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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

Item 14 of the provisional agenda*

RISK ASSESSMENT AND RISK MANAGEMENT (ARTICLES 15 AND 16)

Note by the Executive Secretary

I. INTRODUCTION

1. At their fifth meeting, the Parties to the Protocol considered, among the issues on risk assessment and risk management relating to Articles 15 and 16 of the Protocol: (i) the need for further guidance on risk assessment and risk management; (ii) capacity-building in risk assessment; and (iii) collaboration in identifying living modified organisms (LMOs) that may have or that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. In decision BS-V/12,¹ the Parties issued a specific mandate for further work in these areas of risk assessment and risk management.

2. Accordingly, this note has been prepared by the Executive Secretary to assist the Parties to the Protocol in their consideration of the agenda item on risk assessment and risk management at their sixth meeting. Section II contains an analysis of the main outcomes of the process of developing further guidance on specific aspects of risk assessment and risk management. Section III gives an overview of the capacity-building activities undertaken in response to requests from the Parties. Section IV provides an overview of information submitted regarding living modified organisms that may have or that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. Section V provides an overview of the status of implementation of risk assessment and risk management provisions, in line with the relevant operational objectives of the Strategic Plan for the Cartagena Protocol on Biodiversity for the period 2011–2020. Section VI outlines some suggested elements for a draft decision, for consideration by the Parties.

* UNEP/CBD/BS/COP-MOP/6/1.

¹ <http://bch.cbd.int/protocol/decisions/?decisionID=12325>.

II. FURTHER GUIDANCE ON SPECIFIC ASPECTS OF RISK ASSESSMENT AND RISK MANAGEMENT

3. In decision BS-IV/11,² the Parties to the Protocol established an open-ended online forum, through the Biosafety Clearing-House (BCH), and an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management, with the aim of developing further guidance on specific aspects of risk assessment and risk management.

4. At their fifth meeting,³ the Parties welcomed the Guidance on Risk Assessment of Living Modified Organisms developed through the joint efforts of these two groups and noted that the first version of the Guidance required further scientific review and testing to establish its overall utility and applicability to living modified organisms of different taxa introduced into different environments. In this context, the Parties requested the Executive Secretary to: (i) translate the first version of the Guidance into all United Nations languages with a view to enabling a large number of experts to take part in the reviewing process; (ii) coordinate with Parties and other Governments, through their technical and scientific experts, and relevant organizations, a review process of the first version of the Guidance; and (iii) make the comments of the review process available through the Biosafety Clearing-House.

5. At the same meeting,⁴ the Parties also decided to extend the work of the open-ended online forum and AHTEG. According to the terms of reference annexed to decision BS-V/12, the open-ended online forum and AHTEG were mandated to work primarily online, with AHTEG meeting twice face-to-face prior to the sixth meeting of the Parties, with the aim of achieving the following expected outcomes:⁵

- (a) A revised version of the Guidance on Risk Assessment of Living Modified Organisms;
- (b) A mechanism, including criteria, for future updates of the lists of background materials;
- (c) Further guidance on new specific topics of risk assessment, selected on the basis of the priorities and needs of the Parties and taking into account the topics identified in the previous intersessional period.

A. *Revision of the Guidance on Risk Assessment of Living Modified Organisms*

6. To achieve the first expected outcome, the open-ended online forum and AHTEG worked together in a collaborative process comprising the following step-wise activities:

- (i) Translation of the Guidance into all United Nations languages;
- (ii) A scientific review conducted by Parties, other Governments and relevant organizations with a total of 33 submissions (18 from Parties, three from other Governments and 12 from organizations);
- (iii) Testing of the Guidance by Parties, other Governments and relevant organizations, including during capacity-building activities, with a total of 28 submissions made (23 from Parties, one from another Government and four from organizations);
- (iv) Four rounds of ad hoc discussion groups and one round of regional real-time online conferences within the open-ended online forum;⁶
- (v) Two face-to-face meetings of AHTEG;⁷ and

² <http://bch.cbd.int/protocol/decisions/?decisionID=11690>.

³ Decision BS-V/12, paragraphs 2 and 6.

⁴ *Ibid.*, paragraph 4.

⁵ *Ibid.*, annex, paragraph 3

⁶ Transcripts of the ad hoc discussions and real-time online conferences are available through the Biosafety Clearing-House at http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml and http://bch.cbd.int/onlineconferences/realtime_ra.shtml respectively.

