



## CONVENTION ON BIOLOGICAL DIVERSITY

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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, PARAGRAPH 4)**

*Note by the Executive Secretary*

#### **I. INTRODUCTION**

1. In accordance with its work plan, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) considered, at its second meeting, “other issues necessary for the effective implementation of the Protocol (e.g., Article 29, paragraph 4)”, and made recommendations. The term “other” as used in the work plan of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, was understood to mean issues not specifically identified in the work plan. The work plan mentioned, as an example, Article 29, paragraph 4, which entrusts the Conference of the Parties serving as the meeting of the Parties to the Protocol with a responsibility to regularly review the implementation of the Protocol and to take the necessary decisions to promote its effective implementation. With that understanding, the Intergovernmental Committee for the Cartagena Protocol on Biosafety has considered a number of issues other than those specified in its work plan and made efforts to address them in order to lay the ground work for future consideration, elaboration and adoption by the Conference of the Parties serving as the meeting of the Parties to the Protocol once the Protocol comes into force.

2. The main recommendations were related to mechanisms to promote consideration of issues requiring clarification arising during ratification and implementation of the Protocol, and to items to be included in a medium-term programme of work for the Conference of the Parties serving as the meeting of the Parties to the Protocol and its relevant subsidiary bodies. The second meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety also discussed the question whether it was desirable to address some technical issues identified by certain representatives. However,

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the meeting could not reach a consensus on whether there is a need to look into these scientific and technical issues.

3. At its third meeting, the Intergovernmental Committee for the Cartagena Protocol on Biosafety considered a synthesis of comments and views on mechanisms that could possibly be used to promote the consideration of issues that require clarification, and on the types of issues that may be considered through these mechanisms, bearing in mind the absence of consensus on that at its previous meeting. It also considered a draft medium-term programme of work for the Conference of the Parties serving as the meeting of the Parties to the Protocol prepared by the Executive Secretary based on the core elements identified by the ICCP itself and submissions made by a few Governments. ICCP has made several recommendations that refer, among other things, to mechanisms that might be utilized by the Conference of the Parties serving as the meeting of the Parties to the Protocol to consider, where appropriate, technical and scientific issues associated with the implementation of the Protocol and identified by Parties and other Governments, and a medium-term programme of work for the Conference of the Parties serving as the meeting of the Parties to the Protocol. ICCP had also considered the specific issues raised at its previous meeting such as guidance on transboundary movements of living modified organisms (LMOs) between Parties and non-Parties, and the need for categorization of LMOs as proposed by certain Parties to the Convention for consideration and clarification. The differences reflected during the second meeting still persisted and no consensus was achieved on recommendations.

4. This note presents a summary of the issues raised and recommendations made by the ICCP in addressing the item, "Consideration of other issues necessary for effective implementation of the Protocol (e.g. Article 29, paragraph 4)". The note presents: (i) the recommendations of the ICCP as regards possible mechanisms that the Conference of the Parties serving as the meeting of the Parties to the Protocol might wish to consider for the purpose of facilitating the consideration of technical and scientific issues associated with the implementation of the Protocol, including a synthesis of further views (section II); (ii) a summary of issues identified by some Parties and Governments as requiring clarification and common understanding, and a synthesis of additional views on those issues (section III); (iii) conclusion and background to the proposed elements of draft decisions (section IV); and finally, (iv) elements of a draft decision suggested by the Executive Secretary for the consideration of the Conference of the Parties serving as the meeting of the Parties to the Protocol (section V).

5. By 22 October 2003, submissions were received from Australia, Canada, the European Union, Switzerland, the United States of America, and WWF International. The full texts of the submissions have been compiled and made available in an information document on the consideration of other issues necessary for the effective implementation of the Protocol (UNEP/CBD/BS/COP-MOP/1/INF/10).

6. A separate note regarding a medium-term programme of work has also been prepared in accordance with the relevant recommendations of the second and third meetings of the ICCP and made available in the note by the Executive Secretary on medium term programme of work of the Conference of the Parties serving as the meeting of the Parties to the Protocol (UNEP/CBD/BS/COP-MOP/1/14).

