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Sixth meeting

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Item 10.2 of the provisional agenda\*

### **REPORT ON ANALYSIS OF INFORMATION ON STANDARDS RELEVANT TO THE HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS**

*Note by the Executive Secretary*

1. At their fifth meeting, the Parties requested, in paragraph 1(d) of decision BS-V/9, the Executive Secretary to commission a study to analyse information on existing standards, methods and guidance relevant to the handling, transport, packaging and identification of living modified organisms and to make the study available for consideration by the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. The decision specifies that the study should address in particular:

- (a) Possible gaps in existing standards, guidance and methods;
- (b) Ways to facilitate cooperation with relevant organisations;
- (c) Guidance on the use of existing international regulations and standards; and
- (d) The possible need for the elaboration of standards for handling, transport, packaging and identification of living modified organisms.

2. A summary of the consultant's report is provided in document UNEP/CBD/BS/COP-MOP/6/9. The complete report is circulated herewith for the information of participants in the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety.

\* UNEP/CBD/BS/COP-MOP/6/1

**ANALYSIS OF INFORMATION ON STANDARDS RELEVANT TO THE HANDLING,  
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## **Section 1**

### **General Introduction**

Almost 10 years after the Cartagena Protocol came into force, the Parties continue to negotiate the implementation of the Protocol's Article 18, paragraph 3. Particular national positions reveal different paradigms regarding the environment–trade relationship. These different paradigms are reflected in the fragmented international regulation concerning living modified organisms (LMOs), but this fragmentation, although not “dangerous” from a quantitative perspective, is complicated from a qualitative perspective. Sometimes, international regimes embody diverse and opposing conceptions. This reality implies a contemporary problem and justifies this work.

#### **a- Research Problem and Objectives**

The problem may be summarized in a question. Are standards consistent with each other and, if not, how may it be possible to harmonize fragmented international standards, guidance and methods in the handling, transport, packaging and identification of LMOs?

This question implies a challenge that could be translated into our overall objective. *To explore and to describe ways and means to achieve harmonization of standards, guidance and methods in the handling, transport, packaging and identification of LMOs.*

In accordance with the methodology adopted, there are four secondary objectives:

- (1) To compare international legal standards, guidance and methods in the handling, transport, packaging and identification of LMOs to identify gaps and inconsistencies.
- (2) To describe legal gaps and legal inconsistencies in international standards, guidance and methods in the handling, transport, packaging and identification of LMOs, and their consequences for the international legal system.
- (3) To explore ways to resolve legal gaps and legal inconsistencies in international standards, guidance and methods in the handling, transport, packaging and identification of LMOs.
- (4) To propose alternative mechanisms of international cooperation in the field of handling, transport, packaging and identification of LMOs

#### **b- Structure and Methodology**

This report is divided into four Sections. Section 1 presents a general introduction, which describes the research problem; the principal and the secondary objectives; the methodology; and a summary of recommendations.

Section 2 identifies the current international standards, guidance and methods in the handling, transport, packaging and identification of LMOs.

Sub-section *a* provides a comparative analysis of these standards, guidance and methods as applied by the main international organizations concerned. It uses the categories of “legal status” (substantial equivalence or new food criteria), “product or process assessment”, “voluntary” or “mandatory” standards, and “objectives pursued” (sanitary or non-sanitary).

Sub-section *b* identifies, in the light of the preceding comparative scheme, the legal gaps resulting from the lack of information and coordination, as well as the legal inconsistencies arising from conflicts of norms. This report therefore distinguishes gaps from inconsistencies. It will be considered herein that the gaps can be resolved by systemic or evolutive interpretation; by analogy; or by the elaboration of new standards. In contrast, it will be considered that the inconsistencies will require harmonization by modification or abrogation of some existing international norms.

Section 3 makes some proposals for the harmonization of international regulation of standards, guidance and methods in the handling, transport, packaging and identification of LMOs.

Sub-section *a* proposes possible solutions to the legal gaps and legal inconsistencies identified, distinguishing procedural instruments and substantive mechanisms.

Sub-section *b* suggests some legal, political and administrative channels for international cooperation, exploring ways to maximize existing mechanisms.

In section 4, the report concludes by responding to the four expectations of the present consultancy. It attempts to constitute a clear, precise and useful instrument for facilitating general discussion, understanding and decision-making in the field of handling, transport, packaging and identification of LMOs.

### **c- Summary of Recommendations**

(1) Encourage States to continue using the Cartagena Protocol Commercial Invoice Model; or include in the traditional “bill of lading” the codes and recommendations developed by the World Customs Organization (WCO); the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations; and the Organization for Economic Co-operation and Development (OECD).

(2) Encourage States members of the OECD to develop a new standard for a unique identifier for micro-organisms and animals.

(3) Propose and support the identification of the Cartagena Protocol on Biosafety as a new relevant international standard, under the umbrella of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (Article 12, para. 4, sentence 2 of the SPS Agreement and Article 3 (d) of the Annex A of the SPS Agreement).

(4) Encourage States to inscribe the Cartagena Protocol standards in the SPS list of international standards, guidelines or recommendations applied by the World Trade Organization members (Article 12, para. 4, sentence 3 of the SPS Agreement).

(5) Promote granting the CBD Secretariat observer status in the SPS Committee (WT/L/161 and its Annex 3).

(6) Suggest the creation, under the umbrella of the World Customs Organization, of a new “tariff position” for LMOs and their different uses (direct use as food or feed, or for processing (FFP), contained use, intentional introduction into the environment).

(7) Share the International Portal on Food Safety, Animal and Plant Health with the Food and Agriculture Organization of the United Nations with a view to storing all available information on one web site.

(8) Offer advice to the UN committee of experts on the transport of dangerous goods about LMO risks and, eventually, propose some adaptations to the UN Model Regulations to meet LMO needs and the purposes of the Cartagena Protocol.

(9) Encourage States to use more frequently the procedures and mechanisms on compliance under the Cartagena Protocol to enforce compliance with the Protocol's requirements on the handling, transport, packaging and identification of LMOs and to create specific case law about Cartagena Protocol purposes.

(10) Encourage States to transfer technology from developed countries to developing and less developed countries with a view to improving capabilities to segregate and trace LMOs, and as a mechanism to facilitate LMO identification.

(11) Encourage States to create consumer education programs to widen general knowledge of LMOs, as a mechanism to facilitate the implementation and international recognition of LMO labelling.

## **Section 2: Current International Standards, Guidance and Methods in the Handling, Transport, Packaging and Identification of LMOs**

### **a- A Comparative Analysis of International Standards, Guidance and Methods**

#### **Introduction**

The sub-section *a* addresses the following objective: "To compare international standards, guidance and methods in the handling, transport, packaging and identification of LMOs".

The harmonization of "standards, guidance and methods" in the "handling, transport, packaging and identification" of LMOs appears as an unco-ordinated point of view related to the international regulation of biotechnology. This topic represents much more than a marketing tool to help individualize a product within a market. Rather, it is the materialization of the rationality that is present in the profile of domestic and international norms, and which is in conformity with the pre-assigned role of science in society.

The cross-cutting debate on the harmonization of "standards, guidance and methods" in the "handling, transport, packaging and identification" of LMOs is present in the biological, political and economic sciences, each of which is called upon to provide supporting arguments either in favor of or against the standardization of the handling, transport, packaging and identification of the LMOs. This sub-section analyzes this kind of standardization, taking into account different categories, with the objective of describing the reasons and perspectives involved in this international action.

#### **a.1- The Legal Status of LMOs**

The first point of divergence among the various scientific assessments of LMOs concerns the legal status of LMOs. On the one hand, some States use the criteria of "familiarity" and "substantial equivalence" to compare LMOs with traditional products, and consider that a particular standardization of the handling, transport, packaging and identification of the LMOs is only necessary in cases in which the products compared are significantly different from each other. Only in such situations should the traders and consumers be clearly informed that the product they might transport or buy is an LMO. This information must therefore be consistent and delivered in simple terms, and should not generate unnecessary alarm (HOBAN, 1998:3-7). Supporters of this position consider that this general rule can

only be derogated by scientific evidence proving the contrary and should be provided by those who seek to forbid an LMO (ROSSI DAL POZO, 2005:83). On the other hand, other States consider LMOs as “new organisms” or “new foods”. Therefore, the criteria cited above constitute neither a proof of homogeneity nor, *a fortiori*, a proof of a product’s safety.

#### **a.2- Unity of Analysis: Product or Process**

From another perspective, LMOs can be assessed as *final products* or as *products linked to process and production methods*. On the one hand, some States consider that LMOs have to be assessed only by their physical and chemical composition, their nutritional characteristics and their safety for consumption, without taking into consideration the process or method of production. In contrast, other States consider that the process or method of production is a fundamental characteristic of the product. Therefore, they view the standardization of the handling, transport, packaging and identification of the LMOs as the only tool by which an LMO can be identified, for in most cases, once the production process is finished, it is not possible to visually distinguish LMO from non-LMO products. Additionally, consumers may wish to be informed in case they wish to reject biotechnological processes (PHILLIPS & GRANT, 1998:28; CHESS, 1998: 17-21; MARCHALL, 1998:35-37).

#### **a.3- Voluntary or Mandatory LMO Standards**

It is also possible to distinguish between juridical systems based on *voluntary standards* and juridical systems based on *compulsory standards*. In systems with voluntary standards, producers are called upon to decide whether the LMOs should be identified as such or not. Some authors suggest that voluntary standards can increase the credibility of the producer industry and may increase the consumers’ disposition to accept LMOs (BROW & PING, 2003:208-214). Under this view, LMO standards facilitate free communication among economic actors (CASWELL, 1998:22-24) and help to distinguish between consumers willing to pay higher prices for identified products and those unwilling to bear such cost. Voluntary standards would therefore seem a more efficient and balanced solution in economic cost–benefit terms (CASWELL, 2000:53-57).

