rainer Schweizer*, Das neue Gentechnologierecht: Gen-Lex*, UMWELTRECHT IN DER PRAXIS, URP 2000/1 (2000), 80, 82-83 [hereinafter: *Gentechnologierecht*]; WILDHABER, supra note Error: Reference source not found, at 107-118.

[101] Schweizerischer Bundesrat, *Botschaft zu eine Änderung des Bundesgesetzes über den Umweltschutz (USG)*, BBl **2000** 2391, 2393 (2000) [hereinafter: *Gen-Lex-Botschaft*].

[102] *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 1393-94 and 2397; Stand Gesetzgebung, supra note Error: Reference source not found, at 1658-59; INTERDEPARTEMENTALE ARBEITSGRUPPE FÜR GENECHNOLOGIE (IDAGEN-Bericht), KOORDINATION DER RECHTSETZUNG ÜBER GENTECHNOLOGIE UND FORTPFLANZUNGSMEDIZIN, 10, (1993); KOBAGO, GENTECHNOLOGIE: AKTUELLER STAND UND ZUKUNFTSPERSPEKTIVEN. BERICHT AN DEN BUNDESRAT, 3 and 69, (1992). See generally Patricia Egli, *Das legislatorische Konzept im Gentechnikrecht*, AJP/PJE 4/99 405 (1999), comparing „horizontal" and „vertical" concepts of legislation for genetic engineering; Schweizer, *Gentechnologierecht*, supra note Error: Reference source not found, at 93-94; GERD WINTER, GRUNDPROBLEME DES GENTECHNIKRECHTS (1993), 27ff. See also Christoph Errass, *Die wesentlichsten verwaltungsrechtlichen Aspekte des Gentechnikgesetzes vom 21. März 2003*, AJP, II, (2003) [hereinafter: *verwaltungsrechtliche Aspekte*]. See also infra, subchapter IV.1.3, text accompanying notes Error: Reference source not found-Error: Reference source not found, and subchapter IV.3, text accompanying notes Error: Reference source not found-Error: Reference source not found.

[103] Störfallverordnung, SR 814.012, 1991.

[104] See *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2394-96, providing a tabular overview of the Swiss regulation of genetic engineering.

In May 1992, the Swiss people adopted in a first referendum a constitutional amendment on genetic engineering.[105] This referendum was initiated by a constitutional initiative in 1987 that required legislation against abuses of human reproductive and gene technology.[106] According to the constitutional amendment adopted in 1992, the regulation on genetic engineering must ensure the safety of humans, animals, and the environment, as well as the protection of the diversity of animal and plant species,[107] and it has to respect the "dignity of living beings".[108] Based on this new constitutional provision, the Swiss parliament adopted a regulatory framework which prescribed that GMOs must be handled safely, that work in laboratories with GMOs involving risks for humans and the environment must generally be notified and approved, and that their release into the environment and their marketing needs approval.[109] With regard to GMO food, Switzerland adopted in 1995 a regulation requiring GMO food to be approved before its introduction into the market and to be labeled as such.[110] The requirement to respect the dignity of living beings was at this stage not yet concretized by legislation.

IV.1.2 Second Constitutional Referendum: Rejection of a General ban on Genetic Engineering

In June 1998, the population had to vote on a second constitutional amendment, which would have prohibited all transgenic animals, all releases of transgenic crops into the environment, and the patenting of certain biotechnological inventions.[111] At the beginning of the campaign on this referendum, 62% of the Swiss population generally opposed genetic engineering; nevertheless, a 67% majority finally rejected the amendment. Several reasons have led to this result, including the shift of the discussion away from food, plants, animals and the environment towards medicine, science and education; the fear that the ban would prohibit or hinder medical research and that pharmaceutical companies would move entire research programs abroad; and the limited financial resources of the proponents of a general ban on genetic engineering.[112] Especially, the constitutional amendment was perceived by many as prohibiting all use of genetic engineering in the area of medicine. This can be explained by the fact that the campaign of the opponents, which was strongly financed by the pharmaceutical industry, focused heavily on illnesses and sick people, using emotional images such as sick children sitting on a hospital bed.[113] Interestingly, surveys show that the majority, while favoring the use of genetic engineering for medical purposes, still rejected the use of GMOs in plants and as food at the moment when the second constitutional amendment was rejected.[114] Another important factor was the decision of the Parliament to adopt, prior to the vote on the referendum, the "Gen-Lex-Motion", a parliamentary motion requiring the development of a

[105] See generally: Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found at 590-594.
[106] The constitutional initiative "against abuses of human reproductive and gene technology" was launched on 13 April 1987. Based on the recommendations of an expert group, the Swiss government presented an alternative proposal that was approved by the Swiss population in a referendum of 17 May 1992. See: BBl **1987** II 1208 (initial proposal for a constitutional amendment) and BBl **1989** III 989ff. (proposal of the Swiss government).
[107] Art. 24^{novies} old Swiss Constitution (Art. 120 revised Swiss Constitution). See infra, subchapter IV.2.
[108] Art. 24^{novies}.III old Swiss Constitution (Art. 120.II revised Swiss Constitution). See infra, subchapter IV.3.2. See generally Errass, *Recht und Ethik, at 327-335, supra note Error: Reference source not found*.
[109] Art. 29b)-f Federal Law relating to the Protection of the Environment, (Bundesgesetz über den Umweltschutz (USG), SR 814.01, October 7, 1983) [hereinafter: USG]; Verordnung über den Umgang mit Organismen in geschlossenen Systemen, Einschliessungsverordnung, (ESV, October 25,1999, SR 814.912); Verordnung über den Umgang mit Organismen in der Umwelt, Freisetzungsverordnung (FrSV, October 25,1999, SR 814.911); Verordnung über den Schutz der Arbeitnehmerinnen und Arbeitnehmer vor Gefährdung durch Mikroorganismen (SAMV, August 25, 1999, SR 832.321).
[110] Bundesgesetz über Lebensmittel und Gebrauchsgegenstande, Art. 9 (LMG, SR 817.0, October, 1992); Lebensmittelverordnung, Art. 15 and 22 (Ordinance on Foodstuffs of 1 March 1995, LMV; SR 817.02), Verordnung über das Bewilligungsverfahren für GVO-Lebensmittel, GVO-Zusatzstoffe und GVO-Verarbeitungshilfstoffe (VBGVO, SR 817.021.35, No. 19, 1996) [hereinafter: LMV].
[111] See generally: Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 594-596.
[112] *Lessons*, supra note Error: Reference source not found, at 2-3; Sibylle Hardmeier and Daniel Scheiwiller, VOX-Analyse der eidgenössischen Abstimmung vom 7. Juni 1998, <http://www.gfs.ch/publset.html>, visited April 4, 2003.
[113] *Lessons*, supra note Error: Reference source not found, at 2 and 4.
[114] Bundesamt für Statistik, UMWELTSTATISTIK SCHWEIZ N°8: GENTECHNOLOGIE 12 (1998), at 16-17.

comprehensive and stringent legislatory framework for genetic engineering.[115] This "Gen-Lex" program reassured the public of the willingness to address the challenges of genetic engineering especially in the areas of environment, food and ethics, i.e. the areas, where the majority showed a critical attitude towards genetic engineering.

IV.1.3 The "Gen-Lex": A Comprehensive Legislation on Genetic Engineering

Based on this parliamentary motion requiring a stringent regulatory framework for genetic engineering, the Swiss Government submitted comprehensive draft legislation on genetic engineering to the Parliament in March 2000.[116] It was the goal of this draft to provide science and industry with a clear framework for the utilization of GMOs that ensures a high protection of human health and the environment, respect of the dignity of living beings, the protection and sustainable use of biodiversity, and factual and transparent information of the public.[117] Major focuses concern the concretization of the constitutional provision on the "dignity of living beings", the approval of GMOs for food and agriculture, labeling and certification requirements, liability rules, and access to information. The Government has pursued its decentralized approach[118] and instead of proposing a new, distinct Genetic Engineering Law, it recommended to address the issue comprehensively by amending and complementing the existing laws and regulations. While the Parliament has in principle maintained this approach, it nevertheless created a distinct Genetic Engineering Law which includes the major elements of the legislation on the utilization of GMOs, the protection of human health, animals and the environment, including the biological diversity, the respect of the dignity of living beings, the freedom of choice of the consumers, the prevention of deceptive practices, the information of the public, and strict liability rules.[119] Other issues are however regulated through amendments of specific existing laws such as the law on the protection of the environment, the law on the protection of animals, the law on food products, the law on agriculture, the law on the protection of nature and patrimony, the law on epidemics, and the criminal law.[120] The amendments of the existing laws and the new Gene Technology Law form together the "Gen-Lex". The Parliament adopted the whole legislation after three years of sometimes-fierce negotiations on March 21, 2003.[121]

The major contested issues during the parliamentary debate concerned the introduction of a moratorium on the use of GMOs in agriculture, the requirements for the approval for experimental field testing and for the use of GMOs in agriculture, the protection of GMO-free production from contamination with GMOs, the liability rules and the right of appeal of NGOs against the approval of GMOs intended for use in the environment. Interestingly, the labeling requirements were principally not disputed. The environmental groups requested the introduction of a 10-year moratorium on the use of GMOs in agriculture, arguing that such a moratorium would give the time necessary to improve the understanding of the impacts of GMOs on the ecosystems.[122] On the other side, the representatives of industry interests argued that once a moratorium is introduced it could prove impossible to remove it later.[123] The farmers tended to support the introduction of a moratorium – or even the prohibition of GMOs in

[115] Gen-Lex Motion (Motion WBK-NR (96.3363)), Ausserhumane Gentechnologie. Gesetzgebung), *reprinted in*: AB N 1996, p. 1561.
[116] *Gen-Lex-Botschaft*, supra note Error: Reference source not found.
[117] Id., at 2402.
[118] See supra note Error: Reference source not found. See also Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found at II.
[119] Bundesgesetz über die Gentechnik im Ausserhumanbereich vom 21. März 2003 (Gentechnigkesetz, GTG) SR 814.91 (Federal Law of 21 March 2003 on non-human gene technology (Gene Technology Law, GTG); *reprinted in*: BBl **2003** 2778 ff. [hereinafter: GTG]. An English translation of the text can be found on *http://www.umwelt-schweiz.ch/imperia/md/content/stobobio/biotech/17.pdf.*
[120] Errass, v*erwaltungsrechtlichen Aspekte*, II, supra note Error: Reference source not found.
[121] For a general overview, see <http://www.pd.admin.ch/afs/data/d/rb/d_rb-2000008.htm>. For a description of the sometimes-tense debate, see Roger Monnerat, *Die Demontage der Gen-Lex-Vorlage*, DIE WOCHENZEITUNG 41 / 10, 3, October 2002.
[122] *Fünf Jahre Moratorium*, in: DER BUND, 1. Juni 2002.
[123] *Moratorium – nein danke*, in: NEUE ZÜRCHER ZEITUNG, 9. April 2002.

agriculture – because they feared that if the use of GMO-crops would be permitted, the GMO-free production would become impossible. Finally, the Parliament narrowly rejected the introduction of a moratorium. Concerning the requirements for the approval for experimental field testing and for the use of GMOs in agriculture, environmental groups requested that approval should only be given if it is guaranteed that no crosspollination is possible. Industry and research argued that this requirement would in fact prohibit any use of GMOs and they wanted less restrictive prescriptions. Moreover there was disagreement whether GMOs that include antibiotic resistance marker genes should be prohibited and whether the field testing and the use of GMOs in agriculture must also respect the goals of biodiversity protection, other agricultural policy goal and ethical objectives. These issues were solved by permitting releases if, according to the state of knowledge, crosspollination leading to the spread of the genetic modification can be excluded; by prohibiting the use of antibiotic resistance marker genes in general while permitting antibiotic resistance marker genes for field testing until December 12, 2008; and by requiring that any use of GMOs must not negatively impair the biological diversity or the sustainable use thereof.[124] With regard to the protection of GMO-free production from contamination with GMOs, the farmers, environmentalists and consumers wanted an explicit guarantee of GMO-free production, including a guaranteed and documented separation of the distribution channels. Industry criticized this as too expensive, unpractical and unfeasible. The parliament finally adopted a solution according to which GMOs must be used in a way that does not impair the GMO-free production and the freedom of choice of the consumers and that distribution channels must generally be separated.[125] On the issue of liability, representatives of industry and the insurance sector wanted general liability rules under negligence for GMO food products and medicaments, while the environmentalists and consumers defended a proposal for a strict liability regime for all GMO-related questions. Industry prevailed on this issue.[126] Moreover, the representatives of the industry interests wanted the user of GMOs to be primarily liable, including the farmers. The farmers, supported by environmentalists and consumers, wanted a channeled liability of the producer or importer of GMOs. The farmers prevailed on that issue.[127] With regard to the right of appeal of NGOs, consumer organizations and environmentalists requested a right of appeal of consumer and environmental protection organizations against the approval of GMOs intended for use in the environment; the representatives of the *Swiss People's Party* were against all form of an NGO right of appeal. The Parliament finally decided that environmental NGOs of national relevance have a right of appeal if they were founded at least 10 years before the appeal.[128]

With the entry into force of the Gen-Lex that includes the new Gene Technology Law and several amendments to existing laws in specific sectors, Switzerland will have a modern, comprehensive legislation on genetic engineering. While this legislation seems to be balanced and to reflect the major concerns and priority of the Swiss population, the civil society has expressed its dissatisfaction on the decision not to prohibit the use of genetically modified crops in Switzerland. It has launched a new popular initiative requiring a constitutional amendment imposing a moratorium on the use of GMOs in agriculture.[129] The following paragraphs will therefore present the Swiss legislation as it stands after the adoption of the Gen-Lex.

[124] GTG, supra note Error: Reference source not found, Art. 6 and 37. See also infra, subchapter IV.3.4.3.
[125] GTG, supra note Error: Reference source not found, Art. 7 and 16. See also infra, subchapter IV.3.8
[126] GTG, supra note Error: Reference source not found, Art. 30.4. See also infra, subchapter IV.3.6.
[127] GTG, supra note Error: Reference source not found, Art. 30.2. See also infra, subchapter IV:3.6.
[128] GTG, supra note Error: Reference source not found, Art 28. See also infra, subchapter IV.3.7.2.
[129] BBl **2003** 6327ff; see also: *Anti-Genfood-Initiative ist bereit*, BERNER ZEITUNG, 1.3.2000.

IV.2 CONSTITUTIONAL PROVISION

According to Art. 120 paragraph 1 of the Swiss Constitution, people and their environment shall be protected[130] from abuses of gene technology.[131] To realize this objective, Paragraph 2 of Art. 120 Swiss Constitution gives the federal legislator the mandate to adopt legislation on the use of the reproductive and genetic material of animals, plants and other organisms.[132] Thereby, the dignity of living beings and the safety of people, animal and environment shall be taken into account, and the genetic diversity of animal and plant species shall be protected.[133]

Taking into account the dignity of living beings:[134] The dignity of living beings relates to the inherent value accorded to living organisms[135]. These organisms have an inherent value because they possess their own worth, pursue individual goals and represent organic units.[136] This value prohibits that these living organisms are viewed solely as means to an end. Respecting the dignity of living beings thus means that the handling of animals and plants must ensure that they can exercise the functions and abilities that beings of their species generally exercise (in particular growth, reproduction, movement and social abilities).[137] However, this inherent value is not an absolute value: the inherent value of the living organism must be balanced with other potentially relevant values.[138]

Safety of people, animals and the environment:[139] The term "safety" is to a certain extent complementary to the term "risk".[140] Safety exists where there is no risk. Since no technology is absolutely risk-free, it cannot be absolutely safe either.[141] Technologies that are considered involving an acceptable and justifiable risk are therefore considered as safe. The legislator implements the requirement to take into account the safety of people, animals and the environment through the, i.a., adoption of a step-by-step approach: first, research should be carried out in a contained system, then, if necessary, field trials should be carried out, only then marketing can take place.