## **II. MECHANISMS TO PROMOTE THE CONSIDERATION OF TECHNICAL AND SCIENTIFIC ISSUES**

7. Under the item "Consideration of other issues" ICCP has had the opportunity to raise and examine as many issues as it deems appropriate and necessary for enhancing the ratification and entry

into force of the Protocol on the one hand, and its effective implementation, on the other, following entry into force. <sup>1/</sup>

8. One of those issues that have been extensively addressed by ICCP was the question of mechanisms to promote the consideration of other issues necessary for the effective implementation of the Protocol. ICCP looked at a range of existing and potential arrangements which the Conference of the Parties serving as the meeting of the Parties to the Protocol might wish to consider for the purpose of using one or more of these arrangements as mechanisms for identifying, clarifying and exchanging views as regards scientific and technical issues that may be arising in the implementation of the Protocol. For example, in the case of the Convention, the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) is established to provide the Conference of the Parties with timely expert advice relating to the implementation of the Convention. The question is whether it is feasible and desirable to use SBSTTA as a mechanism also for the Protocol to deal with scientific, technical and technological matters or it would be better to look for a mechanism specific to the Protocol. In that regard, ICCP has identified and explored a range of options for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol.

9. ICCP recommended that the Conference of the Parties serving as the meeting of the Parties to the Protocol utilize mechanisms under the Protocol or the Convention to consider, where appropriate, technical and scientific issues associated with implementation identified by Parties and other Governments as requiring clarification, exchange views and, where appropriate, seek and/or develop draft guidance or clarifications for the consideration of the Conference of the Parties serving as the meeting of the Parties to the Protocol. It considered that such mechanisms could include, *inter alia*:

- (a) Meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
- (b) Monitoring and reporting in accordance with Article 33;
- (c) Subsidiary bodies established in accordance with Article 30 and/or Article 29 paragraph 4 (b);
- (d) Inter-sessional activities;
- (e) The services and cooperation of, and information provided by international organizations and intergovernmental and non-governmental bodies with competence in biosafety issues;
- (f) Periodic assessment and review of the Protocol and its annexes and adoption of amendments, in accordance with Article 35;
- (g) Compliance procedures and mechanisms established in accordance with Article 34;
- (h) The biosafety roster of experts established by decision EM-I/3, paragraph 14, of the Conference of the Parties;

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<sup>1/</sup> The miscellaneous issues addressed under this item (other than the question of mechanisms) include scientific and technical issues arising from the Protocol and that need further consideration and clarification; urging Parties to the Convention to ratify or accede to the Protocol; calling upon States that are not Parties to the Convention to ratify or accede to the Convention so as to be able to become Parties to the Protocol; inviting Parties, as well as non-Parties, to designate national focal points and competent authorities for the Protocol; and items to be included in a medium term programme of work of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

- (i) The Biosafety Clearing-House established in accordance with Article 20;
- (j) The decision-making procedures and mechanism, for paragraph 7 of Article 10;
- (k) Regional networks and centres of excellence with competence in biosafety issues; and
- (l) Visits, and other informal liaison and exchange of views;

10. One of the submissions received in preparation for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol reiterates the view, which was submitted to the third meeting of the ICCP, that a standing advisory board composed of 15 highly recognized experts representing the five regions of the United Nations should be established as a mechanism to promote consideration of issues, exchange views, and the development of draft guidance on issues arising during the implementation of the Protocol and requiring clarification. It is suggested that members of the advisory board would act in their personal capacity. On the other hand, another submission suggests that it is premature to bring up the idea of establishing an open-ended implementation body ("Protocol Committee"), or a standing advisory body of limited number of experts before Parties have had an opportunity to gain some practical experience with the implementation of the Protocol. The view submitted for the third meeting of the ICCP in favour of informal liaison and exchange of views, using the advantage of scheduled meetings and visits, has also been reiterated.

### **III. A SYNTHESIS OF VIEWS ON ISSUES THAT MAY NEED CONSIDERATION AND FURTHER CLARIFICATION**

11. At the second meeting of the ICCP, few issues, which were believed to require consideration and further clarification, were identified. These issues were: (a) categorization of living modified organisms; (b) approaches for risk assessment and risk management; (c) establishment of harmonized rules for unique identification systems; and (d) transboundary movements with non-Parties. The discussions of the ICCP on these issues could not lead to any consensus of views. This was reflected in the reports of the second and third meetings of the ICCP where the relevant recommendations remained under square brackets (recommendation 2/6 paragraph 1, and recommendation 3/8 paragraphs 3, 4, 7, and 8 (a) and (b)).

12. Taking into account the request by some countries to address the need for criteria for categorization of LMOs according to their intended use, ICCP had invited, at its third meeting, Parties to provide their views on operational experience on that issue. However, no views were submitted on this matter.

