



Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/CC/11/3
20 May 2014

ORIGINAL: ENGLISH

COMPLIANCE COMMITTEE UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

Eleventh meeting

Montreal, 28 – 30 May 2014

Item 4 of the provisional agenda*

REVIEW OF CONSISTENCY BETWEEN INFORMATION IN NATIONAL REPORTS AND THE BIOSAFETY CLEARING-HOUSE

I. INTRODUCTION

1. According to paragraph 1 (b) of decision BS-V/1, the Compliance Committee may consider taking measures in a situation where information received from a Party through a national report or the Biosafety Clearing-House (BCH) shows that the Party concerned is faced with difficulties complying with its obligations under the Protocol.

2. In line with the approach and the work plan agreed at its eighth meeting,¹ the Committee is expected to consider, at the present meeting, the compliance of Parties with their obligations under the Protocol by reviewing the consistency or otherwise of information that each Party provided through its second national report and information made available to the BCH by that Party on the same subject.

3. The sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety has also requested the Executive Secretary “to assess, on the basis of the second national reports, the discrepancies and/or gaps in information made available by Parties through the Biosafety Clearing-House, and to assist Parties to submit, through the Biosafety Clearing-House and without further delay, the updated information contained in their reports”.²

4. Accordingly, the Secretariat has cross-checked some categories of information in the second national reports of the 151 out of 161 Parties that were required to submit a report, and have done so, with the corresponding information available in the BCH. A number of national focal points for the BCH were contacted individually by e-mail in February and March 2014, and provided with a detailed assessment of the specific discrepancies and gaps found in their records. The focal points were called upon to update their records in the BCH. A number of them responded to the Secretariat’s call and proceeded to update the relevant information or requested the Secretariat for some assistance and clarification, as appropriate, in order for them to be able to rectify the situation.

¹ UNEP/CBD/BS/CC/8/3, Report of the Compliance Committee on the work of its eighth meeting <http://www.cbd.int/doc/meetings/bs/bccc-08/official/bccc-08-03-en.pdf>

² Paragraph 8 of decision BS-VI/14 on Monitoring and Reporting (Article 33).

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II. THE EXTENT OF CONSISTENCY BETWEEN INFORMATION IN NATIONAL REPORTS AND INFORMATION IN THE BIOSAFETY CLEARING-HOUSE

5. The Secretariat has taken into consideration that three years have elapsed since most Parties have submitted their second national report. Many records have been updated or added on the BCH since then. For the purpose of this report, the information provided by a Party in its second national report has been cross-checked with information made available by that Party to the BCH as of the beginning of April 2014.

6. The cross-checking exercise undertaken by the Secretariat covers the following sets of information that the Protocol requires each Party to make available through the BCH:

- (a) Relevant laws/regulations and guidelines;
- (b) Decisions (Article 10: on the import of living modified organisms for intentional introduction into the environment and Article 11, paragraph 1: living modified organisms approved for domestic use, including placing on the market, and that may be subject to transboundary movement for direct use as food or feed, or for processing);
- (c) Risk assessments corresponding to the decisions referred to in (ii) above;
- (d) Bilateral, regional and multilateral agreements and arrangements; and
- (e) Illegal and unintentional transboundary movements.

7. Questions in the second national report that correspond to the above sets of information were identified and the responses of Parties to each of the questions, as well as their comments provided in their report as 'free text', were cross-checked with what was actually available in the BCH. The current review of the extent of consistency also takes into account the replies received from the respective BCH focal points to the e-mail messages sent to them by the Secretariat earlier this year, as referred to in paragraph 4 above. The communication between the Secretariat and a number of the focal points is still ongoing.

8. It is important to note that in certain cases, the exercise resulted in clarifying as to the possible sources of the discrepancies in the information provided in the second national reports and the BCH. It is also encouraging to witness the increasing commitment by Parties and the measures that are being undertaken by several of them to provide any missing information or otherwise correcting their records with the assistance of the Secretariat, with a view to reflect, more accurately, their current national situation as regards the regulation of the transboundary movement of living modified organisms, and thereby fulfilling their obligations under the Protocol.

