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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
Second meeting
Montreal, 30 May—3 June 2005
Item 11 of the provisional agenda*

RISK ASSESSMENT AND RISK MANAGEMENT (ARTICLES 15 AND 16)

Note by the Executive Secretary

I. INTRODUCTION

1. The Cartagena Protocol on Biosafety contains provisions on risk assessment (Article 15 and Annex III) and on risk management (Article 16) of living modified organisms. Decisions taken under the advance informed agreement procedure of the Protocol must be taken in accordance with Article 15 on risk assessment (Article 10, paragraph 1). Risk assessment is also referred to in the context of living modified organisms intended for direct use as food or feed, or for processing, specifically in paragraph (j) of annex II and in paragraph 6 of Article 11.

2. The Conference of the Parties serving as the meeting of the Parties to the Protocol, at its first meeting, adopted a medium-term programme of work (decision BS-I/12, annex). One of the items that was specified for consideration at the second meeting is risk assessment and risk management (paragraph 4 (b)). In particular, the Conference of the Parties serving as the meeting of the Parties to the Protocol decided to consider the following items:

(a) Clarification of the issues involved;

(b) The development of guidance and a framework for a common approach in risk assessment and risk management;

(c) Cooperation in identifying 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, and taking appropriate measures regarding the treatment of such living modified organisms or specific traits (Article 16, paragraph 5).

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3. The Conference of the Parties serving as the meeting of the Parties to the Protocol requested the Executive Secretary to collect and collate existing guidance materials regarding risk assessment and risk management of living modified organisms for consideration by the second meeting, and invited Parties, other Governments and relevant international organizations to provide relevant information to the Executive Secretary, not later than six months prior to the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, for inclusion in the report (decision BS-I/11, para. 5).

4. In response to this invitation, submissions were received from the following Parties, other Governments and organizations as of 31 January 2005: Australia, Canada, the European Community, Lithuania, Switzerland, the United States of America, the Global Industry Coalition, and the Organisation for Economic Co-operation and Development (OECD).

5. Submissions regarding risk assessment and risk management are compiled in an information document (UNEP/CBD/BS/COP-MOP/2/INF/2). Actual guidance materials are not reproduced in that document but are listed in the annex to the present note.

6. Section II of the note highlights the general nature and scope of existing guidance materials that were collected by the Executive Secretary or received as submissions. Section III summarizes the views on risk assessment and risk management that were received as submissions. Section IV focuses on considerations that may be relevant to a decision by the Conference of the Parties serving as the meeting of the Parties to the Protocol regarding risk assessment and risk management.

II. EXISTING GUIDANCE MATERIALS

7. The annex to the present note lists guidance materials related to risk assessment and risk management of living modified organisms that were either collected by the Executive Secretary or submitted by Parties, Governments, and relevant organizations. The general nature of each reference is briefly characterized, such as the scope and level of detail, in order to provide a general understanding of the types of materials that are available.

8. Existing guidance materials on risk assessment and risk management for living modified organisms vary widely in their scope and application. It is clear that there are a range of approaches, including:

(a) Generic guidance applicable to all types of living modified organisms and risk pathways, similar to annex III of the Protocol;

(b) Guidance that is specific to a particular living modified organism (e.g., genetically modified soybean) or to a particular trait (e.g., glyphosate tolerance);

(c) Guidance that is specific to a category of living modified organism or traits (e.g., genetically modified plants; herbicide resistant plants; genetically modified animals and/or fish; genetically modified micro-organisms);

(d) Guidance that is specific to one or more risk pathways or mechanisms (e.g., weediness; effects on non-target organisms; development of insect resistance);

(e) Guidance that focuses on a particular issue in the practice of risk assessment or risk management for living modified organisms, such as particular elements of methodology (e.g., identification of potential hazards; monitoring) or methodological issues (e.g., characterizing uncertainties);

(f) Case-studies in the application of risk assessment and management.

9. In order to better understand the various approaches, it is important to understand some key differences in terminology and their implications.