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[130] On the protection targets, see RAINER J. SCHWEIZER, in: DIE SCHWEIZERISCHE BUNDESVERFASSUNG, KOMMENTAR (ST. GALLER KOMMENTAR) (Bernhard Ehrenzeller, *et al.* eds., 2002), Rz. 7 ff. to Art. 120 [hereinafter: ST. GALLER KOMMENTAR]; Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at IV.2.

[131] On the definition of gene technology, see SCHWEIZER, ST. GALLER KOMMENTAR, supra note Error: Reference source not found, Rz. 5 to Art. 120; RAINER J. SCHWEIZER, in: KOMMENTAR ZUR BUNDESVERFASSUNG DER SCHWEIZERISCHEN EIDGENOSSENSCHAFT VOM 29. MAI 1874 (J.-F. Aubert, *et al.* eds. 1987) Rz. 12 to Art. 24^{novies} para 1 [hereinafter: KOMMENTAR aBV]; Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at I.

[132] Art. 120 BV is not the only constitutional provision that rules on protection from gene technology. For example, Art. 74 BV (Protection of the Environment) and Art. 118 (Protection of Health) also implicitly rule on protecting the environment and human health, respectively, from gene technology.

[133] Art. 120.II BV, supra note Error: Reference source not found. The three concrete legislative tasks mentioned in the constitution are to be seen as explanatory rather than exhaustive.

[134] Sometimes, the term „dignity of living beings" has also be translated by „dignity of creation" (see e.g. Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 591-594). See generally: Errass, *Recht und Ethik*, supra note Error: Reference source not found, at 327-335; SALADIN and SCHWEIZER, KOMMENTAR aBV, supra note Error: Reference source not found, Rz. 113 ff. to Art. 24^{novies} para. 3.

[135] Which living organisms this refers to is disputed in the literature. On the various interpretations of this, see the references in infra note Error: Reference source not found.

[136] Philipp Balzer, Klaus Peter Rippe and Peter Schaber, *Menschenwürde vs. Würde der Kreatur. Begriffsbestimmung, Gentechnik, Ethikkommissionen*, 50 and 43 (1998); *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2405.

[137] See *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2405; Balzer, Rippe and Schaber, supra note Error: Reference source not found, at 57, 60.

[138] See *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2405; Balzer, Rippe and Schaber, supra note Error: Reference source not found, at 50.

[139] See also SCHWEIZER, ST. GALLER KOMMENTAR, supra note Error: Reference source not found, Rz. 14 ff. to Art. 120 with further references.

[140] See CHRISTOPH ERRASS, KATASTROPHENSCHUTZ: MATERIELLE VORGABEN VON ART. 10 PARA 1 UND 4 USG, 45 (1998) [hereinafter: KATASTROPHENSCHUTZ]; HANSJÖRG SEILER, RECHT UND TECHNISCHE RISIKEN. GRUNDZÜGE DES TECHNISCHEN SICHERHEITSRECHTS, 46 (1997); SALADIN and SCHWEIZER, KOMMENTAR aBV, supra note Error: Reference source not found, Rz. 122 to Art. 24^{novies}; DIETRICH MURSWIEK, DIE STAATLICHE VERANTWORTUNG FÜR DIE RISIKEN DER TECHNIK. VERFASSUNGSRECHTLICHE GRUNDLAGEN UND IMMISSIONSSCHUTZRECHTLICHE AUSFORMUNG, 86 ff (1985).

[141] See ERRASS, KATASTROPHENSCHUTZ, supra note Error: Reference source not found, at 46; MURSWIEK 1985, supra note Error: Reference source not found, at 86.

Protection of the genetic diversity of animal and plant species: The object of protection is genetic diversity, which means the variability of the genome that enables living organisms to adapt to changes in their environment through new genetic combinations,[142] including subspecies and varieties. This involves the conservation of genetic diversity, which is already protected under various constitutional and international provisions.[143]

IV.3 GENE TECHNOLOGY LAW

The Parliament had the impression that the existing Swiss law on non-human gene technology was not entirely clear and that there were repetitions and overlaps. It therefore decided, based on a proposal by the experts, to adopt a coherent gene technology law for the non-human sector, which would cover the main rules for all relevant areas, including therapeutic products, animal experiments and agriculture.[144] This law, the Gene Technology Law (GTG) was adopted on 21 March 2003.[145] This new law cannot neglect its origin or history: it remains in essence an environmental protection law, which has been enriched by general regulations on labelling, regulations on product flow segregation, and a right of access to information. The Gene Technology Law is a cross-sectorial legislation, and thus concurs with the other sectorial legislation.[146]

IV.3.1 General Principles

In order to implement the constitutional requirements that people and their environment shall be protected from abuses of gene technology, that the dignity of living beings shall be respected, and the safety of humans, animals, the environment and the genetic diversity of animal and plant species shall be protected, the GTG has enacted the following general principles: GMOs have to by handled in a way that does neither endanger[147] humans, animals or the environment nor impair biological diversity or the sustainable use thereof.[148] Moreover, the handling of GMOs must neither impair the production of GMO-free products nor the consumer's freedom of choice.[149] And, the modification of genetic material may not lead to a disrespect of the dignity of living beings.[150]

IV.3.2 Respect for the dignity of living beings (Art. 8 GTG)

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[142] See Message of 25 May 1994 on the United Nations Convention on Biological Diversity (Biodiversity Message), in: BBl **1994** III 182 ff., 185, and Art. 3 of the Convention (SR 0.451.43). See also Saladin and Schweizer, KOMMENTAR aBV, supra note Error: Reference source not found, Rz. 109 to Art. 24^{novies}; WISSENSCHAFTLICHER BEIRAT DER BUNDESREGIERUNG. GLOBALE UMWELTVERÄNDERUNGEN (2000), Welt im Wandel. Erhaltung und nachhaltige Nutzung der Biosphäre. Jahresgutachten 1999, p. 35 ff., 461, 463.

[143] See SALADIN and SCHWEIZER, KOMMENTAR aBV, supra note Error: Reference source not found, Rz. 125 ff., 133 to Art. 24^{novies}.

[144] For the Council of States, see Bericht WBK-S of 30 April 2001 (Bericht WBK-S), in: AB S 2001, Beilagen Sommersession, 22 ff., 23. For the National Council, see the German-speaking Rapporteur, HEINER STUDER, AB N 2002, 1522, and the French-speaking Rapporteur, CHIARA SIMONESCHI, AB N 2002, 1524. See on this also supra, text supra, supchapter IV.1, text accompanying note Error: Reference source not found, and subchapter IV.1.3, text accompanying notes Error: Reference source not found-Error: Reference source not found.

[145] See supra note Error: Reference source not found.

[146] e.g. Law on Foodstuffs, Law on Therapeutic Products, Law on Agriculture. See generally Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at II.

[147] The term *endanger* describes a situation that, left alone, would in all probability lead to a protected asset being damaged. *Endanger* thus includes the components of *damage to the protected asset* and the *probability* that such damage will occur. See generally: ERRASS, KATASTROPHENSCHUTZ, supra note Error: Reference source not found, at 30 with further references; Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at IV.2.a.

[148] Art. 6.I GTG, supra note Error: Reference source not found.

[149] Art. 7 GTG, supra note Error: Reference source not found. See also infra, subchapter IV.3.7.1.

[150] Art. 8 and 9GTG, supra note Error: Reference source not found.

In order to protect humans and the environment from abuses of gene technology, Art. 120 of the Swiss Constitution requires the adoption of federal legislation on the handling of the genetic material of animals, plants and other organisms. Thereby, the dignity of living beings has to be taken into account. Art. 8 GTG is a first implementation of this constitutional mandate. According to Art. 8 GTG, the genetic modification of genetic material of animals and plants has to respect the dignity of living beings. Thus, while the constitutional Article refers to the dignity of *living beings*,[151] Art. 8 GTG limits this broad concept to *animals and plants*. By indicating that the dignity of living beings shall be respected only with regard to animals and plants and by excluding other organisms, the legislator has undertaken a first concretization of the constitutional provision.[152] The term "*animals and plants*" is meant as including the totality of naturally occurring flora and fauna. It is irrelevant whether these are wild animals or plants, farm animals, pets, or plants cultivated on farms or in gardens. The dignity of living beings may not be injured *through modification of the genetic material* of animals and plants.[153] Thereby, the "modification of genetic material" is an alteration of the genetic material of animals or plants in a way that does not occur under natural conditions by crossbreeding or natural recombination.[154]

The term "*dignity* of living beings" implies the presence of an inherent value in all non-human organisms. This includes the value of an independent existence of any organism in its species-typical functions, and it forbids the destruction of this function or the functionalization of an organism solely as a means to an end.[155] Thus, animals and plants are accorded their own value and they have significance in themselves, and the dignity of animals and plants should be protected for their own sake, particularly in their species-typical characteristics and behaviors.[156] Furthermore, with regard to organisms capable of feelings and sensations, account should be taken of their subjective welfare.[157]

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[151] Sometimes, the term „dignity of living beings" has also be translated by „dignity of creation" (see e.g. Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 591). On the various interpretations, see generally: Errass, *Recht und Ethik*, supra note Error: Reference source not found, at 332ff., with further references; Errass, *verwaltungsrechtlichen Aspekte*, supra note Error: Reference source not found, at III; Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, 592-593; a brief overview is given by CORINNE SCHAERER, *Die Würde der Kreatur. Eine Gegenüberstellung der Gen-Lex-Vorlage des Bundesrats und des Gentechnikgesetzes des Ständerats*, in: ASPEKTE DER GENTECHNOLOGIE IM AUSSERHUMANBEREICH (Bernhard Schmithüsen and Jörg Zachariae eds., 2002), 121ff.

[152] See PETER BIERI (Rapporteur of the Council of States), AB S 2001, p. 314 f.; *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2405; SALADIN and SCHWEIZER, KOMMENTAR aBV, supra note Error: Reference source not found, Rz. 114 to Art. 24^{novies}.

[153] The Federal Council has regulated the failure to respect the dignity of living beings with regard to genetic engineering, but also generally in Art. 29a draft USG according to which organisms may be handled only in such a way that does not fail to respect the dignity of animals and plants (*Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2435). This confirms the opinion of SALADIN and SCHWEIZER (KOMMENTAR aBV, supra note Error: Reference source not found, Rz. 119 to Art. 24^{novies}), according to which the respect of the dignity of living beings should be a general constitutional principle. According to this, dignity of living beings may be violated not only by genetic modification, but also by other actions (e.g. through the act of marketing itself).

[154] See the legal definition in Art. 5.II GTG, supra note Error: Reference source not found. See also Appendix 1 of the Release Ordinance of 25 August 1999 (SR 814.911) [hereinafter: RO].

[155] *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2405; Report of 30 August 2000 on the result of the EFTA and WTO Notification of the draft of 1 March 2000 regarding amendments to the Federal Law on the Protection of the Environment (EFTA Report/WTO Notification), in: BBl 2000 5029 ff, p. 5032 [hereinafter: EFTA Report/WHO Notification]; see also BALZER, RIPPE and SCHABER, supra note Error: Reference source not found, p. 41 ff., 47 ff.; INA PRAETORIUS and PETER SALADIN, *Die Würde der Kreatur* (Art. 24^{novies} para 3 BV), published by the Swiss Agency for the Environment, Forests and Landscape (SAEFL), Bern, 87 (1996).

[156] See BIERI, supra note Error: Reference source not found, at 315 f; MAYA GRAF, AB N 2002, 1558; PIA HOLLENSTEIN, AB N 2002, 1559; FELIX GUTZWILER, AB N 2002, 1559; KATHY RIKLIN, AB N 2002, 1560; HEINER STUDER, AB N 2002, 1561; *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2405 and 2434; Report of 30 August 2000 on the result of the EFTA and WTO Notification of the draft of 1 March 2000 regarding amendments to the Federal Law on the Protection of the Environment (EFTA Report/WTO Notification), in: BBl **2000**, 5029, 5032. See also PRAETORIUS and SALADIN, supra note Error: Reference source not found; SALADIN and SCHWEIZER, KOMMENTAR aBV, supra note Error: Reference source not found, Rz. 116 to Art. 24^{novies}; PHILIPPE MASTRONARDI, in: ST. GALLER KOMMENTAR, supra note Error: Reference source not found, Rz. 11 to Art. 7; SCHWEIZER, ST. GALLER KOMMENTAR, supra note Error: Reference source not found, Rz. 13 to Art. 120.

[157] See BIERI, supra note Error: Reference source not found, at 315; *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2405. On the question of whether dignity is a fundamental value, see ANTOINE F. GOETSCHEL (1995) in the introduction to GOTTHARD M. TEUTSCH (1995), Die "Würde der Kreatur". Erläuterungen zu einem neuen Verfassungsbegriff am Beispiel des Tieres, Bern/Stuttgart/Vienna, p. IX.

The dignity of living beings is *injured* if species-typical characteristics, functions or behaviours are substantially impaired through modification of the genetic material, and if this cannot be justified by overwhelming legitimate interests. In order to make a modification of the genetic material of animals and plants legal, i.e. to show that the dignity of living beings is respected, the legislator requires a balance of the value of the organism on the one hand against the human interests on the other hand.[158] The terms "*species-typical characteristics, functions or behaviours*" describe those characteristics, functions or activities that animals and plants generally pursue. In particular, this includes growth, reproduction, locomotion and social abilities.[159] Thus, the issue of lack of respect for the dignity of living beings has to be judged on a case-by-case basis, balancing the severity of the impairment to animals and plants against the significance of legitimate human interests.[160] Thereby, the law mentions explicitly the following legitimate interests: human and animal health; the securing of sufficient food; the reduction of ecological impairment; the conservation and improvement of ecological living conditions; a substantial economic, social or ecological benefit to society; the increase of knowledge. Finally, according to Art. 9 GTG, the producing of vertebrates for purposes other than research, therapy and diagnostics on/for humans and animals is always held to be a violation of their dignity. Thus, both the production and the import of such vertebrates are banned. For the purposes of research, therapy and diagnostics on/for humans and animals, each case of production of a vertebrate still requires a balance of interests according to Art. 8 GTG.

IV.3.3 Ethics Committee

In the light of the novelty of the ethical questions raised by gene technology, the Gen-Lex Motion had required the establishment of an ethics committee that undertakes the ethical discussion necessary to make sure that the substantive law fully reflects the underlying ethical values.[161] Through this, the substantive law is subjected to a moral critique, and the discussion on ethics ensures that other values than pure positivism will be taken into consideration.[162]

On 27 April 1998, the Federal Council appointed the Federal Ethics Committee for Non-human Gene Technology (ECNH).[163] Art. 23 GTG now institutionalizes the ECNH by law. The ECNH's task is to follow and to evaluate the developments in and the applications of biotechnology, and to comment on relevant scientific and social issues from an ethical perspective.[164] Especially, it has to counsel the federal government before the enactment of regulations, to advise the federal and cantonal authorities in the implementation of the relevant regulations, and to comment on applications for the authorization to use GMOs and on new research proposals of fundamental or exemplary importance.[165] Thereby, the authorities have to take into account the

[158] See BIERI, supra note Error: Reference source not found, at 315; Bericht WBK-S, see supra note Error: Reference source not found, at 24; *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2405; BALZER, RIPPE and SCHABER, supra note Error: Reference source not found, at 48 ff., 57 f.; Errass, *verwaltungsrechtliche Aspekte*, supra noteError: Reference source not found, at III.2. SCHAERER, supra note Error: Reference source not found, at 138 ff.; SALADIN and SCHWEIZER, KOMMENTAR aBV, supra note Error: Reference source not found, Rz. 116 fn. 380 to Art. 24^{novies}.

[159] See *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2405; BALZER, RIPPE and SCHABER, supra note Error: Reference source not found, p. 57.

[160] Art. 8.II GTG, supra note Error: Reference source not found.

