

**Sub-Committee of Experts on the
Transport of Dangerous Goods**
(Nineteenth session,
2-6 July 2001, agenda item 6)

GENETICALLY MODIFIED ORGANISMS

Cooperation with the Conference of the Parties to the Convention on Biological Diversity Cartagena Protocol on Biosafety

Note by the secretariat

1. The Sub-Committee had been informed at its thirteenth session (7-17 July 1997) that an additional protocol to the Convention on Biological Diversity was under consideration, and that this Protocol was likely to include provisions concerning the international transport of genetically modified microorganisms and organisms (ST/SG/AC.10/C.3/26, paras. 130-134).
2. On the request of the Sub-Committee at that session, the secretariat drew attention of the secretariat of the Convention on Biological Diversity on the legally binding nature of transport regulations based on the Recommendations on the Transport of Dangerous Goods and of the risk of possible conflicts.
3. The "Cartagena" Protocol on Biosafety was adopted on 29 January 2000. It was open for signature until 4 June 2001, and is now open for accession. As of 25 June 2001, it had been signed by 103 States subject to ratification, ratified by 3 States and acceded to by one State, i.e. it counted 4 Contracting States. The entry into force of the Protocol requires the deposit of instruments of ratification, acceptance, approval or accession by 50 States or regional economic integration organizations that are Parties to the Convention on Biological Diversity (presently 180 Parties). Additional detailed information (including the text of the Protocol, etc.) may be found on the web site of the secretariat of the Convention on Biological Diversity (<http://www.biodiv.org>).
4. To prepare the entry into force of the Protocol, the Conference of the Parties to the Convention on Biological Diversity has established an Intergovernmental Committee for the Cartagena Protocol ("ICCP") which met for the first time in Montpellier, France, from 11-15 December 2000, and which will meet for the second time in Nairobi, Kenya, from 1-5 October 2001. ICCP was requested in particular to consider, at its first and second meetings, Article 18 of the Protocol which deals with handling, transport, packaging and identification of living modified organisms, and more precisely to address the following:
 - (a) Overview of relevant international rules and standards pertaining to handling, transport, packaging and identification; and
 - (b) Consideration of modalities for developing standards with regard to handling, transport, packaging and identification.
5. For this purpose, a meeting of technical experts on handling, transport, packaging and identification of living modified organisms has been established and the UNECE secretariat has been invited to participate in a session convened in Paris from 13-15 June 2001. The purpose of this session was to consider the needs and modalities for developing measures for Parties to meet their future obligations with regard to documentation accompanying living modified organisms intended for contained use and those intended for international introduction into the environment pursuant to paragraphs 2(b) and 2(c) of Article 18.

Article 18

6. The text of Article 18 of the Protocol is reproduced hereunder :

"Article 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.
2. Each Party shall take measures to require that documentation accompanying:
 - (a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;
 - (b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and
 - (c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.
3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall 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."

7. Article 18.2 (b) concerns living modified organisms that are destined for contained use, i.e. most cases covered, either as microorganisms or as organisms, by paragraph 2.6.3.1.4 (a) to (d) of the Model Regulations. It should be noted however that the Model Regulations contains appropriate conditions of transport only for cases referred to under 2.6.3.1.4 (a) and (d) since in the other cases ((b) and (c)) reference is made to the competent authorities.

8. Article 18.2 (c) concerns living modified organisms that are intended for international introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol. According to 2.6.3.1.4 (d), when such organisms are microorganisms, they are not subject to

the Model Regulations when authorized for unconditional use by the Governments of the countries of origin, transit and destination. For organisms other than microorganisms, it is not clear whether this case would be covered by 2.6.3.1.4 (b). In any case, it should be noted that the Protocol on Biosafety requires that such living modified organisms are handled, packaged and transported under conditions of safety (Article 18, para. 1), and that shipments should be accompanied with documentation identifying them as living modified organisms, specifying their identity and any requirements for safe handling, storage, transport and use.

9. Copies of all relevant sections of the 12th revised edition of the Model Regulations concerning living modified organisms (identification, classification, packaging, marking, labelling, documentation) have been made available to the Meeting of Experts.

