INTERNATIONAL SAFETY REGULATIONS ON LIVING MODIFIED ORGANISMS : TRADE AND NON-TRADE INTERESTS IN HARMONY OR CONFLICT?

BIRHANU Fikremarkos*

Abstract

Despite the fact that biotechnology has already become a key technology of the 21st century, the global debate over its benefits and risks remains unsettled. On the one hand, there appears to be a general consensus on the potential benefit of biotechnology in general and genetic engineering in particular. On the other hand, concerns are still abound on its potential impacts on human health and the environment. With such a scenario, states have no option but to regulate the safety of the technology both at the national and international level with a view to minimize the potential risks. The increasing trend of the commercialization of genetically engineered organisms and their consequent potential for transboudary movement have made the issue of safety no longer a national agenda and have given impetus to states to look for a multilateral setting on safety issues. The Cartagena Protocol is the first and the only international agreement governing the transboundary movement of genetically engineered organisms. The Protocol lays down different conditions and procedures on the transboundary movement of genetically engineered organisms. The Protocol, being basically an environmental agreement, its relation to and impact on international trade has remained unclear and at times controversial.

Keywords : Biosafety, Cartagena Biosafety Protocol, Convention on Biological Diversity, living modified organism, precautionary principle, risk assessment.

* Doctoral Candidate, School of International Public Policy (OSIPP), Osaka University.
E-mail: f-birhnu@osipp.osaka-u.ac.jp.

1. Introduction

As the global debate on the introduction of living modified organisms[1] (LMOs) continues unabated, sates are increasingly becoming concerned with the potential risks of such organisms on human health and the environment. The concern has further been exacerbated by the increasing trend in the commercialization of LMOs.[2] As a result, the need for regulation of LMOs has recently become high in the agenda of states. A number of countries have already put in place the necessary regulatory framework on LMOs while others are in the process of doing so.

With the expansion of LMOs growing and commercialization, the possibility of their transboundary movement is also increasing and regulation of LMOs is no longer only a national agenda. The aggressive commercialization of LMOs has made it difficult to deal with their safety solely on national regulatory regimes and has necessitated the need for an international biosafety regime.

The Cartagena Protocol on Biosafety (the Cartagena Protocol or the Protocol) was negotiated and adopted to serve as an international regulatory regime on the transboundary movement of LMOs. The Protocol is the only international agreement that specifically deals with cross-boundary transactions involving LMOs. The Protocol being an agreement with an immense implication on international trade involving LMOs, its relation with and impact on the agreements of the World Trade Organization (WTO) remains controversial.

This article attempts to evaluate the relationship between the Protocol and the relevant WTO Agreements and determine whether the agreements are in conflict

1) Different terminologies are used to refer to the organisms such as, genetically modified organisms (GMOs), or genetically engineered organisms (GEOs). While GMO is the most frequently used term, the Cartagena Biosafety Protocol (discussed below at section 2) employs the term LMO. This later term is used in this paper. Even if the drafting history of the Cartagena Biosafety Protocol shows that the term living modified organism was used because of lack of consensus to use the term GMO, the practical difference among the terminologies does not seem to be clear. See in general, A Gupta, "Creating a Global Biosafety Regime" 2 International Journal of Biotechnology (2000).

2) In 2002 GM crops covered 58 million hectares worldwide and several countries are now commercially growing GM crops. By producing 105 acres in 2003-which is about two-third of the total world LMO production-the US remains by far the largest producer of LMOs. Argentina, which produces 85 per cent of all the LMO produced by developing countries in 2003 stands as the second largest producer followed by Canada. For details, see James, C. "Status of commercialized transgenic crops: 2002" *ISAAA Briefs* No. 27, and "Genetically Modified Crops in the United States", *Pew Initiative on Food and Biotechnology* (2004), available at http://www.pewagbiotech.org/resources/factsheet.htm.

or harmony. In doing so, the article will first present a general background to the Protocol and analyze its relationship with the different WTO agreements which are thought to be related with the issue of LMOs. That will be followed by a determination of whether there is a conflict between the two regimes and analysis of different approaches to resolve potential conflicts under different scenarios.

2. The Cartagena Protocol on Biosafety

The parent international instrument for the Cartagena Biosafety Protocol is the Convention on Biological Diversity (CBD) which came to force in 1992. As the name implies, the CBD is concerned with biodiversity. The CBD has three main objectives: the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilization of genetic resources.[3] Articles 16 and 19 recognize the positive role of biotechnology in the fulfillment of the objectives of the CBD, and in particular, Article 16 states that access to and transfer of biotechnology is essential elements for the attainment of the objective of the CBD. Three provisions of the CBD have direct relevance to LMOs. First, Article 19(3) envisages the need for a protocol on biosafety for LMOs. Second, Article 8(g), which deals with national measures, obliges parties to the CBD to regulate, manage and control the risk associated with LMOs resulting from biotechnology which are likely to have impacts on the conservation and sustainable use of biodiversity. The third Article, Article 19(4), requires each member to share information on domestic regulations concerning use and safety of LMOs with any other member.