In normative systems based on compulsory standards, commercialization of LMOs without formal identification is prohibited. The main argument of this position holds that consumers and governments have the “right to know” what they are about to eat or to import into their territories (CARTER, 2002:2-10; CARTER & GRUÈRE, 2003b:2; EINSIEDEL, 2000:231-235; ARHTER, QUTUB, BURNHAM & AKHTAR: 2001). This system is generally chosen by governments that consider that private practices are insufficient, in terms of market communication, to prevent product identification fraud (CASWELL, 2000:54).

Furthermore, some legal systems establish thresholds of tolerance of presence of LMOs under which the obligation of identification is not applied. The threshold set can be quite high, as in Japan (5%), or low, as in the European Union (0.9%). In some circumstances, the threshold can be set at zero per cent, as it is in China. The effectiveness of this measure will depend on the level of technological development in each country. Therefore, the implementation of this threshold generally requires transfer of technology from developed countries to developing and least-developed countries.

#### **a.4- Objectives of LMO Standards**

The first objective pursued by proponents of LMO standards is to ensure “*consumer/public authority information access*”, since identification allows consumers and public authorities to know the characteristics of an LMO and, consequently, enable a free and informed choice. This is one of the most important consumer/public authority rights, among others, because clear and true information is conceived as a necessary condition to ensure respect of all aspects of the consumer/public authority

preferences (economic, religious, ethical, moral, environmental and health) (FAO, 2002:16; STILWELL & VAN DYKE, 1999:7; EINSIEDEL, 2000:232). Within the framework of the “right to know” concept, LMO nutritional facts, uses and functions can be found, so as to facilitate better nutritional and healthier choices (UNNVEHR & HASLER, 2000:10-13). Moreover, some authors consider that consumers constitute a part of the public debate, and labeling has therefore an educational function (STILWELL & VAN DYKE 1999:7). Others, in contrast, stress the view that the inclusion of information in the LMO label is more important in determining whether consumers are actually able to understand its meaning (MARCHALL, 1998:36). Hence, from this viewpoint, governments should increase education programs rather than focus on labeling policies in cases where consumers have a poor knowledge about LMOs (HOBAN, 1998:6; EINSIEDEL, 2000:234).

The second goal pursued by LMO standards is to “*manage the risk potentially generated by LMOs.*” Information included in the label should warn the consumer about the circumstances in which health or environmental damage may become, if ever, real and present (FAO, 2002:42). Moreover, labels constitute a useful tool when damage is detected and it becomes necessary to remove a product from the market. Therefore, labeling may help to minimize the impact and spread of health and environmental damage. In these situations, LMO labeling responds to the application of the precautionary principle, as included in several international legal instruments.<sup>1</sup> On this point, some authors have expressed the view that governments have the responsibility to take effective measures for the prevention of health and environmental threats, even in the absence of scientific consensus or when extensive scientific knowledge on the matter is still lacking.

Regarding the purposes of LMO standards presented here above, there is the objective of preventing the inclusion of false, confusing or misleading<sup>2</sup> (RAAB & GROBE, 2003:155-161; CARTER & GRUERE, 2003a: 70; CARLSSON, FRYKBLUM & LAGERKVIST, 2004:2; MOSCHINI & LAPAN, 2005:2; ROSSI DAL POZZO, 2005:65) information on labels which generally seek to influence the economic behavior that the consumer would normally have endorsed (CARTER & GRUERE, 2003a:68).

To sum up, all these categories of “legal status” (substantial equivalence or new food criteria), “product or process assessment”, “voluntary” or “mandatory” standards, and “objectives pursued” (sanitary or non-sanitary) are presented in the comparative scheme (Table 1). Through this image it is possible to observe the theoretical analysis applied by every international organization involved in the regulation of the LMOs.

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1 This principle has been included in Principle N° 15 of The Rio Declaration on Environment and Development (1992), the Convention on Biological Diversity, and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

2 Often, the label does not provide more or better information, so consumer makes influenced choices.

**Table 1. Comparative Scheme of International Regulations of LMOs**

| International Organizations and Legal Instruments       | Information on Relevant International Organizations   |                   |   | LMO Regulation Categories   |   |  |  |  |   |                    |
|---|---|-------------------|---|---|---|--|--|--|---|--------------------|
|   | Decision-making Method  | Number of Members | Number of Members that are also Parties to the Cartagena Protocol | Types of LMO Covered by Regulation  | Legal Status of LMOs (Substantial Equivalence or New Food/Organism)   | LMO Product or Process Assessment.   | Voluntary or Mandatory LMO Standard  | Thresholds of Tolerance  | Objective Pursued by LMO Standards  | Documents Required |
| <b>Codex Alimentarius Commission (CODEX)</b>            | 1- <b>Consensus</b> is the method usually used by Parties. (Art. XII.2 of the Rules of Procedure of the Codex Alimentarius Commission).<br>2- Adoption of new Standards by a <b>majority</b> of the votes cast. (Art. VIII.2 of the Rules of Procedure of the Codex Alimentarius Commission).<br>3- Amendments of, or additions to, or suspension of, these Rules of Procedure may be adopted by a <b>two-thirds majority</b> of the votes cast. (Arts. VII.6, XV.1 and XV.2 of the Rules of Procedure of the Codex Alimentarius Commission).<br>4- Omission of Steps 6 and 7 and acceleration of the elaboration process by a <b>two-thirds majority</b> of the votes cast. (Introduction, Par. 6 and Part 4, Step 1 of the Procedures for the Elaboration of Codex Alimentarius Standards and Related Texts). | 184               | 158   | 1- Foods derived from modern biotechnology.<br>2- Foods derived from recombinant-DNA plants.<br>3- Foods produced using recombinant-DNA micro-organisms.<br>4- Foods derived from recombinant-DNA animals   |   | Product assessment   | Voluntary. These standards, codes of practice, guidelines and other recommendations are not a substitute for, or alternative to, national legislation. (paragraph. 3 of the General Principles of the Codex Alimentarius).<br>However, SPS Agreement recognizes a <i>rebuttable presumption</i> of legal accordance of those national sanitary measures – based on Codex Alimentarius Standards – with SPS Agreement and GATT Agreement. This presumption is recognized in two cases: directly by Art. 3, paragraph. 2; and indirectly by Art. 5 paragraph 8 of the SPS Agreement. | The Annex III of the Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants describes the recommended approach to the food safety assessment in unauthorized situations of low-level presence of recombinant-DNA plant material. However, the Guidelines do not determine when a recombinant-DNA plant material is present at a low level. This is a national competence. | Protecting the Health of the Consumers and Ensuring Fair Practices in the Food Trade (Art. 1.a Statutes of the Codex Alimentarius Commission) | None               |
| <b>International Plant Protection Convention (IPPC)</b> | The Contracting Parties shall make every effort to reach agreement on all matters by <b>consensus</b> . If all efforts to reach consensus have been exhausted and no agreement is reached, the decision shall, as a last resort, be taken by a <b>two-thirds majority</b> of the contracting parties present and voting. (Art. XI of the International Plant Protection Convention).  | 177               | 151   | 1- LMOs are regulated in order to ensure plant protection. This means that the first objective is to control plant pests.<br>Depending on the LMO, what is regulated is the safety of the pest-free plant.<br>[The types of LMOs that a national plant protection organization (NPPO) may be asked to assess for phytosanitary risk include:<br>- plants for use (a) as agricultural crops, for | New organism<br><b>According to ISPM 11, it should be indicated when an LMO is transported (both exported and imported).</b><br>[The Convention has encouraged countries to ensure, through phytosanitary certification, that their exports are not the means for introducing new pests to their trading partners. Likewise importing countries strive to ensure that | Product assessment<br>ISPM's look at LMOs as a final product.<br>[For LMOs, information required for a full risk analysis may include:<br>- name, identity and taxonomic status of the LMO (including any relevant identifying codes) and the risk management measures applied to the LMO in the exporting country<br>- taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism<br>- description of the nucleic acid or the | Voluntary.<br>[These standards are not legally binding on the Parties to the IPPC; however (...) the WTO SPS Agreement requires WTO members to base their sanitary and phytosanitary measures for plant health on the standards, guidelines and recommendations of the IPPC.]<br>But, once it has been proved that an LMO is assessed as a pest, its identification is an obligation.  | It depends on the country.<br>[The principle of "managed risk" (ISPM 1:1993, Principles of plant quarantine as related to international trade) states that: "Because some risk of introduction of a quarantine pest always exists, countries shall agree to a policy of risk management when formulating phytosanitary measures." In implementing this principle, countries should decide what level of risk is      | Manage the pest risks potentially generated by LMOs.  |                    |



