« Biosafety regulation: the Cartagena protocol »

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LIST OF ABBREVIATIONS

AIA	Advanced Informed Agreement
BCH	Biosafety Clearing-House
Bt	*Bacillus thuringiensis*
CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
COP	Conference of Parties to the Convention on Biological Diversity
DNA	Deoxyribonucleic acid
EU	European Union
EC	European Community
FAO	Food and Agriculture Organization of the United Nations
G-77	Group of 77 developing-countries signatories to Joint Declaration of the Seventy-Seven Countries issued at first session of UNCTAD
GATT	General Agreement on Tariffs & Trade 1994
GEF	Global Environment Facility
GM	Genetically modified
GMO	Genetically modified organism
ICCP	Intergovernmental Committee for the Cartagena Protocol on Biosafety
IPPC	International Plant Protection Convention
LMO	Living modified organism
LMO-FFPs	Living modified organisms intended for direct use as food, feed, or for further processing
MEA	Multilateral Environmental Agreement
MOP	Meeting of the Parties to the Cartagena Protocol
NGO	Non-governmental organisation
OIE	International Office of Epizootics
OECD	Organisation for Economic Co-operation and Development

PPMs	Process and production methods
SBSTTA	The Subsidiary Body on Scientific, Technical and Technological Advice
SPS Agreement	Agreement on Sanitary and Phytosanitary Measures
TBT Agreement	Agreement on Technical Barriers to Trade
UNCTAD	United Nations Conference on Trade and the Environment
UNEP	United Nations Environment Programme
USA	United States of America
WHO	World Health Organization
WTO	World Trade Organization

I. BIOSAFETY IN THE CONTEXT OF THE CARTAGENA PROTOCOL

Genetic engineering is a relatively new technology that can provide considerable benefits but also creates uncertainties and raises questions. The growth of genetic engineering has been made possible in part by the trend towards accepting the patenting on life forms, first in the United States and later on at the international level. This legal protection has encouraged innovators and significant investments have been made in research and development of the various potential applications of biotechnology such as genetically modified organisms, in particular for their agro-industrial use.

Current debates about genetically modified organisms (GMOs) in agriculture reveal substantial differences in perception of the risks and benefits related to biotechnology. While GMOs have the potential to contribute to improving well-being – for instance through increased agricultural yields, improved nutritional content of plants or reduced pressure on the environment – their potential side effects on the environment and human health have been of increasing concern. These have led to calls for the elaboration of 'biosafety' legal frameworks in order to oversee biotechnology development through adequate safety measures. The Cartagena Protocol on Biosafety is a legally binding international agreement that provides the basic lineaments of biosafety regulatory frameworks. It seeks to contribute to ensuring the safe production, use, dissemination and trade in living modified organisms (LMOs) created through modern biotechnology[1].

This "brick" adopts the following structure: as a first step, an overview of the negotiations that brought to the Cartagena Protocol puts forward the main issues that surrounded the development of a regulatory framework on biosafety. Section 3.2 moves on to examine in more detail the major features of the Protocol, with a particular focus on its trade related aspects. Section 3.3 puts into perspective the Protocol within its broader legal context, notably its links with the Convention on Biological Diversity and its relationship with the WTO rules. A brief comparison of the Protocol provisions with existing WTO law and a presentation of the WTO related standard setting reference points, in particular the Codex Alimentarius Commission, is then considered.

[1] LMOs are defined in Article III of the Cartagena Protocol as: 'any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'. For the purpose of this course, the term "living modified organism" can be considered equivalent to the more common "genetically modified organism".

II. BACKGROUND ON BIOSAFETY AND THE CARTAGENA PROTOCOL NEGOTIATIONS

2.1. AGRICULTURAL BIOTECHNOLOGY

Genetic engineering, as a means to insert selected endogenous proteins or entirely different proteins into a plant, presents many promising developments for agricultural and food production. Among the potentially unlimited applications of this technology, those that received the greatest interest from researchers so far principally concerned plant protection against deleterious organisms and weeds (e.g. resistance to herbicides), plant resistance to limiting factors (e.g. drought resistance, nitrogen fixation), and quality improvement of plants products (e.g. nutritional content)[2]. Only recently the products of this technology have developed enough to enter the crop market. Indeed, the commercialised planting of crops modified through modern biotechnologies began in 1994 when the US government first ratified the commercial cultivation of delayed ripening transgenic tomato. Since then, genetically modified cultures have known a rapid expansion and are estimated at approximately 58.7 million hectares in 2002, approximately the joined surface of France and Belgium, against hardly 1.7 million hectares in 1996. This rapid growth took place in four major producing countries of agricultural products: the USA (66.5% of total GM production), Argentina (23%), Canada (6%) and China (3.6%)[3]. Substantial plantings so far largely concern only four crops: soybean, maize, cotton and canola, and about 22% of the total area planted with these major crops is now under GM varieties[4].

This first wave of GM crops is largely tailored to suit temperate climates and to reduce production costs. Indeed, among the four main commercialised crops, only two traits – insect resistance (mainly based on Bt) and herbicide tolerance – have found a large market response among agricultural producers. As a consequence, countries with subtropical and tropical climates as well as

[2] See Bordogna Petriccione B. (2004) «Introduction to GMO : technique and safety », Les Cahiers du RIBIos n° 1, IUED, pp. 17-31 for a more detailed description of the potential applications of biotechnology in the agro-food industry.

[3] China is the only developing country that locally developed and commercialised a GM cotton variety. Other countries obtained genetic constructs or varieties from industrialised countries.

[4] James, C., 'Global Status of Commercialized Transgenic Crops: 2002', ISAAA Briefs No. 27 (Ithaca, NY: ISAAA, 2002). Also available at: http://www.isaaa.org/kc/Bin/gstats/index.htm

consumers have not yet been benefiting from biotechnology progress[5], which may partly explain their basic opposition to the use of GMOs. Nevertheless, the main concern of consumers and developing countries as regard the introduction of biotechnology in the food and agriculture industry is that this may generate unforeseeable negative side effects to health and the environment[6] as well as increased dependence on agri-food corporations of developed countries. These concerns call for an appropriate regulatory framework at the national and international level in order to control the spread of biotechnology products and their related potential side effects.

2.2. TOWARDS THE ADOPTION OF A BIOSAFETY PROTOCOL: INITIAL POSITIONS OF STATES

Uncertainty about the environmental and sanitary impacts of GMOs has led to different national policy reactions. Various forms of biosafety regulatory frameworks have been or are being developed, though their operational implementation requires a well developed regulatory capacity that so far only few countries can effectively afford. Among the existing regulatory frameworks, two approaches can be broadly delineated, depending on the confidence of consumers with respect to their domestic regulators and on the relative weight given by policy-makers on the potential benefits and costs of agricultural biotechnology.

On the one hand, countries that consider genetic modification safe and promising tend to set up "product-based" regulations that test and evaluate a genetically modified food (the final product) according to its characteristics and novel features. Genetically modified products are considered as conventional products and follow the regulations destined to control the introduction of any novel food in the market. The safety assessment of a novel food looks at the molecular, compositional, toxicological, and nutritional characteristics of the novel food in comparison with its conventional counterpart. The principal focus is the protein expression product(s) of the inserted gene(s). The inserted genetic material itself is not of concern. Only possible immediate and short-term effects of specific genetic manipulations on health and the environment are considered making it possible to quantify risks linked to GM foods and to establish a clear decision-making process, which usually declares GM foods as presenting no tangible risk. This operative regulatory system has led to approval and rapid commercialisation of biotechnology products and

[5] The number of GMOs with new properties available for marketing is likely to increase in the next years and is expected to address more closely the concerns of developing countries and consumers.

[6] See Bordogna Petriccione B. (2004) «Introduction to GMO : technique and safety », Les Cahiers du RIBIos n° 1, IUED, Chapter 3 'Environmental and sanitary risks of GMOs in food and agriculture' for a deeper analysis of the potential risks of biotechnology in these fields.

characterises the regulatory framework of producing countries of genetically modified products (USA[7], Canada, Argentina). These countries are seeking foreign market access for their products under the auspices of the World Trade Organisation.

On the other hand, many countries advocate for a restrained market access for LMOs, considering them as specific products that could be carriers of ecological and sanitary hazards which scientific knowledge still cannot fully apprehend. Therefore these national regulations tend to be process-based (they focus on the process by which a food is developed) and plants obtained through the techniques of genetic modification have to go through a specific approval procedure. Restrictive measures to trade in LMOs under various forms such as labelling norms and temporary bans, are applied for instance, in Australia[8], New Zealand[9], Japan, Zambia, India and the European Community (EC), among others[10]. The EC introduced a *de facto* ban on

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[7] In the United States, three main agencies are responsible for the regulation of biotechnology. The Food and Drug Administration (FDA, http://www.fda.gov/) regulates food, feed, and food additives ('safe to eat'). The United States Department of Agriculture's (USDA, http://www.usda.gov/) Animal and Plant Health Inspection Service (APHIS, http://www.aphis.usda.gov/) is responsible for protecting US agriculture from pests and diseases ('safe to grow'). The Environmental Protection Agency (EPA, http://www.epa.gov/) ensures safety of pesticides and plant pesticides ('safe for the environment/safe to eat'). See for instance the main US legislation that applies to GM food (as to any other food), the Federal Food, Drug, and Cosmetic Act (FFDCA): http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm

[8] The Commonwealth Gene Technology Act 2000, (also available at: http://scaleplus.law.gov.au/cgi-bin/download.pl?/scale/data/pasteact/3/3428) is the key component of the australian national regulatory framework. It prohibits the importation of genetically modified organisms (GMOs), subject to a limited range of exceptions. For a brief summary of the Australian GMOs licensing procedure see 'Committee on Import Licensing - Replies to Questionnaire on Import Licensing Procedures - Notification under Article 7.3 of the Agreement on Import Licensing Procedures – Australia' (2002), pp 61-63, WTO-Document G/LIC/N/3/AUS/2, and for more details on the Australian biosafety policy see the Department of Agricuture, Fisheries and Forestry website on Market Acces and Biotechnology: http://www.affa.gov.au/content/output.cfm?ObjectID=3E48F86-AA1A-11A1-B6300060B0AA00010&contType=outputs.

[9] For a brief summary of the New Zealand GMOs licensing procedure see the WTO documents 'Committee on Sanitary and Phytosanitary Measures - Notification - New Zealand - Genetically modified organisms – Addendum' (2002), G/SPS/N/NZL/161/Add.1, and 'Committee on Technical Barriers to Trade - Notification - New Zealand - Genetically modified organisms' (2001) G/TBT/N/NZL/3. For more details on the New Zealand Biosecurity Authority see http://www.maf.govt.nz/biosecurity/

[10] For a list of worldwide trade related measures on GMOs see : http://www.biowatch.org.za/wwinit.htm or the more detailed OECD website, http://www.oecd.org/oecd/pages/home/displaygeneral/0,3380,EN-documentation-531-14-no-no-no-no,00.html

GMOs since several Member States have been blocking the approval procedures. Hence, since October 1998, no GMOs have been approved for release into the environment in the EU[11]. Their concerns are that existing legislation on GMOs is not sufficient to safeguard environmental, health and consumer protection interests. They therefore welcome the entry into force of the Cartagena Protocol, which provides the grounds for the implementation of appropriate environmental policy in the biosafety domain.

As we can see, national regulatory frameworks for ensuring biosafety tend to diverge between producing countries, inclined to promote market access for agricultural biotechnology goods like any other novel good, and importing countries, which tend to regulate in a precautionary way the diffusion of this technology for environmental concerns. As the countries embracing agricultural biotechnology tend to be significant agricultural exporters, trade conflicts are likely. In fact, if this regulatory divergence goes on, this might lead to the development of two distinct markets of agri-food products in countries that accept GMOs and those that do not.

