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## TRADE, THE ENVIRONMENT AND THE INTERNATIONAL REGULATION OF BIOTECHNOLOGY

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## Executive Summary

The purpose of this review article is to provide an overview of the research carried out by a small group of researchers at the Faculty of Law of the University of Geneva from 2001 to 2004, which benefited from cooperation with the Swiss Agency for the Environment, Forests and Landscape. In view of the rapid scientific, technological and legal developments in the realm of agricultural biotechnologies it is not surprising that the focus of the investigation has shifted somewhat during the research. Our research has taken into consideration new rulings of the WTO Dispute Settlement Body (DSB) which have an impact on the regulation of biotechnology as well as the ongoing negotiations under the WTO's Doha Round, at the Cartagena Protocol on Biosafety, and at the Codex Alimentarius.

This research has furthermore received a major input from three scientific Roundtables organized by the Faculty of Law. The topic of the first one was risk assessment with regards to GMOs (January, 2002). The discussions were focused on the Biosafety Protocol's contributions to risk assessment and on its complex relationship with the WTO's agreements and jurisprudence. The Biosafety Protocol does not really differ from the WTO in its scientific approach to risk assessment except that in both the assessment and the management of risk it contains provisions regarding the application of the precautionary principle. At the same time it leaves open or subject to further negotiations several issues such as liability and redress, labelling, compliance, socio-economic considerations, or the acceptance of risk.

The WTO has made rulings which are important for the development of international biosafety regulations, e.g. the 1998 *EC-Hormones* which observes that the precautionary principle "finds reflection" in the much-cited Article 5.7 of the Agreement on Sanitary and Phytosanitary Measures (SPS), and the 2000 *EC-Asbestos* case which allows the consideration of minority scientific opinions for determining the acceptable level of risk. At the same time it has stepped back from the more flexible approach of the Biosafety Protocol by insisting on a rather artificial distinction between a qualitative possibility and a quantitative probability of risk in the 1998 *Australia Salmon*s. In the same vein it has introduced another questionable distinction between scientific uncertainty and the insufficiency of scientific evidence in the 2003 *Japan-Apples* ruling. A key difference between the provisions of the Biosafety Protocol and of the WTO Agreements refers to risk management: the Protocol contains an Article with several provisions describing an acceptable risk management process, whereas the WTO agreements are silent on this crucially important question. This Roundtable has prompted us to investigate the overlapping, interdependent and iterative relationship between risk assessment and risk management.

The second Roundtable focused on the Codex Alimentarius and its positioning between the promotion of fair trade practices and the protection of food safety (June 2002). The Codex turned out to be a very fruitful case study of the nature, the role and the importance of internationally harmonized standards because of the vast economic importance of food trade which it regulates, and because of the fact that it is explicitly recognized by the WTO's SPS and indirectly by the TBT Agreements. Furthermore, it is particularly interesting for this research project because both the Codex and the Protocol cover the regulation of trade in raw genetically modified food but these two jurisdictions are not synchronized with each other.

The Codex is closely related in spirit to the SPS Agreement thanks to its heavy reliance on scientific risk assessment with relatively detailed and highly procedural provisions. On the other hand some of the unresolved issues are the same in Codex and Protocol, especially the politically thorny question of the labelling of GM food which is considered to be misleading and unnecessary by the US but necessary by most other countries, especially in Europe where adequate information on all products, particularly food products, are considered an unalienable consumers' right. The Codex traditionally emphasizes truthfulness and commercially relevant information in its labelling whereas the Protocol has gone a step further by introducing a temporary solution which stipulates that packages containing raw GM food or feed crops for must be labeled as "may contain" living modified organisms. The Codex has not found a solution yet on the two very divisive issues of GM labelling and of precautionary trade restrictions.

The third Roundtable in March, 2003, focused on the impact which the only two pertinent rulings of the WTO so far had on the status of the Codex Alimentarius. In spite of the acknowledged fact that after more than forty years of activity the Codex is the most important collection of food standards its legitimacy is not undisputed. Its legal standing, however, has undoubtedly been enhanced thanks to the WTO's rulings in the 2003 *EC-Sardines* case which confirmed its stature in international trade law. The repercussions of the *EC-Hormones* dispute, however, have not only failed to change the position of the European Union (it continues to outlaw domestic as well as imported beef with raised with growth hormones and prefers to pay a fine to the US and Canada), they have shown the difficulties and the political resistance toward a risk assessment and risk management process based strictly on scientific evidence in complete isolation from other deep-rooted societal considerations.

To conclude, this research project on the legal ramifications of import restrictions and of trade law with regard to genetically modified products has contributed a number of publications on the implications and limits of scientific evidence in the presence of complex, diffuse and scientifically not adequately explained risks to biodiversity and to certain aspects of food safety. The presently established relationship between on one hand the complexities of risk assessment and risk management regarding threats to biodiversity and certain aspects of food safety, and on the other hand the relative simplicity of import restrictions allowed under WTO agreements based on traditional science-based risk assessment procedures is becoming more and more difficult to maintain. It does not take into consideration the nature of recent scientific discoveries and processes. We conclude that the international community needs to arrive at a reconciliation of principles, rules, standards and procedures which have been negotiated under disparate legal frameworks with often divergent objectives. We can see a wide consensus over the need to work toward the twin notions of mutual supportiveness and legal agreements that pay deference to each other in their respective domain of authority such as biodiversity and trade in the cases of the Biosafety Protocol and the WTO. Our research shows that this objective is not only legally coherent but also politically legitimate and realistic.

## CHAPTER 1: THE GENERAL FRAMEWORK

This report represents an overview of a three year research project at the Faculty of Law of the University of Geneva which benefited substantially from cooperation with the Swiss Agency for the Environment, Forests and Landscape, and the Swiss Federal Office of Public Health. We have focused on a particular angle of a subject area that is called 'trade and environment,' and which in turn represents one of the most important sectors of wider societal concerns that are usually termed 'non-trade issues' within the trade community. The international regulation of trade in genetically modified (GM) food and or organisms (GMOs) is at the center of our investigation. We have essentially used two tracks: on one hand we have been guided by the academic research in trade and environment as well as by the multilateral negotiations in this field. Here we have in particular followed the discussions and negotiations at WTO's Committee on Trade and Environment (CTE). On the other hand we have analyzed those rulings of the WTO's Dispute Settlement Body (DSB) which have a bearing on phytosanitary, zoosanitary or on environment-related food safety questions, and which often contain scientific controversies and uncertainties.

It should be noted that the DSB consists of so-called Panels and of the Appellate Body. The Panels comprise three members who are nominated on an *ad hoc* basis according to procedures spelled out in the WTO's Dispute Settlement Understanding (DSU).<sup>1</sup> An appeal can be made to the Appellate Body (AB) whose seven members are appointed for four years with the possibility of one reappointment. Three members of the AB serve for each case, their competence is "limited to issues of law covered in the panel report and legal interpretations developed by the panel,"<sup>2</sup> in other words the fact finding process of the Panel is final and cannot be appealed under WTO law.

Scientific uncertainties and methods of risk assessment and management are more and more entangled with trade topics and with wider societal concerns like protectionism, national sovereignty, precautionary measures, and the interactions between science, technology and law. This research has given us the opportunity to conduct an in depth exploration of the very complex and disputed ramifications and implications of precautionary measures in environmental and in trade law.

The objectives of the liberalization of goods and services and of the development of international economic exchanges have been strongly supported by the ratification of the WTO agreements: trade liberalization in this framework is considered to be beneficial for all WTO member countries. Nevertheless, these same agreements provide certain opportunities to national governments to regulate these trade flows in order to avoid negative externalities. Art. XX of the GATT 1994 Agreement represents the general model for such exceptions. The Agreements on the Application of Sanitary and Phytosanitary Measures (SPS) and on Technical Barriers to Trade (TBT) aim in the same direction, they provide governments the right to impose, under very specific conditions and modalities, certain more specific trade restrictions especially with regard to environmental and public health concerns.

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<sup>1</sup> Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), *The Legal Texts*, WTO (Reprinted as needed by Cambridge University Press).

<sup>2</sup> DSU Art. 17.6.

## **1.1. WTO Agreements and Multilateral Environmental Agreements**

The governments who have become members of the WTO are in most cases the same ones who have signed the major Multilateral Environmental Agreements (MEAs). It stands to reason therefore that one should be able to expect a certain *coherence* among these different kinds of agreements, especially since in both cases the objective of *sustainable development* is usually explicitly stated at least in the preamble of the agreements. It should therefore be possible to make these agreements not only compatible but mutually supportive. Unfortunately, as we shall see, this goal is very difficult to achieve in the real world of politics. The fact that different ministries have negotiated the trade and the environmental regimes have resulted in agreements whose coherence is far from obvious. We have focused our research on the WTO's SPS, TBT and GATT 1994 Agreements, and on the environmental side on the Cartagena Protocol on Biosafety to the Convention on Biological Diversity which is often called the Biosafety Protocol (BP). Furthermore, we have looked at the contribution of the Codex Alimentarius with regard to its mandate in the regulation of GM food.

It should be noted that trade and environment agreements may have similar general goals such as protecting the environment, promoting sustainable development, conservation and sustainable use of natural resources, or emphasizing the need for economic growth, especially for developing countries. These goals may not be specific but they nevertheless have entered the WTO's jurisprudence or case law as a criterion to be taken into consideration.

The relationship between the trade agreements and the BP is particularly interesting in this regard because the latter provides justifications for import restrictions for reasons which are related to the presence of risks. Risk assessment is indeed one of the areas where divergences between trade and environmental agreements may become manifest. The BP provides more detailed procedures on risk assessment than the WTO agreements in spite of the fact that the evaluation of risk is of great importance in the trade regime. There are no plans presently, however, to attempt to negotiate a conceptual harmonization of these procedures. Another problem for which solutions need to be found on a case by case basis due to a lack of relevant provisions may occur in a dispute where one party has ratified both agreements and the other didn't, i.e. most likely where the Multilateral Environmental Agreement was signed only by one of the parties. As we shall see, this question is particularly important in the case of a dispute over import restrictions on GMOs because the United States has not ratified the Cartagena Protocol – to be able to do so it would first have to ratify the Convention on Biological Diversity.

