

Biosafety from an EU perspective

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June, 2009

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INTRODUCTORY COMMENTS

This document is a study carried out in the framework of the project entitled “Managing Biosafety and Biodiversity in a Global World: EU, US, California and Comparative Perspectives”, which is funded by the European Commission, Directorate General for External Relations, under Contract Number S12.484597.

The report draws importantly on background information and comments provided by Alessandro Olper and Liesbet Vranken. Overall guidance and comments on the design and approach of the study were provided by Johan Swinnen.

None of the previously mentioned experts is responsible for the content of this report. The opinions expressed in this study and the analysis and arguments provided are the sole responsibility of the author of this report (Eleni Kaditi).

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ABBREVIATIONS

AIA	Advance Informed Agreement
BCH	Biosafety Clearing House
BSE	Bovine Spongiform Encephalopathy
CBD	Convention on Biological Diversity
EC	European Commission
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organisation
FDA	Food and Drug Administration
GMMs	Genetically Modified Microorganisms
GMOs	Genetically Modified Organisms
LMG	Like-Minded Group
LMOs	Living Modified Organisms
MEAs	Multilateral Environmental Agreements
MFN	Most Favoured Nation
MSs	Member States
NGOs	Non-Governmental Organisations
OECD	Organisation for Economic Co-operation and Development
SPS	Sanitary and Phytosanitary
TRIPS	Trade-Related Aspects of the Intellectual Property Rights
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNEP	United Nations Environment Programme
US	United States of America
USDA	US Department of Agriculture
WHO	World Health Organization
WTO	World Trade Organisation

EXECUTIVE SUMMARY

Agricultural applications of modern biotechnology can have a significant impact on the environment and society, when applied properly. This technology has indeed great potential to contribute to sustainable gains in agricultural productivity, to reduce poverty and to enhance food security in developing regions. Nevertheless, there is a common understanding that a balanced and comprehensive approach of biosafety is needed for evaluating the possible adverse effects from the deliberate release of biotechnology (including genetically modified; GM) products into the environment, as well as their use in human and animal diets.

Developed and developing countries have to establish biosafety regulatory systems to ensure the safe use of biotechnology products. For such policies and procedures to function effectively, they should be flexible to adapt to the evolution of scientific knowledge, to ensure feedback mechanisms and to reflect the conditions of a given country as much as possible.

Despite the increasing economical importance of the agri-biotechnology sector, there is a gap between biotechnological innovation and political responses. Political institutions have reacted only slowly and inadequately to the perceived risks of biotechnology. Regulations in industrial countries have not always assured the public of the safety of biotechnology, and many developing countries lack even minimal regulatory frameworks. More importantly, no comprehensive regulatory system existed until recently, that could deal with the transboundary aspects of the global biotechnology production.

In particular, a number of developed countries that have already established their own regulatory systems, most notably the Member States of the EU, considered aspects of international biosafety in the context of the Convention on Biological Diversity (CBD), taking into account the fast expansion of the sector. This helped to frame the biosafety talks in terms of a North-South issue, focusing on the needs of developing countries. However, the increasing trade flows of GM products in the second half of the 1990s brought the EU into more direct conflict with the US, the world's largest GM products exporter. What has started out as a North-South issue soon developed into a conflict among Northern countries over the potential implications of biosafety regulation for international trade rules and obligations.

Between July 1996 and February 1999, six meetings were held to conclude a Protocol on biosafety, yet a final consensus on all issues could not be reached even at the latest session which met in Cartagena, Columbia, from February 22 to 24, 1999. After five years of informal discussions and negotiations, representatives from over 130 states met in Montreal, Canada, from February 24 to 29, 2000, and managed to finalise the so-called Cartagena Protocol on Biosafety, to the surprise of many negotiators. The Protocol entered into force on September 11, 2003 and it is aimed at protecting the environment from the potential risks caused by the transboundary transfer of living modified organisms, including GM organisms (GMOs), created by modern biotechnology.

In brief, countries participating in the Biosafety Protocol have the right to submit imports of GMOs intended for deliberate release into their environment to an authorisation procedure based on a notification, prior to a first transboundary

movement, and a scientific risk assessment. Exports of such GMOs can only take place after an advanced informed agreement from the importing country. In addition, the Protocol established a system of information exchange about GMOs intended for use as food, feed or processing, as well as a very broad range of relevant information on GMOs.

While the Cartagena Protocol marked a significant step forward in regulating biotechnology trade, its effectiveness with regard to protecting biodiversity and human health depends on its ability to adapt to, and catch up with, the rapid change in biotechnological research and commercialisation.

Consequently, within the EU, the use of GMOs has been supplemented by a revised legislative framework that covers different field of activities such as, inter alia, agriculture, environment, food and plant safety. The primarily EU regulation concerning the use of GMOs is Directive 2001/18/EC. As regards the previous Directive 90/220/CEE, it contains new measures and defines more precisely the procedures for the environmental release of GMOs for both experimental and commercial purposes. Another Directive (98/81/CE) aims at regulating the confined use of GM microorganisms, while Regulation No 1946/2003 regarding transboundary movement of GMOs is harmonised with the Cartagena Protocol on biosafety. New Directives on labelling and traceability (1830/2003) and on GM food and feed (1829/2003) have also been prepared.

BIOSAFETY FROM AN EU PERSPECTIVE

Eleni A. Kaditi

1. INTRODUCTION

Biotechnology offers potential to address global healthcare through innovative approaches, to deliver improved food and environmental quality through agronomically enhanced crops and to improve non-food uses of crops as sources of industrial feedstock or new materials. At the same time, biotechnology raises particular policy and societal challenges related to the creation and use of and trade in genetically modified (GM) products.

Biosafety of GM products is, therefore, a rapidly developing multidisciplinary approach that encompasses science, ethics and societal issues, policy and regulatory frameworks that assess and manage risks for human and animal health (including food and feed safety), and risks for environment associated with the development and application of the products of modern biotechnology. Biosafety is a holistic concept of direct relevance to the sustainability of agriculture, food safety, and the protection of the environment, including biodiversity.

Taking into account the fast expansion of the agri-biotechnology sector and the fact that the worldwide commercialisation of biotechnology has not been accompanied by a build-up of the necessary scientific and regulatory capacities in many parts of the world, there was a need to act swiftly at the international level to promote biosafety. There was also a general understanding among policy makers that trade and the environment had to be mutually supportive, but this had failed to have a concrete impact on international agreements.

The adoption of the so-called *Cartagena Protocol on Biosafety* annexed to the Convention on Biological Diversity (CBD), on February 2000, marked the close of five years of intensive, contentious, and often emotional negotiations on biosafety issues. The Biosafety Protocol is one of the most important multilateral environmental agreements (MEAs) to have been adopted, as it provides a binding framework for assessing and managing the risks to the environment and human health from the movement of living (genetically) modified organisms (LMOs) – or more popularly, genetically modified organisms (GMOs) – between countries.¹ The overall purpose of this United Nations agreement is to establish common rules to be followed in transboundary movements of GMOs in order to ensure, on a global scale, the protection of biodiversity and of human health. It is based on the precautionary approach and it enables an information procedure to ensure that countries are provided with the information necessary to make informed decisions before agreeing to the import of GMOs into their territory.

The Protocol entered into force on September 11, 2003 and currently has 156 parties, including all Member States of the European Union (EU). Further implementation of biosafety policy and its effectiveness with regard to protecting biodiversity and human health though depends on the Protocol's ability to adapt to, and catch up with, the rapid change in biotechnological research and commercialisation. European regulators

¹ The Protocol defines a living modified organism as 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'.

at the national and EU levels introduced then new regulations harmonised with the Biosafety Protocol, continuing to take a very cautious approach to GMOs. In particular, GM foods and crops are treated as different from their conventional counterparts and strict regulatory procedures are adopted for their approval and marketing. As a result, exports of GM products from the US were affected already by the late 1990s, creating a conflict over the potential implications of biosafety regulation for international trade rules and obligations.