9. The summary of the findings of the review with respect to each set or category of the information listed in paragraph 6 above is presented below while the details are provided in the form of tables contained in a separate document, UNEP/CBD/BS/CC/11/3/Add.1.

(a) Information on relevant laws, regulations and guidelines

10. Under Question 20 of the second national report, Parties were asked whether their country's biosafety framework/laws/regulations/guidelines had been submitted to the BCH. 72 Parties reported that they have submitted their country's biosafety framework/laws/regulations/guidelines to the Biosafety Clearing-House; 49 Parties reported that they submitted partially and 29 Parties reported that they have not submitted. One Party did not respond to the question.

11. Bearing in mind each Party's answer to this question and the time elapsed since the submission of the reports, the Secretariat undertook the following approach in order to verify whether the information

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provided by a Party through its second national report concerning national laws, regulations and guidelines corresponded with the information actually made available by that Party through the BCH.

12. As shown in the Table 1 contained in document UNEP/CBD/BS/CC/11/3/Add.1, the Secretariat first reviewed and extracted all reference made to relevant laws, regulations and guidelines provided in the free text of the second national report, in particular in relation to Question 21, but also taking into consideration the text supplied in other free text questions regarding all other laws, regulations and guidelines for implementation of the Protocol that Parties are required to make available to the BCH, such as, but not restricted to, living modified organisms in transit, living modified organisms destined for contained use and the transboundary movement, handling and use of living modified organisms which are pharmaceuticals. The information from the second national report was cross-checked with the list of laws, regulations and guidelines actually made available to the BCH.

13. In most cases, the review shows that a number of Parties have made available more laws, regulations and guidelines than are mentioned in their national report. Out of the 72 Parties that have declared that they made *all* their laws/regulations/guidelines available to the BCH, 17 Parties were found, upon closer consideration of the free text information provided where the existence of relevant laws/regulations/guidelines has been mentioned, to be missing some relevant documents. Nonetheless, most of their records are extensive and include, for the most part, many additional laws/regulations/guidelines to those specifically mentioned in the report. Only three Parties that declared having submitted all relevant documents, had not submitted any at all.

14. Some Parties that had created records in the BCH regarding their laws/regulations/guidelines had not actually uploaded the documents on the BCH or had links to documents that were not functional.

15. Four Parties explained in the free text box of the second national report or in response to the e-mail message sent in this regard by the Secretariat, that their failure to submit their laws/regulations/guidelines is due to the fact that they are still in draft form or require the final approval by their Government. Some also indicated that the law is not available in English or in one of the six UN languages. A few Parties explained that the law is available, but must be accessed through their national BCH site or other similar site.

16. Finally, it should be noted that 5 Parties that had reported, through their second national report, that they had not made any laws/regulations/guidelines available to the BCH have since uploaded several relevant documents, showing an increasing awareness, interest and commitment in making up-to-date information in this regard available, as required by the Protocol.

(b) Information on decisions with respect to import or approval of living modified organisms

17. Thirty eight Parties had reported, in response to Question 38 of the second national reporting format, that they have *taken a decision on an application/ notification regarding intentional transboundary movements of LMOs for intentional introduction into the environment*.

18. Out of the 38 Parties which reported having taken such a decision, 10 Parties reported that, to date, they have approved importation of more than 10 living modified organisms for intentional introduction into the environment; 4 Parties have approved less than 10 living modified organisms; 14 Parties have approved less than 5 living modified organisms, and 11 Parties have approved none.

19. Out of the 10 Parties that have approved importation of more than 10 organisms for intentional introduction into the environment, two, i.e. China and South Africa, have less than this number of records of such decisions in the BCH. The other 8 Parties are either Member States of the European Union and have relevant records of such decisions submitted by the European Union or have submitted more than 10 records of these decisions to the BCH, as reported.

20. Two of the 4 Parties (i.e. Philippines and Uganda) that indicated that they have taken less than 10 decisions, have not submitted any decisions at all to date. Uganda explained, in the free text under the relevant question of the second national report, that the “Information on all applications received and processed so far is being compiled for submission to the BCH”. The other two Parties (Indonesia and Norway) have submitted fewer than five records of decisions and are seemingly missing several records on the BCH.