2.1 Background to the drafting process of the Cartagena Protocol

The Second Conference of the Parties to the CBD[4], which was held in 1995, agreed on the need for a biosafety protocol as envisaged under Article 19 (3) of the Convention and to that end designated an Ad-Hoc Working Group to draft and

3) Article 1 of the CBD.

4) According to Article 23, the Conference of the Parties to the CBD is the highest decision making body which meets at regular intervals determined by the Conference itself to review different issues specifically entrusted to it under Article 23.

negotiate the protocol.[5] The Protocol was then drafted and tabled for negotiation, but the task did not turn out to be easy and negotiating parties were not able to come to consensus on several issues. The Protocol was expected to be adopted during the 1999 Extraordinary Meeting of the Conference of the Parties to the CBD, held in Cartagena, Columbia, but the deep division among members on several issues remained unresolved and the adoption of the protocol had to wait for almost a year when a compromised agreement was reached and the Protocol was adopted on January 29, 2000 in Montreal, Canada, by representatives of 133 countries.[6] The most important issues of friction among the different groups during the negotiation were the scope of the Protocol, the relationship between the Protocol and other international agreements (especially WTO) and issues related to liability and redress in cases where LMOs cause damage.[7] While parties reached a compromised solution on the first two issues albeit with a lot of ambiguity and confusion, the third issue was left for the Conference of the Parties to "adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movement of living modified organisms..."[8]

The objective of the protocol is stated as follows:

> In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that have adverse effects on conservation and sustainable use of biological diversity, taking also in to account risks to human health, and especially focusing on transboundary movements.[9]

5) Second Conference of the Parties to the Convention on Biological Diversity, DecisionII/5, UNEP/CBD/COP/2/19 (Nov.1995).

6) W Schweizer, "The Negotiation of the Cartagena Protocol on Biosafety", 6 *Environment Law Journal* (2000). Three groups emerged during the negotiation: the Miami Group (which includes those countries that have vested interest in trade in LMOs: Argentina, Australia, Canada, Chile, Uruguay and the United States); the like-minded group (which includes the majority of developing countries and China) and the European Union Countries.

7) As above. See also PE Hagen and JH Bellow, "The Cartagena Protocol on Biosafety: New rules for international trade in LMOs", 12 *Georgia International Law Review* (2000).

8) Cartagena Protocol Article 27.

9) Cartagena Protocol Article 1.

The Protocol came in to force on 11 September 2003 and now membership stands at 110.[10]

2.2 Scope of the Cartagena Protocol

The Cartagena Protocol applies to "the trans-boundary movement, transit, handling and use of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking in to account also risks to human health."[11]

The general description of the scope of the Protocol could trigger different questions and queries:

First, the scope of the Protocol is limited only to living modified organisms which are defined by the Protocol itself as "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids."[12] This means that products of LMOs such as food, oil and clothing are excluded from the scope of cover of the Protocol. Given the fact that LMO products constitute most of the trade transactions, their exclusion from the Protocol could substantially reduce the possible dispute over trade in LMOs. Yet, one may wonder why LMO products or commodities are excluded from the Protocol. The issue has to be viewed in light of the objectives of the CBD in general and that of the Protocol in particular. As stated above, the objective of the CBD and the Protocol is the conservation and sustainable use of biodiversity and to that extent, it could be said that LMO products are 'dead' and no longer "biological entity capable of transferring or replicating genetic material", and consequently pose no treat to the conservation and sustainable use of biodiversity. Their regulation is left for national legislation and other international agreements.

Second, Article 4, defining the scope of the Protocol states that the scope of application of the Protocol is the transboundary movement of LMOs which may have adverse effects on the conservation and sustainable use of biological diversity, "taking also in to account risks to human health". The plain reading of the phrase "taking also in to account risks to human health" appears to be ambiguous. Why

10) Information available at http://www.biodiv.org/world/parties.asp (accessed on 25 Nov. 2004).
11) Article 4.
12) Article 3(h).

should a Protocol on conservation and sustainable use of biological diversity take also in to account human health? What is the relationship between biodiversity conservation and human health? The question may become even more puzzling in view of the fact that Article 19(3) of the CBD which envisages the possibility of negotiating the biosafety protocol makes no mention of risks to human health, which may in turn, raises a question on the mandate of the Protocol.[13] Nevertheless, Article 8(g) of the CBD obliges Members to regulate, manage or control the risk associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse environmental impacts. Hence, the possible challenge on the mandate of the Protocol as per Article 19(3) could arguably be countered by the provisions of Article 8(g).

