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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
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Item 11 of the provisional agenda*

RISK ASSESSMENT AND RISK MANAGEMENT

Compilation of information on existing guidance material regarding risk assessment and risk management

CONTENTS

* UNEP/CBD/BS/COP-MOP/2/1.

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SUBMISSIONS FROM GOVERNMENTS

AUSTRALIA

[17 December 2004]
[SUBMISSION: ENGLISH]

The Cartagena Protocol on Biosafety sets out well-defined technical and scientific methodologies and information requirements for risk assessments and risk management of living modified organisms (LMOs) in Article 15, Article 16, and annexes I, II and III. Australia believes that no further guidance is required for parties to meet their obligations in respect of risk assessment and risk management under the Protocol.

Countries have a sovereign right to manage their borders consistent with their national interest. The final decision as to whether or not to permit the entry of LMOs rests with national Governments in accordance with their national regulatory frameworks for managing genetically modified organisms. That decision should be taken in a way which respects all of their international obligations, including World Trade Organization obligations.

CANADA

[5 January 2005]
[SUBMISSION: ENGLISH]

1. Clarification of the issues involved:

Risk assessment and risk management are core requirements for decision making under the Protocol and other international agreements. In addition, inclusion of risk assessment and risk management under the Protocol decision making structure is compatible with WTO disciplines. In Canada's view, knowledge of the importing country's specific environment is required in order to carry out risk assessments of LMOs that are intended for intentional introduction into the environment in the importing country.

With regard to considerations for risk assessment it is Canada's position that the 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).

Canada recognizes the value of appropriate specified risk management measures where a specific risk is identified. For example, Canada currently requires an insect resistance management program to be implemented when LMOs with insect resistant traits are approved for release into the environment, in order to manage the identified risk posed by the potential for selection of Bt-resistant insect pests

2. Guidance and development of a common framework for risk assessment and risk management:

Canada supports a harmonized approach to risk assessment and risk management that builds upon internationally agreed principles and techniques developed by such international organizations as OECD, IPPC and the Codex Alimentarius Commission. In this regard, Canada would welcome a discussion on the elements that might usefully be included in guidance that would support common approaches, criteria, methods or frameworks, and the identification of other intergovernmental bodies with expertise in risk assessment that could add to the discussion.

It is Canada's view that guidance on risk management should be limited to general principles due to the unique nature of national systems and diversity of risk management strategies. Furthermore, when a Party takes a decision to manage an identified risk, following the establishment of an adverse impact to the conservation and sustainable use of biodiversity, based on a science-based risk assessment, socio-economic considerations can be taken into account, provided this is done in a manner consistent with a Party's other international obligations.

It is Canada's view that the provision of information on risk assessment and risk management frameworks from interested intergovernmental organizations and other organizations would benefit informed discussion.

3. Cooperation on identifying LMOs that may have adverse impacts on the conservation and sustainable use of biodiversity:

Canada recognizes that the nature of risk is determined by the interactions between the LMO and the receiving environment.

In Canada's view there is the potential to identify some LMOs that could be classified as having or not having a potential adverse impact on the conservation and sustainable use of biodiversity based on experience with LMOs, traits, receiving environments and combinations thereof.

In order to draw such conclusions Canada believes that there is a need for the sharing of experience with different LMOs in various environments and conditions and recommends the submission of information from governments and Parties on general characteristics or modifications that could predispose to adverse impacts on conservation and sustainable use of biodiversity.

Canada would welcome further discussion on the characteristics of LMOs, traits and modifications that could lead to adverse impacts on biodiversity taking into account human health, with a view to providing guidance that would assist in risk assessment.

EUROPEAN COMMUNITY AND ITS MEMBER STATES

[5 January 2005]
[SUBMISSION: ENGLISH]

In the past the European Union has submitted its views on risk assessment and risk management during the preparations for ICCP-3 and COPMOP/1 (see documents UNEP/CBD/ICCP/3/INF/7 and UNEP/CBD/BS/COP-MOP/1/INF/10).

