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COMPLIANCE COMMITTEE UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

Fifteenth meeting
Montreal, Canada, 8-10 May 2018

ASSESSMENT OF INFORMATION SUBMITTED TO THE BIOSAFETY CLEARING-HOUSE UNDER CONTAINED USE

Note by the Executive Secretary

INTRODUCTION

1. The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, in its decision [CP-VIII/17](#), noted the lack of clarity regarding the type of information that is to be submitted to the Biosafety Clearing-House (BCH) when final decisions are taken regarding the importation of living modified organisms (LMOs) destined for contained use. It requested the Compliance Committee to assess if information that had been submitted to the BCH under contained use was 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.

2. The Committee at its fourteenth meeting reviewed decision CP-VIII/17 in the context of its assessment of the outcomes of the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. The Committee decided to consider the issue at its fifteenth meeting.

3. The present document provides an overview of the decisions submitted to the BCH under contained use in Section II. An overview of the informal discussions held on the Committee's collaborative portal is contained in section III, while section IV provides a synthesis of national guidance on contained use from information received through submissions. Finally, some suggestions for the consideration of the Committee are provided in section V.

I. DECISIONS SUBMITTED TO THE BIOSAFETY CLEARING-HOUSE UNDER CONTAINED USE

4. Article 3, paragraph (b), of the [Cartagena Protocol](#) provides that the term "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.

5. Article 6, paragraph 2, of the Protocol 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.”

6. The Conference of the Parties serving as the meeting of the Parties to the Protocol at its eighth meeting, when considering transit and contained use of LMOs, had before it a note by the Executive Secretary on transit and contained use of living modified organisms ([CBD/CP/COP-MOP/8/10](#)), paragraphs 21 and 22 of which read as follows:

“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.”

7. Following the publication of that document, 10 decisions have been removed or relabelled by the Party concerned and no longer appear under contained use. Furthermore, one decision has been substituted by the Party concerned with another decision labelled “contained use”.¹ Consequently, as of 15 February 2018, the BCH contained 20 decisions labelled as “contained use” submitted by six Parties.²

8. The level of detail of the information available on the BCH associated with each decision varies by decision. For some decisions, information is provided on the facilities in which the LMO is to be used or on the applicable security measures. For other decisions, this information is not or is only partly provided. A few decisions seem to relate to field trials. An overview of the decisions is provided in annex I.

II. INFORMAL DISCUSSIONS ON THE COLLABORATIVE PORTAL OF THE COMPLIANCE COMMITTEE AND FOLLOW-UP

9. At its fourteenth meeting, the Committee agreed to hold informal discussions in preparation for its fifteenth meeting,³ at which the Committee would assess whether information submitted to the BCH as a “decision on contained use of LMOs” is in line with the conditions for contained use provided in the Protocol. The discussions were held on the collaborative portal of the Compliance Committee from 22 January to 9 February 2018.⁴

10. In her opening message on the collaborative portal, the Chair of the Committee invited the members of the Committee to share relevant information from national experience regulating LMOs for contained use, including how this relates to field trials of LMOs. Furthermore, the Chair recalled that, in decision [BS-V/2](#), paragraph 1(a), and decision [BS-VII/2](#), paragraph 2(b), 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.⁵

¹ On 31 January 2018, Kenya submitted a new decision labelled “contained use”. The previous decision labelled as such is no longer available.

² The following Parties have submitted decisions labelled “contained use”: Brazil (2 decisions); Burkina Faso (2 decisions); Colombia (5 decisions); Kenya (1 decision); Swaziland (1 decision); Sweden (9 decisions).

³ See [CBD/CP/CC/14/5](#), para. 20.

⁴ http://bch.cbd.int/onlineconferences/portal_art34/cc_main.shtml

⁵ The text of paragraph 1(a) of decision BS-V/2 and paragraph 2(b) of decision BS-VII/2 is provided in annex II.

11. In their interventions, several Committee members stated that the nature of contained use and introduction into the environment of LMOs is distinct and explained that, in their countries, rules and procedures applying to contained use of LMOs are different from rules and procedures applying to intentional introduction into the environment of LMOs. Some members described that authorizations for contained use and for introduction into the environment are issued by different authorities. Two members explained that, in their countries, those who apply for an authorization for contained use of LMOs are allowed to start the activities as soon as they receive an acknowledgement of receipt of the application from the competent authorities. These members indicated that, in contrast, those applying for an authorization for intentional introduction into the environment would not be allowed to commence these activities until the issuance of the actual authorization.

