



## Convention on Biological Diversity

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

Sixth meeting  
Hyderabad, India, 1-5 October 2012

### REPORT OF THE CARIBBEAN TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

#### INTRODUCTION

1. In decisions BS-IV/11 and BS-V/12, the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety requested the Executive Secretary to convene regional or subregional training courses to enable countries to gain hands-on experience in preparing and evaluating risk assessment reports in accordance with the Cartagena Protocol on Biosafety.
2. Following an offer from the Government of Belize to host such a training course, and a financial contribution from the Government of Japan, the Caribbean Training Course on Risk Assessment of Living Modified Organisms (LMOs) was held in Belize City, from 26 to 30 September 2011.
3. The training course was attended by seven participants from Parties to the Protocol (Antigua and Barbuda, Barbados, Belize, Grenada, Saint Lucia, Saint Vincent and the Grenadines, and Suriname) and two observers representing the Third World Network (TWN) and the Global Industry Coalition (GIC). The complete list of participants and observers is attached as annex I.

#### ITEM 1. OPENING OF THE TRAINING COURSE

4. The training course was opened at 9 a.m. on Monday, 26 September 2011 by Ambassador Adalbert Tucker of the Ministry of Foreign Affairs and Foreign Trade, on behalf of the Government of Belize. In his opening remarks, Ambassador Tucker welcomed participants to Belize and noted the importance of the environment, in particular for the small countries in the Caribbean subregion. He also paid tribute to the "Father of the Nation", George Cadle Price, the first Prime Minister of Belize, who had recently passed away and whose funeral was being held that day. Participants then observed a minute of silence in memory of Mr. Price.
5. Martin Alegria of the Department of the Environment of the Ministry of Natural Resources and the Environment of Belize gave a keynote speech in which he highlighted the importance of reconciling technological development with environmental protection.
6. Miguel Figueroa, Acting Director of the Food Safety Services at the Belize Agriculture Health Authority (BAHA), speaking on behalf of Michael DeShield, Director, welcomed the participants to

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Belize and highlighted the importance of collaboration among the Caribbean countries in issues of biosafety.

7. Charles Gbedemah, Principal Officer, Biosafety Division of the Secretariat of the Convention on Biological Diversity (SCBD), speaking on behalf of Ahmed Djoghlaif, Executive Secretary of the Convention, welcomed participants to the training course and expressed the appreciation of Secretariat to the Government of Belize for hosting the course and the Government of Japan for their financial support.

## **ITEM 2. ORGANIZATION OF WORK**

8. Manoela Miranda, a representative of the Secretariat of the Convention on Biological Diversity, explained the modalities of the training course on the basis of the organization of work contained in the annex to the annotations to the provisional agenda (UNEP/CBD/BS/RAT-CAR/1/1/Add.1). She also provided a brief overview on the objectives and expected outcomes of the training course.

9. A training manual, prepared by the Secretariat, in collaboration with other relevant United Nations bodies and international organizations<sup>1</sup> was distributed to participants as the main training material for the course. A risk assessment case-study, prepared by the Secretariat, for hands-on exercises was distributed along with the training manual.

10. The Secretariat noted that the training manual was a work in progress and therefore participants were invited to provide feedback and input for its improvement.

11. Participants also received a draft of the revised Guidance for Risk Assessment of Living Modified Organisms prepared by collaborative efforts between the Open-ended Online Expert Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management.<sup>2</sup>

## **ITEM 3. INTRODUCTION OF PARTICIPANTS**

12. Participants introduced themselves and gave a brief overview of their experience in fields relevant to biosafety and their expectations of the course.

## **ITEM 4. SUBSTANTIVE ISSUES**

### ***4.1 Overview of biosafety and the Cartagena Protocol on Biosafety***

13. Under this agenda item, the basic concepts in biosafety, the Cartagena Protocol on Biosafety and other international biosafety-related bodies and organizations were introduced and reviewed.

