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PROTOCOL ON BIOSAFETY

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Item 10 of the provisional agenda*

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

Note by the Executive Secretary

I. INTRODUCTION

1. Paragraph 3 of Article 18 of the Cartagena Protocol on Biosafety requires the Conference of the Parties serving as the meeting of the Parties to the Protocol to consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

2. 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 (LMOs) 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 organizations;
- (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 LMOs.

3. Accordingly, the Executive Secretary commissioned a consultant to carry out the work requested. The full report is available as information document UNEP/CBD/BS/COP-MOP/6/INF/24. Section II

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below contains a summary of the report. Section III provides some suggested elements for a draft decision.

II. SUMMARY OF THE REPORT ANALYSING INFORMATION ON STANDARDS RELEVANT TO THE HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

4. 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 regulation¹ 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.

5. This reality raises a contemporary problem which may be summarized as follows: 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?

6. The overall objective of the Report is thus to explore and describe ways and means to achieve the harmonization of standards, guidance and methods in the handling, transport, packaging and identification of LMOs. Methodologically, the Report is divided in two areas of consideration: transboundary movements of LMOs (trade logistics) and LMO labeling for consumers (marketing); it also distinguishes two categories of issues: legal gaps and legal inconsistencies.

1. Analysis of International Norms: Identification of Compatibilities, Legal Gaps and Legal Inconsistencies

1.1 Transboundary Movements of LMOs (Trade Logistics)

7. Firstly, regarding transboundary movements of LMOs (trade logistics), it may be affirmed that the international standards, guidance and methods concerning the commercial uses of maritime transport are globally compatible.² The bill of lading described for all of these instruments 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. However, a gap could possibly be found in the Hague Rules and their amendments, because they have not included the “description of the goods”. Nevertheless, this gap should be solved easily through legal interpretation, since 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. By the same token, 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, by systemic interpretation (see supra); secondly, recourse to evolutive

¹ See the Codex Alimentarius Commission (Codex); the International Plant Protection Convention (IPPC); the World Organization for Animal Health (OIE); the United Nations Recommendation on the Transport of Dangerous Goods – Model Regulations; the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT); the Organisation for Economic Co-operation and Development (OECD); the World Customs Organization (WCO); the United Nations Commission on International Trade Law (UNCITRAL); the World Trade Organization (WTO); and the Cartagena Protocol on Biosafety.

² See 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), 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).

interpretation is possible. The term *identification*³ may be interpreted in an evolutive sense, given that since 1924 the international community has developed several international rules regarding identification of goods,⁴ which shows a persistent interest in a wider identification of LMOs. Consequently, an effective solution would be to include a new box for “Final Use of the LMO” in the bill of lading.

8. With regard to the *identification of LMOs* during the transboundary movement, it is important to note that the existing international standards⁵ should be able to identify – generally, particularly and specifically – all the characteristics of living modified plants during transboundary movements. However, it must be remembered that the Organisation for Economic Co-operation and Development (OECD) has not developed a unique identifier for other types of genetically modified organisms such as microorganisms or animals. In those cases, only the Tariff Position defined by World Customs Organization and the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations could be used. All this information would be included in transport documents so that transboundary movements would be clearly informed.

9. With regard to *packaging of LMOs* during the transboundary movement, the shipper has the obligation to pack all goods properly, taking into account their nature – LMOs in the present case.⁶ Specifically, the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations – affirm that if an LMO is classified as toxic or infectious, it has to be packed in accordance with Instruction No. P620 or P650; and if an LMO is classified as “miscellaneous dangerous substances and articles including environmentally hazardous substances”, it has to be packed in accordance with Instruction No. P904.

10. Regarding the *transport of LMOs* during the transboundary movement, 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.⁷

11. Therefore, it may be concluded that the existing standards should be able to regulate LMO handling, packaging and transport conditions. However, beyond the general concordances among these international standards, there are also some gaps related to LMO trade logistics.

1.2 LMO Labeling for Consumers (Marketing)

12. Secondly, regarding LMO labeling for consumers (marketing), it may be affirmed that this topic is connected to different international regimes.⁸ In this field it is possible to discover a wider debate about the nature of “precaution”, since many norms of the Cartagena Protocol 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, and this situation represents an important legal inconsistency between international norms, even if the Cartagena Protocol calls for mutual supportiveness among trade agreements (such as the World Trade Organization Agreements) and environmental agreements.

³ See the phrase “Leading marks necessary for identification of the goods” included in Article III.3 of the Hague Rules.

⁴ Such as the WCO’s tariff position and the OECD’s “unique identifier” for transgenic plants.

⁵ See the Tariff Position defined by the WCO, 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) and the codes of the United Nations Recommendation on the Transport of Dangerous Goods – Model Regulation.

⁶ Article 3.5 of the Hague Rules could be interpreted systematically with its article 4.2 (n) and article 4.3.

⁷ See article 6 of the Hague Rules and article 32 of the Rotterdam Rules.

⁸ See the Cartagena Protocol, the World Trade Organization Agreements and the Codex Alimentarius Commission.

