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

Fourth meeting

Bonn, 12-16 May 2008

Item 11 of the provisional agenda*

**REPORT OF THE LATIN AMERICA AND THE CARIBBEAN REGIONAL WORKSHOP ON
CAPACITY-BUILDING AND EXCHANGE OF EXPERIENCES ON RISK ASSESSMENT AND
RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS**

Note by the Executive Secretary

INTRODUCTION

1. The Latin America and the Caribbean Regional Workshop on Capacity-building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms (LMOs) was held in Bridgetown, Barbados, from 10 to 12 December 2007.
2. The workshop was attended by 22 participants from 14 countries and 3 organizations that are involved in risk assessment and risk management of LMOs.
3. The following countries were represented: Barbados, Belize, Brazil, Chile, Costa Rica, Cuba, Dominica, El Salvador, Grenada, Jamaica, Mexico, Saint Kitts and Nevis, Saint Lucia, and Saint Vincent and the Grenadines.
4. The following organizations were represented: Caribbean Agricultural Research and Development Institute (CARDI), United Nations Environment Programme-Global Environment Facility (UNEP-GEF), and the Global Industry Coalition (GIC).
5. Seven resource persons from the following organizations facilitated the workshop: Centro de Información de Recursos Naturales (Chile), EMBRAPA-Cenargen (Brazil), UNAM Ciudad Universitaria (Mexico), National Institute of Public Health and Environment (the Netherlands), Secretaria de Agricultura, Ganadería, Pesca y Alimentos (Argentina), the University of the West Indies (Trinidad and Tobago) and Universidad de Concepcion (Chile).

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6. The objectives of the workshop were to enable participants to:
- (a) Learn more about risk assessment and risk management in the context of the Biosafety Protocol and to review the general concepts, principles and methodologies;
 - (b) Exchange practical experiences and lessons learned in conducting/reviewing risk assessments and implementing risk-management measures in Latin America and the Caribbean;
 - (c) Review existing guidance materials on risk assessment and risk management and consider the need for further guidance;
 - (d) Review the format and key elements of risk-assessment reports/dossiers and summaries for LMOs;
 - (e) Identify mechanisms for promoting cooperation and networking in risk assessment and risk management at the regional level, including the exchange of information, expertise, training materials and risk assessment tools.

ITEM 1. OPENING OF THE WORKSHOP

7. The workshop was officially opened by Mr. Philmore Best, Acting Permanent Secretary, Ministry of Energy and the Environment on behalf of Hon. Elizabeth Thompson, Minister of Energy and the Environment. Mr. Charles Gbedemah, Head of the Biosafety Division at the Secretariat of the Convention on Biological Diversity (SCBD) also made opening remarks on behalf of Mr. Ahmed Djoghlaif, Executive Secretary of the Convention on Biological Diversity.

8. In his remarks, Mr. Best welcomed participants to Barbados on behalf of his Government. He expressed gratitude to the SCBD for agreeing to hold the workshop in Barbados and to the Government of Spain for sponsoring it. Mr. Best noted that the Workshop was both timely and significant as most countries in the region had just completed the development phase of their national biosafety frameworks. Accordingly, these countries require significant support in order to strengthen their national institutions and promote intra-regional cooperation and coordination, particularly in the areas of risk assessment and risk management. He further noted that global commercialization of the products of modern biotechnology has led to a general concern about their potential threats to biodiversity, food security, health and national economies, particularly in Barbados and other Small Island Developing States (SIDS). This is due to the high vulnerability of the ecosystems of these countries to natural disasters and external threats by invasive biological agents as well as their heavy dependence on food imports and external agricultural inputs, including seeds. In this regard, Mr. Best underscored the need to put in place systems that would allow for informed decision-making regarding trade in LMOs. He also emphasized the need for harmonization of biosafety policies across the region and identification of measures through which countries can collectively access and use available human and technical resources. He reported that Barbados became a Party to the Protocol in September 2002 and has since then embarked on putting in place its biosafety measures while acknowledging the potential benefits of biotechnology. He also noted that the countries of the Caribbean sub-region recognize the challenges posed to the regulation of trade in the products of modern biotechnology. Accordingly, they are collaborating on a number of subregional initiatives, including the UNEP-GEF Regional Project on the Development and Implementation of National Biosafety Frameworks as well as the ongoing subregional efforts under the Caribbean Single Market and Economy (CSME). He expressed hope that the workshop would identify ways and means of addressing the capacity-building needs of the region and strengthening regional cooperation.

9. In his statement, Mr. Gbedemah, Head of the Biosafety Division of the Secretariat of the Convention on Biological Diversity, underscored the central role of risk assessment and risk management in the realization of the objective of the Protocol. He noted, however, that many developing countries and countries with economies in transition lack the necessary capacity and experience in this field. Accordingly, the Conference of Parties serving as the meeting of the Parties to the Protocol (COP-MOP) requested the CBD Secretariat to organize a series of regional workshops, including the current one which is the third in series after the first one held in Addis Ababa, Africa for the Africa region in August 2007;

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and the second one held in Chisinau, Republic of Moldova for the Central and Eastern Europe region in November 2007. He noted that the workshops were intended, *inter alia*, to contribute to capacity-building in this field, promote the sharing of experiences, review existing guidance materials on risk assessment and risk management and identify gaps that need to be addressed. The outcomes of the workshops would contribute to the discussions at the fourth COP-MOP, which is expected, *inter alia*, to consider the need for developing further guidance on specific aspects of risk assessment and risk management and the appropriate modalities for developing such guidance. Mr. Gbedemah expressed gratitude to the Government of Barbados for hosting the workshop and the Government of Spain for providing the funding support for participants and resource persons, and the Government of the Netherlands for providing a resource person. He further expressed gratitude to the UNDP Resident Representative for providing the conference facilities and specially recognized the contribution made by Prof. Leonard O'Garro, the UNEP-GEF Biosafety Task Manager and his team, in handling the logistics for the workshop. Finally, he expressed the Secretariat's gratitude to the resource persons who agreed to facilitate the workshop.