14. The representative of the Secretariat presented overview of modern biotechnology and its techniques, and provisions of the Protocol relevant to the training course, in particular its scope, objective, Article 15 and annex III on risk assessment and the Biosafety Clearing-House.

15. The role of other international bodies involved in risk assessment in the context of biosafety was also presented, including the Food and Agriculture Organization of the United Nations (FAO), Codex Alimentarius, the International Plant Protection Convention (IPPC), the World Organisation for Animal Health (OIE), the World Trade Organization (WTO), and the Organisation for Economic Co-operation and Development (OECD), and other bilateral and multilateral agreements.

16. The presentations were followed by an exchange of views and experience among participants with emphasis on the relevant risk assessment provisions of the Protocol.

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<sup>1</sup> UNEP/CBD/BS/COP-MOP/5/12, paras. 32-36.

<sup>2</sup> [http://bch.cbd.int/onlineconferences/forum\\_RA.shtml](http://bch.cbd.int/onlineconferences/forum_RA.shtml).

#### **4.2 Introduction to risk assessment and preparatory work**

17. Under this agenda item, the representative of the Secretariat presented an introduction to environmental risk assessment and some elements and actions that may be needed in setting the stage for a risk assessment before the receipt of an LMO application.

18. In reviewing the preparatory work for risk assessment, the representative of the Secretariat explained the importance of understanding the broad context of national policies and the structure of the national regulatory and administrative frameworks, including national risk-assessment practices, general principles and a mandate of risk assessors.

19. The participants discussed the different phases of a risk assessment process and issues regarding setting the scene for a risk assessment, and explained the stage of implementation of their respective national biosafety frameworks.

#### **4.3 Conducting the risk assessment**

20. Under this agenda item, participants reviewed the key elements and steps of annex III to the Protocol for conducting a risk assessment.

21. The Secretariat presented an overview of elements that might be considered when setting the context and scope of the risk assessment, including protection goals, assessment endpoints and the establishment of baseline information.

22. The Secretariat also presented an overview of the elements that form the basis for a scientifically sound risk assessment conducted on a case-by-case basis. For each of these elements, the points to consider of annex III to the Protocol were reviewed along with an analysis as to when the information may be relevant.

23. With the help of a case-study on risk assessment, participants took part in a hands-on group exercise to put into practice some of the concepts presented. Participants identified the elements in the case-study needed for conducting a risk assessment on a case-by-case basis and identified gaps in the information. They also reviewed possible risk scenarios on the basis of the case-study.

24. The Secretariat introduced the risk-assessment methodology and steps of annex III to the Protocol along with examples on how risk assessors might proceed with each of these steps. Participants discussed these issues at length, focusing on the scientific information that might be needed to support each of the actions and steps in the risk-assessment process and how to identify and address information gaps.

25. Participants further took part in a second hands-on group exercise using the case-study to put into practice the steps of the risk assessment in accordance with annex III to the Protocol. Each group presented the results of the exercise, including their conclusions on the likelihood of the adverse effects occurring, the consequences should these adverse effects occur, considerations of uncertainties and identification of risk management and monitoring strategies.

#### **4.4 Preparing a risk assessment report**

26. Under this item, participants discussed how risk assessors may communicate the outcomes of a risk assessment in a structured report so as to provide information on: (i) background, context and scoping of the risk assessment; (ii) characterization and estimation of risks; (iii) identification of risk management and monitoring strategies; (iv) considerations of remaining uncertainties; and (v) recommendations as to whether or not the risks are acceptable or manageable.

#### **4.5 Testing the “Guidance for Risk Assessment of Living Modified Organisms”**

27. Manoela Miranda made a presentation on how the “Guidance for Risk Assessment of Living Modified Organisms”<sup>3</sup> (“the Guidance”) was developed through a process established by the Parties to the Protocol comprising the Open-ended Online Expert Forum and the AHTEG on Risk Assessment and Risk Management. She noted that a large number of experts in risk assessment participated in the development of the Guidance during the last three years.