21. In the remaining categories of Parties that have approved less than 5 living modified organisms, and those that have approved none, 9 Parties and 7 Parties, respectively, have not submitted any record of the decision to the BCH. Other Parties that may have responded as *less than 5* or *none* are Member States of the EU and therefore do not submit records on decisions individually, or they have submitted some records to the BCH.

22. Some Parties provided further information in the relevant free text box of the second national report format. New Zealand explained that it “has received only one application for the release of a GMO into the environment and this came from a New Zealand importer. This application was for the use of an animal vaccine for equine influenza in an emergency situation. The release was approved with controls”. A link to the relevant approval was provided, but the document was not submitted to the BCH.³

23. Similarly, Swaziland which had indicated that it considered applications for intentional introduction of living modified organisms into the environment, but had not approved any import, explained that the three applications were received for the introduction of cotton, maize and soybean to the environment, but that they could not be processed due to the fact that the biosafety legislation is not yet in force. They further elaborated that, “the applications were not in conformity with Annex I to the Protocol, which details information required in notifications and the applicants were requested to furnish additional information, which was never forthcoming”.

24. Finally, Madagascar also provided further clarification on the application it had received to test a transgenic crop for therapeutic purposes. Although authorization was initially given, this was revoked after an environmental impact assessment was carried out and the plants were ordered destroyed. The assessment, however, has not been submitted to the BCH.

25. Under Question 55, 14 Parties reported that they have declared, through the BCH, that in the absence of a regulatory framework its decisions prior to the first import of an LMO-FFP will be taken according to Article 11, paragraph 6 of the Cartagena Protocol on Biosafety. However, only one Party, Saint Lucia, has actually provided such a declaration with an appropriate record in the BCH.

26. In responding to Question 60, 19 Parties reported that, in the current reporting period, they have taken *more than 10* decisions regarding domestic use, including placing on the market, of LMOs-FFP; One Party *less than 10*; 11 Parties *less than 5*; and 11 Parties *none*.

27. Among the 19 Parties that have reported to have taken *more than 10* decisions, 11 are EU Members and the decisions are included in the records submitted to the BCH by the European Union. Six Parties have indeed submitted *more than 10* such decisions to the BCH, as reported. One Party, China, has submitted less (2) than the 10 decisions indicated in the second national report. Another Party, Zimbabwe, has not submitted any decisions.

28. The Party which indicated that it has taken *less than 10* decisions, South Africa, has not submitted any record to the BCH.

³ The Committee may wish to consider, as a general question, and determine whether providing a link to certain information or a document by a Party fulfils the requirement of the Protocol as regards making available information to the BCH.

29. Ten out of the 11 Parties that indicated they had taken *less than 5* decisions, did not submit any decisions at all to the BCH. The remaining Party, Malaysia, has since submitted 11 decisions and has provided a detailed explanation of the discrepancy.⁴

(c) Information on risk assessments

30. Decisions as regards the import of living modified organisms for intentional introduction into the environment and the approval of living modified organisms for domestic use, including placing on the market, that may be subject to transboundary movement for direct use as food or feed, or for processing, are expected to be made on the basis of risk assessment. A Party taking such decisions is, therefore, required to make available the corresponding risk assessments to the BCH.

31. The Secretariat considered, as shown in Table 3 of document UNEP/CBD/BS/CC/11/3/Add.1, the responses of Parties to Question 88 and 89 of the second national report in order to ascertain whether all the relevant decisions reported to have been taken in the second national report were accompanied by the risk assessment required under the Protocol and whether such information has been made available to the BCH.

32. Question 88 of the second national report asks: “If your country has taken decision(s) on LMOs for intentional introduction into the environment or on domestic use of LMOs-FFP, were risk assessments conducted for all decisions taken?” Question 89 asks Parties whether they have submitted summary reports of risk assessments to the BCH. While these risk assessments could include those corresponding to any type of decision, it would certainly need to include those covered in question 88 as well and therefore, the question was considered pertinent to this exercise.

33. Out of the 44 Parties that responded positively to Question 88, 18 did not submit any risk assessments to the BCH. Among these, 14 indicated that they had not made available the summary reports on the risk assessment to the BCH,⁵ however the remaining 4 declared that they had done so either *always* or *in some cases only*.