[161] Gen-Lex Motion, supra note Error: Reference source not found, section 2.8.

[162] On this, see Errass, *Recht und Ethik,* supra note Error: Reference source not found, at 339 ff.

[163] On the ECNH, see generally: Klaus Peter Rippe, *Ethikkommissionen als Expertengremien? Das Beispiel der Eidgenössischen Ethikkommission*, in: ANGEWANDTE ETHIK IN DER PLURALISTISCHEN GESELLSCHAFT 109 (Klaus Peter Rippe, ed., 1999); Ariane Willemsen, *Ethics Committees and their role in the public debate*, in: FOOD SAFETY, FOOD QUALITY AND FOOD ETHICS, 407 (Third Congress of the European Society for Agricultural and Food Ethics, Mathias Pasquali, ed., 2001).

[164] On the ECNH's task to pursue a dialogue with the public on ethical issues of biotechnology (Art. 23 para. 5 GTG, supra note Error: Reference source not found), see generally Willemsen, supra note Error: Reference source not found.

[165] GTG, supra note Error: Reference source not found, Art. 23.III.

comments of the ECNH.[166] Thus, the Ethics Committee does not fulfill a regulatory but an advisory function.

IV.3.4 Authorization

IV.3.4.1 General Remarks

The Gene Technology Law regulates three types of handling[167] of GMOs as subject to authorisation: the contained use, the release for experimental purposes, and the marketing. Once a GMO has been authorized for marketing, no additional authorization is necessary for its use.[168] However, the Federal Council may establish additional authorization requirements for the handling of GMOs if their properties, the methods of their use or the quantities used could lead to a violation of the general principles of Articles 6–9 GTG requiring GMOs to be used and handled only in a manner that does not endanger humans, animals or the environment nor impair the biological diversity or the sustainable use thereof, that does not prevent the production of GMO-free products nor limit the freedom of choice of consumers, and that respects the dignity of living beings.[169]

The Gene Technology Law follows the approach taken by the Environmental Protection Law that has classified the different authorizations according to the intensity of environmental impact of the authorized activity.[170] Thereby, a *step-by-step approach*[171] is taken which assumes that GMOs are used first in a contained system, then in experimental field tests and finally marketed, each step has to be concluded successfully before entering the next one. Moreover, while each step builds on the previous one, the safety requirements become higher with each step.[172]

IV.3.4.2 Contained Use

The work with GMOs begins in a contained system. Any person who handles GMOs in a contained system is required to take all containment measures necessary in the light of the danger posed by these organisms to humans, animals or the environment.[173] Namely, it must be ensured that the contained system is equipped with safety measures according to the level of danger of the activity and of the GMOs used, so that humans, animals, and the environment cannot be endangered nor the biological diversity or its sustainable use impaired.[174] The

[166] However, the comments of the ECNH can only influence a concrete decision of an authority if the relevant regulation is open to legal-ethical considerations. See generally: Errass, *Recht und Ethik*, supra note Error: Reference source not found, at 343 with further refrences; DIETMAR V.D. PFORDTEN, RECHTSETHIK, 95 (2001).
[167] The term "handling" is defined as any activity undertaken in connection with organisms, in particular their production, experimental release, bringing into circulation, import, export, keeping, use, storage, transport or disposal, see GTG, supra note Error: Reference source not found, Art. 5.IV.
[168] Thus, the Swiss legislation does not use the term "commercial release", but only the term "marketing". Once a product is authorised for marketing, it may also be released in to the environment.
[169] GTG, supra note Error: Reference source not found, Art. 19.II.b).
[170] See Art. 29f), 29e) and 29c) of the old USG, Federal Law on the Protection of the Environment (Bundesgesetz über die Umweltschutz, 7 Octobre 1983, SR 814.01)[hereinafter USG], resp. Art. 29b)-29d) of the USG as amended by the GTG, supra note Error: Reference source not found.
[171] This step-by-step approach was influenced by recital 11 of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, *reprinted in*: ABl. L 117, May 5, 1990, 15ff.. It is also reflected by recital 24 of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, *reprinted in*: ABl. L 106, April 17, 2001, 1ff.
[172] See Chiara Simoneschi (French-speaking Rapporteur of the National Council), AB N 2002, 1552 ff (2002); Simonetta Sommaruga, AB N 2002, 1550 (2002); Maya Graf, AB N 2002, 1550 ff. (2002).
[173] Art. 10.I GTG, supra note Error: Reference source not found.
[174] The overarching goal that the protection of humans, animals, the environment and biological diversity must be ensured is established by Art. 6.I GTG, supra note Error: Reference source not found; Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at IV.2.a and IV.3.a.

Federal Council will introduce a notification or authorization procedure for activities in contained systems.[175] According to the present notification and authorization procedure for contained use, anyone using GMOs must notify each first activity involving a risk of class 1 or class 2 and obtain an authorisation for each – not only the first – class 3 or 4 activity.[176] During the notification and authorization procedures, not the constructional or technical safety measures will be examined, but solely the issue of whether the activity in question has been assigned to the correct risk class, whether the risk assessment for this activity has been carried out properly, and whether the prescribed containment measures are planned in the light of the assessed risks.[177] In addition, a person using GMOs in contained systems must ensure the protection of the production without GMOs and of the freedom of choice of consumers, the respect of the dignity of living beings, and that genetically modified vertebrates are only produced for purposes of research, therapy and diagnostics on/for humans and animals.[178]

IV.3.4.3 Release for experimental purposes

IV.3.4.3.a The Swiss regulation of experimental releases

Field trials – i.e. the release of GMOs for experimental purposes[179] – require a federal authorization.[180] Thereby, it must be ensured that there is no danger for humans, animals or the environment and no impairment of the biological diversity or its sustainable use, that the desired findings cannot be obtained by means of experiments in contained systems, that the experiment contributes to research on the biosafety of GMOs, that the organisms do not contain genes that are resistant to antibiotics used in human and veterinary medicine, and that the dispersal of these organisms and their new properties can be excluded according to the current state of knowledge.[181] And, like the contained use, field trials must also observe the principles that the production without GMOs and the freedom of choice of consumers are protected, that the dignity of living beings is respected, and that genetically modified vertebrates may only be produced for purposes of research, therapy and diagnostics on/for humans and animals.[182]

IV.3.4.3.b. Cases of Experimental Release[183]

[175] Art. 10.II GTG, supra note Error: Reference source not found.
[176] Art. 9 para. 2 of the Containment Ordinance of 25 August 1999 (CO, SR 814.912)). Classification of activities is carried out according to Art. 7 CO
[177] See Art. 8 (Risk assessment), Art. 10 (Safety measures) and Appendix 4 CO, supra note Error: Reference source not found. See also Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at IV.3.1. See also Gottlieb Witzig, *Aufgabenteilung und Zusammenarbeit Bund – Kantone beim Vollzug der Einschliessungs- und der Freisetzungsverordnung*, in: URP 17, 22-23 (2000).
[178] Art. 7-9 GTG, supra note Error: Reference source not found. Concerning the protection of the GMO-free production, see infra, subchapter IV.3.8. Moreover, according to Art. 34 GTG, a person subject to notification or authorization may also be required to provide a guarantee for his or her liability.
[179] A field trial of genetically modified organisms is an experimental release of such organisms into the environment. See generally HANSJÖRG SEILER, Kommentar USG, supra note Error: Reference source not found, Rz. 17 to Art. 29e. A field trial differs from *contained use* in so far as an activity in a contained system does not take place in the environment but in a contained systems that must be designed to ensure that an escape of the organisms into the environment can be excluded. A field trial differs from *marketing* by its spatial and temporal limits. See on this: Simonetta Sommaruga, AB N 2002, 1550 (2002).
[180] Art. 11 GTG, supra note Error: Reference source not found. For more detail, see generally Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at IV.3.b; see supra subchapter IV.3.4.1.
[181] Art. 6.I and 6II.a)-d) GTG, supra note Error: Reference source not found.
[182] See supra note Error: Reference source not found.
[183] The decisions considered here are still based on Art. 29a ff. USG, supra note Error: Reference source not found, which will be replaced at the end of 2003 by the Gene Technology Law. But the substantive provisions in the Environmental Protection and Gene Technology Laws are basically identical, and these decisions are therefore still meaningful under the new law. By including a transitional period permitting, until 31 December 2008, the use in field trials of genes conferring resistance to antibiotics used in human and veterinary medicine (Art. 37), however, they become somewhat less meaningful.

The Swiss Agency for the Environment, Forests and Landscape (SAEFL) is the responsible authority for the authorization of field trials with GMOs.[184] The authorization is granted only if the evaluation of the application, in particular the risk assessment, shows that according to the current state of knowledge and experience, a release poses no danger to people or the environment, and if other federal agencies approve the application according to their competencies.[185] To date, SAEFL has turned down two applications for experimental release and granted one authorization that is still pending.

In the first case,[186] Plüss-Stauffer AG, Oftringen, applied for the permission to carry out an experimental release of genetically modified maize T25. The objective of this field trial was to test the biological effectiveness of the herbicide gluphosinate and its selectivity towards genetically modified maize plants. On 16 April 1999, SAEFL rejected the application because it could not be excluded that pollen flight might have lead to the unauthorised growth of genetically modified maize on neighbouring lands belonging to third parties. Moreover, the maize T25 contained an antibiotic resistance marker gene which, given the low level of knowledge about the composition of and the interactions in the existing highly complex soil microflora, was considered to be representing an unnecessary risk.

In the second case,[187] the Swiss Federal Research Station for Plant Production in Changins applied for the permission for an experimental release of transgenic potatoes. The objective of this field trial was to test the resistance of the transgenic potatoes to mildew. On 16 April 1999, SAEFL rejected the application because the material inserted into the potatoes contained marker genes that were resistant against antibiotics used in medicine. Since antibiotics are an extremely valuable instrument in the fight against disease, the use of marker genes resistant to medically used antibiotics – held as unnecessary in this case – was not approved. Moreover, the proposed field testing was criticized because knowledge and characterisation of the genetic construct undertaken were inadequate to enable an evaluation of the consequences of the experimental release. The appeal against this decision was rejected because of lack of standing of the Federal Research Station.

In the third case, the Federal Institute of Technology Zurich (ETH) applied for permission for an experimental release of transgenic KP4 wheat varieties. The genetic modification included a KP4 gene of viral origin that was coded for an antifungal protein, a Bar gene from Streptomyces hygroscopicus that gives resistance to the herbicide (marker gene), and a prokaryotic Bla gene that produces bacterial resistance to the antibiotic ampicillin. The objective of this experiment was to test the resistance against fungal infestation (wheat bunt) and to analyse interactions with other organisms. On 20 November 2001 SAEFL rejected the application,[188] because (1) given the insufficient knowledge of the used organism and the insufficient clarification of its interactions with the environment, the risk assessment undertaken by the application did not permit adequate statements about environmental hazard; (2) the ampicillin resistance gene used as a marker was unnecessary, and that in the light of the uncertainty resulting from the inadequate understanding of the cumulative effects and long-term processes in the environment and the high complexity of the soil microflora, the precautionary principle dictates that unnecessary risks should be avoided; and (3) the safety measures against the possibility of pollen flight were inadequate, and the risk assessment did not show that the experimental release could not endanger people and the environment. The Federal Department of the Environment, Transport, Energy and Communication (DETEC)

[184] Art. 7 RO, supra note Error: Reference source not found.
[185] Art. 19 RO, supra note Error: Reference source not found.
[186] See the decision in URP 1999, p. 746 ff. = BBl 1999 3039 ff.
[187] See a summary in URP 1999, p. 752 f.; in detail in BBl **1999** 2778 ff.
[188] See the SAEFL decree of 20 November 2001, in: BBl **2001** 6294 ff.

upheld an appeal against this decision on 12 September 2002, and instructed SAEFL to approve the application. DETEC justified its decision primarily on the grounds that while there must be convincing reasons to allow deviation from the Statement of the Swiss Expert Committee for Biosafety (EFBS), that had considered the planned experimental release to be safe and permissible, the SAEFL had deviated from the EFBS Statement without convincing reason, that the SAEFL was setting disproportionate safety requirements; and that the use of antibiotic resistance genes did not represent an environmental hazard. As a consequence, the SAEFL approved the application on 20 December 2002.[189] However, this decision was appealed by neighbours of the field where the field test as planned. While administrative appeals have normally a suspensory effect,[190] the DETEC withdrew the suspensory effect from this appeal. The Federal Supreme Court then reinstated the suspensory effect upon appeal, arguing that the DETEC had injured the right of the neighbours to a hearing.[191] The DETEC then upheld the neighbours' appeal. In October 2003, after initiating a new application procedure, this time involving all potentially interested parties, the SAEFL has granted the authorization to conduct the field trial while imposing strict additional safety requirements[192]. In the meantime, the authorization has been appealed.

IV.3.4.4 Marketing

The final step, the marketing,[193] can only take place once the field trials have been concluded successfully. However, no field trials are necessary for therapeutic products, foodstuffs and animal feed. The marketing of GMOs requires a federal authorization.[194] GMOs may only be marketed if human and animal health, environment are not endangered and biodiversity and its sustainable use are not impaired[195]. Moreover, GMOs that have been authorized for marketing can be released into the environment only if they were authorized for that use.[196] GMOS intended for the use in the environment may only be marketed if they do not contain resistance genes to antibiotics used in human or veterinary medicine[197] and if experiments in contained systems or field trials have shown that they do not impair the population of protected organisms or organisms that are important for the ecosystem in question,[198] if they do not lead to the unintended extinction of a species of organisms,[199] do not severely or permanently impair the balance of the environment or any important ecosystem function such as the fertility of the soil,[200] do not disperse or spread their traits in an undesired way,[201] and that they do not

[189] See the SAEFL decree of 20 December 2002, in: BBl **2003** 74 ff.
[190] Art. 55.I of the Federal Law of 20 December 1968 on Administrative Procedure (VwVG; SR 172.021).
[191] BGE 129 II 286.
[192] See Christoph Errass, *Das Gentechnikgesetz vom 21 März 2003 im Überblick* (forthcoming 2004, on file with the author) [hereinafter: *Gentechnikgesetz*].
[193] The term "marketing" is defined as any transfer of organisms to third parties in Switzerland, see GTG, supra note Error: Reference source not found, Art. 5.V. See generally: Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at IV.4; supra subchapter IV.3.4.1.
[194] Art. 12 GTG supra note Error: Reference source not found. The authorisation of marketing is a police licence, if there are no reasons for refusal under criminal or environmental law, there is a right to receive the police licence. See Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at IV.4.b, with further references.
[195] Art 6.I GTG, see supran note Error: Reference source not found.
[196] Thus, a GMO that was authorized for marketing as feed can not be used as seed.
[197] Art 6.III GTG, see supran note Error: Reference source not found.
[198] Art 6.III(a) GTG, see supran note Error: Reference source not found. Populations are the totality of animals of a particular species in a particular area able to ensure its own continuity; they are the elementary living units of ecological processes (see ERRASS, KATASTROPHENSCHUTZ, supra note Error: Reference source not found, p. 160 with further notes; JÖRG LEIMBACHER and PETER SALADIN, Katastrophenschutz: Schutz vor Schädigungen oder Schutz vor Risiken? Elemente zum Verständnis von Art. 10 USG, published by SAEFL, Bern, 31 f. (1990)).
[199] Art 6.III(b) GTG, see supran note Error: Reference source not found.
[200] Art 6.III(c) and (d) GTG, see supran note Error: Reference source not found. Concerning the important functions of ecosystems, see generally SALADIN and SCHWEIZER, KOMMENTAR aBV, supra note Error: Reference source not found, Rz. 123 f. to Art. 24^{novies}; ANDRÉ SCHRADE and THEO LORETAN, Kommentar USG, supra note Error: Reference source not found, Rz. 22 to Art. 14; PIERRE TSCHANNEN, Kommentar USG, supra note Error: Reference source not found, Rz. 15 to Art. 1).
[201] Art 6.III(e) GTG, see supran note Error: Reference source not found.

