



Convention on Biological Diversity

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

Eighth meeting

Cancun, Mexico, 4-17 December 2016

Item 13 of the provisional agenda*

TRANSIT AND CONTAINED USE OF LIVING MODIFIED ORGANISMS

Note by the Executive Secretary

I. INTRODUCTION

1. Article 6 of the Cartagena Protocol on Biosafety addresses transit and contained use of living modified organisms (LMOs). Transit and contained use of LMOs are also addressed in operational objective 1.8 of the Strategic Plan for the Cartagena Protocol on Biosafety for the Period 2011-2020 as contained in the annex to decision BS-V/16.

2. As outlined below, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) decided to consider these topics at its eighth meeting. The present note has been prepared by the Executive Secretary to assist the Conference of the Parties serving as the meeting of the Parties in this regard.

3. Section II of the document provides an analysis of the status of implementation of the provisions of the Protocol and of the decisions by Parties related to the transit of LMOs. In section III, an analysis of the status of implementation of the provisions of the Protocol and the decisions by Parties related to contained use of LMOs is presented, as well as a synthesis of views submitted by Parties and other Governments on information, tools, practical experience and guidance related to their existing mechanisms and requirements relating to the contained use of LMOs, including any specific requirement relating to the type and level of containment with a view to facilitating the implementation of the Protocol's provisions on contained use of LMOs. Section IV provides an overview of the conclusions of the activities relating to Article 6. Finally, Section V contains suggested elements for a draft decision.

II. TRANSIT

A. Background

4. Paragraph 1 of Article 6 of the Cartagena Protocol addresses transit of LMOs and provides that "Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit."

* UNEP/CBD/BS/COP-MOP/8/1.

5. The Conference of the Parties serving as the meeting of the Parties first addressed the issue of transit at its second meeting when, in decision BS-II/14, it invited Parties, other Governments and relevant international organizations to submit views regarding clarification of the rights and/or obligations of transit States. At its third meeting, the Conference of the Parties serving as the meeting of the Parties considered the eight submissions received and, in decision BS-III/16, invited Parties, Governments and relevant organizations to provide further views and experience on the rights and/or obligations of Parties of transit including whether or not a Party acting only as a Party of transit takes on the obligations of a Party of export under the Protocol. Following decision BS-III/16, two Parties submitted their views, stating that they did not have information on the matter.

6. At its fifth meeting, in decision BS-V/10, the Conference of the Parties serving as the meeting of the Parties considered the rights and obligations of Parties of transit of LMOs and, in view of the absence of new submissions of views or information from Parties, encouraged Parties to continue addressing issues related to the transit of LMO through their territories using their domestic administrative and legal systems and decided to consider the issue at its eighth meeting.¹

7. In the Strategic Plan for the Cartagena Protocol on Biosafety for the Period 2011-2020, adopted in decision BS-V/16,² transit is addressed under operational objective 1.8 (*To develop tools and guidance that facilitate the implementation of the Protocol's provisions on transit, contained use, unintentional transboundary movements and emergency measures*). One of the related outcomes refers to transit (*Parties are enabled to manage LMOs in transit*) with indicator 1.8.1 referring to the percentage of Parties having in place measures to manage LMOs in transit.

8. In order to review the status of implementation of the provisions of the Protocol or any decision by Parties related to the transit of LMOs, as set out in the programme of work of the Conference of the Parties serving as the meeting of the Parties, an analysis of information related to transit provided by Parties in their national reports is provided in section B below. An overview of decisions taken by Parties on transit that are available in the Biosafety Clearing-House (BCH) is provided in section C.

B. Status of implementation of the provisions of the Protocol related to transit of living modified organisms

9. The national reports of Parties provide information relating to the implementation of Article 6. The information provided indicates whether Parties regulate transit and whether information on such regulations has been submitted to the Biosafety Clearing-House. When information provided in third national reports was compared with that provided by the same Parties in their second national reports (baseline), the information showed that a total of 63 per cent of Parties regulate transit (74 Parties).³ This constitutes an increase of 3 per cent in comparison to the baseline.⁴ A total of 6 per cent of Parties regulate transit to some extent (7 Parties), which is an increase of 6 per cent, while 31 per cent of Parties (37 Parties) reported not to regulate transit, which is a decrease of 9 per cent in comparison to the baseline.

10. In their written comments, out of the 37 Parties that reported that they do not regulate transit, 11 Parties indicated that relevant draft legislation is under development or pending adoption. On the other hand, among the Parties who reported that they fully regulate transit, two indicated that their current legislation on transit is insufficient and that subsidiary legislation is required. Furthermore, nine Parties indicated that to date there have not been any cases of transit in their countries.

¹ Accordingly, the programme of work of the Conference of the Parties serving as the meeting of the Parties for the period 2012-2016 (adopted as annex II to decision BS-V/16), includes the review of the status of implementation of the provisions of the Protocol or any decision by Parties related to the transit of LMOs by the Conference of the Parties serving as the meeting of the Parties at its eighth meeting.

² See http://bch.cbd.int/protocol/issues/cpb_stplan_txt.shtml.