## **1.2. WTO Agreements and National Environmental Legislation**

Risk assessment plays a key role in the determination of restrictions that WTO members may introduce, especially on the basis of GATT Art. XX and of the SPS Agreement. The relevant domestic law in this case refers to the protection of natural resources and biological diversity. Specific legislation referring to GMOs usually reflects the concern that these resources need to be protected, not to mention in a more general sense global public goods or the global commons. WTO law allows national legislators to institute exceptions to the obligations which are part of the

trade agreements in the case of environmental protection as long as they respect the principles of non-discrimination and of proportionality. Art. XX of GATT thus allows trade measures which protect human, animal or plant life or health, and which relate to the conservation of exhaustible natural resources. The TBT Agreement also allows the domestic implementation of voluntary standards and mandatory technical regulations for essentially the same objectives. The SPS Agreement finally provides explicitly for the right of an importing country to establish sanitary and phytosanitary measures to protect the health and life of humans, animals and plants provided they fulfil strict scientific risk assessment procedures. In Annex A the SPS Agreement spells out definitions, and it specifies the international standards which are to be used for a global harmonization of these measures.<sup>3</sup>

The definition of the protected goods does not seem to be problematic. As far as the environment is concerned, this notion needs to be understood in a broad sense, and it needs to take into consideration the evolution of knowledge in this matter. One may undoubtedly conclude that this protection goes beyond the protection of some specific species such as sea turtles or tropical trees, and specific ecological habitats such as coral reefs or glaciers; rather, this protection should be seen as covering broader ecological concepts such as biodiversity or the respect of animals' needs.

Domestic legislation may restrict or in some cases even ban the circulation of certain goods for reasons or circumstances which are not necessarily accepted under the provisions of WTO agreements, jurisprudence, or decisions as they presently stand. Such cases include goods whose process or production method or whose composition may threaten the environment, or they may represent an environmental threat outside the national borders of the country that takes such measures. All these cases constitute technical barriers to trade. More specifically, as far as process and production methods (PPMs) are concerned, we distinguish between those which are product-related, i.e. which determine the characteristics of the product (e.g. organic food), and those methods which cannot be detected in the product itself (e.g. the method of catching a fish). The first category of PPMs are indeed accepted by the stipulated exceptions under WTO law, whereas the latter category is more problematic. Nevertheless they can be considered to be included in the responsibilities of a national government with regard to the stewardship of global public goods such as the Ozone layer or sustainable climate patterns. The various rulings of the DSB at this time do not allow us to draw a comprehensive conclusion regarding these questions.

Nevertheless, the DSB has already been faced with the challenge of ruling on disputes which may be compared with the presently ongoing dispute over GMOs (*EC-Biotech*) either under the general exceptions of GATT Art. XX or under [the SPS and TBT Agreements](#). It is clear from these rulings that the DSB attaches particular importance on one hand to the kinds of risk evaluation methods that it considers to be 'scientific,' and on the other hand to the reference of those international standards which it has explicitly accepted. Furthermore, the *necessity* of a restriction to protect human, animal or plant life or health must be clearly demonstrated.<sup>4</sup> It should be

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<sup>3</sup> SPS Annex A, Definitions, 3. International standards, guidelines and recommendations

a) for food safety the Codex Alimentarius Commission, b) for animal health the International Office of Epizootics, c) for plant health the International Plant Protection Convention, d) for other matters relevant international organizations which are open to all members and which have been identified by the SPS Committee.

<sup>4</sup> GATT Art. XX b).

noted that this so-called 'necessity test' is relatively difficult to fulfil, and it is not required for measures that aim at the conservation of living and non-living exhaustible natural resources provided they are non-discriminatory.<sup>5</sup> The purpose of both conditionalities is to prevent measures which are imposed not for environmental but for hidden protectionist reasons. As far as new issues like GMOs are concerned it is not easy, however, to fulfil the requirements of the WTO agreements because this new kind of trade regulations tends to have several objectives which include the prevention of losses in biodiversity, informing the public adequately, or the preservation of traditional farmers' rights and livelihood.

### **1.3. Agricultural Biotechnologies: Risk Assessment and Precaution**

#### *Risk Assessment*

GMOs, or Living Modified Organisms (LMOs) as they are called in the Biosafety Protocol, are treated like any other good under the WTO agreements. Their analysis in the context of the relevant agreements therefore depends on their characteristics from an environmental perspective: are they a specific kind of products, or are they just ordinary products with a specific function (e.g. containing integrated pesticides)? The qualification and categorization of these goods determines certain important legal questions. The discriminatory nature of a trade restriction indeed depends on the question whether GMOs are to be considered as a distinct category of goods or simply as a variety of existing ones such as Soya, wheat, canola, cotton etc. The answer to the delicate question whether GM and conventional products are to be considered as so-called 'like' products under GATT Art. III will be a key element in determining the WTO compatibility of restrictive measures. Some of their characteristics will undoubtedly determine the outcome of this presently undecided issue:

- These organisms have been modified in a way which does not occur spontaneously in nature. They are defined as follows: "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."<sup>6</sup>
- They have the capacity of transferring or replicating genetic material.<sup>7</sup>
- Their interactions with their conventional counterparts and with other species in the same ecosystem are only partially known.

The consequence of these characteristics is that in spite of the ongoing risk assessment efforts there continues to be a considerable margin of uncertainty regarding an exhaustive risk assessment and regarding the adequacy of the available scientific methodologies. Furthermore, it is not established whether a certain GMO will behave the same way in a different ecological context and in the presence of different species. It is not surprising, therefore, that national regulations vary considerably. They vary from a straightforward prohibition of all GM plants and products on one end of the spectrum to the denial of any specificity attributed to

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<sup>5</sup> GATT Art. XX g).

<sup>6</sup> Cartagena Protocol on Biosafety, Art. 3 g), Use of Terms

<sup>7</sup> *Ibid.* Art. 3 h).



these products which might allow a differential treatment. The diversity of these approaches has contributed to the perception of a need to negotiate a harmonized regulation of risk assessment under the Biosafety Protocol.

Modern biotechnologies are generally characterized by a relatively high level of uncertainty due to the fact that they are not only still quite new but also due to the fact that their impact on the ecosystem once they have been released into nature is very diverse. Furthermore, WTO law does spell out the need for scientific risk assessment but it doesn't provide any indications as to what ought to be done with the results of these investigations. In the *EC-Hormones* dispute which was based on the application of the SPS Agreement, the Appellate Body limited itself to a procedural approach towards scientific uncertainty which concluded that the EC failed to carry out the burden of proof. Furthermore, the AB doesn't seem to distinguish between a failure to furnish sufficient proofs, and a failure resulting from the fact that there is no specific scientific knowledge available in a given domain.

### *The Precautionary Principle*

The Biosafety Protocol provides an answer to the problem of scientific uncertainty through the application of the precautionary principle. This principle represents a framework of policy and law which provides decision makers with the conceptual tool for an intervention in situations that are characterized on one hand by the absence of scientific certainty, and on the other hand by serious indications of danger to a good that must be protected. The burden of proof which justifies such an intervention lies with the government which implements a policy of precaution, it has to demonstrate the absence of scientific certainty and the presence of a serious danger. The Biosafety Protocol, which has been created as a response to the specific risks that can result from genetic modification, has designated precaution as the most appropriate response to the problem of the uncertainties which characterize this domain (this may be either in the form of a general acceptance of the precautionary 'approach' or else in the form of a principle of customary law). Precaution's compatibility with the WTO agreements in justifying import restrictions on GM products needs to be established in the context of those WTO provisions which spell out the exceptions to the obligations that WTO members have signed on to. This WTO compatibility thus depends on the recognition of the specific character of risk assessment with regards to transgenic biotechnologies.

In its ruling on *EC-Hormones* the Appellate Body has refused to examine the legal nature of the precautionary principle, it found it to be incompatible with the SPS provisions that refer to scientific analysis as the only admissible basis for import restrictions. We may, however, have some doubts about the degree of this contradiction because a scientific investigation may well lead us precisely to the limits of the scientific knowledge available at a given time. Thus the scientific investigation should pinpoint the uncertainties for which a solution needs to be found. It should be noted that the recognition of an uncertainty is just as scientific as the recognition of the existence of a risk or a danger. This is the point where the SPS Agreement does not have any answers to offer to the dilemma of scientific uncertainty, and where it would be natural for the trade law to be guided by an environmental law which was developed specifically to resolve the problems caused by GMOs, i.e. the Biosafety Protocol.

## **CHAPTER 2: GMOs, RISK ASSESSMENT AND WTO LAW**

### **2.1. The Foundation of GMO Regulation: WTO Law**

Recent developments in the scientific research, in the production and in trade flows of GM crops are at the origin of more and more intense debates. It is difficult, under these circumstances, to design, to negotiate, and even more to regulate these exchanges. Nevertheless, the question is of greatest importance since there is a wide agreement that the life sciences and biotechnology constitute, together with information technology, the foundation of the next wave of the knowledge economy. Every country and every region therefore is facing a major political choice: either it accepts a passive and reactive role which will force it to simply adjust to developments in these technologies in other regions, or it develops and implements proactive legal policies with a view to apply and exploit these technologies in a responsible fashion respecting the values and principles which underpin every society. These options and choices obviously will leave their imprint on the national outlook and on governments' understanding of their national interest regarding desirable science and trade policies.

In a geopolitical perspective, we can observe that the development of biotechnologies has resulted in the emergence, starting in the 1980s, of new fracturing lines which increasingly shape the international community. The question of access and benefit sharing with regards to plant genetic resources tends to oppose the global North from the global South. The use and the international regulation of biotechnologies has created different and more complex dividing lines. The confrontation here is played out primarily between the United States which pushes strongly for free trade policies in this area, and the European Union which is reluctant to open up its borders to this trade and insists on the principle of the consumers' right to information. Developing countries on the other hand find themselves in a difficult position, among other reasons because some of them have to develop policies which take into consideration their interests both as importers, as recipients of (American) food aid, and as exporters or potential future exporters. On the whole, they are worried in particular of the socio-economic consequences of the development of agricultural biotechnologies (Maljean-Dubois, 2002).

The United States and the European Union have adopted completely opposed biotechnology policies. US firms have made a strategic choice to invest heavily in research and development of GM crops over the past twenty years. This choice and the resulting domination of world-wide markets in GM crops go hand in hand with the government's generally very supportive policies. As far as the regulation of trade in GM products is concerned, the US government considers that they have to be dealt with as with any other goods under the WTO agreements. Furthermore, since the US has not ratified the Convention on Biological Diversity (CBD) it cannot be a party of the Biosafety Protocol either.