The EU identifies the following documents as existing guidance material regarding risk assessment and risk management for the development of guidance material under the Protocol, while emphasizing the fact that the far-reaching issue of risk assessment at a high safety level still requires further elaboration:

1. Annex II (Principles for the Environmental Risk Assessment) with the relevant guidance notes (Decision 2002/623/EC), Annex VI (Guidelines for the Assessment Reports) and Annex VII (Monitoring Plan) and its guidance notes (Decision 2002/811/EC) to Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms;

2. Annex III (Safety assessment parameters to be taken into account, as far as they are relevant, in accordance with Article 6 (3)), with the relevant guidance notes (Decision 2000/608/EC) to Directive 90/219/EEC on the contained use of genetically modified micro-organisms;

3. The guidance document from the EU Scientific Steering Committee on the information needed for the risk assessment of genetically modified plants and derived food and feed (6-7 March 2003);

4. the guidance document of the European Food Safety Authority on the risk assessment of genetically modified plants and derived food and feed.

Independent bodies have produced the guidance documents mentioned under 3 and 4 above. They do not therefore necessarily represent the views of EU Member States. The documents contain guidance for applicants, which is not binding on EU Member States.

LITHUANIA

[14 December 2004]
[SUBMISSION: ENGLISH]

The essential scientific and technical issue concerned with risk assessment.

Scientific subjects are following:

Participation in scientific research programmes which could benefit risk assessment;

Cooperation on GMO scientific matters;

Risk assessment of genetically modified higher plants and non-plant GMOs.

Technical capacity-building:

Public awareness;

Consumer attitude to GMO and biotechnology;

Information sharing and sub-regional cooperation.

Regulation of Risk Assessment of the GMOs to human health, the environment or agriculture adopted by the Order of the Ministers of Environment, Agriculture, Health and the Director of State Food and Veterinary Service in December 2002, amended in 2004. The order establishes the main principles, methods and performance procedured for the activities related to the risk assessment of GMO and GMP, consisted of GMO, posed to human health and environment. The national order has been approximated according to the requirements of Europe Union (EU) Directive 2001/18/EC decision No. 2002/623/EC.

The order applies to all natural and legal persons, releasing into environment or placing on the market genetically modified organism's or genetically modified product's in the territory of the Republic of Lithuania. There are provisions from the respective annexes of EU Directive 2001/18/EC regarding general principles, steps and methodology of risk assessment. The general principles and criteria for establishing the National GMO Experts Scientific Committee outlined in the annex for the above mentioned order. The Ministry of Environment, the Ministry of Health and State Food and Veterinary Service are responsible for implementation of this order.

The Ministry of Environment, upon receipt of the notification and request for deliberate release into environment or placing on the market GMOs or GMPs, without delay, but no later than 10 days informs and delivers the dossier to the GMO management and GMO Experts Committee requesting them to submit possible risk assessment posed by GMOs and GMPs to human health and environment and preliminary findings.

SWITZERLAND [23 December 2004]
[SUBMISSION: FRENCH]

c) Matériel d'orientation sur l'évaluation et la gestion des risques associés aux organismes vivants modifiés

- Evaluation du risque : Annexe 4 de l'Ordonnance fédérale du 25 août 1999 sur la dissémination d'organismes dans l'environnement (ODE).

Version française, Annexe 4 ODE http://www.admin.ch/ch/f/rs/814_911/app6.html
Version anglaise, texte complet de l'ODE http://www.environnement-suisse.ch/imperia/md/content/stobobio/biotech/odeb/14.pdf

- Classification des organismes selon le risque

Version française http://www.environnement-suisse.ch/buwal/fr/fachgebiete/fg_biotechnologie/national/ouc/classi/index.html
Version anglaise *http://www.environnement-suisse.ch/buwal/eng/fachgebiete/fg_biotechnologie/national/ouc/classi/index.html*

UNITED STATES OF AMERICA (USA) [21 JANUARY 2005]
[SUBMISSION: ENGLISH]

SUMMARY: The purpose of this paper is to inform the discussion related to the current form of Annex III and existing guidance materials used in the risk assessment and risk management of living modified organisms (LMOs). At the second Meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety, participants will discuss and share experiences on this topic. This paper offers the following four main points for consideration:

(1) Numerous international fora have developed consensus guidelines for risk assessment and risk management. Annex III is consistent with the guidance and accepted international standards developed in these other arenas and further elaboration of Annex III is unnecessary.

