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CONSIDERATION OF OTHER ISSUES NECESSARY FOR THE EFFECTIVE IMPLEMENTATION OF THE PROTOCOL (e.g., PARAGRAPH 4, ARTICLE 29)

Note by the Executive Secretary

I. INTRODUCTION

1. At its second meeting, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) considered other issues necessary for the implementation of the Protocol, as, for instance, envisaged in its Article 29, paragraph 4, and made several recommendations. In particular, the Intergovernmental Committee invited Governments to submit comments on mechanisms to promote consideration of issues, exchange of views and provide guidance, as appropriate, on issues requiring clarification arising during ratification and implementation of the Protocol. ICCP also requested Parties to the Convention and other States to provide the Executive Secretary with their views on the items to be included in a medium-term programme of work for the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol and its relevant subsidiary bodies.

2. Essentially, the present document is a synthesis of comments on mechanisms to promote the consideration of other issues necessary for the effective implementation of the Protocol (section II). Bearing in mind that the illustrative list of issues in paragraph 1 of recommendation 2/6 of the second meeting of ICCP is in square brackets, the present note also contains a synthesis of views submitted by Governments concerning the type of issues that might be addressed using the mechanisms under consideration.

3. The comments received with regard to mechanisms to promote the consideration of issues cover a wide range of existing or emerging arrangements. Those arrangements—such as the meetings of the Conference of the Parties serving as the meeting of the Parties, inter-sessional activities, establishment of subsidiary bodies and cooperation with other relevant bodies—are normally mechanisms for promoting the consideration of various issues. The present note focuses on some of the emerging arrangements on

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which a clear and deliberate stance may be required in order to designate them as additional mechanisms for promoting the consideration of other issues. The mechanisms suggested in the submissions are, therefore, consolidated, and only a few of them are proposed for consideration (section III). Finally, the note puts forward some recommendations for consideration by ICCP at its third meeting.

4. The summary of the views submitted regarding elements of a medium-term programme work is presented as an addendum to the present document (UNEP/CBD/ICCP/3/9/Add.1). Any response, views, or information that the Executive Secretary received with regard to other matters, namely information on national focal points and competent national authorities, ratification of the Protocol, and the development of the Strategic Plan of the Convention requested by the ICCP under recommendation 2/6, are highlighted in the report of the Executive Secretary on inter-sessional work (UNEP/CBD/ICCP/3/2).

II. A SYNTHESIS OF COMMENTS ON MECHANISMS TO PROMOTE CONSIDERATION OF OTHER ISSUES NECESSARY FOR THE EFFECTIVE IMPLEMENTATION OF THE PROTOCOL

5. Following the invitation of the second meeting of the ICCP and a notification by the Executive Secretary to Governments, to submit comments on mechanisms to promote consideration of issues, exchange views and, as appropriate provide guidance on issues requiring clarification arising during ratification and implementation of the Protocol, the Executive Secretary had received, as of 10 February 2002, submissions from Australia, Canada, Equatorial Guinea, the European Union, the Republic of Korea, Slovenia and Switzerland. Viet Nam indicated that it had no comments on the item. Below is the synthesis of these submissions. The full texts of the submissions have been compiled and made available as an information document (UNEP/CBD/ICCP/3/INF/7).

6. As indicated above, the following synthesis has two aspects. First, there were some comments submitted by Governments with regard to mechanisms to promote consideration of issues as invited by the ICCP and, secondly, there were views concerning the type of issues that might be addressed using such mechanisms. The Executive Secretary prepared the synthesis of both aspects as appeared in the submissions bearing in mind the fact that the illustrative list of issues in paragraph 1 of recommendation 2/6 of the second meeting of ICCP, is in square brackets. As a matter of fact, some of the submissions referred only to issues and not to mechanisms to promote the consideration of these issues. Owing to the interrelationship between these two aspects, the submissions tend to concentrate more on the identification of issues than on the mechanisms to which comments were invited. ICCP may wish to consider these issues as identified by some Governments during its second meeting and subsequently in their submissions. In this regard, it should also be noted that paragraph 4 of Article 29 of the Protocol has already identified some of the issues that the Conference of the Parties serving as the meeting of the Parties needs to address with a view to making decisions necessary to promote the effective implementation of the Protocol.