The European Union's strategy is less straightforward, the regulatory responsibilities are shared among various bodies or regulatory frameworks as is the case with other commercial sectors. These questions are dealt with rather prudently, the EU hesitates to take a clear position with regard to these new technologies because its members have diverse opinions like in many other domains. It has adopted in 1990 two Directives which provide a quite strict framework for research

and distribution. More recently the legal conditions have been further tightened through the Directives 2001/18 and the Regulation 178/2002 based on case by case evaluative provisions, and on the dominant legal tradition which emphasizes controls through a scientific assessment of potential dangers.

## **2.2. Potential and Latent Conflicts between the Biosafety Protocol and the WTO**

### *Is the Biosafety Protocol Applicable under the Trade Regime?*

Even though trade in GM crops in principle is governed by the WTO agreements like any category of goods, there is no doubt that the application of the specific modalities is complex due to the diversity of GMOs, the risks that they carry, the trade measures that might be applied to regulate their importation, and due also due to the complexity of the relevant WTO agreements. Three agreements can potentially be applied on trade in GMOs: TBT, SPS and GATT 1994; furthermore, to complicate the legal picture, it is not really clear how these three agreements interact with each other in the case of trade in GM products. In view of the very demanding conditions which must be fulfilled under the SPS Agreement to justify a trade restriction, it would seem that an importing country's strategy would be to attempt to shift the dispute under the TBT or GATT 1994 Agreement. In the year 2000 already a first GM-related complaint was launched at the WTO by Thailand against Egypt which wanted to ban the importation of canned Tuna that it suspected to be packed in GM Soya oil.<sup>8</sup> This dispute, however, was settled out of court. More recently, a much expected dispute was triggered when the US asked for the establishment of a Panel to rule on the WTO compatibility of the EU's *de facto* moratorium on GMOs. This *EC-Biotech* dispute has been launched formally in May 2004 through the request for consultations on this issue by the US, Canada and Argentina who consider this *de facto* moratorium, in force since 1999, to originate in protectionist objectives rather than in concerns over the public health of its consumers or its environment.<sup>9</sup>

This or other conflicts over GMOs may well result in a ruling that can be considered as legally inextricable in the sense that the WTO agreements and the Biosafety Protocol might be considered as incompatible. This would represent a serious legal dilemma that could hurt the credibility and legitimacy of the international regulation of trade in GMOs. It should be noted that the complementarity between the WTO and the Biosafety framework is by no means legally established. The DSB in fact is reluctant to systematically refer to conventional and customary international law since the WTO agreements constitute a *lex specialis* with regard to general international law. This status of a *lex specialis* within the body of international law and the corresponding restricted focus given by the trade ministers to the DSB, however, need to be placed in their right legal context. The DSB has solemnly ruled in its very first case *US-Gasoline*<sup>10</sup> that one must not read WTO law in clinical isolation from public international law. The DSB is therefore by no means a hermetically closed system that would be hostile to the general international law (Marceau, 1999: 99).

<sup>8</sup> *Egypt – Import Prohibition on Canned Tuna with Soybean Oil*, Request for Consultations by Thailand, WT/DS205/1 (27 September 2000).

<sup>9</sup> *European Communities – Measures Affecting the Approval and Marketing of Biotech Products (EC-Biotech)*, Request for Consultations by the United States, WT/DS291/1 (20 May 2003).

<sup>10</sup> DSB Report dated 29 April, 1996, WT/DS2/AB/R, p. 19

The Biosafety Protocol, as we have seen, explicitly declares in its preamble that the rights and obligations of a party under other international agreements, meaning primarily the WTO, remain unchanged. This opens the door to the Protocol's applicability in a related dispute unless the DSB - in spite of the above - limits its analysis to WTO law. One way to bring the BP into a ruling might be under Art. 13.1 of the Dispute Settlement Body which gives Panels, under certain conditions or formalities, "the right to seek information and technical advice from any individual or body which it deems appropriate." Thus a Panel may seek guidance from international jurisdictions or international organizations in the evaluation and interpretation of other international instruments.

There are some doubts, however, regarding the value and the importance of such advice or information. Thus the AB has commented in *US-Shrimps* that the right of a Panel to seek information and technical advice is very general, it includes not only the *source* of such information and its evaluation, it includes also the right not to seek any such guidance at all.<sup>11</sup> Furthermore, a Panel is entitled to accept or to reject any information or advice that it may have asked or received, or it may handle it in any other appropriate form.

Furthermore, there is another strictly legal reasoning which may provide the Biosafety Protocol with a firm grounding in a WTO dispute. The AB has ruled in *US-Shrimps* that sea turtles are highly migratory and their protection therefore requires the concerted cooperation of many countries whose boundaries they cross during their periodic migration. The necessity to undertake such efforts has been recognized by the WTO as well as in a considerable number of other international instruments. For instance in the above case it stresses that to the extent possible, preference should be given to multilateral agreements.<sup>12</sup> For example, Principle 12 of the Rio Declaration declares that "Environmental measures addressing transboundary or global environmental problems should, as far as possible, be based on an international consensus."<sup>13</sup> The Biosafety Protocol clearly fulfils these conditions, it is the result of multilateral negotiations on the sensitive subject of trade regulations regarding GM crops. As a consensus instrument it provides a strong incentive against a unilateral approach in the protection of the environment, thus fulfilling in this regard the goal of the WTO as well as of other international organizations.

### *Is the WTO the Appropriate Forum for the Settlement of Disputes over Trade in GMOs?*

The Appellate Body so far has not taken a position on the legal value of a Multilateral Environmental Agreement (MEAs), such as the Biosafety Protocol, in a WTO dispute (Brown Weiss and Jackson, 2001: 30-32; Bernasconi-Osterwalder, 2001). Even though the AB does exhort members to negotiate MEAs, it remains particularly silent on the weight of such agreements in a situation where they allow trade restricting measures in order to protect the environment. As a matter of fact this is precisely the legal void which was criticized in the above case by the representative of Hong Kong, China who pointed out that there is still no answer to the question under which

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<sup>11</sup> *US-Shrimp*, Report WT/DS58/AB/R dated 12 October 1998, para. 104.

<sup>12</sup> *Ibid.* Para. 168.

<sup>13</sup> Rio Declaration on Environment and Development, 1992

<http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm>

circumstances and criteria trade restrictions in an MEA are considered to be fully WTO-compatible.<sup>14</sup>

We have to conclude that the WTO agreements do not really recall the metaphor of a mosaic (Carreau et Julliar, 1998) whose elements form a cohesive and complete image. As Boisson de Chazournes and Mbengue (2002b:189) point out, a more appropriate image for the trade agreement would be a *puzzle* within which the trade and environment pieces are fitting just loosely and need to be better integrated with the remaining pieces. Furthermore, they judiciously add an observation that is very often overlooked, namely that the Dispute Settlement Body plays a fundamental role in determining just how these pieces of the puzzle are to be arranged. The difficulty and the crucial stake lies in the perspective taken by the Panels and the Appellate Body: what weight are they assigning to the environment in the context of a dispute settlement system that is part of an organization which is specialized in international trade issues, and which is mandated *a priori* to settle disputes resulting from trade conflicts?

The WTO's predominant role in the interfaces between trade, environment and public health leads us to ask a fundamental question on the effectiveness of international instruments in these key societal sectors: Do the WTO agreements really constitute the appropriate framework for the settlement of disputes that are located within these domains? The Committee on Trade and Environment (CTE) noted, shortly after its creation, in its 1996 report that the WTO members have never used the Dispute Settlement Body in order to weaken the obligations which they have accepted by ratifying a Multilateral Environmental Agreement, and that the CTE considers that this continues to be the case. WTO members are entitled to bring their complaints to the DSB, but in the case of a conflict regarding the use of a trade-related environment measure between members that are also parties to the relevant MEA they should attempt to solve the dispute through the dispute settlement mechanism that the MEA in question has specified. The improvement of dispute settlement mechanisms specified in an MEA would encourage the settlement of disputes of this kind within the framework of the MEA in question.<sup>15</sup> It is to be expected that governments' behavior will largely depend on their perceived respective interests (which among other things determine the powers given to an MEA!). The preference for a tribunal arguably depends on the efficiency of available dispute settlement mechanisms, and for the time being the WTO's DSB undoubtedly represents one of the most efficient international legal systems (Marceau, 2001: 1119).

#### *GATT Art. XX g) and Environmental Risks due to GMO Dissemination*

Art. XX g) of the GATT Agreement covers trade-restricting measures related to the protection of exhaustible natural resources provided that these measures are also applied to domestic production and consumption. In the dispute *US-Shrimps* the Appellate Body concluded, in view of the danger of extinction of many species, that living natural resources may be just as much exhaustible as fossil or mineral resources.<sup>16</sup> By referring among others to the Convention on Biological Diversity, the

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<sup>14</sup> WT/DSB/M/50, p. 17.

<sup>15</sup> CTE Report WT/CTE/1, dated 12 November 1996, para 178.

<sup>16</sup> *US-Shrimps*, Report WT/DS58/AB/R dated 12 October 1998, para. 128

AB in fact added that recent international conventions and declarations are often referring to natural resources which may consist of biological as well as of non-biological ones.<sup>17</sup> We may therefore conclude that the Biosafety Protocol may indeed be taken into consideration in the context of the interpretation of GATT Art. XX g) since it constitutes an addition to the CBD. With the acknowledgement that biological resources may be potentially exhaustible, the AB has opened new perspectives. In view of the fact that the principle objective of the Biosafety Protocol consists in the prevention of damage to the exhaustible nature of biological resources it is legitimate to consider that the Protocol and GATT Art. XX g) are at the very least to some degree complementary.

The fact that the Appellate Body explicitly takes into consideration environmental provisions – be they international conventions or principles of soft law – in order to interpret GATT Art. XX g) represents an example of the evolution of WTO law. It is noteworthy that in ruling on the relationship between trade interests and environmental considerations the AB does not base its ruling on trade law in a narrow sense. One may hypothesize, therefore, that it has been influenced by the deliberations and negotiations in the Committee on Trade and Environment since 1995.

