



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

Third meeting

Curitiba, Brazil, 13 -17 March 2006

Item 15 of the provisional agenda *

ASSESSMENT AND REVIEW (ARTICLE 35)

Initiating a process of evaluation of the effectiveness of the Protocol

Note by the Executive Secretary

I. INTRODUCTION

1. The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) is required, under Article 35, to undertake an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes. Such review and assessment shall be undertaken five years after the entry into force of the Protocol and at least every five years thereafter. In light of this requirement, the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol adopted a medium-term programme of work (decision BS-I/12), which envisages an initiation of a process of review and assessment to take place at its third meeting, and the review of the implementation of the Protocol, its annexes, procedures and mechanisms, to be undertaken at its fourth meeting.

2. Since the Protocol entered into force in September 2003, the first review of the effectiveness of the Protocol will be due in September 2008.

3. The present note is intended to assist the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol in its consideration of the item on the initiation of a process towards the evaluation of the effectiveness of the Protocol with a view to fulfilling the requirement under Article 35. In that context, section II of the document discusses some considerations that may be pertinent in undertaking evaluation of the effectiveness of the Protocol. Section III attempts to identify possible modalities that the Conference of the Parties serving as the meeting of the Parties to the Protocol

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may wish to take into account in establishing a process to undertake such an evaluation. Finally, section IV submits suggestions of elements of a draft decision for the Conference of the Parties serving as the meeting of the Parties to the Protocol for its consideration.

II. CONSIDERATIONS IN UNDERTAKING EVALUATION OF THE EFFECTIVENESS OF THE PROTOCOL

4. The effectiveness of an international environmental agreement may be measured in terms of the impact of the agreement in preventing, eliminating or mitigating of the actual or potential problem(s) that led to its creation.

5. In the case of the Cartagena Protocol on Biosafety, evaluating the effectiveness of the instrument, its annexes and procedures, at regular intervals, may be as much necessary to keep pace with the possible advance in the science and application of modern biotechnology as to measure impacts in the achievement of its objective. Parties could be compliant with their obligations, procedural as well as substantive, but still the Protocol could remain ineffective in attaining its objective because the agreement might be far from current realities in science and technology, or the regulatory approaches used may not be compatible, for example, with the ways how living modified organisms cross borders.

6. Looking back to the evolution of the Protocol, one can easily see how a consensus had emerged very early in the negotiations for a biosafety protocol in favour of a review mechanism built into the future protocol. It is worth remembering that decision II/5 of the second meeting of the Conference of the Parties to the Convention, which established the Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety, had called upon the Working Group, from the outset, that the protocol had to provide for a review mechanism (paragraph 5 (c), annex, decision II/5). Article 35 of the Protocol on assessment and review appears to respond to that call made by the second meeting of the Conference of the Parties, and sets a timeframe when an evaluation of the effectiveness of the Protocol ought to be undertaken, for the first time and thereafter.

7. Practical experiences of Parties in the implementation of the Protocol form the primary basis for evaluating the effectiveness of the Protocol. The Secretariat has received and analyzed a good deal of information from Parties regarding their experience in the implementation of the Protocol as part of preparations for the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. Interim national reports have been reviewed. A questionnaire was conducted in connection with capacity-building with a view to a possible revision of the existing action plan on capacity building. These review exercises have shown that quite a number of Parties, especially developing country Parties are still at different levels of what could be considered as a preparatory phase towards the full implementation of the Protocol.

8. Some of the preliminary findings of the analysis of the interim national report (UNEP/CBD/COP-MOP/3/12) that may be relevant to the present discussion include, for example: (i) two years after the Protocol has entered into force, no Party has reported on any decision it has taken under the advance informed agreement procedure (AIA) for importing living modified organism for intentional introduction into the environment. That means, as yet there is no practical experience or, at least, no information is made available to the Biosafety Clearing-House as regards the implementation of some of the procedural rules such as those relating to the AIA, which are central to the Protocol; and (ii) in several developing country Parties, national biosafety frameworks are still under preparation or are in draft forms, awaiting adoption by the respective Governments, or even if adopted, quite a number of these frameworks still lack the necessary tools such as detail regulations so as to become operational and effective. Although the absence of a national biosafety framework would not be an excuse for not

implementing the Protocol, the presence of a biosafety policy, legislation or guidelines contributes a great deal, for instance, in clarifying the scope and the extent of the domestic applicability of the several rules of the Protocol, in particular those relevant to taking a decision on the import of living modified organisms.