³ The analysis contained in this section is based on questions 25 and 28 of the third national report format. Third national reports submitted by 31 August 2016 were considered.

⁴ The numbers are based on a comparison of Parties that provided information on this matter in both the second and third reporting cycles. For more information on the methodology regarding the analysis of the third national reports, see UNEP/CBD/BS/COP-MOP/8/12 and UNEP/CBD/BS/COP-MOP/8/12/Add.1.

11. Considerable regional differences are noted in the analysis of national reports. The GRULAC region has the lowest percentage of Parties who reported that they regulate transit (47%) (a decrease of 6% in comparison to the baseline), closely followed by the Asia and the Pacific region with 48 per cent (12% increase) and Africa 51 per cent (no change in relation to the baseline). The percentage of Parties in WEOG and CEE regions that regulate transit are much higher: 100 per cent (no change in relation to the baseline) and 88 per cent (6% increase), respectively. The differences between the regions decrease somewhat when the percentage of Parties that reported that they regulate transit to some extent is combined with the percentage of Parties that reported that they regulate transit, resulting in the following percentages per region: Africa 59 per cent; Asia and the Pacific 56 per cent; CEE 88 per cent; GRULAC 58 per cent and WEOG 100 per cent.

12. While regional differences remain, a number of Parties reported that draft legislation is being developed or pending adoption (six from Africa; two from GRULAC; and three from Asia and the Pacific region). This suggests that Parties are continuing to work on regulating LMOs in transit.

C. Decisions taken by Parties regarding transit of living modified organisms

13. As per Article 6 of the Protocol, a Party may make available to the Biosafety Clearing-House any decision of that Party regarding the transit through its territory of a specific living modified organism. The BCH contains one decision relating to transit in the context of Article 6, dating from 2009.⁵

III. CONTAINED USE

A. Background

14. Article 3 of the Protocol defines “contained use” as “any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment”.

15. Paragraph 2 of Article 6 addresses contained use and provides that “Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import”.

16. Contained use of LMOs is addressed under operational objective 1.8 of the Strategic Plan for the Cartagena Protocol on Biosafety. One of the related outcomes refers to contained use (*Guidance developed to assist Parties to detect and take measures to respond to unintentional releases of living modified organisms*) with indicator 1.8.2 referring to the percentage of Parties having in place measures for contained use.

17. At its seventh meeting, in decision BS-VII/4, the Conference of the Parties serving as the meeting of the Parties considered the issue of contained use of LMOs and decided to:

(a) Invite Parties and other Governments to submit to the Executive Secretary information, tools, practical experience and guidance related to their existing mechanisms and requirements relating to the contained use of LMOs, including any specific requirement relating to the type and level of containment;

(b) Consider, at its eighth meeting, taking into account the information provided through paragraph (a) above, the gaps and needs identified by Parties, if any, with a view to facilitating the implementation of the Protocol's provisions on contained use of LMOs.

18. The following sections provide an analysis of available information related to contained use of LMOs. Section B presents an analysis of information related to contained use provided by Parties in their national reports. Section C provides an overview of decisions taken by Parties on contained use that are available in the

⁵ “Country's Decisions and other Communications” are available at <http://bch.cbd.int/database/decisions/>. It is noted that the BCH contains several decisions on the import of LMOs for intentional introduction into the environment or for direct use as food, feed, or for processing that are also marked as decisions on “transit” and/or “contained use”. It appears as though these decisions have been mislabelled and the Secretariat is liaising with the relevant Parties to rectify the issue.

Biosafety Clearing-House. Section D provides a synthesis of views on information, tools, practical experience and guidance related to existing mechanisms and requirements related to contained use of LMOs.

B. Status of implementation of provisions for contained use of living modified organisms

19. In assessing the status of implementation of provisions for contained use of LMOs, as indicated by Parties in their national reports, 75 per cent of Parties reported that their country regulates the contained use of LMOs.⁶ This represents a 6 per cent increase as compared to the baseline. The remaining 25 per cent of Parties reported that they do not regulate the contained use of LMOs, which corresponds to a 6 per cent decrease in the number of Parties in comparison to the baseline.

20. At the regional level, all Parties in WEOG (no change in relation to the baseline) and 94 per cent of Parties in CEE (6% increase) reported that they regulate contained use, while 67 per cent of countries in Africa and 72 per cent of countries in Asia and the Pacific indicated that they do so, which represents an increase of 11 and 12 per cent, respectively. GRULAC was the only region that showed a downward trend in the number of Parties that regulate contained use with 53 per cent of Parties reporting that they do so which represents a 6 per cent decrease as compared to the previous reporting cycle.

C. Decisions taken by Parties regarding contained use of living modified organisms

21. The Biosafety Clearing-House contains a total of 30 decisions regarding transboundary movements of LMOs that were destined for contained use submitted by seven Parties. The decisions relate to different types of LMOs, for example two decisions concerned living modified microorganisms that were modified for the production of biofuels, and one decision concerned the import of living modified Glofish[®].

22. Furthermore, among the decisions labelled as “contained use”, one regarded an LMO that was imported for a field trial while 12 regarded living modified plants that were destined for field cultivation. Neither of these two intended uses would seem to fall under the definition of contained use as per Article 3 of the Protocol.

