



Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/COP-MOP/6/12
25 July 2012

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY

Sixth meeting

Hyderabad, India, 1-5 October 2012

Item 13 of the provisional agenda*

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS AND EMERGENCY MEASURES (Article 17)

Note by the Executive Secretary

I. INTRODUCTION

1. The fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol adopted a programme of work for the period 2012–2016 (Annex II, decision BS-V/16). In the programme of work, the list of items identified for consideration for the sixth meeting of the Parties to the Protocol includes an item on unintentional transboundary movements of living modified organisms and emergency measures as provided under Article 17 of the Protocol. The purpose, as stated in the programme of work, is to consider the development of tools and guidance that facilitate appropriate responses to unintentional transboundary movements and initiate necessary actions, including emergency measures (item 2.1(j) of annex II of decision BS-V/16). This has also been envisaged in operational objective 1.8 of the Strategic Plan for the Protocol contained in annex I of BS-V/16.

2. With a view to facilitate consideration of the item, this note presents, in section II, information on cases or implementation measures concerning unintentional transboundary movements of living modified organisms as reported by Parties through their second national reports. In section III, the document highlights some existing or ongoing deliberations, decisions and guidance materials relevant to unintentional transboundary movements of living modified organisms. Section IV attempts to derive some conclusions that may help in determining whether there is any need for guidance taking into account the elements highlighted in the preceding section on the one hand, and the need to assist Parties in addressing unintentional transboundary movements of living modified organisms, on the other; and finally section V outlines suggested elements for a draft decision for consideration by the Parties.

* UNEP/CBD/BS/COP-MOP/6/1.

/...

II. MEASURES IN THE EVENT OF UNINTENTIONAL TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS

3. Article 17 of the Cartagena Protocol on Biosafety requires each Party to take appropriate measures to notify and consult with affected or potentially affected States and other relevant bodies when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. These measures are deemed necessary to enable to determine appropriate responses and initiate necessary actions. The notification must be provided as soon as the Party knows of such situation. Each Party is also required to make available to the Biosafety Clearing-House (BCH) the relevant details of its point of contact for the purposes of notification, as well as information on an occurrence of unintentional transboundary movement of living modified organisms.

4. As at 31 December 2011, 143 Parties to the Protocol submitted their second national report on the implementation of their obligations under the Protocol. In their reports, Parties responded to a number of questions in the reporting format relating to unintentional transboundary movements of living modified organisms.

5. The first question relating to unintentional transboundary movements of living modified organisms appears in the context of Article 16 on risk management. Accordingly, Question 95 asks each Party whether it has established and maintained appropriate measures to prevent unintentional transboundary movements of living modified organisms.

- 47 Parties (33% of the respondents to the question) reported having established and maintained appropriate measures to prevent unintentional transboundary movements of living modified organisms;
- 34 Parties (24% of the respondents) to some extent; and
- 61 Parties (43% of the respondents) reported that they have not done so;
- The percentages of Parties, within each regional or economic grouping, that reported that they have not established or maintained such measures are as follows: Africa 54%; Asia & Pacific 51%; Central and Eastern Europe (CEE) 21%; Group of Latin America and Caribbean Countries (GRULAC) 62%; Western Europe and Others Group (WEOG) 0%; Least Developed Countries (LDCs) 67%; and Small-Island Developing States (SIDS) 45%.

6. Question 100 asks Parties whether they have made available to the BCH the relevant details setting out points of contact for the purposes of receiving notifications under Article 17 on unintentional transboundary movements of living modified organisms.

- 93 Parties (65% of the respondents to the question) reported that they have made such information available to the Biosafety Clearing-House;
- The percentages of respondents within the different regions/economic groups are as follows: 59% of the respondents within Africa, 54% in Asia-Pacific, 63% in CEE, 71% in GRULAC, 95% in WEOG, 51% within LDCs and 59% of the respondents within SIDS.

