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ANGLOPHONE AFRICA TRAINING COURSE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS
Accra, Ghana, 12-16 December 2011

REPORT OF THE ANGLOPHONE AFRICA 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 Ghana to host such a training course, and a financial support from the Government of Japan, the Anglophone Africa Training Course on Risk Assessment of Living Modified Organisms (LMOs) was held in Accra, Ghana, from 11 to 16 December 2011.

3. The training course was attended by fifteen participants from Parties to the Protocol (Botswana, Egypt, Ethiopia, Ghana, Kenya, Liberia, Namibia, Seychelles and Uganda) and two observers representing the African Biosafety Network of Expertise and the Global Industry Coalition. 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, 11 December 2011 by Prof. Edward Akaho, Director General, Ghana Atomic Energy Commission, on behalf of the Government of Ghana. In his opening remarks, Prof. Akaho highlighted the importance of risk assessment of LMOs for the effective implementation of the Protocol in ensuring the safe use of LMOs in Africa.

5. Also representing the Government of Ghana at the opening of the training course was Mrs. Salimata Abdul Salam, Acting Chief Director of Ministry of Environment Science, and Technology. In her remarks, she welcomed the participants to the training course and noted the importance of the course in the decision-making process on living modified organisms by Parties. She urged the participants to ensure that they put into practice all that they learn from the workshop.

6. Mr. Charles Gbedemah, Principle Officer of the Biosafety Division of the Secretariat of the Convention on Biological Diversity, on behalf of the Secretariat, welcomed participants to the training course and expressed the appreciation of the Secretariat to the Government of Ghana for hosting the course and the Government of Japan for its financial support. He noted that implementation of the Protocol had been a challenge to most developing Parties and hoped that the course would contribute to the overall implementation of the Protocol.

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ITEM 2. ORGANIZATION OF WORK

7. Ms. Manoela Miranda, Environmental Affairs Officer at the Secretariat, provided a brief overview on objectives and expected outcomes of the training course.

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

9. 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.

10. Participants also received a draft of the revised Guidance for Risk Assessment of Living Modified Organisms prepared through the collaborative efforts of the Open-ended Online Expert Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management.[2]

ITEM 3. INTRODUCTION OF PARTICIPANTS

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

ITEM 4. SUBSTANTIVE ISSUES

4.1 Overview of biosafety and the Cartagena Protocol on Biosafety

12. 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.

13. The representative of the Secretariat presented an overview of modern biotechnology and its techniques, and introduced the main 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.

14. 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.

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

4.2 Introduction to risk assessment and preparatory work

16. 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.

17. 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.

[1] UNEP/CBD/BS/COP-MOP/5/12, paragraphs 32-36.

[2] http://bch.cbd.int/onlineconferences/forum_RA.shtml.

18. 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

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

20. 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.

21. 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.

22. 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.

23. 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.

24. 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

25. 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"

26. Under this agenda item, a member of the Secretariat introduced the "Guidance for Risk Assessment of Living Modified Organisms"[3] ("the Guidance") and explained that it 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.

27. 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 of the Parties to the Protocol.[4] The testing exercise focused on the Roadmap for Risk Assessment of LMOs, including its

[3] http://bch.cbd.int/onlineconferences/forum_ra.shtml.

[4] http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=12325.

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.

28. 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 (2011-182) of 23 September 2011.[5]

29. Results of the questionnaire indicated that the totality of the fifteen participants representing the Parties to the Protocol considered that the Guidance is consistent with the Protocol, particularly with its Article 15 and annex III, and is 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) in various receiving environments.

30. The totality of participants representing the Parties also noted that the Roadmap for Risk Assessment of LMOs (part I of the Guidance) provided useful guidance for conducting risk assessments of LMOs in accordance with the Protocol.

