



**CONVENTION ON
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CONFERENCE OF THE PARTIES TO THE CONVENTION
ON BIOLOGICAL DIVERSITY SERVING AS THE
MEETING OF THE PARTIES TO THE CARTAGENA
PROTOCOL ON BIOSAFETY

First meeting

Kuala Lumpur, 23-27 February 2004

Agenda item 6.10 of the provisional agenda*

**CONSIDERATION OF OTHER ISSUES NECESSARY FOR THE EFFECTIVE
IMPLEMENTATION OF THE PROTOCOL (E.G., ARTICLE 29, PARA. 4)**

Compilation of views submitted by Parties, other Governments and organizations

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SUBMISSIONS FROM GOVERNMENTS

AUSTRALIA

[22 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

Australia continues to support informal liaison and exchanges of view between Governments on issues that arise during ratification and implementation of the Protocol. This can take place in bilateral, regional and multilateral contexts. Australia would encourage Governments to take advantage of scheduled meetings and visits for this purpose.

A number of key decisions required by the Protocol are yet to be made. Australia therefore considers that in the short to medium term, the Conference of the Parties to the Convention on Biological Diversity serving as the first meeting of the Parties to the Cartagena Protocol on Biosafety, after entry into force, and the Secretariat should focus efforts on completing the essential work on those particular issues which are scheduled to be finalized by the Conference of the Parties to the Convention on Biological Diversity serving as the first meeting of the Parties to the Cartagena Protocol on Biosafety. At this stage it would be inappropriate to distract attention from resolving these issues by adding to the existing workload or creating new mechanisms to consider or clarify 'other issues'.

Australia is also concerned about the potential for duplication of work being undertaken by other competent international organizations, including the *Codex Alimentarius* Commission, the Organisation International des Epizooties and the International Plant Protection Convention.

Accordingly, Australia wishes to reaffirm its bracketing of the list of proposed issues for clarification contained in the decision of the third meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), that is:

- categorization of LMOs
- risk assessment and risk management
- establishment of harmonized rules for unique identification systems
- transboundary movements with non-Parties.

In the case of transboundary movement with non-Parties, Australia wishes to reaffirm the status of the negotiated text on Article 24, which contains explicit provisions for trade with non-Parties and about which there are no uncertainties in relation to implementation. For these reasons, the issue requires no clarification.

CANADA

[14 OCTOBER 2003]
[SUBMISSION: ENGLISH]

Canada sees the first and second meetings of the Parties to the Cartagena Protocol on Biosafety as critical decision-making fora for addressing issues that are impediments to the effective functioning of the Protocol and for provision of clarity on the operations of the Protocol that will establish conditions for States to effectively implement the Protocol and move to ratification of the Protocol. It is Canada's view that the obligations under Article 24 are adequately clear and we see no necessity for further Protocol

guidance on this issue. Therefore, Canada would not support the meeting of the Parties to the Cartagena Protocol on Biosafety undertaking additional work on Article 24.

EUROPEAN UNION

[21 OCTOBER 2003]
[SUBMISSION: ENGLISH]

”Other issues necessary for the effective implementation of the Protocol”

General introduction

In addition to the issues mentioned in the other EU submissions, there are three priority issues for the EC and its Member States on which decisions are necessary in order to ensure the effective implementation of the Cartagena Protocol:

- Risk assessment and risk management;
- Harmonized rules for unique identification systems; and
- Relationships with non-Parties.

On all these issues, the EU wishes to recall its former submission of January 2002, and to add the following remarks.

Concerning risk assessment and risk management

One of the core issues in the Cartagena Protocol is the advance informed agreement procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of LMOs into their territory. It is thus essential for the effective implementation of the Protocol that parties of import are actually capable of reaching such informed decisions. An important prerequisite for this is knowing how to perform risk assessment of LMOs. Guidance on how to act on the results of the risk assessment, the risk management phase, is also an important element in reaching an informed decision.

For these reasons, MoP1 should start a process to collect existing guidance material in order to draft further guidance on risk assessment and risk management, where necessary and avoiding duplication. The EU supports the development of guidance documents for risk assessment and risk management. The work on these topics should benefit from and, in our point of view, be based on existing material from countries that already have such guidance. Other internationally developed guidelines should also be used as reference material, e.g. UNEP guidelines on risk assessment and risk management.