The aim of this study is to provide an overview of the EU regulation on GMOs as well as of the international attempts to regulate trade of GMOs by the adoption of the Biosafety Protocol. The analysis is primarily focused on the recent legislative and regulatory developments in the EU (Section 2). A summary of key provisions of all international agreements on biosafety is provided in Section 3, where all the major international instruments relevant to biosafety are presented (i.e. the CDB, the Protocol and the WTO Agreements). The negotiating process for the Protocol is examined in Section 4, presenting the views and perspectives from all negotiating groups, giving though particular emphasis to the EU's position. Section 5 presents the relationship between the Protocol and the WTO Agreements, whereas the next section includes a discussion on the implementation of the international biosafety regulations. Finally, Section 7 concludes.

2. EU REGULATION ON BIOSAFETY

The EU has undertaken extensive measures to regulate GMOs, mainly in response to consumers' concerns with the potential hazards of GM foods and crops.² The main objectives are: (i) to protect human health and the environment and (ii) to ensure the free movement of safe genetically modified products in the European Union. In brief, a GMO or a GM food or feed product can be put on the EU market after it has been authorised on the basis of a detailed procedure. This procedure is based on a scientific assessment of the risks to health and the environment. The authorisation procedure involves all Member States and it has been in place since the early 1990s.

In particular, the first comprehensive legislation for the regulation of biotechnology in the EU came in 1990, with the adoption of two directives by the EU Council of Ministers.³ *Directive 90/219/EEC* on the contained use of GM Microorganisms (GMMs) regulates the use of GMOs in laboratory settings. *Directive 90/220/EEC* on the deliberate release of GMOs into the environment governed for over a decade the approval, planting, and marketing of GM foods and crops within the EU. Each member state is to designate the component authority responsible for the implementation of the directive and to ensure that such authority takes appropriate control measures for such implementation.

In 1997, *Directive 90/220/EEC* was supplemented by *Regulation 258/97*; the so-called Novel Foods Regulation. *Novel foods* were defined as all foods and food ingredients that had not been used for human consumption to a significant degree within the EU and included both foods that had been genetically modified as well as foods produced from, but not containing GMOs. The regulation established an authorisation

² Many EU MSs have unilaterally imposed even more stringent regulations.

³ The Commission's proposal emphasized the scientific uncertainty associated with genetic engineering, and therefore proposed an EU regulatory scheme that would provide for case-by-case assessment and authorization of the release of all new GM varieties into the environment.

procedure similar to that of the directive, as well as labelling requirements for all approved GMOs used in food and foodstuffs. Moreover, the regulation contained a *safeguard clause* allowing member states, as a result of new information or a reassessment of existing information, to temporarily restrict or suspend the trade in and use of the food or food ingredient in question in their territory.

It should be noted that despite the BSE (Bovine Spongiform Encephalopathy) scandal, GM soy was imported from the US to the EU in November 1996, spurring widespread protest by non-governmental organisations (NGOs). The Commission also approved the sale of another GM food crop (Bt corn) in January 1997, over the objection or abstention of all but one of the fifteen member states (MSs). However, the MSs did not accept this decision and by January 2004, nine MS safeguards were in effect (applied by Austria, France, Greece, Germany, Luxembourg, and the United Kingdom). The Commission forwarded a proposal to the regulatory committee to initiate a legal challenge against these bans, but did not proceed further when the committee refused to support it.⁴

For a period of five years, a group of MSs obstructed the authorisation of any new GM variety, pending the adoption of a revised EU regulatory framework, including provisions regarding the labelling and traceability of GM food and crops from *farm to fork*. In 2004, the first new GM variety was approved to be licensed in the EU since 1998 (two GM varieties of carnations had been approved). In the meantime, the Commission issued a *White Paper* on food safety (2000), based on which the European Food Safety Authority (EFSA) was established. The White Paper set forth the EU's general approach to risk regulation in the food sector, dividing *risk assessment* from *risk management*. Specialised scientific committees within the new food authority would conduct risk assessments, and the new authority would provide food safety information to consumers and operate a rapid alert system in conjunction with MS authorities to respond to food safety emergencies. Risk management would remain under the control of the EU's political bodies.

On March 2001, *Directive 2001/18/EC* was adopted, according to which the *precautionary principle* should apply to protect the environment and human health when GMOs or GM products are released into the environment and placed on the market.⁵ In particular, the directive provides for:

- the application of a precautionary approach;
- a case by case evaluation of the environmental risk deriving from the release of GMOs, also considering long-term effects;
- consultation with the ethical and scientific committees from MSs;
- transparency and public accessibility to information related to the release of GMOs;
- institutions of public registers containing the information on genetic modification of GMOs;
- introduction of monitoring improved risk management and labelling;
- approval of the environmental release for no longer than 10 years;
- a procedure for approval renewal;

⁴ Many large European retailers also refused to buy or sell GM foods under pressure from potential consumer boycotts.

⁵ If a MS has justifiable reasons to consider that a GMO, which has received written consent for placing on the market, constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory.

- an institution of public register containing a list of the location of the GMOs releases for either experimentation or commercialization; and
- elimination of antibiotic resistance genes acting as transformation markers (by 2004 for commercial releases and by 2008 for research).

However, this directive did not satisfy some MSs. For this reason, only the directive's provisions governing the release of GMOs into the environment were fully implemented, while its provisions governing the marketing of GMOs used for commercial crops were largely replaced within eighteen months by two new EU regulations regarding the labelling and traceability of GM foods and their use in food and feed, respectively.

These new regulations were adopted in September 2003 and became effective on April 18, 2004. *Regulation (EC) No 1829/2003*, regarding the authorisation of GMOs in food and feed, replaced the provisions of Directive 2001/18/EC governing the authorisation for marketing of GMOs (whether they concern the GMO itself or the food and feed products derived from them), and the labelling provisions of the Novel Foods Regulation.⁶ The regulation puts in place a centralised, uniform and transparent EU procedure for all applications for placing on the market, whereas the Commission has an important role. Notably, it is up to the EC to adopt the final decision and grant or reject the authorisation if the Committee, composed of representatives of the Member States, and the Council have not managed to adopt the decision by qualified majority within the time limit in question.

Regulation (EC) No 1830/2003, in turn, created new rules on the traceability of GM products throughout the production and distribution process.⁷ The traceability rules oblige the operators concerned, i.e. all persons who place a product on the market or receive a product placed on the market within the EU, to be able to identify their supplier and the companies to which the products have been supplied. In addition to the traceability rules, this Regulation also sets out labelling requirements for the GM products. Labelling informs the consumer and user of the product, hence allowing them to make an informed choice. Nevertheless, there are exceptions from the traceability and labelling requirements, as the legislation has set limits above which conventional food and feed must be labelled as products consisting of GMOs, containing GMOs or produced from GMOs.⁸

In particular, one of the most controversial elements of the new regulation was the establishment of a set of *thresholds* for permitted traces of GM ingredients, provided their presence is 'adventitious'. Recognizing that it is practically impossible to ensure that any crop is entirely GM free, the Commission initially proposed a threshold of 1% GM material, below which any crop would not have to be labelled as containing GM foods. The proposed threshold was contested, however, by NGOs, the European Parliament, and member governments, all of which called for lower thresholds. Biotechnology companies and the US government, by contrast, criticised this threshold as unrealistic, unnecessarily costly and scientifically unjustified.⁹ The final

⁶ GM animal feed was covered for the first time.

⁷ The regulation requires producers to collect and retain for five years data regarding the GM content of foods and crops one step backward and one step forward in the distribution chain.

⁸ In line with the general EU rules on labelling, Regulation (EC) No 1829/2003 does not require labelling of products such as meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products.