31. The results of the testing exercise are compiled in annex II and available online through the Biosafety Clearing-House (BCH).[6]

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

32. The Secretariat provided examples of how to search and retrieve guidance materials on risk assessment of LMOs that were available in the Biosafety Information Resource Centre (BIRC)[7] of the BCH.

4.7 Submitting risk assessment summaries to the Biosafety Clearing-House

33. 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.

ITEM 5. CONCLUSIONS AND RECOMMENDATIONS

34. Participants from Parties were invited to undertake an evaluation exercise of the training course and its training material by completing a questionnaire.

35. Results of the questionnaire indicated that most participants agreed that the training: (i) provided tools for understanding how an interdisciplinary team can be established in the context of risk assessment; and (ii) helped develop skills on how to use and interpret existing information, as well as how to identify and address information gaps. With regard to the training material distributed at the beginning of the course, the majority of participants agreed that the training material (i) was a useful tool for training on risk assessment; and (ii) comprised an adequate overview of the risk assessment process. The complete results of the evaluation questionnaire are attached as annex III.

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

37. Participants noted that such a training course was an effective approach for capacity-building in risk assessment among Parties as mandated by the Protocol and emphasized the importance of a continuous process towards capacity-building activities conducted by the Secretariat at regional and

[5] http://www.cbd.int/doc/notifications/2011/ntf-2011-182-bs-en.doc.

[6] http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml.

[7] http://bch.cbd.int/database/resources/.

subregional levels. With the view to enhancing the capacity in risk assessment of a larger number of experts from Parties, the course participants recommended that efforts should be made to:

(a) Translate the training material and delivery of training in all official United Nations languages;

(b) Establish a continuous process for training in risk assessment including training courses:

(i) At advanced and sub-regional levels (e.g. 5 subregional African courses), in collaboration with local relevant organizations;

(ii) Preceded with extensive preparatory work (e.g. reading the national legislation) to enhance exchange and efficacy of the training;

(iii) With visits to laboratories and field trials for a better understanding of how the genetic modification is done;

(iv) Targeting trainers in each (sub-)region including, as appropriate, more than one trainer per country to ensure sustainability and continuity of the capacity building process;

(v) Online through e-learning for cost-effectiveness and to enhance participation.

38. Participants also made the following recommendations that the Parties might wish to consider at the sixth meeting of the Parties to the Protocol:

(a) Request the Executive Secretary to organize and conduct capacity-building activities focusing on the decision-making process;

(b) Develop guidance on establishing a notification system at the national level, including information that would be required from notifier (e.g. parameters, conditions etc);

39. Participants were also of the view that Parties should consider having a dedicated national budget for biosafety which would be distinct from the budget for biodiversity.

ITEM 6. OTHER MATTERS

40. Participants expressed their gratitude to the Governments of Ghana and Japan for hosting and funding the training course as well as to the Secretariat for organizing the course.

ITEM 7. ADOPTION OF THE REPORT

41. The representative of the Secretariat noted that a draft report would be prepared and circulated via email for review and adoption before being posted on the Protocol website.

ITEM 8. CLOSURE OF THE TRAINING COURSE

42. The training course was closed at 5 p.m. on Friday, 14 December 2011.

Annex I

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Annex II

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

Quality assessment	Agreement (%)[8]
Overall Evaluation	
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 *a scientifically sound* and *case-by-case manner*	100
Usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs *introduced into various receiving environments*	100
Part I: Roadmap for Risk Assessment of LMOs	
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	92.3
Is organized in a logical and structured manner	92.3
Is user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity	92.3
Is applicable to all types of LMOs (e.g., plants, animals, micro-organisms)	92.3
Is applicable to all types of introductions into the environment (e.g., small- and large-scale releases, placing on the market/commercialization)	84.6
Contains all necessary relevant issues and concepts	53.8
The flowchart provides a useful graphic representation of the risk assessment process as described in the Roadmap	100

[8] 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 2011-182 (http://www.cbd.int/doc/notifications/2011/ntf-2011-182-bs-en.doc) in relation to the total number of respondents.