10. First, many guidance documents, in particular those from some international organizations, use the term "risk analysis" to refer to risk assessment, risk management and in some cases risk communication. Although the Protocol does not use the term "risk analysis", the text of the Protocol highlights links between risk assessment and risk management. For example, there are provisions that specifically link risk management to risk assessment, including paragraphs 1 and 2 of Article 16, which read:

> "1. The Parties shall, taking into account Article 8(g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movements of living modified organisms.
>
> "2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import."

11. In addition, paragraphs 8 (e) and (f) of annex III to the Protocol explicitly refer to risk-management considerations as part of risk-assessment methodology, as follows:

> "8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:
>
> "(…)
>
> "(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
>
> "(f): 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."

12. It should also be noted that, while many existing guidance materials outline a methodology for risk assessment that is similar to that of annex III, paragraph 8, there is considerable variability in terminology used to describe the particular steps in paragraphs 8 (a) to (d), which read as follows:

> "8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:
>
> "(a) 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;
>
> "(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;"

"(c) An evaluation of the consequences should these adverse effects be realized;"

"(d) An estimation of the overall risk posed by the living modified organism based on evaluation of the likelihood and consequences of the identified adverse effects being realized;"

13. In the case of paragraph 8 (a), many frameworks for risk assessment refer to this first step using specific terminology such as "hazard identification". Although the Protocol does not use such particular terminology and although the scope of "hazard identification" in existing guidance materials may be broader than the scope of paragraph 8 (a), it is useful to recognize that the intent may be similar:

14. Similarly, the Protocol refers to the "likelihood" and "consequences" of potential adverse effects in paragraphs 8 (b)-(d) of annex III.

15. Some existing guidance materials use the same terms while others use different terms to refer to the same general methodological steps. For example, the step referred to in paragraph 8 (b) of annex III uses the term "likelihood" and also the term "exposure". Some existing guidance materials use one of these terms or the other, referring to this step either as "exposure assessment" or "assessment of likelihoods". Similarly, the step referred to in paragraph 8 (c) of annex III uses the term "consequences". Some existing guidance materials use this term while others refer to this step using alternative terms such as "effects assessment".

III. VIEWS ON RISK ASSESSMENT AND RISK MANAGEMENT

16. In addition to providing relevant guidance materials, several submissions provide views on risk assessment and risk management. These views are found in the compilation of submissions contained in an information document (UNEP/CBD/BS/COP-MOP/2/INF/2), and are summarized below.

A. Views on guidance for risk assessment and risk management

17. Two submissions stated that additional guidance expanding on the Protocol text is not necessary. One of those submissions expressed the view that annex III of the Protocol provides a structure for guidance, yet is flexible enough to function as a widely applicable common approach that can be adapted for case-by-case assessments. The same submission referred to several existing guidance documents and accepted international standards, noting that annex III is consistent with those documents and standards. The same submission also noted that food safety assessments are not within the scope of the Protocol and that guidance for such assessments has been and should be developed by the Codex Alimentarius.

18. One submission supported a harmonized approach to risk assessment and risk management that builds on internationally agreed principles and techniques developed by relevant international organizations. The same submission noted that any guidance on risk management should be limited to general principles due to the unique nature of national systems and diversity of risk management strategies.

19. Another submission, while not expressing a view on the need for additional guidance, stated that there are many existing guidance materials that are compatible with the Protocol.

20. Finally, one submission identified several existing guidance materials while expressing the view that risk assessment requires further elaboration.

B. Views on clarification of the issues involved

21. With regard to the clarification of the issues involved, one submission noted that risk assessment should be based exclusively on scientific data (for example dealing with the characteristics of the introduced trait, organism, receiving environment and the interactions thereof).

C. Views on cooperation under Article 16, paragraph 5

22. With regard to cooperation on Article 16, paragraph 5, one submission recommended that the initial step should be sharing of information through submissions from Parties and Governments. Another submission refers to its previous submissions to the third meeting of the Intergovernmental Committee for the Cartagena Protocol and the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, in which it expressed the following views: (i) risk management experiences should be shared through submissions; (ii) experiences in the implementation of Article 8 (g) of the Convention could be shared through the reporting process under the Convention; and (iii) all such information could feed into a knowledge database through the Biosafety Clearing-House.