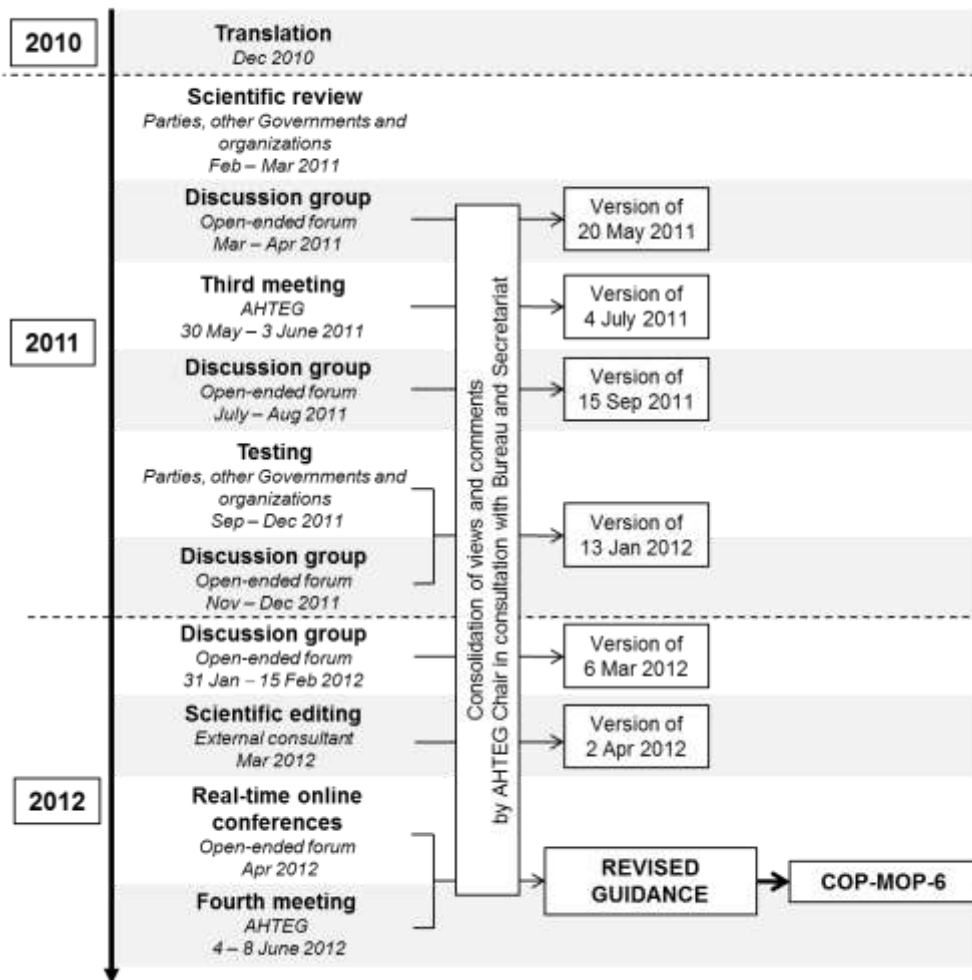
- (vi) Scientific editing by an external consultant.
7. Annex I to the present note summarizes the results of the scientific review and testing of the Guidance, which are also available through the Biosafety Clearing-House.⁸
8. Six draft versions of the Guidance were developed during this continuous process by the Chair of AHTEG, in consultation with its Bureau and the Secretariat. The final outcome, the revised Guidance on Risk Assessment of Living Modified Organisms, is available as document UNEP/CBD/BS/COP-MOP/6/13/Add.1.⁹
9. The following diagram is a schematic summary of the activities carried out within the open-ended online forum and by AHTEG to achieve the first expected outcome. Detailed information on these activities may be found in information documents UNEP/CBD/BS/COP-MOP/6/INF/10 and 11.

⁷ AHTEG held its third meeting from 30 May to 3 June 2011 in Mexico City and its fourth meeting from 4 to 8 June 2012 in Montreal, Canada. The reports of these meetings are contained in documents UNEP/CBD/BS/AHTEG-RA&RM/3/4 and UNEP/CBD/BS/AHTEG-RA&RM/4/6, available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4736> and <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=5037>, respectively.

⁸ The results of the scientific review and testing of the Guidance are available at http://bch.cbd.int/onlineconferences/ra_guidance/review.shtml and http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml.

⁹ Documents for the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (with symbols UNEP/CBD/BS/COP-MOP/6/...) are available at <http://bch.cbd.int/mop6/documents/>.

Outcome (a): Revised Guidance on Risk Assessment of LMOs (decision BS-V/12)