Annex III

ANGLOPHONE AFRICA 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.

Fifteen participants representing Parties 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
The training course:					
Provided tools for understanding how an interdisciplinary team can be established in the context of risk assessment	0	1	0	3	11
Helped develop skills on how to use and interpret existing information, as well as identifying and addressing information gaps	0	0	1	3	11
Helped understand how to establish baseline information relevant for the risk assessment	0	0	2	5	8
Provided hands-on training in preparing and evaluating risk assessment reports in accordance to the articles and annex III of the Protocol	0	0	1	5	9

B. Quality of the training manual

Level of agreement	Disagree	Partially disagree	Neutral / Indifferent	Partially agree	Agree
The training manual distributed at the beginning of the training course:					
Is a useful tool for training on risk assessment	0	0	1	3	11
Is easy to understand and follow	0	0	0	4	11
Comprises an adequate overview of the risk assessment process	0	0	0	6	8
Is useful for a wide range of users	0	1	0	8	6

C. Quality of the training modules

Level of agreement	Disagree	Partially disagree	Neutral / indifferent	Partially agree	Agree
The subjects of the modules listed below were covered adequately:					
Module 1 – Overview of Biosafety and the Cartagena Protocol on Biosafety					
What is biosafety?	0	0	0	5	10
What are living modified organisms?	0	0	0	0	14
History of the Cartagena Protocol on Biosafety	0	0	0	1	14
Objective and scope of the Cartagena Protocol on Biosafety	0	0	0	3	12
LMOs for intentional introduction into the environment - Advanced Informed Agreement (AIA)	0	0	0	3	12
LMOs for direct use as food, feed, or for processing (LMOs-FFP)	0	0	0	6	9
Competent national authorities	0	0	1	3	11
Risk assessment (Article 15 and annex III)	0	0	1	3	10
Biosafety Clearing-House	0	0	0	3	12
Other international biosafety-related bodies	0	0	0	5	9
Module 1 (as a whole)	0	0	0	2	9
Module 2 – Preparatory Work: Understanding the context in which a risk assessment is carried out					
National protection goals and assessment endpoints	0	0	0	8	7
National biosafety framework	0	0	0	7	8
Competent national authorities	0	0	0	5	10
Scientific advisory body	0	0	0	6	9
Responsibilities of the risk assessor(s)	0	0	0	5	9
Roster of experts on biosafety	0	0	2	5	8
Stakeholder participation	0	0	1	8	6
Module 2 (as a whole)	0	0	0	6	4

Level of agreement	Disagree	Partially disagree	Neutral / indifferent	Partially agree	Agree
The subjects of the modules listed below were covered adequately:					
Module 3 – Conducting the risk assessment					
Selecting relevant assessment endpoints or representative species	0	0	1	7	7
Establishing the baseline	0	0	2	6	7
Establishing the appropriate comparator(s)	0	0	1	6	8
Living modified organism	0	0	1	4	10
Likely potential receiving environment(s)	0	0	0	5	10
Intended use	0	0	0	5	10
Step 1 – Identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects	0	0	2	6	7
Step 2 – Evaluation of the likelihood	0	0	2	7	6
Step 3 – Evaluation of the consequences	0	0	2	6	7
Step 4 – Estimation of the overall risk	0	0	0	2	5
Step 5 – Identification of risk management and monitoring strategies	0	0	3	5	7
Module 3 (as a whole)	0	0	1	3	6
Module 4 – Preparing a risk assessment report					
Background, context and scoping of the risk assessment	0	0	0	6	9
Characterization and estimation of risks	0	0	0	6	9
Description of risk management and monitoring strategies	0	0	0	6	9
Consideration of remaining uncertainty	0	0	3	5	7
Recommendations as to whether or not the risks are acceptable or manageable	0	0	1	6	8
Module 4 (as a whole)	0	0	0	5	7