⁹ These divisions were mirrored in the Council, where the UK favoured the proposed 1% threshold, while Austria favoured thresholds as low as 0.1%.

regulation represents a compromise among these two positions, and establishes two distinct thresholds. It provides that food products will not violate labelling requirements if they contain material consisting of or produced from EU approved GMOs in a proportion no higher than 0.9% of the food ingredients considered individually, provided that this presence is adventitious or technically unavoidable. However, the regulation establishes a second and stricter threshold of 0.5% for GMOs not yet approved for environmental release in the EU, and establishes a three-year window after which no residues of such non-approved GMOs are allowed in food and feed products.

All these new rules take account of the EU's international trade commitments and of the requirements of the Cartagena Protocol on Biosafety, specifically as regards the obligations on importers of products in the EU and the obligations on exporters of products to third countries. The Cartagena Protocol on Biosafety is incorporated into EU legislation through a wide range of legislation governing the use of GMOs with the EU. The cornerstone of this legal framework is Directive 2001/18/EC on the deliberate release into the environment of GMOs. It is supplemented by the *Regulation (EC) No 1946/2003*, on the transboundary movements of GMOs, which was adopted in June 2003. The EU ratified the Cartagena Protocol on Biosafety in 2002, in line with CBD Article 19.¹⁰ A Biosafety Clearing House was also established to keep all parties informed on national and regional decisions and legislation concerning GMOs.

The revised EU regulatory scheme is summarised in Table 1; whereas a brief summary of the current authorisation procedures is presented in Table 2.

It should be, finally, emphasised that the implementation of the revised regulatory framework has met a number of challenges. When the approval procedures restarted in 2004, there was concern that the new member states (NMS), most of which were already engaged in the cultivation of GM crops (often without adequate controls), might support the US' and the biotechnology industry's views. Indeed, ensuring adequate testing facilities in the NMS remained a challenge for the EU post-accession, but it seemed clear that the ambivalence toward agricultural biotechnology in the EU-15 was reflected in the public opinion and governmental positions of the NMS as well. Moreover, difficulties are found during the decision making process for authorising the placing on the market of GMOs. Various environmental and safety concerns remain also, despite the revision of the regulatory framework, and have led various MSs to invoke safeguard clauses. Finally, a considerable number of implementing measures to support operation of this overall framework have been adopted by MSs over the past years. These include, amongst others, guidelines for risk assessment, monitoring, formats for submission of notifications, sampling and detection and coexistence measures. The difficult development of national coexistence measures and the unresolved definition of seed thresholds hamper though a comprehensive approach to the cultivation of GMOs.¹¹

¹⁰ Each Contracting Party shall consider the need for a protocol setting out appropriate procedures, including advance informed agreement, and the safe transfer, handling and use of living modified organisms resulting from biotechnology [...]

¹¹ Coexistence is about giving farmers the practical choice between conventional, organic and GM crop production in compliance with the legal obligations for labelling and purity standards. On March 2003, the EC agreed that it should be up to the MSs to develop and implement management measures concerning coexistence, in accordance with the subsidiary principle. On 23 July 2003, the EC adopted a *Recommendation (2003/556/EC)* on guidelines for the development of national strategies and best

Table 1: EU legislation governing GMOs and GM products as of May 2004

Step-by-step activities in the production process	Applicable EU legislation
GMO research in laboratories	Contained use Directive 90/219
GMO experimental releases (trials)	Directive 2001/18
GMO environmental releases for crops	Regulation 1829/2003 and Directive 98/95/EC (common seed catalogue)
Authorization of marketing of GM seeds (for environmental releases for crops)	Regulation 1829/2003 and Directive 98/95/EC
Authorization of marketing of GM food and feed	Regulation 1829/2003
Labelling of GM seed, food and feed	Regulation 1829/2003
Traceability and labelling of GM products	Regulation 1830/2003

Table 2: Authorisation process for GM food and feed under Regulation 1829/2003

1.	An operator submits an <i>application</i> to the competent authority from one of the MSs.
2.	The MS provides the file to the European Food Safety Authority (EFSA).
3.	The EFSA provides a <i>copy</i> to the other MSs and the Commission, and makes a <i>summary</i> of the file publicly available.
4.	Within <u>six months</u> , EFSA submits its opinion based on <i>risk assessments</i> to the Commission, the MSs, and the applicant, and, after the deletion of any confidential information, makes it publicly available.
5.	The Commission is then to issue a <i>draft decision</i> , which may vary from EFSA's opinion, based on the regulatory committee consisting of MS representatives.
6.	The committee is to deliver its <i>opinion</i> on the Commission's proposed decision by a qualified majority. If the committee delivers no opinion or a negative opinion, the Commission must submit its proposal to the Council. If the Council does not adopt (or indicate its opposition to) the Commission's proposal (but this time by a qualified majority vote, as opposed to a unanimous one), then the proposed decision is adopted by the Commission.

To sum-up, the EU revised legislative framework on GMOs started in 1999 in the light of scientific developments and public concerns, and has been fully operational since April 2004. Its main legal instruments are as follows:

1. *Directive 2001/18/EC* on the deliberate release into the environment of GMOs, applying to the intentional introduction of GMOs into the environment without specific containment measures. The Directive introduces a notification obligation and covers both releases of GMOs for experimental purposes and for commercialisation.
2. *Regulation (EC) No 1829/2003* on genetically modified food and feed regulates the placing on the market of GMO for food and feed use, as well as food and feed containing, consisting of or produced from GMOs.
3. Intentional or unintentional movements of GMOs between Member States of the EU and third countries are regulated by *Regulation (EC) No 1946/2003* on

practices to ensure the coexistence of GM crops with conventional and organic farming. The Recommendation states that approaches to coexistence need to be based on technical guidelines and in cooperation with all stakeholders concerned. In spite of these guidelines, some national measures have been refused by the EC as disproportionate to their objective and representing a potential barrier to free circulation of authorised GMOs. In addition, a number of MSs consider the guidelines insufficient and have demanded more precision in terms of guidelines or legislation.

transboundary movements of GMOs, with the exception of intentional movements within the Community.

4. *Directive 90/219/EEC*, as amended by *Directive 98/81/EC*, on the contained use of genetically modified microorganisms (e.g. GM viruses or bacteria). This Directive regulates research and industrial work activities involving GMMs under conditions of containment, i.e. closed environment.
5. Finally, labelling and traceability requirements are laid down in *Regulation (EC) No 1829/2003* and *Regulation (EC) No 1830/2003*, covering all GMOs that have received EU authorisation for their placing on the market, namely all products containing or consisting of GMOs, including food and feed.¹² It introduces then an information obligation and amends Directive 2001/18/EC.

Under Directives 2001/18/EC and 90/220/EC, numerous GMOs have been approved for different uses, some for cultivation, some for import and processing, some as feed and food. Varieties of agricultural products include maize, oil seed rape, soybean and chicory. Some applications for the placing on the market of GMOs for authorisation under Directive 2001/18/EC are though pending. Several applications have a scope which is restricted to import and processing, while some also include cultivation as a requested use.

For reasons of comparison, it should be, finally, noted that the US has no special laws that specifically apply to GM foods. The biotechnology approval process involves three departments: the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). However, biotechnology companies are only required to consult the FDA as they bring new biotechnology products to market, so long as the added genes do not substantially change the nature of the foods. Labelling is also not required.¹³

Consequently, the US and the EU have taken different approaches to the biosafety regulation, with the US opting mainly for science based regulation undertaken largely by relatively independent regulatory agencies that have treated GM products as substantively similar to conventional foods; whereas the EU has adopted and elaborated a distinctive and separate system of approval and labelling for GM products system based on risk management by political bodies that take into account social and economic concerns as well as scientific risk assessment. These very different approaches reflect different cultural attitudes toward food and agriculture, underlying differences in regulatory style, pressures from private interests, and contingent events such as the EU's food safety scandals of the 1990s. Not surprisingly, they have in turn created significant trade frictions between the US and the EU, as it will be analysed below.

¹² Already in 1998, the Council identified as one of the purposes of Regulation No. 1139/1998 the necessity to adopt uniform EU labelling rules for these products because several member states had unilaterally taken measures on labelling and there was concern that 'differences between those measures [could] impede the free movement of those foods and food ingredients and thereby adversely affect the functioning of the internal market'.