A. *Synthesis of comments on mechanisms to promote consideration of issues*

7. One of the submissions that included comments regarding mechanisms identified a number of existing and evolving arrangements that could be used as mechanisms to promote consideration of issues and exchanging views. Basically, Article 29, paragraph 4, of the Protocol has been indicated as the primary source of various mechanisms that might be appropriately adopted for the purpose in question. According to this submission, the provisions of the paragraph represent mechanisms that could be utilized, as appropriate, to promote the consideration and clarification of relevant issues that would enhance the implementation of the Protocol. These provisions include those that require the Conference of the Parties serving as the meeting of the Parties to the Protocol to:

- (a) Establish subsidiary bodies;
- (b) Seek and utilize the services and cooperation of, and information provided by competent international organizations and intergovernmental and non-governmental bodies;
- (c) Consider and adopt amendments to the Protocol and its annexes, as well as any additional annexes to the Protocol.

8. Other mechanisms that were mentioned by the same submission include: ICCP meetings; the inter-sessional activities; the meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol; as well as those currently evolving mechanisms that may come into being after the entry into force of the Protocol, namely:

- (a) The compliance committee;
- (b) The biosafety roster of experts; and
- (c) The decision-making mechanism, for the purpose of paragraph 7 of Article 10.

9. It is also suggested to consider the possibility of using the Biosafety Clearing-House as a general mechanism to host official contributions of views, comments and relevant information on other issues by Governments, as well as intergovernmental organizations, non-governmental organizations and other stakeholders. It is further suggested that a specific section could be organized or allocated within the Biosafety Clearing-House for each issue, following the content of the articles of the Protocol.

10. Some of those suggested mechanisms mentioned under paragraphs 7 and 8 above, such as the meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol, the compliance mechanism, and the use of the services and cooperation of other organizations, are seen favourably by another submission. Regional networks and centres of excellence have also been suggested to be included in the set of mechanisms that could possibly be employed for the purpose of identifying and addressing other issues of importance for the effective implementation of the Protocol.

11. In another submission, it has been proposed to establish an open-ended implementation body, which may be known as the "Protocol Committee" that should meet inter-sessionally or in conjunction with the Conference of the Parties serving as the meeting of the Parties to the Protocol. The suggestion is to create this body as a subsidiary body under paragraph 4 (b) of Article 29 of the Protocol. It is argued that such a mechanism would provide an opportunity to deal with practical issues related with the implementation of the Protocol, and resolve various concerns of Parties at the earliest possible and, to the extent possible, outside the Conference of the Parties serving as the meeting of the Parties to the Protocol. According to the submission, this option would also reduce the need for convening several inter-sessional working groups or experts meetings to deal with specific items, and allows the participation of all Parties, in particular developing countries, and other stakeholders.

12. Similarly, another submission proposed the establishment of a standing advisory board, which would receive, through the Secretariat, a written request for the clarification of technical and scientific issues identified by Parties and Governments, and exchange views and provide draft guidance for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol. Unlike the "Protocol Committee" mentioned above, which is suggested to be an open-ended one, it is proposed that such advisory body may be composed of 15 distinguished experts selected from the five United Nations regions; each region nominating three experts. It is also recommended that members of

the advisory board should act in their personal capacity and serve in the board for a period of two years with a possibility of extension for one more term.

13. According to another submission that similarly addressed this point, meetings under the ICCP process or, subsequently, the Conference of the Parties serving as the meeting of the Parties to the Protocol, supplemented by visits and other informal liaison and exchange of views in a bilateral, regional or multilateral context, would be sufficient to consider or clarify other issues. It has been pointed out that the process of ratification and implementation of the Protocol should not be unnecessarily burdensome, and the work of other relevant international organizations such as the Codex Alimentarius Commission and the Organization Internationale des Epizooties (OIE) unduly duplicated, by creating new mechanisms and considering other issues.