13. Some submissions suggest that in the short to medium term, the Conference of the Parties serving as the meeting of the Parties to the Protocol should focus on resolving issues that are required by the Protocol to be addressed within a specific timeframe. It is further suggested that issues that are required to be dealt with by the Conference of the Parties serving as the meeting of the Parties to the Protocol, at its first meeting or immediately thereafter, are extensive enough to occupy the Conference of the Parties serving as the meeting of the Parties to the Protocol for the coming few years. The submissions advise against overstretching and distracting the Conference of the Parties serving as the meeting of the Parties to the Protocol by adding the consideration of other issues to its workload, which is already heavy. In that regard, the submissions express their opposition to the consideration of the list of issues identified by other representatives and reaffirmed the square brackets put around these issues during the second and third meetings of the ICCP. There is also a concern expressed in one of these submissions that considering these issues might duplicate work that is being undertaken by other international

organizations, including Codex Alimentarius Commission, World Organisation for Animal Health/Office International des Epizooties (OIE), and the International Plant Protection Convention.

14. One of the submissions reminds Parties and other Governments that common standards for risk assessment and risk management; harmonized rules for unique identification systems; and transboundary movements of LMOs involving non-Parties, were all contentious issues resolved by Governments during the final stages of the negotiations of the Protocol, and, therefore, according to this submission, further consideration of these issues would risk re-opening the text of the Protocol for negotiations. Views were also expressed in two other submissions against any consideration of the issue of non-Parties. According to these submissions the issue of non-Parties as provided for under Article 24 of the Protocol is sufficiently clear and does not require further clarification.

15. On the other hand, other submissions take risk assessment and risk management, harmonized rules for unique identification systems, and relationship with non-Parties, as important priority issues on which decisions would be necessary to ensure effective implementation of the Protocol. One of these submissions recalls the view submitted to ICCP, at its third meeting, regarding these issues and provides some more elements in addition to the previous submission. The various views expressed on each of these specific issues, are summarized below.

**A. *Risk assessment and risk management***

16. One submission stated that knowledge on how to perform risk assessments of LMOs and how to act on the result of the risk assessments as important prerequisites for Parties of import under the Protocol to be able to make informed decisions. It suggested that it would be necessary to look together at all the provisions of the Protocol relevant to risk assessment, including annex III, and further clarify the issues arising relating to concepts or methodologies, taking into account the work of other relevant organizations, and the increasing experience in the designing and application of risk assessment methods worldwide. Proposals on the possible techniques for elaborating the issues and creating common approaches include:

(a) The development of standard formats for summaries of risk assessment that need to be made available to the Biosafety Clearing-House in accordance with the requirement of Article 20, and for risk-assessment reports required under annexes I and II of the Protocol;

(b) The development of a framework for a common approach in environmental risk assessment; and

(c) The consolidation of scientific knowledge relevant to risk assessment, taking the Biosafety Clearing-House as the central means for undertaking such organization of knowledge available.

17. In this connection, one other submission advises on the need to integrate the various processes that are under way in some countries and international organizations to develop standards for risk assessment and risk management.

18. With regard to risk management, one suggestion made is to use a step-wise approach, starting by gathering information on mechanisms, measures and strategies established to manage and control risks associated with living modified organisms by Governments as well as relevant international organizations. The objectives, according to the submission, should be to develop mutual understanding and meet the requirements of the Protocol, in particular paragraph 5 of Article 16, under which Parties are to cooperate with a view to identifying living modified organisms or their specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into

account risks to human health, and taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

19. The submission proposes that the Conference of the Parties serving as the meeting of the Parties to the Protocol should start collecting existing guidance materials from countries and relevant international organizations such as UNEP in order to develop a consistent guidance material that ensures a common approach on risk assessment and risk management. For this purpose the submission identifies specific guidance materials that may contribute to developing the guidance document under the Protocol.

#### ***B. Establishment of harmonized rules for unique identification systems***

20. It was emphasized that “unique identification” should be one of those issues requiring clarification for the effective implementation of the Protocol though the reference to it in the Protocol is limited only to annex II and paragraph 2 (a) of Article 18. The same submission points out that if a unique identifier of a certain living modified organism were to be truly and unequivocally unique, it is necessary to harmonize the various identification systems at the international level.