These contours of the very principle of the evolutive character of interpretation are opposed, however, by certain member countries. The question whether the interpretation of trade law ought to be frozen in the temporal context of the negotiations which led to the adoption of an agreement - which would be 1946 in the case of the GATT! - or whether to the contrary the interpretation of the agreements ought to evolve permanently is of fundamental importance for the work of the Dispute Settlement Body. It may be obvious that especially with regard to environmental problems it would be absurd to cling to the perceptions of the first half of the last century. On the occasion of the adoption of the AB's report on *US-Shrimps* Pakistan especially has nevertheless complained that the very notion of evolutive interpretation would endanger the predictability of the WTO's dispute settlement system.<sup>18</sup> It would arguably be difficult to explain, however, how a fixation on a set of view points that goes back nearly sixty years could possibly provide more predictability to the trade system in a world in which economic and environmental problems have taken on unprecedented global manifestations and interactions. Among other things, such a viewpoint would make a mockery out of the very essence of the sustainable development ideal which is incorporated in the preamble of the so-called WTO Agreement; this agreement is fundamental for the WTO because it establishes the organization and gives it legal personality.<sup>19</sup>

#### *Sanitary and Phytosanitary Risk Analysis : is there a Difference between SPS and TBT?*

The most important question in the test for the applicability of the SPS Agreement is whether GMO import regulations are limited to SPS measures within the meaning of the SPS Agreement. It seems that the SPS Agreement is not intended to apply to all products and all risks.<sup>20</sup> It is not necessary here to engage into the debate as to

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<sup>17</sup> *Ibid.*, para. 130.

<sup>18</sup> Doc. *WT/DSB/M/50*, p. 6.

<sup>19</sup> Marrakesh Agreement Establishing the World Trade Organization, Art. VIII, *Status of the WTO*.

<sup>20</sup> Annex A, point 1 of the SPS Agreement provides a definition of sanitary or phytosanitary measures.

whether the SPS Agreement depends on the effect of a measure or on the purposes of that measure. The concept of object and purpose frequently encountered in treaty law nevertheless illustrates that it would be almost impossible or even risky to seek to distinguish concretely between the purpose and the effect sought by a given rule or procedure. The solution concerning the field of application of SPS measures must be sought as much in the TBT Agreement as in the SPS Agreement. According to Article 1.5 of the TBT Agreement, “[t]he provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.” How can we interpret such a formulation?

A reading of the Preamble of the TBT Agreement makes it clear that the Agreement has a broader field of application than the SPS Agreement. First of all, the TBT Agreement is as concerned with sanitary and phytosanitary aspects as it is with environmental aspects *per se*. The Preamble states: “*Recognizing that no country should be prevented from taking measures... for the protection of human, animal or plant life or health, of the environment.*” Secondly, the TBT Agreement enjoys a kind of ‘residual competence’ whereas the SPS Agreement has only its ‘attributed competence.’<sup>21</sup>

The field of application of the SPS Agreement is defined by a limitative enumeration of SPS measures. This is why it would be inadequate to affirm absolutely that the SPS Agreement covers environmental risk *lato sensu*. The SPS Agreement only covers environmental risk in a limited manner through phytosanitary considerations. The protection of plant life or health “from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms”<sup>22</sup> constitutes as much a sanitary objective as an environmental one. Furthermore, Article 5.2 of the SPS Agreement indicates that environmental risk is not excluded from the framework of that Agreement. A dispute on GMOs cannot be limited to the SPS Agreement nor can it be conceived that the TBT Agreement is only concerned in a residual or alternative manner.<sup>23</sup> As the WTO Appellate Body affirmed in *Korea – Dairy Safeguards*, “[i]t is now well established that the WTO Agreement is a “Single Undertaking” and therefore all WTO obligations are generally cumulative and Members must comply with all of them simultaneously.”<sup>24</sup>

### 2.3 Introducing Precaution to the WTO: Limits and Potential

The Biosafety Protocol represents an important phase in the operationalization of the precautionary principle in international law (Boisson de Chauzournes and Thomas, 2000) - in spite of the above-mentioned refusal of the DSB to explicitly recognize its legal status. The EC’s principal argument in *EC-Hormones* was that the precautionary principle is or has become a customary rule of international law or at least a general legal principle. The DSB, however, concluded that the principle’s

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<sup>21</sup> This point is reflected in SPS Agreement, Article 1.4: ‘Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement’.

<sup>22</sup> Annex A (1(a)) of the SPS Agreement.

<sup>23</sup> *EC-Biotech*: a) First Submission of Canada, 21 April 2004;

b) Oral Statement by the US, 2 June 2004. All documents are available at <<http://www.trade-environment.org/page/theme/tewto/biotechcase.htm>>.

<sup>24</sup> WT/DS98/AB/R, Report dated 14 December 1999, para. 74.



status is presently an issue of debate among scholars, lawyers and judges.<sup>25</sup> Thus the position of the DSB is clear: the international law of the environment or of public health cannot override WTO law in any kind of a systematic way no matter what a precautionary approach would imply, and in the same way it does not go as far as declaring that the [precautionary principle](#) can justify trade restrictions under the SPS Agreement.<sup>26</sup> That explains why the concept of ‘scientifically identified risk’ which the Panel had developed in this case<sup>27</sup> prevailed over the rival concept of ‘scientifically uncertain risk’ which is intrinsic to the precautionary principle (Boisson de Chazournes, 2002a).

The Appellate Body has nevertheless made a statement which can be considered as historic, namely that the precautionary principle “finds reflection” in SPS Art. 5.7 and also in Art. 3.3, and it has added for good measure that “there is no need to assume that Article 5.7 exhausts the relevance of the precautionary principle.”<sup>28</sup> These statements, added to the possibility provided under certain conditions in Art. 5.7 to impose trade restrictions on a temporary basis and subject to re-evaluation based on pertinent available scientific knowledge, arguably mean that the SPS Agreement has opened the door for the precautionary principle at least enough to leave options open for future disputes and for a more decisive positioning of the DSB which may then make the WTO Agreements better compatible with MEAs.

The SPS Agreement’s limitative perspective on the treatment of risk causes a problem not only with regard to Multilateral Environmental Agreements. It takes a very narrow approach to dealing with risk which is nearly exclusively focused on risk assessment based on scientific evidence. It does not recognize, except perhaps very indirectly, the notions of risk management or risk communication which are fundamental components of the wider notion of risk analysis according to the Codex Alimentarius’ explicit definition of the term ‘Risk Analysis:’ “A process consisting of three components: [risk assessment](#), [risk management](#) and risk communication.”<sup>29</sup> In view of the fact that the Codex Alimentarius is an officially accepted SPS standard there seems to be a discrepancy between the SPS fixation on risk assessment and the Codex Alimentarius’ use of the more comprehensive term of risk analysis. The reconciliation of the WTO Agreements with environmental and other “non-trade issues” therefore clearly goes beyond some sort of a narrowly defined recognition of certain precautionary aspects of the risk assessment process.

WTO case law shows that there are good reasons to incorporate the possibility of a precautionary treatment of risk in the trade regime. The panel ruling on *EC-Asbestos* has recognized that it is not possible to demand an absolute level of certitude from an importing country intent on invoking GATT Art. XX.<sup>30</sup> The Appellate Body affirmed in *Australia-Salmon* that a risk which is the subject of a risk assessment must be verifiable.<sup>31</sup> But that does not exclude automatically certain categories of risk because they are not verifiable. The Appellate Body in fact has explicitly overridden the Panel in *EC-Hormones* in stipulating that one cannot exclude

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<sup>25</sup> *EC-Hormones*, WT/DS26/AB/R, WT/DS48/AB/R, dated 6 January 1998, para. 124.

<sup>26</sup> *Ibid.*, para 124.

<sup>27</sup> *Ibid.* para 186.

<sup>28</sup> *Ibid.* para. 124.

<sup>29</sup> Codex Alimentarius Procedural Manual 2001, p. 43-44.

<sup>30</sup> *EC-Asbestos*, Panel Report WT/DS135/R dated 18 September 2000, para. 8.221.

<sup>31</sup> *Australia-Salmon*, Report of the Appellate Body WT/DS18/AB/R dated 20 October 1998, para. 126.



from consideration under the SPS Agreement “factors which are not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences.”<sup>32</sup> Or in *EC-Asbestos* the AB has stressed the importance of values such as public health that are absolutely vital.<sup>33</sup> As we can see, it is becoming more and more important to operationalize precaution as a legal instrument, for instance in disputes over GMOs.

#### **2.4. GMOs and Conventional Products: Are they ‘Like Products’ with Regard to GATT Art. III?**

One of the WTO’s most fundamental principles prohibits the discrimination between like products: Like products must be treated equally (GATT Art. I), no matter which country they are imported from, according to this so-called *General Most-Favored-Nation Treatment* provision. In our analysis the question arises whether a GM product is to be considered as a like product with regard to its conventional counterpart. The DSB’s panels have developed the following criteria to determine if two products are similar:

- physical characteristics;
- consumers’ perception;
- the final use of a product;
- the price consumers are willing to pay.

Art. III of the GATT 1994 represents another fundamental concept, the *National Treatment* Provision, whose purpose is to avoid protectionism in the application of internal tax and regulatory measures. More specifically, it aims to make sure that internal measures do not result in the protection of domestic products against imports. To this end, it obliges WTO Members to provide equality competitive conditions for imported products as for domestic products.

Some countries may allege that [GMO import restrictions](#) violate Art. III:4 of the GATT 1994, which stipulates that imported goods shall be accorded a treatment that is no less favorable than like products of national origin in respect of all laws, regulations and requirements. Three cumulative elements need to be satisfied in order for a violation of Art. III:4 to be established: i) the imported and domestic products at issue are ‘like products’; ii) the measures at issue are ‘laws, regulations, or requirements affecting their internal sale, offering for sale, purchase, transportation, distribution, or use’; iii) the imported products are accorded ‘less favourable’ treatment than that accorded to like domestic products.<sup>34</sup> As these criteria are cumulative, the fact that one is not satisfied is sufficient to conclude that Art. III:4 of the GATT has not been violated.

Are imported GMO products and domestic non-GMO products (*i.e.*, conventional products) to be considered as ‘like products’ under WTO law? In the *EC-Biotech* dispute, the US, Canada and Argentina are proceeding on the basis that there is no difference between GM products and their non-GM conventional

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<sup>32</sup> *EC-Hormones*, *op. cit.* 253 j).