9. The state of affairs summarized above as gleaned from the analysis of the interim national reports is also corroborated, to a large extent, by the analysis of the responses to the questionnaire on capacity-building received by the Secretariat. As can be seen from the analysis contained in document UNEP/CBD/BS/COP-MOP/3/4, several countries, especially developing countries, indicated that they have not really began to implement the Action Plan for Building Capacities for Effective Implementation of the Protocol (annex I, BS-I/5), mainly due to the fact that they are still in the process of developing their national frameworks for biosafety which would allow them, once finalized and adopted, to operationalize a number of the elements and activities stipulated in the Action Plan.

10. In that regard, therefore, one may ask whether there has been enough experience gained by Parties that makes any evaluation of the effectiveness of the Protocol in the next few years appropriate and timely. It could also be asked whether there has been any significant scientific and technical development since the entry into force of the Protocol that may again necessitate the review of the provisions of the Protocol, its annexes, procedures and other mechanisms.

11. There are other considerations that need to be taken into account while launching a process to evaluate the effectiveness of the Biosafety Protocol. Measuring effectiveness usually involves the development and use of indicators. Developing indicators to measure effectiveness is a difficult task. Effectiveness in the context of the Protocol may be measured in terms of the Protocol's contribution, as specified in its objective, to ensuring an adequate level of protection to the conservation and sustainable use of biological diversity. Clearly, the Biosafety Protocol represents only a small portion out of the larger set of international regulations or measures that are at work carrying a similar objective of promoting or contributing to the conservation and sustainable use of biological diversity. Factors other than the Protocol affect the level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

12. In that context, it might be difficult to distinctively measure the effects of the Protocol out of the impacts of a wide range of other contributing factors such as other regimes with one or more identical or approximate objectives. For example, the Strategic Plan for the Convention on Biological Diversity adopted in the annex of decision VI/26 and complemented and further clarified by decision VII/30 has, as one of its objectives, the wide implementation of the Protocol on Biosafety, as mentioned under the first goal of the Plan which refers to the fulfillment of the Convention's leadership role in international biodiversity issues. The Convention also has provisional indicators for assessing progress towards the 2010 biodiversity target. The Biosafety Protocol has presumably a role to play in achieving any biodiversity target including the 2010 one. The question that may therefore follow would be whether and how realistic indicators could be developed and used to measure the effectiveness of the Biosafety Protocol separately amidst such a complex web of interdependence, overlap in objectives and interactions of data among various regimes and other relevant factors. Apart from these constraints, however, indicators or some sort of milestones may always be necessary to conduct an orderly evaluation of the effectiveness of an international instrument such as the Biosafety Protocol.

13. It should also be noted that the outcome of an evaluation of the effectiveness of the Protocol also triggers some procedural issues. If the outcome of the evaluation leads to a decision to vary or amend one or the other provisions, annexes, mechanisms and procedures of the Protocol or to add new ones, there is a need to follow certain procedural rules. Article 29 of the Convention, which also applies to the

Protocol, provides that amendments shall be adopted at the meeting of the Parties to the Protocol and in the absence of consensus they shall be adopted by a two-third majority vote of the Parties present and voting. There must be a process of ratification, acceptance or approval of the amendments. The adoption and amendment of annexes are also subject to the same procedure, according to Article 30 of the Convention. Two-third of the Parties to the Protocol have to deposit their instruments of ratification, acceptance or approval before the amendments adopted enter into force on the ninetieth day after the deposit of the instruments. From practice, it is obvious that such processes take long time. The process of adoption and entry into force of any amendment to the Protocol could take well up to or beyond the next cycle of assessment and review.