¹³ Unlike the US FDA, which is an independent agency, EFSA envisions the creation of an advisory body of scientists.

3. INTERNATIONAL REGULATION ON BIOSAFETY

The issue of international biosafety standards was first raised at the diplomatic level in the 1980s. In 1992, at the United Nations Conference on Environment and Development (UNCED), questions of biosafety emerged within the context of the preparations for the CBD. At that time, advances in biotechnology had given rise to concerns about the impact of GMO releases into the environment. Although the new technology had not yet been introduced to agricultural production on a commercial scale, it became clear that it was only a matter of time before genetic engineering would be adopted by the global agriculture and food industries.

A number of international organisations (e.g. FAO, OECD) began to address aspects of international biosafety, although none of them was able to go beyond non-binding standards or codes of conduct. These various efforts to create international biosafety standards demonstrated three important aspects of the new biotechnology agenda. First, a wide range of policy issues and areas are affected, including environmental safety, human health, international trade, food security, technological innovation and industrial policy. Second, considerable difficulties are involved in reaching international agreement on comprehensive and universal biosafety standards. Third, there is a growing gap between economic and technological innovation and international regulatory responses. It is against this background that the parties to the CBD began to consider the need for, and modalities of, an international agreement on biosafety.

Consequently, the UNCED, also known as the Earth Summit, that was held in Rio de Janeiro in Brazil, 172 governments agreed on several documents among which were *Agenda 21* and the *Convention on Biological Diversity*.

Chapter 16 of Agenda 21 deals with the environmentally sound management of biotechnology and recognises two important facts: 1) although not a panacea, modern biotechnology promises significant contributions to sustainable food production, improved health care and environmental protection, and 2) the community can only benefit maximally from the potential of modern biotechnology, if it is developed judiciously and adequate safety mechanisms are set in place. With this context, Agenda 21 provided a blue print for international collaboration for the further development and application of biotechnology and biosafety.

The other key agreement adopted at the UNCED was the Convention on Biological Diversity. The objectives of the CBD are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. As already mentioned, the *Cartagena Protocol on Biosafety*, established under the Convention, has been adopted in 2000. It aims at regulating the transboundary movement of living modified organisms resulting from modern biotechnology, in light of protecting biological diversity from potential risks that may be posed.

Apart from these, *WTO Agreements* are also directly relevant to the international biosafety regulation. Not surprisingly, given the importance of transatlantic trade in foodstuffs, the political pressure from EU farmers to protect the internal market and from US farmers to open it, and the abovementioned differences in the US and EU regulatory systems, a conflict over the potential implications of biosafety regulation for international trade rules and obligations was created.

This section will, therefore, analyse these issues in detail.

3.1. The Convention on Biological Diversity

One of the major international instruments relevant to biosafety is the Convention on Biological Diversity.

The CBD addresses biosafety in two articles. Article 8(g) and Article 19(3) and (4). Article 8(g) requires each Party ‘...to manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity’. In this article the Convention goes even beyond its general scope requiring to take also into account the risks to human health. Environmental impact assessment and minimisation of the adverse impact on biological diversity are relevant obligations (Art. 14.1 (a)). Reciprocity, notification, exchange of information with other countries and international organisations, where activities in one party may adversely affect the biodiversity of another party or an area beyond the limits of any national jurisdiction, are also included (Art. 14.1 (c) and (d)). Moreover, parties have to create emergency response arrangements at national level and joint contingency plans with other countries (Art. 14.1 (e)).

Under Article 19(3), the need of a biosafety protocol, which provides the basis for international measures related to the trade in LMOs, is emphasised. Article 19(4) further creates a bilateral obligation for a CBD party to provide information on the use and handling of LMOs prior to providing such organisms to another CBD party. This information includes: (1) any available information on the regulatory measures taken by the exporting party; and (2) any available information on the potential adverse impact of a particular LMO.

The Convention’s implementation occurs largely at the national level and is the responsibility of each individual party.

3.2. The Cartagena Protocol on Biosafety

The Cartagena Protocol is the first global legally binding instrument focusing on biosafety. The scope of the Protocol is to ensure adequate levels of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biodiversity or pose a risk to human health (Art. 1 and Art. 4). The Protocol is applicable to all LMOs apart from those that are pharmaceuticals for humans and commodities such as soybeans or maize, intended for direct use as food, feed, or processing; LMO-FFPs (Art. 5 and Art. 7). Countries are to develop their own national regimes.¹⁴ Relevant provisions are Articles 6 to 10 and Article 12 establishing an *Advance Informed Agreement* (AIA) which requires, prior to the first intentional introduction into the environment, the exporter to provide detailed information to each importing country in advance of the first shipment, and the importer must then authorise the shipment.¹⁵

¹⁴ As explained further later, the US, although not a party to the CBD and hence not an official participant at the Cartagena and Montreal meetings, expressed its concerns through its allies in the Miami Group, and was the major opponent of any regulation pertaining to food commodities and pharmaceuticals in the proposed Protocol.

¹⁵ The EU and developing countries sought provisions for clear labelling by exporters of any shipment of commodities containing LMOs. To illustrate, at the Cartagena meeting, the EU had submitted its proposal under which an exporter would be required to clearly indicate as LMO commodities ‘intended for direct use as food, feed or processing’. The US and other exporting countries had claimed that such

This procedure is designed to ensure that recipient countries have both the opportunity and the capacity to assess risks pertaining to the products of modern biotechnology.

The AIA procedure only applies to those LMOs intended for intentional introduction into the environment. According to the Protocol, AIA does not refer to LMOs intended for direct use as food, feed or processing. Other exceptions are LMOs identified as not likely to have adverse effects on biodiversity conservation and sustainable use, LMOs in transit, and LMOs for contained use.

For LMOs that may be subject to transboundary movement for direct use as food or feed, or processing, Article 11 provides that a party that makes a final decision for domestic use, including placing on the market, must notify the *Biosafety Clearing House* (BCH) created under the Protocol.¹⁶ In addition, certain information must be provided. Article 11.4 permits parties to take an import decision under its domestic regulatory framework, provided this is consistent with the Protocol. A developing country-party or a party with economy in transition, that lacks a domestic regulatory framework, can declare through the BCH that its decision on the first import of an LMO for direct use as food, feed or for processing will be pursuant to a risk assessment (Art. 11.6). In both cases, lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects shall not prevent the party of import from taking a decision, as appropriate, in order to avoid or minimise potential adverse effects (Art. 11.8).

The Protocol provides risk assessment guidelines in Annex III. The risk assessment must be undertaken in a manner which is scientifically sound and transparent and on a case-by-case basis. The Protocol specifies general risk management measures and criteria. Any measures based on risk assessment should be proportionate to the risks identified. Measures to minimise the likelihood of unintentional transboundary movement of LMOs are to be taken (Art. 16.3). Affected or potentially affected countries are to be notified when an occurrence may lead to an unintentional transboundary movement (Art. 17.1).

The Protocol may also account for socioeconomic considerations arising from the impact of LMOs on biodiversity conservation and sustainable use. The parties are encouraged to cooperate on research and information exchange on any socioeconomic impacts of LMOs, especially on indigenous and local communities (Art. 26.2).

Overall, the Protocol reflects the commitment of the international community to provide for safety in biotechnology and is, indeed, a historic attempt to reconcile economic and trade policies with environmental concerns. It incorporates the *precautionary principle* in the process of decision-making, and underscores the need to enhance the capacity building of the developing countries to ensure biosafety.¹⁷

labelling would be impossible for bulk commodity shipments where grain is mixed from many different sources.

¹⁶ The BCH is designed to assist parties in implementing the Protocol, with special attention to the needs of developing countries. Special provisions address capacity-building of developing countries, including appropriate scientific and technical training; risk assessment and risk management for biosafety; and the enhancement of technological and institutional capacities in biosafety.