<sup>33</sup> *EC-Asbestos*, *op. cit.* para. 172.

<sup>34</sup> *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, Report of the Appellate Body, 11 December 2000, WT/DS161/AB/R, WT/DS169/AB/R, para. 133.

counterparts. Conversely, the European Communities submit that the only 'like' product to a given imported GM product is the same GM product cultivated or processed domestically. It is important in the analysis of likeness to have as a basis for reflection the *dictum* of the Appellate Body in the *Japan - Alcoholic Beverages* case, which states that "...there can be no one precise and absolute definition of what is 'like'. The concept of 'likeness' is a relative one that evokes the image of an accordion. The accordion of 'likeness' stretches and squeezes in different places as different provisions of the WTO Agreement are applied."<sup>35</sup>

This question of likeness is particularly pertinent in the case of GMOs due to the multifaceted character of the notion of GMOs *per se*. Clearly, a genetically modified organism is an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. In different fora, GMOs are referred to as 'living modified organisms'<sup>36</sup>, 'genetically engineered organisms,' 'transgenic organisms,' etc. Although these terms refer essentially to the same products and processes, they may denote slightly different sub-categories.<sup>37</sup>

Without dwelling upon the regulatory implications of the concept of substantial equivalence (for a development of this concept see Christoforou, 2004), two key elements could be taken into account to illustrate that GMO products are not 'like' their conventional equivalent products. One element is procedural and the other is material. Regarding the procedural element, the international community has, through the [Cartagena Protocol on Biosafety](#), recognized that GM products are such that they require their own, distinct authorization procedure (Eggers and Mackenzie, 2000). Indeed, for the transboundary movement of those LMOs which are intended to be introduced into the natural environment (essentially seeds and fish) the Biosafety Protocol requires the parties to follow the so-called advance informed agreement (AIA) procedure.

AIA consists of three steps: notification; acknowledgement of notification; and the decision import regulations. The party of export has the obligation to notify in writing the party of import prior to the intentional transboundary movement of an LMO. The party of import has various options: to approve the import without conditions; to approve the import with conditions; to prohibit the import; to request additional information; or to extend the procedure by a defined period of time. In the event that there is a lack of scientific certainty regarding the extent of potential adverse effects, the party of import retains the right to take a [precautionary decision](#) in order to avoid or minimize such potential adverse effects. The procedural aspect thus illustrates that GM products represent a specific product category and are not subjected to the same legal regime as non-GM products. This is the first distinguishing element to suggest that they are not like products.

An important element relates to the potential risks linked to the spread of GMOs in the environment and to their consumption. Scientific knowledge of genetics is limited and evolving very rapidly.<sup>38</sup> An independent group of experts (the UK's

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<sup>35</sup> *Japan - Alcoholic Beverages*, Report of the Appellate Body, 4 October 1996, WT/DS10/AB/R, WT/DS11/AB/R, WT/DS8/AB/R, at 23.

<sup>36</sup> See Cartagena Protocol on Biosafety to the Convention on Biological Diversity done in Montreal 29 January 2000, available at <<http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf>>.

<sup>37</sup> For instance, in the *EC-Biotech* dispute, the complainants (USA, Argentina, Canada) have chosen the expression 'biotech products', whereas the European Community has opted for the term 'GMOs'.

<sup>38</sup> See Amicus curiae brief submitted by an international coalition of 15 public interest groups to the biotech dispute, 27 May 2004, para. 25: <<http://www.genewatch.org/WTO/Amicus/PublicInterestAmicus.pdf>>.

Science Review Panel) established in 2003 by the UK Government to review the science relevant to GM crops and foods, pointed out that “No other plant breeding technique permits the incorporation of genetic material from such diverse biological sources. Inevitably this raises the possibility that some new consequences of GM plant breeding may be unexpected.”<sup>39</sup> Furthermore it added that “To date worldwide there have been no verifiable untoward toxic or nutritionally deleterious effects resulting from the cultivation and consumption of products from GM crops. However, absence of readily observable adverse effects does not mean that these can be completely ruled out.”<sup>40</sup>

The question of the risks of ‘harm’ or ‘danger’ linked to the dissemination or consumption of GMOs is essential in the analysis of the likeness between GM products and conventional products. The 2001 *EC-Asbestos* case is significant in illustrating the present position of the DSB with regard to this issue of likeness; this is in fact its key contribution to WTO law. The AB emphasized the importance of the criteria of “consumers’ tastes and habits,” explaining that “Consumers’ tastes and habits regarding *fibres*, even in the case of commercial parties, such as manufacturers, are very likely to be shaped by the health risks associated with a product which is known to be highly carcinogenic.”<sup>41</sup> From that perspective, the Appellate Body judged that the ‘risk’ criterion (that is, health risks) is pertinent to the test of the likeness of products, thereby attenuating an exclusively ‘economic’ interpretation of likeness.

Musselli and Zarrilli (2002) in their analysis of the *EC-Asbestos* case conclude that it is of a double importance for the development of WTO law with regard to the question of likeness. On one hand they note that the DSB in this case came very close to pronouncing a groundbreaking distinction with far-reaching implications for international trade. A dissenting member of the Appellate Body questioned that the likeness of two products should be based on essentially economic dimensions, and used health risks as a decisive distinction in determining likeness. The Appellate Body’s other two members, however, refused to base their ruling on this simple and fundamental decision criterion and instead blamed Canada in a much debated and divisive ruling for not having fulfilled the burden of proof of demonstrating that consumers would be prepared to pay the same price for an asbestos-containing and a non-asbestos-containing product. At the same time it noted that the two products are not like.<sup>42</sup>

On the other hand they point out that the ruling should be significant for future GM-related disputes. It would be difficult indeed to argue in *EC-Biotech* that the claimants have satisfied in their written submission the burden of proving that consumers are ready to pay the same price for conventional and for counterpart transgenic products. As far as consumers’ perceptions are concerned – at least in Europe – numerous opinion polls have clearly indicated that conventional and genetically modified products are by no means perceived as equivalent or interchangeable. This is a strong argument against the legal treatment of conventional products and their transgenic counterparts as like products in the sense of the WTO law. As a result, one may conjecture that the Dispute Settlement Body could use the same legal reasoning as in the *Asbestos* case, i.e. it may conclude that

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<sup>39</sup> UK GM Science Review Panel, *An open review of the science relevant to GM crops and food based on the interests and concerns of the public* (2003), First report (Executive Summary), at 10, available at <[www.gmsciencedebate.org.uk/report/pdf/gmsci-report1-pt1.pdf](http://www.gmsciencedebate.org.uk/report/pdf/gmsci-report1-pt1.pdf)>.

<sup>40</sup> *Ibid.*

<sup>41</sup> *EC-Asbestos*, Report of the Appellate Body, 12 March 2001, WT/DS135/AB/R, para. 122.

<sup>42</sup> *Ibid.*, para 192 (d).

GM goods are not *like* their conventional counterparts, and that as a consequence the EC is justified in applying – on a provisional basis as it does – more prudent, slower, comprehensive and indeed precautionary procedures.

A fundamental question here is whether the consumers' widespread distrust is justified and to what extent it is based on scientifically sound information in a comprehensive interdisciplinary sense, i.e. not limited to microbiology, botany and epidemiology but in the sense that the evaluation includes socio-economic considerations as they are stipulated in the Biosafety Protocol's much-cited Art. 26. As a matter of fact, the WHO in 2004 published a document entitled *20 Questions on Genetically Modified Foods*<sup>43</sup> which in the last 'Question' calls for holistic and all-inclusive evaluations rather than focusing solely on public health and biodiversity. Such a broader approach of course will make the challenge for regulatory authorities considerably more complex and difficult than the more traditional narrow and maybe reductionistic [risk assessment](#) and [risk management](#) methods. The price to be paid by the consumer will certainly be an element to be considered but it may not be the most important one. These questions require, especially at the level of the development of risk management methods, a more comprehensive approach at the science-technology-law interface. Our research has not really addressed these issues so far, but we plan to do so in the second phase of this program.

## **CHAPTER 3: THE BIOSAFETY PROTOCOL, RISK MANAGEMENT, AND WTO LAW**

### **3.1. Introduction**

The past 25 years have witnessed a highly active level of development in the domain of biotechnology, both in the laboratory and in international regulatory negotiations. The first field trials of genetically modified plants or transgenic plants took place in the mid 1980s; by around 1994 they started to reach the market and the consumers. These advances generated two very different kinds of reactions: On one hand they were widely seen as offering an unlimited potential for the exploitation and the development of the world's genetic resources, especially in the domains of pharmaceuticals and in the breeding of new varieties and species of plants and animals. On the other hand they were raising fears primarily in terms of biodiversity, food safety and dependence on global monopoly suppliers of patented seeds. In view of the importance of biotechnologies for our era it is very fitting that the Protocol on Biosafety was adopted at the very beginning of this millennium, namely on January 29, 2000, after nearly five years of intense negotiation.

This protocol represents one of those multilateral agreements which are situated at the interface between the trade and the environment negotiations, and it is characterized by the qualified right of its parties to institute explicit environmental trade restrictions on the import of living modified organisms. The beginning of specific negotiations for such a protocol can be traced back to the CBD which was adopted on the occasion of the 1992 Rio Summit Conference, and which in Art. 19.3 calls for the negotiation of such an instrument. The Protocol specifies the rights and obligations of member countries with regard to the regulation of trade in LMOs. The scope of the Protocol covers trade in two categories of these LMOs: first of all those

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<sup>43</sup> Available at <http://www.who.int/fsf/GMfood/q&a.pdf>

which are agricultural commodities directly used for food and feed including those which are directly integrated into processed products, and secondly those which are intentionally introduced into the environment such as seeds or fish.

### **3.2. The Main Features of the Protocol**

#### *Historical background*

Pushed by public concerns over the potential environmental and health impact of genetically modified organisms, the OECD published in 1986 the so-called "Blue Book" on Recombinant DNA Safety Considerations, the first document published by a major intergovernmental organization focusing specifically on biosafety. The authors realized that it was too early to formulate standards for regulating the use of genetically modified organisms, they therefore limited themselves to a focused approach based on case studies. Nevertheless, these guidelines specified, for the first time, the basic principles for risk assessment and management of genetically modified organisms. They also represent the first step towards international harmonization on these issues.

