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INTERGOVERNMENTAL GOMMITTEE FOR THE
CARTAGENA PROTOCOL ON BIOSAFETY
Third meeting
The Hague, 22–26 April 2002

COMMENTS BY JAPAN ON THE RECOMMENDATIONS OF THE INTERGOVERNMENTAL COMMITTEE FOR THE CARTAGENA PROTOCOL ON BIOSAFETY AT ITS SECOND MEETING

Note by the Executive Secretary

1. At the request of the Government of Japan, the Executive Secretary is circulating herewith, for the information of participants in the third meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, the comments of Japan on the on the recommendations of the Intergovernmental Committee for the Cartagena Protocol on Biosafety at its second meeting.

2. The paper is being circulated in the language and form in which it was submitted.

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Regarding the letter from the Secretariat of the Convention on Biological Diversity dated 7 November 2001, Japan, herewith, provides the following information in response to recommendations adopted by the second meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP);

1. Other Issues Necessary for Effective Implementation of the Protocol

Mechanisms to promote consideration of issues, exchange views, and provide guidance on issues requiring clarification arising during ratification and implementation of the Protocol.

(1) Categorization of Living Modified Organisms (LMOs)

It is necessary to clarify criteria for categorizing LMOs into three categories: "LMOs for intentional introduction into the environment," "LMOs intended for direct use as food or feed or for processing" (LMO-FFPs) and "LMOs for contained use." If the criteria for categorizing LMOs subject to the procedure required under the Protocol vary from Party to Party, a situation may arise in which an LMO subject to the AIA procedure in one country will not be subject to the AIA procedure in another, and vice versa. To avoid such situation which may result in trade or other disputes, it is essential that all Parties share the common understanding and practice in categorizing LMOs: they shall be classified in accordance with the definitions in the relevant Articles if the Protocol and reflecting their actual properties and use patterns.

In order to facilitate the consideration of the criteria, we would like to propose that a working group of technical experts examine examples of LMOs that could fall in two categories and therefore are difficult to determine to which category they should be classified, as well as products deriving from technological innovation, clearly indicating scientific justification and criteria. The results of the examination should be made available on the BCH as referential sample to the Parties, and elaborated by the subsidiary body stipulated in Article 30 of the Protocol, for adoption as guidance document by the Conference of the Parties. We do not, however, suggest that the text of the Protocol be amended to clarify the definitions of these categories.

(2) Risk Assessment and Risk Management

(a) While guided by consistent principles and guidelines, risk assessment should be conducted on a case by case basis depending on the characteristics of the environment to which an LMO will be

introduced and the characteristics of a gene inserted into the LMO. As technologies advance, there is a need to develop new scientific data for updating risk assessment. For these reasons, it seems impractical to develop detailed guidance for risk assessment apart from Annex III of the Protocol. It is rather practical to provide a mechanism to utilize the Roster of Experts which enables Parties to easily access and use most advanced scientific information relevant to each specific case.

Each Party should take into consideration scientific information already accumulated by other organizations, such as OECD, when it carries out risk assessment.

(b) The "detection and identification methods" stated in paragraph 9 (f) of Annex III should include the verification of the gene introduced into the LMO subject to "detection and identification" in light of the information on its specific primer. We are assuming that a Party which conducted risk assessment or made a decision to use a LMO domestically shall provide information on the primers of the LMO to other Parties in accordance with Article 20.3 (c), or in accordance with Article 11.1 and Annex II (e) if the LMO is classified as a LMO-FFP. It is also important to recognize intellectual property rights of the developers when such information is requested and handled by the BCH and /or Parties.

(c) In the process of developing genetically modified crops, by crossing a first generation LMO with various conventional varieties the second generation LMO can be obtained. Repeating this process, it is possible to select LMO varieties suitable for growing and marketing from among strains derived from the first generation LMO. In dealing with the environmental safety of these varieties, there can be two possible cases: to assume that all the strains (later generations) derived from the first generation LMO have no adverse environmental effects if any of these strains has been found to pose no risk to the environment; and, to assume that only strains derived from a strain found to pose no risk to the environment are environmentally safe (See the attached scheme). How far the result of the risk assessment of a strain applies in a group of strains sharing the same inserted gene may differ from Party to Party, which may hinder effective implementation of the Protocol. Therefore, we think it necessary to find a mechanism to collect information on how each Party deals with this problem for potential harmonization.

(d) Article 16 allows a Party to establish appropriate measures for risk management. Depending on the measures, there is a possibility to cause a trade dispute in the light of consistency with other international agreements such as the WTO agreements. In order to avoid such a dispute, the Secretariat should gather information on risk management system from the Parties and the

Parties should share information so as to take appropriate measures.

(3) Establishment of Harmonized Rules for Unique Identification System

(a) As internationally agreed rules for the appellation of LMOs are urgently needed for effective implementation of the Protocol, it is desirable to use an appropriate existing system, such as the Unique Identifier system that has been considered by OECD.