IV. CONSIDERATIONS FOR A DRAFT DECISION

23. On the basis of the guidance provided by the medium-term programme of work, and considering the information on existing guidance materials (section II above) as well as the submissions received (section III above), the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to identify specific issues for consideration under risk assessment and risk management, and may also wish to specify activities to address those issues if they are to be considered during the inter-sessional period between its second and third meetings.

A. Capacity-building and exchange of experiences

24. Risk assessment and other scientific and technical expertise, and risk management, have been identified as key elements requiring concrete action under the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety (decision BS-I/5, annex I, para. 3).

25. In this regard, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider specific inter-sessional activities aimed at supporting capacity-building and exchange of experiences related to risk assessment and risk management, such as workshops and/or the use of online discussion forums on the Biosafety Clearing-House.

B. Information exchange

26. In order to further the exchange of information and experiences on risk assessment and risk management, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to request the Executive Secretary to make the guidance materials listed in the annex to this paper available in the biosafety information resource centre, which will be maintained in the Biosafety Clearing-House, as provided for in the elements of the Coordination Mechanism for the Implementation of the Action Plan on Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety (decision BS-I/5, annex IV).

27. Furthermore, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to invite Parties, Governments and organizations to contribute any additional guidance materials or other information relevant to risk assessment and risk management to the biosafety information resource centre.

C. Consideration of the need for a subsidiary body

28. Consideration of risk assessment and risk management issues may be ongoing as particular issues arise, including but not necessarily limited to cooperation as envisaged by paragraph 5 of Article 16.

29. At its third meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol will consider the need for designating one or the other subsidiary body of the Convention to serve the Protocol, and will consider whether there is a need to establish further subsidiary bodies to enhance the implementation of the Protocol (decision BS-I/12, annex, para. 5 (c)).

30. More specifically, the need for designating or establishing a permanent subsidiary body to provide timely advice on scientific and technical issues arising in relation to the implementation of the Protocol will also be considered at the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (decision BS-I/11, para. 2).

31. In this regard, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to solicit views from Parties and Governments regarding the need for and nature of such a subsidiary body, and any particular issues related to risk assessment or risk management that such a body could address, in order to prepare for consideration of that item at its third meeting.

Annex

EXISTING GUIDANCE MATERIALS REGARDING RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

This annex lists existing guidance materials regarding risk assessment and risk management of living modified organisms, collected or received in accordance with the request specified in paragraph 5 of decision BS-I/11. Materials associated with Parties and Governments are listed first, in alphabetical order, followed by materials from other sources.

1. Australia – Risk Analysis Framework. Office of the Gene Technology Regulator, 2005

Method of Collection: Collected by the Secretariat
Availability: http://www.ogtr.gov.au/
Key Characteristics:

- Detailed discussion of the steps and elements of risk assessment, consistent with paragraph 8 of annex III of the Protocol
- Discussion of risk management measures and the relationship between assessment and management
- Consideration of some issues in risk assessment such as dealing with uncertainties

2. Bangladesh – Biosafety Guidelines for Bangladesh. Ministry of Science and Technology, 1999

Method of Collection: Collected by the Secretariat
Availability: Through UNEP/GEF (http://www.unep.ch/biosafety/)
Key Characteristics:

- Framework for field testing for GM plants and for GM microorganisms by type (annex 6)
- Potential risk management measures listed by type of LMO (plants, animals, microorganisms)
- Discussion of options for physical or biological containment
- Classification of microorganisms according to their risk potential (annexes 1 and 4)

3. China – Biosafety Regulations of Agricultural Genetically Modified Organisms. Ministry of Agriculture, 2002

Method of Collection: Collected by the Secretariat
Availability: http://www.agri.gov.cn/zcfg
Key Characteristics:

- Describes a classification system for safety of agricultural GMOs
- Appendices list detailed information requirements for GM plants, GM animals, and GM microorganisms
- Describes safety control measures including required isolation distances

4. European Community – Relevant annexes, and associated guidance notes, to Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (details of each below)

Method of Collection: Submitted by the European Union
Availability: http://europa.eu.int

a. Annex II (Principles for the Environmental Risk Assessment) to Directive 2001/18/EC

Key Characteristics:

- Principles and methodology similar to annex III but more detailed
- Specific information on risks to be considered for GM plants, and for GMOs other than plants

b. Commission Decision of 24 July 2002 establishing guidance notes supplementing annex II of Directive 2001/18/EC (Decision 2002/623/EC)

Key Characteristics:

- Detailed information on general principles and methodology, greatly expanding on annex III of the Protocol

c. Annex VI (Guidelines for the Assessment Reports) to Directive 2001/18/EC

Key Characteristics:

- List of information required by the Directive, some of which cover elements of annex III of the Protocol

d. Annex VII (Monitoring Plan) to Directive 2001/18/EC

Key Characteristics:

- Describes aspects of the principles and design of monitoring plans, expanding on paragraph 8(f) of annex III of the Protocol

e. Council Decision of 3 October 2002 supplementing annex VII to Directive 2001/18/EC (Decision 2002/811/EC)

Key Characteristics:

- Detailed description of the objectives, general principles, strategy, methodology, and analysis of monitoring plans, relevant to paragraph 8(f) of annex III of the Protocol.

5. European Community – Annex III (Safety assessment parameters to be taken into account, as far as they are relevant, in accordance with Article 6(3)) to Council Directive 90/219/EEC on the contained used of genetically modified micro-organisms; and Commission Decision 2000/608/EC of 27 September 2000 concerning guidance notes for risk assessment outlined in that annex

Method of Collection: Submitted by the European Union
Availability: http://europa.eu.int
Key Characteristics:

- Detailed description of risk assessment in the context of contained use of genetically modified micro-organisms, including consideration of containment measures

6. European Community – European Commission Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed, 6-7 March 2003, prepared for the Scientific Steering Committee by the Joint Working Group on Novel Foods and GMOs

Method of Collection: Submitted by the European Union
Availability: http://europa.eu.int
Key Characteristics:

- It should be noted that this document was updated and replaced by the 2004 document produced by the European Food Safety Authority, reviewed below
- Scope is genetically modified plants and derived food and feed
- Description of the comparative approach to risk assessment (paragraph 5 of annex III of the Protocol)
- Detailed description of information requirements related to risk assessment

7. European Community – European Food Safety Authority Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed, 8 November 2004

Method of Collection: Submitted by the European Union, and also by the Global Industry Coalition
Availability: http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html
Key Characteristics:

- Scope is genetically modified plants and derived food and feed
- Description of the comparative approach to risk assessment (paragraph 5 of annex III of the Protocol)
- Detailed description of information requirements related to risk assessment
- Consideration of monitoring requirements
- Detailed discussion of risk characterization (paragraph 8(d) of annex III of the Protocol)

8. New Zealand – Identifying risks for applications under the Hazardous Substances and New Organisms Act. Environmental Risk Management Authority, 1999

Method of Collection: Collected by the Secretariat
Availability: http://www.ermanz.govt.nz/resources/publications/pdfs/ER-TG-01-1.pdf
Key Characteristics:

- Detailed guidance on the process of identifying potential risks (expanding on paragraph 8(a) of annex III)

9. New Zealand – Preparing information on risks, costs and benefits for applications under the Hazardous Substances and New Organisms Act. Environmental Risk Management Authority, 2000

Method of Collection: Collected by the Secretariat
Availability: http://www.ermanz.govt.nz/resources/publications/pdfs/ER-TG-03-1.pdf
Key Characteristics:

- Description of the components of risk and options for risk characterization (e.g., qualitative versus quantitative, etc.)
- Consideration of risks in a decision-making context