7. Question 101 asks Parties whether they have established a mechanism for addressing emergency measures in case of unintentional transboundary movements of living modified organisms that are likely to have significant adverse effect on biological diversity.

- 80 Parties (56% of the respondents to the question) reported that they have established such a mechanism;
- The percentages of respondents within the different regions/economic groups are as follows: 44% of the respondents within Africa, 43% in Asia-Pacific, 74% in CEE, 52% in GRULAC, 100% in WEOG, 38% within LDCs and 32% of the respondents within SIDS.

8. Question 102 asks each Party whether it has implemented emergency measures in response to information about releases that led, or may have led, to unintentional transboundary movements of LMOs.

- 23 Parties (16% of the respondents to the question) reported that they have implemented emergency measures in response to information about releases that led, or may have led, to unintentional transboundary movements of living modified organisms.

9. Question 103 asks how many times, each concerned Party has received, in the reporting period, information concerning occurrences that led, or may have led, to unintentional transboundary movement(s) of one or more LMOs to or from territories under its jurisdiction.

- Two Parties (1% of the respondents to the question) reported more than 10 times; one Party (1% of the respondents) indicated less than 10 times; six Parties (4% of the respondents) less than 5 times; and 133 Parties (94% of the respondents to the question) reported that they have never received such information.

10. Eight (out of the nine) Parties that responded “yes” to question 103 and reported that they have received information concerning occurrences that may have led to unintentional transboundary movements of living modified organisms also responded to questions 104 -106:

- In response to Questions 104 and 105, two Parties (from WEOG) reported that they have notified, for every occurrence, affected or potentially affected States and, where appropriate, relevant international organizations, of the release. Six of the other Parties reported that they have not provided any notification;
- In response to Question 106, one Party (from WEOG) reported that it has immediately consulted the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures; one Party from Asia-Pacific reported that it has done so in some cases; and the remaining six respondents (one Party from Africa, one from GRULAC and four from WEOG) reported that consultation was never made.

11. Question 107 invited Parties to provide further details on the implementation of Article 17. Several Parties elaborated on current domestic legislation that addresses unintentional release of LMOs, including, in some cases, notification to States that may be potentially affected. Several Parties provided further information on the mechanisms that are in place at a domestic level to deal with unintentional releases of living modified organisms, including emergency measures. Many indicated that relevant national contact persons or institutions have been designated, but notification procedures to implement Article 17 are still being defined. Six Parties indicated that capacity to detect LMOs was poor or inexistent in their respective countries.

12. Four Parties described occurrences in their respective jurisdictions where there was an unintentional release of a living modified organism. Zambia reported that only the exporter was notified of the release, but the information was not made available to the BCH nor were concerned States or international organizations notified. Mexico and the Netherlands reported that measures were taken to contain the living modified organisms following certain occurrences. However, in both cases the occurrences were considered not to likely lead to unintentional transboundary movements and, therefore, no further measures as indicated in Article 17 were necessary. Sweden reported that a living modified potato authorized only for field trials was discovered in plantings with another living modified potato that was authorized for commercial cultivation. The co-mingling was not considered as an environmental risk but EU Member States that also cultivated this potato were immediately notified. It is also indicated that since there was no risk for transboundary movement, the BCH or others outside of the EU were not informed.

13. Moldova and Chad suggested that in addition to notifying a potentially affected State of an unintentional release of a living modified organism, the relevant national authority must also inform the public on the measures taken to prevent adverse effects on human health or the environment.

14. Ghana reported that it is aware of potential transboundary transfer of LMOs into its territory, while Venezuela reported that it suspects such cases but that information is unverified. Angola, Czech Republic, France, and Honduras reported unintentional introduction of living modified organisms into their jurisdiction in the form of imports of food or seeds.

III. GUIDANCE TO FACILITATE APPROPRIATE RESPONSE TO UNINTENTIONAL TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS

15. The Conference of the Parties serving as the meeting of the Parties to the Protocol adopted, at its fifth meeting, a Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020, and a programme of work for the period 2012-2016, as contained in annexes I and II of decision BS-V/16, respectively.