28. Ms. Miranda also presented the objectives and structure of the Guidance, and a comparison with the training manual on risk assessment.

29. Participants took part in discussions and in a testing exercise that evaluated the usefulness and effectiveness of the Guidance as a tool to assist Parties and other Governments in implementing the provisions of the Protocol with regards to risk assessment as per decision BS-V/12<sup>4</sup> of the Parties to the Protocol. The testing exercise focused on the Roadmap for Risk Assessment of LMOs, including its overarching issues, the planning phase of the risk assessment, as well as the steps of the risk assessment process. Several suggestions for the improvement of the Guidance were made and thoroughly discussed.

30. At the end of the testing, participants from Parties completed a questionnaire on the overall utility and applicability of the Guidance as per Secretariat notification SCBD/BS/CG/MPM/jh/77649 of 23 September 2011.<sup>5</sup>

31. Results of the questionnaire indicated that the participants agreed that the Guidance is consistent with the Cartagena Protocol on Biosafety, particularly with its Article 15 and annex III, and a useful tool to assist countries in conducting and reviewing risk assessments of LMOs: (i) in a scientifically sound and case-by-case manner; and (ii) introduced into various receiving environments.

32. The participants were unanimous in noting that the Roadmap for Risk Assessment of LMOs: (i) provides useful guidance for conducting risk assessments of LMOs in accordance with the Protocol; (ii) is organized in a logical and structured manner; and (iii) is user-friendly, taking into account that risk assessment is a complex scientific and multidisciplinary activity.

33. The results of the testing exercise are compiled in annex II and available online through the Biosafety Clearing-House (BCH).<sup>6</sup>

#### **4.6 Guidance materials in the Biosafety Information Resource Centre of the Biosafety Clearing-House**

34. The Secretariat provided examples on how to search and retrieve guidance materials on risk assessment of LMOs that were available in the Biosafety Information Resource Centre (BIRC)<sup>7</sup> of the BCH.

#### **4.7 Submitting risk assessment summaries to the Biosafety Clearing-House**

35. The Secretariat also explained how the risk-assessment records are linked to decisions and LMO records in the BCH. Further, the Secretariat provided an overview of key information contained in the common format for submitting risk assessment summaries to the Biosafety Clearing-House.

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<sup>3</sup> [http://bch.cbd.int/onlineconferences/forum\\_ra.shtml](http://bch.cbd.int/onlineconferences/forum_ra.shtml).

<sup>4</sup> <http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=12325>.

<sup>5</sup> <http://www.cbd.int/doc/notifications/2011/ntf-2011-182-bs-en.doc>.

<sup>6</sup> [http://bch.cbd.int/onlineconferences/ra\\_guidance/testing.shtml](http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml).

<sup>7</sup> <http://bch.cbd.int/database/resources/>.

## ITEM 5. CONCLUSIONS AND RECOMMENDATIONS

36. Participants from Parties were invited to undertake an evaluation exercise of the training course and its training material by completing a questionnaire. The results of the questionnaire are attached as annex III.

37. Results of the questionnaire indicated that participants were unanimous in noting that the training: (i) provided tools for understanding how an interdisciplinary team can be established in the context of risk assessment, and (ii) enhanced their knowledge through hands-on training in preparing and evaluating risk assessment reports in accordance to the articles and annex III of the Protocol. The majority of participants agreed that the training course: (i) helped develop skills on how to use and interpret existing information, as well as how to identify and address information gaps; and (ii) helped to understand how to establish baseline information relevant for the risk assessment.

38. With regard to the training material distributed at the beginning of the course, results of the questionnaire also indicated that the majority of participants agreed that the training material (i) was a useful tool for training on risk assessment, (ii) was easy to understand, and (iii) comprised an adequate overview of the risk assessment process.

39. In providing feedback on the training manual, participants made some recommendations for improving its text and flow. The Secretariat explained that these recommendations will be incorporated into a revised version of the training manual.

40. In providing feedback on the course, participants acknowledged that this type of training was needed in all countries of the Caribbean.

