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PROTOCOL ON BIOSAFETY

Seventh meeting

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Item 16 of the provisional agenda*

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES (ARTICLE 17)

I. INTRODUCTION

1. Article 17 on unintentional transboundary movements of living modified organisms (LMOs) and emergency measures states that “[e]ach Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organizations, 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 in such States”.

2. Article 16 on risk management further states that “[e]ach Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism”.

3. In accordance with the operational objective 1.8 of the Strategic Plan and its programme of work for the Cartagena Protocol on Biosafety for the period 2011-2020,¹ the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), at its sixth meeting, considered the development of tools and guidance that facilitate appropriate responses to unintentional transboundary movements and initiate necessary actions, including emergency measures in the context of Article 17.

4. Further, in its decision BS-VI/16, the COP-MOP, inter alia:

(a) Encouraged Parties to use, as guidance, or apply, as appropriate, the following in their efforts to implement the measures specified in Article 17 of the Protocol (i) decisions that have been or may be taken in the context of identifying LMOs under Article 18 of the Protocol, in particular those relating to the detection of LMOs and; (ii) the Guidance on Risk Assessment of Living Modified Organisms developed by the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management with input from the Open-Ended Online Expert Forum;²

* UNEP/CBD/BS/COP-MOP/7/1.

¹ Adopted in decision BS-V/16.

² See UNEP/CBD/BS/COP-MOP/6/13/Add.1.

(b) Invited Parties and other Governments to cooperate in building capacity, transferring the technology and exchanging information necessary to detect and respond to occurrences resulting in a release that could lead to unintentional transboundary movement of an LMO 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;

(c) Requested Parties and invited other Governments and relevant organizations to provide views and information on any challenges and experiences relating to the implementation of Article 17 of the Protocol and on the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of LMOs.

5. Furthermore, in the Framework and Action Plan for Capacity-building for the Effective Implementation of the Protocol, adopted as decision BS-VI/3, Parties called for strategic approaches to capacity-building by broadening the scope and depth of training activities in specific areas of professional responsibilities, including training in LMO detection and in measures to address unintentional and/or illegal transboundary movements of LMOs.

6. It is noted that the capacity to detect and identify LMOs in an accurate and efficient manner is a prerequisite for Parties to take appropriate measures in the context of article 17 and to advance the implementation of the Protocol. In this vein, in order to avoid possible duplication of activities, the COP-MOP may wish to consider all issues related to the detection and identification of LMOs under this agenda item, including the activities of the Network of Laboratories for the Detection and Identification of Living Modified Organisms and any other actions related to the detection and identification of LMOs.

7. The present note is meant to assist the COP-MOP in its consideration of the agenda item on unintentional transboundary movements of LMOs and emergency measures. Section II provides a synthesis of views submitted by Parties, other Governments and relevant organizations on challenges and experiences, as well as on the scope of possible guidance or tools that may facilitate appropriate responses to unintentional transboundary movements of LMOs. Section III provides the status of implementation of provisions related to unintentional transboundary movements and emergency measures, including the detection and identification of LMOs, in line with the relevant operational objectives of the Strategic Plan for the Cartagena Protocol on Biodiversity for the period 2011–2020. Section IV contains an analysis of the main outcomes of the “Network of Laboratories for the Detection and Identification of Living Modified Organisms” related to the development of technical tools and guidance that facilitate appropriate responses to unintentional transboundary movements of LMOs. Section V provides a summary of the Secretariat’s activities to establish cooperation with relevant organizations with a view to building capacity, transferring technology and exchanging information necessary to detect and identify LMOs. Section VI outlines some suggested elements for a draft decision, for consideration by the COP-MOP at its seventh meeting.

II. SYNTHESIS OF VIEWS ON CHALLENGES AND EXPERIENCES, AND ON THE SCOPE OF POSSIBLE GUIDANCE OR TOOLS THAT MAY FACILITATE APPROPRIATE RESPONSES TO UNINTENTIONAL TRANSBOUNDARY MOVEMENTS OF LIVING MODIFIED ORGANISMS

8. In response to decision BS-VI/16, paragraph 4, the Secretariat issued a notification on 12 February 2014 inviting Parties, other Governments and relevant organizations to provide views and information on any challenges and experiences relating to the implementation of Article 17 of the Protocol and on the scope and elements of possible guidance or tools that may facilitate appropriate responses by Parties to unintentional transboundary movements of LMOs.³ A reminder notification was issued on 1 April 2014.⁴

³ Notification: SCBD/BS/CG/ABw/83191.

⁴ Notification: SCBD/BS/CG/DA/83191.