otherwise endanger humans, animals or the environment or impair the biological diversity or its sustainable use.[202] Finally, GMOs may also be marketed only if this does not impair GMO-free production nor the consumers' freedom of choice,[203] and if their production has respected the dignity of living beings.[204]

IV.3.5 Labeling

The Gene Technology Law harmonizes the various different existing sectorial labeling provisions and thereby realizes at least with regard to labeling a horizontal approach.[205] According to this harmonized regulation, any person marketing approved GMOs or products containing approved GMOs must label them as "genetically modified", in order to ensure the freedom of choice of the consumer and to prevent fraud.[206] Products containing non-approved GMOs must not be marketed[207]. Because unintentional contamination with GMOs cannot be excluded, the legislator has given the Federal Council the competence to define a threshold below which labeling is not required if the contamination is unintentional, i.e. if the persons required to label can prove that they have monitored and recorded the product flows carefully and undertaken everything to avoid contamination.[208] According to present law, foodstuff does not have to be labeled if any of its ingredients does not contain more than 0.9 of GMOs.[209] Moreover, a 0,5% threshold has been established for seeds, a 1% threshold for fertilizers and pesticides, and a 0.9% threshold for feed.[210] While the Federal Council is competent to regulate also the labeling of products obtained from GMOs, such products do not have to be labeled so far if no traces of the GMO remain.[211] Finally, the Federal Council has also to regulate the voluntary labeling of products that have been produced without GMOs. According to the present law, food products may be labeled as "produced without genetic engineering" if no GMOs were used during the production and processing of the food or its ingredients, if none of its ingredients contain more than 1% GMO, and if a similar product containing GMOs has been approved for the Swiss market.[212] The Ethics Committee for Non-Human Gene Technology (ECNH) has criticized the present threshold regulation because it veils that products may contain GMOs despite the fact that they are not labeled as such or even labeled as produced without GMOs; the ECNH therefore argues that the threshold should be set the lowest level technical feasible.[213]

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[202] Art. 6.III.f) GTG, supra note Error: Reference source not found.
[203] Art. 7 GTG, supra note Error: Reference source not found. On this, see infra, subchapter IV.3.7.
[204] Art. 8 GTG, supra note Error: Reference source not found.
[205] See: Bericht WBK-S, supra note Error: Reference source not found, at 22, 23, 24 (Ziff. 4). Concerning horizontal versus vertical approach, see supra, note Error: Reference source not found and accompanying text.
[206] Art. 17.I, supra note Error: Reference source not found.
[207] Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at IV.4.b.
[208] Art. 17.II and 17.III GTG, supra note Error: Reference source not found. See also Ruth Genner, AB N 2002, 1567; Liliane Chappuis, AB N 2002, 1567; Chiara Simoneschi, AB N 2002, 1567 f.; Federal councillor Moritz Leuenberger, AB N 2002, 1568.
[209] Art. 22b.VII of the LMV, supra note Error: Reference source not found. Lebensmittelverordnung (Ordinance on Foodstuffs of 1 March 1995, SR 817.02), Article 22b.7. See also: Daniel Wüger, *Am Ziel vorbei oder sinnvoller Kompromiss?*, JUSLETTER 11. April 2005, at RZ 27 (indicating that the 0,9 % threshold was introduced in harmonization with the relevant EU law); Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 597-98; STEFAN KOHLER and ALESSANDRO MARANTA, *Regulation von gentechnisch veränderten Lebensmitteln: Die revidierte schweizerische Lösung im internationalen Kontext*, AJP 1402 (1999).
[210] Art. 17.IV.bis of the Ordinance on Seeds of 7 December 1998 (SR 916.151), Art. 25 of the Ordinance on Plant Protection Agents of 23 June 1999 (PSMV; SR 916.~~151~~161), Art. 25 of the Ordinance on Fertilisers of 10 January 2001 (DüV; SR 916.171) and Art. 23 of the Ordinance on Animal Feed of 26 May 1999; (FMV; SR 916.307).
[211] Art. 17.IV GTG, supra note Error: Reference source not found and Art. 22b.VII LMV, supra note Error: Reference source not found. However, the materials from the parliamentary debate indicate that the Federal Council does not merely have the authority but the obligation to adopt regulation on the labeling of products obtained from GMOs. See Errass, *Gentechnikgesetz*, supra note Error: Reference source not found.
[212] Art. 22.b(VIII) LMV, supra note Error: Reference source not found. See also: Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 597-98.
[213] ECNH, ARIANE WILLEMSEN *et al*., GENTECHNIK FÜRS ESSEN: ETHISCHE ÜBERLEGUNGEN ZUM INVERKEHRBRINGEN VON GENTECHNISCH VERÄNDERTEN LEBENS- UND FUTTERMITTELN, 7. (2003).

IV.3.6 Liability

Before the adoption of the Gen-Lex, Switzerland did not possess a distinct liability regime for GMOs:[214] While strict liability applied to the use of GMOs in agriculture, in industry and research, the general product liability rules requiring products in a defective condition did apply to damages caused by GMOs in food products.[215] This liability regime was perceived as not sufficiently clear and inadequate:[216] it was not entirely clear which activities were falling under the strict liability regime and the strict liability scheme did not apply to damages that were directly caused to humans, i.e. without damaging first the environment; in the light of the complexity of issues involved and the existing uncertainties, there was no liability for environmental or ecologic damages; and, because of possible long-term effects, the application of a normal 10-year limitation period was seen as inadequate.

The new legislation tried to reflect these concerns: A *strict liability* regime was established for the use of GMOs in contained regimes, experimental field testing, the unapproved introduction in the market and for damages from defective organism.[217] Thereby, a genetically modified organism is considered as defective when it does not provide the safety that is to be expected under the normal circumstances. A *strict liability regime with channeled liability* of the importer or producer of the GMOs was adopted for the use of marketed GMOs in agriculture and in agriculture food products, including liability for damages from cross-pollination.[218] The liable importer or producer has a right of recourse against persons who handled the organisms improperly or who have contributed in another way to the damage.[219] Finally, for the use of other marketed GMOs in products such as e.g medicaments, the *general product liability* will apply. This specific liability regime for GMOs does only apply if the genetic modification of the organism was the main cause of the damage.[220] The liability is excluded in situations of *force majeur* or when the damage is the result of the wrongful intentional conduct of a third party including the person who suffered the damage.[221] By bearing the costs of all adequate restoration measures, the liable person must also compensate the damage to the environment.[222] According to the provision on time limit of liability, claims for compensation are not admissible unless they are brought within 30 years from the date of the incident. Moreover, they have to be brought within three years from the date the claimant knew of the damage.[223] The normal limitation periods in Swiss law are 10 years and one year. The new limitation periods are identical with the periods foreseen in the Lugano Convention of the European Council of 21 June 1993 on Civil Liability for activities dangerous to the Environment.[224] While

[214] See generally: Jürg Bally, *Zur USG-Revision bezüglich Umweltschäden und Versicherung*, 9 UMWELTRECHT IN DER PRAXIS 427, 428 (1995); KATHARINA HÄSSIG, HAFTUNGSFRAGEN DER GENTECHNOLOGIE: DAS HAFTPFLICHTRECHT IM UMGANG MIT DEM UNGEWISSEN DE GENTECHNOLOGIE, 110 (1992); Patricia M. Schiess, *Die Haftung gemäss Gen-Lex-Vorlage*, ASPEKTE DER GENTECHNOLOGIE IM AUSSERHUMANBEREICH (Bernhard Schmithüsen and Jörg Zachariae, eds., 2002), 197, 199; SCHWEIZER, BERICHT, supra note Error: Reference source not found, at 64-66; WILDHABER, supra note Error: Reference source not found, at 286-341.
[215] USG, supra note Error: Reference source not found, Art. 59a.1, 59a.2(d) and Art. 59a.4.
[216] See generally: BUNDESAMT FÜR JUSTIZ, BERICHT DER STUDIENKOMMISSION FÜR DIE GESAMTREVISION DES HAFTPFLICHTRECHTS, Bern 1991, at 143ff.; Hässig, supra note Error: Reference source not found , at 146ff.; Fritz Niklisch, *Haftpflichtprobleme der Bio- und Gentechnologie*, in: SYMPOSIUM STARCK, NEUERE ENTWICKLUNGEN IM HAFTPFLICHTRECHT (Heinrich Honsell and Heinz Rey eds, Zürich 1991), 124ff; Massimo Pergolis and Jürg Busenhart, *Unfallbedingte Umweltschäden – Haftung und Versicherun*g, 9 UMWELTRECHT IN DER PRAXIS 408, 412-416 (1995); SCHWEIZER, BERICHT, supra note Error: Reference source not found, at 67-70; WILDHABER, supra note Error: Reference source not found, at 293-296, 306-307, 321-323, 339-340, 347-350.
[217] GTG, supra note Error: Reference source not found, Art. 30.1 and Art. 30.4 – 30.6.
[218] GTG, supra note Error: Reference source not found, Art. 30.2.
[219] GTG, supra note Error: Reference source not found, Art. 30.3.
[220] GTG, supra note Error: Reference source not found, Art. 30.1, 30.2, 30.4 and Art. 30.7.
[221] GTG, supra note Error: Reference source not found, Art. 30.8.
[222] GTG, supra note Error: Reference source not found, Art. 31; Bally, supra note Error: Reference source not found.
[223] GTG, supra note Error: Reference source not found, Art. 32.
[224] Convention on Civil Liability for Damage Resulting From Activities Dangerous o the Environment (Lugano Convention), 21 June 1993, 32 I.L.M. 1228 (1993); SCHWEIZER, BERICHT, supra note Error: Reference source not found, at 67; WILDHABER, supra note Error:

the person claiming compensation bears the burden of proof, this burden can be softened:[225] if the causality can't be proven with certainty or if the presentation of proof cannot be expected, the proof of overwhelming probability is sufficient. Moreover, the court may also have the facts determined proprio motu. Finally, the government is authorized to determine that the liability shall be covered by insurance or other financial guarantees.[226]

IV.3.7 Public participation

Switzerland provides various legal instruments for the participation in governmental decision-making at all levels. Participation is particularly strong in the area of environmental protection and gene technology. At international level, the UN/ECE Convention on access to information, public participation and access to justice in environmental matters (Aarhus Convention) addresses the issue of public participation.[227] Public participation includes the right of access to information (infra, subchapter IV.3.7.1) and the participation in legislative processes and in decision making (infra, subchapter IV.3.7.2).

IV.3.7.1 Right of access to information

According to Art. 18 para. 2 GTG, the authorities may publish information of general interest. This information primarily concerns risks or impairment caused by GMOs, and the state of the environment. Furthermore, according to Art. 26 Para. 2 GTG, the Confederation shall promote the public knowledge and dialogue concerning the uses as well as the opportunities and risks of biotechnology. Art. 18.I establishes that upon application, every person has the right of access to information which has been gathered in the enforcement of this law, of other relevant federal laws, or of GMO-related international agreements. Only overwhelming private or public interests may preclude this right.[228] Art. 18 para. 1 GTG accords a subjective, enforceable right to every individual and corporate person, regardless of its nationality or place of residence, and regardless of the particular interest it may have.

IV.3.7.2 Public participation in decision making

In addition to the right by individuals and groups to participate in the legislative process,[229] the Gene Technology Law provides also the right to participate in the decision making. Thus, the application for a authorization of both the experimental release and the marketing of GMOs must be publicly announced and any person may submit comments on the documents.[230] Decisions on the release for experimental purposes can be appealed not only by the person applying for the authorization, but also by third parties with a considerable, direct interest such

Reference source not found, at 350.
[225] GTG, supra note Error: Reference source not found, Art. 33.
[226] GTG, supra note Error: Reference source not found, Art. 34; see on this also: Bally, supra note Error: Reference source not found.
[227] On the Aarhus Convention, see generally: Christoph Errass (2004), *Die Aarhus-Konvention und ihre Umsetzung ins schweizerische Recht*, URP (forthcoming 2004, on file with the authors); Daniela Thurnherr (2002*), Beteiligung der Öffentlichkeit an Bewilligungsverfahren. Die Rechtslage beim Inverkehrbringen und der versuchsweisen Freisetzung gentechnisch veränderter Organismen im Lichte neuerer umweltvölkerrechtlicher Entwicklungen*, in: ASPEKTE DER GENTECHNOLOGIE IM AUSSERHUMANBEREICH (Bernhard Schmithüsen and Jörg Zachariae eds., 2002), 147, 156 ff; Martin Scheyli*, Aarhus-Konvention über Informationszugang, Öffentlichkeitsbeteiligung und Rechtsschutz in Umweltbelangen*, ArchVR, 217 ff (2000), with further references; ASTRID EPINEY and MARTIN SCHEYLI, DIE AARHUS-KONVENTION. RECHTLICHE TRAGWEITE UND IMPLIKATIONEN FÜR DAS SCHWEIZERISCHE RECHT, (2000).
[228] These interests may for example concern professional, trade or manufacturing secrets, protection of individuality, pending court cases or administrative procedures, national defence (see *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2410 f.).
[229] See supra, subchapter II.2.4.
[230] Art. 18 and 23 RO, supra note Error: Reference source not found.

as the owners or tenants of neighboring property which could be affected by the release of GMOs.[231] And decisions on the authorization of marketing of GMOs can be appealed by the person applying for the authorization and by national environmental protection organizations, provided that they were founded at least 10 years before lodging the appeal.[232]

IV.3.8 Protection of production that does not involve the use of GMOs[233]

According to Article 7 GTG GMOs may be handled only in such a way that they, their metabolites or wastes do neither impair the production of GMO-free products nor restrict consumers' freedom of choice. Art. 7 GTG is intended to ensure the "coexistence"[234] of conventional production methods and production methods involving GMOs. It is a directly applicable rule and places an obligation on anyone who handles GMOs. Thereby, handling means any activity in connection with GMOs.[235] In other words, during sowing, harvesting, transportation, processing and even the sale of GMOs or products that contain such organisms, care must be taken that neither the GMO-free production nor or to freedom of choice is impaired, i.e. that no contamination of GMO-free products with GMOs occurs. And any person handling GMOs must take appropriate care to ensure the segregation of the product flow and to avoid undesired mixing with non-GMOs during transportation and processing.[236] This should ensure that within Switzerland's small area, the production that does not involve GMOs and in particular organic farming and integrated production that does not permit the use of GMOs[237] remain possible.[238]

[231] Art. 6 and Art. 48 VwVG, supra note Error: Reference source not found.
[232] Art. 28 GTG, supra note Error: Reference source not found.
[233] See generally Errass, *verwaltungsrechtliche Aspekte*, supra note Error: Reference source not found, at IV.2.b.
[234] On coexistence, see Recommendation 2003/556/EC of 23 July 2003, on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified (GM) crops with conventional and organic farming, reprinted in: ABl. L 189 of 29.7.2003, 36, 39; KARIN NOWACK HEIMGARTNER, REGULA BICKEL, RACHEL PUSHPARAJAH LORENZEN and ERIC WYSS, SICHERUNG DER GENTECHNIKFREIEN BIOPRODUKTION. EINTRITTWEGE GENTECHNISCH VERÄNDERTER ORGANISMEN, GEGENMASSNAHMEN UND EMPFEHLUNGEN, published by SAEFL, (2002); REGINE BARTH, RUTH BRAUNER, ANDREAS HERMANN, ROBERT HERMANOWSKI, KARIN NOWACK, HANSPETER SCHMIDT and BEATRIX TAPPESER, GRÜNE GENTECHNIK UND ÖKOLOGISCHE LANDWIRTSCHAFT, published by the Umweltbundesamt, Berlin (2003).
[235] See supra note Error: Reference source not found.
[236] Art. 16.I GTG, supra note Error: Reference source not found.
[237] Art. 3 of the Ordinance of 22 September 1997 on Organic Farming and the Labelling of Organically Produced Products and Foodstuffs (SR 910.18).
[238] See the Rapporteur of the National Council CHIARA SIMONESCHI, AB N 2002, p. 1555f.; CÉCILE BÜHLMANN, AB N 2002, 1554ff.; SIMONETTA SOMMARUGA, AB N 2002, 1555; RUEDI AESCHBACHER, AB N 2002, 1555; EUGEN DAVID, Speaker for the Minority in the Council of States in the adjustments, AB S 2002, 1144f.; PETER BIERI, Speaker for the Minority in the Council of States as part of the second stage of the adjustments, AB S 2003, 193f. On the legal bases for organic farming and integrated production, see Art. 70f. LwG (see Conrad Widmer, *Landwirtschaftliche Direktzahlungen als Instrument für den Umweltschutz* (Direct payments to farmers as an instrument of environmental protection), URP, 506f., passim (2002)). On the constitutional principles, see KLAUS A. VALLENDER, in: ST. GALLER KOMMENTAR, supra note Error: Reference source not found, Rz. 21f. to Art. 104.