41. Participants acknowledged that the training course and material were very good teaching tools that provided a well-structured and comprehensive introduction to the risk assessment process and were useful to risk assessors, including those who have limited experience.

42. Participants drew attention to the following elements/activities that the Parties might wish to consider during their deliberations at the sixth meeting of the Parties to the Protocol:

(a) Capacity-building on risk assessment. With the view to enhancing the capacity of a larger number of experts from Parties, the course participants recommended that future capacity-building activities on risk assessment should include:

- (i) Training of trainers in each region; and
- (ii) Online training modules/activities.

(b) Further guidance on risk assessment. With the view to enabling Parties' response to recent technological developments and better assessment of the risks of specific types of LMOs, participants recommended that further guidance be developed on risk assessment of LM animals.

(c) Participants agreed that for biosafety in general, regional engagement was needed at a higher governmental level in all Caribbean countries in order to assess the feasibility of regional institutions and infrastructures aimed at assisting Parties implementing their national biosafety frameworks so as to meet their obligations under the Cartagena Protocol on Biosafety. The regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-region<sup>8</sup> under the Global Environment Facility (GEF) Biosafety Programme, approved at the GEF-CEO level since 2008, may provide the financial and technical platform to develop the needed institutions and infrastructure.

43. Participants also urged Parties in the Caribbean region to cooperate in enhancing public awareness on the Cartagena Protocol.

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<sup>8</sup> <http://www.thegef.org/gef/node/4181>.

**ITEM 6. OTHER MATTERS**

44. Participants expressed their gratitude to the Governments of Belize and Japan for hosting and funding the training course as well as to the Secretariat for its organization.

**ITEM 7. ADOPTION OF THE REPORT**

45. The representative of the Secretariat noted that it would prepare a draft report and circulate it via email for review and adoption before posting it on the Protocol website.

**ITEM 8. CLOSURE OF THE TRAINING COURSE**

46. The training course was closed at 4:10 p.m. on Friday, 30 September 2011.

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*Annex II*

**RESULTS OF THE TESTING OF THE GUIDANCE ON RISK ASSESSMENT OF LMOs**

Quality assessment	Agreement (%) <sup>9</sup>
<b>Overall Evaluation</b>	
Level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and annex III	100
Usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in <i>a scientifically sound and case-by-case manner</i>	85.8
Usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <i>introduced into various receiving environments</i>	100
<b>Part I: Roadmap for Risk Assessment of LMOs</b>	
Provides useful guidance for conducting risk assessments of LMOs in accordance with the Protocol	100
Is useful to risk assessors who have limited experience with LMO risk assessment	85.8
Is organized in a logical and structured manner	100
Is user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity	100
Is applicable to all types of LMOs (e.g., plants, animals, micro-organisms)	57.1
Is applicable to all types of introductions into the environment (e.g., small- and large-scale releases, placing on the market/commercialization)	85.8
Contains all necessary relevant issues and concepts	80
The flowchart provides a useful graphic representation of the risk assessment process as described in the Roadmap	71.4

<sup>9</sup> The percentage of agreement was calculated on the basis of the responses that were equal to "good" and "very good" (questions 5-7) or that were equal to "yes" (questions 8-15) in the questionnaire contained in notification SCBD/BS/CG/MPM/jh/77649 (<http://www.cbd.int/doc/notifications/2011/ntf-2011-182-bs-en.doc>) in relation to the total number of respondents.

*Annex III*

**CARIBBEAN TRAINING COURSE ON RISK ASSESSMENT OF LMOs  
EVALUATION QUESTIONNAIRE**

Participants were invited to undertake an exercise to evaluate the training course and the “Training Manual on Risk Assessment of LMOs” by completing the questionnaire below. Participants were instructed to select one of the boxes that best reflected their level of agreement with each of the statements.

Seven participants took part in the exercise. The number of respondents for each option is shown below.