16. The Strategic Plan has strategic objectives consisting six focal areas prioritized according to their contribution to the full implementation of the Protocol. Focal area 1 is intended to concentrate, as a matter of top most priority, on the facilitation of the establishment and further development of effective biosafety systems for the implementation of the Protocol by putting in place further tools and guidance necessary to make the Protocol fully operational. In that vein, operational objective 1.8 identifies, among others, unintentional transboundary movements and emergency measures, as one of the areas where there is a need for the development of tools and guidance that facilitate implementation and assist Parties to detect and take measures to respond to unintentional releases of living modified organisms. This operational objective has also been reflected in the list of items¹ identified for the work of the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol in annex II of decision BS-V.

17. There are at least four important areas where earlier and ongoing deliberations and where decisions taken by the Parties could be worth considering in order to take an informed decision as regards the consideration of the development of guidance to facilitate efforts to detect and take measures to respond to unintentional transboundary movements of living modified organisms as specified in the Strategic Plan and the programme of work mentioned above. These are: (a) handling, transport, packaging and identification; (b) risk assessment and risk management; (c) liability and redress; and (d) capacity building.

(a) Handling, transport, packaging and identification

18. Parties to the Protocol have been debating on issues related to the adventitious or unintentional presence of living modified organisms. The debate started at the second meeting of the Parties to the Protocol in the context of considering a trigger for the identification requirements under paragraph 2 of Article 18 of the Biosafety Protocol, in particular the identification of bulk shipments or transboundary movements of living modified organisms intended for direct use as food, feed, or for processing, (paragraph 2 (a), Article 18) and the issue of adventitious presence of living modified organisms in non-living modified shipments. The debate further continued in the context of appropriate techniques for sampling and detection of living modified organisms.

19. The Conference of the Parties serving as the meeting of the Parties to the Protocol took a series of decisions, including encouraging Parties and other Governments to cooperate in exchanging experiences and building capacities in the use and development of easy to use, rapid, reliable and cost-effective sampling and detection techniques for living modified organisms;² accreditation of laboratories involved in sampling and detection of living modified organisms; access to reference materials.³

20. These particular discussions in the context of paragraph 2 of Article 18 and in particular in relation to detection of living modified organisms are obviously relevant to any consideration of guidance on detecting unintentional transboundary movements of living modified organisms. The latest decision⁴ in this regard, requests Parties and encourages other Governments and relevant organizations to make available to the Biosafety Clearing-House methods for the detection and identification of living modified organisms and anticipates the establishment, through the BCH, of electronic network of laboratories to facilitate the identification of living modified organisms as well as the sharing of information and experiences.

¹ Item 2.1(j) of annex II of decision BS-V/16

² Paragraph 10 and 11, decision BS-III/10: paragraph 2(a) of Article 18

³ Decision BS-IV/9

⁴ Decision BS-V/9

(b) Risk assessment and risk management

21. The Open-ended Online Expert Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management established and extended under decisions BS-IV/11 and BS-V/12 by the Conference of the Parties serving as the meeting of the Parties to the Protocol,⁵ have developed the “Guidance on Risk Assessment of Living Modified Organisms”⁶. The objective of the Guidance, as stated in the document, is to provide a reference that may assist Parties and other Governments in implementing the provisions of the Protocol with regards to risk assessment. It is said to be a “living document” which may be updated from time to time as the need arises and when requested by the Parties to the Protocol.

22. Part II of the Guidance provides for guidance on the risk assessment of specific types of living modified organisms and traits. The specific types of living modified organisms currently addressed in the Guidance include living modified trees⁷ and mosquitoes.⁸ In that regard, the Guidance highlights some elements that need to be considered during the risk assessments of these types of living modified organisms in order to account for potential adverse effects arising from their unintentional transboundary movements.