2. Solutions for Legal Gaps and Legal Inconsistencies

2.1 Solutions for Cases of LMO Trade Logistics

13. In the cases linked to transboundary movements of LMOs (trade logistics), several substantive actions are necessary:

- (a) Adoption of a new standard on unique identifiers for microorganisms and animals;
- (b) Ratification of international treaties in which international standards are included;
- (c) Taking into account that the ratification process of the Rotterdam Rules is very slow, it would therefore be better to continue working on existing agreements, such as the Hague Rules and their possible adaptation through legal interpretation;
- (d) Regarding the lack of communication about valid standards applicable in each country and about technical and scientific information managed by all the international organizations analysed, it would be interesting to formalize, through an inter-secretariat administrative agreement, the transformation of the International Portal on Food Safety, Animal and Plant Health developed by the Food and Agriculture Organization of the United Nations (FAO) into an inter-organizational project. This unified portal could be a virtual place where all information linked to LMOs and GMOs could be stored;
- (e) The Secretariat of the Convention on Biological Diversity may explore, through inter-agency administrative agreements, the possibility to strengthen inter-organizational cooperation, such as:
 - (i) To suggest the creation, under the umbrella of the World Customs Organization, of a new tariff position for LMOs and their different uses (for direct use as food or feed, or for processing (FFP); contained use; intentional introduction into the environment);
 - (ii) To share the International Portal on Food Safety, Animal and Plant Health with FAO with a view to storing all available information on one website;
 - (iii) To advise the UN Committee of Experts on the Transport of Dangerous Goods about LMO risks and, eventually, propose some adaptations to the UN Model Regulations.

2.2 Solution for Cases of LMO Marketing

14. In the cases linked to LMO labeling for consumers (marketing), procedural actions are necessary:

15. 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”, and the sanitary and phytosanitary (SPS) obligations linked to the Appellate Body’s rejection of “precaution” as a general international principle or custom.

16. Technically, if the term “insufficient scientific evidence”,⁹ is interpreted in an evolutionary spirit, taking into account the international community’s current interests contained in such international

⁹ See Article 5, paragraph 7, of the SPS Agreement.

instruments as the Cartagena Protocol, it would appear that the concept of precaution is evolving from a rigid to an intermediate concept.

17. 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. Consequently, the apparent inconsistency may be resolved through evolutive interpretation, but such a mechanism requires inter-organizational cooperation. Taking into account that no party has used the procedure to resolve possible cases, the purposes of the Cartagena Protocol still lack an international jurisprudential infrastructure, so 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 case law and thus be able to influence international regimes at the same time.

3. Conclusion and Recommendations

18. 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. 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. However, after more than 10 years of almost no progress in this field, the recommendation to develop a new standard could be described, at least, as naive.

19. For this reason, having made an extensive and deep legal study in the handling, transport, packaging and identification of LMOs, the Report concludes that the existing international standards, guidance and methods are sufficient to achieve the purposes of the Cartagena Protocol. By the adoption of a combination of these mechanisms and instruments, transboundary movements of LMOs will be informed and safe. 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.

20. The Report thus recommends the following actions:

(a) 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 Organisation for Economic Co-operation and Development;

(b) Encourage Member States of the OECD to develop a new standard for a unique identifier of microorganisms and animals;

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

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

(e) Promote granting the Secretariat of the Convention on Biological Diversity observer status in the SPS Committee (WT/L/161 and its Annex 3);

(f) 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);

(g) Share the International Portal on Food Safety, Animal and Plant Health with FAO with a view to storing all available information on one website;

(h) 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;

(i) 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;

(j) 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;

(k) 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.

III. SUGGESTED ELEMENTS FOR A DRAFT DECISION

21. Based on the above analysis, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to:

(a) Urge Parties and invite other Governments to continue to require the information for the identification of living modified organisms specified in paragraph 2 of Article 18 and related decisions to be incorporated into documentation accompanying their transboundary movement, such as the bill of lading or the commercial invoice, with consideration given to the templates annexed to decision BS-I/6;

(b) Encourage Parties and other Governments to continue to require the use of the United Nations Recommendations on the Transport of Dangerous Goods – Model Regulations and the Organisation for Economic Co-operation and Development’s system of unique identification for transgenic plants in the implementation of the documentation and identification requirements of paragraph 2 of Article 18;

(c) Encourage the Organisation for Economic Co-operation and Development to renew efforts to develop unique identification systems for living modified microorganisms and animals, further to paragraph 3 of section C of the annex to decision BS-I/6;

(d) Request Parties and invite other Governments to support, in meetings of the Sanitary and Phytosanitary Measures Committee of the World Trade Organization, the request of the Secretariat of the Convention on Biological Diversity for observer status in the Committee;

(e) Request the Executive Secretary to:

(i) Develop a proposal for the addition of new codes for living modified organisms and their different intended uses (direct use as food or feed, or for processing;

contained use; or intentional introduction into the environment) for inclusion in the next revision of the Harmonized Commodity Description and Coding System of the World Customs Organization;

- (ii) Continue collaborating with the Food and Agriculture Organization of the United Nations on the International Portal on Food Safety, Animal and Plant Health;

(f) Decide that, should any living modified organisms or specific traits of living modified organisms be identified as having adverse effects on the conservation and sustainable use of biological diversity pursuant to paragraph 5 of Article 16 of the Protocol, the Conference of the Parties serving as the meeting of the Parties to the Protocol may develop advice for the United Nations Committee of Experts on the Transport of Dangerous Goods and propose appropriate adaptations to the United Nations Model Regulations on the Transport of Dangerous Goods, Draft Recommendations;

(g) Encourage Parties to use, as appropriate, the procedures and mechanisms on compliance under the Cartagena Protocol on Biosafety to promote compliance with the Protocol's requirements on the handling, transport, packaging and identification of living modified organisms;

(h) Encourage Parties and other Governments to:

- (i) Support the recognition of the Cartagena Protocol on Biosafety standards in the list of international standards, guidelines or recommendations applied by Members of the World Trade Organization under the Agreement on the Application of Sanitary and Phytosanitary Measures;
- (ii) Transfer technology to developing countries with a view to building capacity in the identification of living modified organisms;
- (iii) Implement the programme of work on public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms as adopted in decision BS-V/13 in order to widen general knowledge about living modified organisms and requirements for their handling, transport, packaging and identification.