2.3. NEGOTIATIONS FOR THE CARTAGENA PROTOCOL

The elaboration of the Cartagena Protocol was started in 1996 by a decision of the Conference of the Parties to the Convention on Biological Diversity establishing an open ended Ad Hoc Working Group on Biosafety with the purpose of developing a draft text of the Protocol, in pursuance of Article 19(3) of the Convention. The negotiations were at first marked by a strong North-South division[12]. In the first stages, developing countries were driving the biosafety agenda. They sought the development of a legal instrument covering most aspects of the development and use of LMOs, treating all kind of LMOs under the same procedure and including detailed risk assessment

[11] See Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms, repealing Council Directive 90/220/EEC Official Journal of the European Communities – 17.04.2001 – L 106 p. 0001–0038, also available at:
http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=32001L0018&model=guichett.
Due to perceived flaws of the new regime some Member States insist that additional rules on labeling and traceability of GM food and feed shall be enacted before approvals can be re-started. In response, the Community bodies are discussing two new regulations, a Regulation concerning traceability and labeling of GMOs and treaceability of food and feed products produced from GMOs that will amend Directive 2001/18/EC and a Regulation on GM food and feed. More details on the European biosafety regulatory framework are provided at:
http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html

[12] A detailed history of the Protocol's negotiations can be found on IISD's 'Linkages' Web site at: http://www.iisd.ca/biodiv/excop/

and management procedures, fearing that the lack of proper international regulatory framework would put their environments at risk[13]. On the other hand, developed countries were generally not keen on the development of a comprehensive instrument which could restrict the development of their biotechnology industry in the longer term.

This initial fault line evolved over the four years of negotiations. At the end, the Protocol negotiations were mainly polarised between the positions of producing countries and those of potential importing countries, which do not produce LMOs. The former sought a limited codification, based on free market and scientific evidence, whereas the latter called for a restrictive approach of trade in LMOs, grounded on advanced informed procedures and precaution.

Over time, five interest groups emerged in the negotiating process.

The Miami Group

At one end of the spectrum, a coalition of the major exporters of genetically modified agricultural commodities (comprising Argentina, Australia, Canada, Chile, Uruguay and the USA) came to be known as the Miami Group (from the meeting they held in that town in July 1998 to deal with the trade implications of the Protocol). Their aim was to avoid the imposition of excessive restrictions on international trade in LMOs.

Core concerns of this Group were that the Protocol should be consistent with World Trade Organisation (WTO) rules and based on "sound science", that is, scientific evidence[14]. In addition, they claimed that the scope of regulation should be limited to categories of LMOs, which could properly be judged to pose potential risks to biological diversity. Therefore they argued in favour of excluding LMOs for Food, Feed and Processing (LMO-FFPs), which are not destined to introduction into the environment, from the strict Advanced Informed Procedure (AIA, see below).

Moreover, they sought to limit the use of the precautionary principle and socio-economic considerations in decision-making on the grounds that this

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[13] Falkner, R., 'Negotiating the Biosafety Protocol: The International Process', *in* Christoph Bail, Robert Falkner and Helen Marquard (eds.), *The Cartagena Protocol on Biosafety – Reconciling trade in Biotechnology with Environment and Development?* (London: Earthscan, 2002).

[14] "Scientific evidence" implies that a set of data, facts, or conclusions of a scientific nature are supported by studies that follow the high standards of the scientific method. Information developed through a scientific method is considered valid, or "scientifically sound", because it has been tested and shown to accurately describe what it purports to describe. Scientific evidence does not imply that the information developed through a scientific method is generally accepted or readily believable, it simply states that the generated information responds to the procedural requirements necessary to consider it scientific, so that it can ground a decision of preventive measure.

would be open to protectionist abuse. Scientific evidence, as interpreted by the WTO, should constitute the ground for any restrictive measure.

The Like-Minded Group

By contrast, the largest negotiating group (measured in terms of the number of countries, population and biodiversity), the 'Like-Minded Group', emerged from the countries ranging from those with no domestic regulatory structures, legislation or biotechnology industries to those with fairly developed systems (G-77 and China).

For many of them, the concerns over genetically modified crops and foods was closely tied to intellectual property rights, farmers rights and traditional knowledge, issues that already raised at the time of the negotiation of the Biodiversity Convention. Therefore, they put forward proposals to give importing countries extensive rights to refuse GM imports, including LMO-FFPs, in the light of ongoing scientific uncertainty over potential long-terms effects, and the lack of risk assessment and risk management capacity in developing countries that could become guinea-pigs for fields trials of LMOs.

They demanded the inclusion of the precautionary principle to guide decision-making on imports of LMOs, the right to take into account potential socio-economic impacts of LMOs, and effective liability and redress mechanisms (to provide compensation for any damage caused by LMOs). In addition, they sought commitments from developed countries on financial assistance and capacity building.

The European Union

The EU position emerged broadly between these polarised positions, under increasing pressure from environmental and consumer groups given public outrage over food safety scandals such as mad cow disease or dioxin-tainted chicken, and, towards the end of the negotiation process, the WTO's failed Seattle Ministerial Conference. Central components of the EU's position were the inclusion of the precautionary principle, support for clear identification and labelling requirements for shipments of LMOs (in response to public desire to choose), and the need to reflect potential risks to human health in the Protocol. The EU also pushed for the inclusion of LMO-FFPs within the scope of the AIA procedure. The EU supported the inclusion of a non-discrimination provision, stating that countries would not discriminate among domestically produced LMOs and those being imported. However, they strenuously opposed the inclusion of a 'savings clause' regulating the relationship between the Protocol and other international agreements, which had been promoted by the Miami Group and would have expressly subordinated the Protocol to WTO rules.

The Compromise Group

A Compromise Group (consisting of Japan, Mexico, Norway, Singapore, South Korea, Switzerland, and in the final stages New Zealand) emerged during the final days of the Cartagena negotiations. Its objective was to bridge gaps between the other negotiating blocs by elaborating compromise positions and alternative formulations.

The Group did have joint positions supporting a comprehensive scope and the precautionary principle, although they acknowledged internal differences about the savings clause.

The Central and Eastern Europe Group

The fifth negotiating bloc was formed of the countries of Central and Eastern Europe and generally reflected a middle-of-the-road position, often falling in line either with the EU (particularly those states in line for EU membership) or the Like-Minded Group.

Non-official groups flanked these five groups. The Biotechnology Industry Organization[15] on the one hand, representing agricultural, food and pharmaceutical companies promoting the goals of the Miami group on trade, and, on the other hand, an international coalition of consumer and green groups supporting the Like-Minded Group and maintaining pressure on the EU.

2.4. ADOPTION OF THE PROTOCOL

On the whole, the negotiations were difficult, because of the uncertainties surrounding the use of genetically modified materials and the fact that the Protocol concerns not only environmental issues but also trade issues. Despite intense negotiations, it proved impossible to finalise the Protocol in Cartagena, Colombia, during the Extraordinary Conference of the Parties to the Convention held in February 1999 for adopting the draft Protocol. Delegates disagreed primarily over the following issues:

1. the domain of application of the Protocol and of the Advanced informed Agreement procedure
2. the treatment of LMO-FFPs
3. the application of a precautionary approach in decision-making
4. the relationship between the Protocol and other international agreements, especially regarding trade issues and WTO rules

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[15] For additional information on the Biotechnology Industry Organization, visit their website http://www.bio.org.

5. the setting up of an information exchange system as well as the institutional and technical capacity building for developing countries
6. socio-economic considerations

In early 2000, following the breakdown of trade talks at the Seattle ministerial conference of the WTO, the Protocol's negotiators reconvened in Montreal in a more conciliatory mood and managed to bring the negotiations to a close. Indeed, the Seattle Ministerial Conference had been marked by public protests against the elevation of commercial interests over other social-policy concerns, including the environment. In addition, the interests of developing countries seemed once again relegated in the background. Therefore, key governments, under NGOs pressure, clearly had no desire to undermine progress on a treaty that so directly aimed to protect the environment and build capacity in developing countries—and certainly not in the name of trade interests[16]. Therefore, the Protocol is the result of a balance between market access for products of biotechnology, as sought by the Miami Group, and environmental and health policy concerns promoted, not always for the same reasons, by the other negotiating parties.

[16] Cosbey, A. and Burgiel, Stas, 'The Cartagena Protocol on Biosafety: An analysis of results', (Winnipeg, Manitoba: International Institute for Sustainable Development, 2000). Also available at http://www.iisd.org/publications/publication.asp?pno=332.

III. THE CARTAGENA PROTOCOL

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity[17] (Cartagena Protocol) was adopted in Montreal after four years of negotiations by the 135 present countries on 29 January 2000. To date, 103 countries have signed the Protocol, indicating their general support for the principles in the Protocol and committing themselves to take the steps necessary to consider and pursue its ratification. As of June 2003, 51 countries had deposited an instrument of ratification with the United Nations[18] so that the entry into force of the Protocol, which takes place 90 days after the ratification of the fiftieth state or regional economic integration unit, will occur on 11 September 2003.

The first Meeting of the Parties to the Protocol (MOP) will take place at the first meeting of Conference of the Parties (COP) of the Convention on Biological Diversity following the entry into force of the Protocol, that is, in March 2004 in Kuala Lumpur, Malaysia. Until then, the COP has decided to establish an open-ended ad hoc Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) with a mandate to undertake the preparations necessary for the first Meeting of the Parties to the Protocol. The ICCP, which is mainly a technical group, has been operational since December 2000 and focuses principally on the following issues:

- Preparing the operational mechanisms of the Protocol, such as the BCH;
- Implementing capacity building for developing countries, which constitutes a vital condition to secure their ratification of the Protocol;
- Preparing the tasks of the MOP 1 as regards the functioning of the Protocol and the continuation of the undetermined issues such as the question of LMO-FFPs identification or the one of liability and redress.

3.1. SCOPE OF THE PROTOCOL

The Protocol establishes an internationally binding framework of minimum biosafety standards to be implemented at the national level. Within this legal framework, national authorities can set up the level of protection deemed appropriate with regard to trade in LMOs. The Protocol derives much of its significance from the fact that it provides the first lineaments of a legal regime

[17] The Protocol on Biosafety is linked to the Convention on Biological Diversity which is presented in Section 3.2.1.

[18] See http://www.biodiv.org/biosafety/signinglist.asp?sts=rtf for an up to date list. Note that the ratification of the European Union will not be counted as additional to those deposited by member States of such regional organization

addressing some environmental and human impacts of genetic engineering. It does so on the basis of the precautionary principle, a principle of international environmental law, which provides that conservationist measures can be undertaken even in the absence of complete scientific information regarding the potential adverse effects that they intend to prevent.

> *The scope of the Cartagena Protocol on Biosafety 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.*[19]

It is therefore an environmental and to some extent sanitary agreement that aims to provide safeguards against the potential risks of living organisms created by means of modern biotechnology through the regulation of trade in LMOs. It does not prohibit trade in LMOs but in fact requires that environmental protection measures taken under the Protocol should be the least trade restrictive as possible. Therefore, the Cartagena Protocol can be summarized as an Agreement that supports trade in biotechnology products while at the same time seeking to ensure that such trade is environmentally safe[20].

In principle the Protocol applies to all LMOs. This is, however, qualified by several exceptions concerning the type of LMO, the type of activity, and the type of risk.

- Firstly, the scope is limited to LMOs that may have adverse effects on the conservation and sustainable use of biological diversity.
- Secondly, the procedures outlined in the Protocol only apply to the first transboundary movement for intentional introduction into the environment[21].
- Thirdly, the Protocol does not apply to pharmaceuticals for humans that are regulated by other treaties.[22]

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[19] Article 1 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 Jan. 2000, reprinted in 39 International Legal Materials 1027 (2000) [hereafter Cartagena Protocol]. Also available at: http://www.biodiv.org/biosafety/protocol.asp.

[20] Mann, H., 'The Cartagena Protocol on Biosafety: an analysis' (Bangkok, Thailand: document prepared for the ASEAN Workshop on International Trade in ASEAN Agricultural and Forest Products and Measures to Align Trade and Environment, 2000,). Available at: http://www.isdlaw.com/docs/ASEAN%20-Mann%20paper.doc.