ITEM 2. ORGANIZATIONAL MATTERS

10. The participants elected Dr. Amanda Galvez Mariscal from Mexico to serve as Chairperson of the workshop and Mrs. Angela Alleyne (Barbados) as Rapporteur.

11. The workshop adopted its agenda on the basis of the provisional agenda proposed by the Executive Secretary. 1/ The proposed programme of work for the workshop 2/ was also adopted (see annex I).

12. The following substantive items were addressed:

- (a) Introduction to risk assessment and risk management of LMOs;
- (b) National and regional experiences and lessons learned in the implementation of the risk-assessment and risk-management provisions of the Protocol;
- (c) Guidance materials for risk assessment and risk management;
- (d) Key considerations in the preparation and/or review of risk assessments; and
- (e) Regional cooperation and sharing of information and expertise on risk assessment and risk management.

ITEM 3. INTRODUCTION TO RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

13. Under this item, two presentations were made. 3/ The first one, entitled "Introduction to risk assessment and risk management of living modified organisms in the context of the Cartagena Protocol" was made by Mr. Erie Tamale from the SCBD. The second one, entitled: "Risk assessment and risk management concepts, general principles, steps and methodologies: An overview", was presented by Dr. Sofia Valenzuela, University of Concepcion (Chile).

14. Mr. Tamale described the Cartagena Protocol's provisions on risk assessment (i.e. Article 15 and annex III) and risk management (Article 16) and underlined the central role of risk assessment in decision-making regarding the import or release of LMOs into the environment. He noted that annex III of the Protocol provides a general harmonized framework for risk assessment agreed to by the Parties to the Convention on Biological Diversity during the negotiation of the Protocol. He explained how annex III describes the objective and use of risk assessments under the Protocol, the general principles

1/ UNEP/CBD/BS/RW-RA&RM/LAC/1/1

2/ UNEP/CBD/BS/RW-RA&RM/LAC./1/1/Add.1

3/ Copies of the presentations made during the Workshop are available at the following website: <http://www.cbd.int/doc/meeting.asp?mtg=RWCBGRULAC-01>

and methodology of risk assessment and the key points to consider in carrying out a risk assessment. Mr. Tamale also described the inter-linkage between risk assessment and risk management. Finally, he outlined the programme of work and the decisions of the COP-MOP with respect to risk assessment and risk management and the issues to be addressed at its next meeting.

15. Dr. Valenzuela gave general definitions for commonly used terms (e.g. biosafety, hazard and risk) and briefly described some of the relevant concepts, including the precautionary approach, familiarity and substantial equivalence. She also outlined, in general terms, the principles of risk assessment specified in the Protocol and described the methodology of risk assessment, including hazard identification, hazard characterization (dose-response assessment), exposure assessment and risk characterization. Furthermore, she described briefly the key steps involved in the ecological risk assessment model used by the US Environmental Protection Agency. These include: problem formulation, analysis involving data integration and characterization of exposure and effects (ecological responses), risk characterization (involving estimation of risk, evaluation of exposure and description of risk) and risk management (involving practices to mitigate or manage risks). Dr. Valenzuela also highlighted some of the existing methods for detection of LMOs, including: protein assays, chromatography and microchips. She emphasized the need to develop internationally accepted, harmonized sampling plans based on sound scientific and statistical principles. Finally, she briefly highlighted the importance of LMO field monitoring, further studies and surveillance while cautioning against protracted long-term monitoring aimed at producing "nice-to-know" rather than "need-to-know" information.

16. In the ensuing discussion, many participants emphasized the need to build capacities at the national level. They emphasized the need to organize training workshops and share experiences and information, including existing risk-assessment guidance materials.

ITEM 4. NATIONAL AND REGIONAL EXPERIENCES AND LESSONS LEARNED IN THE IMPLEMENTATION OF THE RISK-ASSESSMENT AND RISK-MANAGEMENT PROVISIONS OF THE PROTOCOL

17. Under this item, workshop participants shared information on the current status, experiences and lessons learned in the implementation of risk assessment and risk management as set out in the provisions of the Biosafety Protocol. They discussed the challenges they encountered as well as their capacity-building needs. The following subregional case-study presentations were made: Dr. Pathmanathan Umaharan of Trinidad and Tobago (Caribbean sub-region); Dr. Jorge Ernesto Quezada Diaz of El Salvador (Central America sub-region); and Dr. Moisés Burachik of Argentina (South America sub-region). Ms. Leticia Pastor Chirino of Cuba also made a presentation on the Cuban experience in risk assessment and risk management. In addition, a brief country presentation was made by the participant from Brazil, Dr. Rubens Onofre Nodari. Finally, a participant from the GIC, Dr. Thomas Nickson, made a short presentation on the activities and experiences of his organization in the area of risk assessment and risk management.