(2) Annex III of the Protocol currently provides guidance that is adequate to ensure a common approach in risk assessment and risk management that lays out a thorough and structured approach that is still flexible enough to be used in assessing a wide range of LMOs and their potential impacts on the sustainable use of biodiversity.

(3) The approach outlined in Annex III is consistent with the risk assessment and risk management processes performed by the United States' federal regulatory agencies that conduct environmental risk assessments of LMOs. Detailed examples of how this approach can be applied for specific LMOs in a manner consistent with Annex III can be found in the risk assessment documents developed by the United States and available electronically.

(4) The Codex Alimentarius has adopted appropriate guidance for the risk analysis of foods derived from modern biotechnology. The United States strongly supports the work of Codex in the field of food safety. Food safety assessments are not within the purview of the Protocol.

CONCLUSION: Annex III as currently written is appropriately focused, useful, and consistent with other international agreements. The United States does not see a need for additional work on Annex III at this time.

INTERNATIONAL CONSENSUS DOCUMENTS: Guidance on risk assessment and risk management has been developed in regional plant protection organizations, such as the North American Plant Protection Organization (NAPPO); and in a number of international forums, such as the Organization for Economic Cooperation and Development (OECD), the United Nations Environmental Program (UNEP), and the International Plant Protection Convention (IPPC). A number of available guidance documents are noted in the table below. The United States believes the available guidance from these fora indicate a general international consensus on the approach to be used for LMO environmental safety evaluation that is both sufficient to ensure a common approach among countries, yet allows for adoption of procedures that are appropriate to individual country needs. Annex III is consistent with the existing guidance and it appears that additional elaboration of the Annex would be duplicative and provide little added value.

The following table provides a listing and brief description of currently existing international documents pertaining to risk assessment and risk management of LMOs.

Organization	**Links to Documents**	**Description**
UNEP (United Nations Environment Programme)	http://www.unep.org/Documents.Multilingual/?Default.asp?DocumentID+96&ArticleID=1473&1=en	International Technical Guidelines for Safety in Biotechnology (1995) provide assistance for risk assessment and risk management of products of biotechnology.
IPPC (International Plant Protection Convention)	https://www.ippc.int/servlet/BinaryDownloaderServlet/ISPM_11_2004_En.pdf?filename=1086078360577_ISPM_11_2004.pdf	A standard for pest risk analysis of LMOs was developed as a supplement to an existing IPPC standard, ISPM-11, and adopted at the meeting of the Interim Commission on Phytosanitary Measures in April 2004. The document contains an annex providing guidance on determining if an LMO poses a risk as a potential plant pest. This guidance is consistent with the risk assessment guidance provided in Annex III of the Protocol. The scope of the guidance under the IPPC includes risks to plant health, and includes risks to both managed and unmanaged ecosystems posed by plants or other organisms, including risks to plant biodiversity.
NAPPO (North American Plant Protection Organization)	http://www.nappo.org	Three modules of a regional standard for importation of transgenic plants into NAPPO member countries (United States, Canada, and Mexico) have been adopted. The modules provide guidance based on intended use of the transgenic plant, including importation for contained use, importation for confined environmental release, and importation for unconfined environmental release. A fourth module regarding importation of transgenic plants into NAPPO member countries

		for non-propagative use only, is under consideration.
ISO (International Standards Organization)	http://www.iso.org/iso/en/CatalogueListPage.CatalogueList	A system of standards is available for environmental management systems and a standard for environmental performance that includes a standard category for environmental risk assessment.
OECD (Organization for Economic Cooperation and Development)	http://www.oecd.org/findDocument/0,2350,en_2649_34387_1_119829_1_1_1,00.html http://www.oecd.org/searchResult/0,2665,en_2649_37437_1_1_1_1_37437,00.html	The OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology has prepared a number of documents to assist in performing environmental risk assessment for products of biotechnology. These include a number of consensus documents on the biology of crops and traits, as well as guidance documents for safety considerations for working with recombinant organisms.