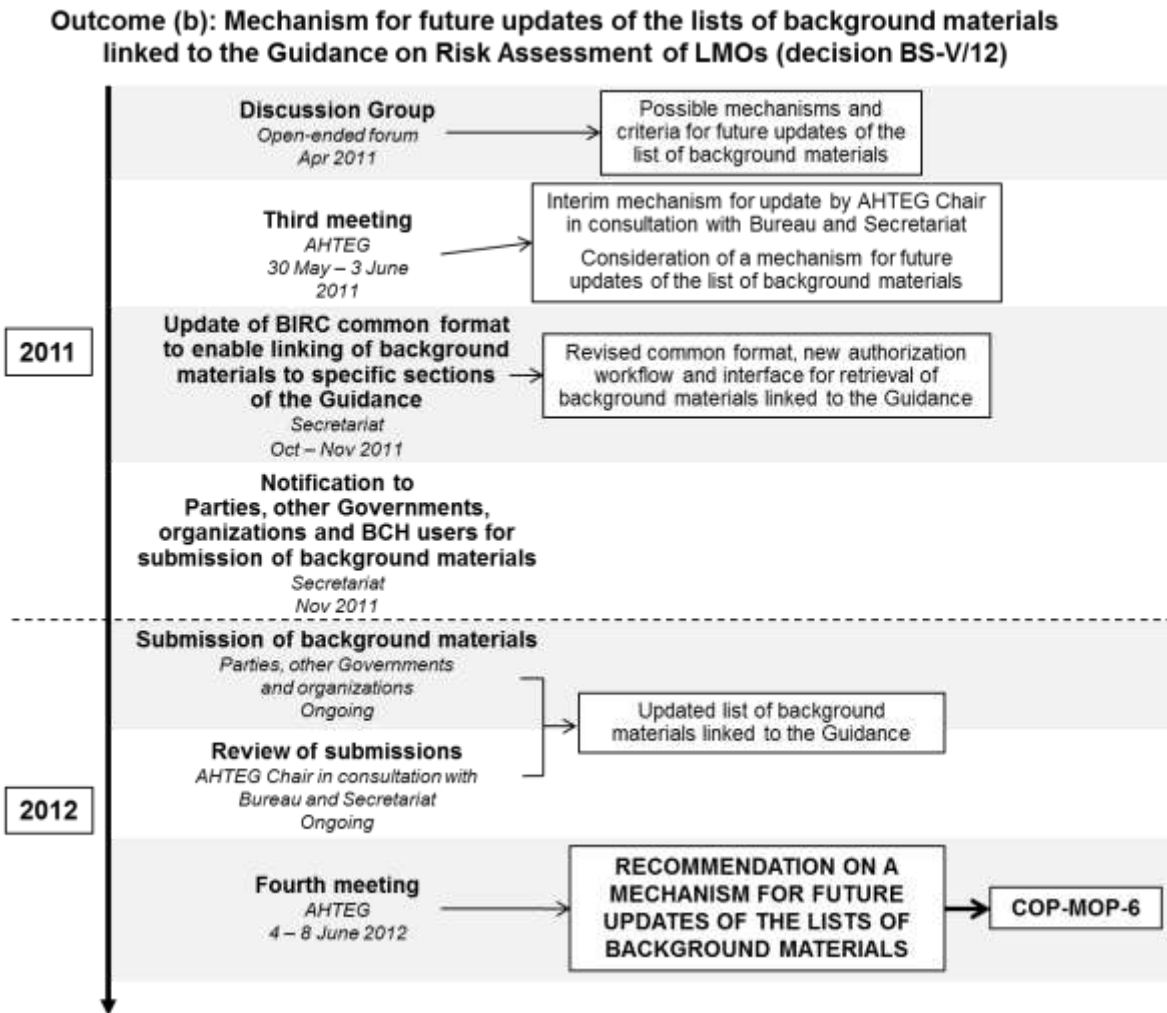
B. Possible mechanisms, including criteria, for future updates of the lists of background materials

10. To achieve the second expected outcome, the open-ended online forum and AHTEG took part in a collaborative process that involved the following activities:

- (i) One round of an ad hoc discussion groups within the open-ended online forum;⁶
- (ii) Two face-to-face meetings of AHTEG;⁷
- (iii) Updates to the common format for submission of records to the Biosafety Information Resource Centre (BIRC) of the Biosafety Clearing-House so that relevant background materials can be linked to specific sections and steps in the Guidance;
- (iv) Submission of background materials by Parties, other Governments, relevant organizations and Biosafety Clearing-House users;¹⁰ and
- (v) A review, by the AHTEG Bureau, of the background materials submitted.

¹⁰ Notification SCBD/BS/CG/MPM/jh/78075, available at <http://www.cbd.int/doc/notifications/2011/ntf-2011-208-birc-en.pdf>.

11. The following diagram is a schematic summary of the activities carried out within the open-ended online forum and by AHTEG to achieve the second expected outcome. Detailed information on these activities is available in information documents UNEP/CBD/BS/COP-MOP/6/INF/10 and 11.



12. The collaborative work outlined above resulted in a recommendation to establish a regionally balanced group of experts (for instance, ten experts, two from each region), appointed periodically by the Parties (perhaps every four years), who would work online, in collaboration with the Secretariat, to update, rearrange or remove background materials linked to the Guidance.

C. Specific topics for the development of further guidance

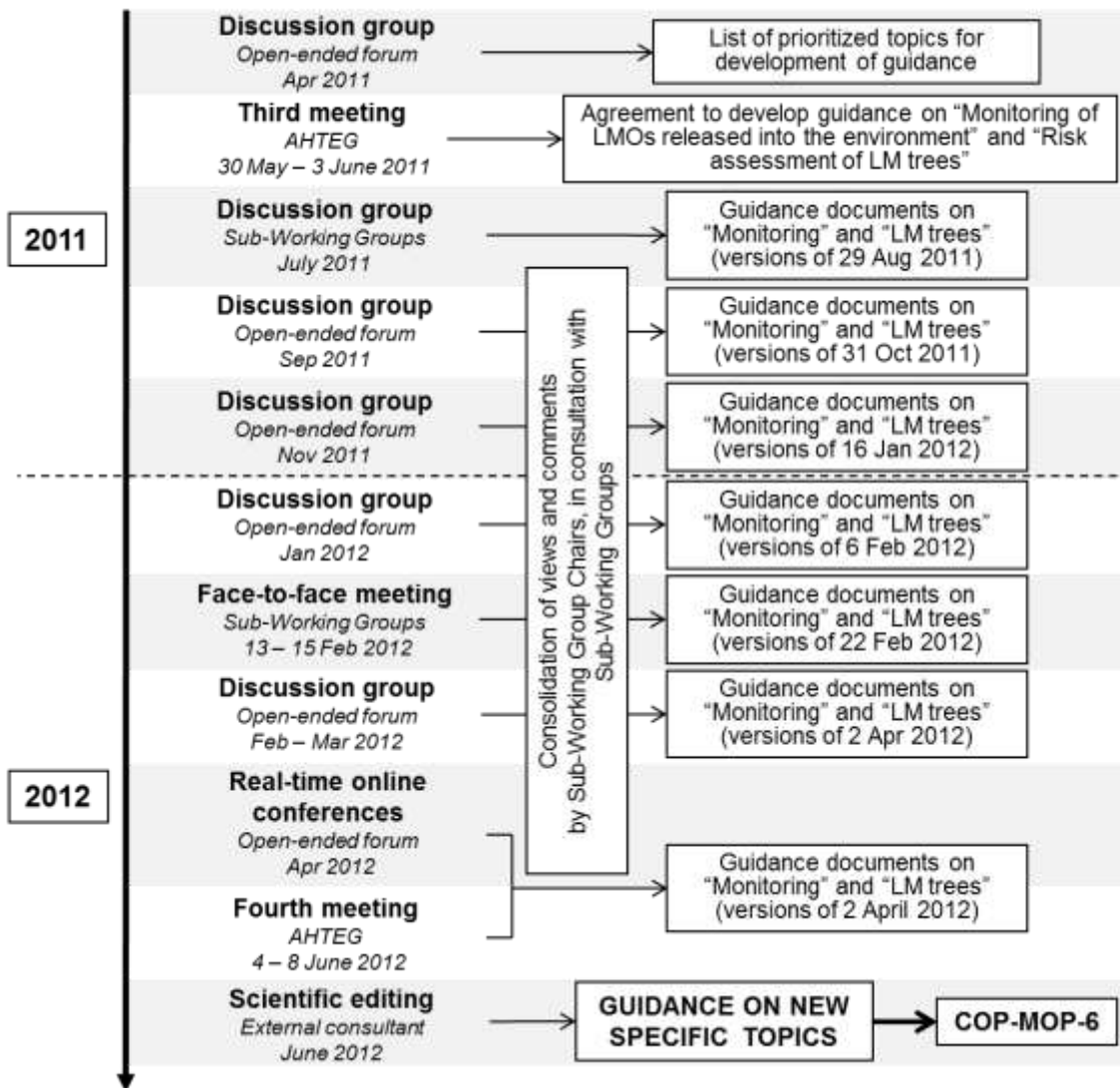
13. To achieve the third expected outcome, the following activities were undertaken:

- (i) Four rounds of ad hoc discussion groups and one round of real-time online regional conferences within the open-ended online forum;⁶

- (ii) One face-to-face meeting of the Sub-Working Groups established by AHTEG at its third meeting to develop guidance on monitoring of living modified organisms released into the environment and risk assessment of living modified trees;¹¹
- (iii) Two face-to-face meetings of AHTEG;⁷ and
- (iv) Scientific editing by an external consultant.

14. The following diagram is a schematic summary of the activities carried out within the open-ended online forum and by AHTEG to achieve the third expected outcome. Detailed information on these activities may be found in information documents UNEP/CBD/BS/COP-MOP/6/INF/10 and 11.

Outcome (c): Further guidance on new specific topics (decision BS-V/12)



¹¹ The meeting of the Sub-Working Groups was held from 13 to 15 February 2012 in Bonn, Germany. The report of this meeting is contained in document UNEP/CBD/BS/AHTEG-RA&RM/SWGs/1/2, available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=5028>.

15. The outcome of the above process is guidance on two new topics: risk assessment of living modified trees, and monitoring of living modified organisms released into the environment. These guidance documents have been integrated into the revised Guidance on Risk Assessment of Living Modified Organisms as Parts II.C and III, respectively.

D. Conclusions and recommendations of the open-ended online expert forum and the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management

16. The three expected outcomes established by the Parties in the terms of reference for the open-ended online forum and AHTEG have been successfully achieved. Members of the open-ended online forum and AHTEG collaborated in a series of online discussions, enabling a large number of experts, appointed by Parties, other Governments and organizations and representing various scientific and technical fields relevant to risk assessment, to provide input into the revision of the existing Guidance and the development of guidance on new specific topics in a cost-effective manner, within the limited financial resources available.

17. The process also included face-to-face meetings of AHTEG, which were held at key stages during the revision of the Guidance and development of guidance on new topics. While the bulk of the discussions were successfully carried out online, face-to-face meetings were crucial at moments when compromise among diverging views was needed but was proving difficult to achieve in an online setting.

18. The open-ended online forum and AHTEG have made recommendations regarding the revised Guidance for consideration by the Parties at their sixth meeting, including: (i) endorsement of the Guidance by the Parties; (ii) using and testing the Guidance in actual cases of risk assessment and sharing the experience gained; (iii) appointing a small group of experts to update the list of background materials linked to the Guidance; and (iv) developing an advanced educational package that integrates the Guidance into the training manual “Risk Assessment of Living Modified Organisms”.

19. Members of AHTEG and the open-ended online forum are of the view that further development of guidance on additional specific topics of risk assessment and risk management is still needed. They therefore recommend that the mandates of the open-ended online forum and AHTEG be extended beyond the sixth meeting of the Parties, with revised terms of reference, so that guidance on new topics can be developed.

20. The sets of recommendations made by AHTEG and the open-ended online forum are available in the annexes to information documents UNEP/CBD/BS/COP-MOP/6/INF/10 and 11, respectively.

III. CAPACITY-BUILDING IN RISK ASSESSMENT

21. At their fourth meeting,¹² in considering capacity-building in risk assessment, the Parties requested the Executive Secretary to coordinate and facilitate the development of training on risk assessment and risk management with regard to living modified organisms, and 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 articles and Annex III of the Protocol.

22. At their fifth meeting,¹³ the Parties welcomed both the development of a training manual on risk assessment of living modified organisms and the reports of two subregional training courses on risk assessment, held in the Asian and Pacific subregions.