B. A synthesis of views regarding other issues that may need consideration, clarification or exchange of views

14. With the exception of one submission that reaffirmed the square bracketing, and another one that refrained from making any comments regarding the issues, arguing that such issues might not usefully be predicted in advance, there seems to be a strong support for the consideration of all or some of the issues listed in paragraph 1 of ICCP recommendation 2/6. In fact, in the case one submission, extensive comments were provided in favour of addressing the issues under subparagraphs (b), (c) and (d) (namely, risk assessment and risk management; establishment of harmonized rules for unique identification systems; and transboundary movements with non-Parties). Several submissions indicated support for the inclusion or consideration of the item in subparagraph (a) (Categorization of living modified organisms), as well. There follows a summary of comments on the specific issues suggested under subparagraphs 1 (b)-(d) of recommendation 2/6.

1. Risk assessment and risk management

15. It is 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 world wide. The 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.

16. 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.

17. 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.

2. *Establishment of harmonized rules for unique identification systems*

18. It is 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 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.

19. It is suggested that a decision for the establishment of harmonized rules for the development and assignment of unique identifiers to living modified organisms may be made by the Conference of the Parties serving as the meeting of the Parties to the Protocol, taking into account the relevant provisions of the Protocol, as well as paragraph 10 (a) of ICCP recommendation 2/8, in which the ICCP invited any international organization to make available harmonized unique identification systems in relation to databases on living modified organisms. Another submission also favoured the establishment of harmonized rules for unique identification systems and supported its inclusion under other issues that may need further elaboration.

3. *Transboundary movement with non-Parties*

20. 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.

21. 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 aimed at 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 national focal point and to inform the Secretariat of their competent national authorities, voluntarily.

III. PROPOSED MECHANISMS TO PROMOTE CONSIDERATION OF ISSUES NECESSARY FOR THE EFFECTIVE IMPLEMENTATION OF THE PROTOCOL

22. The success of an instrument such as the Cartagena Protocol on Biosafety in regulating conduct at the international level is determined by the extent to which its provisions are implemented effectively. Effective implementation of the Biosafety Protocol in turn requires, among other things, proper understanding of the rights and obligations involved, adequate capacity and information sharing. These elements in turn require the establishment of appropriate mechanisms. In the final analysis, the existence of few or no cases of non-compliance, few or no disputes among and between Parties, and above all, avoidance or minimization of risks caused by transboundary movement of living modified organisms and increased safety would be the major indicators of success or effective implementation.

23. In the process of preparing for the entry into force of the Protocol, ICCP has managed to develop a number of mechanisms that will enhance implementation. The tools under development intended to contribute to the effective implementation of the Protocol include the pilot phase of the Biosafety Clearing-House and the evolving procedures and mechanisms for decision-making, compliance and the use of the biosafety roster of experts. These procedures and mechanisms will eventually be considered and adopted by the Conference of the Parties serving as the meeting of the Parties to the Protocol. Mechanisms to promote the consideration of issues, the exchange of views and, as appropriate, the provision of guidance on issues of significance for the entry into force and implementation of the Protocol are some of the tools that contribute to a better implementation of the provisions of the Protocol.

24. As seen from the submissions synthesized in the preceding section, there are several ways by which the ICCP or the Conference of the Parties serving as the meeting of the Parties to the Protocol could promote the consideration and elaboration of issues with a view to enhance early ratification or effective implementation of the Protocol. In the submissions, the following mechanisms have been proposed:

- (a) Meetings of the ICCP;
- (b) Meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
- (c) Subsidiary bodies;
- (d) Inter-sessional activities;
- (e) The services and cooperation of, and information provided by competent international organizations and intergovernmental and non-governmental bodies;
- (f) Periodic assessment and review of the Protocol and its annexes and adoption of amendments, as appropriate;
- (g) A compliance body;
- (h) The biosafety roster of experts;
- (i) The Biosafety Clearing-House;
- (j) The decision-making mechanism, for paragraph 7 of Article 10;

- (k) Regional networks and centres of excellence;
- (l) Advisory board; and
- (m) Visits, and other informal liaison and exchange of views

25. One of the submissions, which favoured addressing some of the illustrative issues under paragraph 1 of recommendation 2/6, suggested the inclusion of such issues in a medium-term programme of work. By implication, therefore, a medium-term programme of work would be one of the proposed mechanisms for promoting the consideration of other issues. ICCP may wish to consider all or some of the mechanisms consolidated above and focus its efforts on identifying the most realistic and efficient ones. ICCP meetings, inter-sessional activities or the future meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol are, obviously, the principal mechanisms where specific issues are identified and clarified. Furthermore, any issue identified or clarified using any of the mechanisms proposed needs, in the final analysis, to be submitted to the Conference of the Parties serving as the meeting of the Parties to the Protocol, so that there is a uniform implementation based on mutual understanding of that particular issue.