V. SPECIFIC ISSUES

V.1 DEALING WITH THE RISKS OF GMOS UNDER UNCERTAINTY

V.1.1 Risks Assessment and Uncertainty

Technologies involve risks for human life and health, the environment, the integrity of the ecosystems but also for the distribution of basic goods and resources in the population. The term "risk" refers to an undesired result that may happen with a certain probability and risk is seen as a combination of the probability of the realization of a threat and the magnitude of the potential damage, whereby both, the probability and the damage can be determined quantitatively and/or qualitatively.[239] In Switzerland, relevant policy decisions on the management of risks are generally based on scientific risk assessment.[240] While the risk of traditional technologies can be assessed, a similar conclusive quantitative risk assessment is not possible with regard to genetic engineering because of the existing scientific uncertainties. In such situations involving scientific uncertainties, Switzerland generally applies a precautionary approach.[241]

V.1.2 Precaution

The precautionary principle, according to the internationally generally accepted understanding, indicates that if there are warnings of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing measures to prevent environmental degradation.[242] At the international level, it has become a tool to pierce the traditional trade law requirement that the necessity of measures for the protection of the environment or human health has to be proven scientifically if such measures have an impact on trade.[243] Precaution evolved first at the national level and today, most countries apply the concept. At the international level, the precautionary principle has been further concretized in several international instruments and it has also entered international jurisdiction.[244] It is generally said that the principle is in the process of crystallizing into a rule of international customary law.[245]

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[239] Laurence Boisson de Chazournes, *Le principe de précaution: Nature, contenue et limites*, in: LE PRINCIPE DE PRÉCAUTION: ASPECTS DE DROIT INTERNATIONAL ET COMMUNAUTAIRE 65, 71 ff, (Charles Leben et Joe Verhoeven eds., 2002); OTHMAR KÄPPELI AND ELISABETH SCHULTE, BIO- UND GENTECHNOLOGIE II, TECHNIKBEURTEILUNG GESCHLOSSENER SYSTEME (Zürich 1998) 27ff.; WILDHABER, supra note Error: Reference source not found, at 57-58 with further references.

[240] Bundesamt für Umwelt, Wald und Landschaft, Handbücher I-III zur Störfallverordung (Bern 1991) (administrative guidance of the Swiss Agency for the Environment, Forests and Landscape for the assessment of risks). See generally: Errass, Katastrophenschutz, supra note Error: Reference source not found, at 46; Rainer J. Schweizer and Urs Schlegel*, Staatliches Risikomanagement: Länderbericht Schweiz*, RISIKOMANAGEMENT IM ÖFFENTLICHEN RECHT (Eibe Riedel ed., Baden-Baden 1996) 110, 1341-149 [hereinafter: *Risikomanagement*].

[241] See e.g.: ALAIN GRIFFEL, DIE GRUNDPRINZIPIEN DES SCHWEIZERISCHEN UMWELTRECHTS, 60-61 (2001); Seiler, *Kommentar USG*, supra note Error: Reference source not found, Art. 29a Rz. 63, 74ff.; Schweizerischer Bundesrat, *Botschaft zu einem Bundesgesetz über den Umweltschutz (USG)*, BBl **1983** 26-27 (1983).

[242] Principle 15 of the Rio Declaration on Environment and Development, *reprinted in:* 31 I.L.M. 874 (1992). See generally: Franz Xaver Perrez, *The World Summit on Sustainabel Development: Environment, Precaution and Trade - a Potential for Success and/or Failure*, RECIEL 12/1 12, 15-18 (2003) [hereinafter: *WSSD*], providing an overview of the evolution of the precautionary principle from its emergence to the World Summit on Sustainable Development and of the different meanings of precaution. See also: Boisson de Chazournes, supra note Error: Reference source not found; Franz Xaver Perrez, COOPERATIVE SOVEREIGNTY: FROM INDEPENDENCE TO INTERDEPENDENCE IN THE STRUCTURE OF INTERNATIONAL ENVIRONMENTAL LAW, 289ff. (2000) [hereinafter: COOPERATIVE SOVEREIGNTY]; PHILIPPE SANDS, PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW, 208ff. (1995) [hereinafter: PRINCIPLES].

[243] PERREZ, COOPERATIVE SOVEREIGNTY, supra note Error: Reference source not found, at 290; Philippe Sands, *The "Greening" of International Law: Emerging Principles and Rules*, 11 IND. J. GLOBAL LEGAL STUD. 293, 297-298 (1994).

[244] See generally: Geneva Environment Network, *Report of the Round Table of the Geneva Environment Network on Precaution*, available at <http://www.environmenthouse.ch/roundtables.htm>; Perrez, *WSSD*, supra note Error: Reference source not found.

[245] Perrez, *WSSD*, supra note Error: Reference source not found, at 15; PERREZ, COOPERATIVE SOVEREIGNTY, supra note Error: Reference source not found, at 291, with further references in note 317.

V.1.2.1 The Precautionary Principle in Switzerland

The precautionary principle finds its bases in the Swiss Constitution and Swiss Legislation, it is firmly established in the Swiss jurisdiction, and it is an integral part of Swiss environmental and health legislation and policy implementation.[246] Precaution has become in Switzerland a broad concept requiring that possible negative effects be prevented even before they may become a danger or a threat.[247] The precautionary principle, as implemented at the national level in Switzerland, embraces on the one side ongoing governmental control and self-control according to the actual state of technology and knowledge.[248] On the other side, it also requires that measures are taken in the absence of scientific certainty but on the basis of well-founded assumptions that specific effects might eventually result in damage for human health or the environment.[249] However, according to the Swiss understanding, the precautionary principle does not prohibit any risk: like any governmental action, precautionary measures must be proportional, transparent and non-discriminatory, and they must not constitute a disguised restriction to trade.[250] Finally, precautionary measures for the protection of the environment must be "economically bearable".[251]

According to the Swiss view, the precautionary principle is relevant for the management of risks and it should not be confused with the caution or prudence scientists apply in their assessment of scientific data: While prudence and caution are part of any scientific approach, precaution becomes relevant only once a scientific evaluation based on sound science has been completed and if at that stage a degree of uncertainty attached to the results of the evaluation of the available scientific information remains. Thus, as the risk assessment based on sound science is the prerequisite for triggering the precautionary principle, the principle stands in no contradiction to but is based on sound science.

At the international level, Switzerland – without yet formally expressing its view whether the precautionary principle has already become a rule of customary international law – has always supported the further concretization, operationalization and strengthening of the principle at the international level both as treaty and as customary law. Thereby, Switzerland fully agrees that precaution must not be used as a pretext for protectionism and it does not see a conflict between the WTO trade rules and the validity of the precautionary principle. Switzerland also strongly favors a strengthening and further clarification of the principle, not only within the WTO context, but also generally as a binding rule of international environmental law.[252] For Switzerland, the precautionary principle is a valid and relevant principle applicable at the national and the international level in situations of uncertainty.

V.1.2.2 Precaution and GMOs in Switzerland

[246] Art. 74.2 BV; Art. 1.2 and 11.2 USG, supra note Error: Reference source not found; BGE 113 Ib 376, 293 f. Erw. 7b; BGE 117 Ib 28, 34 Erw. 6a; BGE 126 II 366, 368 Erw. 2b; see also references supra note Error: Reference source not found.
[247] Art. 1.2 USG, supra note Error: Reference source not found; see generally: CHRISTOPH ERRASS, KATASTROPHENSCHUTZ, supra note ERROR: REFERENCE SOURCE NOT FOUND, at 93-96; Griffel, supra note Error: Reference source not found, at 60-65; ECNH, supra note Error: Reference source not found, at 12.
[248] RAINER J. SCHWEIZER, GENTECHNIKRECHT; ZWISCHENBILANZ DES GESETZGEBUNGSPROZESSES IM GENTECHNIK- UND GENSCHUTZBEREICH, 69 (1996) [hereinafter: ZWISCHENBILANZ].
[249] Griffel, supra note Error: Reference source not found, at 60-61 with further references.
[250] Griffel, supra note Error: Reference source not found, at 117-128.
[251] Art. 11.2 USG, supra note Error: Reference source not found; see also: Griffel, supra note Error: Reference source not found, at 119-126; BGE 124 II 517, 522f. Erw. 5a.
[252] Schweizerischer Bundesrat, *Bericht zur Aussenwirtschaftspolitik 99/1+2*, BBl **2000** 1369, 1378; Franz Xaver Perrez, *Switzerland's International Environmental Policy in 2001*, 12 YIEL 451, 455 (2001); Franz Xaver Perrez *Switzerland's International Environmental Policy in 2002*, 13 YIEL (forthcoming 2002) (manuscript at 1, on file with the author).

By indicating that threats and negative interferences from GMOs are to be limited in the spirit of precaution, article 2.1 of the GTG establishes the precautionary principle as an overarching principle of the Swiss policy on genetic engineering in the same manner as it is done by art. 1.2 USG for the environmental policy.[253] In the light of article 2.1 GTG, the precautionary principle has to be taken into account in every policy decision on genetic engineering. This means that if there are reasonable grounds for concern that a certain activity or a certain product may cause potentially dangerous effects to humans, animals, plants or the environment – e.g. based on preliminary scientific evaluations – precautionary action should be taken despite the uncertainties with regard to the probability of these dangers. This action has however to be proportional and to reflect the generally accepted level of protection and risk.[254] When determining the proportionality, the general objectives of the Swiss legislation on genetic engineering have to be given special consideration, i.e. the protection of humans, animals and the environment from misuses of genetic engineering, the well-being of humans, animals and the environment, the protection of human and animal health and the environment, the preservation of biological diversity and of the productivity of the soil, the respect of the dignity of living beings, the freedom of choice of consumers, the prevention of deceptive practices, the public information and the relevance of scientific research in the area of genetic engineering for humans, animals and the environment.[255]

While art. 2.1 GTG generally establishes precaution as an overarching principle of the Swiss policy on genetic engineering, numerous specific provisions further concretize and operationalize the principle: thus, experimental field-testing is only permitted if the same information cannot be gained through tests in contained regimes;[256] the introduction in the environment of genes which are resistant to antibiotics which are used in human and veterinary medicine is generally prohibited;[257] the safety of GMOs has to be demonstrated through tests in contained systems and experimental field-testing before they can be used in agriculture,[258] and the fact that approvals for the use of GMOs have to be regularly re-assessed[259] recognizes that uncertainties remain. Thus, the Swiss legislation on genetic engineering does not only recognize the importance and necessity of proportional precautionary measures as a general principle, it does also operationalize the precautionary principle through several concrete provisions.

V.1.3 Risk-Benefit Analysis and Proportionality

The precautionary principle provides the possibility to act even if the necessity of such action is not yet scientifically fully proven. The precautionary principle does however not prescribe the adoption of a specific measures – it merely opens the possibility to a wide range of available risk-management options. In theory, a functional cost-benefit or risk-benefit analysis could provide the necessary information to decide between these different options: once the costs, the risks and the benefits of the different options have been determined, the option can be chosen which objectively reflects best the common interest. However, by assuming that it is possible to assess objectively all costs and benefits of particular interactions through monetary valuations, and based on these evaluations, the overall welfare can be maximized through

[253] Art. 2.1 GTG, supra note Error: Reference source not found.
[254] See supra, note Error: Reference source not found, and accompanying text, and infra, subchapter V.1.3.
[255] Art. 1 GTG, supra note Error: Reference source not found.
[256] Art. 6.2(a) GTG, supra note Error: Reference source not found.
[257] Art. 6.2(c) and 6.3 GTG, supra note Error: Reference source not found. Art. 37 GTG, supra note Error: Reference source not found, provides for an interim regulation allowing the use of antibiotic resistant genes until 31.12.2008.
[258] Art. 6.3 GTG, supra note Error: Reference source not found.
[259] Art. 13 GTG, supra note Error: Reference source not found.

rational, value-neutral decisions, this approach suffers important limitations.[260] This is even more the case in situations involving risks and uncertainty: the perception of risk may be more important than the actual risk.[261] And while risks may be quantified, this is not possible with uncertainties. Moreover, the unknown may often be seen as more threatening than the known risk.[262] All this makes the cost-benefit analysis problematic concept for dealing with issues involving uncertainties such as GMOs. The Swiss legislation on genetic engineering does therefore not require quantitative cost-benefit analyses.

Nevertheless, there is no unlimited freedom for policy making and policy implementation. In fact, the Swiss constitution and legislation provide guidance on how to manage the risks involved with GMOs by outlining the overarching interests and priorities that are to be respected. The Swiss constitution clarifies that humans and the environment have to be protected against the abuses of genetic engineering and it outlines the overarching principles of the Swiss legislation in this field, namely the respect of the dignity of living beings, the safety of humans, animals and the environment, and the protection of biological diversity.[263] The Gene Technology Law clarifies that the legislation on genetic engineering shall serve the well-being of humans, animals and the environment.[264] Moreover, it has complemented the overarching constitutional objectives with the goals to protect lastingly the productivity of the soil, to ensure the freedom of choice of consumers, to prevent deceptive practices, to promote the public information, and to consider the relevance of scientific research in the area of genetic engineering for humans, animals and the environment.[265] Risk management decisions must pursue these objectives. This does however not require the absolute protection of the human health and the environment:[266] decisions must always be proportional. Thus, not cost-benefit analysis but proportionality in the pursuit of the defined objectives guides the concrete decisions on different risk management options.

V.2 INTERNATIONAL ASPECTS

For Switzerland, a small country that heavily relies on international trade and good international relations, the conformity of its legislation with international law is a priority.[267] With regard to biotechnology, the conformity is especially important in three major areas: the legislation of the European Union, the international environmental law and the international trade rules. There are no major differences between the Swiss and the EU legislation. Moreover, the general international environmental legislation is flexible – or not binding – enough to easily avoid conflicts. Therefore, the major focus of this analysis of international aspects concentrates on the Biodiversity Convention, the Biosafety Protocol and the international trade rules as established by the WTO.