¹⁷ The precautionary principle says that, in some cases, preventive action should be taken, even without full scientific certainty about the problem being addressed. In practice this gives governments a fair amount of discretion in setting environmental policy. At Cartagena, the Miami Group took the position that reference to the precautionary approach in the Protocol must be simply noted, and any reference to

Finally, the question of the relationship between the Protocol and the WTO was resolved by noting in the preamble that the Protocol would not be subordinate to other international agreements, which in this context meant primarily the WTO. The point of contention was that under trade rules it was not the precautionary approach but certain scientific evidence that would determine if an importing country could block the shipment of a LMO.¹⁸

3.3. The WTO Agreements

Most relevant in the biosafety area is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), which underlying objective is to ensure that members do not use food safety, animal and plant health regulations as unjustified trade barriers to protect their domestic agricultural industries from competitive imports. However, apart from the SPS Agreement, several other WTO agreements are also directly relevant in the biosafety area.

3.3.1. GATT

The original *General Agreement on Tariffs and Trade* (GATT 1947) was revised as part of the Uruguay Round and the revised text (GATT 1994) constitutes an integral part of the WTO. GATT 1994 is the umbrella agreement for trade in goods and covers the basic principles that form the foundation of the multilateral trading system. Its rules continue to apply where not superseded by a more specific WTO Agreement. Article I prohibits discrimination between products imported by members, also referred to as the *Most Favoured Nation* (MFN) principle. Article III prohibits discrimination between imported and domestic goods, also referred to as the principle of national treatment, whereas Article XI prohibits quantitative restrictions on trade.

Exceptions to the basic principles are contained in Article XX (b) and (g). They permit members to take measures necessary to protect human, animal and plant health, or relating to the conservation of exhaustible national resources, as long as they do not arbitrarily or unjustifiably discriminate between countries where the same conditions prevail or constitute a disguised restriction on international trade. In other words, this article gives members the legal means to balance their trade obligations with non-trade objectives such as health protection or the environment. As further discussed below, the SPS Agreement builds on this general exception and provides additional rules in this regard.

3.3.2. TBT Agreement

The WTO also oversees the implementation of the *Agreement on Technical Barriers to Trade* (TBT Agreement). Technical regulations and industrial standards are important but vary from country to country. Having too many different standards may create difficult situations for producers and exporters. If standards are set arbitrarily, they could be used as an excuse for protectionism. The TBT Agreement aims to

the precautionary approach should be deleted from the decision procedure. The Group was unsuccessful in its attempt.

¹⁸ It may be recalled that at the WTO meeting in Seattle in the fall of 1999, no decision could be taken about the regulation of biotechnology under the WTO processes.

ensure that regulations, standards, testing and certification procedures do not create unnecessary obstacles to trade. However, the Agreement recognises members' rights to adopt the standards they consider appropriate; for instance, to protect human, animal or plant life or health, or the environment, or to meet other consumer interests.¹⁹

The Agreement may be of relevance to biosafety for its relevance to biotechnology products, because it generally applies to technical regulations and standards, including packaging, marking and labelling requirements. The Agreement applies to all products (Art. 1.3), though it does not apply to SPS measures (Art. 1.5). The SPS Agreement would, therefore, apply where a biotechnology product may be a risk to human, plant or animal health. On the contrary, the TBT Agreement would likely apply to technical barriers to the import of LMOs imposed to inform consumers or to protect a state's culture or economy.

3.3.3. *TRIPS Agreement*

Moreover, the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS Agreement), which establishes minimum levels of protection that each member has to give to the intellectual property of other members, should be noted. In particular, the issue of obtaining patents on live plants and animals, including biotechnological inventions and plant varieties, is an intensely debated topic. Concerns are expressed about the economic, social, environmental and ethical impacts of life patenting. In addition, developing countries are concerned that life patenting could affect their development prospects and could have an impact on their food security situation.

3.3.4. *SPS Agreement*

Finally, the SPS Agreement provides for a common approach to different sectors in the context of biosafety by applying to all sanitary and phytosanitary measures, which may directly or indirectly affect international trade (Art. 1). The SPS Agreement, while permitting governments to maintain appropriate sanitary and phytosanitary protection, reduces possible arbitrariness of decisions and encourages consistent decision-making. A member's SPS measures: (1) must only be applied to the extent necessary, (2) be based on scientific principles, and (3) must not be maintained without sufficient scientific evidence (Art. 2.2). Measures must also not arbitrarily or unjustifiably discriminate between members and they cannot be applied in a manner that would constitute a disguised restriction on international trade (Art. 2.3).

In brief, the SPS Agreement covers all measures whose purpose is to protect: (1) human or animal health from food-borne risks, (2) human health from animal- or plant- carried diseases, (3) animals and plants from pests or diseases, and (4) the territory of a country from other damage caused by the entry or spread of pests. This protection applies regardless whether these are technical measures or not.

Consequently, the SPS Agreement ensures that governments can give health protection priority over trade. It grants governments the explicit right to impose restrictions on international trade when these are necessary to protect human, animal

¹⁹ A contribution to harmonisation within the Agreement is the development of international standards.

or plant health from certain risks (Article 2.1). The SPS Agreement requires governments to also recognise that there may be more than one way to ensure a product is equally safe. If an exporting country can demonstrate that the safety of its product is equivalent to that required by the importing country, then the product should be permitted, even though it was not produced according to the standards or processes normally required by the importing country (Article 4). In addition to imposing disciplines on the selection of SPS measures, this Agreement also requires that testing and inspection procedures used by governments to enforce these measures do not themselves act as unnecessary trade barriers.

3.4. Codex Alimentarius

The *Codex Alimentarius* is the primary collection of internationally adopted food standards and as such is of great relevance to biosafety. The Codex is an intergovernmental body established in 1962 by the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to promote international trade in food through the adoption of international food safety standards. The Codex has in fact become the seminal global reference point for consumers, food producers and processors, national food control agencies and the international food trade. It is the primary forum in which the food safety aspects of LMOs are addressed, whereas it also considers the issue of labelling biotechnology foods to allow the consumer to make an informed choice.

Both the US and the EU have placed increasing importance on the negotiation of new regulatory principles and standards within Codex, since these will be invoked in the decisions of WTO panels. This enhanced importance of Codex also led to the formal accession of the EU in the Codex on November 2003.

The subject of biosafety regulation first came before Codex during the 1990s. A Working Group on Biotechnology was established in 1999, and adopted a number of international guidelines on biosafety regulation before being disbanded in 2003. First, in terms of the application of the precautionary principle, the Codex Commission acknowledges precaution as an inherent element of risk analysis, while offering little clarification about its use at either the national or international levels. For the invocation of other legitimate factors (OLFs) in Codex decision-making, a series of more or less vaguely stated restrictions constrain the invocation of unspecified OLFs. Finally, with regard of labelling and traceability of GM foods, the Codex members eventually agreed in July 2003 to new ‘Principles and Guidelines on Foods Derived from Biotechnology’; a document that provides no guidance regarding the labelling of GM foods because US and EU positions proved impossible to reconcile. On traceability, the use of tracing of products is acknowledged as a risk management tool, but it is noted in a footnote that they ‘should be consistent with the provisions of the SPS and TBT Agreements’.

4. THE BIOSAFETY PROTOCOL: THE NEGOTIATING PROCESS

4.1. Background of the negotiations

The negotiations on biosafety, or safety in modern biotechnology, carried out under the Convention on Biological Diversity since 1996 were completed in January 2000. The biosafety protocol negotiations followed though a somewhat curious course. For

the first two years, they were essentially a discussion and debate and not a negotiation. The negotiations only really began in Cartagena, a reality that made reaching agreement on a balanced and workable text an impossible task.

