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ON BIOLOGICAL DIVERSITY SERVING AS THE
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PROTOCOL ON BIOSAFETY

Ninth meeting

Sharm El-Sheikh, Egypt, 17-29 November 2018

Item 17 of the provisional agenda*

TRANSIT AND CONTAINED USE OF LIVING MODIFIED ORGANISMS

Note by the Executive Secretary

I. INTRODUCTION

1. Article 3 (b) of the Cartagena Protocol on Biosafety states that, for the purposes of the Protocol, “‘contained use’ means 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”.

2. Article 6 of the Protocol further provides that, notwithstanding the scope of the Protocol 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 the 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.

3. In paragraph 5 of its decision [CP-VIII/17](#), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested the Compliance Committee to assess if information that has been submitted to the Biosafety Clearing-House (BCH) under contained use is in accordance with Article 6 of the Cartagena Protocol, and make a recommendation in this regard for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its ninth meeting.

4. In paragraph 6 of the same decision, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol invited Parties and other Governments to submit to the BCH 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, in the context of operational objective 1.8 of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020.¹ In paragraph 8 (a) of the decision, the Executive Secretary was requested to compile the information submitted for the consideration of the Conference of the Parties serving as the meeting of the Parties to

* CBD/CP/MOP/9/1.

¹ Operational objective 1.8 of the Strategic Plan: “To develop tools and guidance that facilitate the implementation of the Protocol’s provisions on transit, contained use, unintentional transboundary movements and emergency measures”.

the Protocol at its ninth meeting with a view to identifying areas where activities might be needed to support Parties in their efforts to develop national measures on contained use.

5. The present document provides a summary description of the assessment carried out by the Compliance Committee on information registered in the BCH under contained use (section II), an overview of submissions received (section III), and elements of a draft decision (section IV).

II. SUMMARY OF THE ASSESSMENT BY THE COMPLIANCE COMMITTEE OF INFORMATION REGISTERED IN THE BIOSAFETY CLEARING-HOUSE UNDER CONTAINED USE

6. At its fourteenth meeting, held from 16 to 18 May 2017, the Compliance Committee reviewed decision [CP-VIII/17](#), and decided to carry out the assessment referred to in paragraph 5 of the decision at its fifteenth meeting, and in preparation for this, agreed to hold informal online discussions among its members through its collaborative portal.

7. To facilitate the preparatory online discussions, the Secretariat made available to the Committee an overview of national records that had been published by Parties in the BCH and that contained decisions on transboundary movement of living modified organisms destined for contained use.²

8. The online discussions were held from 22 January to 9 February 2018 on the collaborative portal of the Compliance Committee. During the online discussions, members of the Committee shared national practices concerning decision-taking on the introduction of living modified organisms intended for contained use, in comparison with procedures for decision-taking on introduction of living modified organisms into the environment. Members recalled decision [BS-V/2](#), paragraph 1 (a), and decision [BS-VII/2](#), paragraph 2 (b) and suggested that the Conference of the Parties serving as the meeting of the Parties to the Protocol had associated decisions regarding field trials with decisions concerning introduction into the environment.

9. Following the online discussions, the Chair of the Committee requested the Secretariat to seek additional information from the Parties identified by the Committee members on a number of BCH records, with a view to clarifying whether the records concerned decisions on contained use, as defined in the Protocol, or decisions on intentional introduction into the environment.

10. At its fifteenth meeting, held from 8 to 10 May 2018, the Committee considered the issue on the basis of a note by the Executive Secretary, [CBD/CP/CC/15/3](#), which provided an overview of the decisions submitted to the Biosafety Clearing-House under contained use, a summary of the informal discussions held on the Committee's collaborative portal, and additional information provided by the Parties concerned following the informal discussions. Document [CBD/CP/CC/15/3](#) also contained a brief summary of relevant aspects of national guidance on specific measures for contained use submitted by Parties in response to notification [2017-087](#), issued on 8 September 2017.³

11. At the meeting, the Committee reviewed the information provided in the note, and members shared additional information on national approaches to contained use. In this context, they also discussed domestic rules and procedures concerning introduction into the environment and field trials.

² The overview contained the 30 national records, submitted by seven Parties, to which reference had been made in UNEP/CBD/BS/COP-MOP/8/10, para. 21. At the time the online discussions, ten of these records had already been relabelled in the BCH, by the Party concerned, as national records containing decisions concerning introduction into the environment.