The seemingly unlimited prospects of biotechnology provoked increasing expectations and great hopes, particularly in developing countries. These expectations are reflected in another key outcome of the Rio Earth Summit, "The UN Programme of Action from Rio," better known as *Agenda 21*. The importance given to the then emerging modern biotechnologies is reflected in Chapter 16 "Environmentally sound management of biotechnology." This is in fact the only chapter of *Agenda 21* which is dedicated to one specific technology. Biotechnology is again presented as a source of opportunities for a global partnership: On one hand there are those countries which are rich in biological resources, but which lack the experience and the investments that are necessary in order to make possible the use of these resources for economic development, and on the other hand there are those which possess this technological know-how. As far as the program of action is concerned, the emphasis is placed on environmentally safe applications of biotechnology in agriculture, in the environment, in human health care and on the promotion of related capacity building activities.

In 1994, the CBD's first Conference of the Parties (COP) in Nassau, the Bahamas, decided to hold an open-ended *ad hoc* group of experts' meeting with the objective of preparing a decision on the establishment of a Protocol independently of the UNEP Guidelines. It was not clear at this time, however, what legal form and what relationship with other guidelines and agreements this new instrument was going to assume. The CBD subsequently established an Open-ended *ad hoc* Working Group on Biosafety (BSWG) at its second COP in Jakarta in 1995 which met six times from 1996 to 1999. Its last meeting in Cartagena in February, 1999, was scheduled to be followed back-to-back by an Extraordinary Meeting of the COP (EXCOP) which would adopt the Protocol according to the rules of procedures of the CBD. The work of the BSWG, that started off as typical pre-negotiation preliminaries became increasingly difficult, however, as the process advanced in time. At the last meeting differences turned out to be unbridgeable between the countries exporting or intending to export LMOs (later known as the Miami Group, led by the U.S.), and the other countries. In the end, the EXCOP had to be officially suspended because these negotiations in Cartagena had broken down completely.



It is interesting to note in retrospective that during most of the negotiations within the BSWG, the issue of agricultural commodities, specifically the trade of LMOs intended for direct use as food, feed, or for processing (the so-called LMO-FFPs, i.e. unprocessed crops) were hardly addressed as a major issue, in spite of the fact that the US and Canada had never hidden their fierce opposition against the inclusion in the Protocol of references to their genetically modified staple export crops. Until Cartagena, negotiations were largely dominated by the reference to LMOs "for intentional introduction into the environment," and by the threats to biodiversity which may be caused as a consequence especially of planting GM seeds. This ambiguity played a key role in the deadlock at Cartagena because it reflected - or maybe one might say it covered up - one of the fundamental issues which shaped the whole negotiation process, namely the two-pronged question of the *scope* of the agreement to be negotiated: First of all, which kinds of products should be covered by the Protocol? Should it cover only LMOs or also "products thereof" derived from LMOs, such as processed food or pharmaceuticals? Secondly, which kinds of products should be placed, within the Protocol, under the provisions of the advance informed agreement procedure? The detailed and demanding information and consent procedure of this AIA met strong resistance from the LMO exporting countries.

The developing countries took the opposite view, they insisted from the beginning of the negotiations that all transboundary movements of all LMOs should be covered by the AIA, independently of their intended use. This position was based primarily on the fact that in developing countries even grains imported as foodstuff are sometimes used as seeds by farmers, especially in a crisis situation, and they could therefore directly affect the biodiversity (Pythoud, 2002a: 324). The exporting countries, on the other hand, defended the view that the application of AIA procedure was not appropriate for LMO-FFPs due to the specificities of agricultural products. The Uruguay Round has brought the trade of such products under the umbrella of the WTO. They are essentially treated like other goods in the trade regime, although the very complex provisions on subsidies and other support measures continue to be negotiated with great intensity.

The biosafety negotiations are not occurring in isolation, they need to be put into the context of the wider ongoing multilateral trade negotiations. We also have to realize that trade negotiations in agricultural products tend to be particularly politicized, in fact they represent undoubtedly the most important portion of the WTO's recently concluded 'July Package'<sup>44</sup> to prepare the Hong Kong Ministerial Conference. This decision of the General Council determines the framework of the ongoing preparations for the 2005 Hong Kong Ministerial Conference. It has scaled down the 2001 Doha Development Agenda into a more modest set of negotiation objectives. The conclusion of this very tensely debated agreement was made possible through the establishment of a core negotiating group called the Five Interested Parties, namely the US, the EU, Australia, Brazil, and India.

The handling of *scientific uncertainty* and the application of the [precautionary principle](#) in decision-making procedures has been one of the Protocol negotiators' key challenge. Two different views regarding the basis for risk assessment and risk management came into conflict. The representatives of the LMO export countries promoted the application of principles and practices which are often called 'sound science.' These consist in standardized procedures that are widely considered as

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<sup>44</sup> [http://www.wto.org/english/tratop\\_e/dda\\_e/draft\\_text\\_gc\\_dg\\_31july04\\_e.htm](http://www.wto.org/english/tratop_e/dda_e/draft_text_gc_dg_31july04_e.htm)

being objective. On the other hand, importing countries emphasized that the potential dangers posed by LMOs at the present time remain insufficiently understood, they might be irreversible, and as a consequence precautionary measure need to be an available option for an importing country. It should be emphasized that this perspective does not question in any way the importance of scientific knowledge and methodologies in risk assessment and risk management, but it refuses a predetermined standardized methodology. Proponents of this approach have called from the beginning of the negotiations for a pragmatic operationalization of the precautionary approach. That is how the relationship between the BP and the WTO became one of the central and most difficult tasks for the negotiators because the WTO does not really accept trade measures based on precaution.

Thus the impasse of the 1999 Cartagena meeting was primarily due to two interconnected but distinct issues. First of all, the new Protocol and the WTO reflect very different approaches to risk assessment and risk management. Secondly, the protocol itself regulates two fundamentally different kinds of products, namely on one hand seeds and transgenic fish which constitute the primary dangers to biodiversity, and on the other hand crops which are not intended for planting, that is especially food and feed, but also other agricultural products like cotton. The stalemates over these issues was in many cases overcome through procedural innovations in the usual negotiation techniques such as the formation of country alliances not along traditional geographical regions as is the general practice in UN negotiations, but rather through the formation of groups of countries with common interests and objectives. These techniques started to emerge in Cartagena and continued to play an important role all the way to the final negotiations in Montréal. They were to an important degree the achievement of Columbian Environment Minister Mayr who led these negotiations skilfully. This innovative approach was introduced most notably at a meeting in Vienna which is the reason why it has entered diplomatic history under the term of 'Vienna Setting.' The good climate and the constructive attitude of course depended entirely on the goodwill and the cooperation of the delegates.

The failure of the WTO's Seattle Ministerial Conference a few weeks earlier increased the pressure on member countries to avoid another diplomatic deadlock on an issue which was and is very much in the media's spotlight. Public concern over LMOs was by that time voiced not only in Western Europe and South-East Asia, but more and more also in North America. Several NGOs managed thanks to their personal connections and their subject-related competence to play an important role in catalyzing and channeling political support in Europe and most of the developing countries. Furthermore they were successful in translating a wide-spread but diffuse popular encouragement into a focused political momentum, which after many exasperating and exhausting late-night negotiations succeeded to overcome the continuing resistance of the GMO exporting countries. These factors converged in January, 29, 2000, and they resulted, with a one year delay and three major additional informal meetings, in the adoption of the Cartagena Protocol.

### *Different Regulations According to Product Categories*

The market access rights under the WTO are not absolute, they are subject to certain exceptions in those cases where it is necessary to protect human, animal or plant life or health, and where the conservation of exhaustible natural resources is threatened. Furthermore, WTO member countries are entitled under certain conditions to restrict

market access through the adoption of (provisional) sanitary or phytosanitary measures in cases where relevant scientific evidence is insufficient. This provision *a priori* represents a possibility for an importing country to base its decision about importing regulations of LMO-FFPs on precaution.

The WTO agreements, however, in reality make it quite difficult for an importing country to use such arguments effectively in order to prevent the importation of genetically modified agricultural commodities. The central issue here is the establishment and the [interpretation of authoritative rules](#) to settle potential disputes in cases where there is scientific uncertainty. The WTO dispute settlement system is well established, and it does not constitute one among several options, rather, it is automatically applicable and enforceable in trade matters covered by the WTO agreements. The question of the rights and obligations of an importing country in regulating market access for LMO-FFPs and the role that a precautionary approach may play were indeed among the most difficult questions to be resolved in the negotiations leading to the Biosafety Protocol.

The import regulations for genetically modified export crops or LMO-FFPs (at this time primarily soya beans, corn, rapeseed or canola, and cotton) became the key stumbling-block at the negotiations in Cartagena and thereafter. This problem was resolved by devising a less cumbersome set of regulations for commodities, and to limit the application of the above-mentioned AIA procedures to LMOs intended for introduction into the environment. The acceptance by the LMO-importing countries of a restricted use of the AIA formula -- and only for the first shipment -- turned out to be the 'deal-maker' in very tense negotiations. This less demanding solution for LMO-FFP crops consists in the crafting of a separate set of decision-making criteria. The key provision in this regard is Art. 11 of the BP. The heart of the procedures described in that Article consists in an innovative advance notification: When a member country allows the planting and commercialization of a transgenic crop that might be used and exported as LMO-FFP, it has to notify all Parties through the information sharing mechanism of the BP, the Biosafety Clearing-House (BCH). The decision-making criteria incorporated in Art. 11 have the advantage that they are relatively speedy, but they nevertheless do allow an importing country to exercise some degree of sovereignty and control over the regulation of imports of LMO-FFP commodities, including the reference to the precautionary approach.

LMOs destined for contained use (Art. 6) are also covered by the Protocol, even though the AIA procedure does not apply. At the beginning of the negotiations most OECD countries insisted on excluding contained use (a term which is only vaguely defined) from the scope of the Protocol. In the final version, however, the BP contains identification requirements for LMOs intended for contained use and leaves open the possibility that future liability clauses could apply also to contained use. On the other hand, the position of OECD countries regarding products *derived* from LMOs prevailed in the definition of the scope. These countries argued successfully that such products (e.g. GM coffee powder) do not constitute a threat to biodiversity because they cannot reproduce and therefore should not be included in the Protocol. This means that processed food products derived from LMOs are completely exempted from the Protocol's obligations. Their transboundary movements are essentially regulated by general international trade agreements and national legislation. As far as genetically modified *raw food products* are concerned, we are presently facing a somewhat unclear situation because these are regulated by both the BP and the Codex Alimentarius. There are some informal discussions going on between the two, but so far they have not been institutionalized yet. Such a



development is vaguely envisaged but at this time there are not even any joint regular working or expert groups. Coordination does take place, however, at the level of certain delegations, which means that it functions better in some countries than in some others.