10. Nigeria – Nigeria Biosafety Guidelines

Method of Collection: Collected by the Secretariat
Availability: Biosafety Clearing-House
Key Characteristics:

- Includes description of information requirements related to risk assessment and risk management

11. Singapore – Singapore Guidelines on the Release of Agriculture-Related GMOs. Genetic Modification Advisory Committee

Method of Collection: Collected by the Secretariat
Availability: http://www.gmac.gov.sg/guidelines/agriculture.html
Key Characteristics:

- These guidelines are virtually identical to the guidelines developed by the Association of Southeast Asian Nations (see below)
- Includes description of information requirements related to risk assessment and risk management, including for numerous specific types of LMOs including plants, fish, other vertebrates, invertebrates, several categories of microorganisms, and foods

12. Switzerland – Ordinance on the Release of Organisms into the Environment. Appendix 4: Risk Assessment. 1999

Method of Collection: Submitted by the Government of Switzerland
Availability http://www.environnement-suisse.ch/imperia/md/content/stobobio/biotech/odeb/14.pdf
Key Characteristics:

- Not specific to LMOs
- Lists considerations for determining the probability and extent of potential damage due to release of organisms into the environment, as well as considerations for determining required safety measures

13. Switzerland – Ordinance on the Contained Use of Organisms, 1999 - Classification of Organisms according to risk to human health and the environment (Article 22 and Appendix 2.1)

Method of Collection: Submitted by the Government of Switzerland
*Availability:*http://www.environnement-suisse.ch/buwal/eng/fachgebiete/fg_biotechnologie/national/ouc/index.html
Key Characteristics:

- Not specific to LMOs
- The ordinance requires that organisms be assigned to one of four risk classes according to specified criteria, and reports on the website give rankings for bacteria, parasites, and fungi

14. United States of America – Environmental Protection Agency, Guidelines for Ecological Risk Assessment, (EPA/630/R-95/002F, April 1998)

Method of Collection: Submitted by the Global Industry Coalition
Availability: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460
Key Characteristics:

- Detailed discussion of general principles and considerations associated with risk assessment methodology, particularly relevant to paragraphs 8(a) to 8(d) of annex III
- Scope is any ecological stressor (chemical, physical or biological)

15. AGBIOS (Agriculture & Biotechnology Strategies) – Environmental Risk Assessment Case-Study

Method of Collection: Collected by the Secretariat
Availability: http://www.agbios.com/main.php
Key Characteristics:

- Practical teaching module for risk assessment based on maize line MON810
- Includes assessment of various types of risk pathways such as gene transfer, weediness, non-target effects, and insect resistance

16. ASEAN (Association of Southeast Asian Nations) – ASEAN Guidelines on Risk Assessment of Agriculture-Related GMOs, 1999

Method of Collection: Collected by the Secretariat
Availability: http://www.aseansec.org/6226.htm
Key Characteristics:

- Intended to ensure a common framework among ASEAN member countries for assessment of risks associated with the transboundary movement of agriculture-related GMOs
- Includes description of information requirements related to risk assessment and risk management, including for numerous specific types of LMOs including plants, fish, other vertebrates, invertebrates, several categories of microorganisms, foods

17. BIO-EARN (East African Regional Programme and Research Network for Biotechnology, Biosafety, and Biotechnology Policy Development) – Resource Book for the Implementation of Biosafety in East Africa

Method of Collection: Collected by the Secretariat
Availability: http://www.bio-earn.org/resource%20book/Home.htm
Key Characteristics:

- Broad scope, not too detailed
- Includes methodology similar to paragraph 8 of annex III
- Includes sections on risk assessment reviews (2 pages)
- Includes a focus on containment as part of risk management

18. Codex Alimentarius Commission – Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, 2003

Method of Collection: Submitted by the Global Industry Coalition
Availability: http://www.codexalimentarius.net
Key Characteristics:

- Scope is food safety and does not cover environmental risks
- Lists principles for risk assessment and risk management related to food safety of genetically modified foods, including some elements of annex III of the Protocol