18. These presentations identified the following as the main limitations/challenges for most countries in the region:

- (a) Lack of experience in risk assessment and risk management in many of the GRULAC countries;
- (b) Lack of adopted consensus and procedures for specific LMO risk assessment;
- (c) Lack of relevant information regarding local biodiversity;
- (d) Small land areas are available for the establishment of 'confinement' conditions and difficulties in maintaining eco-reserves;
- (e) 'Organic agriculture' is a means of livelihood in small island states and therefore different systems of agriculture cannot co-exist;

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- (f) Hurricanes capable of breaching ‘containment’ facilities and ‘confinement’;
 - (g) Island ecosystems are very vulnerable;
 - (h) Lack of financial, technical or infrastructural resources to carry out risk assessment and management;
 - (i) Insufficiency of accredited laboratories for LMO detection and analysis;
 - (j) Lack of dossiers for tropical crop species, particularly indigenous ones;
 - (k) Lack of experience on how to handle local biodiversity and protected areas;
 - (l) Lack of information on crop ecology in island ecosystems, including short-, medium- and long-term effects;
 - (m) Insufficient coordination among regulatory authorities (i.e., environment, agriculture, science and technology);
 - (n) Unstable regulatory and administrative systems, partly due to changes in the responsibilities and structure of agencies;
 - (o) Insufficient human capacity (e.g., experienced risk-assessment experts);
 - (p) Poor equipment facilities in institutions/laboratories;
 - (q) Difficulty in assessing, sorting and implementing available guidance materials;
 - (r) Limited experience in the use of the precautionary approach or risk-benefit analysis in decision-making;
 - (s) Difficulties arising from the complexity of the region (e.g., country, economy, biological diversity, societal values, etc.);
 - (t) Absence of national risk-assessment systems (methodology, steps, rules, etc.);
 - (u) Some countries in the GRULAC region are experiencing difficulties in accessing information for risk assessment (scientific publications, databases, etc);
 - (v) Difficulties in organizing constructive public participation in risk assessment and decision-making.
19. The following were identified as some of the main priority needs:
- (a) Establishment of consensus criteria for risk assessment and risk management at the national level;
 - (b) Adoption of a common format for the submission of risk-assessment summaries;
 - (c) Establishment of subregional, regional and international cooperation to ensure the exchange of experience, available capacity and development of guidance materials relevant to the region;
 - (d) Establishment of LMO monitoring and inspection (surveillance) systems at the national level;
 - (e) Establishment of specialized laboratories for detection of LMOs;
 - (f) Better knowledge management and information sharing on biosafety;
 - (g) Development/compilation of guidelines for risk assessment and risk management related to LMOs in tropical environments;
 - (h) Establishment of relationships between perceived risks and variables that can be measured/monitored;

- (i) Development of baseline information relevant to the region (e.g. centres of origin, reproductive biology, etc.);
- (j) Based upon the model developed in Mexico ^{4/}, establishment of measurable ecological models (e.g. using GIS to establish species distribution);
- (k) Increase of government support for risk-assessment programmes;
- (l) Mobilization of financial and technical resources from different sources; and
- (m) Training on risk assessment and risk management.

20. Following the presentations and brief discussions in the plenary, two focus discussion groups (one for the English-speaking countries and another for the Spanish-speaking countries) were established to deliberate on the following questions and make recommendations:

- (a) What are the main capacity-building priority needs in the area of risk assessment and risk management in the sub-region (at the individual, institutional and systemic levels)?
- (b) What measures should be taken to address the identified needs at: (a) national level; (b) regional/sub-regional level; and (c) international level? (NB: Be specific on what exactly should be done, by whom and by when?)
- (c) What are the existing and potential opportunities and mechanisms for sub-regional and regional cooperation and how should they be maximized/developed?

21. The following recommendations were made for improvement of risk assessment and risk management and for building capacities in the region:

- (a) Improve technical capacity to carry out risk assessment and studies on the environmental impact of LMOs through training of regulators, professors and trainers;
- (b) Training on assessing, reviewing and interpreting risk-assessment data and guidance materials (i.e. case-studies, workshops, etc.);
- (c) Training of certified regulators (at the national and regional levels in the agricultural, environmental and health/food safety areas);
- (d) Technical training on risk management, including sampling and detection methods, frequency, statistical analysis and emergency measures;
- (e) Training in compliance monitoring;
- (f) Enhance national and regional capacities to apply statistical methods on the reliability of LMO risk assessments, geographical information systems, estimation of long term effects of LMOs and the parameters for the detection of LMOs;
- (g) Acquire experience in the use of the precautionary principle or risk-benefit analysis in decision making;
- (h) Improve the capacity for LMO monitoring, including their potential effects as part of risk management;
- (i) Include biosafety in the university curricula of relevant courses;
- (j) Establish dedicated programmes in biosafety at the graduate level;
- (k) Establishment of mechanisms for regional and international cooperation and sharing of experiences in risk assessment and risk management; and

^{4/} Additional details in the presentation made by Mexico available at <http://www.cbd.int/doc/meeting.asp?mtg=RWCBGRULAC-01>

(l) Development of methodological manuals on risk assessment, taking into account international requirements and technologies.