12. In some interventions, members recognized, however, that there are certain uses of LMOs for which it is difficult to determine whether it relates to contained use or introduction into the environment. In that context, the example was provided of genetically modified plants grown in a greenhouse where windows are regularly opened. It was mentioned that, in such situations, authorities would impose appropriate measures necessary to control the risk of the LMO spreading into the environment based on a case-by-case assessment. One member mentioned that physical or a combination of physical and biological barriers would be required in that respect. Where such measures were not imposed, the use would be regarded as introduction into the environment. Some members suggested that that approach would be in line with the definition of the term “contained use” provided in Article 3(b) of the Cartagena Protocol.

13. In some interventions, members described that, in their countries, field trials or experimental release of LMOs would be treated as introduction into the environment even though biosafety measures would be imposed to limit the interaction of the LMO with the environment.

14. In one intervention, however, a member described that, in his country’s national regulatory framework, contained use referred to an array of uses, ranging from use of LMOs in laboratories, greenhouses and growth chambers to use in confined field trials,⁶ and that, for each use, prior approval was required. Depending on the activity, different containment measures would be imposed.

15. Following the discussion, the Chair of the Committee requested the Secretariat to seek additional information on a number of decisions from the Parties concerned for which it was not clear whether their decisions in the BCH related to contained use as defined in the Protocol or to intentional introduction into the environment. Consequently, the Secretariat contacted Colombia, Kenya and Swaziland by e-mail and invited these Parties to provide additional information on the decisions concerned.⁷

16. Kenya explained that the decision submitted under contained use relates to a confined field trial of genetically modified sweet potato which is not intended for transboundary movement but purely for research purposes, and that a risk assessment report had been made available together with the decision in the BCH. Kenya provided information on the requirements applying to confined field trials, explaining that confined field trial sites may not exceed 5 hectares, must be properly fenced off, may only have one entrance/exit, and must be continuously guarded by security guards. Kenya also indicated that any produce from confined field trials must be destroyed on site and that no introduction into the food or feed chain is allowed. Kenya further clarified that, after harvest, confined field trial sites are monitored for a minimum of six months, and volunteer crops are uprooted and destroyed before they flower. Kenya also stated that confined field trials are subject to the [Biosafety \(Contained use\) Regulations, 2011](#), as are

⁶ It is noted that the term “confined field trial” is used by some Parties and other stakeholders, but this term is not used in the Protocol.

⁷ Following the identification by the Committee of the decisions by Colombia and Swaziland, a new decision was submitted to the BCH under contained use by Kenya which seemed to relate to a field trial. The Secretariat also requested additional information about this decision.

laboratory and greenhouse experiments. Kenya confirmed that a copy of these regulations is available in the BCH.

17. Swaziland explained that the decision in question concerns field trials of *Bacillus thuringiensis* (Bt) cotton that are carried out at the country's Agricultural Research Station and indicated that the field trials are carried out according to containment levels 1 and 2 in accordance with the [draft Biosafety Regulations](#). Swaziland clarified that level 1 applies to "activities with no or negative risk of adverse effect on human health, the environment and biological diversity"; level 2 applies to "activities with low risk of adverse effect on human health, the environment and biological diversity that can easily be eliminated using generally known procedures for which the level of containment and protective are laid down".

18. Colombia indicated that it would liaise with the appropriate authorities for them to provide the necessary information. To date, no additional information has been received.

III. NATIONAL GUIDANCE ON CONTAINED USE SUBMITTED BY PARTIES AND OTHER GOVERNMENTS

19. In its decision CP-VIII/17, the Conference of the Parties serving as the meeting of the Parties to the Protocol invited 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 LMOs with, and their impact on, the external environment.

20. In the same decision, the Conference of the Parties serving as the meeting of the Parties to the Protocol requested the Executive Secretary to compile the information submitted for its consideration 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.

21. In the light of the above, the Secretariat issued a notification⁸ to Parties and other Governments inviting the submission of relevant information on contained use of LMOs. A total of 27 submissions were received.⁹

22. The submissions were primarily intended to share existing guidance on specific measures for contained use. A number of submissions included information that may be of relevance to the Compliance Committee in the context of its assessment of whether information submitted to the BCH under contained use is in accordance with Article 6 of the Protocol. A number of submissions showed that four containment levels are recognized, which are determined on the basis of the risk to the environment and human health posed by the LMO and activity concerned.

23. Some submissions contained references to "field trials" or "confined field trials". The submission by the Philippines, for example, referred to a definition of "release into the environment" which includes confined field trials and field trials.¹⁰ In the submission by Belarus, reference is made to a regulatory instrument which determines that "works of risk level I of genetic engineering activity in self-contained systems shall be carried out in isolated units (premises), excluding release of genetically engineered

⁸ <https://www.cbd.int/doc/notifications/2017/ntf-2017-087-bs-en.pdf>

⁹ The full text of the submissions is available online: http://bch.cbd.int/protocol/cpb_art6/contained_submissions.shtml.