[21] See articles 7-10 and 18 of the Cartagena Protocol, supra note 19.

- Fourthly, the procedure concerning the first intentional transboundary movement of LMOs does not apply either in case of transit[23] or in cases where LMOs are destined for contained use[24] (for instance national breeding programs and research).
- Fifthly, the procedure outlined with respect to the first transboundary movement of LMOs does not apply in the case of LMOs intended for direct use as Food, Feed, or Processing (LMO-FFPs, *e.g.* commodities such as corn cereal, soybean oil or Mexican corn snacks), since they are not destined to be introduced in the environment. In this case, lesser obligations only provide that states must endeavour to exchange relevant information with regard to LMO-FFP[25].

On the whole, the Protocol distinguishes three categories of LMOs covered by separate provisions:

1. LMOs intended for introduction into the environment (such as transgenic seeds, subject to the AIA procedure, Articles 7-10 and Annex I)
2. LMOs intended for contained use (for research purposes, free trade as far as it follows the importing country's standards, Article 6.2)
3. LMOs intended for Food, Feed, or for further Processing (such as canola oil. Their trade is conditioned by Article 11 and Annex II)

3.2. PRECAUTION IN THE PROTOCOL

Reliance on precaution as a regulatory instrument is based on the need to deal with uncertainty or scientific disagreement concerning the potential negative impacts of human activity on the environment of activities such as biotechnology whose full impacts on the environment are not known at present. It is essentially a matter of making assumptions about consequences and likelihood of risk. It provides government a tool to regulate activities even if the full impacts of a given activity are not known.

The precautionary principle has developed rapidly in international environmental law over the past couple of decades. It first emerged in American and German law, was progressively incorporated in international documents until its inclusion in the Declaration of the 1992 UN Conference on Environment and Development (the Rio Declaration) conferred it a global recognition. Principle 15 of the Rio Declaration concerning precaution reads as follows:

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[22] See Article 5 of the Cartagena Protocol, *supra* note 19.

[23] See Article 6 of the Cartagena Protocol, *supra* note 19.

[24] See Articles 6 and 18 of the Cartagena Protocol, *supra* note 19.

[25] See Articles 11 and 18 of the Cartagena Protocol, *supra* note 19.

> *In order to protect the environment, the precautionary approach shall be widely used by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

Principle 15 constitutes a significant step forward in the development of international environmental law principles but it is noteworthy that the opposition of some states to the development of a precautionary 'principle' led to the adoption of the watered down 'precautionary approach'. Following the lead provided by the Rio Declaration, the Cartagena Protocol also uses the term 'approach' rather than 'principle'.

The Convention on Biological Diversity of June 1992 also recognises the important role of precaution in biodiversity-related matters, but only in its preamble which does not gives a precise definition and content to the principle.[26]

The Cartagena Protocol goes much further than the Convention and gives a central importance to the precautionary approach in the case of biotechnological risks. It not only reaffirms it in its preamble and in its objectives clause (Article I) but also in Articles 10(6) and 11(8), which are more precise operational provisions. Article 10(6) which determines the conditions for taking decisions on the first intentional transboundary movement of LMOs states that:

> *Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism.*

The central place of the precautionary approach in the Protocol is reflected in the fact that the Protocol explicitly allows parties to take precautionary measures. The right to set up precautionary measures may nonetheless be limited by the obligation in Article 12 on the importing party to review the decision in the light of new scientific evidence on request of the exporting party. The Protocol binds national regulatory authorities to implement a decision-making process ensuring precaution. It obliges states to make an effort in good faith to use the existing means at its disposal to prevent possible detrimental effects on the environment. It implies, however, the need

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[26] Paragraph 9 of the Preamble reads as follows: "Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat".

to clarify how a risk-based approach can continue to be followed when the scientific uncertainty is such that conventional risk assessment cannot in itself determine the level of risk, and how decisions should be made on appropriate precautionary measures.

The importance of the precautionary approach in the Cartagena Protocol has been well captured by Robert Falkner who notes that:

> *the Cartagena Protocol was negotiated without evidence of concrete environmental damages resulting from the release of GMOs into the environment. What is more, the scientific community was deeply divided over the potential risks involved. Thus the biosafety agreement is a truly precautionary instrument, setting rules for decision-making that seek to minimize the risk of future, potential, damage. This precautionary character goes some way in explaining the difficulties encountered in reaching agreement on the protocol. Although most countries accepted the need for precautionary action, some feared that the biosafety regime would unnecessarily slow down progress in biotechnological development and hamper international trade in biotechnology.*[27]

3.3. THE ADVANCED INFORMED AGREEMENT PROCEDURE

The major aim of the Cartagena Protocol is to regulate transboundary movements of LMOs by specifying the conditions under which trade can be undertaken.

Articles VII to X and Annex I of the Protocol detail the requirements of identification and notification, incumbent to the exporting country before the first international transfer of living modified organisms intended to be introduced into the environment (e.g. seeds for propagation, seedlings, fish for release, and microorganisms for bioremediation). This is called the procedure of 'advanced informed agreement' (AIA). In essence, exporters will be required to obtain prior approval from the party of import, and the AIA procedure gives the importing state the prerogative to refuse entry to LMOs covered by the procedure on the basis of a risk assessment carried out according to the provisions of the Protocol.[28]

More specifically, the first time that a new GM variety is exported for intentional introduction into the environment (e.g. as seed or micro-organism), the exporting country would notify in writing the importing

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[27] Falkner, R., *supra* note 13, p. 4.

[28] See Articles 10 and 15 of the Cartagena Protocol, *supra* note 19.

country, before the movement of LMOs takes place.[29] Information requirements for this notification are included in Annex I, which notably entails the obligation to provide to the importing country and the Biosafety Clearing House (BCH, see section 3.2.8):

- information about the characteristic of the LMO,
- the size of the shipment
- a copy of the risk assessments that was done in the party of export, and
- its regulatory status in the exporting country.

The state of import must then, within 90 days, acknowledge receipt of the notification and indicate whether the procedure is to follow the importing state's regulations – which must comply with the Protocol – or the procedure outlined in Article 10 of the Protocol.[30]

Importantly, failure to acknowledge receipt of a notification does not signify that the state of import agrees to the LMO movement.

The importing country would then have nine months (270 days) to decide whether to approve or decline the shipment because of risks identified through a risk assessment carried out in a scientifically sound manner according to the methodology outlined in Annex III. The importing country may require the exporter to carry out the risk assessment as well as to undertake the costs of the assessment. The decision has then to be communicated, in writing, to the exporter and to the Biosafety Clearing House, in order to inform other parties on the position held by the importing country.

Two specific features of the procedure must be highlighted.

- Firstly, if the state of import fails to notify the exporting state its decision within the agreed time frame, this cannot be construed as an acceptance of the shipment.
- Secondly, the risk assessment whose purpose is to identify and evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity or human health in the likely potential receiving environment must be carried out by the state of import in a scientifically sound manner in accordance with Annex III.[31] The Protocol, however, recognises that there may be cases where scientific information and knowledge regarding the extent of the potential adverse effects of a living

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[29] See Article 8 of the Cartagena Protocol, *supra* note 19.

[30] Article 9 of the Cartagena Protocol, *supra* note 19.

[31] Annex III sets out a number of requirements that States must fulfil for their risk assessment to be deemed compliant with the Protocol. *See* Annex III of the Cartagena Protocol, *supra* note 19.

> modified organism on the conservation and sustainable use of biological diversity in the importing state may be insufficient to provide firm conclusions. In such cases, in accordance with the precautionary approach the importing state is authorised to take a negative decision with regard to the proposed transboundary movement with a view to avoid or minimise potential adverse effects.[32]

The AIA procedure therefore only applies to the first transboundary movement of LMOs that have not been excluded from its scope. In practice, this implies that the AIA procedure mainly applies to seeds and micro-organisms, which constitute only a small part of genetically modified products, in order to prevent their uncontrolled dissemination into the environment.

3.3.1. LMOs for Food, Feed and further Processing (Article 11).

As noted, the AIA procedure does not apply to LMO-FFPs, despite the insistence of developing countries. The latter asked for their inclusion in the AIA procedure referring to their domestic situation where accidental dissemination of LMOs during the transport and use of LMO-FFPs as well as the use of food grains as seeds during crisis periods could not be prevented. Finally, LMO-FFPs were covered by separate provisions under Article 11. In effect, in the case of LMO-FFPs, state parties to the Protocol only undertake to provide each other with information concerning the regulatory framework that they adopt in this field. Within 15 days of domestic regulatory approval having been granted for a new GM variety, a country would notify the Biosafety Clearing House with information about the traits, the, evaluations, and the regulatory decision adopted.

With regard to import decisions, importing states must take decisions in pursuance of their legal framework, which must be consistent with the overall objectives of the Protocol. When such regulatory systems do not exist, the decision, which shall be made within a time frame of 270 days, must be based on a risk assessment (in conformity with the dispositions detailed in Annex III), and can refer to the precautionary approach.

3.4. RISK ASSESSMENT AND RISK MANAGEMENT

Both the AIA procedure and the procedure for LMO-FFPs set out in Article 11 require considering a risk assessment in the approval process of proposed imports. Risk assessment is the process of identifying, evaluating and selecting actions to prevent or reduce risk. This process enables informed decisions regarding the transboundary movement of LMOs, and thus underpins the

[32] Article 10.6 of the Cartagena Protocol, *supra* note 19.

operation of the Cartagena Protocol. It is the central requirement prior to decision-making by the country of import, which has the right to require the exporting country to undertake the risk assessment or to pay for an assessment undertaken by the state of import or an agency they assign this responsibility (Article 15.2, 15.3). It is worth noting that this shifting of responsibility is a major change from the existing trade law under the WTO Agreements, which impose the burden of proof on the importing country.

Risk assessments must be undertaken in a scientific manner based on recognised risk assessment techniques, taking into account advice and guidelines developed by relevant international organizations[33].

Annex III of the Protocol details the risk assessment procedure, which aims to identify and evaluate the "*potential adverse effects*" of LMOs. This procedure has to be carried case-by-case for the "likely potential receiving environment"[34], since the possible adverse effects of a LMO depend not only on the LMO itself, but also on the potential receiving environment and, in addition, the assessments and procedures may not be adequate to protect all the different receiving environments and their biological diversity, taking also into account risks to human health.

The risk assessment involves several steps[35], including:

- the identification of potential adverse effects,
- an assessment of the likelihood that the potential adverse effects occur,
- an evaluation of the consequences that may arise where these adverse effects come to be realized[36], and

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[33] Such as the UNEP International Technical Guidelines for Safety in Biotechnology adopted by the Global Consultation of Government-designated Experts (Cairo, Egypt: 1995), available at: http://www.unep.org/unep/program/natres/biodiv/irb/unepgds.htm
The OECD is also drawing consensus and regulatory harmonisation documents enlisted at: http://www.oecd.org/oecd/pages/home/displaygeneral/0,3380,EN-document-529-14-no-27-9897-529,00.html
For a complete view of the most relevant documents and guidelines concerning biotechnology released by international organisations see also: http://www.field.org.uk/fieldmain/tigo_feb03.2.html

[34] Annex III.1 of the Cartagena Protocol, supra note 19. A potential receiving environment is an ecosystem or habitat, including humans and animals, which is likly to come in contact with a released organism. This definition is taken from 'UNEP International Technical Guidelines for Safety in Biotechnology', supra note 33, at Annex 2.18.

[35] Annex III.8 of the Cartagena Protocol, *supra* note 19, enumerates six steps.

[36] The consequences of adverse effects, should they occur, may take many forms, include damage to biodiversity, damage to genetic resources, damage to livelihoods anddamage to agriculture.

- an estimation of the overall risk in relation to each adverse effect, based on evaluation of its likelihood and consequences.