10. Since the main topic under discussion was documentation, it has been found that the requirements of Article 18.2(b) and 18.2 (c) were mostly covered by the Model Regulations in certain cases (notably UN 3245), partially in other cases (UN 2814 and 2900, where the proper shipping name does not make any difference between microorganisms and genetically modified microorganisms) and not at all in the cases where reference is made to the competent authorities or where the organisms are not subject to the Model Regulations.

11. It was noted however that the Model Regulations could be amended to take account of the requirements of the Protocol on Biosafety, and the Meeting of Experts recommended to ICCP to invite the Sub-Committee of Experts on the Transport of Dangerous Goods to provide advice on its ability to assist Parties to the Convention on Biological Diversity to meet the requirements of Article 18.2 (b) and 18.2 (c) of the Protocol on Biosafety and its ability to adjust the Model Regulations.

12. The question whether UN 3172 could be used for organisms/microorganisms intended to release toxins was also raised during discussion at working group level.

13. A copy of the recommendations of the Meeting of Experts to ICCP (advance, unedited) is reproduced as an annex hereto.

14. The other organizations concerned by these recommendations are OECD for their seed certification schemes (www.oecd.org/ehs/icbg/biodiv.htm) and FAO for the International Plant Protection Convention (IPPC) and related standards (International Standards for phytosanitary measures: Guidelines for phytosanitary certificates) (Appendix V to the report of the third Interim Commission on Phytosanitary Measures (ICPM)) (web site : www.fao.org/ag/AGP/AGPP/PQ/).

15. Recommendations concerning the transport of animals, procedures for import/export of animals and international transfer and laboratory containment of animal pathogens are also contained in the International Animal Health Code (mammals, birds and bees) published by the "Office international des épizooties" (World organization for animal health) (available on OIE web site, www.oie.int). This code also contains model international veterinary certificates. The activities of OIE include also the standardisation of diagnostic tests and vaccines and harmonization of provisions related to the preparation, storage and distribution of various biological products.

16. The Sub-Committee may wish to consider how to cooperate with the Conference of the Parties to the Convention on Biological Diversity on the basis of the above information, bearing in mind that the use of existing documentation systems and the development of a new specific system of documentation for living modified organisms are still two options to be discussed by ICCP.

Annex

(unedited advance version, by courtesy of the secretariat of the Convention on Biological Diversity)

The Technical Experts' Meeting,

Having met to consider the needs and modalities for developing measures for Parties to the Protocol to meet their obligations under paragraphs 2 (b) and 2 (c) of Article 18 of the Article 18 of the Cartagena Protocol on Biosafety;

Recognizing that the Biosafety Protocol applies to the transboundary movement, transit, handling and use of all LMOs that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health,

Acknowledging that there are a range of international systems and documentation practices that may be relevant to Article 18.2 (b) and 18.2 (c);

Having identified during its deliberations three major options that may address the documentation requirements under Article 18.2 (b) and 18.2 (c), namely: i) existing documentation practices supplied by the originator; ii) existing international documentation systems; and, iii) a new documentation mechanism tailored on existing systems;

Having concluded that measures are required to assist Parties to meet their obligations under Article 18.2 (b) and 18.2 (c);

Noting the need for a simple, visible, legible and adequate documentation to meet the requirements of Article 18.2 (b) and 18.2 (c);

Recommends that

(a) ICCP considers the following options:

- (i) Parties use an accompanying document provided by the originator and/or existing international documentation systems that incorporate the information required under Article 18.2 (b) or 18.2 (c), as relevant, to enable Parties to fulfil their obligations as required in the Protocol (options (i) and (ii));
- (ii) Parties to keep under review and discuss the need to develop a new system of documentation under Article 18.2 (b) and 18.2 (c) (option (iii));

(b) International organizations responsible for the following instruments and other relevant international organizations be invited to provide advice on their ability to assist Parties to meet the requirements of Article 18.2 (b) and 18.2 (c) of the Protocol and their capacity to adjust their systems, should adjustment be necessary; IPPC , OECD seed certification, UN Model Regulations on TDG, Division 6.2 and Class 9.