| International Organizations and Legal Instruments | Information on Relevant International Organizations  |                   |   | LMO Regulation Categories  |   |   |  |   |   |                    |
|---|--|-------------------|---|--|---|---|--|---|---|--------------------|
|   | Decision-making Method   | Number of Members | Number of Members that are also Parties to the Cartagena Protocol | Types of LMO Covered by Regulation   | Legal Status of LMOs (Substantial Equivalence or New Food/Organism)   | LMO Product or Process Assessment.  | Voluntary or Mandatory LMO Standard  | Thresholds of Tolerance   | Objective Pursued by LMO Standards  | Documents Required |
|   |  |                   |   | <p>food and feed, ornamental plants or managed forests; (b) in bioremediation (as an organism that cleans up contamination); (c) for industrial purposes (e.g. production of enzymes or bioplastics); (d) as therapeutic agents (e.g. pharmaceutical production)</p> <p>- biological control agents modified to improve their performance in that role</p> <p>- pests modified to alter their pathogenic character and thereby make them useful for biological control (see ISPM 3:2005)</p> <p>- organisms genetically modified to improve their characteristics, such as their usefulness for bio-fertilizer or other influences on soil, bioremediation or industrial uses.] (ISPM 11:2004)</p> | <p>measures they have in place for protection are technically justified. Measures that deviate from international standards or measures that exist in the absence of international standards must be developed through the assessment of the risk to plant life or health and must be based on scientific principles and evidence.]</p> | <p>modification introduced (including genetic construct) and the resulting genotypic and phenotypic characteristics of the LMO</p> <p>- details of the transformation process</p> <p>- appropriate detection and identification methods and their specificity, sensitivity and reliability</p> <p>- intended use including intended containment</p> <p>- quantity or volume of the LMO to be imported.]</p> <p>[In the case of LMOs, identification requires information regarding characteristics of the recipient or parent organism, the donor organism, the genetic construct, the gene or transgene vector and the nature of the genetic modification. Information requirements are set out under section 1.3 of ISPM 11.]</p> |  | acceptable to them.]  |   |                    |
| World Organization for Animal Health (OIE)        | <p>Decisions or elections shall be based on a <b>simple majority</b> (1/2+1), that is, more than one half of the votes cast.</p> <p>In almost all cases, standards are adopted by <b>consensus</b>. In a small minority of cases, where it is not possible to achieve consensus, standards have been adopted after a vote (enough <b>two-thirds</b> majority).</p> <p>In making decisions to adopt, amend or delete standards, the Assembly shall make every effort to reach agreement by consensus. Decisions to adopt, amend or delete standards may be taken by voting only if such</p> | 178               | 146   | <p>1- LMOs are not explicitly regulated. Documents do not distinguish LMOs from other products.</p>  | <p>Familiarity. Neither the Terrestrial Code and its Manual, nor the Aquatic Code and its Manual, deal with GMOs. This means that the “genetically modified organism topic” is not taken into account. This could mean that GMOs are seen as a traditional product, and that there is no need to identify them as such.</p>             | <p>Process. [This section also defines a genetically altered or cloned animals being one that has “undergone genetic modification of its nuclear or mitochondrial genomes through a deliberate human intervention, or the progeny of such an animal(s), where they have inherited the modification” (para 5. of Art. 7.8.7 of the Terrestrial Code). It states that if genetically altered or cloned animals are used, such use should be conducted</p>   | <p>Voluntary. There is no specific rule requiring States to mention a GMO. [The WTO SPS Agreement requires members to base their sanitary and phytosanitary measures in the area of animal health and zoonoses on the standards, guidelines and recommendations of the OIE. For this reason, the OIE considers the Code and associated Manuals to be legally binding.]</p> | <p>[OIE Members who are WTO Members may comply with their obligations under the SPS Agreement either by basing their measures on relevant OIE international standards, or by carrying out a scientific risk analysis as outlined in Section 2 of the Terrestrial Code (2008). The standards and recommendations contained in the Code are designed to facilitate and promote international trade.</p> | <p>Consumer/country information access. [Art 6.3.4: Labeling should be informative, unambiguous, legible and conspicuously placed on the package if sold in package form and on the waybill and other sales documents if sold in bulk, un-packaged form, and should comply with regulatory requirements and Section 4.2.10 Labeling of Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).</p> |                    |

| International Organizations and Legal Instruments | Information on Relevant International Organizations  |                   |   | LMO Regulation Categories          |   |  |                                     |  |   |                    |
|---|--|-------------------|---|------------------------------------|---|--|-------------------------------------|--|---|--------------------|
|   | Decision-making Method   | Number of Members | Number of Members that are also Parties to the Cartagena Protocol | Types of LMO Covered by Regulation | Legal Status of LMOs (Substantial Equivalence or New Food/Organism) | LMO Product or Process Assessment.   | Voluntary or Mandatory LMO Standard | Thresholds of Tolerance  | Objective Pursued by LMO Standards  | Documents Required |
|   | efforts to reach consensus have failed. In such cases, the standards shall be adopted by a two-thirds majority of the votes cast. (Art. 50 of the OIE) |                   |   |                                    |   | <p>in accordance with relevant regulatory guidance.</p> <p>[The aim of the Code is, inter alia, to ensure the sanitary safety of international trade in terrestrial animals and their products by detailing science-based health measures to be used by the veterinary authorities of the importing and exporting countries to avoid the transfer of agents pathogenic for animals or humans, while avoiding unjustified sanitary barriers.]</p> <p>[Exporting countries should provide the following sanitary information, as listed in Article 5.1.3. of the Terrestrial Code (2008), at the request of the importing country:</p> <ul style="list-style-type: none"> <li>- the animal-health situation and the national animal-health information systems;</li> <li>- the occurrence of notifiable diseases;</li> <li>- the ability to apply measures to control and prevent the relevant OIE-listed diseases;</li> <li>- the structure of the veterinary services and the authority under which they exercise;</li> <li>- technical information, particularly on biological tests and vaccines applied in all or part of the national territory.</li> </ul> <p>For trade in animals and some animal products, it is usual for an official veterinarian (or a private veterinarian with appropriate official approval) to inspect the consignment prior to export.]</p> |                                     | The OIE Code is a reference document for use by veterinary authorities, those responsible for making decisions on the import and export of animals and their products, and all those involved in international trade. The application, by members, of the OIE standards is the best means of avoiding disagreement and other problems in international trade.] | including listing of ingredients and instructions on the handling, storing and use. All claims made on a label should be able to be substantiated.] |                    |

| International Organizations and Legal Instruments  | Information on Relevant International Organizations   |                   |   | LMO Regulation Categories  |   |                                    |   |   |  |   |
|--|---|-------------------|---|--|---|------------------------------------|---|---|--|---|
|  | Decision-making Method  | Number of Members | Number of Members that are also Parties to the Cartagena Protocol | Types of LMO Covered by Regulation   | Legal Status of LMOs (Substantial Equivalence or New Food/Organism) | LMO Product or Process Assessment. | Voluntary or Mandatory LMO Standard   | Thresholds of Tolerance   | Objective Pursued by LMO Standards   | Documents Required  |
| <b>United Nations Recommendation on the Transport of Dangerous Goods – Model Regulations</b> | Decisions of the Economic and Social Council shall be made by a majority of the members present and voting. The Council has 54 members elected by the United Nations' General Assembly. (Art. 61 and 67 UN Charter) | 193               | 163   | 1- Genetically modified organisms (GMOs) (Animals are included)<br>2- Genetically modified micro-organisms (GMMOs) | New organism  | Product assessment                 | The Model Regulations are not binding per se. They become binding only once they have been transposed into national legislation or legally binding international instrument   | The Model Regulations have not fixed threshold of tolerance.    | The objective of the Model Regulations is the provision of simple and harmonized recommendations on the transport of dangerous goods to ensure the safety of people, property and the environment. | If GMOs or GMMOs are classified as toxic substances (Type 6.1), they have to be identified (UN 3172).<br>If GMOs or GMMOs are classified as infectious substances (Type 6.2), they have to be identified (UN 2814 or 2900), if they are class A, or (UN 3373), if they are class B.<br>If GMOs or GMMOs are classified as Miscellaneous Dangerous Substances (Type 9), they have to be identified (UN 3245). This category is subject to packing instructions P904 (to be transported in intermediate bulk containers –IBC99) Class 9 label and mention in transport documents are no longer required.<br>All these classifications are assigned after a risk assessment. |
| <b>Organization for Economic Co-operation and Development (OECD)</b>                         | 1- Decisions shall be taken and Recommendations shall be made by mutual agreement of all the Members. (Art. 6 of the Convention on the Organization for Economic Co-operation and Development)                      | 34                | 27  | Living modified plants   | New organism  | Process assessment                 | No decision shall be binding on any member until it has complied with the requirements of its own constitutional procedures. (Art. 6 of the Convention on the Organization for Economic Co-operation and Development) | The Organization has not fixed a maximum threshold of tolerance | The major objective of “unique identifier for transgenic plants” was to identify the most efficient means of establishing a unique identifier for transgenic plants                                |   |

| International Organizations and Legal Instruments                                       | Information on Relevant International Organizations   |   |  | LMO Regulation Categories  |  |  |  |  |  |   |
|---|---|---|--|--|--|--|--|--|--|---|
|   | Decision-making Method  | Number of Members   | Number of Members that are also Parties to the Cartagena Protocol  | Types of LMO Covered by Regulation   | Legal Status of LMOs (Substantial Equivalence or New Food/Organism)  | LMO Product or Process Assessment.   | Voluntary or Mandatory LMO Standard  | Thresholds of Tolerance  | Objective Pursued by LMO Standards   | Documents Required  |
| <b>World Customs Organization (WCO)</b>   | Decisions concerning amendments to the Convention are taken by a <b>majority of not less than two-thirds of the votes</b> cast by members (Rule 19 of the Rules of Procedure of the HS Committee) followed by unanimous acceptance of the CPs (Article 16 of the HS Convention).<br>Other decisions (classification decisions, adoption of the Explanatory Notes, Classification Opinions, etc.) are taken by a <b>simple majority</b> of the votes cast by the members of the Committee (Rule 19 of the Rules of Procedure of the HS Committee), followed by a deemed approved procedure of the Council (Articles 8.2. and 8.3 of the HS Convention.)] | 177   | 148  | LMOs are not regulated. The Codes of the Harmonized System do not distinguish LMOs from other products.  | Familiarity.<br>The HS does not differentiate GMOs from other traditional products. Therefore, the legal nature would be according to familiarity criteria.<br>[Ex: Cap 12. -12.01 refer to soya beans, whether or not broken. But it does not say whether those soya beans are transgenic or not] | Product assessment<br>The main objective of the HS is to set international trade of goods in order. That way, if one country imports "coffee, not roasted, not decaffeinated", all countries bound by the HS will know it is about 09.01.11.<br>It does not matter how the product was made, but it is important to know which products are being exchanged. | Voluntary.<br>There is no specific rule requiring States to mention a GMO.   |  | The objective of the HS is to set international trade in order, by informing concerned organizations which product is being exchanged.<br>It may be a question of consumer (in this case, country) information access. | - International Convention on the Harmonized System - HS Nomenclature 2012 Edition  |
| <b>United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT)</b> | Recommendations, business standards and technical standards through two methods:<br>1- <i>Plenary</i> : by a <b>majority</b> of the members present and voting (Rule 39 of the Terms of Reference and Rules of Procedure of the Economic Commission for Europe, Fifth Revised Edition)<br>2- <i>Intersessional</i> : Heads of Delegations do not present negative comments or do not request substantive changes or do not respond. (paragraphs. 5 and 6 of the Revised UN/CEFACT intersessional approval process)  | 56  | 47   | There are no specific recommendations regarding LMOs.  | There are no specific recommendations regarding LMOs.  | There are no specific recommendations regarding LMOs.  | Voluntary. The recommendations and guidelines do not prescribe how a country should standardize its information and documentation requirements for import, export and transit. | There are no specific recommendations regarding LMOs. Thresholds of tolerance  | Simplification and harmonization of processes, procedures and information flow. These recommendations do not have a sanitary purpose or a consumer-information objective   | 1- Recommendation N. 1 (1973) has established need to consign exporter, consignee, description of goods, commodity number – custom code).<br>2- Recommendation N. 33 (2004) has developed a single window for exchange of information between trade and government. |
| <b>United Nations Commission on International Trade Law (UNCITRAL)</b>                  | The adoption of the text of a treaty takes place by the <b>consent</b> of all the States participating. If this consensus is not possible, by a <b>two-thirds majority of the States present and voting</b> . (Art. 9 of the Vienna Convention on the Law of Treaties – 1969)   | 1- The International Convention for the Unification of Certain Rules of Law Relation to Bills of Lading (Hague Rules 1924) has 52 States Parties.<br>2- The | 1- The Hague Rules 1924 and its amendments, Hague-Visby 1968 and Brussels 1979 shares 64 States Parties.<br>2- The Hamburg Rules 1978 shares 17 States Parties<br>3- The Rotterdam | There are no specific recommendations regarding LMOs. The Hague Rules address responsibilities of carriers of goods. Article 1.C defines "goods" as goods, wares, merchandise, and articles of every | There are no specific recommendations regarding LMOs. Legal nature   | There are no specific recommendations regarding LMOs.  | Mandatory after treaties enter into force among the States Parties.  | There are no specific recommendations regarding LMOs. Thresholds of tolerance. |  | 1- The Hague-Visby Rules require a bill of lading and It has to contain the leading marks for the identification of the goods and the apparent order and condition of the goods.<br>2- The Rotterdam  |