(c) Liability and redress

23. The Conference of the Parties serving as the meeting of the Parties to the Protocol adopted, at its fifth meeting held in Nagoya, Japan in October 2010, the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress. The Supplementary Protocol represents the culmination of a lengthy negotiation process that was carried out in response to Article 27 of the Cartagena Protocol on Biosafety.

24. The Supplementary Protocol applies to, or its scope covers, damage resulting from living modified organisms which find their origin in a transboundary movement.⁹ It is further provided that the Supplementary Protocol also applies to damage resulting from unintentional transboundary movements as referred to in Article 17 of the Cartagena Protocol on Biosafety.¹⁰ At its core, the Supplementary Protocol is about measures that need to be taken by operators and/or public authorities in response to damage or in the event where relevant information indicates that there is a sufficient likelihood of damage resulting from living modified organisms. Article 5 of the Supplementary Protocol addresses issues related with the how, who and when response measures ought to be taken. Response measures, according to the Supplementary Protocol are reasonable actions to prevent, mitigate or avoid damage, or to restore biological diversity that has been adversely affected by a living modified organism that has its origin in a transboundary movement.¹¹

25. The purpose of the requirements in Article 17 of the Biosafety Protocol and Article 5 and related provisions of the Supplementary Protocol appears to be minimizing or avoiding significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. According to Article 17, in the event a Party knows an occurrence within its jurisdiction resulting in a release of living modified organism that leads, or may lead to unintentional transboundary movement that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, that Party is required to take appropriate measures to notify and consult with the State that is affected or potentially affected. On the other hand, Article 5 of the Supplementary Protocol specifies measures that a Party needs to take or require the operator to take in response to damage or sufficient likelihood of damage including that which arises from unintentional transboundary movement of living modified organism. Clearly, the provisions under Articles 5 and 2 of the Supplementary Protocol complement the requirements specified in Article 17 of the Cartagena Protocol on Biosafety.

⁵ The terms of reference of the Open-ended Online Expert Forum and the AHTEG as provided in the annexes to decisions BS-IV/11 and extended in decision BS-V/12 are available online at: <http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11690>
<http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=12325>

⁶ Annex, UNEP/CBD/BS/COP-MOP/6/13

⁷ *Ibid*, Risk Assessment of Living Modified Trees (section C), p.38

⁸ *Ibid*, Risk Assessment of Living Modified Mosquitoes (section D), p. 47

⁹ Article 3

¹⁰ Paragraph 3, Article 3

¹¹ Paragraph 2(d), Article 2

(d) Capacity-building

26. The fifth Coordination Meeting for Governments and Organizations Implementing or Funding Biosafety Capacity-Building Activities held from 9 to 11 March 2009 in San José, Costa Rica, had tentatively considered elements that may be relevant to promoting regional and subregional cooperation on capacity-building, which include cooperation in the implementation of Article 17 of the Protocol on unintentional transboundary movement of LMOs likely to have significant adverse effects on biodiversity and human health, including determination of appropriate responses and initiation of necessary actions, including emergency measures.

IV. CONCLUSION

(a) Domestic implementation

27. The information synthesized from the second national reports show that a little more than half of the respondents have to still establish and maintain measures to prevent unintentional transboundary movement of living modified organisms in the broader risk management scheme under Article 16 of the Protocol. A large number of Parties has made information available through the BCH on the details of contact for the purpose of notifications on unintentional transboundary movements. Few have reported that they had incidents of unintentional transboundary movement and one reported to have, in fact, made consultations with the other concerned Party. Some developing country Parties indicated that they lack capacity necessary to deal with an occurrence that may lead to unintentional transboundary movement of living modified organisms. Otherwise, no Party reported any difficulties arising from the implementation of the requirements under Article 17 of the Protocol.

(b) The need for guidance

28. As indicated in section III above, there are decisions, ongoing discussions as well as guidance, that are relevant to the implementation of requirements under the Protocol and that could probably serve as guidance to facilitate detection and response action in the event of unintentional transboundary movements of living modified organisms.