The EU can contribute the following material:

- Annex II (Principles for the Environmental Risk Assessment), with the relevant guidance notes, and Annex VI (Guidelines for the Assessment Reports) to Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms;
- Annex III (Safety assessment parameters to be taken into account, as far as they are relevant, in accordance with Article 6 (3)), with the relevant guidance notes, to Directive 90/219/EEC on the contained use of genetically modified micro-organisms; and

- the preliminary guidance document from the EU's Scientific Steering Committee on the information needed for the risk assessment of genetically modified plants and derived food and feed.

Concerning harmonized rules for unique identification systems

The presentation of the "OECD Guidance for the designation of a unique identifier for transgenic plants" has considerably advanced work on a coherent, internationally agreed system of unique identification as an important tool which facilitates risk assessment and makes more effective risk management in the field of biosafety, including for the correct identification of LMOs.

The EU supports the unique identifier that the OECD has presented and welcomes the establishment of further international work, possibly under the OECD Working Group, to examine the issue of unique identification systems for micro-organisms and animals, not yet addressed.

The EU is of the opinion that the first meeting of the Parties to the Cartagena Protocol on Biosafety should take a decision which endorses the OECD's unique identifier for transgenic plants as part of the system to identify LMOs and which, in the absence of a unique identifier for micro-organisms and animals before the first meeting of the Parties to the Cartagena Protocol on Biosafety, includes a wording that will ensure the best possible coverage of micro-organisms and animals, or at least operative paragraphs to ensure swift development of a complete system.

Concerning relationships with non-Parties

The implementation of Article 24 will be highly relevant during the early stages of the activities of the Cartagena Protocol.

Due to the fact that a number of signatories to the Protocol as well as other countries, will be non-Parties at the Conference of the Parties to the Convention on Biological Diversity serving as the first meeting of the Parties to the Cartagena Protocol on Biosafety, the EU believes that it is important to address the implementation of Article 24 at the first meeting of the Parties to the Cartagena Protocol on Biosafety. In particular, the EU believes that it is important that the first meeting of the Parties to the Cartagena Protocol on Biosafety provides guidance in order to ensure:

- that Parties know how to act in relation to non-Parties,
- that non-Parties, especially those which are signatories, are informed about the approach taken by Parties, and
- the coherent application, to the extent possible, of Article 24.

The EU submitted its preliminary views on these important issues in January 2002. In that submission, the EU proposed that the meeting of the Parties to the Cartagena Protocol on Biosafety MoP provide guidance to Parties and non-Parties. The EU believes that such guidance from the first meeting of the Parties to the Cartagena Protocol on Biosafety should be limited to what is essential for the basic operations of the Protocol, including guidance for the Parties, non-Parties and the Secretariat. Such guidance might address for example the meaning of "consistent with the objective of the Protocol", the relevance of certain provisions of the Convention on Biological Diversity, in particular Article 8 (g) and Article 19.4, and how to implement the basic obligations of the Protocol in relation to non-Parties.

The main elements for such guidance were outlined in our previous submission (see doc. UNEP/CBD/ICCP/3/INF/7, page 5). The EU is of the opinion that any such guidance should cover LMOs for intentional introduction into the environment, LMOs for use as food, feed or processing and LMOs intended for contained use.

SWITZERLAND

[26 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

4.1.7 Other issues necessary for effective implementation of the Protocol

We would like to reiterate our proposal made at the third meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) for a mechanism to promote consideration of issues, exchange views, and provide guidance on issues requiring clarification arising during ratification and implementation of the Protocol. Such a mechanism will have to meet the criteria of efficiency, effectiveness, and transparency.

Under this mechanism, we recommend the establishment by first meeting of the Parties to the Cartagena Protocol on Biosafety of a standing advisory board (hereinafter the Advisory Board), composed of 15 highly recognized experts representing all five United Nations regions (three per region). The members of the Advisory Board should act in their personal capacity. They should be nominated by the relevant region. They should serve for a period of two years and be eligible for a maximum of one consecutive term. The main task of the Advisory Board would be to consider issues, exchange views, and provide draft guidance on scientific and technical issues requiring clarification identified by Parties and Governments during the ratification and implementation of the Protocol.

Parties and Governments that have identified technical and scientific issues requiring clarification during ratification and implementation of the Protocol should provide them in writing to the Secretariat. The Secretariat, after consultation of the Bureau, should transmit those requests to the Advisory Board for draft guidance. The draft guidance should then be submitted to the meeting of the Parties to the Cartagena Protocol on Biosafety for consideration.