V.2.1 EU

The EU is the major trading partner of Switzerland. While over 60% of Switzerland's Export go to the EU, over 80% of Switzerland's imports come from the EU.[268] Coherence with the rules of

[260] For a general discussion of the limitations of functional analysis, see generally Franz Xaver Perrez, *The Efficiency of Cooperation: A Functional Analysis of Sovereignty*, 15 ARIZ. J. INT'L & COMP. L 515, 518-521 (1998) [hereinafter: *Efficiency*].
[261] De Greef, supra note Error: Reference source not found, at 582, with further references.
[262] Jungemann, Helmut, *Subjektive Wahrnehmung von Risiken*, SPEKTRUM, 2/1998, 98-100 (1998).
[263] Art. 120 Swiss consitution. See also supra, subchapter IV.2.
[264] GTG, supra note Error: Reference source not found, art 1.1(b).
[265] GTG, supra note Error: Reference source not found, art 1.2. See also supra, subchapter IV.3.1.
[266] Stand Gesetzgebung, supra note Error: Reference source not found, at 1676.
[267] Wasescha, supra note Error: Reference source not found.
[268] Schweizerischer Bundesrat, *Bericht zur Aussenwirtschaftspolitik 2002*, BBl **2003** 826, 932.

the EU is therefore of overarching importance. This is also the case with regard to legislation on genetic engineering. But as the public concerns and sensibilities and the relevant interests involved do not differ substantially between the EU and Switzerland, the policy on GMOs in the EU and in Switzerland follow the same priorities and principles.[269] However, while the legislation in Switzerland usually follows the related legislation in the EU, this was not always possible with regard to the legislation on genetic engineering. The legislatory process in Switzerland in this area was more advanced than the one in the EU. Thus, while the development in the EU was closely followed throughout the legislatory process in Switzerland,[270] the Swiss legislation was often adopted before the similar EU legislation. Switzerland was e.g. among the first states to require labeling of food products containing GMOs.[271] Switzerland's introduction of the concept that the dignity of living beings must be respected was a legislatory novelty. Nevertheless, Switzerland prepared its legislation in close contact with the EU and Switzerland generally knew the direction the EU-legislation was going to take. This is the reason, why it was possible to prevent any substantial conflict between the Swiss and the EU rules and standards on GMOs. While the Swiss and the EU GMO-legislation are in most areas consistent, Switzerland's legislation differs with regard to the implementation of the constitutional requirements that the biological diversity must be protected and that the dignity of living beings must be respected, and with regard to civil liability.[272] Despite the fact that the Swiss legislation is more stringent than the EU legislation in those areas, it is not expected that these differences will create any major problems.

V.2.2 International Environmental Law: Protection of the Environment, Biodiversity and Biosafety

The international environmental law has established a general duty to protect the environment.[273] This general duty has been further concretized by numerous international environmental agreements establishing concrete obligations for the protection of the environment. In the context of genetic engineering and GMOs, reference is generally made specifically to the Biodiversity Convention[274] and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Biosafety Protocol).[275] However, it should not be forgotten that there are numerous other environmental instruments such as global and regional agreements relating to the protection of freshwaters and wetlands, the maritime environment, specific fragile ecosystems such as alpine ecosystems, hazardous wastes, transboundary impact assessments and access to information that could be or become relevant for GMOs.[276]

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[269] For an overview of the EU-legislation on GMOs, see e.g. Jeffrey K. Francer, *Frankenstein Foods or Flavor Savers? Regulating Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 278-289 (2000); Ruth MacKenzie and Silvia Francescon, *The Regulation of Genetically Modified Foods in the European Union: An Overview*, 8 N.Y.U. ENVT. L.J. 530 (2000).

[270] See e.g.: SCHWEIZER, ZWISCHENBERICHT, supra note Error: Reference source not found, at 27-54 (providing a detailed analysis of the relevant EU-legislation for the Swiss parliamentary Commission); Stand Gesetzgebung, supra note Error: Reference source not found, at 1678-1679; *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2398-2400 and 2431.

[271] Switzerland introduced its first labeling requirement for genetically modified food in 1995 (amendment of articles 15 and 22 of the food ordinance of 1 March 1995, Lebensmittelverordnung SR 817.02); the EU introduced its compulsory labeling requirement only in 1997 through Commission Directive 97/35 of 18 June 1997 adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environmen of genetically modified organisms, 1997 O.J. (L169) 72; see on this: MacKenzie/Francescon, supra note Error: Reference source not found, at 539.

[272] *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2400.

[273] Jörg Lücke, *Universelles Verfassungsrecht, Völkerrecht und Schutz der Umwelt*, 35 ARCHIV DES VÖLKERRECHTS 1, 7, 10-13, 15-16 (1997); PERREZ, COOPERATIVE SOVEREIGNTY, supra note Error: Reference source not found, at 239-241 with further references in note 341.

[274] Convention on Biological Diversity, 5 June 1992, 31 I.L.M. 818 (1992) [hereinafter: CBD].

[275] Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Biosafety Protocol), 20 January 2000, 39 I.L.M. 1027 (2000).

[276] Other global and regional instruments which could be relevant include the Ramsar Convention on Wetlands of Inenational Importanc Especially as Waterfowl Habitat (Ramsar Convention), 2 February 1971, 22 I.L.M. 698 (1982); the United Nations Convention on the Law of the Sea, 10 December 1982 (UNCLOS), 21 I.L.M. 1261 (1982); the Basel Convention on the Control of Transboundary

During the parliamentary debate of Switzerland's GMO-laws, specific attention concerning international environmental obligations was given with regard to the Biodiversity Convention and its Biosafety Protocol.[277] It was generally assumed that Swiss GMO-legislation stands in no contradiction with the other general and concrete obligations of international environmental law.

The objectives of the Biodiversity Convention are the conservation of the biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits derived from utilization of genetic resources.[278] While the Convention requires the parties generally to protect the biodiversity and it includes several specific obligations,[279] the following obligations are especially relevant for GMOs: to promote the protection of ecosystems;[280] to identify and regulate or manage processes and activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity;[281] to regulate, manage or control the risks to biological diversity and human health posed by the use and release of GMOs;[282] to prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species;[283] to develop or maintain necessary legislation and/or other regulatory provisions for the protection of threatened species and populations;[284] and to provide any available information on the potential adverse impact of GMOs to contracting parties into which such GMOs are to be introduced.[285]

The Biosafety Protocol aims at ensuring that GMOs that pose a potential threat to biodiversity and its sustainable use are transported, used and handled safely.[286] It requires that an importing country has to agree to the importation of GMOs prior to its first importation based on a notification from the exporter that includes all information relevant for the assessment of the risk of that GMO for the environment and human health.[287] In situations of scientific uncertainties about the possible effects of GMOs, the importation of such GMOs can be prohibited based on the precautionary principle.[288] The Biosafety Protocol also requires that GMOs must be identified as such in the accompanying documents.[289]

Thus, the Biodiversity Convention and its Biosafety Protocol establish together a framework with several important obligations for the national policy on GMOs. Moreover, this framework

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Movement of Hazardous Wastes and Their Disposal (Basel Convention), 22 March 1989, 28 I.L.M 657 (1989); the Convention on the Ban of Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa (Bamako Convention), 19 January 1991, 30 I.L.M. 775 (1991); the UN/ECE Convention on Environmental Impact Assessment in a Transboundary Context (Espoo Convention), 25 February 1991, 30 I.L.M. 802 (1991); the Convention on the Protection of the Alps, 7 November 1991, 31 I.L.M. 767 (1991); the UN/ECE Convention on the Protection and Use of Transboundary Watercourses and International Lakes (1992 Watercourse Convention), 17 March 1992, 31 I.L.M. 1312 (1992); The Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention), 22 September 1992, 32 I.L.M. 1068 (1993); the Convention on the Law of the Non-Navigational Uses of International Watercourses (1997 Watercourse Convention), 1997, 36 I.L.M. 700 (1997); and Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention), available at: www.unece.org/env/pp/welcome.htm.

[277] *Gen-Lex-Botschaft*, supra note Error: Reference source not found, at 2400-2401.

[278] CBD, supra note Error: Reference source not found, Art. 1. For an overview of the convention and its history, see generally: Désirée M. McGraw, *The Story of the Biodiversity Convention: From Negotiation to Implementation*, in: GOVERNING GLOBAL BIODIVERSITY (Philippe G. Le Prestre, ed., 2002) 7-38; SANDS, PRINCIPLES, supra note Error: Reference source not found, at 381-387.

[279] See generally: SANDS, PRINCIPLES, supra note Error: Reference source not found, at 382ff.

[280] CBD, supra note Error: Reference source not found, Art. 8(d)

[281] CBD, supra note Error: Reference source not found, Art. 7(c) and 8(l).

[282] CBD, supra note Error: Reference source not found, Art. 8(g).

[283] CBD, supra note Error: Reference source not found, Art. 8(h).

[284] CBD, supra note Error: Reference source not found, Art. 8(k).

[285] CBD, supra note Error: Reference source not found, Art. 19.4. See also: SANDS, PRINCIPLES, supra note Error: Reference source not found, at 386-87.

[286] Biosafety Protocol, supra note Error: Reference source not found, Art. 1.

[287] Biosafety Protocol, supra note Error: Reference source not found, Art. 7-12. See also: François Pythoud, *The Biosafty Protocol: Regulatory Innovation and Emerging Trends*, RSDIE 10/4, 528-537 (2000), at 530-531.

[288] Biosafety Protocol, supra note Error: Reference source not found, Art. 1 and 10.6; see also Francer, supra note Error: Reference source not found, at 309-310.

[289] Biosafety Protocol, supra note Error: Reference source not found, Art. 18. See also: See also Francer, supra note Error: Reference source not found, at 309; Pythoud, supra note Error: Reference source not found, at 532-533.

explicitly affirms the state's right to prohibit in situations of scientific uncertainty the importation of products containing GMOs. The Swiss legislation on genetic engineering reflects and implements these international environmental obligations and rights. Thus, the preamble of the Gene Technology Law indicates specifically that this legislation is part of the implementation of the Biodiversity Convention and the Biosafety Protocol.[290] Interestingly, no reference is made to other international rules or agreements. Moreover, several provisions of the Gene Technology Law make reference not only to the general goal to protect the environment, but also explicitly to the protection and sustainable use of biodiversity.[291] The task to identify and regulate or manage processes and activities with adverse impacts on the biodiversity[292] is implemented by enacting specific rules for GMOs. At the same time, the Swiss legislation on GMOs addresses specifically the risks to biological diversity and human health posed by of the use and release of GMOs.[293] And by admitting deliberate release of GMOs into the environment only upon proof that - according to the actual sound scientific knowledge - the release will not have any harmful effect on the environment and the ecosystem,[294] and by requiring that field releases must be accompanied by a risk assessment and the monitoring of possible effects upon the environment,[295] the Swiss legislation meets the CBD's requirement to prevent or control the introduction of alien species which can pose a threat to biodiversity.[296] By establishing the precautionary principle as an overarching policy instrument for dealing with GMOs,[297] the Swiss legislation is rules and procedures for the exportation of GMOs to meet the obligations established by the Biodiversity Convention and the Biosafety Protocol concerning the provision of relevant information on the potential adverse impacts of GMOs.[298] And, according to this legislation, in accordance with the corresponding provisions of the Biosafety Protocol, [299] GMOs that are exported from Switzerland will have to be accompanied by documents identifying them as genetically modified.

V.2.3 WTO

V.2.3.1 The applicable WTO-Rules

The international trade law as established by the WTO agreements promotes an open, non-discriminatory and transparent international trade regime by prohibiting states from unnecessarily restraining international trade.[300] The General Agreement on Tariffs and Trade (GATT), which establishes the general framework of the WTO regime, indicates that member states must not discriminate between the imports from different countries and imports must be treated no less favorable than like products of national origins.[301] However, sates have the right to adopt measures necessary to protect human, animal or plant life or health and, in conjunction with restrictions on domestic production or consumption, measures relating to the

[290] GTG, supra note Error: Reference source not found, 2nd preambular paragraph ("in implementing international agreements", the footnote attached to this paragraph refers only to the Biodiversity Convention and the Biosafety Protocol).
[291] GTG, supra note Error: Reference source not found, Art. 1.2(b) and 6.1(b).
[292] CBD, supra note Error: Reference source not found, Art. 7(c) and 8(l).
[293] Obligation established in Art. 8(g) of the CBD. For its implementation in Switzerland, see supra, subchapters IV.3.1 and IV.3.4.
[294] See supra, subchapter IV.3.4.
[295] See supra, subchapter IV.3.4.
[296] CBD, supra note Error: Reference source not found, Art. 8(h).
[297] See supra, subchapter V.1.2.3.
[298] CBD, supra note Error: Reference source not found, Art. 19.4; Biosafety Protocol, supra note Error: Reference source not found, Art. 7-12.
[299] Biosafety Protocol, supra note Error: Reference source not found, Art. 18.
[300] See generally: JOHN H. JACKSON, THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS, 223-224 (2nd ed. 1998).
[301] General Agreement on Tariffs and Trade (GATT), RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEOTIATONS: THE LEGAL TEXTS, 485, Art. I and III (1994).

conservation of exhaustible natural resources if such measures do not discriminate arbitrarily or unjustifiably between countries or constitute a disguised restriction of international trade.[302]

These general principles are further clarified by the Agreement on Technical Barriers to Trade (TBT-Agreement) and the Agreement on Sanitary and Phytosanitary Measures (SPS-Agreement). According to the TBT-Agreement, states have the right to adopt non-discriminatory and transparent technical regulations necessary to realize legitimate objectives such as the protection of humans, animals, plants and the environment or the prevention of deceptive practices. [303] The SPS-Agreement recognizes that no WTO member should be prevented from adopting or enforcing measures that are based on scientifically sound risk assessments and that are necessary to protect human, animal or plant life or health if these measures are neither discriminatory nor a disguised restriction on international trade and if their necessity is based on scientific evidence. [304] Both, TBT- and SPS-measures must follow relevant international standards unless additional measures are necessary for the fulfillment of a higher standard chosen by a state.[305]

While relevance of the GATT and the TBT-agreement for GMOs is generally recognized, this is not as clear with regard to the SPS-Agreement. The SPS-Agreement was specifically negotiated and adopted for measures against traditional diseases and pests, at this time, nobody thought of the risks involved with new technologies such as genetic engineering. This is reflected by the SPS-Agreement itself, which states that it is only applicable for sanitary and phytosanitary measures as defined in the annex A to the agreement.[306] According to this annex, SPS measures are measures applied to protect animal or plant life or health from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; to protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; to protect human life or health from diseases; and to prevent or limit the damage of pests.[307] However, GMOs are not “pests”, “diseases”, “additives”, “contaminants” or “toxins”. And, many potential risks associated with GMOs are neither “pests” nor “diseases” but relate to other threats such as not yet fully understood risks of horizontal or vertical gene transfers or the emergence of antibiotic resistances. Thus, the relevance of the SPS-rules for GMOs remains unclear.[308] In the light of this, Switzerland, like all the other European states, has made so far no notification of its GMO-regulation under the SPS-Agreement.[309] Thus, for several – if not most – aspects of the GMO-legislation, such as e.g. the labeling requirements, only the requirements of the GATT and the TBT-agreement, but not those of the SPS-Agreement are relevant.

V.2.3.2 GMOs and the Issue of “Like Product”

[302] GATT, supra note Error: Reference source not found, Art. XX(b) (g) and Chapeau.
[303] Agreement on Technical Barriers to Trade (TBT-Agreement), RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEOTIATONS: THE LEGAL TEXTS, 138, Art 2.1, 2.2, 2.4, 2.9, 10 (1994).
[304] Agreement on Sanitary and Phytosanitary Measures (SPS-Agreement), RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEOTIATONS: THE LEGAL TEXTS (1994) at 69, preambular paragraph 1 and Art. 2.1, 2.2, 2.3 and 5.
[305] TBT-Agreement, supra note Error: Reference source not found, 6th para of the Pramble, Art. 2.4, 9. SPS-Agreement, supra note Error: Reference source not found, Art. 3.1, 3.3.
[306] SPS-Agreement, supra note Error: Reference source not found, Art. 1.1 and 1.2.
[307] SPS-Agreement, supra note Error: Reference source not found, Annex A, Art. 1.
[308] Similar: Krisztina Bende, *La régulation des organisms génétiquement modifés au sein des accords de l’OMC* (2003, on file with the author), at 17.; Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by Word Trade Rules*, 13 TUL. ENVTL. L.J. 271 (2000), at 276-277; Thomas Cottier *Die kanalisierte Gefährdungshaftung für Genetisch Modifizierte Organsimen (GMOs): Beurteilung aus Sicht des internationalen Wirtschaftsrecht*, July 2002, on file with the author, at 7. The unclarity concerning the relevance of the SPS agreement lead the US and others to propose the establishment of a specific WTO-Working group on GMOs at the Seattle WTO ministerial conference, see *WTO Members ponder Biotech Working Group*, BRIDES 3/45 of November 15, 1999.
[309] Moreover, as the EU considers the TBT-Agreement to be the relevant agreement for issues relating to GMOs and not the SPS-Agreement, it refused to enter into a discussion when the US wanted to place the issue of GMOs on the agenda of the SPS Committee (see: *EU resists biotech discussion in SPS committee*, in: BRIDGES 5/38 of November 6, 2001).