ANNEX III PROVIDES BOTH STRUCTURE AND FLEXIBILITY: Useful guidance for evaluating LMOs must provide a balance of both structure and flexibility. A well structured approach is useful for ensuring the assessments are scientifically and logically sound. In addition, the use of a common structure among countries makes it easier to share information and understand how others have done their individual assessments. Ideally, the structured approach should also be able to accommodate the wide range of possible LMOs, the large number of potential uses, and the wide variety of environment-dependent interactions.

The structured yet flexible approach of Annex III is similar to the approach promoted by a number of other guidance documents (see table above) that address environmental risk assessments of LMOs. Again, these other documents were developed cooperatively among countries to enable the use of a widely applicable common approach that could be adapted for case-by-case reviews that would be consistent with a range of environmental laws and regulations.

UNITED STATES APPROACH TO RISK ASSESSMENT: The United States has been evaluating LMOs for potential adverse effects on the environment and human health for over two decades. The two agencies in the United States government responsible for ensuring that LMOs can be safely released to the environment (The United States Department of Agriculture and the Environmental Protection Agency) utilize science-based risk assessment approaches that are compatible with the flexible and robust guidance of Annex III

Many features of the United States system for environmental risk assessment of LMOs are consistent with Annex III and are important aspects of any risk assessment procedure. Risk assessment and risk management by the United States government are carried out on a case-by-case basis, looking at the specific characteristics of the product under consideration as compared to the characteristics of the conventional counterpart. Data requirements are flexible to ensure appropriate information is collected for each product, and additional information may be requested from applicants during the review process. The United States risk assessment process follows the well-recognized procedure of considering both hazard and exposure when evaluating risk and considering the consequences of potential adverse effects when evaluating products. The United States Regulatory Agencies Unified Biotechnology Website at

http://usbiotechreg.nbii.gov provides links to the scientific assessment data provided by applicants and to decision documents for products that have completed reviews by the United States regulatory agencies. Such publicly available information demonstrates one way that Annex III could be implemented to achieve a robust regulatory review process for LMOs.

CODEX ALIMENTARIOUS PROVIDES THE APPROPRIATE GUIDANCE FOR FOOD SAFETY REVIEWS OF LMOS: Internationally agreed guidelines for safety assessment of foods derived from biotechnology were established by Codex Alimentarius in 2003. The United States strongly supports the principles and guidance developed under Codex Alimentarius, as well as the continuing of the Ad hoc Biotechnology Task Force under Codex to address outstanding issues on food safety. Annex III of the Protocol currently focuses on potential adverse effects of LMOs on the conservation and sustainable use of biological diversity. The United States believes this focus is appropriate. The United States does not believe that human or animal health issues related to direct consumption of LMOs is within the purview of the Protocol.

SUBMISSIONS FROM ORGANIZATIONS

GLOBAL INDUSTRY COALITION (GIC) [21 DECEMBER 2004]
[SUBMISSION: ENGLISH]

The users and developers of biotechnology submit the following list of guidance materials in response to Decision BS-I/11 of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, inviting Parties, other Governments and relevant international organizations to provide to the Executive Secretary relevant existing guidance materials regarding risk assessment and risk management of living modified organisms (LMOs) for consideration by the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. In addition, the Global Industry Coalition has provided a brief analysis of each of these guidance materials in the annex attached to this list.