| International Organizations and Legal Instruments | Information on Relevant International Organizations  |   |   | LMO Regulation Categories   |   |   |   |                         |  |   |
|---|--|---|---|---|---|---|---|-------------------------|--|---|
|   | Decision-making Method   | Number of Members   | Number of Members that are also Parties to the Cartagena Protocol | Types of LMO Covered by Regulation  | Legal Status of LMOs (Substantial Equivalence or New Food/Organism) | LMO Product or Process Assessment.                      | Voluntary or Mandatory LMO Standard                           | Thresholds of Tolerance | Objective Pursued by LMO Standards   | Documents Required  |
|   |  | <p>International Convention for the Unification of Certain Rules of Law Relation to Bills of Lading (Hague-Visby Rules 1968) has 27 States Parties</p> <p>3- The International Convention for the Unification of Certain Rules of Law Relation to Bills of Lading (Brussels Protocol 1979) has 18 States Parties</p> <p>4- The United Nations Convention on the Carriage of Goods by Sea (Hamburg Rules 1978) has 20 States Parties</p> <p>5- the Convention on Contracts for the International Carriage of Goods Wholly or Partly by Sea (Rotterdam Rules 2008) has 1 State Party.</p> | Rules 2008 shares 1 State Party                                   | <p>kind whatsoever except live animals. This is a general agreement; consequently, it rules LMOs as ordinary goods.</p> <p>The Rotterdam Rules include in the term "goods" live animals.</p>  |   |   |   |                         |  | <p>Rules require delivery of the goods in such conditions that they will not cause harm to persons or property. Shipper has to provide to the carrier information, instructions, documents relating to the goods for their proper handling and carriage.</p> <p>"When goods by their nature or character are, or reasonably appear likely to become, a danger to persons, property or environment" the shipper must mark or label dangerous goods in accordance with any law or regulation.</p> |
| <b>Cartagena Protocol</b>                         | The Parties shall make every effort to reach agreement on all matters of substance by <b>consensus</b> . | 163   | 163   | <p>All LMOs that may have adverse effects on the conservation and sustainable use of biological diversity</p> <p>1- LMOs for intentional introduction into the environment.</p> <p>2- LMOs for direct use as food or feed, or for processing.</p> <p>3- LMOs for contained use)</p> | New organism  | Process assessment (Art. 3,g of the Cartagena Protocol) | Mandatory after treaty enters into force among States Parties |                         | 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. (Art. 1 of the Cartagena Protocol) | The COP/MOP-1 (Decision BS-I/6 Ap. B) has created a commercial invoice model. It includes existing international standards and added specific items for confined use and for intentional introduction into the environment. Additionally, it imposes the obligation to inform concerned organizations of any requirements for the safe  |

| International Organizations and Legal Instruments | Information on Relevant International Organizations   |                   |   | LMO Regulation Categories  |   |   |  |   |   |  |
|---|---|-------------------|---|--|---|---|--|---|---|--|
|   | Decision-making Method  | Number of Members | Number of Members that are also Parties to the Cartagena Protocol | Types of LMO Covered by Regulation   | Legal Status of LMOs (Substantial Equivalence or New Food/Organism) | LMO Product or Process Assessment.                    | Voluntary or Mandatory LMO Standard  | Thresholds of Tolerance   | Objective Pursued by LMO Standards                              | Documents Required   |
|   |   |                   |   |  |   |   |  |   |   | handling, storage, transport and use of the living modified organisms under applicable existing international instruments. |
| <b>World Trade Organization (WTO)</b>             | <p>1. The WTO shall continue the practice of decision-making by <b>consensus</b>, where a decision cannot be arrived at by consensus, decisions of the Ministerial Conference and the General Council shall be taken by a majority of the votes cast.</p> <p>2. In specific situations, decisions shall be taken by a <b>three-fourths majority</b> of the Members.</p> <p>3. Amendments taken by <b>consensus</b>. If consensus is not reached, decisions, in some cases, shall be decided by a <b>two-thirds majority</b> of the Members, but in other cases, by a <b>three-fourths majority</b> of the Members. (articles IX and X of the WTO Agreement)</p> | 153               | 133   | LMOs are not regulated. Documents do not distinguish between LMOs from other traditional products. | There are no specific recommendations regarding LMOs. Legal nature  | There are no specific recommendations regarding LMOs. | National mandatory standards have to be consistent with SPS or TBT or GATT agreements. | There are no specific recommendations regarding LMOs. Thresholds of tolerance | National standards could pursue technical or sanitary purposes. | No regulation regarding documents.   |

## **b- An Exploratory Analysis of Legal Gaps and Legal Inconsistencies in International Standards, Guidance and Methods**

### **Introduction**

The sub-section *b* addresses the following objective: “To describe legal gaps and legal inconsistencies in international standards, guidance and methods in the handling, transport, packaging and identification of LMOs, and their consequences for the international system.”

Methodologically, two areas of research are adopted: Transboundary movements of LMOs (trade logistics); and LMO labeling for consumers (marketing). This division allows the analysis of agreement and disagreement among States at each stage of this integrated process, through time.

States tend to avoid conflicts of norms in the international arena. For this reason, a distinction has been made herein between gaps and inconsistencies, as analytical tools for the interpretation and comprehension of the States’ attitudes.

Gaps can be resolved by: systemic or evolutive interpretation; analogy; or elaboration of new standards. In contrast, inconsistencies require harmonization by modification or abrogation of existing international norms.

This second type of legal problem should expose an analytical difficulty, because the preamble to the Cartagena Protocol contains very strong statements rejecting conflict of norms, through the inclusion of a “mutual supportive” clause. This clause will be analyzed here below.

### ***b.1- Legal Gaps in the International Regulation of LMOs***

To identify gaps with respect to international standards, guidance and methods, due either to a lack of information or to current regulation, the following organizations and texts were assessed: the United Nations Recommendation on the Transport of Dangerous Goods – Model Regulations; World Customs Organization; United Nations Centre for Trade Facilitation and Electronic Business; the International Convention for the Unification of Certain Rules of Law Relating to Bills of Lading (Hague 1924 and its amendments: the Hague-Visby Rules 1968 and the Brussels Protocol 1979); and the Convention on Contracts for the International Carriage of Goods Wholly or Partly by Sea (Rotterdam Rules 2008).

Every relevant international norm has been analyzed taking into account the main objective of the Cartagena Protocol: *“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.”*

From this objective a fundamental consideration emerges: to regulate handling, transport, packaging and identification of living modified organisms resulting from modern biotechnology is not an objective *per se*. This regulation has also to take into account the conservation and sustainable use of biological diversity and the risks to human health.

Consequently, it appeared necessary to examine the existing international norms on trade logistics, with a view to deciding whether the current regulations allow an efficient result – the safe transboundary movement of LMOs – or not.

Having established this fundamental premise, national authorities, given the required LMO risk assessment, should be able to give or to reject an authorization demanded by an applicant. In other words, after the scientific assessment, governments have all the necessary scientific information required by the legal procedures, and, taking into account their national and/or international standards, are in a position to distinguish whether a particular LMO may be authorized or not.

The risk assessment is the decisive stage, because it determines whether an LMO is toxic or infectious, whether it constitutes a pest for plants or a pathogenic agent for animals, or whether it is an unhealthy good for food, for animal feed or for food processing.

With this scientific information and the administrative decision regarding the authorization or the rejection of a demand, it is feasible to analyze the international logistics norms for the conduct of international maritime and inland trade. On this point it is important to highlight that while Article 18 of the Cartagena Protocol sets general requirements for handling, transport, packaging and identification, the risk assessment may lead to specific handling, storage, transport and use measures to manage the risks that have been identified.

Concerning the commercial uses of maritime transport, contained in the International Convention for the Unification of Certain Rules of Law Relation to Bills of Lading (Hague 1924 and its amendments: the Hague-Visby Rules 1968 and the Brussels Protocol 1979), the Convention on Contracts for the International Carriage of Goods Wholly or Partly by Sea (Rotterdam Rules 2008), and the Recommendation N° 1 of the UN/CEFACT (1973), the bill of lading has to include the following information related to the goods: (a) description of the goods; (b) leading marks necessary for identification of the goods; (c) number of packages or pieces; (d) quantity of the goods; (e) the weight of the goods; and (f) a statement of the apparent order and condition.