23. In decision BS-V/12, paragraph 9, the Parties also requested the Executive Secretary, *inter alia*, to:

¹² BS-IV/11, paragraph 13.

¹³ BS-V/12, section II.

(i) Convene further regional or subregional training courses to enable countries to gain hands-on experience in the preparation and evaluation of risk assessment reports in accordance with the relevant articles and Annex III of the Protocol;

(ii) Improve the training manual by revising it on the basis of recommendations made during capacity-building activities and feedback from Parties; and

(iii) Develop an interactive learning tool based on the training manual and make it available through the Biosafety Clearing-House in all United Nations languages with a view to developing a more cost-effective way of delivering training on risk assessment.

A. *Training courses on risk assessment of living modified organisms*

24. In response to these requests, subregional training courses on risk assessment of living modified organisms were held in Belize City (26 to 30 September 2011) for the Caribbean, Havana (7 to 11 November 2011) for Latin America, and Accra (12 to 16 December 2011) for Anglophone countries in Africa. The reports of these training courses are contained in information documents UNEP/CBD/BS/COP-MOP/6/INF/15, 16 and 17.

25. A total of 47 participants from 29 Parties (Caribbean: Antigua and Barbuda, Barbados, Belize, Grenada, Saint Lucia, Saint Vincent and the Grenadines, and Suriname; Latin America: the Plurinational State of Bolivia, Brazil, Colombia, Costa Rica, Cuba, the Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Paraguay and Peru; Africa: Botswana, Egypt, Ethiopia, Ghana, Kenya, Liberia, Namibia, Nigeria, Seychelles and Uganda) and five organizations (the Third World Network and the Global Industry Coalition in the Caribbean, Desarrollo Medio Ambiental Sustentable in Latin America, and the African Biosafety Network of Expertise and Global Industry Coalition in Africa) took part in the training courses.

26. At the end of each course, participants were invited to respond to a questionnaire to evaluate the quality of the training manual and whether the objectives of the training course had been achieved, and also to make recommendations on ways to improve the manual. The results of the questionnaire revealed overall agreement that the courses had provided hands-on training in preparing and evaluating risk assessment reports in accordance with the articles and Annex III of the Protocol (97 per cent agreement), provided tools for understanding how an interdisciplinary team could be established in the context of risk assessment (95 per cent), helped develop skills in how to use and interpret existing information and identify and address information gaps (95 per cent), and helped in understanding how to establish baseline information relevant to a risk assessment (95 per cent).

27. The results of the questionnaire also indicated that a large majority of participants agreed that the training manual prepared by the Secretariat, in collaboration with other United Nations bodies and relevant organizations, was a useful tool for training on risk assessment (95 per cent agreement), was easy to understand (100 per cent), comprised an adequate overview of the risk assessment process (92 per cent), and was useful for a wide range of users (87 per cent).

28. A summary of the results of the questionnaire to evaluate training courses and the training manual is provided in annex II to this note. The full results can be found in the reports of the three training courses.

29. Course participants drew attention to elements and activities that the Parties might wish to consider during deliberations at their sixth meeting. These include:

(a) Translating the training manual into, and delivering training in, all official United Nations languages;

(b) Establishing a continuous process for capacity-building in risk assessment, to include:

- (i) Advanced-level training and subregional courses, in collaboration with relevant local organizations;
 - (ii) Targeting trainers in each (sub)region (more than one trainer per country, if appropriate) to ensure the sustainability and continuity of the capacity-building process;
 - (iii) Online training, to increase cost-effectiveness and enhance participation; and
 - (iv) Capacity-building activities focusing on the decision-making process;
- (c) Preparing further guidance on risk assessment with a view to enabling Parties to respond to recent technological developments and better assess the risks presented by specific types of living modified organisms, such as living modified animals; and
- (d) Developing guidance on how to establish a notification system at national level, including specifying the information that would be required from the notifier (parameters, conditions, etc.).
30. Participants were also of the view that Parties to the Protocol should consider having a dedicated national budget for biosafety, which would be distinct from their budgets for biodiversity.

B. Improvement of the training manual “Risk Assessment of Living Modified Organisms” and development of an e-learning tool

31. The training manual “Risk Assessment of Living Modified Organisms” has been revised and improved on the basis of recommendations made during capacity-building activities by participants nominated by the Parties.
32. The revised version of the training manual is contained in information document UNEP/CBD/BS/COP-MOP/6/INF/12, and is also available online at http://bch.cbd.int/protocol/training_RA.shtml.
33. At the request of the Parties, and with a view to delivering training on risk assessment in a more cost-effective manner, the Secretariat has developed an initial concept for an e-training tool based on the revised training manual and has made it available through the Biosafety-Clearing House.¹⁴

IV. INFORMATION SUBMITTED REGARDING LIVING MODIFIED ORGANISMS THAT MAY HAVE OR THAT ARE NOT LIKELY TO HAVE ADVERSE EFFECTS ON THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY, TAKING ALSO INTO ACCOUNT RISKS TO HUMAN HEALTH

34. At their fifth meeting,¹⁵ in their deliberations concerning the identification of living modified organisms that may have or that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, the Parties:
- (a) Urged Parties and invited other Governments to submit to the Biosafety Clearing-House decisions and risk assessments where potential adverse effects had been identified, as well as any other relevant information that might assist Parties in the identification of living modified organisms or specific traits that might have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, including information, if possible, when a decision was not taken due to the potential of a living modified organism to cause adverse effects when introduced into specific environments;

¹⁴ http://bch.cbd.int/protocol/e-training_RA.shtml.