4.1.1. *First intervention in Aarhus*

From the moment that the protocol negotiations started in Aarhus, Denmark, in July 1996, many delegates understood the complexity of the relevant task. In contrast to previous MEAs, the impact of LMOs on the global biological diversity was unknown, and it could not serve to unite governments on a concrete course, sustainable from beginning to end. There was no widespread recognition of the potential trade impact of the protocol, the need to take international trade rules into consideration or to take account of the regulatory principles that underpinned the WTO Agreement on SPS measures. As a result, differences over single issues were to become so acrimonious that at times completion of the agreement appeared beyond reach.

However, the onset of the BSE crisis in the EU in 1997 led to a growing public opposition to biotechnology, to criticism of the existing regulatory process and to the gradual politicisation of the negotiation. A variety of mechanisms were then proposed by a number of countries to address the potential environmental impacts resulting from the transboundary movement of agricultural LMOs.

4.1.2. *The Cartagena experience*

After five negotiating sessions, delegations arrived in Cartagena, Colombia, in January 1999, knowing that none of the critical issues had been resolved, still hoping that the protocol would be concluded. Multiple negotiating groups operated simultaneously causing a management problem for even the largest delegations, whereas the time allowed for debate and negotiation of the most controversial issues proved deficient. Positions on issues related to the capacity to apply biotechnology effectively and address potential risks were divided primarily along North-South lines. Differences regarding trade-related issues, on the other hand, were most pronounced among the largest global agricultural trade competitors – all of which had invested heavily in modern biotechnology, but only a few of which were producing and exporting LMOs. In Cartagena, three main negotiation groups emerged as pivotal to the conclusion of the negotiations. These were the *EU*, the *Like-Minded Group* of developing countries and the *Miami Group*.

Finding a way of dealing responsibly with biotechnology within the EU and at the international level was of primary importance to both NGOs and the industry. At stake was the credibility of governments in addressing the concerns of civil society, as well as the future of the CBD as an instrument for international cooperation in protecting natural heritage and promoting sustainable development. Consequently, the **EU** took a more sensitive attitude to the use of modern biotechnology and a more realistic view of the risks involved than did the US, Canada and Australia. Moreover, the EU had second thoughts about the suitability of the WTO for fully dictating the norms of trade in GMOs, and, supported by all but the Miami Group, it fought to prevent the subjugation of the biosafety protocol to the WTO agreements.

The EU negotiated as a common bloc throughout the biosafety negotiations. Given public outrage over food safety scandals, the EU strove for a strong Protocol

including coverage of risks to human health. On scope, the EU had pushed for inclusion of LMO-FFPs, while acknowledging that they might merit special treatment under the AIA procedure. They also supported alternative considerations for contained use, transit and pharmaceuticals for humans. On these issues, their position generally fell somewhere between those of the Miami Group and the Like-Minded Group. The EU also supported visible identification and documentation for LMOs, given the EU desire to identify GM products through labelling. The EU objected to the inclusion of a savings clause, arguing that it would threaten decisions to deny LMO imports on environmental grounds. The EU instead supported the inclusion of a non-discrimination provision, stating that countries would not discriminate among domestically produced LMOs and those being imported. They also argued for strong language on the precautionary principle and on human health.

Most of the developing countries had no experience with modern biotechnology and were concerned that without a protocol they would be exposed to possible consequences of LMO import and use by potentially irresponsible actors. As the negotiations continued, however, a widening gap in experience and diversity of motivations among developing countries posed challenges of coordination and cohesion for the so-called **Like-Minded Group** (LMG)²⁰. Within the group were countries at differing levels of economic development, with different political structures and systems, different cultural practices and certainly different economic agendas. This was the largest negotiating group (measured by the number of countries, population and biodiversity), whereas included countries were ranging from those with no domestic regulatory structures, legislation or biotechnology industries to those with fairly developed systems.

This group supported a strong Protocol, in light of the unknown effects of LMOs on the environment and human health, and given the need to protect countries without adequate regulatory or institutional capacity to effectively handle LMO imports. They were also concerned that they might become ‘guinea pigs’ for field trials of LMOs. Consequently, the Like-Minded Group called for a comprehensive scope, including LMO-FFPs, arguing that seeds and other LMO products intended for consumption might actually be planted in many developing countries. They also argued for the Protocol to take into account human health and socioeconomic considerations, and for comprehensive identification and documentation requirements on LMO imports. This group, finally, supported a strong statement of the precautionary principle, and was the prime backer of tough and concrete text on liability and redress.

The **Miami Group** was formed around the common interests of its members as agricultural producers and exporters. It was composed of Argentina²¹, Australia, Canada²², Chile, Uruguay and the US. The US, in particular, was initially criticised for not supporting the idea of a protocol as the world’s leading producer and exporter of LMO crops, and for negotiating as a non-party to the protocol’s parent agreement, the CBD. US officials claimed though that their aim was to develop an international regime to promote the safe movement of LMOs. It should be noted that all other countries are also members of the Cairns group, which seeks liberalisation of agricultural trade with a particular focus on market access problems and subsidy practices in the EU. Although group members shared a number of key concerns, not

²⁰ This group operated along the same lines of procedure as the G-77 (and China) of the UN grouping.

²¹ At that time, the world’s second largest producer of LMO crops.

²² More than half of the area planted to canola, Canada’s major oilseed crop, consists of LMO varieties.

all issues were of equal concern, and in a few cases they found themselves on different sides of an issue.

In general, the group's interest was to enable free trade of GM products without burdensome bureaucratic approval procedures, and without allowing room for protectionist trade barriers concealed as environmental protection. In Cartagena, the Miami Group's aim was to keep LMO–FFPs outside the scope of the Protocol's AIA procedure. They argued that goods traded in these volumes were not amenable to AIA, and that since such products were safe for consumption and not intended for introduction into the environment, their biodiversity impacts were minimal. The group supported a savings clause within the agreement, and sought to limit the use of the precautionary principle and socioeconomic considerations in decision-making. Given existing trade frictions, the group was also keen to ensure that decisions should be based on risk assessments and scientific evidence. Overall, the Miami Group did not want provisions in the Protocol that might be used to defend elements of regulations they regard as unfair (e.g. mandatory labelling of LMOs).

Having all groups' views in mind, at the end of the negotiating session, a conclusion was beyond reach. It was, therefore, a surprise to all when the draft negotiating text, which was acceptable to no one, was delivered. Changes to this text were allowed, but by consensus only. As a result, differences began to be identified between the aforementioned groups, almost no changes were made to the text and eventually the Miami Group blocked consensus. A negotiating structure that allowed for broader representation was then introduced to reduce the frustration felt by many delegations over the previous lack of transparency. This format known as the **Friends of the Chair** format remained in place until the conclusion of the agreement a year later in Montreal.²³

4.1.3. Montreal – a Protocol

Cartagena ended in disappointment on all sides. Within weeks, though, all groups were back at work. A FAO meeting on April, a September meeting in Vienna and the WTO Ministerial in Seattle²⁴ on December 1999 had no impact on the protocol's negotiation progress. Delegates arrived in Montreal, Canada, in January 2000, with much work ahead of them. All groups were better prepared and familiar with one another's positions, and the informal contacts needed to reach compromises occurred more easily and frequently. Finally, the presence of ministers helped negotiators to adjust their negotiating positions more quickly and thus to facilitate achievement of the necessary compromises.

Among the critical issues to be examined were the *scope* of the protocol, the *AIA* procedure, the treatment of LMO *commodities* for food, feed or processing, the expression of the *precautionary principle*, the so-called *socioeconomic clause*, the protocol's *relationship with other agreements* (mainly, but not exclusively, the WTO agreement), *liability* and *redress*, and *identification* and *labelling*.

In terms of the protocol's scope, a major issue was whether all LMOs (for scientific research, commodities, pharmaceuticals, etc.) should be included in the protocol and

²³ Negotiations through five groups with two spokesmen for most and a limited number for the G-77 and China.