D. Synthesis of views on information, tools, practical experience and guidance related to existing mechanisms and requirements relating to the contained use of living modified organisms

23. In response to decision BS-VII/4, paragraph 1, the Secretariat issued a notification inviting Parties and other Governments to provide views, information, tools, practical experience and guidance related to their existing mechanisms and requirements relating to the contained use of LMOs, including any specific requirement relating to the type and level of containment.⁷

24. Twenty nine Parties (Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Costa Rica, Finland, France, Germany, Hungary, Islamic Republic of Iran, Iraq, Japan, Latvia, Lithuania, Malaysia, Mexico, Nigeria, Peru, Philippines, Republic of Korea, Slovakia, Slovenia, South Africa, Spain, Sudan, Sweden, Trinidad and Tobago, United Kingdom of Great Britain and Northern Ireland and Viet Nam) and two non-Parties (Australia and the United States of America) had submitted their views on this matter as of 2 August 2016.⁸

25. In their submissions, most Parties provided an overview of the status of the regulation of contained use of LMOs within their national frameworks, with a particular focus on the contained use of living modified microorganisms. Some Parties also outlined the procedures they have in place for the contained use of other types of LMOs such as living modified plants and living modified animals.

26. Most Parties indicated that facilities that carry out work on LMOs within a contained environment must obtain permission from the relevant competent authority before commencing with any activities. Some Parties also indicated that field trials are within the scope of their regulatory frameworks for contained use of LMOs.

27. Furthermore, most submissions described the provisions in place for the classification of the levels of containment, including the requirements for the risk assessment of the LMOs as well as the monitoring of

⁶The analysis was based on question 26 of the online format for the third national reports. Third national reports submitted by 31 August 2016 were considered.

⁷Notification: SCBD/BS/CG/MPM/DA/85327 of 14 January 2016.

⁸Original submissions can be found at http://bch.cbd.int/protocol/cpb_art6/contained_submissions.shtml.

facilities for compliance. A few submissions also provided an overview pointing to the kinds of procedures that should be in place for waste management and unintentional release of an LMO under contained use.

28. It is noted that the majority of the submissions did not include practical guidance on the contained use of LMOs, they rather pointed to the existence of such guidance and regulations at the national and international levels that are sufficiently applicable to the contained use of LMOs.

IV. CONCLUSIONS

29. During the third national reporting cycle, Parties indicated that they have made progress towards achieving the outcomes under operational objective 1.8 that are relevant to transit and contained use, as compared to the previous reporting cycle. Furthermore in assessing the progress made towards indicators 1.8.1 and 1.8.2, the percentage of Parties reporting having in place measures to manage LMOs in transit and measures for contained use have both increased in this reporting cycle in comparison to the baseline.

30. The third national reports also indicated positive upward trends in comparison to the baseline with respect to the regulation of both transit and contained use in most regions. However, substantial differences still exist among the regions.

31. Some decisions on LMOs destined for contained use have been posted to the BCH although in some cases, the information that has been made available suggests that the decisions may not address contained use as defined in the Protocol. This suggests that there are various interpretations and/or lack of clarity as to what type of information is required to be submitted to the BCH when final decisions regarding the import of an LMO destined for contained use are taken.

32. From the submission of views on information, tools, practical experience and guidance related to existing mechanisms and requirements relating to the contained use of LMOs, it appears as though a number of Parties have developed practices to manage the contained use of LMOs.

V. SUGGESTED ELEMENTS FOR A DRAFT DECISION

33. Taking into account the information provided above, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to:

(a) Welcome the progress towards operational objective 1.8 of the Strategic Plan for the Cartagena Protocol on Biosafety for the Period 2011-2020;

(b) Note the limited number of decisions related to transit and contained use that have been made available to the Biosafety Clearing-House;

(c) Note the lack of clarity regarding the type of information that is to be submitted to the Biosafety Clearing-House when final decisions are taken regarding the importation of living modified organisms destined for contained use;

(d) Encourage Parties and invite other Governments to make available to the Biosafety Clearing-House the text of their laws, regulations and decisions regarding contained use and transit of living modified organisms;

(e) Invite Parties and other Governments, in the context of operational objective 1.8 of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020, to submit to the Biosafety Clearing-House practical guidance on specific measures for contained use that effectively limit the contact of living modified organisms with, and their impact on, the external environment;

(f) Encourage Parties to further develop measures to manage living modified organisms in transit and to make available in the Biosafety Clearing-House information on such measures;

(g) Request the Compliance Committee to provide guidance on what information may be submitted to the Biosafety Clearing-House when a final decision is taken regarding the import of a living modified organism that is destined for contained use;

(h) Request the Executive Secretary:

- (i) To continue improving in the Biosafety Clearing-House the means to allow easy retrieval of information relating to transit and contained use, including the information submitted under paragraphs (c) and (e) above;
 - (ii) To monitor and assess for gaps in existing tools and practical guidance regarding contained use, based on, among other things, the information submitted under paragraph (e) and through other relevant activities under the Protocol, as appropriate.
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