These instruments are globally coincidental, but a possible gap could be found in The Hague Rules and their amendments, because they have not included the “description of the goods”. However, this gap should be solved easily through legal interpretation, because Article III.3 of the Hague-Visby Rules states that the information shown in the bill of lading includes topics (b), (c), (d), (e) and (f), “among other things”; from which it may be concluded that this list is only an indicative list.

With regard to the *identification of LMOs* during the transboundary movement, in the present section (b.1) three existing international standards are described. Although the Tariff Position defined by the World Customs Organization does not identify LMOs in particular, it is a code able to identify the product generally. It is important to note that the Tariff Position is one of the topics required by the United Nations Layout Key for Trade Documents (Recommendation N° 1), so this harmonized code is currently used in international commerce.

Another existing identification method is the “Unique Identifier for Transgenic Plants” developed by the OECD in 2002 (revised in 2006) and suggested by the Conference of the Parties serving as the meeting of the Parties of the Cartagena Protocol (COP-MOP) (para. 1, section C, decision BS-I/6, COP-MOP 1), as a useful tool for LMO identification. For this reason, the COP-MOP urged all Parties to adopt the OECD’s unique identifier.

Consequently, using the general code provided by the World Customs Organization and the Unique Identifier for Transgenic Plants developed by OECD, LMOs may be identified integrally. All this information would be included in transport documents, and transboundary movements would be clearly informed.

Furthermore, taking into account the risk-assessment results and the national administrative resolutions, it is possible to know an LMO’s dangerousness (toxicity or infectiousness), its



environmental impact (e.g. as a plant pest or a pathogenic agent for animals), and its safety (healthiness for food, for animal feed or for food processing). These conclusions could be adapted to the United Nations Recommendation on the Transport of Dangerous Goods – Model Regulation. So, if an LMO has been assessed as toxic, it is labeled UN3172; if it has been classified as infectious, it is labeled UN2814 or UN2900, class A (capable of causing permanent disability); if it has been classified as infectious, it is labeled UN3373 class B (not class A); and, finally, if an LMO has not been authorized for use by one of the countries of origin, transit or destination, it may be classified as “miscellaneous dangerous substances and articles including environmentally hazardous substances” and is labeled UN3245.

Therefore, these three existing international standards, described here above, should be able to identify – generally, particularly and specifically – all of living modified plants’ characteristics during transboundary movements. However, it must be remembered that the OECD has not developed a unique identifier for other types of genetically modified organisms such as micro-organisms or animals. In those cases, only the Tariff Position defined by World Customs Organization and the United Nations Recommendation on the Transport of Dangerous Goods – Model Regulation could be used.

Additionally, the COP-MOP (para. 1, section B, decision BS-I/6, COP/MOP-1), requested Parties to the Protocol and urged other Governments to take measures to ensure the use of a commercial invoice or other documents required or utilized by existing documentation systems, with consideration given to the formats outlined in the example templates annexed to the decision, as documentation that should accompany living modified organisms for confined use and living modified organisms for intentional introduction into the environment of the importing Party. Some years later, the COP-MOP (decision BS-III/10 – COP/MOP-3) specified the requirements for documentation for LMOs for direct use as food or feed or for processing.

This commercial invoice model is coherent with other existing international documents included in the standards cited so far.

The same considerations regarding LMO identification during transboundary movements can be applied to LMO handling, packaging and transport, because, in the light of the international standards analyzed herein, all circumstances liable to determine the specifics of handling, packaging and transport conditions have to be made known to the carrier.

Finally, it is necessary to mention that in case of “low-level presence of transgenic grains in conventional seeds or commodities” there are several agreements that regulate the appropriate behavior<sup>1</sup>, but there is no agreement on how low should the low-level presence be. This is a very complex topic and no solution has emerged yet.

In regard to *packaging of LMOs* during the transboundary movement, Article 3.5 of the Hague Rules states that “the shipper shall be deemed to have guaranteed to the carrier the accuracy at the time of shipment of the marks, number, quantity and weight, as furnished by him, and the shipper shall indemnify the carrier against all loss, damages and expenses arising or resulting from inaccuracies in such particulars (...).” Although this article does not include packaging, it has to be interpreted systemically with Article 4.2: “Neither the carrier nor the ship shall be responsible for loss or damage arising or resulting from: (...) (n) Insufficiency of packing” and with Article 4.3 “The shipper shall not be responsible for loss or damage sustained by the carrier or the ship arising or resulting from any cause without the act, fault or neglect of the shipper, his agents or his servants.”

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<sup>1</sup> See the column on ‘thresholds of tolerance’ in Table 1.

In the light of such a systemic interpretation, the shipper has the obligation to pack all goods properly, taking into account the nature of the goods; in the present case, the nature of the LMOs. This conclusion seems logical, since Article 4.2 excludes carrier responsibility for loss or damage arising or resulting from insufficiency of packing, and Article 4.3 excludes shipper responsibility if he has acted legally.

In the same sense, Article 27.1 of the Rotterdam Rules declares that “Unless otherwise agreed in the contract of carriage, the shipper shall deliver the goods ready for carriage. In any event, the shipper shall deliver the goods in such condition that they will withstand the intended carriage, including their loading, handling, stowing, lashing and securing, and unloading, and that they will not cause harm to persons or property.” This article is clearer than The Hague Rules, although it also proclaims the shipper’s responsibility for safe packaging.

The United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations – affirms that if an LMO is classified toxic or infectious, it has to be labeled UN 3172, UN2814, UN2900 or UN3373 and it has to be packed in accordance with instruction No. P620 or P650. In a second category, if an LMO is not authorized for use by one of the countries of origin, transit or destination, and is consequently classified as “miscellaneous dangerous substances and articles including environmentally hazardous substances”, it has to be labeled UN3245 and it has to be packed in accordance with instruction No. P904.

Regarding the *transport of LMOs* during the transboundary movement, Article 6 of the Hague Rules states that “(...) if dangerous goods are shipped without carrier, master or agent of the carrier consent with knowledge of their nature and character, they may at any time before discharge be landed at any place, or destroyed or rendered innocuous by the carrier without compensation and the shipper of such goods shall be liable for all damages and expenses directly or indirectly arising out of or resulting from such shipment. If any such goods shipped with such knowledge and consent shall become a danger to the ship or cargo, they may in like manner be landed at any place, or destroyed or rendered innocuous by the carrier (...).”

Article 32 of the Rotterdam Rules proclaims that “when goods by their nature or character are, or reasonably appear likely to become, a danger to persons, property or the environment: (a) the shipper shall inform the carrier of the dangerous nature or character of the goods in a timely manner before they are delivered to the carrier or a performing party. If the shipper fails to do so and the carrier or performing party does not otherwise have knowledge of their dangerous nature or character, the shipper is liable to the carrier for loss or damage resulting from such failure to inform; and (b) the shipper shall mark or label dangerous goods in accordance with any law, regulations or other requirements of public authorities that apply during any stage of the intended carriage of the goods. If the shipper fails to do so, it is liable to the carrier for loss or damage resulting from such failure.

In conclusion, these articles affirm, in similar terms, that the shipper’s obligation to inform the carrier about the dangerousness of goods is founded on the principle that this characteristic determines the carrier’s responsibilities regarding the goods carried (Articles 3.2 of the Hague Rules and 13.1 of the Rotterdam Rules).

Finally, regarding the *handling of LMOs* during the transboundary movement, The Hague Rules have not proclaimed any disposition on this topic. However, Article 29.1 (a) of the Rotterdam Rules states that the shipper shall provide to the carrier in a timely manner such information, instructions and documents relating to the goods that are not otherwise reasonably available to the carrier, and that are reasonably necessary for the proper handling and carriage of the goods, including precautions to be taken by the carrier or a performing party.

Therefore, it may be concluded that the existing standards, described above, should be able to regulate LMO handling, packaging and transport conditions. However, under these international standards, LMO handling, packaging and transport conditions will be tied to the results of the LMO risk assessment, not on the condition of an LMO *per se*.

Moreover, the Conference of Parties serving as the meeting of the Parties of the Cartagena Protocol (paras. 3(a)(iii) and 3(b)(ii) of section B of decision BS-I/6, COP/MOP-1), has included the obligation to state any requirements for the safe handling, storage, transport and use of the LMOs under applicable existing international instruments.

However, beyond the general concordances among these international standards, there are also some gaps related to LMO trade logistics; for instance:

(1) OECD rules have not developed a unique identifier for other types of genetically modified organisms such as micro-organisms or animals. Hence, existing international standards do not resolve every issue related to LMO identification. In this context, only the identification of GM plants would be resolved.

(2) Transport documents include a lot of information about general, particular and specific LMO characteristics, but they do not include a specific reference to the final use of LMOs (confined use, intentional introduction into the environment, food, feed or processing).

(3) These international standards are not binding until countries ratify treaties where they are included, or until countries adopt the recommendation through internal legislation.

### ***b.2- Legal Inconsistencies in International Regulation of LMOs***

Following the subdivision, decided here above, into two areas of consideration (Transboundary Movements of LMOs (Trade Logistics); and LMO Labeling for Consumers (Marketing)), the present sub-section (b.2) addresses the last one, bearing in mind that LMO Labeling for Consumers<sup>2</sup>, under the Cartagena Protocol, may comprehend a legal inconsistency, in the light of the goals of the Protocol and of other internationally binding norms, such as the World Trade Organization's Agreements.

The norms embodied in the Cartagena Protocol, the World Trade Organization Agreements and the Codex Alimentarius have established the conditions under which parties can require LMO labeling. Consequently, the aim of LMO labeling<sup>3</sup> may connect different international regimes, thus showing elements of comparison and allowing an analysis of potential normative inconsistencies. If the Cartagena Protocol proposes a sanitary objective, such a purpose has to be referenced within the SPS Agreement, which establishes that if a country bases its measures on international standards, like the Codex Alimentarius, these measures will benefit from a presumption of legality. Nevertheless, WTO Parties are not legally bound by an obligation to act exclusively in this sense. They can choose to implement other solutions, provided that these are always based on a scientific justification (KELCH, SIMONE & MADELL, 1998:34-35).