³ <https://www.cbd.int/doc/notifications/2017/ntf-2017-087-bs-en.pdf> (Ref. No.: [SCBD/SPS/DC/MM/DA/86806](#)).

12. The Committee assessed the decisions submitted to the BCH under “contained use” and noted that some records made available in this category were not fully in accordance with Article 6 of the Protocol and that some of these records related rather to intentional introduction into the environment.

13. The Committee made a number of recommendations on contained use, as contained in section C of the annex to the report of the Committee on the work of its fourteenth and fifteenth meetings (CBD/CP/MOP/9/2) and reflected in section IV of the present document.

14. In accordance with the Committee’s organization of work, the Committee will review compliance on the basis of information provided in the Biosafety Clearing-House at its sixteenth meeting (which is expected to take place in 2019). At that meeting, the Committee is expected to return to the matter, and will follow up with the Parties concerned, as required.

15. In order to facilitate the consideration of the issue by the Committee in the future, the Secretariat has added a question in the draft revised format for the fourth national report under the Protocol, as contained in CBD/CP/MOP/9/5,⁴ to ask whether Parties have taken any decision concerning the import of living modified organisms for contained use.

III. SUBMISSIONS ON THE CONTAINED USE OF LIVING MODIFIED ORGANISMS

16. A total of 28 submissions were received in response to notification 2017-087, out of which 25 were from Parties to the Protocol (Austria, Belarus, Belgium, Benin, Bhutan, Bulgaria, Burkina Faso, European Union, Finland, Germany, Iran (Islamic Republic of), Japan, Mexico, Netherlands, Nigeria, Oman, Philippines, Slovakia, South Africa, Spain, Sudan, Switzerland, Uruguay and Venezuela (Bolivarian Republic of)), and three were from other Governments (Argentina, Australia and United States of America). The original submissions are available on the Biosafety Clearing-House.⁵

17. The submissions provided information on various topics related to contained use of living modified organisms, ranging from general comments about national instruments that address this topic to detailed descriptions of conditions and measures that are applied by some of the countries.

18. Some submissions provided detailed information on particular containment conditions that have to be met for activities with living modified organisms. In this context, examples were provided for physical and biological containment measures.

19. In relation to physical containment, the following measures have been suggested:

(a) The containment facility must be a fully enclosed space that is surrounded by rigid and durable boundaries, which must withstand the expected wear and tear without losing their properties;

(b) Transparent sections of containment facilities must be made of durable materials (i.e. glass, polycarbonate sheeting);

(c) All boundaries must be impact resistant;

(d) The design of a containment facility must be such as to prevent the entrance of surface run-off water;

(e) The containment facilities must consist of an anteroom (i.e. a room separating the areas where living modified organisms are kept under containment from the external environment);

⁴ Question 25 in the annex to document CBD/CP/MOP/9/5.

⁵ https://beh.cbd.int/protocol/cpb_art6/contained_submissions.shtml; two submissions were received from Uruguay.

(f) The containment facilities must contain washbasins and first aid kits, among other safety equipment;

(g) Appropriate barriers must be present for containment facilities in order to limit exposure of the environment; in the case of facilities handling plants, for instance, seed harvesting/collecting devices, pollination bags, and insect meshes could be useful;

(h) Open spaces between and under benches, cabinets and equipment in the containment facilities must be accessible for decontamination when necessary;

(i) Living modified organisms must be placed in containers that prevent escaping and other forms of dispersion; the containers should be properly labelled to indicate the presence of living modified organisms, and stored separately from other living organisms.

20. In relation to biological containment, the following requirements were noted as necessary for the handling of living modified plants, as appropriate:

(a) Measures to prevent flowering and vegetative propagation;

(b) Use of male-sterile or non-flowering lines;

(c) Temporal isolation (cultivation/flowering scheduled outside the flowering period of wild relatives), and a distance of no less than 300 metres from nurseries, greenhouses and fields growing sexually compatible species.

21. For living modified animals, biological containment measures such as using species that cannot survive and have no relatives in the surrounding environment, and using juvenile individuals that have not reached sexual maturity, were indicated.

22. Regarding operations of the containment facility, the following elements were noted:

(a) There should be a detailed record of information from the moment a living modified organism enters the containment facility until the time when it leaves the facility, or is destroyed and disposed of;

(b) Waste products of living modified organisms generated as a result of the work conducted in the containment facilities should be deactivated by a method that destroys all parts of the organisms, including spores, pollen, fruits and seeds;

(c) There should be emergency protocols in case of spills and/or accidental releases.