UNITED STATES OF AMERICA

[21 OCTOBER 2003]
[SUBMISSION: ENGLISH]

**Views of the United States on Consideration of Other Issues Necessary
for Effective Implementation of the Biosafety Protocol (Article 29)**

The United States believes that Parties to the Cartagena Protocol on Biosafety urgently need to focus on those issues of immediate importance for implementing the Protocol. As a member of the former Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), the United States consistently urged that the ICCP's limited resources be directed toward those provisions that had to be in place by the time the Protocol entered into force.

Now that the Protocol is in force (effective September 11, 2003), we believe it is even more important that Parties concentrate on the essential tasks of implementing the Protocol, as outlined in the Secretariat's notice of 5 September 2003 (SCBD/BS/CS/WD/jh/36477).

We would caution against creating mechanisms to re-open old issues that might distract attention from these obligations. Common standards for risk assessment, harmonized rules for unique identification systems and transboundary movements of LMOs involving non-Parties were all contentious issues resolved by Governments at the final Protocol negotiations in Montreal in January, 2000.

Allowing these issues to be re-opened would risk re-opening the Protocol text to negotiation, a development that would surely divert resources away from the urgent need for implementation.

We are also concerned about raising issues now that we believe to be premature in light of the extremely limited practical experience in implementing the Protocol. Until Parties acquire a reservoir of actual experience in executing the requirements of the Protocol, we would caution against establishing an open-ended implementation body ("Protocol Committee") or a standing advisory body of "distinguished experts" from the five United Nations regions. These proposals can be better assessed after Parties have had an opportunity to gain some practical working experience with Protocol implementation.

SUBMISSIONS FROM ORGANIZATIONS

WWF INTERNATIONAL

[30 SEPTEMBER 2003]
[SUBMISSION: ENGLISH]

Item 6.10 - Consideration of other issues necessary for the effective implementation of the Protocol (e.g., Article 29, para.4)

WWF welcomes the recommendation of the Intergovernmental Committee for the Cartagena Protocol on Biosafety to the first meeting of the Parties to the Cartagena Protocol on Biosafety, as set out in decision 3/8, concerning other issues for effective implementation, and supports retention of all the bracketed text contained in this decision (i.e. retention of bracketed paragraphs 3, 4 and 8, and bracketed text in paragraph 7 of decision 3/8).

In relation to paragraph 3, WWF notes the need for a standardized and thorough system of identification for all LMOs, including LMOs for food, feed or processing (LMO-FFPs), and suggests that the first meeting of the Parties to the Cartagena Protocol on Biosafety should decide to move ahead with adoption of a system of unique identification in relation to LMO-FFPs, and that consideration be given by the meeting of the Parties to the Cartagena Protocol on Biosafety to extending unique identification to cover all LMOs subject to transboundary movements. Application of this system to all LMOs would assist measures to ensure traceability of LMOs (see comments on provisional agenda item 6.4).

In relation to paragraph 4, WWF believes that it could be useful for the meeting of the Parties to the Cartagena Protocol on Biosafety to provide guidance on the issues of risk assessment and risk management, and that such guidance should be facilitative and not prescriptive.

In relation to paragraphs 7 and 8, WWF feels that it is important for the meeting of the Parties to the Cartagena Protocol on Biosafety to address the issue of transboundary movement of LMOs and LMO-FFPs between Parties and non-Parties, and to provide guidance to Parties on this issue.

In addition to the issues covered in the recommendation to the first meeting of the Parties to the Cartagena Protocol on Biosafety contained in decision 3/8, WWF also suggests that the first meeting of the Parties to the Cartagena Protocol on Biosafety consider:

- setting out guidelines on minimum requirements for legal, institutional and administrative measures to fulfil the provisions of the Protocol with regard to the safe transfer, handling and use of LMOs and LMO-FFPs, including minimum requirements in relation to risk assessment, risk management, and enforcement, and public awareness raising (see comments on provisional agenda item 6.1).
- addressing how to apply the Ecosystem Approach (decision V/6 of the Conference of the Parties to the Convention on Biological Diversity) in the implementation of the Cartagena Protocol (and particularly

in relation to adaptive management); and how take into account developments in other relevant areas of the Convention on Biological Diversity, such as ongoing work on alien and invasive species.