²⁴ There was the impasse on establishing a WTO Working Group on Biotechnology.

submitted to the same disciplines.²⁵ Regarding the commodities issue, almost until the very last moment of the negotiations, it was not clear that commodities should have a special AIA regime.²⁶ The EU and the LMG strongly advocated the inclusion of the precautionary principle among the operative articles of the protocol. This was the basis for the majority of their positions in favour of a biosafety protocol. It was though believed that, in spite of its indisputable environmental value, it would serve the purposes mainly of those countries wishing to build new and higher barriers to legitimate trade. The LMG also pushed for the clause of the socioeconomic considerations as well as the protocol's relationship with other agreements. For the latter, it should be decided whether the protocol should be allowed to become the ultimate arbiter on issues falling under its specific scope, which includes if trade in LMO commodities were to be dealt with exclusively under the WTO liberalising regime, or otherwise. Of the two extreme views about it, one maintained that the protocol should be subordinated to the WTO agreements. According to the other view, the protocol should prevail over relevant trade rules. In terms of liability and redress, the question was whether, and in what form, to create a relevant mechanism for any damage resulting from the transboundary movements of LMOs. In some form this would involve the exporter, or an insuring agent, to pay for damages resulting from the import of its product. Finally, some negotiators recognised the need for a set of regulations as regards identification and labelling; whereas some attempted to have strict labelling norms for LMOs as dangerously close to technical barriers to trade.

Overall, a wide array of negotiating tools was necessary to resolve the key issues and successfully conclude the protocol in Montreal. A three-way negotiation process was followed. In the scope group, the main protagonists were the Like-Minded Group and the EU. In the commodities group, the LMG had to face the Miami Group, while the EU played a mediating role. In the trade-related group, which started somewhat later, the LMG left the debate to the EU and the Miami Group.

A brief presentation of the Protocol is given in Section 3.2. Here, major failings of the protocol will be addressed. First, any action taken under the biosafety protocol should be consistent with other international obligations, opening up room for squabbles on trade issues. Another major weakness of the protocol is that the inclusion of the products of GMOs was opposed by all the OECD countries, and even by some developing countries. This was done in the name of making trade easier, it creates though a serious gap in the protocol. Moreover, it is required that each party has procedures to protect confidential information. Even the TRIPS Agreement of the WTO does not impose a requirement to protect confidentiality. In addition, the US was given the right to take part in negotiating the biosafety protocol, even though it did not intend to be a party to it. In fact Article 24.1 could encourage countries to stay out of the protocol and simply enjoy its rights without carrying out its obligations. The exclusion of the socioeconomic considerations in risk assessment is another weakness of the protocol, whereas the protocol leaves pharmaceutical GMOs covered by international agreements or organisations outside its scope. But at that moment no other international agreement or organisation was dealing with their environmental impacts. Finally, the final text does not settle the question of how the Protocol relates

²⁵ It had been agreed by Cartagena that LMO-FFPs would fall under the Protocol's scope. The tough negotiations then concerned whether they would fall under the scope of the Protocol's AIA provisions.

²⁶ The Miami group wanted commodities to be excluded altogether from the protocol or, as a second-best option, to be submitted to a special and more lenient regime.

to the WTO and other international agreements. In fact it looks like a conflict postponed, rather than a conflict avoided.

Nevertheless, the Cartagena Protocol on Biosafety is one of the most significant MEAs to have been adopted. It provides a binding framework for assessing and managing the risks to the environment and human health from the movement of LMOs between countries. Despite the enormous difficulties and the compromises that were ultimately necessary to achieve it, the protocol contains measures that contribute significantly to the evolution of international environmental law. It is the first international environmental agreement to place the precautionary principle in a specific operational context. To this end, the objective of the Protocol

*is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.*²⁷

4.2. The EU negotiating position

Since the beginning of the negotiation process, many European governments were clear that an international agreement on biosafety was needed. The interest of the European Union in the biosafety protocol negotiations changed as they went on. When it entered the biosafety talks, the EU had no real concerns about its ability to deal with the transboundary movements of LMOs. It had in any case already introduced a stringent and comprehensive regulatory framework for safety in biotechnology from the research to the marketing stages of products (EC Directives 90/219, 90/220 and their subsequent revisions). By 1995, the EU believed that the demand of a number of (developing) countries to develop an internationally legally binding instrument was acceptable and indeed reasonable. Also the fact that, at the start of the negotiations, the EU did not have any strong biotechnology export interests gave additional weight to the development and environment angle in its negotiating position.

By the end of the negotiations, however, the EU's interest had changed dramatically. A successful outcome now seemed highly important for the EU itself, for several reasons. In particular, the EU had to reassure a public opinion extremely worried about food safety and increasingly sceptical towards biotechnology. The protocol had also become a central battleground for the definition of the relationship between MEAs and WTO. Moreover, it now seemed possible that the protocol might be a vehicle for introducing the precautionary principle firmly into an international legally binding agreement.

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

²⁷ Protocol, *supra* note 1, Art. 1.

The Commission came out in favour of a position balancing environmental and trade concerns, and then maintained it (a unified internal position and a coherent outward presentation of views). At the first meeting of the Intergovernmental Committee of the CBD (October 1993), the EU indicated the importance it attached to the development of an international binding instrument on biosafety, complementary to increasing national capacities and the development of technical guidelines, but it did not express its preference as to the nature of this instrument.

Having observed the very big differences between the negotiating positions of the major exporters, on the one hand, and the majority of the G-77 countries on the other, the EU decided at an early stage to engage in building bridges and trust and maintaining contacts with all other groups. The EU also consulted regularly with NGOs and biotechnology industry representatives throughout the process.

Early points the EU had to make clear were that it would not be possible to include all products derived from biotechnology in the protocol and that including socioeconomic considerations in a broad manner could lead to serious conflict with the WTO. Overall, the following elements of the EU position were already well established when the EU team went to Cartagena in February 1999: the mutual supportiveness of the protocol and other international agreements; a broad scope with limited exemptions; AIA (not applying to contained use or transit); the possibility to go back to a domestic regulatory framework; the possibility to block imports as a consequence of the precautionary principle; labelling or documentation of LMOs; the detailed principles and the methodology for risk assessment; and the non-application of the protocol to intra-EU trade.

At the end, the EU went to Montreal with a strong will to conclude the protocol. A positive outcome was necessary in order to protect the environment, assist developing countries to deal responsibly with biotechnology and provide predictability for the biotechnology industry. Their strategy was to put public pressure on the Miami Group to show more flexibility than it had done in Cartagena, while discouraging developing countries from reopening already agreed issues.

The final result was fully in line with the EU's negotiating objectives. The core of the protocol is that it enables countries to take responsible decisions on imports of GMOs through the advance informed agreement procedure and the alternative system created for commodities.

5. THE BIOSAFETY PROTOCOL VS. THE WTO RULES

In terms of the relationship of the Biosafety Protocol to WTO rules and institutions, the protocol does not purport to override or alter the existing rules of trade law as they affect biosafety, nor does it attempt to establish an alternative self-contained regime to deal with trade and biosafety disputes. Rather, as interpretive sources for WTO dispute settlement, the rules in the protocol are complementary to the WTO regime, allowing a more effective and legitimate application of WTO norms in biosafety-related trade disputes.

Nevertheless, the Protocol's provisions raise a number of questions with respect to their relationship to WTO rules, since both disciplines regulate the transboundary movement of GMOs. Tensions between the two regimes are also reflected in the Preamble to the Protocol. On the one hand, it states that the Protocol shall not be interpreted as implying a change in the rights and obligations of a party under any

existing international agreement and, on the other hand, that the Preamble is not intended to subordinate the Protocol to other international agreements.

As already mentioned, the main concern of GMO producing and exporting countries, such as the US, Canada and Argentina, is to have reliable access to foreign markets. Other countries, such as the EU, have adopted what they consider to be a pragmatic precautionary approach. Both sides claim to have strict import and approval measures to guarantee a high level of health and environmental protection. Developing countries are often somewhere in between. They are concerned about health and environmental risks, but at the same time, they wish to preserve their export opportunities, in particular to markets that are sceptical about GMOs.