34. Five⁶ of the 44 Parties that reported having conducted risk assessments in order to take a decision on living modified organisms for intentional introduction into the environment or on domestic use of LMOs-FFP, have records of such decisions in the BCH that are lacking the corresponding risk assessment, with three of them having no risk assessments summaries whatsoever in the BCH.

35. Two Parties that responded “n/a” (not applicable) to question 88, had indicated, in question 89, that they have *always* submitted summary reports of the risk assessments to the BCH. This would suggest that risk assessments were undertaken without it necessarily being for the purpose of taking a decision in the context of the Protocol, or that the risk assessments envisaged might correspond to other types of living modified organisms. Whatever it may be, the two Parties, namely, Bulgaria and Switzerland, did not, in fact, submit any risk assessments to the BCH.

36. It may also be noted that an answer of “no” or “*in some cases only*” to question 89 was one of the criteria used when considering which Parties should be contacted by e-mail in order to point out the discrepancy and to offer the Secretariat’s assistance. Malaysia was the only Party to reply to the e-mail sent by the Secretariat. Although it had indicated that risk assessments were submitted to the BCH *in some cases only*, they have since proceeded to update their records in the BCH to reflect the situation. Fourteen risk assessment summaries were submitted by the Party and every decision that was made available to the BCH has a corresponding risk assessment summary.

⁴ See Table 2, contained in document UNEP/CBD/BS/CC/11/3/Add.1 for further details.

⁵ Including Malta, which actually answered “n/a” to question 89.

⁶ China, Mexico, New Zealand, Romania and South Africa.

(d) Information on bilateral, regional and multilateral agreements and arrangements

37. In their response to Question 77, 24 Parties reported that they have *entered into bilateral, regional or multilateral agreements or arrangements*. 23 of those Parties also responded to Question 78 on whether they have made that information available to the BCH. Seven Parties reported that they have *always informed the Parties through the BCH of the agreements or arrangements*, three Parties responded that they have done so *in some cases only*; and 12 Parties reported that they have never done so.

38. Out of the 10 Parties that reported having informed the BCH of these agreements or arrangements *always or in some cases*, seven of them have submitted to the BCH at least one record under the category *Bilateral, Regional or Multilateral Agreement or Arrangement*. Three of them have not submitted any such record as presented in Table 4 of document UNEP/CBD/BS/CC/11/3/Add.1.

(e) Illegal and unintentional transboundary movements

39. Question 170 asked countries to indicate how many times they received information concerning cases of illegal transboundary movements of an LMO to or from territories under their jurisdiction during the current reporting period. One Party reported *more than 10 cases*; two Parties reported *less than 10 cases*; 17 Parties reported *less than 5 cases* and 130 Parties reported that they *never* received such information. One Party did not respond.

40. Question 171 requested further details from the 20 Parties which reported having received information concerning cases of illegal transboundary movements. No Party reported having *informed the BCH and the other Party(ies) involved*; Two Parties reported having done so *only in some cases*; Nine Parties reported having informed *only the other Party(ies) involved*; One Party *only the BCH*; and Seven Parties reported that they have informed *neither the BCH nor the other Party(ies) involved*. One Party that is also an EU Member state answered, “*not applicable*”, explaining that the details may be found in the EU report.

41. The Secretariat has found that there are currently records in the BCH on illegal transboundary movements from only three Parties.⁷ However, the only Party that had reported having informed the BCH of cases of illegal transboundary movements, Peru, has not, in fact, provided any such records to the BCH. Two records were submitted by Japan which also reported, in its second national report, to have informed the BCH *only in some cases*. Another record appears to be a new submission by New Zealand that had not previously reported any illegal transboundary movements in its national report. The third record was submitted by Norway and occurred after the period covered by the second national report. The only other Party that had reported having informed the BCH *only in some cases*, Italy, has not submitted any record to the BCH. When contacted by the Secretariat, they responded that the incident referred to in the report was concerning an unauthorized placing on the market of an imported genetically modified fish that occurred in some Member states of the European Union. Member states were informed in accordance with the EU directive 2001/18/EC and hence “it is impossible to update the BCH because there isn’t any Country decision or communication about this illegal transboundary movement.”