**A. Objectives of the training course**

Level of agreement	Disagree	Partially disagree	Neutral / Indifferent	Partially agree	Agree
<i>The training course:</i>					
Provided tools for understanding how an interdisciplinary team can be established in the context of risk assessment	0	0	0	0	7
Helped develop skills on how to use and interpret existing information, as well as identifying and addressing information gaps	0	0	0	2	5
Helped understand how to establish baseline information relevant for the risk assessment	0	0	0	2	5
Provided hands-on training in preparing and evaluating risk assessment reports in accordance to the articles and annex III of the Protocol	0	0	0	0	7

**B. Quality of the training manual**

Level of agreement	Disagree	Partially disagree	Neutral / Indifferent	Partially agree	Agree
<i>The training manual distributed at the beginning of the training course:</i>					
Is a useful tool for training on risk assessment	0	0	0	2	5
Is easy to understand and follow	0	0	0	1	6
Comprises an adequate overview of the risk assessment process	0	0	0	1	6
Is useful for a wide range of users	0	0	1	2	4

### C. Quality of the training modules

Level of agreement	Disagree	Partially disagree	Neutral / indifferent	Partially agree	Agree
<i>The subjects of the modules listed below were covered adequately:</i>					
<b>Module 1 – Overview of Biosafety and the Cartagena Protocol on Biosafety</b>					
What is biosafety?	0	0	0	0	7
What are living modified organisms?	0	0	0	0	7
History of the Cartagena Protocol on Biosafety	0	0	0	1	6
Objective and scope of the Cartagena Protocol on Biosafety	0	0	0	0	7
LMOs for intentional introduction into the environment - Advanced Informed Agreement (AIA)	0	0	0	0	7
LMOs for direct use as food, feed, or for processing (LMOs-FFP)	0	0	1	1	5
Competent national authorities	0	0	0	1	6
Risk assessment (Article 15 and annex III)	0	0	0	1	6
Biosafety Clearing-House	0	0	0	0	7
Other international biosafety-related bodies	0	0	1	2	4
<b>Module 1 (as a whole)</b>	0	0	0	0	4
<b>Module 2 – Preparatory Work: Understanding the context in which a risk assessment is carried out</b>					
National protection goals and assessment endpoints	0	0	0	2	5
National biosafety framework	0	0	0	1	6
Competent national authorities	0	0	0	1	6
Scientific advisory body	0	0	0	1	6
Responsibilities of the risk assessor(s)	0	0	0	0	7
Roster of experts on biosafety	0	0	0	0	7
Stakeholder participation	0	0	0	1	6
<b>Module 2 (as a whole)</b>	0	0	0	1	4

Level of agreement	Disagree	Partially disagree	Neutral / indifferent	Partially agree	Agree
<i>The subjects of the modules listed below were covered adequately:</i>					
<b>Module 3 – Conducting the risk assessment</b>					
Selecting relevant assessment endpoints or representative species	0	0	0	4	3
Establishing the baseline	0	0	0	4	3
Establishing the appropriate comparator(s)	0	0	0	2	5
Living modified organism	0	0	0	0	7
Likely potential receiving environment(s)	0	0	0	0	7
Intended use	0	0	0	1	6
Step 1 – Identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects	0	0	0	0	7
Step 2 – Evaluation of the likelihood	0	0	0	1	6
Step 3 – Evaluation of the consequences	0	0	0	0	7
Step 4 – Estimation of the overall risk	0	0	0	2	5
Step 5 – Identification of risk management and monitoring strategies	0	0	0	0	7
<b>Module 3 (as a whole)</b>	0	0	0	1	4
<b>Module 4 – Preparing a risk assessment report</b>					
Background, context and scoping of the risk assessment	0	0	0	0	7
Characterization and estimation of risks	0	0	0	1	6
Description of risk management and monitoring strategies	0	0	0	2	5
Consideration of remaining uncertainty	0	0	0	0	7
Recommendations as to whether or not the risks are acceptable or manageable	0	0	0	0	7
<b>Module 4 (as a whole)</b>	0	0	0	0	6

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