23. Some submissions also included information that must be included in an application for handling a living modified organism in contained use. The following information was listed as requirements to be included in such applications:

(a) The name and type of living modified organism;

(b) The name and location of the containment facility where the living modified organism would be handled;

(c) The intended use of the living modified organism;

(d) Contact details of the applicant.

24. Likewise, it was mentioned in a submission that the permit for contained use in that country require permit holders to, among others:

(a) Store all transgenic material and materials associated or used in the contained use activities in the registered storage facility to prevent release of the organism or material associated with the contained use activities;

(b) Keep accurate records of all activities pertaining to the management of the registered facility, including an inventory of the quantity of living modified organisms/material and records of their disposal at the end of the contained use period;

(c) Store any surplus genetically modified material in a secure place within the facility in closed bags/containers to ensure that the material is not dispersed, and submit a declaration to the registrar stating that the surplus material will be shipped back to the foreign supplier.

25. The submissions also provided examples of activities that must not be undertaken in the containment facilities, such as maintaining any living organisms that have not been approved for use in the same containment facility.

26. Some countries noted that contained use was already captured through their existing national biosafety regulations and, therefore, specific practical guidance on contained use had not been developed. Other countries indicated that they were still in the process of developing their national biosafety frameworks, and as such, specific information on contained use was not available at the moment.

27. A non-Party indicated its view that as a general principle, unmodified pathogens of humans, animals and plants pose a similar or greater risk than those risks of living modified organisms, and that the principles of containment that apply to pathogens are transferable to different types of organisms, including living modified organisms. In this respect, the submission pointed out that the extensive international, regional and national guidance on regulation of the handling, transport, packaging and identification of organisms which is already in place could also apply to living modified organisms destined for contained use.

28. In relation to risks that living modified microorganisms might present to human health and the environment, some submissions indicated that contained uses of these organisms are classified from class 1 to 4, for example in Directive 2009/41/EC of the European Union on genetically modified microorganisms. Another submission remarked that the type of equipment and conditions for contained use related activities will vary according to the level of risk that has been identified by the authorities.

29. A submission noted that at European Union level, the contained use of living modified organisms other than microorganisms is not covered by Directive 2009/41/EC, but Regulation (EC) No 1946/2003 on the transboundary movements of genetically modified organisms applies also to genetically modified organisms other than microorganisms. Other submissions pointed out that their legislation has a broader scope of application, and legislation on contained use is not limited to microorganisms. In this sense, activities with living modified plants or mice, for instance, are also regulated.

30. Other countries have additional rules for gene drive applications under contained use, so that all gene drive applications require a permit, and appropriate containment levels will be determined on a case-by-case basis. Another submission indicated that, the legislation of that country also applies to contained use of living modified organisms resulting from new scientific developments, including recent developments in synthetic biology and engineered gene drives.

31. It was also pointed out, by a further submission, that effective biological safety programmes have been operative in a variety of laboratories for many years and that considerable information already exists, including specific guidelines for practices for developing and handling (a) recombinant nucleic

acid molecules, (b) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can bind with naturally occurring nucleic acid molecules, and (c) cells, organisms, and viruses containing such molecules.

32. Another submission noted that a contained use permit is required once the research is scaled up from basic research to product development, or when the containment level is above II; while another submission indicated that research activities are exempt from requesting a permit as per the national law.

33. Finally, another submission indicated that their national biosafety law determines that genetic engineering activities of risk levels II, III and IV should be carried out exclusively by State legal entities.

IV. SUGGESTED ELEMENTS OF A DRAFT DECISION

34. As reflected in the annex to the report of the Compliance Committee under the Cartagena Protocol on Biosafety on the work of its fourteenth and fifteenth meetings (document CBD/CP/MOP/9/2), on the issue of contained use, the Compliance Committee recommended that the Conference of the Parties serving as the meeting of the Parties to the Protocol, at its ninth meeting, decide to:

(a) Take note of the Committee's assessment of information in the Biosafety Clearing-House submitted by Parties as decisions under contained use;

(b) Remind Parties of their obligation under Article 20, paragraph 3 (d), and encourage other Governments, to publish in the Biosafety Clearing-House their final decisions regarding the importation or release of living modified organisms;

(c) Remind Parties that:

(i) Article 3 (b) of the Protocol sets out the definition of contained use, namely "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";

(ii) Intentional introduction into the environment can include introduction both for experimental or for commercial purposes;

(iii) A field trial, confined field trial or experimental introduction is to be regarded as intentional introduction into the environment and not as contained use.