Moreover, as part of the risk assessment, Annex III provides for a recommendation to be made as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks. However, risk assessment sometimes cannot provide clear-cut information on which to base a decision. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level or risk, an absence or risk, or an acceptable risk[37]. Therefore, areas where uncertainty remains regarding the level of risk may be addressed by further investigating on the specific issues of concern or by implementing appropriated risk management strategies[38]. Besides, monitoring the LMO in the receiving environment would provide further information on the LMO and would enable to institute appropriate risk management measures should any adverse effects be detected. Nevertheless, if there is insufficient information available or an inadequate risk assessment on which to base a decision, the party of import ultimately has the right to refuse the import[39] on a precautionary basis.

3.5. HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION PROCEDURES

In order to give some expression to the broader focus that developing countries had promoted, in particular their claim to include LMO-FFPs in the AIA procedure, obligations with regard to handling, transport, packaging and identification have been incorporated into the Protocol (Article 18). The

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[37] Annex III.4 of the Cartagena Protocol, *supra* note 19.

[38] The purpose of risk management as stated in Article 16 of the Cartagena Protocol is to regulate, manage and control risks identified in the risk assessment carried out under the Protocol. Indeed, the Protocol considers the risk assessment and risk management as related processes. Risk management measures will be proposed following a risk assessment, and it will likely be necessary to reassess risks after risk management measures are applied. Therefore, it may be necessary to iterate between risk assessment and consideration of appropriate risk management measures to achieve prevention of any risk, or its minimization or reduction to an acceptable level. IUCN Environmental Policy and Law Paper No. 46, *An explanatory guide to the Cartagena Protocol on Biosafety*, (IUCN-FIELD-WRI: 2002), p. 123. Document available at: www.iucn.org/themes/law/pdfdocuments/BiosafetyGuide%20launch%20text.pdf.

[39] Therefore, in circumstances of uncertainty, determining what is an acceptable level of risk does not depend on the availability of scientific knowledge or scientific consensus. Whether or not a risk identified by a risk assessment is acceptable or not, is a matter to be considered by decision-makers, and may, under Article 23(2) of the Protocol, involve consultation with the public.

Protocol provides specific obligations concerning the documentation accompanying all categories of LMO covered under the Protocol.

LMOs meant for intentional release into the environment shall identify the shipment as containing LMOs and indicate the identity and relevant traits of the LMOs and/or its characteristics.[40] Any requirements for safe handling, storage, transport and use, as well as the contact point for further information, a declaration that the movement is in conformity with the Protocol and, as appropriate, the name and address of the importer and exporter, shall also be included in the documentation accompanying the shipment.

In the case of LMO-FFPs, the documentation accompanying a shipment must clearly indicate that it 'may contain' LMOs and that the commodities are not intended for intentional introduction into the environment.[41] Moreover, a contact point for further information shall be indicated.

Finally, LMOs intended for contained use must identify the shipment as containing LMOs, and must specify any requirements for safe handling, storage, transport and use, and the contact point for further information.

Beyond these general identification obligations for transportation purposes stated in Article 18, the question of labelling for consumer retailing has been deferred. The Conference of the Parties (COP) to the Convention on Biological Diversity has been given the task to take further action in this area within two years after the entry into force of the Protocol, in consultation with other relevant international bodies. The OECD and above all the Codex Alimentarius Commission (see section 3.3.3) are dealing with this specific issue. The main issues at stake concern the type and extent of information that should be specified in documentation, the standards to define when labelling is to be used and the development of a unique identification system[42].

3.6. TRADE-RELATED MEASURES

The Cartagena Protocol is not only an environmental agreement but also a trade agreement, since it provides for trade in LMOs regulation. Indeed, besides technical and financial support, as well as information exchange, trade regulation is considered the main and most effective instrument to promote

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[40] The OECD Biotech Database provides a prototype of standard biotech product information table. See: http://www.olis.oecd.org/bioprod.nsf

[41] Article 18.2(a) of the Cartagena Protocol, *supra* note 19

[42] See http://www.biodiv.org/biosafety/handling.asp to follow up the ICCP work on this issue. See also the document 'OECD guidance for the designation of a unique identifier for transgenic plant' (Paris: OECD, 2002) ENV/JM/MONO(2002)7, also available at: http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)7.

the goals of the Protocol. Parties to the protocol are entitled to set up measures, such as bans or notification and labelling requirements, to control international trade in LMOs to safeguard environmental and health concerns. It is worth noting that these trade-related environmental measures can be applied for precautionary purposes, therefore may be applied without supporting scientific evidence concerning the risks the measures intend to prevent. However, this leeway is balanced by the requirement that measures may only be imposed to the extent necessary to prevent the adverse effects of LMOs to the conservation of the environment and human health[43]. Moreover, decisions can be reviewed on request by the exporting country when new circumstances or information could influence the outcome of the risk assessment upon which the decision was based[44]. These latter provisions clearly aim at ensuring WTO-consistency by preventing trade discrimination and unjustified measures, and reflect the endeavours to balance trade interests and environmental protection concerns.

The following table enumerates the principal trade related measures stated by the Protocol.

[43] Article 16 of the Cartagena Protocol *supra* note 19

[44] Article 12 of the Cartagena Protocol *supra* note 19

Examples of trade-related measures under the Protocol

Article	Trade-related measure	Measure taken by	Product	Timing	Character
8.1	Notification of Party of Import prior to export	Party of Export	LMOs	Prior to first intentional trans-boundary movement	Required
10.3(a)	Conditions attached to the import that affect internal sale	Party of Import	LMOs	Prior to first intentional trans-boundary movement	Authorized
10.3(b)	Import ban	Party of Import	LMOs	Prior to first intentional trans-boundary movement	Authorized
10.3(c)	Request for additional information prior to import	Party of Import	LMOs	Prior to first intentional trans-boundary movement	Authorized
10.3(a), 4	Unconditional approval of import	Party of Import	LMOs	Prior to first intentional trans-boundary movement	Authorized
12.4	Risk assessment	Party of Import	LMOs	Subsequent to first intentional introduction	Authorized
15	Risk assessment	Party of Import	LMOs	Prior to first intentional trans-boundary movement	Required
18.2(a)	Identification as 'may contain' LMOs	Party of Export	LMO-FFPs	Prior to any intentional trans-boundary movement	Required
18.2(b)	Identification as LMOs	Party of Export	LMOs destined for contained use	Prior to any intentional trans-boundary movement	Required
18(c)	Identification as LMOs	Party of Export	LMOs destined for introduction into the environment	Prior to any intentional trans-boundary movement	Required

Source: IUCN-FIELD-WRI, *An explanatory guide to the Cartagena Protocol on Biosafety* (2002). Also available at: http://iucn.org/themes/law/info04.html

These measures can be classified in three categories:

- The requirements of identification and notification (Articles 8, 18 and Annex I), entailing that the first transboundary movement of LMOs cannot take place without the prior informed consent of the importing country through notification by the exporting country.
- The procedures of risk assessment (Article 15 and Annex III) intended to evaluate the potential harmful effects of LMOs on biological diversity and health. Given the increasing number of varieties (with new traits) of GM products that will presumably be asked for market access, their examination will involve long delays, especially for countries with limited regulatory capacity.
- The import ban or other restrictive measures like the procedures for handling and packaging or the labelling standards that a Party can implement consecutive to the approval procedure based on a risk assessment.

The Protocol therefore emphasises the sovereignty of importing countries[45] and "(…) could be characterised as an effort to counter, by recourse to national sovereignty, the trend of increasing discipline imposed on governments by the liberal international trading order.[46], due to environmental and health concerns.

3.7. COMPATIBILITY WITH OTHER INTERNATIONAL AGREEMENTS: THE "SAVINGS CLAUSE"

The relationship between the Protocol and other international agreements, in particular the WTO agreements, has been one of the difficult issues that negotiators had to address but failed to clearly solve in the end.

The question at stake is the hierarchy between environmental and trade agreements. Some negotiating parties, especially countries producing LMOs gathered in the Miami group, wanted to make sure that the Protocol would not justify unnecessary protectionism (not fully based on scientific principles) or discriminatory treatments disguised under environmental measures. Others, in particular the EU and the Like-Minded group, wanted to prevent the subordination of environmental concerns to trade interests, and make sure that any trade related environmental measure they might set up by virtue of

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[45] Article 2.3 of the Cartagena Protocol *supra* note 19

[46] Cottier, Thomas, 'Implications for Trade Law and Policy: Towards Convergence and Integration', *in* Christoph Bail, Robert Falkner and Helen Marquard eds, *The Cartagena Protocol on Biosafety – Reconciling trade in Biotechnology with Environment and Development?* p. 469 (London: Earthscan, 2002).

the Protocol would not be challenged under the WTO. Both claims have been reflected in two separate clauses of the preamble of the Protocol.

1. The first clause highlights that the Protocol does not imply "a change in the rights and obligations of a Party under any existing international agreement".[47] This is commonly referred to the savings clause, which cautions parties to implement the Protocol in a manner that is consistent with their other international rights and obligations. It was inserted at the behest of countries that were worried the Protocol might be interpreted as altering the obligations contained in WTO treaties, in particular the non-discriminatory requirements and the requirements that sanitary and phytosanitary measures must be based on scientific principles. In particular, the Miami Group wanted to protect WTO rights and obligations in order to provide sustained market access for their biotechnology products.
2. The second clause emphasises that the "the above recital is not intended to subordinate this Protocol to other international agreements". This is meant to highlight that while WTO obligations are not affected by the Protocol, the former should not detract anything from the substance of the new obligations adopted under the Protocol, satisfying the claims of the EU and the Like-Minded group.

While the two clauses just mentioned are phrased generically, they appear just after a paragraph recalling that trade and environment should be mutually supportive with a view to achieving sustainable development. The relationship envisaged here thus concerns mainly the interaction between the Protocol as an environmental agreement and the WTO agreements as trade agreements.

The two clauses inserted in the Protocol make the situation inconclusive with regard to the interpretation of environment and trade agreements in the case of a conflict between states' obligations under the Protocol and under WTO agreements. The second clause seems intended to counterweight the clear scope of the savings clause, as if it aimed at undermining it, which would raise questions on the coherence of the Protocol.

However, in the absence of a binding dispute settlement mechanism in the context of the Biodiversity Convention[48], these clauses provide a reminder to any other adjudicative body, such as a WTO Dispute Settlement Body, that obligations under the Protocol cannot be sidelined as irrelevant to the solution of a dispute.

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[47] Preamble of the Cartagena Protocol, *supra* note 19.

[48] The Convention provides that disputes between parties should in principle be solved by negotiation. *See* Article 27 for further details.

3.8. INFORMATION EXCHANGE UNDER THE PROTOCOL: THE BIOSAFETY CLEARING HOUSE

Beyond the regulation of trade envisaged for the different categories of LMOs covered, one of the important functions of the Protocol is to foster information exchange among state parties. On this basis, an internet-based Biosafety Clearing-House directly linked to the clearing house mechanism established under the Convention on Biological Diversity (CBD, see section 3.3.1) will be set up[49] (Article 20). Its purpose will be to:

- Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs.
- Gather all national regulations as well as the final decisions, with a summary of the risk assessment underlying them.

In practice, governments shall indicate to the BCH one national focal point to be responsible on its behalf for administrative liaison with the Secretariat of the Protocol. In addition, governments shall indicate their 'Competent National Authority(ies)' with a defined area of competence whose function is to:

- exercise responsibility for undertaking risk assessments; and
- making risk management decisions following notification under either the procedure for AIA or FFP-LMOs.

Competent National Authorities are required to provide the Biosafety Clearing-House with information specified in paragraphs (a) to (e) of Article 20(3), in particular :

- Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the AIA procedure;
- Any bilateral, regional and multilateral agreements and arrangements;
- Summaries of risk assessments or environmental reviews of living modified organisms.
- Final decisions regarding the importation or release of living modified organisms; and

[49] See the pilot model on: http://bch.biodiv.org/Pilot/Home.aspx. At the first meeting of the COP-MOP after the entry into force of the Protcol, the Parties will draw on the experiences of the 'pilot phase' to decide how the BCH will function. Also visit another interesting international biosafety information exchange mechanism: the http://binas.unido.org/binas/regs.php3 for extensive information on regulations, fields trials and products around the world.