Different interpretations could be given to the phrase "taking also in to account risks to human health." One may argue that the plain reading of Article 4 makes human health risks an independent consideration under the Protocol in addition to conservation and sustainable use of biodiversity. This argument could be defended on the rule of interpretation of legal texts which states that no interpretation should be made when the text is clear. Nevertheless, whether the phrase is clear from the full reading of Article 4 is arguable, and even if it were clear, its compatibility with the issue of conservation and sustainable use of biodiversity would be questionable. Rather, the phrase "taking also in to account risks to human health" should be considered in light of the scope and general objective of the Protocol rather than on the basis of the mere phraseology under Article 4. It is true that human health risks should be regulated, but the issue is whether such risks should be regulated by an agreement dealing with conservation and sustainable use of biodiversity. It does not seem that the Cartagena Protocol is the appropriate regulatory platform for human health concerns as such. For example, it would obviously be out of scope if the Protocol were intended to include human health risks arising from consumption of LMO food. The Protocol is a biodiversity protocol and not a food safety regulation. Human health issues arising from the consumption of LMOs should be taken care of by other regulations at the national

13) Article 19(3) reads: "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".

and international levels.

Yet, one has to give a meaning to the phrase "taking in also in to account human health risks." It could be argued, in light of the objective of the Protocol, that human health risks should be considered only in relation to the environment, i.e., human health risks which are incidental to or arise from the release of the LMO to the environment and not from mere consumption of the LMO. There could be situations where human health risks would result from direct biodiversity impact. For example, there could be human health risks from direct contact with LMOs such as allergenic reactions. Such kinds of risks are the result of direct contact with the LMO released to the environment and not from consumption of the products as such and they could still be covered under the Cartagena Protocol. This interpretation seems to be more pertinent within the context of the objectives and scope of the Protocol and the CBD as well.

LMO pharmaceuticals are excluded from the application of the Protocol but only under specific conditions.[14] Thus, to what extent pharmaceuticals are excluded from the Protocol is far from clear. In the first place, pharmaceuticals containing the organisms in living form appear to be uncommon; in most cases, they are processed from the LMOs in which case they are automatically excluded from the application of this Protocol by virtue of Article 4 which states that the Protocol applies only to living modified organisms. This means that, Article 5 applies to those pharmaceuticals which are released in to the environment in living forms, if at all there are any such kinds of pharmaceuticals. Still, the exclusion of pharmaceuticals under Article 5 applies only to those pharmaceuticals which are for humans and not addressed by other international agreements, and even then, the exclusion is not mandatory since a party has always the right to subject all living modified organisms to risk assessment prior to decision on imports under Article 4.

14) Article 5 reads as follows: "Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on imports, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations".

2.3 Key features of the Cartagena Protocol

2.3.1 Advanced Informed Agreement (AIA) procedure

The AIA procedure seems to be at the heart of the Cartagena Protocol. How does the AIA operate? First the party of export is obliged to notify or insure notification in writing to the party of import about its intention to export a particular LMO, before the first intentional import of any given type of LMO.[15] The party of import will then have 90 days to acknowledge receipt of the notification, and advise that it intends to proceed with the Protocol's decision procedure, or according to its domestic regulatory framework.[16] Before the party of import makes a decision, a risk assessment must be carried out and the party of import should inform the notifier that either it will have to wait for written consent or it may proceed with the import with out a written consent.[17] If the exporter has to wait for written consent, the party of import should decide within 270 days on the fate of the application.[18] The decision could be approval of the import with or with out condition, prohibition of the import, requesting additional information, or extending the deadline for response by a definite period.[19] All decisions are to be relayed on the Internet-Based Biosafety Clearing-House which is established by the Protocol.[20] Some LMOs are not subject to the AIA procedure: LMOs in transit to a third party[21], LMOs destined for contained use[22], LMOs for food and feed and processing[23], and those declared safe by a meeting of the Parties.[24] It has to be noted that such LMOs should still be living (such as LMO tomato, soya and cotton) so that they will fall be within the scope of the Protocol since the processed foods and feed are already excluded from the application of the

15) Article 8(1) Cartagena Protocol. The fact that the AIA procedure applies only for the first international import LMO could be one concession given to those LMO exporting countries that have been arguing that the procedure is cumbersome. The exporter's obligation under the AIA procedure is a one-time obligation which need not be done for subsequent shipments of same LMO.
16) Article 9(1).
17) As above.
18) Article 10(3).
19) As above.
20) As above.
21) Article 6(1).
22) Article 6(2). The term "contained use" is defined in the Protocol as "any operation undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment".
23) Article 7(2).
24) Article 7(4).

Protocol.

Yet, even if LMOs for food, feed and processing are not subject to the AIA Procedure, they are still governed by a different set of rules under the Protocol itself.[25] So, what we see in the Protocol is that there are two distinct regimes, one for LMOs to be directly released in to the environment and another for LMOs for food, feed and processing.