Another demand of industrialized countries, in particular the European Union, concerned the exclusion of LMOs which are pharmaceutical products for humans. These are also excluded as long as they are "addressed by other relevant international agreements or organizations (Art. 5)." This conclusion represents a victory of the OECD countries over the position of the developing countries who wanted to include them in the Protocol.

### *The Challenge of Negotiating Mutual Supportiveness*

As far as the development of public international law is concerned, there is no doubt that a new approach to dealing with scientific uncertainty through the operationalization of the precautionary principle represents the most important achievement of the BP negotiations. The reason why this is crucial is that it determines, at least *de jure*, the Protocol's position vis-à-vis the WTO. It remains to be seen how WTO case law treats these provisions *de facto*. The diplomatic solution that was achieved consists in language that may be considered as contradictory but which for the time being satisfies both LMO importers and exporters, even though they have, as is not unusual in international agreements, interpreted the legal text very differently. The question whether or not there should be a hierarchical relationship between the BP and the WTO was at the heart of these very vigorous debates which have not subsided since. The preamble attempts to satisfy both view points. It specifies on one hand that "this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements (i.e. primarily the WTO)." On the other hand, however, it stipulates that "...the above recital is not intended to subordinate this Protocol to other international agreements." In other words, the rights to market access will not be infringed upon by the Protocol because the WTO-related rights will be maintained, but at the same time this does not mean that the BP is subordinated to the WTO. This is essentially the same as saying that the Parties are entitled to disagree with regards to the relation between the two agreements, and also with regards to the interpretation of the preamble.

A qualifying statement right before the above-cited ones tries to induce parties to take a conciliatory attitude: "*Recognizing that [trade and environment agreements](#) should be mutually supportive with a view to achieving sustainable development...*" This seemingly innocuous if not self-evident statement contains in fact an innovative element that provides a contribution towards overcoming this interorganizational stalemate. Indeed, since the adoption of the BP, the concept of mutual supportiveness with a view to achieve sustainable development has been used in other international agreements, especially the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture, and it has recently become an important concept in the development of public international law and in the literature in this field (Perrez, 2000: 523-525). This FAO treaty which entered into force in June 2004 complements in some ways the Biosafety Protocol by addressing access and benefit sharing aspects with regards to germplasm resources in general, including those which are genetically modified. In the case of the BP, the 'mutually supportive'

statement reflects the fact that in the eventuality of a potential future dispute before the WTO's DSB, its panels or Appellate Body should arrive at a ruling which should be supportive of the goals of the BP. The opposite is true too, of course, but the CBD's dispute settlement system is not very constraining, it provides the option of submitting a dispute to the International Court of Justice.

The problem to be overcome consisted not only in different perspectives about the importance of assessing potential risks which may be associated with LMOs, but also in differences of opinion regarding the management of risk. The much-cited Art. 5.7 of the WTO's SPS Agreement does mention risk assessment, but it is silent about risk management. In the end, thanks to the diplomatic solution found for the relationship between the BP and the WTO, the BP contains not only a risk management procedure (Art. 16) based on the data gathered under the risk assessment phase (Art. 15), but it gave the precautionary approach, as we have seen, a considerably greater importance than it has in the SPS agreement. It is mentioned explicitly in the preamble and the objectives of the BP but - more importantly - it is also implicitly operationalized in the decision procedures (Art. 10.6 and 11.8).

### *Unsettled Issues*

The dynamics of the biosafety negotiations were characterized by a significant widening of the issues discussed compared to the initial preconceptions. The emphasis on the need to establish what some analysts call a policy space for national governments which can serve for the recognition of mutual supportiveness between trade and biodiversity concerns is undoubtedly one of the major achievements of the Biosafety Protocol. This concerted effort to reconcile these very different spheres has arguably become a major trend in the negotiation of multilateral instruments for risk management such as this Protocol or the Codex Alimentarius. Furthermore, this agreement on LMOs may be interpreted as an implicit acceptance of uncertain risks in the context of exceptions to the WTO's trade disciplines. This would be an important development in international law, specially since at this time there is no consensus on the substantial equivalence or likeness between conventional and genetically modified products and on the nature of risks associated with GM products. Some jurisprudence or negotiated decisions in this domain are to be expected in the near future with potentially far reaching consequences.

We may conclude this review of the negotiations by noting that arguably the biggest problem for the Protocol lies in the fact that none of the major GMO exporters has chosen to ratify it, and especially the United States is not even a member of the CBD which is a condition for becoming a party. On the positive side, the adoption of the Biosafety Protocol was possible because the CBD members realized that this compromise was better than not having any agreement at all, and also due to the fact that there was really no loser or winner. Even environmental NGOs and the biotechnology industry expressed on the whole their satisfaction with the content of the final outcome. After the Seattle failure, the Montréal success demonstrated that, with the goodwill of all partners, it was still possible to find balanced solutions between trade and environmental interests even on difficult issues. The negotiation process re-emphasized the importance of ensuring at each step full transparency and participation of all partners, including civil society which as we have seen was very much involved in this negotiation process. The Protocol has entered into force in

September 2003 thanks to the ratification by fifty parties, and the first Meeting of the Parties has taken place in Kuala Lumpur, Malaysia, 23-27 February 2004. For reasons of diplomatic procedures a Protocol's Conference is called a Meeting, and at least at the formal level it must take place back-to-back with the relevant Convention's Conference of the Parties (resulting in the so-called COP-MOP). The meeting was generally considered a success even though there was strong critique about the high-profile role played by non-members, especially the United States. On the other side industry representatives complained that practical and market aspects were not sufficiently integrated into the negotiations.

The three most important outstanding issues are [handling and labelling](#) (Art. 18), liability and redress (Art. 27), and compliance (Art. 34). Handling and labelling procedures were further operationalized by requesting parties to mention the vaguely formulated "may contain LMOs" and the "not intended for intentional introduction into the environment" provisions of the Protocol either on the commercial invoice or on other documents. Furthermore, the elaboration of the application of the 'unique identifier' system was assigned to a technical expert group. The procedures and institutional mechanisms for compliance proved to be one of the main sticking points in the negotiations, in particular the question of who could submit a complaint. In the end, a 15-member Compliance Committee was created. The contentious issue of how to address repeated non-compliance, for instance through the use of trade sanctions, was left to be discussed at the MOP-3 which is scheduled to be held in about two years. The issue of liability and redress finally was particularly emphasized by the African Group whose spokesperson Twolde Egziabher from Ethiopia stressed the great importance which these countries attach to this question. The Group called for legally binding provisions that would allow importing countries to seek compensation from exporters if LMOs contaminate their environment or damage their health. The negotiators set up a working group of legal and technical experts for this issue charged with elaborating various options for elements of rules and procedures by the year 2007.

### **3.3. The Relationship between Risk Management and Risk Assessment**

#### *Scientific Risk Assessment*

The Codex Alimentarius' Procedures Manual as we have seen divides risk analysis into three distinct processes which may be summarized as follows: Risk assessment consists in a scientific understanding of the nature and the complexities of the potential risks. Risk management represents the weighing of various alternatives at the policy and regulatory levels. Risk communication, finally, covers interactive information exchanges among the most important stakeholders. The three fields of activity are functionally distinct from each other even though they may overlap. It is important to realize also that they are not sequential tasks to be carried out according to a guideline. Rather, they are iterative, interdependent, and they ought to be mutually supportive and coherent. Risk assessment and management especially are linked intricately, they are by no means two autonomous phases of the wider notion of risk analysis but rather they are interacting in a constant back-and-forth process (Noiville et de Sadeleer, 2001).

There are many ways to demonstrate the interdependence of the two processes, for instance by the fact that it is the political level which finances the

research of public institutions, and it may thus determine priorities. At the same time, however, the scientists may prompt the political instances through the communication of the fruits of their research either into action or into justifying benign neglect. It is important to realize that in spite of this connection between assessment and management the political decision-makers are the ones which have to assume the final responsibility. They therefore need to maintain their autonomy and distance from the scientists in order to be able to act on the scientific findings. That is particularly important in an area that is as new and evolving as quickly as the evaluation of the safety of GM crops which is fraught with incomplete knowledge, controversies, and scientific uncertainties. The risk managers and the scientists of the authorities in charge of dealing with potential threats to both public health and to biodiversity are constantly facing the dynamic relationship between the assessment and the management of risk. Not surprisingly, the Biosafety Protocol addresses these two components of risk analysis separately (Art. 15 and 16).

The distinction between the assessment and the management of risk is not just an analytical question with regard to the functioning of the process. The importance of the separation of the two processes can be seen from the fact that the interface between the two processes reflects the philosophy of government policy regarding how the relevant authorities assume their food safety-related responsibilities either in a proactive way, or else passively hoping that nothing unplanned will happen. In a proactive management of risk the ultimate decision makers will attempt to control as much as possible the interface between risk assessment and risk management. The hierarchical superposition of risk management with regards to risk assessment can be justified by the fact that the political authorities need to take into consideration not only the soundness of the scientific assessment but also the fundamental socio-economic and wider societal (non-scientific!) context which may determine the utility of a product. They may face for instance the public's hostility toward a certain risk, or a comprehensive analysis which will include the evaluation of other risks that may be incurred by avoiding the risks that are accruing from GMOs.

### *Risk-Benefit Analysis, Precaution and Proportionality*

A risk-benefit analysis is often situated more or less explicitly at the center of risk management. The precautionary principle may be used to justify a course of action even if the necessity of such action can not yet be demonstrated through full scientifically sound evidence. The precautionary principle does however not prescribe the adoption of a specific measure – it merely opens up the possibility of a wide range of available risk-management options. In theory, a functional cost-benefit or risk-benefit analysis could provide the information which is necessary to decide between these different options: once the costs, the risks and the benefits of the different options have been determined, then the option which objectively reflects the common interest to the greatest satisfaction can be chosen.