The SPS Agreement is based on the principle of "scientific justification", which is included in Articles 3.3 and 5.7 of this Agreement, and is interpreted by the WTO Appellate Body in the sense that a theoretical risk cannot be considered as a scientific justification to restrict international trade. According

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<sup>2</sup> In the context of the Cartagena Protocol, the term consumer identifies people buying whole foods (e.g. maize), or farmers buying seeds, or processing companies buying raw goods to process them afterwards, but it will not be as relevant for people purchasing packaged goods as the Cartagena Protocol does not apply to foods after they have been processed.

<sup>3</sup> See Section 2.a.4 of this Report.

to the Appellate Body, the risk has to be possible and probable. Moreover, the SPS Agreement calls upon Parties to create and follow international standards, recognizing the important role of the Codex Alimentarius as a focal point for international cooperation (APPLETON, 2000:566-578).

If labeling requirements are based on economic, ethical or religious considerations instead of sanitary principles, LMO labeling regulations will be compared with the regulations contained in the Agreement on Technical Barriers to Trade (TBT) and would have to comply with three main obligations: (a) to pursue legitimate objectives; (b) not to discriminate among similar products; and (c) not to create a measure with a more trade-restrictive effect than what is actually necessary to meet a legitimate objective (APPLETON, 2000:574 et seq.). Governments are strongly encouraged to base their national requirements on relevant internationally adopted standards, although the TBT Agreement does not recognize which international standards would be considered relevant.

Consequently, taking into account the fact that the Cartagena Protocol proclaims expressly that its objective has a sanitary purpose, and if there is no pre-existing risk-assessment report describing any environmental or human hazard caused by the LMO assessed<sup>4</sup>, these norms may be considered part of a conflict of norms or an international legal inconsistency.

This proposition could find support in the history of the Codex Alimentarius: after more than 10 years working on this subject, countries still disagreed on a technical or sanitary approach to GMO labeling. On the one hand, some countries were of the view that GMO labeling has to be based on risk-assessment results. On the other hand, some countries believed that GMO labeling responds to wider objectives. So, this disagreement seems to justify the more than 10 years of unsuccessful negotiation, although the Codex Alimentarius Commission, at its 34<sup>th</sup> session in July 2011, adopted the “Proposed Draft Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology at Steps 5/8”.

Behind this particular disagreement, it is possible to discover a wider debate about the nature of “precaution”, since many of the Cartagena Protocol norms are based on or linked to the “precautionary (principle)”. However, there is no international agreement on the nature of the term “precautionary” in the present context.

Two main international positions have emerged. On the one hand, some scholars believe that the precautionary principle could be considered as a source of international law. On the other hand, others think that the precautionary principle is only a planning tool or an instrument for the management of public policies, but that it is not binding.

In the first category, some classify the “precautionary principle” as a soft-law interpretative principle (MARTIN-BIDOU, 1999:658) or in some cases, as a general international legal principle (DI BENEDETTO, 2006:352; TROUWBORST, 2002; HOHMANN, 1994) or an international environmental legal principle (SANDS, 2007:266 et seq.).<sup>5</sup> In both the latter cases, these scholars believe that this principle is in the process of consolidating an international custom (SANDS, 2007:279; BROWN &

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<sup>4</sup> It should be borne in mind that Article 26 of the Cartagena Protocol allows the inclusion of socio-economic considerations in decision-making.

<sup>5</sup> See the separate opinion of the Judge CANÇADO TRINIDADE; he stated “Only the ICJ did not acknowledge, nor affirmed, the existence of those principles, nor elaborated on them, thus missing a unique occasion for their consolidation in the present domain of contemporary International Law (...) The Court had a unique occasion, in the circumstances of the case of the Pulp Mills, to assert the applicability of the preventive as well as the precautionary principles; it unfortunately preferred not to do so, for reasons which go beyond, and escape, my comprehension”. See: Separate Opinion of the Judge Cançado Trinidad in Case Concerning Pulp Mills on the River Uruguay (Argentina v Uruguay), Judgment, I.C.J. Reports 2010, paragraph 113.

DAUD, 2005:116; MARR, 2000:827),<sup>6</sup> even though there is a very strong and systematic resistance from some countries, such as the United States, to the recognition of the “precautionary principle” as an international principle or custom (BRUNNÉE, 2004:11; CAMERON, 1994: 270 et seq.; FREESTONE, 1999:135-164; TROUWBORST, 2002; GULLETT, 1997:52; STEWAR & JOHANSON, 2003:40; SEIN & MAHMUD, 2008:69; CHRISTOFOROU, 2003:Chapter 16).

In the second category, others believe that precaution only configures a policy-making tool able to respond to catastrophes and situations of uncertainty (BOISSON DE CHAZOURNES, 2002:10), or only a legal or political approach (WARD, 2000:220; GÜNDLING, 1990:23-30; BODANSKY, 1991:413-417; AGUILAR & JORDAN, 2003:78; SHAW & SCHWARTZ, 2005:6).

However, the view that sees “precaution” as an embryonic concept (DUPUY, 2002:95-111), hence still emerging and not yet a consolidated concept (JIMENEZ DE PARGA y MASEDA, 2003:16; SHAW & SCHWARTZ, 2005:5.), is accepted in the present report. An important indication of this proposition is represented by the International Court of Justice’s statement, in the case of *Pulp Mills on the River Uruguay (Argentina v. Uruguay)*, in which the Court has preferred to classify “precaution” as an approach, rather than an international principle. Furthermore, the Court has stated that there is no international convention in which a change in the burden of proof has been established<sup>7</sup> and characterized as one of the main effects attributed to “precaution” as an international principle.

This context of scholarly and jurisprudential indeterminacy justifies the questioning of “precautionary measures”, as applied to international law, because “precaution”, as a principle, continues to be described in an unclear and legally vague way (MARR, 2000:816). This situation explains contradictions between environmental positions and other approaches (MARR, 2000:820), and it stimulates countries around the world to contribute to international consolidation of the “precautionary principle” as a legal structure classified as an international principle or international custom.

### **b.3- Consequences of Legal Gaps and Legal Inconsistencies**

The consequences of gaps and inconsistencies in international law imply the existence of concrete facts that are apparently unregulated. Such facts may range from a major problem to a minor detail falling outside legal regulation. However, the theory of law has developed some general principles of law, analogy, customary law, jurisprudence and interpretation, as tools for resolving such legal problems.

International law comprehends a strong presumption against conflict of norms (INTERNATIONAL LAW COMMISSION, 2006:37; HELLIO, 2009:72). As a general rule, governments, in negotiating new agreements, take into account precedent agreements, so that all of these agreements have to be interpreted as confirming all the relevant international rules in force among them. But, during negotiation, States rarely address the question of conflict of norms, because they normally try to find a pragmatic solution. It is not reasonable to presume that negotiators suffer a kind of schizophrenia that compels them to conclude agreements that are not consistent with precedent agreements (HELLIO, 2009:72). For this reason, the general principle operating against conflict of norms

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<sup>6</sup> BROWN & DAUD believe that the precautionary principle, through the influence of the Cartagena Protocol, will become an international custom. On the other hand, MARR thinks that “the precautionary approach is a process of evolution, even inside international economic law, because it is increasing the inter-state *opinio iuris*, and also several international commissions have applied the precautionary principle and the conservative principle in their strategies (...)”. Today, it is possible to affirm that the precautionary principle is becoming a universal custom of international law.

<sup>7</sup> Case Concerning Pulp Mills on the River Uruguay (*Argentina v Uruguay*), Judgment, I.C.J. Reports 2010, paragraph. 164.

presumes that negotiators keep in mind at least the spirit of precedent agreements (McLACHLAN, 2005:282).

The “mutual supportiveness” clause is one of the most important clauses for inter-regime cooperation, even though the International Law Commission has expressed the view that this kind of clause postpones the solution of conflict of norms to the future, recognizing that these problems could be solved by mutual agreement (INTERNATIONAL LAW COMMISSION, 2006:276). BOISSON de CHAZOURNES and MBENGUE (2007:861-862) confidently express the view that this clause facilitates the coherence of international regimes, because it can be used flexibly and it could adopt different forms, implicitly or explicitly, even if its role may be principal or marginal. This clause also allows the affirmation that *ipso jure* conflicts of norms do not exist.

The International Law Commission believes that this clause could be useful in the negotiation of agreements within the same international regime, although it is quite difficult to solve conflicts of norms between different regimes, because these norms have diverse objectives; these norms could also be contradictory.

In such a situation, each State must choose what norms it wishes to apply and omit the application of the other norms. This action may, however, configure international responsibility for an internationally wrongful act and each State has to respond to the legal implications. The inconsistencies game is a zero-sum game. In this sense, the mutual supportiveness clause is only purposeful if the entity that applies it is an impartial third party outside both regimes (INTERNATIONAL LAW COMMISSION, 2006:280). Some scholars classify this clause as a viable technique to solve normative problems, but in some circumstances it could be uncertain and ambiguous (WOUTERS & DE MEESTER, 2008:206).

### **Section 3: Proposals for Harmonization of International Regulation of Standards, Guidance and Methods in the Handling, Transport, Packaging and Identification of LMOs**

#### **a. Ways to Resolve Legal Gaps and Legal Inconsistencies**

##### **Introduction**

Sub-section *a* addresses the following secondary objective: “To explore ways to resolve legal gaps and legal inconsistencies in international standards, guidance and methods in the handling, transport, packaging and identification of LMOs”.

The presentation is divided into two areas: “Procedural Mechanisms” and “Substantive Mechanisms”. The procedural mechanisms seek to resolve legal problems *ex post facto* and the substantive mechanisms are generally used to resolve them *ex ante*, during the negotiating period.

These gaps can be resolved by: a systemic or evolutive interpretation; analogy; or elaboration of new standards. In contrast, inconsistencies generally require harmonization by modification or abrogation of existing international norms. Although the Cartagena Protocol calls for mutual supportiveness among trade agreements, such as the World Trade Organization Agreements, and environmental agreements, it was shown in sub-section 2.b.2 that legal inconsistencies are evident in some fields, so there is a big dilemma to be faced between the *declarative coherence* and the *substantial inconsistency*.