- Reports of monitoring on the implementation of its obligations under the Protocol

The BCH will therefore help parties in fulfilling their obligations by making available useful information for national competent authorities, such as rosters of biosafety experts, risk assessment reports, and national decisions regarding the imports of LMOs. Moreover, It will increase transparency vis-à-vis consumers by facilitating their access to information on biosafety[50]. The effective operation of the BCH will notably depend on the active participation of parties.

3.9. FINANCIAL ASPECTS AND CAPACITY BUILDING

The Protocol takes into account at Article 28 the fact that developing countries or countries with an economy in transition may need financial resources for its implementation. This provision is derived from the overarching framework constituted by the Convention on Biological Diversity (see section 3.2.1) which requests the allocation of 'new and additional financial resources' to enable developing countries to meet the 'agreed full incremental costs' of implementing measures which fulfil the obligations of this Convention[51] and its related Protocols.

Hence, Article 28 of the Protocol designates the financial mechanism established for the Convention on Biological Diversity, the Global Environment Facility (GEF), as its financial mechanism[52]. In practice, developed countries discharge their financial commitments through the GEF, nevertheless Article 28 of the Protocol encourages developed countries to also provide financial and technological resources through bilateral, regional, and multilateral channels.

Guidance with respect to the programmes and issues that will have priority in the utilisation of financial resources will be determined in a democratic and transparent system by the COP-MOP (Meeting of the Parties to the Cartagena Protocol) and communicated to the COP of the Convention. The

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[50] Article 23 of the Cartagena Protocol, *supra* note 19.

[51] Article 20 of the Convention on Biological Diversity, Rio de Janeiro, 5 June 1992, 31 *International Legal Materials* 818 (1992). Also available at http://www.biodiv.org/convention/articles.asp [hereafter the Biodiversity Convention]. The importance of financial commitments for developing countries is illustrated by the fact that under the Convention developing countries have the option to make the implementation of their commitments dependent on the effective implementation by developed countries of their commitments related to financial resources and transfer of technology.

[52] The GEF has operated as the financial mechanism since the Biodiversity Convention's entry into force. *See* Instrument for the Establishment of the Restructured Global Environment Facility, Geneva, 16 Mar. 1994, *reprinted in* 33 *International Legal Materials* 1273 (1994).Also available at http://www.gefweb.org/public/instrume/instrume.htm

COP in turn forwards its recommendations to the Global Environment Facility.

At the initial stage, the primary task of the financial mechanism is to assist developing countries in capacity-building for the Protocol's ratification and effective implementation[53]. To this end, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) developed, in 2001, a global 'Action Plan for Building Capacities for the Effective Implementation of the Protocol'[54] which provides a framework to assist governments and organisations to better address priority capacity-building elements in a strategic, systematic and integrated manner.

Each capacity-building activity should be tailored to fit the specific national context of the country whose capacity is to be developed, therefore the first stage implies an identification of existing capacities and the country's needs in the following general areas:

- scientific and technical training in the proper and safe management of biotechnology;
- scientific and technical training in the use of risk assessment and risk management for biosafety; and
- the enhancement of technological and institutional capacities in biosafety.

A Coordination Mechanism is being developed to facilitate coherent and collaborative implementation of the Action Plan and to ensure mutual supportiveness among different initiatives. In addition, a roster of experts has been established to provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of living modified organisms.

Governments and organisations have also initiated various capacity-building activities, projects and programmes related to biosafety In particular, UNEP and the GEF are implementing a global project intended to help developing

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[53] The UNEP document 'Biosafety capacity-building: completed, ongoing and planned projects/programmes' (First meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, Montpellier, France : 2000. UNEP/CBD/ICCP/1/INF/1) provides a quite complete listing of capacity building projects at http://www.biodiv.org/doc/meetings/bs/iccp-01/information/iccp-01-inf-01-en.pdf. See also the pilot website of the Biosafety Clearing House in this regard http://bch.biodiv.org/Pilot/CapacityBuilding/GettingStarted.aspx and more precisely the database on capacity building projects: http://bch.biodiv.org/Pilot/CapacityBuilding/SearchProjects.aspx

[54] The 'Action Plan for Building Capacities for the Effective Implementation of the Protocol', adopted at ICCP-2 , is also available at: http://www.biodiv.org/doc/ref/bs-cb-en.pdf

countries to prepare their National Biosafety Frameworks as required by Article 22 of the Cartagena Protocol. This mainly consists of support for the elaboration of draft legal instruments, administrative systems, risk assessment procedures, and systems for public participation and information[55].

3.10. OTHER FEATURES OF THE PROTOCOL

3.10.1. Socio-economic considerations

The Protocol authorises state parties to take into account the socio-economic consequences of the impact on biodiversity arising from the import of a given LMO, in particular with regard to the value of biodiversity for local communities.[56] This implies that when a risk assessment is conducted prior to a decision on import and an adverse impact on biodiversity is identified, socio-economic considerations arising from such an impact can be taken into account in the risk management process.

This provision aims at countering the risk of genetically modified seeds replacing traditional ones and affecting local environment, culture, knowledge and tradition. Indeed, developing countries feared that the introduction of LMOs cultures would lead to the displacement of traditional varieties, the substitution of traditional crops by transgenic crops promoted by multinational corporations, and more broadly a weakening of their agricultural exporting sector.

3.10.2. Liability and Redress

A consensus could not be reached regarding liability and redress for damages resulting from transboundary movements of LMOs. Developing countries asked for substantive provisions for a liability regime that would determine the extent to which each actor would be liable for damages, while producing countries wanted no provision at all on liability. Finally, the Protocol provides that the Conference of the Parties will have the task of elaborating rules and procedures in this regard within four years of the Protocol's entry into force.[57]

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[55] See http://www.unep.ch/biosafety/ for further information on the UNEP-GEF global project on the development of National Biosafety Frameworks.

[56] Article 26 of the Cartagena Protocol, *supra* note 19.

[57] Article 27 of the Cartagena Protocol, *supra* note 19. The following webpage informs on the ongoing discussion on this topic: http://www.biodiv.org/biosafety/liability.asp

IV. THE CARTAGENA PROTOCOL IN ITS BROADER CONTEXT

The Cartagena Protocol must be understood in the legal and institutional context in which it arises. Two main points must be made at the outset in this regard.

- Firstly, as a Protocol to the Biodiversity Convention (section 3.3.1), the fundamental principles and objectives of the Convention also apply here. This implies, for instance, that the Protocol follows not only the objective of biodiversity conservation but also the objectives of sustainable use and fair sharing of the benefits arising out of the utilisation of biological resources.
- Secondly, while the Protocol is an environmental law treaty by virtue of being linked to the Biodiversity Convention, it is also an international trade agreement insofar as it principally seeks to regulate trade in LMOs.[58] (section 3.3.2) Indeed, the Protocol can be seen as a trade regulation treaty, which authorises import restrictions on certain products on the basis of their potentially harmful impact on the environment. This is made clear by the fact that the Protocol applies mainly to the first transboundary movement of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity. As such, it is concerned equally with the environmental impacts of genetic engineering and the economic interests of exporting states.

Therefore this section will firstly describe the main features of the CBD, the overarching framework of the Cartagena Protocol. It will also present the modalities of functioning of the Protocol, its administrative structure being the reproduction of that of the CBD. The second part of this section will focus on the relationships of the Protocol with other international trade regulation organisations, more specifically the World Trade Organisation and its international standard setting reference points, in particular the Codex Alimentarius Commission (CAC).

4.1. THE CONVENTION ON BIOLOGICAL DIVERSITY

The Biodiversity Convention, adopted in 1992 in the form of a binding framework treaty, provides the first comprehensive legal framework for the conservation and management of biological resources.

Since the 1972 Stockholm United Nations Conference on the Human Environment, states have signed various regional and international

[58] Cottier, *supra* note 46.

agreements designed to deal with various environmental issues, from the protection of specific species, habitats or ecosystems to treaties dealing with the use and exploitation of environmental resources as well as treaties addressing some of the consequences of industrial activity, such as air pollution or hazardous wastes. These treaties predate the Biodiversity Convention and carry on their mandates as before. However, even though the Convention does not supplement other treaties, it provides the missing general framework for the conservation and use of all biological and genetic resources. This is what gives the Convention its importance.

4.1.1. Purpose of the Biodiversity Convention

The Convention reaffirms the principle of state sovereignty over resources which grant states sovereign rights to exploit their own resources pursuant to their own environmental policies together with the responsibility to ensure that activities within their own jurisdiction or control do not cause damage to the environment of other states. The Convention, however, innovates in bringing a new qualification to the principle of sovereignty. It introduces the notion that the conservation of biological diversity is a 'common concern of humankind' whereby states have a duty to cooperate in the sustainable management of resources found under their jurisdiction.

The three main goals of the Convention are :

1. the conservation of biological diversity
2. the sustainable use of its components,[59] and
3. the fair and equitable sharing of the benefits derived from the use of genetic resources.[60]

4.1.2. Main Provisions of the Convention

The Biodiversity Convention provides a number of general obligations for member states. These include in particular a commitment to develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity. Member states must also integrate the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral

[59] Sustainable use is defined under Article 2 of the Biodiversity Convention, *supra* note 51, as the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

[60] Article 1 of the Biodiversity Convention, *supra* note 51.

plans, programmes and policies. Generally, member states are required to promote the sustainable use of biological resources by:

- integrating consideration of the conservation and sustainable use of biological resources into national decision-making,
- adopting measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;
- protecting and encouraging customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;
- supporting local populations to develop and implementing remedial action in degraded areas where biological diversity has been reduced;
- and encouraging cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources.[61]

4.1.3. Achieving Conservation of Biological Diversity

Conservation under the Biodiversity Convention is to be achieved in two main ways.

Firstly, the Convention emphasises *in situ* conservation, which proposes the conservation of genes, species, ecosystems and natural habitats in the surroundings where they have developed their distinctive properties. This mainly consists in the development of protected areas and in the restoration of degraded ecosystems, but also in the protection of the environment from human pressure, including from the risks associated with the use of living modified organisms and the introduction of alien species[62]. Financial and other cooperation between parties to the Convention, particularly in favour of developing countries, is deemed necessary to achieve these goals.

Secondly, supplementary *ex-situ* conservation outside the natural habitats of the protected biodiversity components is also proposed. *Ex situ* conservation requires the use of gene banks and zoological and botanical gardens to conserve species, which can contribute to saving endangered species. *Ex situ* measures are preferably undertaken in the country of origin. It includes a duty to maintain facilities for the conservation of and research on plants, animals and micro-organisms, to seek the rehabilitation of threatened species and their reintroduction into their natural habitats, to regulate the collection of biological resources from natural habitats for *ex situ* conservation so as not to

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[61] Article 10 of the Biodiversity Convention, *supra* note 51.

[62] Environmental concerns relating to biotechnology were just emerging at the time of the redaction of the CBD, developing countries dreading they could be spoiled of their biological patrimony.

unnecessarily threaten ecosystems and *in situ* populations of species, and to provide financial support for *ex situ* conservation, especially to developing countries.[63]

4.1.4. The institutional structure of the Convention

The institutional structure of the Biodiversity Convention includes a number of bodies, in particular the Conference of the Parties (COP), the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) and the Secretariat. This institutional structure comprising three bodies applies to all protocols adopted under the Convention, including the Cartagena Protocol, as set out in Articles 29 to 31 of the Protocol.

❖ **The Conference of Parties (COP)**, brings together every two years all member states and is the governing body of the Convention. It advances implementation of the Convention through the decisions it takes at its periodic meetings and is generally mandated with keeping the implementation of the Convention under review. More specifically, it

- reviews progress under the Convention,
- identifies new priorities to be pursued,
- sets work plans for members,
- amends the Convention,
- creates expert advisory bodies,
- reviews progress reports by member nations, and
- collaborates with other international organizations and agreements.