For LMOs released into the environment in living form, the full AIA process applies. As described above, the AIA places the burden on the exporting party or on the actual exporter to notify the country of import, prior to any shipment, the intention to export LMOs, and to receive their consent accordingly.[26] For LMOs used as food, feed or for processing, the burden lies on a Party to put in place a domestic regime applicable to any use of LMOs, and inform the other Parties that this regime will also be applicable to imported LMO products like food and feed.[27] While LMOs are governed by the provisions of Article 7-10 the LMO products like food and feed are governed by those of Article 11. The difference is that the initial responsibility of notification of exporting LMOs falls on the exporter while it is the responsibility of the importing country to take prior action and notify to other parties its domestic regulation for food, feed and processing products. Once this latter responsibility is met, however, importing states can control imported LMO for food, feed and processing just like LMOs themselves.[28] Hence, the decision making procedure under Article 11, while allowing faster transaction still gives much power to the importing country to control the import of LMOs for food, feed or processing.

2.3.2 The precautionary principle

Precautionary principle has been a subject of immense controversy.[29] It is

25) Article 11 Cartagena Protocol.

26) Articles 7-10 Cartagena Protocol.

27) Article 11.

28) The fact that LMOs for food, feed and processing are excluded from the AIA procedure is a compromise between the LMO exporting countries which insisted on the exclusion of such LMOs from the Protocol as being not a threat to the environment and the majority of developing countries which argued for their inclusion in to the full AIA procedure. The reason for the developing countries to take their position was that even grains imported as foodstuff are often used as seeds by farmers, especially in a crisis situation and hence could pose threat to biodiversity. See F Pyhthoud and U.P. Thomas, "The Cartagena Protocol on Biosafety" in P.G. Le Prestre (ed.), *Governing Global Biodiversity* (2002)45.

29) For a detail discussions on the precautionary principle see, T. O'Riordan and J Cameron (eds.), *Interpreting the Precautionary Principle* (1994); P. Sands, *Principles of International Environmental Law*, Vol I (1995) and D. Freestone and E. Hey (eds.), *The precautionary Principle in international Law*, Kluwer, (1996).

basically an environmental law principle which is said to have been designed to protect the environment from irreversible damage. Environmental damages could be irreversible or even if they are reversible, they could be extremely expensive to repair. Hence, prevention of environmental harm has always been considered the best option. Environmental harm prevention is unarguable when there is clear scientific evidence about the harm. However, the precautionary principle goes further and provides that environmental harm prevention and protection measures should not be deterred by lack of scientific evidence about the harm. The principle was clearly articulated in the 1992 Rio Declaration, adopted by the United Nations Conference on Environment and development (the Rio Declaration). Principle 15 of the Rio Declaration provides:

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

Thus, the precautionary principle enables states to take preventive measures in the area of environment even in situations where there are scientific uncertainties about the harm. The principle gives states some discretion to evaluate the potential risks, even in cases of scientific uncertainty about the risk, weigh the potential harm and take the appropriate measure. The issue is not whether the risk will certainly materialize or not, it is rather the impact of the risk in case it materializes. Given the fact that environmental harm is irreversible and consequences are immense, the principle sounds convincing, at least in theory. The problem is in the practical applicability of the principle. There are opinions against this principle which, *inter alia*, include that the principle is against science and that it could be taken as disguised protectionism in trade. In the case of LMOs, the possible explanation of the precautionary principle is the absence of scientific certainty and consensus as to their potential risks on the environment and human health.

A number of provisions in the Cartagena Protocol incorporate or indicate the precautionary principle. It is in fact natural for the Protocol to incorporate the precautionary principle since, it is also reflected in its parent legislation, the

CBD.[30] The preamble and Article 1 of the Protocol simply refer to the precautionary principle as enshrined in Principle 15 of the Rio Declaration. Nonetheless, the precautionary principle as stated in the preamble is just a declaration of intention of the Parties whereas its mention under Article 1 is general which is stated in the context of the objective of the Protocol. This means that, the precautionary principle as incorporated in the preamble and Article 1 is not operational and enforceable. Yet, the Protocol also includes provisions on the precautionary principle in its operational part as well. For example, Articles 10(6) and 11(8) clearly state that lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of LMOs shall not prevent a party of import from taking a decision, as appropriate, with regard to the import of the LMO in question. The two articles clearly allow the party of import to take measures on LMOs on the basis of the precautionary principle.[31]

2.3.3 Risk assessment and risk management

The Protocol obliges parties to carry out risk assessment before making a decision on the request to export LMOs.[32] The risk assessment should be carried out in a scientifically sound manner, and in accordance with Annex III of the Protocol, taking into account recognized risk assessment techniques.[33]