29. As far as techniques or methods for sampling and detection of living modified organisms, any consideration of elements for guidance should take into account the relevant decisions taken to date in the context of paragraph 2 of Article 18 and any follow up discussions and possible decisions.

30. The elements in the Guidance for the Risk Assessment of Living Modified Organisms relevant to unintentional transboundary movement of living modified trees and living modified mosquitoes are particularly important in any future consideration of guidance in the context of operational objective 1.8 of the Strategic Plan of the Protocol. In fact, in view of the largely scientific and technical nature of the issues involved, any consideration of further guidance on measures in response to unintentional transboundary movement of living modified organism may be better handled by the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management.

31. The Supplementary Protocol on Liability and Redress, which also applies to unintentional transboundary movements of living modified organisms, also provides guidance on response actions¹² that need to be taken beyond the notification and consultation measures specified in Article 17 of the Protocol.

32. In view of the above, a conclusion could be made that there is already a good deal of guidance that Parties could use to facilitate their actions in response to unintentional transboundary movements of living modified organisms. In the event there is still a need for further guidance to meet operational objective 1.8 (Annex I, decision BS-V/16), the task may be referred to the existing or subsequent processes established or may be established for the purpose of developing guidance on risk assessment.

¹² Article 5 and paragraph 2(d), Article 2 of the Supplementary Protocol.

V. SUGGESTED ELEMENTS FOR A DRAFT DECISION

33. The Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to:

(a) Take note of the following elements as constituting guidance to facilitate appropriate responses to unintentional transboundary movements and to initiate necessary actions, including emergency measures, as envisaged in operational objective 1.8 of the Strategic Plan: (i) decisions taken or may be taken in the context of identification of living modified organisms under Article 18 of the Protocol, in particular those relating to detection of living modified organisms; (ii) relevant sections of the Guidance for the Risk Assessment of Living Modified Organisms developed by the Open-ended Online Expert Forum and the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management; (iii) Article 5 and related provisions of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress, which provide for response measures in the event of damage or sufficient likelihood of damage resulting from living modified organisms that have their origin in transboundary movements, including unintentional transboundary movements;

(b) Encourage Parties to use, in addition to the measures specified in Article 17 of the Protocol, the guidance or information referred to in (a) above, as appropriate, in their efforts to determine and take appropriate response measures, including emergency measures, in the event of an occurrence that leads or may lead to unintentional transboundary movement of a living modified organism that is likely to cause significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;

(c) Urge Parties and invite other Governments and relevant organizations which have not yet done so to: (i) make available to the Biosafety Clearing-House the relevant details of their point of contact for the purposes of receiving notifications under Article 17 of the Protocol; (ii) establish and maintain appropriate measures to prevent unintentional transboundary movements of living modified organisms; and (iii) establish a mechanism for addressing emergency measures in case of unintentional transboundary movements of living modified organisms that are likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;

(d) Invite Parties and other Governments to cooperate in building capacities necessary for detecting occurrences that could lead to a release of a living modified organism that may result in unintentional transboundary movement of the organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

34. The Conference of the Parties serving as the meeting of the Parties to the Protocol may also wish to consider the following elements either in addition to or in lieu of (a) and (b) above:

(a) Request:

- (i) Parties, and invite other Governments and relevant organizations to provide their views to the Executive Secretary by 31 January 2013, on what constitutes unintentional transboundary movement of a living modified organism, and the scope and elements of a possible guidance that may facilitate appropriate responses by Parties to unintentional transboundary movements of living modified organisms;
- (ii) The Executive Secretary to prepare a synthesis of the views referred to above, for the consideration of the Open-ended Ad Hoc Expert Group on Risk Assessment and Risk Management;
- (iii) The Open-ended Ad Hoc Expert Group on Risk Assessment and Risk Management to review issues related to unintentional transboundary movements of living modified organisms in the context of its work relating to the Guidance on Risk Assessment of Living Modified Organisms taking into account the synthesis of views referred to above.