Periodic state reports to the Conference of the Parties constitute one of the main monitoring instruments instituted under the Convention. State parties must report on the means they have adopted to implement the objectives of the Convention and the level of success of such measures. The Conference of the Parties has launched a number of thematic programmes covering, for instance, the biodiversity of inland waters, forests, marine and coastal areas, dry lands and agricultural lands, agricultural biodiversity and cross-cutting issues such as the control of alien invasive species, strengthening the capacity of member countries in taxonomy, and the development of indicators of biodiversity loss.

Article 29 of the Cartagena Protocol states that the Conference of the Parties to the Convention shall serve as the meeting of the Parties to the Cartagena Protocol, with the aim of keeping under regular review the implementation of the Protocol. The first meeting of the Conference of the Parties serving as the

[63] Article 9 of the Biodiversity Convention, *supra* note 51.

meeting of the Parties to the Protocol (COP-MOP) is now planned to take place in March 2004. Only Parties to the Protocol will have the right to vote on matters concerning the Protocol. Other parties of the Convention who are not Parties to the Protocol may attend the meetings, but only as observers.

❖ **The Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA)** has been established to undertake specific tasks, such as providing expert advice to the other organs of the Convention. It is a multidisciplinary expert body which has the mandate of

- providing scientific and technical assessments of the status of biological diversity and of the effects of different measures taken in accordance with the Convention;
- identifying innovative, efficient and state-of-the-art technologies and know-how relating to the conservation and sustainable use of biological diversity and advising on the ways and means of promoting development and/or transferring such technologies;
- providing advice on scientific programmes and international cooperation in research and development related to conservation and sustainable use of biological diversity.

Any subsidiary body serving the Convention may impart information related to the Protocol from the functions attributed to it by the meeting of the Parties. The Protocol may also establish any other subsidiary bodies they feel necessary, and will designate the issues the body will work on at the COP.

❖ **The Secretariat,** plans and organises meetings, drafts documents, assists member Governments in the implementation of programmes, coordinates with other international organizations and collects and disseminates information.[64] As stated in Article 31 of the Cartagena Protocol, the Secretariat also extends its functions to serve as the Secretariat to the Protocol.

The Biodiversity Convention generally provides for the adoption of protocols. Given the broad scope of the Convention, a great number of specific issues could be taken up by subsequent protocols. More specifically, the Convention called on member state to negotiate a protocol on biosafety.[65] In keeping with this mandate, the COP launched the negotiation process of the Biosafety Protocol during its second session.[66]

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[64] Article 24 of the Biodiversity Convention, supra note 51.

[65] Article 19(3) of the Biodiversity Convention, supra note 51.

[66] See decision II/5 from the meeting of the Conference of the Parties, 'Consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms' (Jakarta, Indonesia: 1995), also available at : http://www.biodiv.org/decisions/default.asp?lg=0&dec=II/5

4.2. BIOSAFETY AND TRADE REGULATION (THE PROTOCOL AND THE WTO)

As noted in the first section, the rapid expansion of biotechnology in agriculture in the late nineties increased the commercial stakes with respect to the biosafety regulation. The increasing commercial interest in agricultural biotechnology put many obstacles in the way of the Biosafety Protocol negotiations and an agreement on the final text was reached only by leaving somewhat undetermined the most contentious issues such as the treatment of LMO-FFPs (labelling issue) and the question of the relationships with other international agreements, in particular with the WTO. The Protocol on Biosafety is sometimes presented as an agreement that supplements WTO rules by clarifying how trade in living modified organisms should be conducted in order to prevent its potential adverse effects. The Protocol accurately incorporates its own anti-discrimination clauses in order to ensure WTO-consistency, however trade measures taken by parties to it may still conflict with WTO rules. In particular, trade-related measures taken pursuant to the AIA procedure, such as import bans, or the labelling requirements taken pursuant to Article 18 could be challenged under the Dispute Settlement system of the WTO by a non-party to the Protocol.

This section will therefore describe the approach that the WTO may take with respect to measures intended to prevent detrimental impacts of trade in biotechnology products,

Main WTO treaties relevant in the context of the Cartagena Protocol

The World Trade Organization has the primary responsibility for establishing rules for trade in goods and services. It was set up in 1995 to replace the General Agreement on Tariffs and Trade (GATT), which had been the framework for eight international trade negotiations since the end of the Second World War. The WTO establishes the legal and institutional foundations of the international trading system and determines government obligations in trade legislation and regulation, and specifies trade dispute resolution mechanisms. The WTO is an established institution conferred with considerable authority in the international legal system; an authority which is reinforced by an effective dispute settlement mechanism that has no equivalent in the international legal system.

The primordial goal of the WTO is to foster trade and protect firms that wish to invest in international commercial endeavours from the use of trade

barriers by governments[67]. With this aim it monitors whether or not measures are being used as disguised trade barriers to shield domestic producers from economic competition. The WTO allows countries to set their own trade-restrictive regulations only to the extent necessary to reach an appropriate level of protection against a recognised adverse affect[68]. Two WTO agreements have been designed to prevent industrial standards from being used as barriers to trade:

- The Agreement on Sanitary and Phytosanitary Measures[69](SPS Agreement), which sets the criteria to evaluate whether a sanitary (i.e., human and animal) or phytosanitary (i.e., plant) standard is appropriate to reach its legitimate objective. The SPS is the WTO agreement likely to be the most relevant to analyse trade measures taken in pursuance of the Protocol's AIA procedure.
- The Agreement on Technical Barriers to Trade[70] (TBT Agreement) has been designed to regulate the use of non-tariff barriers to trade and to ensure that technical regulations, standards and conformity assessment procedures do not create unnecessary barriers to international trade. Labelling provisions for consumer information purposes typically fall within its scope.

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[67] Phillips, P.W.B., and Kerr W. A. 'The BioSafety Protocol and International Trade in Genetically Modified Organisms' (CATRN Paper, University of Saskatchewan: 2000). Also available at: www.eru.ulaval.ca/catrn/protocol.pdf

[68] Relevant justifications to restrict trade are laid out in Article XX of GATT 1947. Paragraphs b) and g) in particular recognise the right of countries to adopt measures necessary for the protection of human, animal, and vegetal life (paragraph b), or to protect non-renewable natural resources from exhaustion (paragraph g). These exceptions are subordinated to the general provisions of the 'chapeau' of GATT Article XX, which provides that parties may not apply these measures in a manner that arbitrarily or unjustifiably discriminates 'between countries where the same conditions prevail' or that would constitute 'a disguised restriction on international trade'.

[69] Agreement on the Application of Sanitary and Phytosanitary Measures, Marrakesh, 15 Apr. 1994, in World Trade Organization, The Legal Texts – The Results of the Uruguay Round of Multilateral Trade Negotiations (Cambridge: Cambridge University Press, 1999). Also available at: http://docsonline.wto.org:80/DDFDocuments/t/UR/FA/15-sps.doc

[70] Agreement on Technical Barriers to Trade, 15 Apr. 1994, in World Trade Organization, The Legal Texts – The Results of the Uruguay Round of Multilateral Trade Negotiations (Cambridge: Cambridge University Press, 1999). Also available at http://docsonline.wto.org:80/DDFDocuments/t/UR/FA/17-tbt.doc.

Trade-related environmental measures and the SPS Agreement

The SPS Agreement sets out the requirements with which SPS measures, such as those that could be taken pursuant to the Cartagena Protocol, must comply. It can be considered the WTO equivalent of the Cartagena Protocol in terms of scope, as both aim at regulating trade in goods that could threaten the environment and human health. However, while the Protocol has been designed to permit countries to address biological safety in circumstances of uncertain scientific knowledge, the SPS is more generally designed to apply to various contexts and relies on scientific evidence in order to define the appropriate level of trade protection that a country can erect.

According to the SPS, sanitary and phytosanitary measures are allowed if they are "based on scientific principles and … not maintained without scientific evidence[71]". The SPS Agreement requires the importing country to provide a risk assessment in order to justify the introduction of any human or plant health measure. It has to be based on the existing scientific information, 'taking into account risk assessment techniques developed by the relevant international organizations'[72], in particular the International Plant Protection Convention (IPCC), the International Office of Epizootics (OIE) and the Codex Alimentarius Commission (CAC) (see below section 3.3.3).

Member States are allowed to set up more restrictive measures than those established by international standard setting organisations[73], in particular when these do not allow the achievement of the suitable level of protection specific to the climatic, geographical or technological factors proper to the country. Nevertheless, scientific evidence shall be always provided to demonstrate this necessity.

The Cartagena Protocol also promotes an informed decision-making process relying on scientifically sound risk assessments and is therefore consistent with the SPS Agreement on this point. However, it places the responsibility to undertake or fund an assessment on the exporting country, which is a significant procedural change from the SPS provision that obliges the importing country to justify its trade restrictive measures. This point is especially interesting for developing countries, which often lack of means to set up environmental and sanitary measures.

Another difference between these two international agreements arise from the specification of the risk assessment requirements: Annex III of the Protocol gives detailed provisions on what a risk assessment is, while the SPS

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[71] Article II.2 of the SPS Agreement, supra note 69.

[72] Article V.1 of the SPS Agreement, supra note 69.

[73] Article III.3 of the SPS Agreement, supra note 69.

Agreement does not go in detail on this respect, leaving this technical task to its standard setting reference points, more competent to address this issue.

The Protocol goes into further detail by specifying provisions concerning risk management (in Article 16). It makes it clear that both risk management and risk assessment are necessary, defining the latter as the gathering of the data, and the former as the building of a regulatory regime based on that data. It further sets out some guidance in creating that regime; for example, asking Parties to try to ensure that any LMO should undergo an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use.

Compared to these provisions, the SPS Agreement appears narrowly based on scientific evidence without offering latitude for interdisciplinary policy-making.

This difference in the scientific support required to adopt a measure is even more acute when it comes to precautionary measures. The SPS Agreement does not require in the risk assessment the establishment of a certain magnitude or threshold level of risks arising from LMOs, a qualitative assessment of the risk is sufficient. Generally mainstream scientific opinion is considered, however 'divergent opinion coming from qualified and respected sources'[74] can provide a basis for legitimate measures, especially in front of potentially high risks. Indeed, when scientific evidence is insufficient or in the process of being established, the SPS Agreement allows the application of a precautionary approach in policy-making. Article V.7 allows for:

- provisional preventive measures,
- based on available pertinent information,
- but on condition to seek to obtain the additional information necessary for a more objective assessment of risk and
- to review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

These conditions apply cumulatively, so where one is not met the measure in question will not be compatible with the SPS Agreement. This is the most explicit provision of a precautionary approach in the WTO. The use of precaution finds its foundation in science and risk assessment and is conceived as a temporary measure that does not relieve one from the duty of applying the normal reading of the SPS Agreement provisions, which aim at reducing distortions to trade.

In comparison, the Cartagena Protocol offers more latitude for precautionary measures. It has to be noticed that the Protocol is specifically geared towards

[74] Paragraph 194 of EC Measures Concerning Meat and Meat Products (Hormones), Report of the Appellate Body, 16 Jan. 1998, WTO Doc. WT/DS26/AB/R - WT/DS48/AB/R.

an area characterised by many uncertainties, while the SPS is more general since it has to apply in various contexts.

Nevertheless, the Cartagena Protocol does not explicitly require one to seek and obtain additional scientific information necessary for a more objective assessment of risks. It does not either require a review of the measure within a reasonable period of time. It affords however the revision of a measure on request of the exporting country if new information or circumstances could influence the outcome of the decision-making process.

Further, the Protocol does not require that precautionary measures have to be temporary in nature.

Finally, Article 5.7 of the SPS Agreement applies in the event of 'insufficient scientific evidence' for proven risks whereas the principle of precaution of the Biosafety Protocol applies 'in absence of scientific certainty' and for not necessarily proven risks. To sum up, the entire approach to trade barriers at the SPS is to justify measures that minimise trade distortions, while the approach under the precautionary principle is to prove that measures are not necessary to protect the environment and human health, reversing the burden of proof from the importer to the exporter. Thus, there is a fundamental difference in the WTO approach to trade restrictions and those built into the BSP.