The Protocol also puts obligation on the Parties on risk management. Accordingly, parties should establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol.[34] In relation to this each Party should endeavor to ensure that any LMO, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.[35] On the other hand, the Protocol states that such risk management measures should be imposed only to the extent necessary to prevent adverse effects of LMOs on the conservation

30) The precautionary principle is reflected in the preamble of the CBD.
31) It s to be noted that the Articles 10(6) and 11(8), and any other article of the Protocol, for that matter, except the inoperable preambular provision and Article 1,never use the phrase 'precautionary principle'.
32) Articles 10(1) and 15 Cartagena Protocol.
33) Article 15.1 Cartagena Protocol.
34) Article 16(1).
35) Article 16(4).

and sustainable use of biological diversity, taking also into account risks to human health.[36]

3. WTO Agreements and LMOs

Trade-related measures related to LMOs could fall under three WTO agreements-the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT) and the General Agreement on Tariffs and Trade (GATT).

3.1 The SPS Agreement

The SPS Agreement regulates sanitary and phytosanitary (SPS) measures which Members may take in order to protect the life and health of human beings, animals and plants from pests and diseases, disease- causing organisms, toxins, additives and contaminants.[37] The Agreement defines SPS measures as those measures applied to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms; to protect human or animal life or health within the territory of the member from risks arising from additives contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; and to protect human life or health within the territory of the member from risks arising from disease carried by animals, plants or products thereof or from the entry, establishment or spread of pets.[38]

The SPS measures are to be taken on the basis of scientific principles and should be supported by scientific evidence.[39] Such measures should not discriminate among members and should not be used as a disguised barrier to trade.[40] Members are also required to base their SPS measures on international standards, guidelines or recommendations where they exist.[41] To that end, the Agreement refers to three

36) Article 16(2).
37) See Article 2 of the SPS agreement on the general rights and obligations of Members.
38) Annex 1 SPS Agreement.
39) Article 2.2 SPS Agreement.
40) Article 2.3.
41) Article 3.

international organizations as standard-setting institutions: the Codex Alimentarius Commission in relation to food safety standards; the international Office of Epizootics in relation to animal health and zoonoses; and the Secretariat of the International Plant Protection Convention in relation to plant health.[42]. However, Members are also allowed under certain circumstances to adopt higher standards than those set by the international organizations.[43] SPS measures should be taken after a risk assessment which should take in to account, *inter alia* , the available scientific evidence, relevant processes and production methods, relevant inspection, sampling and testing methods.[44]

Once the risk is assessed, the measures to be taken are generally left for the Member, but the latter is required to minimize the negative effects of the measures on trade and must ensure that the measure are not more trade-restrictive than required to achieve the desired level of SPS protection.[45]

3.2 The Agreement on Technical Barrier to Trade (the TBT Agreement)

The TBT Agreement regulates measures affecting trade which are technical and industrial standards, and that do not fall under the SPS Agreement, i.e. measures which are not sanitary or phytosanitary.[46] The TBT Agreement allows Members to formulate national regulations, which should not be more trade-restrictive than necessary, to fulfill a legitimate objective.[47] Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices and protection of human health or safety, animal or plant life or health, or the environment.

While recognizing the right of Members to adopt the standards they consider appropriate, the TBT Agreement tries to ensure that the regulations, standards, testing and certification procedures (which vary from country to country) do not create unnecessary obstacles.[48] Accordingly, Members should ensure that their

42) Annex A.
43) Provided they are based on scientific justification or are made in accordance with the other requirements of Article 3.3, the SPS Agreement.
44) Article 5.2.
45) Article 5.4 and 5.6.
46) See Articles 2.2 and 1.5 of the TBT Agreement.
47) Article 2 of the TBT Agreement.
48) Article 2.2 the TBT Agreement.

technical regulations do not discriminate products from different countries (MFN principle) and between domestic and imported products (national treatment).[49] TBT measures should not also create unnecessary barriers to trade and hence they should not be more trade-restrictive than necessary for a legitimate objective.[50] In assessing the risk, Members should consider the available scientific and technical information, related processing technology or intended end-uses of products.[51] The TBT Agreement also requires Members to apply their technical regulations based on available and relevant standards formulated by an international body unless those standards would be ineffective or inappropriate to fulfill the legitimate objective the parties want to pursue.[52]

3.3 GATT

The core principles under the GATT are the Most Favored Nation (MFN) and the National Treatment. GATT obliges Members not to discriminate between "like products" imported from different Members but give them equal treatment.[53] Similarly, Members are required not to discriminate between domestic and imported products.[54] The two principles are meant to prohibit discrimination in international trade so that the trade will be 'free' and 'fair'. But the GATT prohibits discrimination between "like products" and hence determination of what products are like is fundamental for the application of the core principles of the GATT. Even if the GATT does not clearly define what products are to be considered like, the jurisprudence of the WTO dispute settlement body, which has addressed the issue in several cases, provides some clue. An often-quoted case that provides a general guideline on the issue is the *European Communities Measures Affecting Asbestos and Asbestos-Containing Products* where the Appellate Body stated that whether two products are alike should be determined on a case-by-case basis and provided some criteria to help determine whether products are like: the physical properties of the products, the extent to which the products re capable of serving the same or similar end-uses, the extent to which consumers perceive and