42. Out of the seven Parties that declared having received information concerning cases of illegal transboundary movements, but having informed *neither the BCH nor the other Party(ies) involved*, two of them provided explanations in the free text box available under question 175 of the report. Zambia explained that the “illegal transboundary movements were due to trade and relief efforts”, while Mexico explained that, just as with unintentional transboundary movements, the cases were dealt with by the competent national authorities and that there were no transboundary implications to third parties. A link

⁷ Japan, New Zealand and Norway.

was provided to a document by the Commission for Environmental Cooperation reporting on one of the most relevant such cases. The other five Parties⁸ did not provide any details on why the information concerning the reported cases has not been made available to the BCH or to other Parties involved. The concerned Parties have not responded to the Secretariat's enquiry.

43. Many Parties that reported that *only the other party(ies) involved* were informed of the illegal transboundary movement, elaborated further in the free text box available in the second national report under Question 175 with some Parties providing specific information on the LMOs in question and the decision and action taken, while a few others provided only general information on the nature of the illegal transboundary movement.

44. 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 reported *more than 10 times*; one Party indicated *less than 10 times*; six Parties indicated *less than 5 times*; and 141 Parties reported that they have *never* received such information. One Party did not respond to this question.

45. Nine Parties reported that they have received information concerning occurrences that may have led to unintentional transboundary movements of living modified organisms. Eight of these Parties also responded to Question 104 regarding whether they have notified, for every occurrence, affected or potentially affected States, the BCH and, where appropriate, relevant international organizations, of the release.

46. Three Parties responded that they did not notify other States and the BCH of the release, but did not provide any explanations as to why they did not do so. One of the Parties, Italy, recently responded to the Secretariat's e-mail correspondence requesting further clarification by explaining that action was taken in the context of a decision from the EU to end the unauthorized placing on the market of the LMO, but that no further action was taken in the context of Article 17 of the Protocol.

47. Three Parties did not notify the BCH of the release, but did however provide details in the free text box under Question 107. Zambia, simply 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 without providing further justification for the omission. The Netherlands reported that measures were taken to contain the living modified organism following an incident, however it was not considered likely to have an adverse effect on the conservation and sustainable use of biological diversity, taking into account human health, and therefore, no further action was undertaken in the context of Article 17. Norway, explained that none of the incidents were considered to lead to unintentional transboundary movements.

48. Finally, the two Parties that reported that they have notified, for every occurrence, affected or potentially affected States and the BCH, did not, in fact, inform the BCH. In the free text box available under question 107, these two EU member states, France and Sweden, provided further information to explain that only other EU Member states were notified. Sweden explained that the notification was not submitted to the BCH as there was no risk for transboundary movement that would require other non-EU Parties to be informed. France explained that the situation was not covered under Article 17 as there was no transboundary movement of LMOs that could have an impact on biodiversity.

⁸ Bolivia, Madagascar, Mongolia, Paraguay and Suriname

49. Explanations provided by some Parties regarding occurrences of illegal and unintentional transboundary movements seem to suggest that in many cases, the understanding of “illegal” and “unintentional” is not clear to many Parties or the occurrences are considered as both unintentional and illegal. The terms are used interchangeably and the same examples are used for both types of occurrences.⁹

III. SUGGESTION

50. The Committee may, taking into account the review by the Secretariat contained in this document, wish to:

- (a) Request the Secretariat to:
 - (i) Continue to assess any lack of consistency between the information that Parties provide through their national report on the one hand, and the Biosafety Clearing-House on the other, and to notify the concerned Parties;
 - (ii) Identify the Parties that are not responding to its notification or are not taking the necessary actions to rectify any lack of consistency and report to the Committee;
- (b) Authorize the Chair of the Committee to write a letter to the concerned Parties identified by the Secretariat as referred to in paragraph (ii) above, reminding them of their obligations to provide complete and consistent information required under the Protocol;
- (c) Consider whether providing only a link to a certain information or document by a Party fulfils that Party’s obligation under the Protocol with respect to making the concerned information available to the BCH.

⁹ See Table 5 in document UNEP/CBD/BS/CC/11/3/Add.1 for details.