Concerning the treatment of precautionary measures challenged at the Dispute Settlement Understanding of the WTO, a precedent case can provide some indications. The USA and Canada recently won a major dispute against a European Community (EC) ban on hormone-treated beef that resulted in the prohibition of American beef exports towards Europe.[75] As the international *Codex Alimentarius* standards existed for five of the six hormones at issue, the panel judged that the EC was required to justify its ban by proper risk assessments. Since the EC could not provide sufficient risk assessments of the risks to human health, the US argued that the ban was not based on scientific evidence. The EC maintained that it was justified, among other arguments, by the precautionary principle (as a general principle), however the Appellate Body concluded that this did not relieve them from carrying out a proper risk assessment, leaving the burden of proof upon the party invoking scientific uncertainty. Finally, the US were allowed by the WTO to raise by 100% their customs duties on a group of European products for an amount of 116.8 million dollars as indemnify for the meat export losses provoked by the European import ban.

This case is often quoted to assert that precautionary measures have no room under the WTO law. In fact, it must be noted that precautionary measures

[75] *See generally* Report of the Appellate Body, *supra* note 74.

taken without a prior risk assessment would also not be acceptable under the Cartagena Protocol.

4.2.1. Labelling and the TBT

Another potential contentious area between provisions taken pursuant to the Cartagena Protocol and the WTO could be the identification (labelling) of commodities (LMO-FFPs). Article 18 of the Cartagena Protocol requires shipments to be clearly identified as containing LMOs, and further debates are taking place under the ICCP and other relevant international organisations (notably the *Codex Alimentarius Commission* and the OECD) concerning the need for and modalities of developing standards on handling, transport, packaging and identification practices. The main issues at stake are the determination of a unique identifier[76] and the determination of a threshold level of adventitious presence of LMOs in commodities[77].

These identification requirements aiming at the separation in the supply chain of genetically modified grain varieties and non-genetically modified grain varieties would add significant compliance costs for exporters[78]. It could therefore be possible that a non-party to the Protocol, considering that the measures of commodities identification taken pursuant to the Protocol create unnecessary barriers to trade, challenge the measures under the WTO law. If this were the case, the WTO would firstly consider what the scope of the measure is: environmental protection, health protection or consumer information.

If labelling requirements were justified for health or environmental purposes, the measure would then presumably be analysed under the SPS Agreement, which notably enjoins the importing country to scientifically prove the risk. However, labelling measures are more likely to be set up for the purposes of consumer information, as consumers demand information to actively contribute to sustainable production through their individual consumption. In such circumstances, the TBT Agreement would be more appropriate to consider the WTO conformity of the measure. This Agreement states that for labelling to be permissible, the benefits must demonstrably exceed the costs. Moreover, technical norms shall not establish discrimination between two

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[76] This issue has already been essentially addressed by the OECD, *see supra* note 42.

[77] The presence in bulk shipments of material that has been genetically modified could notably occur through cross pollination in the field and co-mingling in the handling, storage and transportation process.

[78] The cost range will vary considerably (from 5 to 15% of the production costs, according to various estimates) depending on the need to declare events (traits), the number of possible events contained in the cargo, and the threshold level permitted.

"like-products"[79] on the basis of their process and production methods (PPMs), if these do not directly affect the end products (non-product-related). Only PPMs that affect the final characteristics of a product and differentiate it from national production can lead to legitimate trade measures within the meaning of WTO.

The Cartagena Protocol expressly acknowledges that LMOs are different from conventional products since they are produced through modern biotechnology. From the WTO viewpoint, clarity has not been established since several countries (mostly producing countries) consider GM food like all other traditional foodstuffs. Therefore, in the event of a dispute, the WTO would resort to the advice of its international standard setting reference points, notably the Codex Alimentarius Commission in this circumstance, in order to determine if a different treatment for genetically modified products is admissible. The Codex is likely to soon adopt biotechnology standards which will provide further guidance in this area.[80]

[79] The GATT does not specify what is a 'like product', a definition is only given in the Antidumping Code of 1979 (GATT, 1979) that later became Article II(6) of the WTO antidumping Agreement (GATT, 1994): 'the term 'like product' shall be interpreted to mean a product which is identical, i.e. alike in all respects to the product under consideration, or in the absence of such a product, another product which, although not alike in all respects, has characteristics closely resembling those of the product under consideration'. The OECD provides the principle of 'substantial equivalence', which has been endorsed by the FAO and the WHO. Determining substantial equivalence entails consideration of the trait encoded by the genetic modification, phenotypic characterisation of the new food source, compared with an appropriate comparator already in the food supply; and compositional analysis of the new food source or the specific food product, compared with the selected comparator. *See* Organisation for Economic Co-operation and Development, Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles (Paris: OECD, 1993). Also available at http://www.oecd.org/pdf/M00033000/M00033002.pdf.

[80] The Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology at its 11-14 March meeting (http://www.codexalimentarius.net/ccfbt4/bt03_01e.htm) adopted the Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms. This is the last of three draft standards on biotech food adopted by the Task Force, which will be submitted for approbation to the Codex Alimentarius Commission in July 2003. See also http://www.who.int/fsf/GMfood/scientific_advice_index.htm for more reports of the Joint FAO/WHO Consultation on Foods Derived from Biotechnology

4.3. STANDARD SETTING ORGANISATIONS

As we saw, WTO agreements recommend the use of international standards for the determination of the appropriate level of protection of national regulations. As long as a country employs these international standards and their related guidelines and recommendations, its measures are presumed to be consistent with WTO provisions. Harmonising standard contributes to a better foreseeability and transparency of markets. Moreover, in the event of a dispute, international standards offer scientific criteria of reference to determine if a national measure is excessively restrictive to reach its objective. The recourse to international standards as benchmark in international trade disputes has considerably improved interest in them.

4.3.1. The Codex Alimentarius Commission (CAC)

The Codex Alimentarius Commission[81] was created in 1961 and is the implementing arm of the Joint Food and Agriculture Organisation (FAO)/World Health Organisation (WHO) Food Standards Programme. With over 160 member states[82], it is the most important multilateral organisation responsible for the elaboration international standards and guidelines as regard foodstuffs.

As a global harmonisation organisation, the Codex Alimentarius provides a set of international standards[83] for food quality and safety presented in a uniform manner. All the principle foods destined for distribution to consumers, whether processed, semi-processed or raw, fall within the scope of the CAC. The Codex Alimentarius includes provisions in respect of:

- food hygiene
- food additives
- pesticide residues
- contaminants
- labelling and presentation
- methods of analysis and sampling

It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures.

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[81] For further details, see FAO & WHO, Understanding the Codex Alimentarius, (Rome: FAO & WHO, 1999). Also available at : http://www.fao.org/docrep/w9114e/w9114e00.htm

[82] http://www.codexalimentarius.net/member_countries.stm

[83] http://www.codexalimentarius.net/standard_list.asp#top

These food standards have two joint objectives:

- protecting consumers' health and
- ensuring fair practices in food trade

Therefore, the CAC is a hybrid food safety/trade promoting agency. Its sanitary threshold standards on food are the international reference point that justify the trade related measures that a country can set up for consumer's health protection.

Codex and biotechnology

The subject matter of the Codex is not exactly the same as the one of the Cartagena Protocol: the former deals with the safety of all edible genetically modified products, whether living or not (chocolate), while the latter addresses all LMOs whether edible or not (such as cotton). However, both aim at ensuring that genetically modified food is safe for human health.

The CAC created in 1999 a group of research on food derived from biotechnology (the ad hoc Codex Intergovernmental Task Force on Foods Derived from Biotechnology) in order to provide the necessary scientific basis for decision making on health and nutritional aspects of foods derived from biotechnology. This working group is preparing standards and guidelines for risk assessment for foods derived from biotechnology or traits introduced into foods by biotechnology.[84].

Codex as international point of reference of WTO

The Codex is a nonconstraining Code that has received greater significance since the creation of the WTO in 1995 due to the fact that both the SPS[85] and the TBT[86] agreements recognise it as their reference point in the WTO. Therefore, its standards, if not mandatory, cannot be called fully voluntary: under the WTO law, an importing country is entitled to ban or restrict the

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[84] The proposed 'Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology', the 'Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants' and the 'Draft Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms' of the Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology will be submitted for adoption at the 26th Session of the Codex Alimentarius Commission (30 June to 7 July 2003). If approved, they will be published and issued at the end of the year. The proposed 'Draft Recommendations for the Labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering' are still under elaboration.

[85] SPS Agreement, Annex A, Section 3, supra note 69.

[86] The TBT Agreement indirectly calls for compatibility with Codex standards through its mandatory referral to international standards in Articles I(1) and II(5).

importation of a food product that goes beyond the thresholds specified by the Codex. If an importing country set up trade related measures based on stricter thresholds than those specified in the Codex, it could be called by an exporting to justify with scientific evidence its measure under the WTO dispute settlement framework.

Risk Analysis in the CODEX

The core business of the Codex Alimentarius resides in the management of risk based on scientific principles and processes in the area of food safety.

Risk Analysis in the Codex treats risk assessment, risk management, and risk communication as three separate and distinct components. It is relevant that food sanitary thresholds can generally be quite precisely established in scientific terms, therefore,

> *consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment.*[87]

The Codex Alimentarius can be considered as a multilateral regulating agency that commissions risk assessment to external experts. The findings and conclusions of these experts represent the foundation of the Codex standards which in turn represent the point of reference for the WTO. Therefore the work carried out by these experts is of the greatest importance in assuring food safety worldwide, and takes increasing relevance when they apply to products susceptible of being traded internationally in large volumes, such as LMOs.

The FAO and the WHO attach great value to the technical quality and independence of the participating experts as well as to the transparency of the selection process[88].

4.3.2. Other International Standard Setting Organisations

The Imternational Plant Protection Convention (IPPC)[89] is a multilateral agreement legally constraining created in 1951 and revised in 1997. Its principal objective is the prevention of risks of biological contamination and the promotion of suitable measures for their control. Protection against the

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[87] FAO-WHO , supra note 81 at p. 165.

[88] In this regard, see the call for submission of applications for a roster of experts http://www.who.int/fsf/GMfood/Biocall%20for%20expert.pdf or the more general webpage on biosafety experts : http://www.fao.org/es/ESN/food/risk_biotech_experts_en.stm

[89] http://www.ippc.int/IPP/En/default.htm

introduction and the propagation of new diseases of the plants is considered essential for food safety. The standards, directives and recommendations worked out within the framework of the IPPC provide useful guidelines for governments, and are recognized under the SPS Agreement as being the most adequate instruments of harmonization in their field. The IPPC currently develops, in coordination with Convention on Biological Diversity, standards on plant health risks assessment for LMOs.

The International Office of Epizootics (IOE)[90] was created in 1924 (162 Member States in May 2002). The main objectives of OIE are to inform governments of the occurrence and course of animal diseases throughout the world and to establish international animal health standards for movement of animals and animal products. The OIE has had a working group on biotechnology since 1996.

Both institutions nominate experts for WTO SPS dispute panels and provide technical background information to the panels. As such, they can have far-reaching economic and political consequences on food trade.

[90] http://www.oie.int/fr/fr_index.htm

V. IN CONCLUSION

The development of biotechnology and its applications in the agricultural sector has sparked significant confrontation between commercial interests and environmental concerns. While biotechnology adopting countries have striven to promote their products worldwide, this has in reaction spurred the elaboration of biosafety regulatory frameworks in many countries where genetically modified products are seen with suspicion. The negotiations of the first Protocol to the Convention on Biological Diversity, the Cartagena Protocol, tried to achieve a compromise between the two distinct strands of environmental protection and market access for biotechnology products.