A thorough review of existing guidance materials on risk assessment and risk management shows that many models exist that are, in principle, compatible with the Protocol, and when appropriately integrated into the process required by the Protocol, will facilitate decision-making for LMOs.

I. GUIDANCE MATERIALS DIRECTLY APPLICABLE TO RISK ASSESSMENT AND RISK MANAGEMENT OF LMOs UNDER THE PROTOCOL

A. Organisation for Economic Co-operation and Development (OECD) (documents available at www.oecd.org)

1. Guidance Document on Methods for Detection of Micro-Organisms Introduced into the Environment: Bacteria (No. 30, 2004 ENV/JM/MONO(2004)7);
2. Safety Considerations for Biotechnology: Scale-up of Crop Plants (1993);
3. Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-Organisms: Bacteria (No. 29, 2003 ENV/JM/MONO(2003)13);
4. Points to Consider for Consensus Documents on the Biology of Cultivated Vascular Plants (ENV/JM/BIO(2004)4; 4 June 2004 – this document is not yet declassified);

5. Environmental Risk Assessment of Transgenic Plants: A Comparison of International Pre-Market Data Requirements (ENV/JM/BIO(2004)6; 8 June 2004 – this document is not yet declassified) declassified).

B. United Nations Environment Programme (UNEP) (document available at **www.unep.ch/biosafety/resources.htm**)

1. UNEP International Guidelines for Safety in Biotechnology (1995).

C. International Plant Protection Convention (IPPC) (documents available at www.ippc.int) (documents available at www.ippc.int)

1. International Standards for Phytosanitary Measure #02 (ISPM #02 (1996): Guidelines for pest risk analysis)
2. International Standards for Phytosanitary Measure #11 (ISPM #11 (2004): Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms) organisms)

D. European Union Guidance (document available at www.europa.eu.int)

1. 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)

E. Environmental Protection Agency (EPA) Guidelines (document available at www.epa.gov)

1. U.S. EPA (1998) Guidelines for Ecological Risk Assessment (EPA/630/R-95/002F, April 1998)

F. Food and Agriculture Organization of the United Nations (FAO) (document available at http://www.fao.org/ag/cgrfa/biocode.htm)

1. International Code Of Conduct On Plant Biotechnology As It Affects The Conservation And Utilization Of Plant Genetic Resources (DRAFT 1995)

II. GUIDANCE MATERIALS APPLICABLE TO PRODUCTS NOT WITHIN THE SCOPE OF THE PROTOCOL (FOOD SAFETY CONSIDERATIONS)

A. Codex Alimentarius (documents available at http://www.codexalimentarius.net)

1. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44, 2003);
2. Food Safety Assessment of Foods Derived from Recombinant DNA Plants (CAC/GL 45, 2003);
3. Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAC/GL 46, 2003);
4. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (13th Procedural Manual, pg 42, 2003).

B. Food and Agriculture Organization of the United Nations (FAO) (document available at http://www.fao.org/es/ESN/food/risk_biotech_animal_en.stm)

1. FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from GM Animals, including Fish (FAO Food and Nutrition Paper 79, 2003) 2003)

C. World Health Organization (WHO) (www.who.int)

III. GENERAL GUIDANCE ON RISK ASSESSMENT AND RISK MANAGEMENT OF LMOs

A. International Organization for Standardization (ISO) (documents available at www.iso.ch)

1. Environmental Management: The ISO 14000 Family of International Standards (2002)
2. Guide 73, Risk Management (2002)
3. ISO 22000 (2004)

Annex I

BRIEF ANALYSIS OF EXISTING GUIDANCE MATERIALS ON RISK ASSESSMENT AND RISK MANAGEMENT OF LMOS

I. GUIDANCE MATERIALS DIRECTLY APPLICABLE TO RISK ASSESSMENT AND RISK MANAGEMENT OF LMOS UNDER THE PROTOCOL

A. Organisation for Economic Co-operation and Development (OECD)

The OECD is well-recognized for its work toward developing science-based, consensus documents in an effort to promote harmonized approaches for risk assessment. The work of the OECD in biotechnology began in the 1980s. Some of the documents developed during this period provide the earliest guidance for environmental and food & feed risk assessment for biotechnology derived products. As such, there are a number of OECD documents that can provide guidance to the risk assessment and risk management process under the Protocol.