¹⁵ Decision BS-V/12, paragraphs 10 to 13.

(b) Requested Parties and invited other Governments and relevant organizations to submit to the Executive Secretary (i) information on risk assessments, carried out on a case-by-case basis with regard to the receiving environment of the living modified organism, that might assist Parties in the identification of living modified organisms that were not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and (ii) the criteria that had been considered for the identification of such living modified organisms; and

(c) Requested the Executive Secretary to compile the information received as a result for consideration by the Parties at their sixth meeting.

35. With regard to the identification of living modified organisms or specific traits that may have adverse effects, only one decision resulting in a prohibition on importing or using living modified organisms has been submitted to the Biosafety Clearing-House since the fifth meeting of the Parties. In this case, a decision by Colombia not to authorize the import of maize MON-88017-3 was based, among other things, on the considerations that: (i) the benefits to the country should outweigh the risks; and (ii) the pest to which this living modified maize is tolerant (*Diabrotica*) is not a pest of economic importance in maize-growing areas of Colombia.

36. No other information regarding the identification of living modified organisms or specific traits that may have adverse effects has been submitted to the Biosafety Clearing-House or the Secretariat since the fifth meeting of the Parties.

37. With regard to the identification of living modified organisms that are not likely to have adverse effects, the Executive Secretary has invited Parties, other Governments and relevant organizations to submit the information referred to in paragraph 34(b) above.¹⁶

38. Thirty two Parties (the Plurinational State of Bolivia, Brazil, the European Union and its member states, Mexico and Norway), three non-Party countries (Australia, Canada and the United States of America) and five organizations (the African Centre for Biosafety, the Global Industry Coalition, the Centre for Integrated Research in Biosafety, the Public Research and Regulation Initiative and the Third World Network) had submitted their views on this issue by 11 July 2012. On the basis of these submissions, the Secretariat has prepared a synthesis and made it available, together with the submissions, as information document UNEP/CBD/BS/COP-MOP/6/INF/18 for consideration by the Parties.

39. Parties may wish to consider further gathering of information that could assist in the identification of living modified organisms that may have or that are not likely to have adverse effects for future assessment, whether or not a process can be established for the identification of such organisms.

V. STATUS OF IMPLEMENTATION OF RISK ASSESSMENT AND RISK MANAGEMENT PROVISIONS IN LINE WITH THE RELEVANT OPERATIONAL OBJECTIVES OF THE STRATEGIC PLAN OF THE PROTOCOL

40. At their fifth meeting,¹⁷ the Parties adopted the Strategic Plan for the Cartagena Protocol on Biosafety, which consists of a vision, a mission, and five strategic objectives covering five focal areas. The focal areas, in order of priority, are intended to be implemented through a ten-year programme of work and contain several operational objectives each.

41. Three operational objectives within the Strategic Plan are of relevance to deliberations on risk assessment and risk management of living modified organisms:

¹⁶ Notification SCBD/BS/MPDM/jh/67587, available at <http://www.cbd.int/doc/notifications/2012/ntf-2012-016-bs-lmos-en.pdf>.

¹⁷ Decision BS-V/16, annex I.

(a) Operational objective 1.3 – Risk assessment and risk management: To further develop and support implementation of scientific tools on common approaches to risk assessment and risk management for Parties;

(b) Operational objective 1.4 – LMOs or traits that may have adverse effects: To develop modalities for cooperation and guidance in identifying LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(c) Operational objective 2.2 – Risk assessment and risk management: To enable Parties to evaluate, apply, share and carry out risk assessments and establish local science-based capacities to regulate, manage, monitor and control risks of LMOs.

42. Annex III to this note lists the indicators for the three operational objectives on risk assessment and risk management and elaborates on possible sources of information that could help in establishing baselines to measure these indicators.

43. It should be noted that, while relevant information can be drawn from the second national reports on implementation of the Protocol and from the Biosafety Clearing-House, there are several indicators for which there is currently no source of information available.

44. Parties may wish to consider additional mechanisms through which the information needed to establish baselines to measure the indicators for the three operational objectives on risk assessment and risk management could be obtained.

VI. SUGGESTED ELEMENTS FOR A DRAFT DECISION

45. Taking into account the above information, and on the basis of the recommendations made by the open-ended online forum, AHTEG and participants in training courses conducted by the Secretariat, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to:

Regarding the Guidance on Risk Assessment of Living Modified Organisms

- (a) Endorse the Guidance on Risk Assessment of Living Modified Organisms;
- (b) Encourage Parties, as appropriate, to translate the Guidance into national languages and make such translations available through the Biosafety Clearing-House for wide dissemination;
- (c) Encourage Parties, other Governments and relevant organizations, through their risk assessors and others who are actively involved in risk assessment, to use and test the Guidance in actual cases of risk assessment, and request the Executive Secretary to gather and analyse feedback provided by Parties on the practicality, usefulness and utility of the Guidance and to make recommendations to the next meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol on possible points for improvement;
- (d) Establish a mechanism to ensure that the background documents to the Guidance are updated regularly, in accordance with the recommendations contained in annex III to the report of the fourth meeting of the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management;

Regarding the development of additional guidance on specific topics of risk assessment and risk management

(e) Continue the open-ended online forum and AHTEG process beyond the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol with new membership, as appropriate, with the objective of developing guidance on new topics of risk assessment and risk

management, selected on the basis of the needs of Parties and taking into account the list of topics in annex IV to the report of the fourth meeting of AHTEG;