19. Codex Alimentarius Commission – Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants, 2003

Method of Collection: Submitted by the Global Industry Coalition
Availability: http://www.codexalimentarius.net
Key Characteristics:

- Scope is food safety and does not cover environmental risks
- Describes considerations for the assessment and management of risks associated with foods consisting of, or derived from, genetically modified plants

20. Codex Alimentarius Commission – Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms, 2003

Method of Collection: Submitted by the Global Industry Coalition
Availability: http://www.codexalimentarius.net
Key Characteristics:

- Scope is food safety and does not cover environmental risks
- Describes considerations and approaches for the safety assessment of foods produced using recombinant-DNA micro-organisms

21. Codex Alimentarius Commission – Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, 2003

Method of Collection: Submitted by the Global Industry Coalition
Availability: ftp://ftp.fao.org/codex/PM/Manual13e.pdf (pages 42-48)
Key Characteristics:

- Includes general principles and key elements of risk assessment and risk management in the context of food safety and human health, covering many aspects of annex III of the Protocol

22. Food and Agricultural Organization of the United Nations – International Code of Conduct on Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources (draft 1995)

Method of Collection: Submitted by the Global Industry Coalition
Availability: http://www.fao.org/ag/cgrfa/biocode.htm
Key Characteristics:

- The actual document was not available on the submitted website and therefore was not reviewed. It should be noted that the FAO Commission on Genetic Resources for Food and Agriculture had postponed this work, but is now developing a code of conduct on biotechnology which will be further considered at its next session

23. Food and Agricultural Organization of the United Nations and the World Health Organization – FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from GM Animals, including Fish (FAO Food and Nutrition Paper 79, 2003)

Method of Collection: Submitted by the Global Industry Coalition
Availability:
http://www.fao.org/documents/show_cdr.asp?url_file=/DOCREP/006/Y5316E/Y5316E00.HTM
Key Characteristics:

- Describes general principles and considerations relevant to risk/safety assessment of GM animals and derived foods, including fish

24. International Organization for Biological Control – Global Working Group on Transgenic Organisms in Integrated pest Management and Biological Control, and the Scientific and Technical Advisory Panel of the Global Environment Facility – Series on Environmental Risk Assessment of Genetically Modified Organisms – Volume 1, A Case Study of Bt Maize in Kenya

Method of Collection: Collected by the Secretariat
Availability: CABI Publishing (orders@cabi.org)
Key Characteristics:

- Detailed case-study development of the methodology for a risk assessment, focusing on a particular trait in a particular receiving environment
- Includes detailed chapters on risk pathways related to (a) impacts on non-target organisms, (b) gene flow and its consequences, (c) insect resistance
- Includes a component that helps to frame the risk assessment in the broader context of decision-making, taking into account risks of alternatives, and incorporating public and stakeholder inputs

25. International Organization for Standardization – General guidance on risk assessment and risk management (see details below)

Method of Collection: Submitted by the Global Industry Coalition and referred to by the United States of America
Availability: http://www.iso.org

a. Environmental Management: The ISO 14000 Family of International Standards (2002)

Key Characteristics:

- Various standards related to Environmental Management; the specific standards were not available for review

b. Guide 73, Risk Management Vocabulary Guidelines for Use in standards (2002)

Key Characteristics:

- This document was not available for review.

c. ISO 22000 (2004)

Key Characteristics:

- This document was not available for review.

26. International Plant Protection Convention – Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, International Standard for Phytosanitary Measures #11, 2004

Method of Collection: Submitted by the United States of America and by the Global Industry Coalition
Availability: www.ippc.int
Key Characteristics:

- Applicable to any LMO that meets the definition of a quarantine pest, namely any LMO that is a potential plant pest (any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products), which is of economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled
- Includes detailed discussion of elements of methodology in particular estimating the probability and potential economic consequences (including environmental impacts) of introduction and spread
- Includes detailed discussion of risk management options

27. International Plant Protection Convention – Guidelines for Pest Risk Analysis, International Standard for Phytosanitary Measures #2, 1996