49) Article 2 TBT Agreement.
50) Article 2.2.
51) As above.
52) Article 2.4.
53) Article I GATT.
54) Article III.

treat the product as alternative means of performing particular functions in order to satisfy a particular want or demand, and the international classification of products for tariff purposes.[55] These are possible considerations and it seems that the list is not an exhaustive and the requirements are not cumulative. The issue should still be considered on a case-by-case basis as determined by the Appellate Body.

GATT provides exceptional situations where Members could derogate from the application of the MFN and the national treatment principles. According to Article XX, Members could take necessary measures to protect human, animal or pant life or health or for the conservation of exhaustible natural resources with out the need to be bound by the MFN and national treatment principles. But such measures should not be applied as means of arbitrary or unjustifiable discrimination between countries or as a disguised restriction on international trade.[56]

3.4 Determining the WTO agreement applicable to LMOs

Authorities differ on the issue as to which WTO agreement applies to measures taken on LMOs under the Cartagena Protocol. For example Cors[57] argues that the SPS Agreement is the pertinent Agreement that should be applicable, whereas Torres[58] alleges that TBT or the GATT is applicable in relation to trade on LMOs. The issue should be determined in light of the objective and purpose of the measures taken in accordance with the Cartagena Protocol. As discussed earlier, measures taken under the Protocol are related to biodiversity conservation and its sustainable use, taking also in to account human health risks. On the other hand, SPS measures are to be taken to protect the life or health of human beings, animals or plants. Could it be said that the protection of human, animal or plant life or health under the SPS Agreement is directly related to conservation of biological diversity? Some commentators answer the question in the negative:

55) WTO Appellate Body Report On European Communities Measures Affecting Asbestos and Asbestos-containing Products, WT/DS135/AB/R (March 12, 2001).
56) Article XX GATT.
57) TA Cors, "Biosafety and international trade: conflict or convergence", 2 *Journal of Biotechnology* (2000).
58) OR Torres, *The Biosafety Protocol and the WTO* (2002).

> Biodiversity is a distinct environmental concern that transcends typical sanitary and phytosanitary concerns. According to the definition of biodiversity in the CBD, this term focuses on the diversity among genes, the diversity among and within species, and the diversity among and within ecosystems. This last concept of ecosystem biodiversity is not solely centered around the extinction of one genetically unique organism, but around the effects that extinction of an organism can have on the remaining environment. Thus the question of whether a ban undertaken by a party to the Protocol with the objective of conserving biodiversity should be considered as SPS measure must be addressed seriously.[59]

The argument seems to make a kind of not-easy-to-comprehend distinction between biodiversity and its constituent parts and suggests that the protection of the latter may not necessarily be protection of the former. Yet, it is the animals and plants that constitute the biodiversity and to that extent protecting those living things has a direct impact on the conservation of biodiversity. In other words, protecting plant and animal life/ health by SPS measures is at the same time protecting biodiversity. Treating biodiversity as something independently existing from its component parts appears to be at best unwarranted abstraction of the issue. Hence, one could counter the above argument and say that SPS measures are directly relevant to biodiversity conservation and the SPS Agreement could be the appropriate agreement applicable to measures taken in relation to LMOs under the Protocol. Concerning human health risks, their inclusion in the SPS Agreement is clear in cases where such risks are taken as an independent consideration under the Protocol different from biodiversity, and the above argument would apply to them when their inclusion in the Protocol is considered within the broader biodiversity conservation objective.

Once it is established that measures taken under the Protocol could be taken as SPS measures, then the possibility of applicability of the TBT Agreement will automatically be ruled out by virtue of Article 1.5 of the Agreement which

59) Torres (above) 18.

specifically states that measures covered by SPS Agreement are excluded from the TBT Agreement. As stated earlier, the GATT also allows parties to take measures which are considered legitimate with a view to protect human, animal or plant life or health or in relation to conservation of exhaustible natural measures (Article XX GATT). It seems that under certain circumstances measures taken against LMOs in accordance with the Protocol could fall under Article XX of the GATT. In such cases, the *lex specialis* rule could apply and the SPS Agreement, being a special Agreement within the GATT, prevails over the general GATT rules.

4. WTO rules and the Cartagena Protocol in conflict or harmony?

In order to determine whether or not the WTO rules and the Cartagena Protocol are in conflict, it must first be established that there is a common area of operation for the two agreements. In the absence of a common area of application, a conflict would not arise and this makes any discussion on interpretation superfluous.

