





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

Fourth meeting Bonn, 12-16 May 2008 Item 18 of the provisional agenda*

REVIEW OF OPTIONS FOR THE IMPLEMENTATION OF THE NOTIFICATION REQUIERMENTS (ARTICLE 8)

Note by the Executive Secretary

I. INTRODUCTION

- 1. In accordance with its medium-term programme of work, the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol considered, at its second meeting, an item on the implementation of the notification requirements as provided for in Article 8 of the Protocol. It decided to keep the item "under review with a view to elaborating and developing, if appropriate, at its fourth meeting, modalities of implementation" of the requirements, taking into account national implementation and experiences that may be communicated through national reports and the Biosafety Clearing-House (decision BS-II/8, para. 1).
- 2. The Conference of the Parties serving as the meeting of the Parties to the Protocol also recommended to Parties to consider elements and options that facilitate the implementation of the requirements associated with notification, including (i) applying necessary measures to enforce the requirements; (ii) requiring the exporter to use the language as determined by the Party of import in notifications; and (iii) acknowledging the right of a Party of transit to regulate the transport of living modified organisms through its territory, including requiring communication in writing to the competent national authority of the Party of transit if so required by the regulations of that Party of transit (decision BS-II/8, para.2).
- 3. The Executive Secretary has prepared this note to assist the Parties to the Protocol in their further consideration of the item at the present meeting. The note presents an analysis of information regarding the status and experience of implementing requirements under Article 8 of the Protocol on notification, as provided through the first regular national reports. Finally, the note suggests some elements for a draft decision for consideration by the Parties to the Protocol.

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^{*} UNEP/CBD/BS/COP-MOP/4/1.

II. EXPERIENCES ON THE IMPLEMENTATION OF THE NOTIFICATION REQUIREMENTS UNDER ARTICLE 8 OF THE PROTOCOL COMMUNICATED THROUGH THE FIRST REGULAR NATIONAL REPORTS

- 4. The Advance Informed Agreement procedure (AIA) of the Protocol requires that the Party of import be notified about any planned first-time transboundary movement of a specific living modified organism intended for intentional introduction into the environment of the Party of import. This involves the provision of information by the exporter about the living modified organism and its intended use, and the opportunity available to the Party of import to decide whether or not to allow the import of the living modified organism, and upon what conditions.
- 5. The Secretariat received first regular national reports from a little more than a third of Parties to the Protocol. The analyses of the reports and the records in the Biosafety Clearing-House show that the experience by Parties in the use of the AIA procedure of the Protocol is very limited. In fact, those transboundary movements of living modified organisms reported by a few Parties in the context of Articles 7 to 10 and 12 were not, strictly speaking, initiated or planned in line with the AIA procedure of the Protocol. Most of them were conducted in the context of regional agreements or domestic regulatory frameworks.
- 6. Parties were asked if they were involved in exporting living modified organisms during the reporting period and what their experiences were, including any obstacles or impediments they encountered in implementing Articles 7 to 10 and 12 of the Protocol. 1/ One developing country Party reported to be a Party of export during the reporting period, and that the transboundary movement concerned was arranged with a non-Party. An experience has also been reported in this respect from a developed country Party which indicated some difficulties that arose in connection with the interpretation of the list of information in Annex I of the Protocol that a notification is required to contain. It is stated that: (i) the reference to "a previous and existing risk assessment report" under item (k) of Annex I of the Protocol; (ii) the number of and the relationship between various events [specific genetically modified organisms] that may be included in one single notification; and (iii) what the language of notification should be, were some of the areas that were found to be unclear and posing some difficulties of implementation. Another national report received, again from a developed country Party, reported that consent for import and release into the environment for the purpose of field trials has been granted for six notifications and that no difficulties were reported in the process. 2/
- 7. On the other hand, Parties were also asked if they had taken any decisions on import of living modified organisms intended for release into the environment and to describe their experiences and progress in implementing Articles 7 to 10 and 12 of the Protocol, including information on any obstacles or impediments encountered. One developing country Party reported having received several requests for importing living modified organisms for the purpose of confined field trials, and that under all the circumstances, the authorities had to request for more information from the applicants as the first submissions were deemed insufficient. As a result, it was reported that two confined field trials were approved with conditions, one rejected and the other is still under review. Some other developing country Parties reported that they have gone through decision-taking processes consistent with the objective of the Protocol, on the one hand, and their national legislation on the other, involving import of living modified organisms from non-Parties. Another developing country referred to some obstacles faced including inadequate information about the living modified organisms to be imported, lack of testing and other technical standards, and reference materials.