21. The submission supports the OECD unique identification system as an important tool, which facilitates risk assessment and makes more effective risk management in the field of biosafety, including for clear identification of LMOs. It is in favour of further international work to examine the issue of unique identification systems for micro-organisms and animals, which do not have any unique identifiers yet. It suggests that the Conference of the Parties serving as the meeting of the Parties to the Protocol should take a decision endorsing the OECD’s unique identifiers for transgenic plants as part of the system to identify LMOs, and calling for the development of similar unique identifiers for micro-organisms and plants.

#### ***C. Transboundary movement between Parties and non-Parties***

22. The submission on this issue is quite extensive and includes proposed elements of a possible recommendation. It is argued that the issue of non-Parties under Article 24 would be highly relevant immediately after the entry into force of the Protocol, as many countries would still remain non-Parties. The submission favours action in accordance with Article 24 at the earliest convenience that ensures a coherent application of the provisions by letting Parties to the Protocol know how to act *vis-à-vis* non-Parties, and informing the latter, in particular those signatories to the Protocol, of the “standards” that Parties are going to apply in this respect. It is suggested, as a first step, that guidance should be provided to Parties, as well as non-Parties, in the form of a recommendation concerning transactions of living modified organisms intended for intentional introduction into the environment. The submission advises a step-wise treatment and improvement of the relationship with non-Parties, taking also into account the different situations of non-Parties as exporting or importing countries of living modified organisms.

23. With regard to the structure of the recommendation that the Conference of the Parties serving as the meeting of the Parties to the Protocol might wish to consider in addressing the issue of non-Parties, the submission proposes that it be divided into: (i) a preamble; (ii) a section containing recommendations to Parties; (iii) a section on recommendations to non-Parties; and (iv) a section on the Secretariat. The suggested elements of the recommendation that would address non-Parties include, encouraging them to adhere to the Protocol, to implement the provisions, and in particular to make available appropriate information to the Biosafety Clearing-House, to observe the advance informed agreement procedure, to designate a national focal point and to inform the Secretariat of their competent national authorities, voluntarily.

#### IV. CONCLUSION AND BACKGROUND TO THE PROPOSED ELEMENTS OF A DRAFT DECISION

24. As pointed out earlier, ICCP has considered a number of issues under this item. By the time ICCP concluded its meetings, three major issues were clearly identified and recommended to be submitted to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol for its consideration. These sets of issues were: (i) medium-term programme of work for the Conference of the Parties serving as the meeting of the Parties to the Protocol; (ii) issues of scientific and technical nature that might need further consideration and clarification; (iii) mechanisms for the consideration of these scientific and technical issues. As indicated in the first section of this document, the issue relating to the medium-term programme work is now presented as a separate item in the note by the Executive Secretary on the same subject (UNEP/CBD/BS/COP-MOP/1/14). Therefore, this note and the draft decision suggested in section V below address the last two sets of issues.

25. The elements of the draft decision include recommendation 3/8 of the ICCP regarding mechanisms to consider other issues; draft guidance on the transboundary movement of LMOs between Parties and non-Parties prepared on the basis of submissions; and other elements that the Executive Secretary feels appropriate to be considered by the Conference of the Parties serving as the meeting of the Parties to the Protocol at this stage in order to follow up the discussions that have transpired during ICCP.

#### V. DRAFT DECISION

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may wish to consider adopting a decision along the following lines:

*The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,*

*Noting* the range of mechanisms recommended by the ICCP to be utilized, as appropriate, for the purpose of considering, and clarifying scientific and technical issues associated with the implementation of the Protocol;

*Recognizing* the difficulty involved in building a common view on what scientific and technical issues may need to be addressed at this stage, in order to enhance the effective implementation of the Protocol by creating a common understanding and approach to these issues;

*Recognizing further* the need for and the advantages of developing and implementing various tools such as common formats, guidance documents, and frameworks for harmonized or common approaches, with regard to several scientific and technical concepts and requirements included in the Protocol,

1. *Decides* to use, as appropriate, all mechanisms available for considering scientific and technical issues arising from the Protocol, and formulating consensual views and common guidance necessary for the effective implementation of the Protocol. These mechanisms include:

(a) The meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

(b) The monitoring and reporting process in accordance with Article 33;

(c) Subsidiary bodies established in accordance with Article 30 and/or Article 29 paragraph 4 (b);

(d) Inter-sessional activities;

(e) The services and cooperation of and information provided by international organizations and intergovernmental and non-governmental bodies with competence in biosafety issues;