¹⁰ The Philippines Biosafety Guidelines for Contained Use of Genetically Modified Organisms (GMO), page 9 "release into the environment", available at: <http://bch.cbd.int/database/record.shtml?documentid=108054>

organisms into the environment.”¹¹ This description seems to indicate that contained use needs to take place in isolated conditions and that it excludes release of LMOs into the environment.

24. The submission by South Africa included a reference to a definition of “contained use” in the country’s [Genetically Modified Organisms Act](#). According to section 1 of the Act, “contained use” means the “development, production, cultivation, use, application, storage, movement, destruction or disposal of genetically modified organisms within a facility, installation or other physical structure, including a greenhouse, that are controlled by specific measures, including physical barriers or a combination of physical barriers together with chemical or biological barriers or both, that effectively limit contact of the genetically modified organisms with humans, animals, and the external environment and their impact on humans, animal and the external environment.” Field trials do not seem to fall under this definition, but would rather fit the definition of “trial release”, defined as “the deliberate release of genetically modified organisms into the environment in the open under conditions where the degree of dissemination of the genetically modified organisms is limited by chemical or physical barriers or by built-in barriers which prevent the survival of such organisms in the environment.”

25. The review of consistency between information in national reports and the Biosafety Clearing-House also identified some relevant issues (see CBD/CP/CC/15/2). In reporting in their third national reports on decisions regarding intentional transboundary movements of LMOs for intentional introduction into the environment and explaining why information had not been made available to the BCH, some Parties indicated that these decisions were for confined field trials and/or contained use.

IV. SUGGESTIONS FOR THE CONSIDERATION OF THE COMMITTEE

26. To facilitate subsequent consideration of this matter, the Committee may wish to request the Secretariat to contact those Parties that have submitted decisions to the BCH under contained use that prima facie do not seem to relate to contained use or where such determination cannot be made for lack of information, and invite those Parties to provide additional information or to re-label the decision, as appropriate.

27. To assist Parties in publishing the correct information under contained use in the BCH, the Committee may wish to request the Secretariat to make the necessary changes in the BCH in order to ensure that Parties, when submitting information under contained use, are reminded of the definition of contained use as provided in Article 3(b) of the Protocol and of previous decisions by the Conference of the Parties serving as the meeting of the Parties to the Protocol associating field trials with intentional introduction into the environment, in particular decision BS-V/2, paragraph 2(b) and decision BS-VII/2, paragraph 1(a).

28. The Committee may also wish to keep under review the issue of contained use in the context of the Committee’s assessment of the consistency of information provided in the national reports and in the BCH, as set out in the Committee’s organization of work, agreed to at the Committee’s eighth meeting.¹²

29. The Committee may also wish to consider making a recommendation to the Conference of the Parties serving as the meeting to the Parties at its ninth meeting:

(a) To take note of the Committee’s assessment of information on the BCH submitted by Parties as decisions under contained use;

(b) To remind Parties of their obligation to publish in the BCH their final decisions regarding the importation or release of LMOs;

¹¹ Resolution of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus of 17 August 2006, No. 50, available at: <http://bch.cbd.int/database/record.shtml?documentid=103684>

¹² See [UNEP/CBD/BS/CC/8/3](#).

(c) To urge Parties and encourage other Governments to make available to the BCH all final decisions on import of LMOs destined for contained use and to provide available information on the applicable containment measures, in accordance with the elements of the definition of “contained use” as provided in Article 3(b) of the Cartagena Protocol;

(d) To recall paragraph 1(a) of decision BS-V/2 and paragraph 2(b) of decision BS-VII/2 and remind Parties that a field trial of a living modified organism is to be regarded as intentional introduction into the environment unless the LMO is subject to specific measures that effectively limit its contact with, and its impact on, the external environment;

(e) To urge Parties and encourage other Governments to make available to the BCH all final decisions relating to the first intentional transboundary movement of LMOs for intentional introduction into the environment and related risk assessments, with special emphasis on the first intentional transboundary movement of LMOs intended for field trials.

*Annex I***OVERVIEW OF DECISIONS REGISTERED AS “CONTAINED USE” IN THE BIOSAFETY CLEARING-HOUSE**

	<i>Party</i>	<i>Decision record URL</i>	<i>Title</i>	<i>Additional information</i>
1.	Brazil	http://bch.cbd.int/database/record.shtml?documentid=105209	Yeast modified for the production of Farnesene	This yeast is commercially approved for use in distilleries for a biofuel production
2.		http://bch.cbd.int/database/record.shtml?documentid=109753	Prototheca moriformis modified for the synthesis of biofuel	
3.	Burkina Faso	http://bch.cbd.int/database/record.shtml?documentid=103632	Sorghum with modified levels of vitamin A; zinc and iron	
4.		http://bch.cbd.int/database/record.shtml?documentid=103634	Cowpea resistant to lepidoptera pests	
5.	Colombia	http://bch.cbd.int/database/record.shtml?documentid=7108	Resolution 1219: By which the introduction of genetically modified carnation plants is authorized.*	Authorisation of the production of carnations that are genetically modified
6.		http://bch.cbd.int/database/record.shtml?documentid=105538	Resolution 3786: By which the import is authorized of the reproductive material of Genetically Modified Roses for the color of the flower through the binary Vector pSPB130 for production of cut flowers for export.*	
7.		http://bch.cbd.int/database/record.shtml?documentid=105540	Resolution 3932: By which the importation of reproductive material of modified carnations is authorized.*	

* Courtesy translation. The text appears in Spanish in the Biosafety Clearing-House.