Indeed, the different trade concerns and perspectives on GMOs may lead to different trade regimes, which may in turn give rise to disputes between GMO-exporting countries and potential importers. If all countries in such a conflict are not only WTO Members but also parties to the Protocol, then the conflict is likely to be addressed through mechanisms established under the Protocol itself. However, if the exporting country is not a party to the Protocol, then the case is more likely to be decided before the WTO. The risk of such potential conflict further increases as the parties to the Protocol adopt more detailed rules and implementation requirements over time.

A detailed analysis of these issues as well as a comparison of the Protocol's and WTO's rules in detail fall outside the scope of this study. In Box 1, though, two WTO dispute settlements on (bio)safety are presented to illustrate the conflict reacted over the potential implications of biosafety regulation for international trade rules and obligations.

Box 1: WTO Dispute Settlements on (Bio)Safety

The first and most important food safety dispute under the SPS Agreement was brought in 1995 by the US against the EU, over the issue of hormone-treated beef. The dispute began in 1989, when the EU (acting under the terms of a 1988 directive) instituted a ban on the use of synthetic growth hormones in beef cattle, and prohibited the import of animals, or meat from animals, that had been treated with such hormones. The US alleged that the EU ban was inconsistent with the terms of the SPS Agreement because it was not based on scientific evidence, a risk assessment, or agreed international standards, and it arbitrarily differentiated between products. The EU, by contrast, argued that the SPS Agreement acknowledges the right of members to determine the appropriate level of health protection for their consumers, and that the ban was justified under the precautionary principle.

A WTO dispute settlement panel was established in May 1996, and issued its report in favour of the US in August 1997. The EU appealed the panel's decision, and the WTO Appellate Body issued a second report in January 1998, once again in favour of the US. In accordance with the Appellate Body's findings, the Dispute Settlement Body ruled in February 1998 that the EU ban was inconsistent with the terms of the SPS Agreement, and instructed the EU to bring its regulations into compliance by no later than 13 May 1999.

Facing continuing pressure from its own consumers, however, and hopeful of producing additional scientific findings that might justify the ban, the EU failed to act, and the US retaliated on 17 May 1999, applying tariffs in the amount of \$116.8 million targeted against specific EU products such as foie gras, Roquefort cheese and Dijon mustard. The transatlantic dispute over the approval of new GM varieties by the EU is similar to this dispute over hormone-treated beef.

As mentioned in Section 2, in the beginning of the 1990s, the EC authorised in accordance with its legislation a number of GMOs for commercial release into the environment for

different uses, some for cultivation, others as food or feed. By the mid-‘90s, however, several EC member states started to express concerns. They believed that the existing regulatory framework was not adequate, in particular with regard to issues such as risk assessment, labelling and traceability. As a result of these concerns, and in reaction to rapid scientific developments and the negotiation of the Protocol, no new GMOs were approved under the legislation in force during the period October 1998 until May 2004. By that time, the EC had adopted a new set of rules.

However, in August 2003, just a few weeks before the Protocol entered into force, the US, Canada and Argentina, all major GMO producers and exporters, requested the establishment of a panel under the WTO dispute settlement procedure. In brief, the countries claimed that the EC had failed to approve specific GM products, and that the EU MSs had prohibited products which had been approved by the EC after consideration by its own scientific regulatory approval process. It was then argued that an unjustified barrier to their trade in agricultural and food products was created, violating the SPS and TBT Agreements as well as GATT.

The panel concluded in favour of the claimant countries. More importantly, the panel ruled that it was not required to take the CBD into account in interpreting the WTO Agreements at issue in the dispute, given that the US was not a party to the CBD. Similarly, the panel considered that it was not required to take the Protocol into account since Argentina, Canada and the US were not parties to it. Moreover, the panel noted that the Protocol had entered into force after the panel was established.

6. IMPLEMENTATION OF INTERNATIONAL BIOSAFETY REGULATIONS

It is now clear that several international instruments that consider different aspects of the trade, transboundary movement and potential adverse effects for the environment of GMOs have been agreed in the past years. In most of the cases, closer interaction and cooperation, as well as further harmonisation among these agreements would be recommendable. However, unified stricter regimes may lose on flexibility and would not be able to satisfy the needs and interests of every country, particularly developing countries.

In particular, cooperation, capacity-building and the exchange of information are key to the successful implementation of international biosafety regulations. International harmonised biosafety rules could limit the perceived concerns associated with the release of GMOs, and could enhance international collaboration and prevent experiments from being relocated to countries with more lax regulations thus avoiding bans. Moreover, standards, legal measures and regulations concerning biotechnology should fix only the essential requirements (i.e. notification, authorisations and procedures) and several product-based directives and regulations, leaving space for voluntary actions by manufacturers. There is a concern, especially in the developing world, that if strictly unified regulations would be adopted, then they would not take into account the specific requirements of every country. They would then be less effective and could potentially damage the indigenous resources regulations.

In addition, countries that trade in GMOs need to have the capacity to implement the Protocol. They need skills, equipment, regulatory frameworks and procedures to enable them to assess the risks, make informed decisions, and manage or avoid any potential adverse effects of GMOs on their natural relatives. Those governments that do not already have a domestic regulatory system for biosafety need to develop one as soon as possible. The Protocol, therefore, actively promotes international cooperation to help developing countries and transition economies build the human resources and

institutions needed for biosafety. It also encourages governments to assist others with scientific and technical training, to promote the transfer of technology and know-how and to provide financial resources to those countries.

It should be, finally, noted that the Cartagena Protocol can only ensure that the global use of biotechnology is safe if each and every country actively promotes biosafety at the national level. National policy makers and legislators have a vital role to play in establishing and strengthening laws and standards for reducing the potential risks of GMOs. Governments also need the active involvement and cooperation of other stakeholders, in particular agricultural and health-care research institutes and the biotechnology industry, as they have the expertise, the resources and the incentive for keeping biotechnology and its products safe and beneficial. As for civil society, individual citizens and NGOs need to understand the issues and make their views clear to both policy makers and industry.

7. CONCLUSION

To conclude, the European Union's regulatory framework for the approval, tracking, marketing, and labelling of GMOs has been substantially overhauled over the past years, in the light of external as well as domestic pressures. Some of these reforms, such as the increased emphasis on scientific risk assessment by the EFSA and the approval of new GMOs, appear to be responses to international pressures, adopted in the hope of mitigating or forestalling WTO legal challenges. Nevertheless, new regulations on traceability and labelling now impose further constraints on GM foods and crops, whereas risk management remains in the hands of political bodies which can take decisions according to socioeconomic as well as scientific criteria.

Although the use of biotechnology in agricultural practices has increased substantially in the US and other major food exporting countries, consumer resistance to GM foods in Europe has been intense. The CBD offered then a forum within which the EU could press for an international environmental agreement supporting its precautionary approach to biosafety regulation. The Biosafety Protocol is a promising regulatory step internationally, yet European regulations are more effective.

In brief, EU rules are spelled out in a directive on the deliberate release of GMOs into the environment; in a regulation on the transboundary movement of GMOs, a regulation on GM food and feed; a directive on the contained use of GMMs, and in regulations concerning the traceability and labelling of GMOs and food and feed products produced from GMOs. The EU promotes also implementation of the Cartagena Protocol both within its own boundaries and with regard to third countries.

It can be concluded that the EU's position has been strengthened by the Protocol. The treaty does not add significantly to the EU's existing regulatory system, it does though provide it with greater international legitimacy. The Cartagena Protocol does not establish a global standard by which to judge the environmental impact of agricultural biotechnology as such. Recognising that modern biotechnology has 'potential for human well-being', the Protocol instead aims to empower governments with internationally sanctioned regulatory instruments for assessing the biosafety of GM trade. This agreement has, therefore, reduced the likelihood of an open trade conflict over GMOs within the WTO. It contains though a number of compromises, exemptions and omissions, so that its effectiveness in safeguarding biosafety depends on the ability of the parties to broaden the Protocol's scope and strengthen its control mechanisms in future revisions of the regime.

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