Method of Collection: Submitted by the Global Industry Coalition
Availability: www.ippc.int
Key Characteristics:

- Not specific to LMOs, but applicable to any species, strain or biotype of plant or animal or any pathogenic agent that is injurious to plants or plant products.
- Describes risk assessment methodology in some detail, in particular the methodological steps analogous to paragraphs 8(a) to 8(d) of annex III of the Protocol, with a focus on risks associated with potential spread and establishment.
- Lists risk management and mitigation options and considerations, consistent with paragraph 8(e) of annex III of the Protocol.
- It should be noted that the Interim Commission on Phytosanitary Measures is in the process of revising this standard, in part to make it consistent with the more recent standard ISPM#11 described above.

28. North American Plant Protection Organization – Regional Standard for Phytosanitary Measures #14: Importation and Release (into the environment) of Transgenic Plants, in NAPPO Member Countries

Method of Collection: Submitted by the United States of America
Availability: http://www.nappo.org
Key Characteristics:

- Guidance on evaluation of risks to plant or plant health associated with import and release of transgenic plants
- Divided into three modules on (1) importation into contained facilities, (2) confined release into the environment, and (3) unconfined release into the environment

- Lists information requirements regarding the transgenic plant, risk management measures, assessment criteria, potential for reproduction and survival, potential for interactions with sexually compatible relatives, and potential for effects on non-target organisms

29. OECD (Organisation for Economic Co-operation and Development) – An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonization in Biotechnology

Method of Collection: Submitted by the OECD, and referred to by the United States of America
Availability: http://www.oecd.org
Key Characteristics:

- This document explains the background and scope of OECD consensus documents developed by the working group. These documents compile information relevant to risk/safety assessment of several transgenic products, and focus on either (a) the biology of particular host species or crops, or (b) traits used in genetic modification. They comprise technical information for use during the regulatory assessment of products of biotechnology and are intended to be mutually recognized among OECD Member countries

The following consensus documents have been published:

- General Information concerning the Biosafety of Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection (1996)
- Information Used in the Assessment of Environmental Applications Involving *Pseudomonas* (1997)
- The Biology of *Brassica napus* L. (Oilseed Rape) (1997)
- The Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato) (1997)
- The Biology of *Triticum aestivum* (Bread Wheat) (1999)
- General Information Concerning the Genes and their Enzymes that Confer Tolerance to Glyphosate Herbicide (1999)
- General Information Concerning the Genes and their Enzymes that Confer Tolerance to Phosphinothricin Herbicide (1999)
- The Biology of *Picea abies* (L.) *Karst* (Norway Spruce) (1999)
- The Biology of *Picea glauca* (Moench) Voss (White Spruce) (1999)
- The Biology of *Oryza sativa* (Rice) (1999)
- The Biology of *Glycine max* (L.) Merr. (Soybean) (2000)
- The Biology of *Populus* L. (Poplars) (2000)
- The Biology of *Beta vulgaris* L. (Sugar Beet) (2001)
- Information used in the Assessment of Environmental Applications Involving Baculovirus (2002)
- The Biology of *Picea sitchensis* (Bong.) Carr. (Sitka Spruce) (2002)
- The Biology of *Pinus strobus* L. (Eastern White Pine) (2002)
- The Biology of *Prunus sp*. (Stone Fruits) (2002)
- Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants (2002)

- The Biology of *Zea maize subsp.mays* (Maize) (2003)
- The Biology of European White Birch (*Betula pendula Roth*) (2003)

The following additional consensus documents were in preparation at the time of writing of the OECD introduction to consensus documents:

- The Biology of Banana
- The Biology of Chilli Pepper
- The Biology of Citrus
- The Biology of Cotton
- The Biology of Oyster Mushroom
- The Biology of Papaya
- The Biology of Sunflower
- The Biology of Tomato
- The Biology of Douglas Fir
- The Biology of Jack Pine
- The Biology of Larches
- The Biology of Lodgepole Pine
- The Biology of Western White Pine
- Insect Resistance
- Selective Markers
- Glufosinate-Ammonium Tolerance (Module III)
- *Acidithiobacillus*
- *Acinetobacter*
- *Fusarium*