However, there are some juridical instruments to help obtain an acceptable resolution of the legal problems previously described herein.

The gaps and inconsistencies identified in Section 2 are:

- (1) Inexistence of a unique identifier for genetically modified organisms other than plants, e.g. micro-organisms and animals.
- (2) Transport documents do not include a specific reference to the final use of an LMO (contained use, intentional introduction into the environment, food, feed or processing).
- (3) Existing international standards are not binding.
- (4) Lack of information on valid standards in each country.
- (5) Lack of communication about the information each concerned organization manages.
- (6) Conflict of norms relating to LMO labeling for marketing.

#### **a.1- Procedural Mechanisms**

In cases of (2) and (6) some procedural actions are necessary:

(1) Case (2) could be resolved through two interpretation mechanisms. The three instruments concerned with trade logistics, referred to in Section 2.b.1, are, overall, in agreement, but a possible gap may exist in the Hague Rules, since they do not include the topic “description of the goods”. However, this gap should be resolved easily through legal interpretation, because Article III.3 of The Hague Rules describes an indicative list, into which other details could be included.

By the same argument, the final use of an LMO (contained use, intentional introduction into the environment, food, feed or processing) may be included in the bill of lading. This inclusion may be justified in two ways: firstly, because Article III.3 of The Hague Rules uses the expression “among other things”, which would permit the inclusion of such elements as the final use of the LMOs; secondly, recourse to evolutive interpretation is possible. The phrase “*Leading marks necessary for identification of the goods*” included in Article III.3 of the Hague Rules, allows the term *identification* to be interpreted in an evolutive sense, because, since 1924, when the International Convention for the Unification of Certain Rules of Law Relating to Bills of Lading was signed, the international community has developed several international rules regarding identification of goods, such as the WCO’s tariff position and the OECD’s “unique identifier” for transgenic plants. Additionally, by the Cartagena Protocol, with respect to the conservation and sustainable use of biological diversity, the concerned international community has shown a persistent interest in a wider identification of LMOs. An effective solution would be to include a new box for “Final Use of the LMO” in the bill of lading.

Moreover, the Conference of the Parties serving as the meeting of the Parties of the Cartagena Protocol has provided templates for how the information regarding LMOs for contained use and LMOs for introduction into the environment may be included in existing types of shipping documentation (section B and annex of decision BS-I/6, COP/MOP-1). Although, there is no requirement that LMOs for intentional introduction into the environment be identified as such. The LMO has to be identified but there is no requirement to specify that it is an LMO for introduction into the environment.

Operationally, this inclusion does not imply a high cost to traders, because generally the final use of the goods is included in the contract, so the shipper only has to rewrite the information from the contract onto the bill of lading.

(2) The main problem identified is the possible conflict of norms between the Cartagena Protocol and the trade agreements, specifically regarding LMO labeling linked to the application of the “precautionary principle”<sup>8</sup>, and the SPS obligations linked to the Appellate Body’s rejection of “precaution” as a general international principle or custom.<sup>9</sup>

However, this argument will not be easy to apply, for two reasons. Firstly, conceptual positions appear to be strongly in conflict. On the one hand, some countries are promoting the application of the precautionary principle as an international principle, while others do not agree with this aim. On the other hand, the second position appears to have been adopted by WTO’s Appellate Body and by the International Court of Justice.

Secondly, even when the Conference of Parties serving as the meeting of the Parties of the Cartagena Protocol, adopted procedures and mechanisms on compliance with the Cartagena Protocol on Biosafety (decision BS-I/7 - COP/MOP-1) as an autonomous, simple and cooperative mechanism, no party, to date, has used the procedure to resolve possible cases. For this reason, the purposes of the Cartagena Protocol still lack an international jurisprudential infrastructure (CARDESA SALZMANN, 2010:1-28).

However, if the term “insufficient scientific evidence”, in Article 5, paragraph 7, of the SPS Agreement, is interpreted in an evolutionary spirit, taking into account the international community’s current interests contained in such international instruments as the Cartagena Protocol, it would appear that the concept of precaution is evolving from a rigid to an intermediate concept.

The interpretation of “insufficient scientific evidence” includes only the impossibility to carry out a risk assessment and this is due to what may be called “absolute scientific uncertainty”, but if a risk assessment has been carried out, in which a presumption of adverse events based on clues has been established, the term “relative scientific uncertainty” may be applied.

This new interpretation widens the margins of political appreciation, although it does not exclude the international obligation to undertake a new and complete risk assessment on which to base all trade-restrictive sanitary measures (DONADIO LINARES, 2012).

Consequently, the apparent inconsistency described in case (6) may be resolved through evolutive interpretation, but such a mechanism requires inter-organizational cooperation; this will be analyzed in the following sub-section.

## **a.2- Substantive Mechanisms**

In the cases (1), (3), (4) and (5), several substantive actions are necessary:

(1) Adoption of a new standard on unique identifiers for micro-organisms and animals. The COP/MOP-1, in paragraph 3 of section C of decision BS-I/6, encouraged the OECD to develop a unique identifier for micro-organisms and animals. These codes will be extremely useful for the complete identification of such LMOs. Nevertheless, the technical difficulties of cataloguing all existing micro-organisms manipulated around the world must be recognized.

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<sup>8</sup> In Cases when an identification measure is applied, taking into account sanitary purposes, without scientific justification and, consequently, based on precautionary principle.

<sup>9</sup> European Communities — Measures Concerning Meat and Meat Products (Hormones) – Report of the Appellate Body, paragraph 114, (DS26 and DS48).



(2) Ratification of international treaties in which international standards are included, such as the World Customs Organization's Statutes or the treaties sponsored by the United Nations Commission on International Trade Law, and/or the adaptation and transposition of domestic law to international standards, such as the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations. Today, 75 countries apply the Hague Rules.<sup>10</sup> Additionally, the Hamburg Rules require that a State that ratifies them is obliged to denounce the Hague Rules, so these treaties are contradictory.<sup>11</sup>

(3) The entry into force of the Rotterdam Rules may help to achieve the objectives of the Cartagena Protocol, since they include several specific details about the information required in the bill of lading, and they take into account environmental hazards as a dangerous effect to be prevented during the transport of goods. On the other hand, the ratification process is very slow. So far, only Spain has ratified the treaty. It would therefore be better to continue working on existing agreements, such as The Hague Rules and their possible adaptation through legal interpretation.

(4) Regarding the lack of communication about valid standards applicable in each country and about technical and scientific information managed by all the international organizations analyzed herein, and others, it would be interesting to formalize, through an inter-secretariat administrative agreement, the transformation of the FAO initiative “The International Portal on Food Safety, Animal and Plant Health”<sup>12</sup> into an inter-organizational project. This unified portal could be a virtual place where all information linked to LMOs and GMOs could be stored<sup>13</sup>.

## **b- Multilevel International Cooperation Mechanisms**

### **Introduction**

Sub-section *b* addresses the following objective: “To suggest ways to facilitate cooperation with relevant organizations”.

The analysis of this objective falls under three headings: “Legal Mechanisms”, “Political Mechanisms” and “Administrative Mechanisms”. The first group is intended to facilitate inter-jurisdictional cooperation; the second group is intended to adapt international rules to give them systemic coherence; and the third group is intended to channel ordinary matters.

### **b.1- Legal Mechanisms**

In section 3.a.1, it was stated that through evolutive interpretation it would be possible to achieve a more flexible interpretation of the term “insufficient scientific evidence”. However, as Ms. Gretchen

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<sup>10</sup> Article 11.2 of the Protocol to Amend the International Convention for the Unification of Certain Rules of Law Relating to Bills of Lading (Visby Rules, 1968) and Article VI.2 of the Protocol (SDR Protocol) amending the International Convention for the Unification of Certain Rules of Law Relating to Bills of Lading, of 25 August 1924 (The Hague Rules), as amended by the Protocol of 23 February 1968 (Visby Rules), establish that the ratification of one of them shall have the effect of ratification of the Convention for the Unification of Certain Rules of Law Relating to Bills of Lading (The Hague Rules, 1924).

<sup>11</sup> See Article 31 of the United Nations Convention on the Carriage of Goods by Sea (Hamburg Rules, 1978)

<sup>12</sup> See “The International Portal on Food Safety, Animal and Plant Health (IPFSAPH)” web site [at <http://www.ipfsaph.org/servlet/CDSServlet?status=ND1jdGh0dHB3d3dmYW9vcmdhb3NpcGZzYXBoaW5mb3JtYXRpb25zb3VyY2VpbmZvcmlhdGlvbnNvdXJjZSY2PWVuJjMzPSomMzc9a29z>]

<sup>13</sup> Taking into account the information given by Mr. Kusakawa in the Online Forum organized by the Secretariat (SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, 2011:14-15), the International Portal on Food Safety, Animal and Plant Health created by FAO update regularly by an automated process, extracting data from several online resources including the BCH and the OECD BioTrack Product Database and only selecting data for recombinant-DNA plants authorized for use as food, it allows countries to enter relevant data manually if the information has not been captured through the automated process.

Stanton<sup>14</sup> noted in the Online Forum organized by the Secretariat (SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, 2011:11), according to the Vienna Convention on the Law of Treaties, a treaty can be interpreted only in the light of other rules of international law which are applicable to all the parties in the treaty being interpreted. In this sense, the WTO Panel has declined to consider the Cartagena Protocol as a useful instrument for the interpretation of the SPS Agreement.<sup>15</sup>

However, there is a theoretical tool to facilitate co-operation among the various international regimes. This tool facilitates the circulation of legal concepts and the modulation of too-rigid concepts, in accordance with the current interests of the international community. Consequently, it constitutes a legal mechanism for inter-organizational cooperation.

One of the main problems that judges or arbiters have to face in each dispute-settlement mechanism is the concept of “applicable law”, because they have been empowered to resolve disputes in the light of a specific law and are authorized only to apply a specific law. This is known as the “four corners scheme” and under this argument, the position of the Panel, mentioned here above, is understandable.