The GATT- and the TBT-Agreement require that "like products "are treated the same way.[310] While the WTO-agreements do not further specify the meaning of "like product", the WTO jurisprudence has developed a number of criteria to determine when products are supposed to be alike, namely their physical characteristic, consumer perception, their end-use, and its tariff classification.[311] All relevant evidence with regard to all of the four criteria along with other relevant evidence has to be considered for making an overall determination.[312] Thereby, evidence related to health risks associated with a product is relevant for both the criteria concerning physical characteristics and concerning consumers' tastes and habits.[313] And the fact that risk to health is "a defining aspect of the physical properties" is a clear indication of the un-likeness of products.[314] The goal of the requirement to treat like products equally is to prevent protectionism.[315] The SPS-Agreement, on the other hand, does not mention the concept of like-products, but it prohibits unjustifiable discrimination between identical or similar situations.[316]

According to the Swiss perception, products containing GMOs and products without GMOs are clearly not like products: the existence of a physical difference is obvious. In fact, this physical difference is so important that the producers are willing to invest millions of dollars for being able to obtain precisely this difference. Moreover, the risks linked to GMOs are a defining aspect of the physical properties of GMOs. According to the test applied by the WTO Appellate Body in the Asbestos case, this aspect is crucial for accepting the un-likeness of products.[317] Also the consumers perceive the physical difference as so significant to require different treatment. Thus, while the end-use could in theory be the same, consumers do not see products containing GMOs and products without GMOs as similar and interchangeable.[318] Finally, it is important to note that the motivation for the different treatment of products that contain GMOs and traditional products does not pursue a protectionist objective: the goal of the Swiss regulatory differentiation between GMOs and non-GMOs is to protect human health. Products containing GMOs that are produced in Switzerland would receive exactly the same treatment like imported products. And, as the Swiss regulation is not aimed at giving Swiss products a competitive advantage compared with imported products, the differential treatment of GMOs- and non-GMOs by Switzerland stands not in conflict with the WTO's anti-protectionist motivation to require an equal treatment of like products.[319] Thus, it can be concluded that products containing GMOs and traditional products are clearly not "like products" but substantial different because of their physical differences, the clear distinction consumers make, and especially the understanding that genetic modification could entail substantial and not yet fully understood risks per se. [320]

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[310] GATT, supra note Error: Reference source not found, Art. III.4; TBT-Agreement, supra note Error: Reference source not found, Art. 2.1.
[311] WTO Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, 99-103 (2001) [hereinafter: *Asbestos*].
[312] WTO AB Report, *Asbestos*, supra note Error: Reference source not found, at § 109.
[313] WTO AB Report, *Asbestos*, supra note Error: Reference source not found, at § 113.
[314] WTO AB Report, *Asbestos*, supra note Error: Reference source not found, at § 114.
[315] WTO AB Report, *Asbestos*, supra note Error: Reference source not found, at §§ 97-98, with reference to GATT, supra note Error: Reference source not found, Art. III.1.
[316] SPS-Agreement, supra note Error: Reference source not found, Art. 2.3.
[317] WTO AB Report, *Asbestos*, supra note Error: Reference source not found, at § 114.
[318] Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, p.586-588; Mühlethaler, supra note Error: Reference source not found, at 17.
[319] WTO AB Report, *Asbestos*, supra note Error: Reference source not found, at §§ 97-98. See also: Robert Howse and Donald Regan, *The Product/Process Distinction - An Illusory Basis for Disciplining "Unilateralism" in Trade Policy*, 11 EJIL, 249, 249 (2000) (regulatory distinctions objectively related to actual non-protectionist policies are consistent with GATT Art. III, whether product- or process-based) and 268 ("like" should be read in the light of the anti-protectionist policy of GATT Art. III).
[320] Similar: Thomas Cottier, supra note Error: Reference source not found, at 8.

V.2.3.3 The WTO-Conformity of the Approval Requirements

According to the Swiss perception, GMOs pose a significant potential of risks to human, animals, and the environment[321]. As indicated above, the Swiss requirement that the introduction of GMOs into the Swiss food market and the release of GMO into the environment need approval is a procedure to make sure that there will be, according to the actual sound scientific knowledge, no threat to human and animal health or the environment.[322] This is made specifically clear by the general prohibition of antibiotic resistances genes,[323] the requirement that the spread of GMOs must be precluded according to the actual state of science,[324] and the requirement that field trials have proven that the GMOs do not pose a threat to the functions of the ecosystem[325] and that they generally don't pose a danger for humans, animals, the environment or the biodiversity and its sustainable use.[326]

The protection of human health and the environment is clearly a legitimate objective for adopting trade restrictive measures, both under the GATT-, the TBT- and the SPS-agreement.[327] Thus, even if the SPS-agreement would be applicable, the Swiss requirements for introducing GMOs in the Swiss market and for the release of GMOs in the Swiss environment do, in principle, not create a conflict with the WTO rules: if there is no risk for humans, animals or the environment, the use of GMOs in Switzerland is approved and thus possible. The major difference to more liberal approaches such as the US approach to GMOs relates to the fact that according to the Swiss perspective, genetic modification per se is seen as involving an important potential for substantial risks that makes an approval procedure necessary to ensures that only safe GMOs are permitted on the market and in the environment. According to the concept of "substantial equivalence", a concept developed within the WHO and the OECD, a new food product can be treated in the same manner as the existing food with respect to safety, if it is deemed to be "substantially equivalent" with an existing food product or food component.[328] The concept thus allows that existing food products or food components are used as the basis of comparison in the assessment of new products. If the levels and variations for characteristics in the new food are within the natural range of variation for the same characteristics in the comparator, no new standards and procedures are necessary; if however the new product is not found to be substantially equivalent to an existing food, its safety must be evaluated on the basis of its unique composition and properties.[329] The US perspective considers GMO-products as substantially equivalent to traditional products. However, this use of the concept of substantial equivalence in relation to GMO foods is controversial.[330] In Switzerland as in the rest of Europe, GMOs are seen as substantially different because it is understood that the modification of genes could entail greater and not yet fully understood risks.

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[321] See supra, subchapter III.2.2.4.
[322] See supra, subchapter IV.3.4; Kohler/Maranta, supra note Error: Reference source not found, at 1406-07; Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 601-602;
[323] GTG, supra note Error: Reference source not found, Art. 6.2(c) and 37 (providing for an interim regulation that allows the use of antibiotic resistant genes until 31.12.2008.
[324] GTG, supra note Error: Reference source not found, Art. 6.2(d).
[325] GTG, supra note Error: Reference source not found, Art. 6.3(d).
[326] GTG, supra note Error: Reference source not found, Art. 6.3(f) in combination with Art. 6.1.
[327] See supra, notes Error: Reference source not found - Error: Reference source not found and accompanying text.
[328] OECD, SAFETY EVALUATION OF FOODS DERIVED BY MODERN BIOTECHNOLOGY CONCEPTS AND PRINCIPLES (1993); Richard Braun and Klaus Ammann, *Die Prüfung neuartiger Lebensmittel: Das Prinzip der substantiellen Äquivalenz*, NEUE ZÜRCHER ZEITUNG, March 3, 2000; MacKenzie/Francescon, supra note Error: Reference source not found, at 544; ECNH, supra note Error: Reference source not found, at 10-11.
[329] Braun and Ammann, supra note Error: Reference source not found; MacKenzie and Francescon, supra note Error: Reference source not found, at 544, with further references.
[330] MacKenzie and Francescon, supra note Error: Reference source not found, at 544; Erik Millstone *et al*., *Beyond Substantial Equivalence*, 401 NATURE, 525, 525-526 (1999); Francer, supra note Error: Reference source not found at 267.

Finally, the Swiss approval procedure does not discriminate between products nor between states, it is transparent, it relies on scientific evidence and as it does ensure the confidentiality of information of commercial interest. It is therefore also fully in line with the relevant WTO-rules for such procedures.[331] Switzerland also implements whenever possible adequate international standards; when such standards do not exist on the multinational level, Switzerland refers to regional standards. Only when no adequate international standards exist at all, a national standard is developed.[332] It can therefore be concluded that the Swiss approval requirements for the use of GMOs is in full line with the relevant WTO-rules.

V.2.3.4 The WTO-Conformity of the Labeling Requirement

As indicated above, products containing GMOs have to be labeled in Switzerland as "genetically modified".[333] As GMOs must already have been determined as safe in the approval procedure before being permitted on the market, the Swiss labeling requirement for GMOs does not aim at ensuring food safety. The Swiss law clarifies that the main motivation for the labeling requirements is to ensure freedom of choice for the consumers and the prevention of deceptive practices.[334] Several elements of the Swiss labeling scheme underline its goal to prevent deceptive practices.[335] Namely, as the Swiss consumers assume that products do not contain GMOs and as they have a clear preference for GMO-free products, selling a product that contains GMO without proper information would be a deception. And, the 1% threshold is aimed at preventing that products must be labeled as "produced with GMOs" which were contaminated with GMOs without purpose - indeed, consumers are deceived only if GMOs are added intentionally to a product, but not because of incidental minimal contamination which cannot be prevented.[336] Moreover, in order to prevent deception, the voluntary label for products that have been produces without genetic engineering may only be used when a similar product is admitted on the Swiss market which contains GMOs.[337] Finally, as it has become impossible to guarantee that products are totally free of GMOs because of incidental contamination during growth, harvest, transportation and processing, even those products for which there is proof that no GMOs were used during their production may not be labeled as "GMO-free" but only as "produces without genetic engineering."[338].

Labeling requirements such as the Swiss labeling requirements for GMOs that are not related to food safety are technical regulations covered by the TBT-Agreement.[339] The TBT-Agreement requires such regulations not to be more trade-restrictive than necessary to fulfill a legitimate objective.[340] The prevention of deceptive practices is explicitly mentioned as a legitimate objective for the adoption of technical regulation.[341] However, the list of legitimate objectives mentioned in the TBT-Agreement is not exhaustive and the objective to inform consumers about the physical characteristics and the process and production method of a product may

[331] TBT-Agreement, supra note Error: Reference source not found, Art. 5; SPS-Agreement, supra note Error: Reference source not found, Art. 7, 8, Annex B and Annex C.
[332] See supra note Error: Reference source not found and accompanying text.
[333] See supra, subchapter IV.3.5.
[334] GTG, supra note Error: Reference source not found, Art. 17.1; Errass, *verwaltungsrechtliche Aspekte*, supra noteError: Reference source not found, at IV.2.a; Martin Schrott, *Neue Bestimmungen zur GVO-Deklaration: Informierter Entscheid beim Lebensmittelkauf*, BIOTECH FORUM, Sept. 1999; ECNH, supra note Error: Reference source not found, at 6.
[335] See also: Perrez, *Taking consumers seriously*, supra note Error: Reference source not found, at 602.
[336] Schrott, supra note Error: Reference source not found. See also Perrez, *Taking consumers seriously*, supra note Error: Reference source not found, at 602.
[337] Art. 22b.8 LMV, supra note Error: Reference source not found.
[338] *Id*.; Schrott, supra note Error: Reference source not found.
[339] Arthur E. Appleton, *The Labeling of GMO Products Pursuant to International Trade Rules*, 8 N.Y.U. ENVTL. L.J. 566, 571-572 and 574 (2000).
[340] TBT-Agreement, supra note Error: Reference source not found, Art. 2.2; Appleton, supra note Error: Reference source not found, at 576.
[341] TBT-Agreement, supra note Error: Reference source not found, Art. 2.2.

well be also a legitimate objective.[342] Some authors even argue that there is in international law a general principle of informed consent requiring that persons are informed about possible genetic modification of products.[343] Thus, a labeling requirement for GMO-food could probably also be justified as a means necessary for legitimate consumer information.[344] As indicated above, Swiss consumers are very sensitive about genetically modified food product and a majority opposes the sale of such products.[345] In the light of this, the labeling requirement is the least restrictive measure to prevent deception and to enable consumer information and freedom of choice for the consumers. As such, it fully fulfills the requirements of the TBT-agreement.

V.2.3.5 The WTO-Conformity of the Liability Rules

Switzerland has established a distinct liability regime for GMOs: the use of GMOs in contained regimes, experimental field testing, the unapproved introduction in the market and damages from defective organism are governed by strict liability; agriculture including liability for damages from cross-pollination and agriculture food products are governed by strict liability with channeled liability of the importer or producer of the GMOs; in all other situations, the general product liability rules apply.[346] Moreover, the distinct liability regime for GMOs provides for liability for environmental damages, for the extension of the limitation period, for a softening of the burden of proof and for the possibility of compulsory insurance or other financial guarantees.[347] This specific liability regime for GMOs does only apply if the genetic modification of the organism was the main cause of the damage.[348]

Until now, no relevant legal relationship between trade, market access and liability rule has been determined within the WTO-context.[349] In fact, the WTO-law does not prescribe specific liability schemes and countries are free to adopt the liability level that they consider to be appropriate.[350] As discussed above, the SPS-agreement is clearly not relevant for assessing the WTO-compatibility of the Swiss liability rules for GMOs.[351] Moreover, as GMOs and non-GMOs don't have to be treated as "like products", the liability rules do create no conflict with the GATT- and TBT-prohibition of unjustifiable discrimination:[352] The Swiss liability rules establish the same conditions for GMOs that have been imported and GMOs that have been produced in Switzerland. There is no discrimination between imported and domestically produced products. By reflecting the distinct differences between the known and predictable risks of traditional products and the unknown and unpredictable potential risks of GMOs, the liability rules do also not lead to a "de facto discrimination" but to recognition of different circumstances and risks.[353]

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[342] Art 2.2 TBT-Agreement, supra note Error: Reference source not found, reads: "... Such legitimate objectives are, *inter alia*: ...; the prevention of deceptive practices; ...". See also: Appleton, supra note Error: Reference source not found, at 576-577.

[343] Frank Bodendiek and Karl Nowrot, *Bioethik und Völkerrecht*, 37 ARCHIV DES VÖLKERRECHTS 175, 182-186 (1999) (while Bodendiek and Nowrot focus on biotechnology in the area of medicine, the principle of informed consent might be extended also to food products).

[344] However, a labeling requirement pursuing the objective of consumer-information would probably have to adopt rather a 0% threshold than a 1% threshold for GMOs. See on this also SWISS ETHICS COMMITTEE ON NON-HUMAN GENE TECHNOLOGY, supra note Error: Reference source not found, at 6.

[345] See supra, subchapter III.2.3.

[346] See supra, subchapter IV.3.6, notes Error: Reference source not found-Error: Reference source not found and accompanying text.

[347] *Id*., notes Error: Reference source not found-Error: Reference source not found and accompanying text

[348] GTG supra note Error: Reference source not found, Art. 30.1, 30.2, 30.4 and Art. 30.7.

[349] Thomas Cottier *Die kanalisierte Gefährdungshaftung für Genetisch Modifizierte Organsimen (GMOs): Beurteilung aas Sicht des internationalen Wirtschaftsrecht*, July 2002, at 3 (on file with the author).

[350] Cottier, supra note Error: Reference source not found, at 12.

[351] The liability rules can not be seen as SPS-measures according to Annex A to the SPS-Agreement, see supra subchapter V.2.3.1, notes Error: Reference source not found-Error: Reference source not found and accompanying text.