1. Guidance Document on Methods for Detection of Micro-Organisms Introduced into the Environment: Bacteria (2004)

Description/Purpose: This document is meant to offer guidance to regulators and applicants on how to interpret and evaluate data on marking and detection of micro-organisms in environmental studies for use in risk assessments of genetically modified micro-organisms.

Relevance to Annex III: This document relates specifically to Annex III Points to Consider 9(f) (Detection and identification of the living modified organism).

Limitations in Applicability: This document only provides guidance for micro-organisms and its applicability is limited to situations where the introduced bacteria have previously been characterized in laboratory studies.

2. Safety Considerations for Biotechnology: Scale-up of Crop Plants (1993)

Description/Purpose: This document identifies pertinent scientific considerations regarding modern biotechnology crops in order to create a framework to evaluate environmental safety issues. This report is a continuation of previous OECD work on "Recombinant DNA Safety Considerations" (1986) and "Good Developmental Principles for Small-Scale Field Research" (1992). It is the first document to lay out the concept of "familiarity."

Relevance to Annex III: This consensus document outlines many of the fundamental principles of risk assessment used globally today, including those in Annex III of the Protocol. Corresponding to the

General Principles, this document identifies the notion of familiarity, lays out definitions for risk assessment and risk management, and identifies principles for stepwise development and evaluation. Corresponding to Methodology, this document identifies and discusses six possible safety issues (gene transfer, weediness, trait effects, genetic and phenotypic variability, biological vector effects and genetic material from pathogens, worker (human) safety) (Methodology 8(a-b), and lays out appropriate risk management practices for each issue(Methodology, 8(e)).

Limitations in Applicability: This report applies to genetically modified plant crops only.

3. Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-Organisms: Bacteria (2003)

Description/Purpose: This document, intended for use by risk assessors, addresses the use of microbial taxonomy in assigning or confirming the identity of a subject micro-organism.

Relevance to Annex III: It provides guidance for Points to Consider 9(a) – 9(b).

Limitations in Applicability: This document deals with only the most current, frequently used detection methods for micro-organisms released into the environment.

4. Points to Consider for Consensus Documents on the Biology of Cultivated Vascular Plants (4 June 2004 – this document is not yet declassified)

Description/Purpose: This document is meant to serve as a template for the creation and/or revision of biology consensus documents drafted by the OECD's Working Group on the Harmonization of Regulatory Oversight of Biotechnology. It also explains how the information contained in such consensus documents relates to an environmental risk safety assessment.

Relevance to Annex III: Points to Consider 9(a). Biological characteristics and their relevance to risk assessment are outlined, including: species classification and taxonomy; geographical distribution, habitats and centers of origin/diversity; reproductive biology; hybridization and introgression; interactions with other organisms; and relevant human safety concerns.

Limitations in Applicability: This document applies directly to the biology of the unmodified crops. The document, however, provides guidance for assessing the modified crops and their potential effects on ecosystems.

Note: The OECD has compiled a significant number of consensus documents primarily on the biology of unmodified crops. These documents are useful in providing baseline information so that assessors can determine whether any significant changes have occurred when a crop has been genetically modified.

5. Environmental Risk Assessment of Transgenic Plants: A Comparison of International Pre-Market Data Requirements (8 June 2004 – this document is not yet declassified)

This document presents a comparison of pre-market information requirements for environmental risk assessments published in regulations and guidance documents from various countries and international agreements. It demonstrates a general consensus in what regulatory agencies are looking for across various regions.