ITEM 5. GUIDANCE MATERIALS FOR RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

22. Four presentations were made under this item. The first two presentations on the “Nature, scope and applicability of existing guidance materials on risk assessment and risk management of LMOs” were given by Dr. Amanda Gálvez Mariscal, from the Universidad Nacional Autónoma de México, and by Dr. Hans Bergmans, from the National Institute for Public Health and the Environment, the Netherlands. A third presentation was given by Ms. Velia Arriagada Rios from the Centro de Informacion de Recursos Naturales, Chile, on the “Synergies between pest risk analysis under the International Plant Protection Convention (IPPC) and risk assessment of living modified organisms under the Cartagena Protocol on Biosafety”. The fourth and last presentation under this item was given by Dr. Eliana M.G. Fontes, from Embrapa Genetic Resources and Biotechnology in Brazil, on the “Outcomes of the Canada-Norway Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology”, which was held in Montreal, 4-6 June 2007. Prior to the workshop, each participant was given a CD-ROM containing the above presentations as well as some of the existing guidance materials on risk assessment and risk managements and other relevant resource materials.

23. Dr. Gálvez Mariscal presented an overview of different existing guidance materials, examples of guidelines available within the Latin America and the Caribbean region; examples of any existing guidelines for post-release environmental monitoring of LMOs; and the need for further risk-assessment guidance at the regional and international levels. This was done for consideration by the participants and, ultimately, by COP-MOP 4 to make recommendations, if any, on how such guidance could be developed. She set out the characteristics of the main international (UNEP, FAO/Codex Alimentarius, OECD), regional (NAFTA/NAPPO, EU, ASEAN Australia/New Zealand) and national (Argentina, Brazil, Costa Rica, Mexico, New Zealand, Peru, USA) guidelines on risk assessment and risk management of LMOs that are currently available. She ended the presentation with the following recommendations to workshop participants: i) read the different documents that are available; ii) adapt the recommendations to country needs; iii) take into consideration that different environments have different needs and that different policies have different interests; and iv) plan in advance for applications of new LMOs (e.g., applications for modified ornamental fish in Mexico). She also recommended the development of guidelines for the monitoring and harmonization of methodologies.

24. Dr. Bergmans highlighted some of the existing guidance materials, which range from specific scientific articles to national-level guidelines to generic guidance documents agreed to in international fora. He pointed out that at different stages of risk assessment, different guidance materials are relevant. He provided examples of possible sources where they can be obtained, including: the Biosafety Information Resource Centre (BIRC) in the Biosafety Clearing House (BCH), international organizations (e.g. FAO, OECD, ICGEB CGIAR centres, etc.), websites of national regulatory agencies (e.g. EU, USA, etc.) and reliable bibliographic databases and search engines (e.g. Google scholar). He indicated that the BCH also contains guidance materials and links to relevant databases, websites and bibliographic information provided by Governments and relevant organizations. He advised that BCH users need to take into account the following general considerations in deciding which existing guidance materials and information to use: (i) the type of resource (scientific paper, book, conference report, interpretative report, etc.); (ii) the author of the material/information (scientific expert, regulator, NGO activist, etc.); (iii) the purpose for which they were compiled (scientific discussion, regulatory underpinning, NGO dissident view, etc); (iv) the ‘endpoints’ of the process (environmental safety, food/feed safety, etc); and (v) publication date.

25. Ms. Arriagada Rios explained that pest Risk Analysis (PRA) is a process, under the International Plant Protection Convention (IPPC), of evaluating biological or other scientific and economic evidence to determine: (i) if the organism is a pest; (ii) if it should be regulated; and (iii) the strength of any

phytosanitary measures for its regulation. Parallels between the PRA process and the risk assessment of LMOs under the Cartagena Protocol were drawn particularly in relation to identifying potential risks, assessing the probability of these risks, determining the need for management of the potential risks and strategies to communicate the risks. Ms. Arriagada Rios explained that risk assessment of LMOs under the IPPC (ISPM 2) is usually concerned with phenotypic rather than genotypic characteristics. However, in some cases genotypic characteristics should also be considered. The IPPC also includes elements of risk assessment to determine the probability and potential economic consequences, including the environmental impacts of introduction and spread of LMOs. In conclusion, she noted that the principles, objectives and methodologies under the IPPC and the Cartagena Protocol are fully compatible.

26. Dr. Fontes presented the main outcomes (observations and recommendations) of the Canada-Norway expert workshop, which focussed on the following emerging applications of living modified organisms (LMOs): transgenic fish, trees, pharmaplants and viruses for the management of animal populations. The workshop, she noted, i) addressed the availability of guidance materials on risk assessment for emerging applications of modern biotechnology; ii) identified gaps in information or science that could impact appropriate risk assessments; and iii) evaluated the appropriateness of current models for risk assessment applied to emerging applications. She noted that the workshop considered risk assessments for environmental release and for field trials a priority and observed that the general principles and methodologies for risk assessment as contained in annex III of the Protocol also apply to transgenic fish, trees, viruses and pharmaplants. However, the workshop noted that there is a need to develop specific methodologies and specific protocols for conducting risk assessments for transgenic fish, trees and viruses. It was also noted that there is insufficient guidance on how to perform risk assessment for transgenic fish and viruses. Furthermore, the workshop observed that there are major gaps in knowledge on several elements necessary to conduct risk assessments for all of the above applications, which include a lack of baseline data and the empirical data needed for modelling purposes. Accordingly, the report of the Canada-Norway expert workshop recommended that further research should be undertaken to fill the knowledge gaps, including those specific gaps identified during the workshop. The workshop also recommended that new information as well as existing guidance materials, methodologies, baseline information and risk assessments should be made readily available through the BCH and other relevant international databases. It is expected that the report of this workshop will be submitted as an information document to the fourth meeting of the Parties to the Protocol.