14. In the final analysis, however, notwithstanding: (i) the limited operational experience gained so far or that may be gained in the next few years in implementing the Protocol which could render any effort to evaluate the effectiveness of the Protocol premature; (ii) the inevitable difficulties in developing a workable set of indicators to measure the effectiveness of the Protocol; and (iii) the lengthy procedural requirements for adoption and entry into force of amendments, if any; it should be clear that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may have no or little options to set aside its task of initiating a process for the evaluation of the effectiveness of the Protocol and pursuing the fulfilment of its obligation under Article 35 as laid out in the medium-term programme of work. While the above considerations present important checklist of what constraints might lay ahead of assessment and review of the Protocol, some of the conclusions that could possibly be made should reasonably wait until the process to undertake the evaluation is actually put in place.

15. Therefore, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may wish to proceed with fulfilling the task set out in Article 35 by establishing a process on the basis of clear understanding of the issues involved and a modality that would facilitate the achievement of a realistic and useful outcome.

III. POSSIBLE MODALITIES TO INITIATE A PROCESS OF EVALUATION OF THE EFFECTIVENESS OF THE PROTOCOL

16. There are some possible modalities that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may wish to consider for launching a process of evaluation of the effectiveness of the Protocol with a view to fulfilling the requirement under Article 35 and the medium-term programme of work. In that regard, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may wish to:

(a) Invite Parties to submit their views to the Secretariat not later than three months after the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety evaluating the effectiveness of the Protocol, including an assessment of procedures and annexes, taking into account paragraph 6 (b) of the medium-term programme of work in the annex of decision BS-I/12*, which specifies the items that are expected to be the subject of review by the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety;

* At its *fourth meeting*, the Conference of the Parties serving as the meeting of the Parties to the Protocol might wish to consider, *inter alia*, the following items: [...]

(b) Review of the implementation of the Protocol:

(i) To consider and adopt, as required, amendments to the Protocol and its annexes, as well as additional annexes, that are deemed necessary for the implementation of the Protocol (Article 35 and Article 29, paragraph 4(e));

(ii) Review of the decision-making procedures and mechanisms adopted in accordance with paragraph 7 of Article 10;

(iii) Review of the compliance procedures and mechanisms.

(b) Request the Executive Secretary to prepare a synthesis of the views submitted by Parties to the Protocol in accordance with paragraph (a) above;

(c) Establish an ad hoc technical expert group on assessment and review that would be convened by the Executive Secretary prior to the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to assess, on the basis of the synthesis of views prepared by the Secretariat in accordance with paragraph (b) above, and other relevant sources of information: (i) the effectiveness of the Protocol, including its annexes; (ii) the decision-making procedures and mechanisms adopted in accordance with paragraph 7 of Article 10, and the compliance procedures and mechanisms adopted under decision BS-I/2; (iii) the need for amendments to any of the provisions of the Protocol as well as its annexes; and (iv) submit its findings to the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety.

17. Instead of constituting an ad hoc technical expert group, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety may wish to give the assignment described in paragraph 16 (c) above to the Compliance Committee on the basis of the mandate that the Committee has to review general issues of compliance as provided in paragraph 1 (d), section III of the Procedures and Mechanisms on Compliance (annex, decision BS-I/7) or under paragraph (f) of the same section where the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety could assign the Committee to carry out any other functions than those specifically provided for under the functions of the Committee;

IV. ELEMENTS OF A DRAFT DECISION

18. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the following elements in developing and adopting its decision under this agenda item:

(a) Take note of the considerations highlighted in section II of the present document that may be taken into account in initiating a process of evaluation of the effectiveness of the Protocol;

(b) Consider the suggestions in section III above, with a view to determine on the most appropriate modality of a process to undertake the evaluation of the effectiveness of the Protocol, its annexes, procedures and mechanisms as required by Article 35.