(b) To determine whether an LMO has already undergone risk assessment and been found not to pose environmental risk, the information about the primers in possession of its developer is essential for Parties of import. It is thus necessary that the developer or a country, be it a Party or non-Party, where the developer is located provide the relevant information to BCH. It is also important to recognize the intellectual property right of the developers when such information is requested and handled by the BCH and /or Parties.

(4) Transboundary Movements with Non-Parties

Based on the objective of the Protocol, the Parties should act positively towards letting non-Parties ratify the Protocol. In order to promote the objective of Article 24.1 of the Protocol, the Secretariat should gather and provide information on how non-Parties deal with transboundary movements of LMOs including their use of the AIA procedure.

(5) Review of Procedures for Implementation of the Cartagena Protocol

We believe it necessary to hold regular meeting of relevant officials after entry into force of the Protocol to exchange information on the operational practice of the Party in the implementation of the Protocol, to review the effectiveness of the procedure and, if necessary, to discuss on how to deal with the practical problems.

(cf.) Article 8 of the Protocol provides two ways to notify the competent national authority of the Party of import: one is directly from the exporter, and another is from the Party of export. It is anticipated that some problems in operation, which should be resolved, may occur after entry into force of the Protocol, e.g., route of notification, language barrier, etc..

(6) Article 7.4 of the Protocol provides that the advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as

being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

We believe it necessary to establish a mechanism and procedures to put the content of this paragraph into practice; for example, an expert group or a subsidiary body should be established to make recommendations to the MOP if a Party notifies the secretariat.

2. Information Sharing and the BCH

It is necessary to examine and define contents of information to be provided to the BCH.

(cf.) we think it necessary to identify if information that Parties are required to submit under Article 20.3 (c) of the Protocol include the information on the primers of an LMO.

3. Capacity-building(Roster of Experts)

The nomination forms of Drs. Tsuyoshi Mitamura, Akira Hasebe, Akihiro Hino shall be replaced by those attached. Dr. Toshiaki Kayano shall be deleted from the Roster.

4. Handling, Transport, Packing and Identification

(1) The definition of the terms and the criteria of the LMO-FFPs mentioned in the first sentence of Article 18.2 (a), in particular the interpretation of the term "may contain," should be thoroughly considered at the next meeting of experts taking into consideration activities and decisions of other relevant international bodies for providing ICCP with guidance on discussion of this Article.

(2) The "detailed requirements" which will be decided on the basis of the second sentence of Article 18.2 (a) should include a minimum set of information in a accompanying document with which Parties of import can determine if a commodity LMO has been confirmed to have no adverse effects on the environment. If the document does not have any information about the name and identity of the LMO, it would be difficult for the Parties of import to confirm its environmental safety. Therefore, it is essential that the document specifies the name and identity or identifier of all LMOs potentially contained in a cargo. However, we also recognize that requiring a list of the names and identity, or identifiers of all LMOs transported in bulk is impracticable. Therefore, to be pragmatic, we should request only information to the extent that the exporters of commodities can

obtain without significant difficulties.

As for an accompanying document, whether it is a commercial invoice or formal certificate will not affect the impact of commodities on the environment. We should decide on one suitable for the current practice of trading commodities.

(3) Cooperation with Relevant International Fora

We believe that discussion on the first and second sentence of Article 18.2 (a) should take into account the information from and activities of other relevant international fora, such as IPPC, UNRTDG and Consultative Group on International Agricultural Research (CGIAR) and endeavor to harmonize with them.

5. Compliance

(1) In paragraph 3 of section I of the compliance text, two phrases, "and common but differentiated responsibilities," "and take into account principle 7 of the Rio Declaration on Environment and Development, that States have common but differentiated responsibilities" should be deleted.

It is not clear why the operation of the compliance procedures and mechanisms should be based on the principles "common but differentiated responsibilities." Measures to address cases of non-compliance should be taken on a case by case basis, taking into account such factors as the cause, degree, frequency of non-compliance and the capacity of the Party concerned. In this context the precondition that responsibilities between developing country Parties and developed country Parties are different is not appropriate.

(2) In paragraph 2 of section II of the text, the phrase ", and ensuring a balance between importing and exporting countries" should be deleted.

There is no clear criterion for division between exporting and importing country under the Protocol.

(3) In subparagraph 2 (d) of section VI of the text, the phase "suspend the specific rights and privileges of the concerned Party under the Protocol (consistent with international law)" should be deleted.

Article 34 of the Protocol describes that compliance mechanisms adopted by the Conference

of the Parties serving as the meeting of the Parties to this Protocol (COP/MOP) should be cooperative and promote compliance with the Protocol. Therefore measures to suspend rights under the Protocol do not always conform to this provision.

Article 29 which describes the COP/MOP can not be interpreted as vesting the COP/MOP with competence to modify rights and obligations of the Parties under the Protocol. It can not be therefore interpreted that there are legal grounds for vesting The Compliance Committee established by the decision of the COP/MOP with such competence.