27. During the question and answer session, participants noted that although a number of risk-assessment guidance materials have been developed, many institutions and individuals in the region do not have easy access to them. They also took note of the outcomes of the Canada-Norway workshop and underscored the need to address the gaps identified by the workshop and to implement its recommendations.

28. Following the presentations and brief discussions in the plenary, two focus discussion groups (one for the English-speaking countries and another for the Spanish-speaking countries) were established to deliberate on the following questions and make recommendations:

(a) On what specific aspects of risk assessment and risk management might additional guidance be required?

(b) What would be the most appropriate modalities for the development of any such guidance materials?

29. The discussion groups further shared experiences gained in using existing guidance materials and discussed the need for additional guidance on specific aspects of risk assessment and risk management. The results of the discussion groups were discussed in the plenary and the following recommendations were adopted for consideration by the COP-MOP:

(a) Further guidance is needed for specific types of LMOs, particularly for fish, invertebrates, orchard and timber trees, pharmaplants, algae with respect to, *inter alia*, risk pathways, genetic stability, containment and confinement issues;

- (b) Further guidance is needed on specific types of introduced traits, particularly for disease and insect tolerance (other than Bt), resistance to abiotic stress (e.g., drought, salinity and cold), multigene traits, nutraceuticals, gene pyramiding/stacking, gene shuffling, bioremediation, altered reproductive traits (e.g., fertility restoration and sterility) and growth;
- (c) Further guidance is needed on particular receiving environments, such as centres of origin, aquatic environments, fragile ecosystems (e.g., altiplano, Patagonia and small islands);
- (d) Guidance on long-term monitoring of LMOs released into the environment, particularly for sampling techniques, frequency, laboratory techniques, statistical analyses and emergency measures;
- (e) Guidance on baseline information;
- (f) Promotion of regional networks and collaboration between competent national authorities responsible for risk assessment;
- (g) Requesting Parties to send submissions related to their specific needs, particularly for specific environments such as centres of origin, aquatic environments and fragile ecosystems;
- (h) An Ad Hoc Technical Experts Group (AHTEG) is recommended with the involvement of regulators and scientists to draft a strategic plan on which guidelines could be developed and compiled and how they could be implemented. This AHTEG could be followed-up by small technical focus groups.

ITEM 6. KEY CONSIDERATIONS IN THE PREPARATION AND/OR REVIEW OF RISK ASSESSMENTS

30. Under this item, two presentations were made. The first presentation, entitled: “Key considerations in the review of environmental risk assessments of living modified organisms: A Regulator's Perspective”, was made by Dr. Amanda Gálvez on behalf of Dr. Francisca Acevedo Gasman of the National Commission for the Knowledge and Use of Biodiversity (CONABIO), Mexico. The second presentation, “Format for risk assessment summaries submitted to the Biosafety Clearing-House in accordance with paragraph 3 (c) of Article 20 of the Protocol”, was made by Dr. Hans Bergmans.

31. Dr. Gálvez outlined the regulatory framework and institutional mechanism for handling risk assessment and risk management in Mexico and described in detail the role of CONABIO. She also described the key steps involved in the decision-making process regarding LMOs, from the stage of receipt of application, through risk assessment and review to issuance of the permit. She reported that CONABIO has been giving technical and scientific opinions related to the potential risks of LMOs to biodiversity since 1998. The final permit is issued by the Ministry of Agriculture (SAGARPA), taking into account the legally-binding opinion given by CONABIO through the Ministry of Environment (SEMARNAT, DGIRA). Dr. Gálvez described the key elements considered during the review of environmental risk assessments to facilitate decision-making, using the Mexican experience. She noted that the following information is used for risk analysis: (i) molecular characterization of the LMO; (ii) biological characterization (including: reproductive biology, interactions, wild relatives, etc); (iii) site of release, i.e. receiving environment; (iv) spatial analysis to, *inter alia*, identify the LMO's wild relatives and detect the possibility of gene flow in the field; and (v) management practices. She reported that CONABIO has developed a number of tools to facilitate its risk assessment and risk management work. These include: (i) a risk-assessment methodology; (ii) an LMO information system (SIOVM database) to provide easy access to information used in the analysis and decision-making process.

32. Dr. Gálvez also presented a number of lessons learned from the Mexican experience. *Inter alia*, she noted that:

- (a) Risk assessment and decision-making must be balanced between relevant competent authorities (i.e., agriculture and environment);
- (b) Competent authorities and their technical branches should include solid and established teams dedicated to biosafety (especially those doing the analysis);

(c) It is important to have a reliable and replicable process to do the analysis based on the best and most up-to-date information available; and

(d) It is also important to put in place a multidisciplinary team, both in house and outsourced for consultation and to capitalize on the existing human resources.