9. Nine Parties (Brazil, China, European Commission, Japan, Republic of Korea, Malaysia, Mexico, Norway and South Africa), one non-Party country (United States of America) and five organizations (Global Industry Coalition, International Grain Trade Coalition, NO! GMO Campaign, Testbiotech and Third World Network) had submitted their views on this issue as of 21 May 2014.⁵

10. Several Parties and organizations emphasized the importance for countries to exchange and make available, through the Biosafety Clearing-House (BCH), information on incidents where unintentional transboundary movements have occurred. This includes ensuring that Parties have Emergency Measures Contact Points in place to communicate such occurrences. One Party was also of the view that information on any unintentional release of an LMO, e.g. an LMO under contained use being accidentally released into the environment, should also be submitted to the BCH in the event that an unintentional transboundary movement occurs as a result of such a release.

11. Parties also emphasized the need for countries to work towards implementing guidelines and mechanisms for addressing emergency measures in cases of unintentional transboundary movements within their jurisdiction. It was noted that it would be beneficial to have clarity on what constitutes an “unintentional transboundary movement”.

12. It was noted that guidance is needed on how to: (a) respond and implement emergency measures when a unintentional transboundary movement is detected; and (b) develop a process for consultation and collaboration between possibly affected countries, including building regional and subregional collaborative systems to encourage, facilitate and enable Parties to take appropriate measures to notify affected or potentially affected States of the transboundary movement.

13. It was also noted that Parties and other Governments could make use of existing processes taking place under the Protocol such as the “Guidance on Risk Assessment of Living Modified Organisms” and the activities of the “Network of Laboratories for the Detection and Identification of Living Modified Organisms” to address some of the issues referred to in paragraph 12 above.

14. Finally, some of the submissions included requests for assistance in building capacity and transferring technology to detect and take appropriate measures to respond to unintentional transboundary movement of LMOs.

III. STATUS OF IMPLEMENTATION OF UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES PROVISIONS, INCLUDING THE DETECTION AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

15. In its decision BS-V/14, the COP-MOP requested Parties to submit to the Secretariat their Second National Report on the implementation of the Cartagena Protocol on Biosafety including relevant sections on Article 17.

16. Furthermore, in its decision BS-VI/15, the COP-MOP requested the Executive Secretary to undertake a survey with a view to gathering information corresponding to all indicators in the Strategic Plan that could not be obtained from the second national reports or through other existing mechanisms. In implementing this decision, the Executive Secretary launched a survey through the BCH wherein Parties responded to a number of questions relating to unintentional transboundary movements as well as the detection and identification of LMOs.

⁵ The original submissions are compiled in UNEP/CBD/BS/COP-MOP/INF/11.

17. The following paragraphs provide a snapshot of the current status of implementation by Parties of unintentional transboundary movements and emergency measures provisions and, in particular, of measures for sampling, detecting and identifying LMOs.⁶

18. Based on the responses submitted in the second national report, the majority of countries in the African, Asia-Pacific, and Latin American and Caribbean regions have not established procedures for the sampling or detection of LMOs.⁷

19. An analysis of the responses submitted in the survey noted that the majority of developing country Parties and Parties with economies in transition are yet to develop the capacity to take appropriate measures in the event of an unintentional or unauthorized release of an LMO into the environment.

20. In their responses to the survey, many Parties indicated a need for capacity-building activities to implement the appropriate measures in response to unintentional transboundary movements, including training in sampling, detection and identification of LMOs.

21. Several Parties also indicated that there are gaps in the availability of guidance that specifically addresses how countries are to implement appropriate response measures in the event that an unintentional transboundary movement has been detected.

22. Regarding the access to laboratories for the detection of LMOs, several Parties indicated that while they have reliable access to laboratories, many of these laboratories are not certified for LMO detection.

23. Furthermore, it is noted that, while the Protocol and its Strategic Plan refer to “unintentional transboundary movement” and “unintentional releases”, the responses from several Parties use other terms — such as “adventitious presence”, “low level presence of LMOs” and “unauthorized release” — which may or may not have overlapping meanings with the terms used in the Protocol.

IV. DEVELOPMENT OF TOOLS AND GUIDANCE TO FACILITATE APPROPRIATE RESPONSES TO UNINTENTIONAL TRANSBOUNDARY MOVEMENTS

24. In its decision BS-V/9, the COP-MOP established an electronic network of laboratories with a view to bringing together representatives of laboratories involved in the detection of LMOs for the sharing of information and experiences that could help facilitate the identification of LMOs. The COP-MOP requested the network to carry out online discussion fora and workshops to exchange information and experience on the implementation of relevant standards and methods involved in the detection and identification of LMOs.