 $[\]underline{1}$ Question 10 of the reporting format in the annex to decision BS-III/14.

 $[\]underline{2}$ / Although this response was provided under question 10 of the reporting format, which asks about experience obtained as a Party of export, the experience described herein sounds more like a decision taken by the respondent based on its capacity as a Party of import, and not as a Party of export.

- 8. The above summary of experiences in the implementation of the rules of the Protocol with respect to the AIA procedure show, generally, a low level of application of the entire procedure 3/ in general and the notification requirements under Article 8 in particular for initiating and effecting transboundary movements of living modified organisms for intentional introduction into the environment of the importing Party.
- 9. The information communicated through the first national reports does not seem to provide sufficient basis to make any conclusive or firm suggestion with respect to options for the implementation of the notification requirements under Article 18 of the Protocol. This could partly be attributed to the fact that Parties are using their domestic regulatory framework or bilateral, regional or multilateral agreements and arrangements 4/ as envisaged in paragraph 2 (c) of Article 9 and Article 14 of the Protocol, respectively, instead of the AIA procedure of the Protocol. However, there may be other reasons too such as, in the case of several developing country Parties, the lack of necessary legal or administrative arrangements in place at the national level. 5/ In the case of some developing country Parties, the lack of a workable regulatory system at the national level and lack of coordination among relevant national agencies, 6/ and limitations in capacities have resulted in lack of control of the transboundary movement of living modified organisms that are being imported into their jurisdiction.

 $[\]underline{3}$ / See paragraph 97 (e), section IV of the note by the Executive Secretary on monitoring and reporting (UNEP/CBD/BS/COP-MOP/4/13), which contains an analysis of information contained in the first national reports.

^{4/} See, for example, paragraph 29 of document UNEP/CBD/BS/COP-MOP/4/13.

^{5/} This observation is also shared by the Compliance Committee which reviewed general issues of compliance with the Protocol on the basis of analysis of the first regular national reports. See report of the Compliance Committee on the work of its fourth meeting (UNEP/CBD/BS/CC/4/3) http://www.cbd.int/doc/meetings/bs/bscc-04/official/bscc-04-03-en.pdf

^{6/} See paragraph 86 of document UNEP/CBD/BS/COP-MOP/4/13.

III. OPTIONS FOR ELEMENTS OF A DRAFT DECISION

- 10. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to:
- (a) Address the question of lack of clarity as indicated in one of the national reports reviewed above regarding: (i) the reference to "a previous and existing risk assessment report" under item (k) of Annex I of the Protocol; (ii) the number of and the relationship between various events that may be included in one single notification; and (iii) what the language of notification should be; OR
- (b) Refer the issues to an *ad hoc* technical expert group which may be established for the purpose of examining these specific issues and which develops and submits its recommendations to the next meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. This could also be combined with the task of any *ad hoc* technical expert group that may be established to continue further the issues relating to risk assessment and risk management under agenda item 11 of the present meeting; OR
- (c) Refer the issues to a scientific or technical advisory body, if and when established, following consideration under agenda item 13 (subsidiary bodies) at the present meeting; OR
- (d) Defer any further discussions relating to options for the implementation of the notification requirements under Article 8 of the Protocol until more practical experience is gained by Parties and impediments and limitations are clearly identified calling for action by the Conference of the Parties serving as the meeting of the Parties to the Protocol.