33. Dr. Bergmans highlighted the recommendations of the Ad Hoc Technical Expert Group on Risk Assessment, which met in Rome, from 15 to 18 November 2005. One of these recommendations encouraged Governments to submit risk-assessment summaries to the BCH in a standardized format and explain, as appropriate, how risk-assessment problems have been solved, in particular to which extent the existing information and guidance materials have been used to support the risk assessments. Dr. Bergmans noted that the current BCH Common Format for risk assessments lacks certain elements/fields that would enable countries to submit key useful factual information. In this regard, he made a number of recommendations for additional elements/fields or sub-headings to the current common format and the rationale for the different additions was discussed and agreed upon in a plenary session. In summary, the main proposed changes included the following:

(a) Under the section, “general information”, add the following fields:

- (i) Name and contact details of the applicant;
- (ii) Scope of the risk assessment; and
- (iii) Methodology of the risk assessment (to provide information on the methodology used, including the objectives and links to applicable legislation, guidance materials and other relevant documents).

(b) Under the section, “LMO information”:

- (i) Add a new field, “Characteristics of the recipient organism” to describe the characteristics that are relevant to the risk assessment.

(c) Under the section “Characteristics of modification”:

- (i) Add a new field “Method of transformation” to describe the methodology employed and the vector/DNA sequences used in the transformation process; and
- (ii) Expand the field entitled "Insert or inserts" to add the following elements/sub-headings:
 - Molecular characterization of DNA inserted into the genome of the recipient; and
 - Functional characterization of the coding sequences inserted into the genome of the recipient.

(d) Modify the section “further information” to highlight, *inter alia*: (i) issues taken into consideration; (ii) the potential risk scenarios; (iii) the point in the risk assessment at which the conclusion is drawn that the scenario poses no risk; and (iv) how and on what grounds was it decided that the information provided is sufficient.

34. Following the presentations and discussions in the plenary, participants reviewed and proposed a revised draft BCH common format for risk assessments. In doing so, they took into account the proposals that were made by the other regional workshops. The revised common format, contained in annex II to this report, was adopted at the end of the plenary discussions. Participants agreed to submit it to the SCBD for incorporation in the BCH Management Centre.

ITEM 7. REGIONAL COOPERATION AND SHARING OF INFORMATION AND EXPERTISE ON RISK ASSESSMENT AND RISK MANAGEMENT

35. Under this item, Prof. Leonard O'Garro of the UNEP-GEF Biosafety Programme gave a presentation entitled "Mechanisms, opportunities and challenges for regional cooperation and sharing of information and expertise in risk assessment and risk management in Latin America and the Caribbean". This was followed by discussions in the plenary and working groups.

36. In his presentation, Prof. O'Garro described the situation in the Caribbean subregion and noted that 13 of 14 Caribbean countries had finished the development of their draft national biosafety frameworks. He outlined existing mechanisms that would facilitate subregional cooperation on biosafety issues. He reported that the Caribbean Community (CARICOM) had established a working group on genetically modified organisms (encompassing biosafety and biotechnology) and had endorsed regional biotechnology and biosafety policy, a regional biotechnology programme and the UNEP/GEF project for implementing NBFs in Member States. He also reported that the CSME would provide a legal foundation permitting trade in LMOs. Prof. O'Garro noted that many countries in the region required capacities in risk assessment and risk management; detection of LMOs; administrative oversight; public participation; enforcement and monitoring; environment and socio-economic impact assessments; and in integration and coordination of relevant government agencies. In this regard, he emphasized the need to harness and augment financial resources, relevant regional skills and infrastructure in an institutional arrangement to establish an improved common human resource base and technical capacity for all participating countries to adequately address country-specific and common biosafety concerns. He noted that the UNEP/GEF project will provide capacity-building assistance to countries to enable them to give effect to the Biosafety Protocol through implementation of their national biosafety frameworks.

ITEM 8. CONCLUSIONS AND RECOMMENDATIONS

37. Participants made a number of general observations/conclusions and recommendations on the different issues. The main issues raised and discussed during the workshop focussed upon: (i) human resources and institutional capacity-building; (ii) data and information to support risk assessments and risk management guidance materials; (iii) a common format for risk assessments submitted to the BCH; and (iv) regional and technical cooperation on biosafety in general and risk assessment in particular.

38. In addition, UNEP-GEF and the SCBD were invited to:

(a) Organize an Ad Hoc Technical Experts Group (AHTEG) meeting to draw a roadmap for the development and compilation of guidance materials on the specific aspects of risk assessment (identified in item 3);

(b) Invite submissions from Parties related to their specific needs for further guidance materials, *inter alia*, for specific environments (e.g., small islands, tropical and Andean regions, centres of origin, etc.) to be submitted prior to the AHTEG meeting. These materials should be used at the meeting as a basis to draft a strategy to fill the gaps for further guidance materials;

(c) Organize informal technical fora (using online tools) to follow-up on the recommendations of the AHTEG;

(d) Organize regular educational training sessions for risk-assessment and risk-management experts;

(e) Organize regular workshops for experts and authorities to exchange experiences;

(f) Publish and distribute educational materials, guidelines for risk assessment and risk management and materials about global experiences in these fields;

(g) Organize a more efficient and user-friendly system (e.g. the roadmap mentioned above) to disseminate information.

ITEM 9. OTHER MATTERS

39. There were no other matters.

ITEM 10. ADOPTION OF THE WORKSHOP REPORT

40. During the last session, participants considered the draft report prepared by the Rapporteur with the assistance of the SCBD. The draft report included preliminary conclusions and recommendations directed to Governments, other relevant organizations and the fourth meeting of the COP-MOP.