B. United Nations Environment Programme (UNEP)

1. UNEP International Guidelines for Safety in Biotechnology (1995)

Description/Purpose: The UNEP Technical Guidelines were produced following a Global Consultation in full recognition of the work of the Conference of the Parties to the Convention on Biological Diversity in its efforts to develop the Biosafety Protocol. The Guidelines were to serve as an interim mechanism in various substantive ways, including facilitating the development of national capacities to assess and manage biotechnology risks. Developed on the basis of common elements and principles derived from relevant existing regional and international instruments as well as national regulations and guidelines, the Guidelines thus essentially provide a summary of the existing models of risk assessment/risk management. In addition, they address the human health and environmental safety of all applications of biotechnology, from research and development to commercialization.

Relevance to Annex III: The Guidelines apply directly to LMOs as defined by the Protocol. They have strong similarities to Annex III, and they formed the basis for the Annex III "Points to Consider" and for the development of the national biosafety frameworks capacity building project.

Limitations in Applicability: This is a thorough document that can be directly applied and compared to the Annex III requirements; in fact they provide nearly identical parameters for conducting a risk assessment as Annex III. This document is useful for interpreting Annex III as it provides very thorough examples of the Points to Consider in risk assessments. It also provides examples of various risk management practices. While the Guidelines do offer basic concepts and foundations, they should be updated to ensure they are current, and should be developed to provide further detail in order to provide maximum guidance to Parties on risk assessment/risk management under the Protocol.

C. International Plant Protection Convention (IPPC)

Description/Purpose: The IPPC is an international convention whose purpose is to prevent or limit the introduction and spread of pests and diseases of plants and plant products. The convention comprises a phytosanitary import regulatory system, which is composed of a framework of phytosanitary legislation, regulation and procedures overseen by National Plant Protection Organizations (NPPOs). Because all national governments maintain sovereignty, under the IPPC each contracting government assumes the responsibility to comply with the requirements of the convention within their territories and establish the level of protection deemed appropriate for the region. National regulatory phytosanitary systems under the IPPC can also be affected by other international agreements such as the WTO-SPS agreement. The NPPO in a country is responsible for oversight of the local phytosanitary regulatory system. The IPPC applies only to plants, plant parts, and seeds as well as the means of conveyance, storage and handling of these plant products. Lastly, under the IPPC, it is the responsibility of the exporting nation to ensure that measures are taken to eliminate or reduce the risk of transboundary movement of a plant pest. The importing country may take measures to evaluate the available information and appropriateness of the phytosanitary measures taken by the exporting country.

Relevance to Annex III: The IPPC uses International Standards for Phytosanitary Measures (ISPM) as tools for risk assessment and standardization, which are endorsed by FAO. ISPMs are documents, prepared and reviewed by scientific committees that are comprised of experts from the member countries and agreed upon by the Commission on Phytosanitary Measures. Pest risk assessment (PRA) is described in ISPM 2, which has been adapted for LMOs in ISPM 11. PRA is a three-stage process

involving initiation, pest risk assessment and risk management. Furthermore, the Interim Commission on Phytosanitary Measures (ICPM) has recognized the need to develop ISPM 11 specifically for PRA of LMOs. The principles of PRA are harmonized with the principles outlined in Annex III of the Protocol, such as use of comparators and focusing on the characteristics of the LMO that could make it persist in the environment render it or invasive to natural environments. Furthermore, both Annex III and ISPM 11 see risk management as a mechanism to deal with residual uncertainty in the risk assessment.

Limitations in Applicability: As already noted, the scope of IPPC is plants and its standards do not address issues with animal LMOs. Under the IPPC model, the country of export would make the assessment of the pest potential of the LMO, and the importing country would review the information to make a country-specific determination. The scientific committee of the ICPM has acknowledged that ISPM 11 would not apply to many LMOs because they do not have the characteristics of a quarantine pest. ISPM 11 provides reasonable guidance for a country of import to review existing risk assessment information for completeness, especially as it applies to LMO-FFPs. However, this information may be insufficient for LMOs for full release, and another risk assessment standard may be needed like the 1995 UNEP Guidelines noted above. A further gap would be in the area of risk management, which under ISPM 11 is an outcome of Stage 2 (pest risk assessment), while under Annex III it would be an outcome of the initial risk assessment conducted as a part of Stage 1 under ISPM 11. Under Annex III, risk management could be required in the absence of certainty about the pest potential of the plant product(s). This would not be the case under ISPM 11.