(f) Periodic assessment and review of the Protocol and its annexes and adoption of amendments, in accordance with Article 35;

(g) Compliance procedures and mechanisms established in accordance with Article 34;

(h) The biosafety roster of experts;

(i) The Biosafety Clearing-House;

(j) The decision-making procedures and mechanism, for paragraph 7 of Article 10;

(k) Regional networks and centres of excellence with competence in biosafety issues; and/or

(l) Visits, and other informal liaison and exchange of views;

2. *Decides* to consider, at its second meeting, the need for designating or establishing a permanent subsidiary body that provides the Conference of the Parties serving as the meeting of the Parties to the Protocol with timely advice on scientific and technical issues arising in relation to the implementation of the Protocol;

3. *Adopts* the guidance on transboundary movement of LMOs with non-Parties annexed to the present decision;

4. *Invites* Parties, other Governments, and relevant international organizations to submit their views to the Executive Secretary, not later than five months prior to the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, regarding what other scientific and technical issues may need to be addressed as a matter of priority in order to formulate common approaches towards these issues and to promote the effective implementation of the Protocol;

5. *Requests* the Executive Secretary to synthesize the views that may be received in accordance with paragraph 4 above and submit a report to the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.



*Annex*

**GUIDANCE ON THE TRANSBOUNDARY MOVEMENT OF LIVING MODIFIED ORGANISMS BETWEEN PARTIES AND NON-PARTIES**

*Recalling* Article 24 of the Protocol, which requires that transboundary movements of LMOs between Parties and non-Parties be consistent with the objective of the Protocol and that Parties encourage non-Parties to adhere to the Protocol,

*Acknowledging* that the achievement of the objective of the Protocol depends not only on the compliance of Parties to the Protocol, but also on good faith participation and wide cooperation of States non-Parties to the Protocol with Parties, in particular as regards information sharing through the Biosafety Clearing-House,

*Recognizing* the need to keep non-Parties informed of the process of implementation of the Protocol on the one hand, and to take into account their views as regards transboundary movement of LMOs between Parties and non-Parties, on the other,

*Recalling* the relevant provisions of the Convention on Biological Diversity, in particular Articles 8 (g), which requires each Party to the Convention to regulate, manage and control the risks associated with LMOs, and Article 19, paragraph 4 which calls upon each Party to the Convention to ensure the provision of available information, regarding the use, potential adverse impact and safety of these organisms, to another Party into which the organisms are intended to be introduced,

*Recognizing* the need for and advantages of providing general guidance to Parties to the Protocol on how to handle transboundary movements of LMOs with non-Parties in ensuring a coherent approach in the implementation of Article 24 of the Protocol and facilitating the participation of non-Parties in the Protocol process,

*The Conference of the Parties serving as the meeting of the Parties to the Protocol,*

1. *Recommends* that each Party to the Protocol should:
  - (a) Notify or ensure prior notification of exports of LMO to non-Parties and make available to them information as required by the Protocol;
  - (b) Encourage and assist, as appropriate, non Parties to make informed decisions regarding imports of LMOs consistent with the objective of the Protocol;
  - (c) Apply its domestic regulatory framework consistent with the Protocol, or the advanced informed agreement procedure of the Protocol, or a comparable procedure, as appropriate, in importing LMOs from a non-Party;
  - (d) Protect confidential information received from non-Parties in relation to transboundary movements of LMOs;
  - (e) Monitor and report, in accordance with Article 33 of the Protocol transboundary movements with non-Parties, including difficulties encountered or best-practices identified and implemented;

2. *Encourages* non-Parties to:

- (a) Cooperate with Parties in their efforts to achieve the objective of the Protocol;
- (b) Adhere to the provisions of the Protocol, in particular those regarding the advanced informed agreement procedure; risk assessment; risk management; and handling, transport, packaging and identification of LMOs, on a voluntary basis;
- (c) Make available to the Biosafety Clearing-House information required under the Protocol, especially that under Articles 11.1, 17, and 20 (3);
- (d) Participate in capacity-building activities designed and implemented to promote the effective implementation of the Protocol;
- (e) Inform the Secretariat of its competent national authorities and national focal point;

3. *Requests* the Executive Secretary to:

- (a) Facilitate the participation of non-Parties in the process of the Protocol, in accordance with the appropriate rules of procedure;
- (b) Compile and disseminate information on cooperative undertakings between Parties to the Protocol and non-Parties in promoting the effective implementation of the Protocol.

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