ITEM 11. CLOSURE OF THE WORKSHOP

41. The workshop was closed at 14:15 on Wednesday, 12 December 2007.

Annex I

WORKSHOP PROGRAMME

Plenary	
Monday 10 December 2007 9 a.m. – 9.30 a.m.	<i>Agenda item:</i> 1. Opening of the Workshop.
9.30 a.m. – 10.15 a.m.	<i>Agenda items:</i> 2. Organizational matters: 2.1. Election of officers; 2.2. Adoption of the agenda; 2.3. Organization of work. 3. Introduction to risk assessment and risk management of living modified organisms in the context of the Cartagena Protocol on Biosafety.
10.15 a.m.– 10.45 a.m.	Coffee/Tea Break
10.45 a.m. – 1 p.m.	<i>Agenda items:</i> 4. National and regional experiences and lessons learned: • Case-study presentations from different subregions • Short presentations on national experiences by participants
1 p.m. – 2 p.m.	Lunch Break
2 p.m. – 3.30 p.m.	<i>Agenda item:</i> Item 4 (<i>continued</i>)
3.30 p.m. – 4 p.m.	Coffee/Tea Break
4 p.m. – 5.30 p.m.	<i>Agenda items:</i> 5. Guidance materials for risk assessment and risk management of living modified organisms: 5.1. Overview of the nature, scope and applicability of existing guidance materials;
Tuesday 11 December 2007 9 a.m. – 10.30 a.m.	<i>Agenda items:</i> Item 5 (<i>continued</i>) 5.2. Consideration of the need for further harmonized guidance on specific aspects of risk assessment and risk management.
10.30 a.m. – 11 a.m.	Coffee/Tea Break
11 a.m. – 1 p.m.	<i>Agenda items:</i> 6. Key considerations in the preparation and/or review of risk assessments of living modified organisms: 6.1. Basic elements, and considerations in the preparation and/or review, of environmental risk assessments of living modified organisms and the key scientific capacity and information requirements.
1 p.m. – 2 p.m.	Lunch

	Plenary
2 p.m. – 3.30 p.m.	<i>Agenda item:</i> 6.2. Format for risk assessment summaries submitted to the Biosafety Clearing-House in accordance with paragraph 3 (c) of Article 20 of the Protocol.
3.30 p.m. – 4 p.m.	Coffee/Tea Break
4 p.m. – 5.30 p.m.	<i>Agenda item:</i> 7. Regional and subregional cooperation on risk assessment and risk management, including the sharing of information and expertise.
Wednesday 12 December 2007 9 a.m. – 10.30 a.m.	<i>Agenda items:</i> Item 7 (<i>continued</i>) 8. Conclusions and recommendations.
10.30 a.m. – 11.00 a.m.	Coffee Break/Tea
11 a.m. – 1 p.m.	<i>Agenda item:</i> Item 8 (<i>continued</i>) 9. Other matters.
1 p.m. – 2 p.m.	Lunch
2 p.m. – 4 p.m.	<i>Agenda items:</i> 10. Adoption of the Workshop report. 11. Closure of the Workshop.

Annex II

**REVISED BCH COMMON FORMAT FOR
RISK ASSESSMENT SUMMARIES 1/**

General information	
1. Country taking decision or making declaration:	<Controlled vocabulary: countries <u>2/</u> >
2. Title of risk assessment: <u>3/</u>	<Text entry>
3. Competent National Authorities:	<Competent National Authority common format <u>4/</u> >
4. Name and contact details of the Applicant:	<Text entry>
5. Scope of the risk assessment:	<Text entry> <u>5/</u> <Controlled vocabulary> <u>6/</u>
LMO information	
6. Living modified organism:	<Choose from list: LMOs <u>7/</u> > or <Living modified organism common format <u>8/</u> > or <text entry> <u>9/</u>
CHARACTERISTICS OF MODIFICATION	
7. Characteristics of the recipient organism: <u>10/</u>	<Text entry>

1/ The procedure for risk assessments is further elaborated in annex III of the Biosafety Protocol. Summaries of risk assessments or environmental reviews generated by a government's regulatory process are made available to the BCH in accordance with Article 20, paragraph 3 (c) of the Protocol.

2/ The BCH Controlled Vocabulary for Countries is available at:
<http://bch.biodiv.org/thesaurus/domain.aspx?domainid=1>.

3/ The complete title of the risk assessment and/or the reference number to an entry in a national database where information on the risk assessment can be found, and that can be used to identify it.

4/ Please provide a BCH record number for previously registered information, or complete the Competent National Authority common format, available under the "National Contacts" heading at:
<http://bch.biodiv.org/resources/commonformats.shtml>.

5/ Provide a reference to the national or regional legislative system applicable to the risk assessment, and a description of the scope if 'other' is chosen from the controlled vocabulary.

6/ Provide a description of the scope of the risk assessment from the list: 'commercial cultivation'; use for food, feed or processing; field trial; contained use; other scope.

7/ The List of LMOs includes all living modified organisms currently in the LMO Registry, available at
<http://bch.biodiv.org/organisms/lmoregistry.shtml>.

8/ If the LMO is not already in the database (i.e. included in the controlled vocabulary), please complete the living modified organism (LMO) common format available under the "Organisms" heading at:
<http://bch.biodiv.org/resources/commonformats.shtml>.

9/ If no unique identification is provided (yet), for instance because the risk assessment concerns a field trial at an early stage of development, another reference number should be considered, e.g., the reference number mentioned in footnote 3.