This approach suffers from important limitations, however. It is based on the double assumption that first of all it is possible to assess objectively all costs and benefits of a particular course of action through monetary valuations, and secondly that based on these evaluations, the overall welfare can be maximized through rational, value-neutral decisions. These limitations are particularly serious in situations which involve risks and uncertainties because the perception of risk may

be more important than the actual risk. Furthermore, a risk may be quantified through a percentage of probability, but this is not possible with an uncertainty. Moreover, the unknown may often be seen as more threatening than the known risk. All this makes the cost-benefit analysis a problematic concept for dealing with issues involving uncertainties such as GMOs. That is why for example the Swiss legislation on genetic engineering does not require quantitative cost-benefit analyses.

## **CHAPTER 4: INTERNATIONAL STANDARDIZATION AND THE DEBATE OF TRADE IN GM PRODUCTS**

### **4.1. The Importance of International Standards in the WTO System**

The concept of an international standard has a double meaning. It may either refer to a recognized norm of international law, or else to a principle of international law that does not (yet) enjoy this kind of a general recognition. Either way, however, it does refer to some kind of a level or a model whose realization is desirable, and which ought to serve as a benchmark for the evaluation of a situation or of a behavior.<sup>45</sup> In international trade the use of standards aims at the prevention of hidden protectionist trade measures or at abusive discriminations. They reflect the approval of certain governments and/or intergovernmental organizations which have participated in their elaboration and adoption.

The two most important WTO agreements for our issue area, the SPS and the TBT Agreements are essentially based upon international standards such as the Codex Alimentarius. Compliance with these standards is considered to provide a high level of certainty and confidence that a certain measure is WTO-compatible. Art. 3.2 of the SPS Agreement thus declares that "Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994." This means that a WTO member which imposes an import restriction that is in full conformity with a standard of the Codex Alimentarius will in principle not be obliged to furnish any scientific proof of its justification. On the other hand, a government that uses norms which are more demanding than the most pertinent international standard will have to scientifically demonstrate its rationale.

### **4.2. The Example of International Standards Related to GMOs**

Standard setting work has been going on in various bodies of international organizations dealing with issues at the interface of trade, agriculture, environment and health issues. Many of them are part of the UN Inter-Agency Network for Safety in Biotechnology (IANB), which was set up in 1999 to enhance the exchange of information and facilitate cooperation. In 1999, the Codex Alimentarius Commission established an Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology (TFFBT) to consider the health and nutritional implications of such

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<sup>45</sup> *Dictionnaire de droit international public*, sous la direction de Jean Salmon, Bruylant/AUF, Bruxelles, 2001, p. 1049.

foods. The objectives for the Task Force's work were to develop standards, guidelines or recommendations for foods derived from biotechnology on the basis of scientific evidence and risk analysis.

The Task Force has elaborated three texts, which were adopted at the 26th session of the Codex Alimentarius Commission in Rome in July 2003, i.e. Principles for risk analysis, Guidelines for the conduct of food safety assessment, and Guidelines regarding foods produced through the use of recombinant-DNA micro-organisms. The risk analysis Principles specify that "A pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis (paragraph 12);" and that "Risk management measures may include, as appropriate, food labelling, conditions for marketing approvals and post-market monitoring (paragraph 19)." It is of particular importance to note that similar risk assessment and risk management procedures, which are characteristic of a precautionary approach to food safety, are not provided for by *Codex Alimentarius* in respect of conventional food.

Work on issues related to the [risk assessment and management](#) of GMOs and GM-derived products is also ongoing in other Codex committees. Thus, for example, the Codex Committee on Methods of Analysis and Sampling is currently working on methods of analysis for GM foods (CCMAS). The labelling of GM foods and food ingredients has been under discussion in the Codex Committee on Food Labelling (CCFL) for several years. The World Health Organisation (WHO) has been addressing a wide range of issues in the field of biotechnology and human health, including the safety evaluation of vaccines produced using biotechnology, human cloning and gene therapy. Regarding the issue of safety assessment of genetically modified food, WHO, from the 1990s onwards, has engaged in a series of Joint Expert Consultations with FAO on safety aspects of GM foods. The outcome of these consultations has been extensively used by the Codex TFFBT to develop the above-mentioned principles and guidelines. Furthermore, the WHO Food Safety Department is currently conducting a study of the implications of GM foods on human health and development.

FAO's work on a different set of GM issues was taken up by its Commission on Genetic Resources for Food and Agriculture in the early 1990s. An initiative to draft a Code of Conduct on Biotechnology as it relates to genetic resources for food and agriculture was launched. Pending the negotiation of the Biosafety Protocol and the re-negotiation of the International Undertaking on Plant Genetic Resources for Food and Agriculture, work on the draft code was suspended, but has recently been re-launched. FAO is also home to the Interim Commission on Phytosanitary Measures (ICPM), a body established in accordance with the International Plant Protection Convention (IPPC), which was negotiated under the auspices of FAO. The ICPM develops and adopts international standards for phytosanitary measures. The ICPM has recently been working on a standard for pest risk analysis for LMOs and, at its sixth meeting in March-April 2004, it considered a Supplement to ICPM No. 11 on pest risk analysis for living modified organisms. With its Statement on Biotechnology in 2000, FAO renewed its commitment to provide GM-related services in areas such as technical assistance or the monitoring of scientific developments.

The United Nations Environmental Programme (UNEP) finally has been involved in international regulatory work on GMOs since the mid-1980s. It is currently implementing a project financed by the Global Environment Facility on the development of national biosafety frameworks. 123 countries are participating in this project, which is designed to assist countries to set up a national framework for LMOs

so that they can meet the requirements of the Biosafety Protocol. The project also aims at promoting appropriate regional and sub-regional cooperation.

#### **4.3. Some General Elements of a Solution in the *EC-Biotech* Dispute at the WTO**

In view of the fact that so far no GMO dispute has been ruled upon by the WTO it should be noted that a legal analysis of the issues involved in the *EC-Biotech* dispute which the Dispute Settlement Body is dealing with at the time of this writing is necessary conjectural. The DSB ruling (assuming that there will not be an out of court settlement) may be expected to set important and perhaps fundamental accents in the trade system's jurisprudence. This is because of the unprecedented combination of a comprehensive evaluation of a new technology and of very large economic as well as environmental and sociopolitical stakes. Perhaps the most basic issue that the DSB will have to decide at the very beginning is the question of the applicability of its rules to this new technology. There are three responses to this question, and each one can be supported with valid arguments:

The restrictive response argues that the WTO's rules have been developed for ordinary products which carry specific, well known and well understood risks. At the time of the Uruguay Round, however, genetically modified products were not internationally commercialized yet, they were essentially unknown outside the world of scientific research. It may be argued therefore that the negotiators have not taken into consideration the trade implications of these products and of the uncertainties related to them. Modern biotechnologies represent a scientific revolution which provides us with both dangers and promises that were unknown previously. As a result, the rules which were developed for traditional commercial goods like furniture, clothes or engines may be seen as not being adequate to resolve the problems that are generated by these biotechnologies. This approach is based on the principle of *rebus sic stantibus*, which means that an agreement's provisions are based on the understanding of continuity and predictability of the key contextual factors; should these factors change, then the agreement's provisions need to be adjusted to the new situation. This perspective therefore concludes that the WTO's rules cannot be applied to GMOs since their development has created a fundamentally different context.

The free-trade response argues that it is a legal tradition to apply rules which have been used in a certain scientific or technological context also to later technological evolutions and applications. As an example, the rules which have been adopted for maritime navigation have become the basis for civil aviation. There is therefore no reason in this perspective why the WTO's rules should not be applied to GMOs. The WTO's rules have been developed in order to combat discrimination and protectionism, and this principle applies to traditional goods and to genetically modified products equally. This approach argues that any exceptions to the WTO rules must be interpreted restrictively in order to maintain the free flow of goods and services because there is always a temptation to put up trade barriers for reasons of political expediency.

The pragmatically-precise response finally accepts the application of the WTO rules in principle but it applies them pragmatically and very precisely in light of the objectives for which they were developed and only with regards to the questions for which they were originally intended. In the application of predictable, non-



protectionist and non-discriminatory rules it therefore does not make any sense to exclude new products as long as the WTO law is not abused. Thus it may be argued that it is not legitimate to use the WTO rules in order to impose new technologies and new products upon governments that reject them. If for instance a government would not allow cars within its borders then the importation of cars would not be a question for the WTO to decide.

Furthermore, rules to protect the environment need to be applied in a flexible and pragmatic fashion, and they have to reflect legal developments outside the trade regime: The notion of *necessity* as it is used by the WTO cannot be taken to mean the same thing in situations where related interdependencies and risks are well known, and in those situations where there are vital scientific uncertainties and risks. As far as the SPS Agreement is concerned, finally, its Annex A clearly defines its scope, namely measures which are intended to provide protection against pests, diseases, disease-carrying organisms or disease-causing organisms, and against additives, contaminants, and toxins. The risks associated with GMOs are of a different nature, none of these descriptions apply to them. Thus, it would seem that the SPS Agreement would not apply to measures related to GM products. This conclusion seems to be supported by the fact that the large majority of the WTO members have notified their GM-related rules and measures only under the TBT Agreement and not under SPS.

#### **4.4. GMO Labelling**

The WTO rules allow not only measures to protect the environment but also measures to inform consumers, such as labels, even though they may contribute to the protection of the environment only indirectly. Art. 2.2 of the TBT Agreement thus specifies that technical regulations (which refer to mandatory standards in WTO parlance) shall not be more trade-restrictive than necessary to fulfill “legitimate objectives.” It also lists a few such objectives as well as the types of information which are acceptable. In both cases it uses the expression *inter alia* which provides national authorities with a certain leeway for the introduction of other objectives and kinds of information. Providing consumers with adequate information might very well constitute such an objective especially since the related objective of the prevention of deceptive practices is mentioned as one of the legitimate objectives.

In countries like Switzerland where consumers essentially assume that the food products on the shelves do not contain and are not produced with GM ingredients it would seem that the sale of GM food products without a label mentioning this characteristic would be considered as a misleading sales practice. This means that compulsory labels for GM products, ingredients or manufacturing processes are not only covered by the consumers’ legitimate demands for information but furthermore also by the objective of the prevention of misleading practices specifically mentioned in the TBT Agreement. It should be emphasized that the Codex Alimentarius has been trying for several years to negotiate the terms of reference for GM food labeling but has so far not managed to reach a conclusion in this politically sensitive issue.



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