	<i>Party</i>	<i>Decision record URL</i>	<i>Title</i>	<i>Additional information</i>
8.		http://bch.cbd.int/database/record.shtml?documentid=105542	Resolution 3857: By which it is authorized to advance experimental planting in a greenhouse of Genetically Modified Roses for the color of the flower by means of the binary Vector pSPB130.*	
9.		http://bch.cbd.int/database/record.shtml?documentid=105544	Resolution 3858: By which it is authorized to advance experimental seeding of genetically transformed lines of carnation (<i>Dianthus caryophyllus</i>) using the transformation vectors pCGP2355; pCGP2442; pCGP3365; pCGP3366 and pCGP3367.*	
10.	Kenya	http://bch.cbd.int/database/record.shtml?documentid=113090	Decision on Field trial of sweet potato containing elements conferring siRNA resistance to sweet potato virus disease.	
11.	Swaziland	http://bch.cbd.int/database/record.shtml?documentid=111456	Approval for Confined Field Trials of Bt hybrid cotton containing Cry 1Ac gene (Event-1) developed by JK Agri Genetics Ltd.	
12.	Sweden	http://bch.cbd.int/database/record.shtml?documentid=10051		Safety requirements for basic lab research on HIV involving GMM; risk class 3
13.		http://bch.cbd.int/database/record.shtml?documentid=10053		Safety requirements for basic lab research; risk class 3
14.		http://bch.cbd.int/database/record.shtml?documentid=10055		Safety requirements for basic research in lab; GMM use risk class 3
15.		http://bch.cbd.int/database/record.shtml?documentid=10058		Safety requirements for basic research in lab; GMM use risk class 3

	<i>Party</i>	<i>Decision record URL</i>	<i>Title</i>	<i>Additional information</i>
16.		http://bch.cbd.int/database/record.shtml?documentid=10059		Safety requirements for basic research in lab; GMM use risk class 3
17.		http://bch.cbd.int/database/record.shtml?documentid=10061		Safety requirements for basic research in lab; GMM use risk class 3
18.		http://bch.cbd.int/database/record.shtml?documentid=10661		Safety requirements for lab research with genetically modified and unmodified prions (associated with spongiform encephalopathy; TSE) Classified as risk class 3. The permission is for contained use of GMMs in risk class 3. The language of the permission is Swedish.
19.		http://bch.cbd.int/database/record.shtml?documentid=11686	New uses of GMMs in existing activity; risk class 3	The decision allows new uses in basic research on genetically modified EHEC (Enterohaemorrhagic E. coli) until 31-04-2008. The strain used is O113:H21. The activity is performed at Lunds University; Box 117; SE-221 00 Lund; Sweden. The attached decision document is in Swedish.
20.		http://bch.cbd.int/database/record.shtml?documentid=11980	Consent for use of genetically modified <i>Francisella tularensis</i> type A	Consent for contained use in risk class 3 until 28th Feb 2011. Purpose of the research is to create mutants of deletion. The PDF file attached hereby is the full consent in Swedish given by the Swedish Work Environment Authority

Annex II

Paragraph 1(a) of decision BS-V/2 and paragraph 2(b) of decision BS-VII/2

Decision BS-V/2 - Operation and Activities of the Biosafety Clearing-House

[...]

1. *Reminds* Parties of their obligations, and *invites* other Governments, to:

(a) Provide to the Biosafety Clearing-House, in a timely manner, complete and accurate information on final decisions pertaining to living modified organisms and the risk assessment summaries regarding such decisions, as well as risk assessment summaries for all instances when requested by the Protocol including, *inter alia*, intentional introductions of living modified organisms into the environment for field trials regardless of whether or not the living modified organism will be subjected to future transboundary movements or commercialization;

Decision BS-VII/2 - Operation and Activities of the Biosafety Clearing-House

2. *Urges* Parties and *invites* other Governments:

[...]

(b) To register in the Biosafety Clearing-House all their final decisions on the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import and related risk assessments as requested under the Protocol, with special emphasis on the first intentional transboundary movement of living modified organisms intended for field trials, since this category is currently underrepresented in the Biosafety Clearing-House, while recalling paragraph 1(a) of decision BS-V/2;