[352] GATT, supra note Error: Reference source not found, Art. I and III; TBT-Agreement, supra note Error: Reference source not found, Art, 2. See supra, subchapter V.2.3.2, similar: Cottier, supra note Error: Reference source not found, at 8-9.

[353] Cottier, supra note Error: Reference source not found, at 9-10 indicates however that if GMOs and non-GMOs would be seen as like-products, liability rules could result under very specific circumstances and depending their concrete operationalization in a de facto discrimination of imported goods.

The Swiss liability regulation for GMOs aims at reflecting the specific risks and uncertainties of GMOs, the specific complexity of the underlying causalities and the potential of long time impacts.[354] By holding those who benefit from the specific advantages of GMOs fully responsible for their potential risks and externalities, the distinct liability regime ensures that all measures are undertaken to prevent the materialization of the risks specifically linked to GMOs. Thus, it would have to be seen as either a measure necessary for the protection of humans, animals and the environment or a measure relating to the conservation of exhaustible natural resources.[355] Finally, some elements of the liability scheme such as the extension of the limitation period reflect international standards.[356] It can therefore be concluded that there is no conflict between the Swiss liability rules for GMOs and the WTO-law.

V.2.3.6 The WTO-Conformity of the Precautionary Approach

The Gene Technology Law establishes the precautionary principle as an overarching principle of the Swiss policy on genetic engineering and if there are reasonable grounds for concern that GMOs may cause potentially dangerous effects to humans, animals, plants or the environment proportional precautionary action should be taken despite the uncertainties with regard to the probability of these dangers.[357] As indicated above, the Swiss perception sees no conflict between precaution and the WTO -requirements.[358] Moreover, the WTO-rules do not prevent the application of the precautionary principle: While the SPS-agreement – however not relevant for this area[359] – itself operationalizes the precautionary principle by allowing provisional measures in cases where relevant scientific evidence is insufficient,[360] a flexible interpretation of the "necessary"-requirements of the GATT- and the TBT-Agreements[361] would similarly permit the adoption of precautionary measure. In fact, the precautionary principle precisely reflects the fact that in the light of scientific uncertainty, precautionary measure might be necessary for the protection of the environment.[362] The WTO-Appellate Body, by requiring that WTO-rules must be interpreted "in the light of contemporary concerns of the community of nations about the protection and conservation of the environment", supports such a flexible interpretation that gives way for the precautionary principle.[363] It can therefore be concluded that the application of a precautionary approach as required by the Swiss legislation on GMOs does not create a conflict to the WTO-law.

V.2.3.7 The WTO-Conformity of a possible moratorium

During the parliamentary debate, the introduction of a moratorium for the use of GMOs in agriculture was one of the most fiercely debated issues, and while the parliament finally rejected the inclusion of such a moratorium in the new legislation, the issue is not yet definitively resolved as efforts for the adoption of a moratorium continue both through an initiative for a constitutional amendment and through the revision of the federal law on

[354] See supra, subchapter IV.3.6.
[355] GATT, supra note Error: Reference source not found, Art. XX(b) and (g).
[356] Supra, note Error: Reference source not found and accompanying text.
[357] Supra, subchapter I.1.2 (ii), note Error: Reference source not foundff. and accompanying text.
[358] See supra, subchapter V.1.2.1.
[359] See supra, subchapter V.2.3.1, and especially note Error: Reference source not found and accompanying text.
[360] SPS-Agreement, supra note Error: Reference source not found, Art. 5.7.
[361] GATT, supra note Error: Reference source not found, Art. XX(b); TBT-Agreement, supra note Error: Reference source not found, Art. 2.2.
[362] Perrez, *WSSD*, supra note Error: Reference source not found, at 15 with further references.
[363] The WTO Appellate Body has required that the WTO-rules are interpreted in the light of contemporary concerns for the environment, see WT/DS58/AB/R, § 129. See also Gabrielle Marceau, *A Call for Coherence in International Law – Praises for the Prohibition Against "Clinical Isolation" in WTO Dispute Settlement*, 33 JOURNAL OF WORLD TRADE, 87, 100-102 and 120 (1999); Franz Xaver Perrez, *The Cartagena Protocol on Biosafety and the Relationship between the Multilateral Trading System and Multilateral Environmental*

agriculture.[364] The WTO-compatibility of a moratorium was put on the forefront of the GMO-debate when the US has initiated a dispute settlement procedure against the EU on its de facto Biotech moratorium.[365] However, it is important to note that the moratorium on GMOs discussed in Switzerland concerned a totally different issue: while the Swiss moratorium would have prohibited the use of GMOs in agriculture for a certain limited time-period after which the issue would be re-assessed and would not have concerned the use of GMOs in other areas or the importation of GMO food products, the EU's de facto moratorium concerned the suspension of approvals of new agricultural GMO-products pending the adoption of rules ensuring labeling and traceability of GMOs.

In order to assess the WTO-compatibility of a moratorium for the use of GMOs in agriculture as it was and still is discussed in Switzerland, the motivation of such a measure must have to be analyzed. The main reason put forward in favor for the introduction of such a moratorium was that a GMO-free agriculture can only be assured in Switzerland if there is a general prohibition of using GMOs in agriculture. This is because given the small geographic situation in Switzerland, once the use GMO-seeds is allowed, cross-pollination will be inevitable and it will be impossible to maintain GMO-free production. [366] Moreover, it was also argued that such a moratorium would give the time necessary to better understand the impacts of GMOs on the ecosystems.[367] Similarly, the Swiss Ethics Committee on Non-human Gene Technology favored on a moratorium to allow time to think about ethical issues of genetic engineering and its role on the market.[368] This motivation makes it clear, that such a moratorium would not be a sanitary or a phytosanitary measure and thus would not fall under the SPS-Agreement.[369]

The effect of the discussed moratorium for the use of GMOs in agriculture would be that no GMO-seeds could be sold in Switzerland. The effect of this prohibition could be seen as a quantitative restriction of imports of GMO-seeds into Switzerland.[370] However, the WTO was not created in order to impose a certain method of agriculture or technology on a country, but to prevent protectionism. Thus, if a country would decide to prohibit use of cars or the growing of carrots, it would not be the aim of the WTO to impose the use of cars or the growing of carrots in that country. The WTO is about trade, not about internal traffic or agriculture policy – as long as such internal policy does not have a protectionist effect. Therefore, the WTO-compatibility of a moratorium would not have to be assessed as a potential prohibition of quantitative restrictions but as a potential discrimination of like products.[371] However, as indicated above, in Switzerland, GMOs are not seen as like products.[372] And the moratorium would concern both imported and Swiss GMO seeds. Moreover, as such a moratorium aims at protecting GMO-free crops from crosspollination, it would be permitted under WTO law as a measure necessary for the protection of plant life or relating to the conservation of exhaustible natural resources even if GMO seeds and traditional seeds would be seen as like products.[373]

V.2.3.8 WTO-Compatibility of the Swiss GMO-legislation

Agreements (MEAs), RSDI 10/4, 518, 523 and 524-525 (2000).

[364] See supra, subchapter IV.1.3, and notes Error: Reference source not found-Error: Reference source not found, Error: Reference source not found, and accompanying text.

[365] See e.g.: *US takes next step in EU Biotech Challenge*, BRIDGES 7/23 of June 25, 2003. See generally: www.ictsd.org/issarea/environment/biotech_case.htm, last visited October 7, 2003.

[366] *Gentechnik: Keine Koexistenz*, DER BUND, September 19, 2002. See supra, subchapter III.2.2.2, and note Error: Reference source not found.

[367] *Fünf Jahre Moratorium*, in: DER BUND, June 1, 2002.

[368] Daniel Amman, *Moratorium, der Weg aus dem Dilemma*, SAG, August 2002

[369] See supra subchapter V.2.3.1, notes Error: Reference source not found-Error: Reference source not found and accompanying text.

[370] GATT, supra note Error: Reference source not found, Art. XI.

[371] GATT, supra note Error: Reference source not found, Art. III.4

[372] See supra, subchapter V.2.3.2.

[373] GATT, supra note Error: Reference source not found, Art. XX(b) and XX(g).

The debate on the WTO-compatibility of different approaches to GMOs is often too much dominated by ideological and emotional arguments. However, in order to assess the WTO-compatibility of any legislation, three basic core-principles should never be forgotten: First, the WTO is concerned at ensuring an open, transparent and non-protectionist market – therefore, WTO-member states have the primary obligation to ensure that their legislation does not pursue protectionist goals. Second, the WTO does not aim at imposing environmental standards or priorities – therefore, all WTO member states have under the WTO the full right to adopt the level of environmental protection that they deem to be appropriate and that reflects their priorities and values. Third, by providing for an open, transparent and competitive market in which resources are used according to the preferences and priorities of consumers, the WTO pursues to promote the well-being of all – therefore, the WTO should not be misused as in instrument to impose its values and its preferences on others, and it should especially not be misused as a tool to oblige consumers to buy products that they don't want. Hence, one has to conclude that the Swiss regulation, by assuming that GMOs and non-GMOs are not like products, by differentiating between GMO- and traditional food according to their un-likeness only in order to serve legitimate objectives such as the protection of the environment and human health, the prevention of deceptive practices or the information of consumers necessary to enable a transparent and effective market, by basing such differentiation on sound science, and finally by being transparent and non-discriminatory between states, the Swiss regulatory approach also fully reflects the existing international obligations under WTO-law.

VI. CONCLUSIONS

This case study has given an overview of the Swiss regulatory approach to genetic engineering in the non-human area. After a short introduction to Switzerland and its regulatory and political system, we have presented the major actors, values and interests involved in Switzerland's GMO-policy making. We have then given a brief synopsis of the history of the Swiss GMO-regulation, which can be structured in three phases: the phase up to the first constitutional referendum in 1992 which led to the adoption of a constitutional amendment that protects humans and the environment from misuses of genetic engineering and that requires specific legislation for the protection of humans, animals and the environment, the genetic diversity of animal and plant species and the dignity of living beings. This first period also led to the adoption of first labeling and approval requirements for GMOs. During the second phase, the legislation on GMOs was further developed, and it culminated in a second constitutional referendum in 1998 which rejected a proposal for a constitutional amendment which would have banned genetic engineering to a large extend. Finally, the third phase lead to the adoption by the parliament of a comprehensive package of legislation on genetic engineering in March 2003. We have then presented this Swiss GMO-legislation in more depth and further discussed specific issues such as the question how Switzerland deals with the risks of GMOs under uncertainty and the international aspects of the Swiss GMO-legislation.

This analysis of this case study has shown that six main elements have shaped and are reflected in the Swiss regulatory approach to GMO:

1) The perception that GMOs are not substantial equivalent to non-GMOs but substantially different: Genetic engineering, that enables for the first time to cross the genetic borders of species, is seen in Switzerland as a new technology that constitutes a fundamental break with traditional technologies. At the same time, GMOs and non-GMOs are seen as unlike products.[374] Genetic engineering and GMOs raise therefore new and specific questions and challenges that need specific regulation.[375]

2) The perception of genetic engineering primarily as an environmental issue involving specific risks and not as a trade issue: Genetic engineering and GMOs are seen as involving specific risks for human, animal and plant life and risks for the environment, the balance of ecosystems and biological diversity. On the other hand, the importation of GMOs is not seen as a threat to Swiss producers. Because genetic engineering is seen primarily as an environmental issue and not as a trade issue, the Swiss government tasked the Swiss Agency for the Environment, Forests and Landscape and not the competing State Secretariat for Economic Affairs with the preparation of the new legislation on genetic engineering.

3) The perception of new risks involving scientific uncertainties: Genetic engineering is perceived in Switzerland as a novel issue involving new and not yet fully understood risks and challenges. It is generally understood that these novel risks are not yet well understood and that therefore caution and precaution are necessary.[376] There is general agreement that further research has to be undertaken until these new risks and challenges are better understood. At the same time, a concept of absolute security is clearly rejected.[377]

[374] See supra, subchapter V.2.3.2.
[375] See e.g. Stand Gesetzgebung, supra note Error: Reference source not found, at 1651.
[376] See supra, subchapter V.1.2.2.
[377] Stand Gesetzgebung, supra note Error: Reference source not found, at 1676.

4) The perception that genetic engineering and GMOs involve specific ethical values and questions: Genetic engineering is seen as a technology that raises fundamental ethical questions. In order to ensure that basic ethical values are respected, specific provisions and mechanisms such as the obligation to respect the dignity of living beings or the establishment of an Ethics Committee were adopted.[378]

5) Strong rejection of genetic engineering in the food sector and high acceptance in field of medicine and pharmaceutics:[379] While the Swiss consumers generally reject GMO food products and therefore want to be in a position to buy GMO-free food products, they feel much more positive about the use of genetic engineering in the field of medicine and pharmaceutics. One reason may be that the functioning of human body is much better understood than the functioning of ecosystems. Another important reason relates to the balance of values and interests involved. The interest to a safe life through effective medicine is valued much higher than the interest in more efficient agriculture. And food products containing GMOs are not seen as enhanced but as inferior as compared with traditional product that are perceived as more natural and thus also healthier.

6) The acceptance of the right to be informed and to have the freedom of choice: Because of the concerns about safety and impact, the concern to be informed whether a product is produced through genetic engineering has emerged as a "new" consumers' concern.[380] At the same time, producers and industry do not perceive the requirement to provide consumers with the desired information as problematic – in fact, they argue that they do not want to produce products that consumers do not want to buy and they therefore accept labelling requirements as an effective tool to ensure the freedom of choice as long as no unnecessary obstacles are created.[381]

By analysing the Swiss regulation in its political and socio-economic context, this study reflects the fact that two characteristics of Switzerland strongly influence its approach to genetic engineering and to GMOs. First, its participatory political system that ensures through several institutional characteristics that any legislation has to take into account and reflect the major different interests involved.[382] Secondly, despite its small size, numerous seemingly conflicting interests on GMOs have an important constituency in Switzerland:[383] thus, Switzerland has a strong pharmaceutical industry and Switzerland is a leading country in the area of medical research; Switzerland also hosts important biotechnology, chemical and seed industries; the Swiss farmers want to be able to produce in a most cost-efficient manner products that the consumers will buy; retailers and distributors want to avoid unnecessary technical and financial obstacles and trade barriers; consumers have an interest in effective medicine and a high food quality, and they want to be informed about what they are going to buy in order to make a choice according to their preferences; consumers also have developed interests in process and production methods of the products; there is a general desire to ensure an adequate protection of the environment and of human, animal and plant health; the respect of ethical values is seen as important; and finally, the respect of international obligations, especially with regard to the international trade and environmental regimes, is seen as crucial for a small country like Switzerland. Switzerland's approach to genetic engineering and to GMOs tries to reflect and bring together all these different interests and values.

[378] See supra, subchapters III.2.4.1, IV.3.2 and IV.3.3.
[379] See supra, subchapters III.2.3 and IV.1.2.
[380] See supra, subchapters III.2.4 and IV.1.2.
[381] See on this generally: De Greef, supra note Error: Reference source not found, at 582.
[382] See supra, subchapters II.2.4 and IV.3.7.2.
[383] See supra, subchapters III.1 and III.2.

This study has shown that the issue of genetic engineering in general and GMO food in special includes numerous environmental, ethical, developmental, economic, pharmaceutical, medical, scientific, and consumer concerns. All these interests, opportunities, fears, concerns and considerations establish the political framework of any regulator and of every government. Because the Swiss population directly influences the political process, the Switzerland's GMO-legislation had to respond to these interests and concerns – in fact, any regulation that does not adequately reflect these concerns would be challenged and rejected in a popular referendum. We believe that the Swiss approach, by brining together and integrating the concerns of producer and consumers, of industry, science and ethics, and of trade and environment, could therefore serve as a valuable stimulant for the international community in its search for a fair, democratic, and effective approach to GMOs.[384]

[384] Concerning lessons that can be learned from the Swiss experience on GMO-legislation, see generally: Perrez, *Taking Consumers Seriously*, supra note Error: Reference source not found, at 604.