The Cartagena Protocol constitutes therefore an important treaty because it is the first binding international legal instrument addressing some environmental and health impacts of modern biotechnology. However, the present treaty remains limited in scope, both with regard to the coverage of LMOs and the kind of activities it seeks to regulate. In effect, the Protocol restricts itself to providing a framework for trade in LMOs from an environmental perspective. It generally seeks to facilitate trade in LMOs by laying down certain obligations for exporters and importers and therefore creating clear rules for transboundary movements of LMOs. This implies, for instance, that importers must undertake risk assessment in what is recognised as a scientifically sound manner. The Protocol, however, goes much further than its WTO equivalent, the SPS Agreement, and establishes a procedure which not only gives the importing state the final say in a decision on a transboundary movement but is also based on the precautionary principle which permits importing states to put restrictions on imports even in the absence of scientific certainty with regard to the potential adverse effects of LMOs on the environment.

Nevertheless, this trend towards diverging national regulations supported by the Cartagena Protocol in its endeavour to promote environmental protection through the reinforcement of the importing countries sovereignty, intensifies the tensions between exporting countries and those that restrict market access for LMOs. Exporting countries consider that the protection of the environment and of the consumer by virtue of the precautionary approach promoted under the Cartagena Protocol might be used as a disguised mean to protect national sectors threatened by international competition. This would constitute an overburdening barrier to free trade and might be subject to challenge under the WTO.

Indeed, the potential conflict between WTO rules and national measures intended to prevent potential risks caused by biotechnology has recently become a reality: on 20 May 2003, the three major producing countries of genetically modified products (comprising about 96% of total gentically modified agricultural production, which are also three major exporting countries of agricultural products in general, requested consultations in the WTO context against the EU concerning its procedures for market approval

and the *de facto* ban in place since 1998[91]. The complaining parties claim that their agricultural and food exports have been damaged by the EC's measures, and considers that these measures have been set up and maintained without sufficient scientific evidence. They therefore directly contest the validity of the measures taken by the EC, considering that these measures were not supported by scientific evidence. If this problem is solved by consensual agreement between the parties within 60 days, the case may then be brought under the Dispute Settlement Body of the WTO. If this happens, the final decision may provide indications concerning the solution of future potential conflicts between precautionary measures taken pursuant to the Cartagena Protocol and WTO law and more broadly concerning the trade off between environmental and trade concerns in international law.

[91] Note that the three complaining countries are not parties to the Protocol. Moreover, the USA, which is the single largest producer of GM crops, has not ratified the 1992 CBD which is a precondition for ratifying the Protocol.

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LIST OF ABBREVIATIONS AND GLOSSARY

AIA — **Advanced Informed Agreement**. The AIA procedure under the Protocol applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import. AIA includes steps of notification by an exporting Party or exporter, acknowledgement of notification and risk assessment and decisions making by an importing Party.

BCH — **Biosafety Clearing-House**. The BCH was established under Article 20 of the Biosafety Protocol in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and to assist Parties to implement the Protocol.

Bt — ***Bacillus thuringiensis***, a natural enemy of insects which was isolated from dead silk worms. This bacterium kills insects with the help of a protein, the so-called Bt-toxin. More than 50 Bt-toxins have been detected, each with its own characteristics.

CAC — **Codex Alimentarius Commission**. The CAC is responsible for execution of the Joint FAO/WHO Food Standards Program. The Codex Alimentarius standards are a set of international food mandates that have been adopted by the Commission in order to harmonize food standards across the world.

CBD — **Convention on Biological Diversity**. The international treaty governing the conservation and use of biological resources around the world, that was signed by more than 150 countries at the 1992 United Nations Conference on Environment and Development

CEE — **Central and East European countries** and former republics of the Soviet Union that are in transition to a market economy.

COP — **Conference of Parties to the Convention on Biological Diversity**. The COP is the intergovernmental supreme decision-making body with regard to the implementation of the Convention

COP/MOP — **Conference of the Parties serving as the Meeting of the Parties to the Protocol**. The Conference of the

Parties (the COP) adopted the Protocol as a supplementary agreement to the Convention on Biological Diversity, and the COP will serve as the meeting of the Parties to the Protocol (the COP-MOP) after its entry into force. The COP-MOP consists of all Parties to the Protocol and its main functions are to review the implementation of the Protocol and make decisions necessary to promote its effective implementation.

DNA **Deoxyribonucleic acid**, the long chain of molecules in most cells that carries the genetic message and controls all cellular functions in most forms of life

EU **European Union**. a regional organization created in 1958 providing for the gradual elimination of customs duties and other intraregional trade barriers, a common external tariff against other countries and gradual adoption of other integrating measures, including a Common Agricultural Policy and guarantees of free movement of labor and capital. Formerly called the European Community (EC), the organization became the European Union in January, 1994. It does not have a separate vote from its members under the CBD.

EC **European Community** (see EU)

FAO **Food and Agriculture Organization**, an organization of the United Nations, founded in 1945, whose objectives are to raise levels of nutrition and standards of living, to improve agricultural productivity, to better the living conditions of rural populations, and to conserve natural resources. FAO conducts agricultural research, provides development assistance, collects and disseminates information, and provides policy advice to governments.

FFDCA **Federal Food, Drug, and Cosmetic Act**. It is the main legislation applied to GM foods by the Food and Drug Administration (FDA) - the federal agency charged with approving all pharmaceutical and food ingredient products sold within the U.S.

G-77 **Group of 77 developing-countries** signatories to Joint Declaration of the Seventy-Seven Countries issued at first session of UNCTAD in 1964 and progressively expanded to include 133 countries.

GATT **General Agreement on Tariffs & Trade**. The GATT was signed in 1947 as the basis for a multilateral trading system to increase international trade by reducing tariffs

and other trade barriers. The multilateral agreement provides a code of conduct for international commerce. GATT also provides a framework for periodic multilateral negotiations on trade liberalization and expansion.

GEF **Global Environment Facility**. The multi-billion-dollar GEF was established by the World Bank, UNDP and UNEP in 1990. It operates the Convention's 'financial mechanism' and funds developing-country projects that have global biodiversity benefits.

GM **Genetically modified**

GMO **Genetically modified organism**. The modification of the genetic characteristics of a micro-organism, plant or animal by inserting a modified gene or a gene from another variety or species. GMOs may be micro-organisms designed for use as biopesticides or seeds that have been altered genetically to give a plant better disease resistance or growth

ICCP **Intergovernmental Committee for the Cartagena Protocol on Biosafety** established by the COP with a mandate to undertake the preparations necessary for the first meeting of the Parties to the Protocol, at which time the Committee will cease to exist.

IPPC **International Plant Protection Convention**. The IPPC is the worldwide authority for development of plant health standards, guidelines, and recommendations (e.g., to prevent transfer of a plant disease or plant pest from one country to another).

LMO **Living modified organism**. A living organism possesses a novel combination of genetic material obtained through the use of modern biotechnology.

LMO-FFPs **Living modified organisms intended for direct use as food, feed, or for further processing**

MEA **Multilateral Environmental Agreement**. An agreement (e.g., treaty) between a number of nations, that is intended to protect/benefit the environment.

MOP **Meeting of the Parties to the Cartagena Protocol** (see COP/MOP)

NGO **Non-governmental organisation**

OIE **International Office of Epizootics**. The OIE is the worldwide authority for development of animal health and zoonoses standards, guidelines, and recommendations.

OECD **Organisation for Economic Co-operation and Development**. The OECD is an international organization of 30 developed countries that provides governments a setting in which to discuss, develop and perfect economic and social policy. Best known for its publications and its statistics, its work covers economic and social issues from macroeconomics, to trade, education, development and science and innovation.

PPMs **Process and production methods**. The way in which products are manufactured or processed, or natural resources are extracted or harvested. Frequently used to justify environmental-related restrictions on trade, thus can have significant impacts on trade flows and on market access.

SBSTTA **The Subsidiary Body on Scientific, Technical and Technological Advice**. The SBSTTA is a subsidiary body of the Conference of the Parties (COP) that provides assessments of the status of biological diversity; assessments of the types of measures taken in accordance with the provisions of the Convention; and responds to questions that the COP may put to the body

SPS Agreement **Agreement on Sanitary and Phytosanitary Measures**, a multinational trading agreement that 'sets the rules' that govern international trade. Sanitary (i.e., human and animal) and phytosanitary (i.e., plant) standards are important in preventing the transfer of diseases from one nation to another via international trade. The SPS Agreement covers mandatory (technical regulations) or voluntary (standards) measures intended to protect human, animal, or plant life and health against risks arising from food or feed as well as from pests or diseases. In particular, these measures aim at guaranteeing that human and animal food does not contain harmful additives, contaminants, toxins or bacteria. Moreover, they state the standards related to the prevention of the diffusion in the environment of parasites, diseases, carrying diseases organisms or pathogenic organisms.

Measures necessary to protect human, animal or plant life or health should not be misused for protectionist purposes and do not result in unnecessary barriers to international trade. Therefore, the SPS Agreement encourages its Members to use the methods developed by the relevant international organisations, which are the Codex Alimentarius Commission, the International Plant

Protection Convention, and the International Office of Epizootics. Measures set up following these international standards are considered consistent with the SPS Agreement. Higher levels of protection are allowed if specific conditions of the country justify them, in particular climatic conditions. However, the justification must be proven as much as possible by analysis and assessment of objective and accurate scientific data.

This Agreement provides the most appropriate WTO provisions to consider trade-related measures intended to protect from adverse effects of the LMOs consumption and release into the environment.

TBT Agreement **Agreement on Technical Barriers to Trade**, a WTO agreement designed to regulate the use of non-tariff barriers to trade and ensure that technical regulations, standards and conformity assessment procedures do not create unnecessary barriers to international trade.

The Agreement on Technical Barriers to Trade (TBT) covers all technical regulations, voluntary standards and procedures of conformity, except when these measures are intended to prevent sanitary or phytosanitary risks as defined in the SPS agreement. The TBT Agreement has a broad field of applications, as stated in Article II.2: '(…) legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment'.

This Agreement treats only technical regulations (mandatory), standards (voluntary), and procedures of evaluation of conformity referring to products or processes and methods of production. The aim of this agreement is to ensure that standards do not become unnecessary obstacles to trade, therefore technical regulations and standards have to be applied in a non-discriminatory way (that is, in conformity with the principles of the most favoured nation and of the national treatment). The TBT Agreement also recommends the use of international standards in order to ensure the harmonisation of national regulations.

The identification requirements of the Cartagena Protocol are measures that could be analysed under this agreement.

UNCTAD **United Nations Conference on Trade and the Environment** established in 1964 as a permanent

intergovernmental body, UNCTAD is the principal organ of the United Nations General Assembly in the field of trade and development.

UNEP **United Nations Environment Programme**, a body of the United Nations created in 1972 to promote environmental concerns within the United Nations.

USA **United States of America**

WHO **World Health Organization**, an international organization established in 1948 with the goal of improving human health. WHO assists countries in strengthening their health services, provides technical assistance in health emergencies, promotes disease prevention and control, and promulgates international food safety and medical standards. Currently has 191 member countries.

WTO The World Trade Organisation (WTO) is the primary international institution responsible for establishing rules for trade of goods, services and property rights. Its main function is to serve as framework for:

- Permanent trade negotiations
- Trade policies examinations
- Administrate dispute settlement between Members of the organisation.

In order to promote international competition the WTO oversees that trade barriers are the lowest possible in order to reach their objective and that they do not introduce discrimination between national and foreign producers. To this end, the legal structure of the WTO is articulated around the non-discrimination principle that consists of two components:

- The principle of the most-favoured-nation indicates that a WTO Member shall offer the same treatment to all similar products, whatever may be their origin, hence it shall not discriminate between its trading partners. This implies the automatic extension to all contracting parties of an advantage consented to one of them.
- The National Treatment rule stipulates that a WTO Member shall accord to the imported goods a treatment that is not less favourable than the one accorded to similar national goods.

Following these articles, WTO Members are obliged to grant the same treatment to equivalent goods of national and foreign origin. This applies also to traded LMOs, therefore national biosafety regulations shall prevent any discrimination.

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