The Cartagena Protocol is basically an environmental agreement where as WTO is a trade agreement. Yet, this does not automatically mean that the two agreements have no common area of application. Though with the objective of conservation and sustainable use of biodiversity, the Protocol deals with international transactions involving LMOs- an area of international trade. Hence, it is clear that the two agreements have a common area of operation/application. Once it is established that there is a common area of application between the two agreements, the next issue to be analyzed is where there could be a potential conflict between the two agreements.

As discussed above, SPS measures should be taken based on scientific principles and be supported by scientific evidence. A risk assessment has to first be carried out before SPS measures are taken. According to Annex A of the SPS Agreement, risk assessment is to be carried out with a view to:

1. evaluate the likelihood of entry, establishment, or spread of a pest or disease within the territory of an importing member according to the sanitary and phytosanitary measures which might be

applied, and of the associated potential biological and economic consequences; or

2. evaluate the potential for adverse effects on human or animal health arising from the presence of additives, contaminates, toxins or disease-causing organism in food, feedstuffs and beverages.

Similarly, the decision on importation of LMOs under the Protocol should be made on the basis of a risk assessment carried out in a scientifically sound manner.[60] Annex III of the Protocol also provides the detail risk assessment procedure and affirms that the risk assessment should be made in a scientifically sound and transparent manner. The objective of the risk assessment as stated in Annex III of the Protocol is to "identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also in to account risks to human health". As sated earlier, protection of plant and animal life and health is directly related to protection of the biodiversity or the environment since the plants and animals are the components of the biodiversity or environment. Thus, in principle there appears no conflict between the SPS agreement and the Protocol on the objective of the risk assessment and the way it has to be undertaken.

Still, the SPS Agreement requires that the SPS measures which have to be taken after a risk assessment should take in to account the objective of minimizing negative effects on trade and should not be more trade-restrictive than required to achieve the intended purpose of SPS protection.[61] Similarly, the Protocol requires that the measure to be applied on LMOs should be based on a risk assessment and should be applied to the extent necessary to prevent adverse effects on biological diversity.[62] This suggests that the Party to the Protocol should apply less restrictive measures when they are available and are sufficient to achieve the purpose sought to be achieved. Hence, in this regard, too, there appears no apparent conflict between the two agreements.

60) Articles 10(1) and 15(1), Cartagena Protocol.
61) Article 5.4 and 5.6 SPS Agreement.
62) Article 16(2) Cartagena Protocol.

While the principle under the Protocol is that measure against LMOs should be taken on the basis of a scientifically sound risk assessment, it is also stated that lack of scientific evidence should not deter a party from taking measures as appropriate (the precautionary principle). Article 10(6) reads:

> 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... shall not prevent a party from taking a decision as appropriate....

The precautionary principle is in the same way incorporated under Article 11(8) of the Protocol in relation to LMOs for direct food, feed or processing. Further more, the precautionary principle is mentioned in Annex III of the Protocol as one important principle of risk assessment. Indeed, the fact that precautionary principle is mentioned in the preamble and article 1(objective) shows the weight the parties have given to the principle and suggests that it is a fundamental principle under the Protocol.

Precautionary principle is also recognized under the SPS Agreement, albeit as an exception. Article 5.7 states:

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary and phytosanitary measures on the basis of available pertinent information, including that from relevant international organizations as well as from sanitary and phytosanitary measures applied by other members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measures accordingly within a reasonable period of time.

The WTO Appellate Body also affirmed that the precautionary principle is recognized under Article 5.7 of the SPS Agreement but it also emphasized that the

principle as stated under article 5.7 cannot override the provisions of article 5.1 and 5.2.[63] Article 5.1 and 5.2 state that SPS measures should be taken on the basis of a risk assessment carried out in accordance with scientific principles and scientific evidences. In this context the Appellate Body seems to recognize that a member country may invoke the precautionary principle when determining its level of protection, as long as long as a risk has been identified pursuant to article 5.1 and 5.2.[64] Thus, what we see is that the precautionary principle as stated under article 5.7 of the SPS Agreement and as interpreted by the WTO Appellate Body does not apply to risk assessment but only to determine the level of SPS measures once the risk is identified pursuant to a scientific based risk assessment. This appears to be one possible area of conflict between the SPS Agreement and the Cartagena Protocol. As far as the latter is concerned, precautionary principle is applicable not only merely to determine the extent of measures to be taken against LMOs but also as one basic principle of risk assessment. The Protocol clearly states that "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk". It is fairly clear that the precautionary principle in the Protocol applies in the process of risk assessment whereas it is applied in the SPS Agreement only to determine the measures to be taken after a risk has been identified. Hence, there appears an apparent conflict in the two agreements on the application of the precautionary principle.