(f) Request the Executive Secretary to bring to a close the current open-ended online forum and establish a new open-ended online forum with fresh nominations from Parties, other Governments and relevant organizations, based on a standardized common format for submission of experts' *curricula vitae*;

(g) Request the Executive Secretary, in consultation with the Bureau of the Conference of the Parties serving as the meeting of the Parties to the Protocol, to select experts for AHTEG from among those nominated by Parties, in accordance with paragraph 18 of the consolidated *modus operandi* of the Subsidiary Body on Scientific, Technical and Technological Advice of the Convention on Biological Diversity (decision VIII/10, annex III);

(h) Request the Executive Secretary to ensure that the participation of experts nominated by other Governments and relevant organizations to the open-ended online forum and AHTEG is in accordance with rules 6 and 7 of the rules of procedure for meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

(i) Request the open-ended online forum and AHTEG to work primarily online, with AHTEG meeting face-to-face if needed and subject to the availability of funds;

(j) Request the Executive Secretary to ensure that online discussions of the open-ended online forum and AHTEG are moderated to enhance their efficiency;

Regarding capacity-building in risk assessment

(k) Request the Secretariat, subject to the availability of funds, to:

(i) Convene, at the earliest convenient date and subject to the availability of funds, further training courses on risk assessment for Francophone African countries and the Central and Eastern Europe subregion to enable the countries concerned to gain hands-on experience in the preparation and evaluation of risk assessment reports in accordance with the relevant articles and Annex III of the Protocol;

(ii) Develop an advanced educational package that integrates the Guidance on Risk Assessment of Living Modified Organisms (i.e., Roadmap into the training manual "Risk Assessment of Living Modified Organisms" in a coherent manner;

(iii) Use this advanced educational package to conduct training for risk assessors, taking into consideration actual cases of risk assessment;

(iv) Follow up on training by gathering additional feedback from Parties on the practicality, usefulness and utility of the Guidance through online discussions or other means, as appropriate;

(v) Conduct international, regional and/or subregional workshops on risk assessment and risk management, with special emphasis on applying the Guidance in the decision-making process under the procedures of the Protocol;

(l) Request the Global Environmental Facility and invite Parties, other Governments and international organizations to provide funds and in-kind assistance to implement the capacity-building activities included in these recommendations, as appropriate;

Regarding the identification of living modified organisms or specific traits that (i) may have or (ii) are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health

(m) Urge Parties to provide the Secretariat with scientific information that may assist in the identification of living modified organisms or specific traits that may have or that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;

(n) Request the Secretariat to create sections in the Biosafety Clearing-House where such information can be submitted and easily retrieved;

Regarding the status of implementation of risk assessment and risk management provisions

(o) Request the Executive Secretary to conduct an online survey on the status of implementation of operational objectives 1.3, 1.4 and 2.2 of the Strategic Plan for the Cartagena Protocol on Biosafety, with a view to establishing baselines for and measuring the indicators concerned.

Annex I

SUMMARY OF RESULTS OF THE SCIENTIFIC REVIEW AND TESTING OF THE GUIDANCE SUBMITTED BY PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY¹⁸

A. Scientific review of the Guidance

Quality assessment	Agreement (%)
Consistency with the Cartagena Protocol on Biosafety, particularly Article 15 and Annex III	
Roadmap for Risk Assessment of Living Modified Organisms	88
Risk assessment of living modified organisms with stacked genes or traits	75
Risk assessment of living modified crops with tolerance to abiotic stress	75
Risk assessment of living modified mosquitoes	71
Usefulness for assisting countries in conducting and reviewing risk assessments of living modified organisms in a scientifically sound manner on a case-by-case basis	
Roadmap for Risk Assessment of Living Modified Organisms	81
Risk assessment of living modified organisms with stacked genes or traits	69
Risk assessment of living modified crops with tolerance to abiotic stress	69
Risk assessment of living modified mosquitoes	71
Usefulness for assisting countries in conducting and reviewing risk assessments of living modified organisms introduced into various receiving environments	
Roadmap for Risk Assessment of Living Modified Organisms	81
Risk assessment of living modified organisms with stacked genes or traits	75
Risk assessment of living modified crops with tolerance to abiotic stress	75
Risk assessment of living modified mosquitoes	79
Usefulness of the Roadmap as a tool for assisting countries in conducting and reviewing risk assessments of living modified organisms of different taxa	
Roadmap for Risk Assessment of Living Modified Organisms	63

B. Testing of the Guidance

Quality assessment	Agreement (%)
Consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly Article 15 and Annex III	78
Usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of living modified organisms in a scientifically sound manner on a case-by-case basis	70
Usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of living modified organisms introduced into various receiving environments	61

¹⁸ The agreement percentages have been calculated on the basis of the number of participants who responded with “good” or “very good”. The full results of the scientific review and testing of the Guidance are available through the Biosafety Clearing-House at http://bch.cbd.int/onlineconferences/ra_guidance/review.shtml and http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml.