26. It should also be noted that some of the proposed mechanisms are already provided for in paragraph 4 of Article 29 of the Protocol. As pointed out above, others are also under construction in the context of one or the other aspect of the Protocol and hence are bound to address issues of relevance to the Protocol. There may be a need to re-model some of these potential mechanisms to suit the desired objective. Otherwise, they are all relevant mechanisms that could be used, in combination and in a mutually consistent manner, for identifying and entertaining issues of importance for the effective implementation of the Protocol. There follows a further elaboration of some of these proposed mechanisms in the event that ICCP may wish to focus on them for possible consideration and recommendation.

A. *Medium-term programme of work*

27. ICCP has viewed the development of a medium-term programme of work as important for guiding the process of implementation of the Protocol. There has been a similar experience in the Convention process, which appeared to be worth pursuing before engaging in the development of a long-term programme of work or, for that matter, a Strategic Plan. Accordingly, a draft medium-term programme of work for the Conference of the Parties serving as the meeting of the Parties covering the period from its second to its fifth meeting has been prepared and submitted to ICCP for its consideration. The medium-term programme of work should obviously be the primary tool to identify and include issues that may be deemed necessary for the effective implementation of the Protocol.

B. *A subsidiary body*

28. A subsidiary body may be established or designated to consider technical and scientific issues identified by Parties and other Governments as requiring clarification, exchange views and develop draft guidance or clarifications for the consideration of the Conference of the Parties serving as the meeting of the Parties to the Protocol. As suggested by several submissions, the subsidiary body could take the form of either an open-ended implementation body ("Protocol Committee") or an advisory board with a limited membership of experts representing the five United Nations regions.

29. Alternatively, this task may be allocated to one of the existing or emerging mechanisms under the Protocol or the Convention. For instance, this task could be allocated to the compliance mechanism that is

under consideration. In fact, the compliance committee, when established, may have the responsibility to review general issues of compliance by Parties and to make recommendations to the Conference of the Parties serving as the meeting of the Parties to the Protocol with a view to promoting compliance. The committee would therefore be considered as a mechanism suitably placed to identify issues that may hinder effective implementation and to provide advice on the appropriate measures to overcome them.

30. In considering these alternative mechanisms, however, it may be worth noting some relevant principles, such as transparency, timeliness, fairness and inclusiveness of participation in the implementation of the Protocol, that were emphasized in the submission favouring an open-ended mechanism.

C. Submissions using the Biosafety Clearing-House

31. As suggested in one of the submissions, the Biosafety Clearing-House could be organized in a manner that would provide opportunity to all stakeholders to submit their views, to comment on the agenda and the work of the Conference of the Parties serving as the meeting of the Parties to the Protocol and its subsidiary bodies, or to make available any information they deem appropriate. Parties to the Protocol, other States, relevant intergovernmental organizations and non-governmental organizations could be invited, as a matter of standard procedure, to submit, if they so wish, issues of importance for the effective implementation of the Protocol, or provide comments or explanations for issues raised. The Biosafety Clearing-House could therefore offer, in addition to its regular tasks, a means by which issues would be raised and clarified, as appropriate, with a view to strengthening the implementation of the Protocol.

IV. RECOMMENDATIONS

32. The ICCP may wish to:

- (a) Consider the submissions regarding mechanisms to promote the consideration of issues, and the priority issues that might be addressed under these mechanisms;
- (b) Further consider, in light of the submissions received by the Secretariat, those issues in square brackets in paragraph 1 of recommendation 2/6 of its second meeting;
- (c) Consider and further develop the proposed mechanisms for the consideration and clarification of issues arising during ratification or implementation of the Protocol; and
- (d) Make appropriate recommendations to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol regarding issues in subparagraphs (a), (b) and (c) above.