Further, SPS measures could only be taken provisionally in accordance with the precautionary principle, and a member that has taken such measures is obliged to seek to obtain additional information necessary for a more objective assessment of the risk and review the measures accordingly within a reasonable period of time. While review of decisions is a possibility under Article 12 of the Protocol, such a review is not mandatory for the party that took the measures and in any event such a Party is not bound to change the decision based on the new scientific information.

63) WTO Appellate Body Report on European Community Measures Concerning Meat and Meat Products, WT/DS26/AB/R (Jan.16, 1998).
64) Torres (note 55 above) 15.

Once it is shown that there could be a conflict between the SPS Agreement and the Cartagena Protocol, the next issue is as to how to resolve these potential conflicts.

On the relationship between trade and environment on the one hand and the Protocol and other agreements on the other, the pertinent part of the preamble of the Protocol states as follows:

> Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,
>
> Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a party under any existing international agreements,
>
> Understanding that the above recital is not intended to subordinate this Protocol to other international agreements...

The preambular paragraphs, confusing as they are, seem to create more problem than they solve on the relationship between the Protocol and other agreements like the WTO. While the second paragraph states that the Protocol should not bring about a change in other obligations of parties in other international agreements including the WTO, the third paragraph asserts that the Protocol is not subordinate to any international agreement, including WTO. Read together, the two preambular paragraphs seem to suggest that there should be no hierarchy between the Protocol and other international agreements including WTO. This makes the matter more complicated since in case of conflict between the Protocol and the WTO Agreements, one should necessarily prevail over the other, provided, of course that there will be no possibility of applying the two agreements in a harmonious manner as stated in the first paragraph of the preamble.

Despite the above complication, the main issue remains as to how to resolve possible conflicts between the Protocol and the WTO Agreements. For example, if a country bans a particular LMO on the basis of the Protocol and such measure is challenged as contrary to WTO rules, how should the issue be resolved? This issue should be addressed in two different scenarios: when a dispute arises in the

WTO between a party and non-party to the Protocol, and between parties to the Protocol and the WTO.

4.1 Dispute in the WTO between a party and non-party to the Cartagena Protocol

Article 24(1) of the Protocol provides that "Transboundary movements of living modified organisms between parties and non-parties should be consistent with the objective of this Protocol". The Article further allows parties to enter in to bilateral, regional and multilateral agreements and arrangements with non-parties regarding such transboundary movements. If such bilateral, regional or multilateral agreements exist, then the possibility of conflict being addressed by the WTO will be unlikely. Yet, in the absence of such agreements or arrangements, the party to the Protocol would require the non-party to comply with the procedures in the Protocol for exporting LMOs in the territory of the party, or the party to the Protocol could ban importation of a particular LMO pursuant to the provisions of the Protocol, and this could trigger complaint under WTO rules.

In such circumstances, the Vienna Convention on the Law of Treaties[65] could be of help. According to the Vienna Convention, when there is a dispute concerning two treaties on the same subject matter between a state that is a party to both and a state that is a party to one, the treaty to which both states are parties governs their mutual rights and obligations.[66] In cases concerning measures on LMOs, the SPS Agreement will determine a dispute where both states are members of the WTO but only one is a party to the Cartagena Protocol. In relation to the precautionary principle, the implication of this interpretation is that the principle will be applicable in relation to determination of the level of measure to be taken and not for risk assessment as is enshrined in the SPS Agreement and interpreted by the WTO Appellate Body.

4.2 Conflict between parties to both agreements

In cases where a dispute arises between members of both agreements, two principles could apply, at least. The first is the one provided in the Vienna

65) Vienna Convention on the Law of Treaties, May 23, 1969, UN Doc.A/Conf.39/27 (1969).
66) Article 30(4)(b), Vienna Convention on the Law Of Treaties.

Convention and which states that the later treaty in time will prevail over the former.[67] The SPS Agreement came to force in 1994 while the Cartagena protocol in 2003, which means that the latter will prevail over the former in relation to trade in LMOs.

The other possibility is the *lex specialis* principle according to which when two agreements deal with the same issue, the more specific or special agreement will prevail (lex *specialis derogate generalis*). This principle, hence, calls for determination of which agreement is more specific than the other, in our case, the SPS or the Cartagena Protocol. In relation to LMOs, it appears that the Cartagena Protocol is the one that specifically deal with them and hence it can be argued that the Protocol should prevail over the SPS Agreement.

5. Conclusion

As the commercialization and transboundary movement of LMOs increase the need for regulation appears to be crucial. The Cartagena Protocol is the result of the need for harmonization of regulations on LMOs. It is an important development at the international level concerning the safe use of LMOs. The Protocol's relation with WTO rules has yet to be settled but there are several cases where the provisions of the Protocol could be used without violating the WTO rules. Whether the WTO dispute settlement body will recognize the Protocol as a standard in relation to trade on LMOs or will discard it as inconsistent with the WTO agreements is yet to be seen.

67) Article 30(4)(a) and article 59.