Annex II

SUMMARY OF EVALUATION RESULTS FOR TRAINING COURSE OBJECTIVES AND QUALITY OF THE TRAINING MANUAL “RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS”¹⁹

A. Training course objectives

	Agreement (%)
<i>The training course:</i>	
Provided tools for understanding how an interdisciplinary team can be established in the context of risk assessment	95
Helped develop skills in how to use and interpret existing information and in identifying and addressing information gaps	95
Helped in understanding how to establish baseline information relevant to a risk assessment	95
Provided hands-on training in preparing and evaluating risk assessment reports in accordance with the articles and annex III of the Protocol	97

B. Quality of the training manual “Risk Assessment of Living Modified Organisms”

	Agreement (%)
<i>The training manual:</i>	
Is a useful tool for training on risk assessment	95
Is easy to understand and follow	100
Comprises an adequate overview of the risk assessment process	92
Is useful for a wide range of users	87

¹⁹ The agreement percentages have been calculated on the basis of the number of participants who responded with “agree” or “partially agree”, as opposed to those who responded with “neutral”, “partially disagree” or “disagree”. The full results of the questionnaires are annexed to the reports of the training courses (UNEP/CBD/BS/COP-MOP/6/INF/15, 16 and 17).

Annex III

OPERATIONAL OBJECTIVES AND INDICATORS OF THE STRATEGIC PLAN THAT ARE RELEVANT TO RISK ASSESSMENT AND RISK MANAGEMENT

<i>Operational Objectives</i>	<i>Outcomes</i>	<i>Indicators</i>	<i>Possible source of information for establishing baseline</i>
<p>1.3 Risk assessment and risk management</p> <p>To further develop and support implementation of scientific tools on common approaches to risk assessment and risk management for Parties</p>	<ul style="list-style-type: none"> • Guidance on risk assessment and risk management including guidance on new developments in modern biotechnology • Common approaches to risk assessment and risk management established and adopted by Parties and other Governments, as appropriate 	<ul style="list-style-type: none"> • Percentage of Parties adopting and using guidance documents on risk assessment and risk management for the purpose of: <ul style="list-style-type: none"> ○ Performing their own risk assessment and risk management; 	Question 83 of the second national report (“Has your country established guidelines for how to conduct risk assessments prior to taking decisions regarding LMOs?”)
		<ul style="list-style-type: none"> ○ Evaluating risk assessment reports submitted by notifiers. 	Information not available.
		<ul style="list-style-type: none"> • Percentage of Parties adopting common approaches to risk assessment and risk management. 	Information not available.
		<ul style="list-style-type: none"> • Percentage of Parties that undertake actual risk assessment pursuant to the Protocol. 	Question 86 of the second national report (“Has your country ever conducted a risk assessment of an LMO for intentional introduction into the environment?”)
<p>1.4 LMOs or traits that may have adverse effects</p> <p>To develop modalities for cooperation and guidance in identifying LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health</p>	<ul style="list-style-type: none"> • Modalities developed and put in place • Parties enabled to identify, assess, and monitor LMOs or specific traits that may have adverse effects 	<ul style="list-style-type: none"> • Guidance on living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, developed by Parties and available 	Information not available.
		<ul style="list-style-type: none"> • Number of Parties that have the capacity to identify, assess and monitor living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of 	With regard to the identification of such LMOs, the answers to Question 97 of the second national report (“Has your country cooperated with other Parties with a view to identifying LMOs or specific traits that may have adverse effects on the conservation

		biological diversity, taking into account risks to human health.	and sustainable use of biological diversity?") may provide useful information. No information is available with regard to the capacity to assess and monitor such LMOs.
<p>2.2 Risk assessment and risk management</p> <p>To enable Parties to evaluate, apply, share and carry out risk assessments and establish local science-based capacities to regulate, manage, monitor and control risks of LMOs</p>	<ul style="list-style-type: none"> Resources, including human resources required to assess risks of living modified organisms are available and administrative mechanisms are in place Training materials and technical guidance on risk assessment and risk management developed and used by Parties Infrastructure and administrative mechanisms established for the management of risks of living modified organisms at national, subregional or regional level 	<ul style="list-style-type: none"> Ratio of risk assessment summary reports as against number of decisions on LMOs on the BCH 	BCH: number of records submitted by Parties under "Country's Decision or any other Communication" with "Subject" including "Decision on LMOs for intentional introduction into the environment (under Article 10 or domestic regulatory framework)" and/or "Decision on LMOs for direct use as food or feed, or for processing (Article 11, LMOs-FFPs)" with at least one LMO and a risk assessment summary attached.
		<ul style="list-style-type: none"> Number of risk assessment summary reports in the BCH that are in compliance with the Protocol 	Information not available. It is understood that, for a risk assessment summary to be "in compliance with the Protocol", it must summarize a risk assessment that was carried out in a scientifically sound and transparent manner and on a case-by-case basis for each LMO, its intended use and the likely potential receiving environment. Information related to the number of risk assessment summaries in the BCH that comply with these principles is not available.
		<ul style="list-style-type: none"> Number of people trained on risk assessment, as well as in monitoring, management and control of LMOs 	Answers to question 85 of the second national report ("Has your country established a mechanism for training national experts to conduct risk assessments?") No information is available on how many people have been trained in monitoring, management and control of LMOs.
		<ul style="list-style-type: none"> Number of Parties that have infrastructure, including laboratories for monitoring, management and control 	Answers to question 94(a) of the second national report ("Has your country established and maintained appropriate and operational mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments for LMOs for intentional introduction into the environment?")
		<ul style="list-style-type: none"> Number of Parties that are using the developed training materials and technical guidance 	Information not available.
		<ul style="list-style-type: none"> Number of Parties that are of the opinion that the training materials and technical guidance are sufficient and effective 	Information not available.