30. OECD (Organisation for Economic Co-operation and Development) – Guidance Document on Methods for Detection of Micro-Organisms Introduced into the Environment: Bacteria. 2004

Method of Collection: Submitted by the Global Industry Coalition
Availability: http://www.oecd.org
Key Characteristics:

- Not specific to, but applicable for, genetically modified micro-organisms
- Relevant for detection and identification of LMOs (paragraph 9 (f) of annex III of the Protocol), which can be important for the purposes of evaluating and characterizing risks (paragraphs 8(b) to 8(d)) and for monitoring (paragraph 8 (f)).

31. OECD (Organisation for Economic Co-operation and Development) – Safety Considerations for Biotechnology: Scale-Up of Crop Plants. 1993

Method of Collection: Submitted by the Global Industry Coalition
Availability: http://www.oecd.org/dataoecd/26/26/1958527.pdf
Key Characteristics:

- Considers specific risk pathways and associated management options for GM crop plants, relevant to several aspects of annex III of the Protocol

32. OECD (Organisation for Economic Co-operation and Development) – Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-Organisms: Bacteria. 2003

Method of Collection: Submitted by the Global Industry Coalition
Availability: http://www.oecd.org
Key Characteristics:

- Not specific to LMOs but relevant for genetically modified micro-organisms
- Detailed description of methods for classifying and identifying micro-organisms, relevant for identifying characteristics of organisms that may pose risks, in accordance with paragraph 8(a) of annex III of the Protocol
- Relevant to risk assessment where information on non-modified or parental organisms are used as part of the basis for risk assessment (paragraphs 5, 9(a) and 9(b) of annex III)

33. OECD (Organisation for Economic Co-operation and Development) – Draft Points to Consider for Consensus Documents on the Biology of Cultivated Vascular Plants. 2004

Method of Collection: Submitted by the Global Industry Coalition
Availability: Not yet available – classified.
Key Characteristics:

- This document was not reviewed as it is not yet declassified.

34. OECD (Organisation for Economic Co-operation and Development) – Environmental Risk Assessment of Transgenic Plants: A Comparison of International Pre-Market Data Requirements. 2004

Method of Collection: Submitted by the Global Industry Coalition
Availability: Not yet available – classified.
Key Characteristics:

- This document was not reviewed as it is not yet declassified.

35. OECD (Organisation for Economic Co-operation and Development) – Safety Considerations for Biotechnology, 1992

Method of Collection: Collected by the Secretariat
Availability: http://www.oecd.org/dataoecd/8/3/2375496.pdf
Key Characteristics:

- Considers specific risk pathways for field trials of GM plants and micro-organisms

36. OECD (Organisation for Economic Co-operation and Development) – Safety Considerations for Biotechnology: Scale-Up of Micro-Organisms as Biofertilizers. 1993

Method of Collection: Collected by the Secretariat
Availability: http://www.oecd.org/dataoecd/46/8/1943506.pdf
Key Characteristics:

- Detailed consideration of potential risk pathways, and associated management options, associated with micro-organisms used as biofertilizers
- Numerous case-studies provided

37. Scientists' Working Group on Biosafety – Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms. 1998. Publication of The Edmonds Institute

Method of Collection: Collected by the Secretariat
Availability: http://www.edmonds-institute.org/manual.html
Key Characteristics:

- Detailed flowchart-based approach for hazard identification and for consideration of specific risk pathways
- Risk management options also discussed
- Includes some case-studies

38. United Nations Environment Programme – International Technical Guidelines for Safety in Biotechnology. 1995

Method of Collection: Collected by the Secretariat. Also submitted by the United States of America
Availability: http://www.unep.org/ or http://www.unep.ch/biosafety
Key Characteristics:

- Gives some general principles, information requirements and points to consider for risk assessment and management of LMOs

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