25. The initial activities of the “Network of Laboratories for LMO Detection and Identification” took place under the “Portal on the Handling, Transport, Packaging and Identification of LMOs” on the BCH in early 2012. The online discussions held initially as part of the activities of the Network in the previous intersessional period had rather modest participation.⁸

26. Following the sixth meeting of the COP-MOP, in response to its request in decision BS-VI/16, paragraph 1(a) and taking into account the fact that the detection and identification of LMOs is a cross-cutting issue with relevance to several provisions of the Protocol, a new section on “Sampling, Detection and Identification” was created under the key Protocol issues in the BCH. The Secretariat moved the Network from its original location to the new section on “Sampling, Detection and Identification” and re-

⁶ A more detailed overview of the status of implementation of provisions related to the unintentional transboundary movements and emergency measures and to the detection and identification of LMOs is available as document UNEP/CBD/BS/COP-MOP/7/INF7.

⁷ Question 114 in the second national report (<http://bch.cbd.int/database/reports/>).

⁸ A report of the activities of the Network during the previous intersessional period was submitted to the sixth meeting of the COP-MOP as document UNEP/CBD/BS/COP-MOP/6/INF/9.

launched its activities. The number of participants in the Network has since increased from 30 to 88, and the level of participation has improved considerably.

27. The specific objectives of the Network during the past intersessional period were to develop:

(a) A detailed implementation strategy for the detection and identification of LMOs consisting of a plan of action to assist Parties in making progress toward the outcomes under operational objectives 1.6, 1.8 and 2.3 of the Strategic Plan that are relevant to the detection and identification of LMOs;

(b) A set of recommendations identifying possible key players and specific activities to assist in the implementation of the plan of action in (a) above.

28. The first series of online discussions was held from May to July 2013 with a view to fostering an exchange of views and gathering input from a large number of participants to pave the way forward.

29. Further to the first series of online discussions, the “Workshop of the Network of Laboratories for the Detection and Identification of Living Modified Organisms” was held at the European Commission’s Joint Research Centre (JRC), Institute for Health and Consumer Protection, in Ispra, Italy, from 25 to 27 November 2013.⁹

30. The outcomes of the face-to-face workshop of the Network included a plan of action for the development of technical tools and guidance to assist countries in fulfilling their relevant obligations under the Protocol and achieving the outcomes of the Strategic Plan that are relevant to the detection and identification of LMOs.

31. Following the workshop and in accordance with the agreed plan of action, the Network held further rounds of online discussion aiming at compiling technical tools and guidance to facilitate the detection and identification of LMOs on the following topics:

(a) Overview of available detection methods, including validated methods;

(b) Overview of available databases for methods and sequence information, and available screening matrixes;

(c) Minimum performance criteria for sample handling, extraction, detection and identification methodology;

(d) Experience and case studies on detection and identification.

32. Introductory texts were produced by the participants of the Network for each of the topics above and made available through the BCH along with the compilations of technical tools and guidance.¹⁰

33. Furthermore, participants in the workshop put forward a set of recommendations, which were endorsed in subsequent online discussions by the Network, for the consideration of the COP-MOP at its seventh meeting outlining possible future actions relating to the detection and identification of LMOs. These recommendations are reproduced in annex I to the present note.

V. OUTLOOK AND POSSIBLE COOPERATION FOR BUILDING CAPACITY ON THE DETECTION AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS

34. With a view to facilitating the implementation of operational objectives 1.6, 1.8 and 2.3 of the Strategic Plan, and taking into account the needs and gaps identified by the Parties through the Second National Report, survey of indicators of the Strategic Plan and submissions in response to

⁹ The reports of the face-to-face workshop and online discussions of the Network of Laboratories for the Detection and Identification of Living Modified Organisms are available as documents UNEP/CBD/BS/COP-MOP/7/INF8 and UNEP/CBD/BS/COP-MOP/7/INF9, respectively.

¹⁰ Available at http://bch.cbd.int/protocol/cpb_detection/toolsandguidance.shtml.

decision BS-VI/16, paragraph 4, the Secretariat is seeking opportunities to establish cooperation with other United Nations bodies and relevant organizations to help in building capacity, transferring technology and exchanging information necessary to detect and identify LMOs.

35. As part of these efforts, discussions were held between the CBD Secretariat and representatives of the Joint Research Centre (JRC) at the Institute for Health and Consumer Protection of the European Commission to identify possible areas of common interest. Both sides expressed a firm interest in establishing cooperation for conducting regional or subregional capacity-building and training activities in the context of detection and identification of LMOs. Further steps towards this cooperation will depend upon a possible decision by the COP-MOP at its seventh meeting.