10/ Provide relevant specific information on the characteristics of the recipient organism used to value the outcome of the risk assessment, e.g. persistence or presence of crossable relatives in the specific receiving environment.

/...

8. Vector characteristics: 11/	<Text entry> [Explore the possibility of a controlled vocabulary]
9. Insert or inserts: 12/	<Text entry> [Explore the possibility of a controlled vocabulary, next to the text entry]
a) Molecular characterization of DNA inserted into the genome of the recipient: 13/	<Text entry> <Link to the record in the BCH where molecular characterization can be found> 14/
b) Functional characterization of the coding sequences inserted into the genome of the recipient: 15/	<Text entry> [Explore the possibility of a controlled vocabulary, next to the text entry]
c) Selectable markers used:	<Text entry> [Explore the possibility of a controlled vocabulary, replacing the text entry]
10. Method of transformation:	<Text entry> [Explore the possibility of a controlled vocabulary, replacing the text entry]

Detection and identification of the living modified organism

11. Detection and identification methods: [16/](#) <Text entry>

Intended use and receiving environment

12. Intended use of the LMO: [17/](#) <Text entry> [Explore the possibility of a controlled vocabulary]

13. Receiving environment: [18/](#) <Text entry> [Explore the possibility of a controlled vocabulary]

[11/](#) Characteristics of the vector, should include its identity, if any, and its source or origin, and its host range, as elaborated in annex III paragraph 9 (c) of the Protocol.

[12/](#) Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced, as elaborated in annex III paragraph 9 (d) of the Protocol.

[13/](#) If a molecular characterisation of the LMO is available elsewhere in the CBH, describe which, if any, details of the molecular characterization were taken into specific consideration in the risk assessment.

[14/](#) If no reference is available, describe as appropriate: a) the criteria used to check the completeness and validity of the data supplied by the notifier; b) the type of data (e.g. hybridization and sequence data) used, *inter alia*, for determining the overall structure and for detailed characterization of the insert; c) an interpretation of the characterization data, in terms of genes and relevant ORFs that are expected to be expressed; and d) the explicit conclusion drawn from the data, and the list of items stemming from the molecular characterization that are relevant for the risk assessment.

[15/](#) Describe the phenotypic characteristics that (are expected to) result from expression of the sequences described in the molecular characterization, taking into account as appropriate, the level of expression and the specific tissues where and the timing when expression occurs.

[16/](#) Suggested detection and identification methods and their specificity, sensitivity and reliability, as elaborated in annex III, paragraph 9 (f) of the Protocol.

[17/](#) Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms, as elaborated in annex III paragraph 9 (g) of the Protocol.

Risk assessment summary 19/

14. Novel genotypic and phenotypic characteristics: 20/ <Text entry>

15. Potential adverse effects that may be realized: 21/ <Text entry >

16. Likelihood of the potential adverse effects to be realized: 22/ <Text entry>

17. Possible consequences: 23/ <Text entry>

18. Estimation of overall risk: 24/ <Text entry>

19. Recommendation on risks: 25/ <Text entry>

20. Risk management strategies: 26/ <Text entry>

OVERALL RISK ASSESSMENT SUMMARY

21. Overall summary of the risk assessment or environmental review: 27/ <Text entry>

18/ Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment, as elaborated in annex III paragraph 9 (h) of the Protocol. Also provide a general discussion on the expected impact of the intended use of the LMO on the receiving environment, and how this is taken into account within the scope of the risk assessment.

19/ Provide a summary of the risk assessment information in accordance with paragraphs 8 (a) to 8 (f) of annex III to the Protocol.

20/ An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health, as elaborated in annex III paragraph 8 (a) of the Protocol.

21/ Provide an identification of adverse effects that may be realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism, as elaborated in annex III paragraph 8 (b) of the Protocol.

22/ Provide an evaluation of the likelihood that the potential adverse effects listed in item 15 may occur.

23/ An evaluation of the consequences should these adverse effects be realized, as elaborated in annex III paragraph 8 (c) of the Protocol.

24/ An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized, as elaborated in annex III paragraph 8 (d) of the Protocol.

25/ A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks, as elaborated in annex III paragraph 8 (e) of the Protocol.

26/ Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment, as elaborated in annex III paragraph 8 (f) of the Protocol.

27/ Provide an overall executive summary of the risk assessment.

Access to the detailed risk assessment information

22. Availability of, and ways of accessing, the detailed risk assessment information: 28/ <Text entry>

Additional information

23. Any other relevant information: 29/ <Text entry>

24. Relevant documents or links: 30/ <Web address (URL and website name or description) or attachment>

25. Notes: 31/ <Text entry>

Name of person authorizing publication:**Signature:****Date:**

Please return to:

Secretariat of the Convention on Biological Diversity

413 rue Saint-Jacques, suite 800
Montreal, Quebec, H2Y 1N9 Canada

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Email: bch@cbd.int

BCH website: <http://bch.cbd.int>

SCBD website: <http://www.cbd.int>

28/ Please indicate whether more details on the risk assessment are available and how they can be accessed.

29/ Please use this field to provide any other relevant information that may not have been addressed elsewhere in the record.

30/ Please provide website addresses containing relevant information, and/or attach one or more relevant documents that will be stored in the database for users to download.

31/ The notes field is for your personal use only: you can see it when you edit the record, but it is not visible to others when the record is viewed through search pages.

/...

Annex III

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