Regarding the above-mentioned legal mechanisms, the Goldschmidt *juridical use* theory argues that the judge or the arbitrator does not apply the foreign, extra-regime law, but looks at how the foreign norm has been interpreted and applied by the juridical authorities of the regime to which the norm belongs. The judge predicts the probable judgment, regarding the maximum possible probability,<sup>16</sup> ordered by a foreign judge (GOLDSCHMIDT, 1988:137).

Hence, the judge or the arbitrator does not apply the foreign law, but will imitate the probable judgement ordered by a foreign judge, in respect of the norm applicable to a specific case.

The juridical use theory defines the limits of the evolutive interpretation, since the judge or the arbitrator does not make an autonomous interpretation, but observes the interpretation made by foreign judges. This interpretation will be used by the judge or the arbitrator to inform the evolution of the legal term that is being interpreted. As Goldschmidt has highlighted, the foreign law enters the judge’s or the arbitrator’s regime as a *known fact*. Its nature implies that it is not a fact known by all, though it is truly accessible to all. For this reason, it is not necessary for the Parties to allege or approve it and it could be explored *ex officio* by the competent judge (GOLDSCHMIDT, 1988:145).

To sum up, according to this legal mechanism, a more fluent circulation of legal concepts among international organizations is predictable, but it would also be advisable that States use more frequently the compliance procedures and mechanisms under the Cartagena Protocol as a mechanism to stimulate their own jurisprudence and thus be able to influence international regimes at the same time.

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<sup>14</sup> Ms Gretchen Heimpel Stanton is a Senior Counsellor in the Agriculture and Commodities Division of the Secretariat of the World Trade Organization (WTO). She joined the Secretariat of the General Agreement on Tariffs and Trade (GATT) in 1985. During the Uruguay Round negotiations, she served as the Chairman of the Working Group that negotiated the Agreement on the Application of Sanitary and Phytosanitary Measures (the “SPS Agreement”). She is now Secretary of the WTO Committee on Sanitary and Phytosanitary Measures.

<sup>15</sup> European Communities – Measures Affecting the Approval and Marketing of Biotech Products, paragraph 7.75, (DS291, DS292, DS293).

<sup>16</sup> Scholars have distinguished different grades of probable notoriety of the foreign law (extra-regime), such as immediate, intermediate, accidental and remote. See GATTARI, C., La ley extranjera como hecho notorio. In *El Derecho*, Vol. 36, p. 913.

## **b.2 Political Mechanisms**

Regarding a possible political mechanism to ensure the compatibility and coherence of the Convention on Biological Diversity, in general, and the Cartagena Protocol, in particular, with other rules relevant to the handling, transport, packaging and identification of LMOs, a good political move would be to propose and support the identification of the CBD and the Cartagena Protocol as new and relevant international standards, under the umbrella of the SPS.<sup>17</sup>

However, this scenario is improbable, for many reasons. Taking into account that such recognition would imply a sort of mandatory nature for all WTO members;<sup>18</sup> and that the SPS Committee's decision-making is by consensus;<sup>19</sup> it is predictable that States that are not Parties to the CBD or the Cartagena Protocol will reject this proposition, since it implies the assumption of international obligations that have been rejected in other forums.

A second possibility is that the Parties to the Cartagena Protocol would inscribe the Cartagena Protocol standards in the SPS list of international standards, guidelines or recommendations applied by the WTO members.<sup>20</sup> At present this option is probably practiced by the members, since according to the WTO transparency principle, it constitutes a multilateral obligation.

Thirdly, the Parties to the Cartagena Protocol could promote the CBD Secretariat to the status of observer to the SPS Committee. This status would permit a closer working relationship between them. Generally, the SPS Committee takes decisions on granting observer status to organizations on the basis of consensus but it is also possible for a vote to be held where it has not been possible to reach consensus (WT/L/161 and its Annex 3). In such a case, the number of Cartagena Protocol Members would be sufficient to approve the observer status of the CBD Secretariat.

These alternatives could be classified as political mechanisms, since they imply increasing the influence of the CBD and the Cartagena Protocol on the World Trade Organization, which could signify a political change in international law. However, regarding the relation between environmental agreements and trade agreements, there are many points in which the international community has to address - such questions as intellectual property rights and traditional knowledge, scientific risk assessment and socio-economic considerations, etc.

## **b.3 Administrative Mechanisms**

Taking into account the suggestions made by Mr. Shcheglov (World Customs Organization), by Mr. Kusakawa (Food and Agriculture Organization of the United Nations) and by Mr. Kervella (United Nations Economic Commission for Europe) during the Online Forum organized by the CBD Secretariat (SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, 2011:12, 14, 16), the Secretariat may explore, through inter-agency administrative agreements, the possibility to strengthen inter-organizational cooperation, such as:

(1) To suggest the creation, under the umbrella of the World Customs Organization, of a new tariff position for LMOs and their different uses (FFP, contained use, intentional introduction into the environment).

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<sup>17</sup> See paragraph 3(d) of Annex A of the SPS Agreement.

<sup>18</sup> The presumption of legal agreement is recognized in two cases: directly, by Article 3, paragraph 2; and indirectly, by Article 5, paragraph 8 of the SPS Agreement.

<sup>19</sup> See Article 12, para. 1 of the SPS Agreement.

<sup>20</sup> See Article 12 para. 4 sentence 3 of the SPS Agreement.

(2) To share the International Portal on Food Safety, Animal and Plant Health with the FAO with a view to storing all available information on one web site.

(3) To advise to the “UN Committee on the Transport of Dangerous Goods” about LMO risks and, eventually, propose some adaptations to the UN Model Regulations to meet LMO needs and the purposes of the Cartagena Protocol.

#### **Section 4: General Conclusions and Recommendations**

The field of international standards, guidance and methods in the handling, transport, packaging and identification of LMOs is characterized by the fragmentation of the relevant international regulations. There are numerous relevant standards in different organizations and instruments, such as: the Codex Alimentarius Commission; the International Plant Protection Convention; the World Organization for Animal Health; the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations; the United Nations Centre for Trade Facilitation and Electronic Business; the Organization for Economic Co-operation and Development; the World Customs Organization; the United Nations Commission on International Trade Law; the World Trade Organization; and the Cartagena Protocol.

This suggests that it would be optimal to design, under the umbrella of the Cartagena Protocol, a new international standard unifying the best and most complete international norms to achieve the purposes of the Cartagena Protocol. Such a proposition is a traditional conclusion and a frequent recommendation of the concerned academic community. After more than 10 years of almost no progress in this field, however, the recommendation to develop a new standard could be described, at least, as naive.

For this reason, having carried out: a general revision of existing international standards, guidance and methods in the handling, transport, packaging and identification of LMOs; having identified possible gaps and inconsistencies among them; and having proposed several mechanisms and instruments to resolve the gaps and inconsistencies, we conclude that the existing international standards, guidance and methods are sufficient to achieve the purposes of the Cartagena Protocol. We are convinced that by adopting a combination of these mechanisms and instruments, transboundary movements of LMOs will be informed and safe.

Obviously, this is not the perfect scenario, but it constitutes an acceptable scheme in which States may continue to work. The biotechnology field represents a sensitive sector in which negotiations proceed slowly, so we believe that this is a period for using existing standards and sharing experience in their use. Maybe, in the future, the conditions will be more suitable for designing a new unified standard.

Although the Parties to the Cartagena Protocol share a general purpose and they are able to achieve the majorities needed to take decisions in other relevant international organizations;<sup>21</sup> regarding the approach and time of regulation, they are divided. These Parties are heterogeneous: some of them are mega-producers or big-producers of LMOs, whereas, in others, LMOs are forbidden. Regarding the territorial aspect, some countries are enormous and others are small islands. From an economic development perspective, there are developed countries, developing countries and less developed countries. According to CLIVE (2011) taking into account all the cultivated land with LMOs around the world, only 35.5% is situated in countries that have ratified the Cartagena Protocol. Consequently, all

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<sup>21</sup> See Column 2, 3 and 4 in the Table 1

these differences are reflected in the different approaches and different structural problems to be faced before applying new standards.

However, States should continue working on the construction of an international practice with a view to recognition of the precautionary principle as a general international principle or custom. This process is always slow, but it is the correct procedure to change the structure of international law.

Our recommendations are:

(1) Encourage States to continue using the Cartagena Protocol Commercial Invoice Model; or include in the traditional “bill of lading” the codes and recommendations developed by the World Customs Organization; the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations; and the Organization for Economic Co-operation and Development.

(2) Encourage States members of the Organization for Economic Co-operation and Development to develop a new standard for a unique identifier for micro-organisms and animals.

(3) Propose and support the identification of the Cartagena Protocol on Biosafety as a new relevant international standard, under the umbrella of the SPS Agreement (Article 12, Para. 4, Sentence 2 of the SPS and Article 3 (d) of the Annex A of the SPS Agreement).

(4) Encourage States to inscribe the Cartagena Protocol standards in the SPS list of international standards, guidelines or recommendations applied by the World Trade Organization members (Article 12, para. 4, sentence 3 of the SPS Agreement).

(5) Promote granting the CBD Secretariat observer status in the SPS Committee (WT/L/161 and its Annex 3).

(6) Suggest the creation, under the umbrella of the World Customs Organization, of a new “tariff position” for LMOs and their different uses (FFP, contained use, intentional introduction into the environment).

(7) Share the International Portal on Food Safety, Animal and Plant Health with FAO with a view to storing all available information on one web site.

(8) Offer advice to UN committee of experts on the transport of dangerous goods about LMO risks and, eventually, propose some adaptations to the UN Model Regulations to meet LMO needs and the purposes of the Cartagena Protocol.

(9) Encourage States to use more frequently the procedures and mechanisms on compliance under the Cartagena Protocol to enforce compliance with the Protocol’s requirements on the handling, transport, packaging and identification of LMOs and to create specific case law about Cartagena Protocol purposes.

(10) Encourage States to transfer technology from developed countries to developing and less developed countries with a view to improving capabilities to segregate and trace LMOs, and as a mechanism to facilitate LMO identification.

(11) Encourage States to create consumer education programs to widen general knowledge of LMOs, as a mechanism to facilitate the implementation and international recognition of LMO labelling.

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