36. Furthermore, an informal meeting was held at the CBD Secretariat on 30 June 2014 with a representative of the Food Safety and Quality Unit (AGND) of the Food and Agriculture Organization of the United Nations (FAO). During the meeting, areas of common interest to the AGND Unit of FAO and the Biosafety Unit of the CBD Secretariat regarding the detection and identification of LMOs were identified. Representatives of both parties expressed a strong willingness to seek opportunities to combine efforts through formal future cooperation.

VI. SUGGESTED ELEMENTS FOR A DRAFT DECISION

37. Taking into account the above activities, information and on the basis of the recommendations made during the Workshop of the Network of Laboratories for the Detection and Identification of Living Modified Organisms, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to:

(a) Remind Parties of their obligations, and invite other Governments, to register in the Biosafety Clearing-House all their decisions on living modified organisms and related risk assessments as requested under the Protocol, with special emphasis on first intentional transboundary movements of living modified organisms for intentional introduction into the environment that are intended for field trials since this category is currently underrepresented in the Biosafety Clearing-House;

(b) Invite Parties and other Governments to submit to the Executive Secretary information and case studies related to their existing mechanisms for 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;

(c) Encourage Parties and other Governments, without prejudice to article 21 on confidential information, to ensure that the information provided by a notifier at the time of notification includes all the information necessary to detect and identify the LMO including, as appropriate, the sequences of vectors, modified genetic elements and their flanking regions;

(d) Request the Online Network of Laboratories for the Detection and Identification of Living Modified Organisms to continue working on the development of technical tools and guidance relevant to detection and identification of LMOs;

(e) Request the Executive Secretary to:

(i) Continue organizing online discussions through the Network of Laboratories focusing on the detection and identification of LMOs;

(ii) Compile and synthesize the information and case studies submitted by Parties of their existing mechanisms for emergency measures in case of unintentional transboundary movements of living modified organisms;

(iii) Organize, in cooperation with relevant organizations, subject to the availability of funds, capacity building activities such as online and face-to-face training workshops on sampling, detection and identification of LMOs to assist Parties in fulfilling the

requirements under article 17 and towards achieving the relevant outcomes of the Strategic Plan;

- (iv) Seek further assistance from an informal advisory committee, constituted and coordinated in a transparent manner, with a particular focus on providing guidance with respect to matters relevant to detection and identification of LMOs, including further development of technical tools and guidance to facilitate appropriate responses to unintentional transboundary movements by convening a face-to-face meeting.

Annex I

**RECOMMENDATIONS OF THE ONLINE NETWORK OF LABORATORIES FOR THE
DETECTION AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS**

The Online Network of Detection Laboratories for the Detection and Identification of Living Modified Organisms endorses the following recommendations made during the “Workshop of the Network of Laboratories for the Detection and Identification of Living Modified Organisms” held in Ispra, Italy, from 25 to 27 November 2013, for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its seventh meeting.

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

- (a) Encourage Parties, with a view to facilitating the detection and identification of LMOs, to require LMO developers to make available, as appropriate, the sequences of transgenes, vectors and flanking regions of LMOs at the time of submission of an LMO application, and to provide the appropriate control samples in the event that an LMO is approved;
 - (b) Invite Parties and other Governments to provide information regarding their capacity and needs in the detection and identification of LMOs, including a list of laboratories and their specific activities;
 - (c) Establish an informal advisory committee to advise the Executive Secretary on matters relevant to the network on detection and identification of LMOs;
 - (d) Urge Parties, with a view to facilitating the detection and identification of LMOs, to meet their obligations under Articles 17 and 25 and make available to the BCH information concerning cases of unintentional and illegal transboundary movements of LMOs;
 - (e) Urge Parties to establish a rapid alert system at the national and/or (sub)regional levels in cases where unauthorized LMOs and unintentionally released LMOs are detected;
 - (f) Encourage Parties, with a view to facilitating the identification of LMOs unintentionally introduced into the environment, to submit to the BCH information on LMOs undergoing field trials;
 - (g) Request the Executive Secretary to:
 - (i) Improve the accessibility and availability in the BCH of information related to appropriate control samples, including certified reference materials and other reference materials, validated methods and protocols for LMO detection, including those protocols with limits of detection (LOD) and limits of quantification (LOQ);
 - (ii) Explore the possibility, with LMO developers, of including the DNA sequence information of transgenes, vectors and flanking regions, as appropriate, in the LMO records available through the BCH;
 - (iii) Convene a meeting of the informal advisory committee referred to in paragraph (c) above in early 2015;
 - (iv) Organize an ongoing online discussion through the Network of Laboratories where questions and answers can be posted pertaining to the detection and identification of LMOs;
 - (v) Organize, in cooperation with relevant organizations, subject to the availability of funds, capacity-building activities, such as online training and face-to-face meeting/workshops in the fields of sampling, detection and identification of LMOs.
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