Note: ISPM 11 provides appropriate guidance for PRA for LMOs. The Scientific Committees are addressing the main gap, which is the information needed to determine whether an LMO is a quarantine plant pest and subject to further PRA under IPPC. This is a gap that could be filled by a risk assessment guidelines for countries intending to intentionally release the LMO into the environment.

D. European Union Guidance

1. 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)

Description/Purpose: On 24 September 2004, the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA) concluded and published its guidance document for the risk assessment of genetically modified plants and derived food and feed. It was developed in order to provide detailed guidance to applicants in the preparation and presentation of applications within the framework of Regulation (EC) 1829/2003 on GM food and feed, and of Directive 2001/18/EC on the deliberate release of genetically modified organisms into the environment.

Relevance to Annex III: Many of the countries that comprise the EU have ratified the Biosafety Protocol. As such, much effort has been expended in the EU to ensure that Directive 2001/18 is compliant with the Protocol. Several guidance documents have been published in the EU:

> The risk assessment procedure for contained use is indicated in Directive 90/219/EEC, Annex III. The Commission Decision 2000/608/EC of 27 September 2000 gives Guidance Notes for Risk Assessment based on Annex III of Directive 90/219/EEC.
>
> Directive 2001/18/EC of 12 March 2001 provides for risk assessment for deliberate release.

Directive 2001/18/EC also refers to the Cartagena Protocol and the precautionary principle.

The Council and Commission decisions 2002/812/EC of 3 October 2002, 2002/813/EC of 3 October 2002, 2003/701/EC of 29 September 2003, and 2004/204/EC of 23 February 2004 give some additional information on administrative aspects of the implementation of Directive 2001/18/EC.

The risk assessment portions of the EU documents are complementary to Annex III; however, unlike Annex III, the Directive adopts the Precautionary Principle, which indicates zero risk as the most acceptable or best case scenario.

Limitations in Applicability: The EU Guidance is specific to modified plants and derived food and feed. It also goes further than the Protocol in requiring information on the changes in crop ecosytems resulting from changes in pesticide applications, rotations and other crop management practices. In addition, the Protocol appears to provide more flexibility as it relates to risk management. Under Directive 2001/18, risk management is based on the nature of the LMO and the risk assessment. As such, monitoring is a requirement of approval regardless of the results of the risk assessment. Article 16(2) of the Protocol specifies that measures for risk management will be based on the risk assessment.

Notes: The EU Guidance is constrained by the Precautionary Principle and its diverse interpretations within the EU. As such, the distinction between the Precautionary Principle in the EU and the Precautionary Approach in the Protocol has significant implications in risk assessment and risk management decision-making. For example, note that the EU Guidance has resulted in very few approvals of LMO-FFPs or LMOs for intentional release despite EFSA conclusions of no evidence of increased risk relative to the conventional crop.

E. Environmental Protection Agency (EPA) Guidelines

1. U.S. Environmental Protection Agency Guidelines for Ecological Risk Assessment (April 1998)

Description/Purpose: In 1998, the US EPA published its finalized Guidelines for Ecological Risk Assessment. The final guidelines expand upon and replace an earlier framework (1992), and included input from stakeholders within and outside the EPA. These guidelines are EPA's response to increasing interest in ecological risk assessment. They encompass a wide diversity of environmental stressors including those that are chemical, physical and biological in nature. These guidelines codify principles, terminology and process used in ecological risk assessment by describing the individual components (hazard, exposure, uncertainty, roles of risk managers and risk assessors, etc.) within a logical framework that is useful for decision-making.

Relevance to Annex III: The EPA Guidelines are relevant to Annex III in that they broadly address ecological risk assessment for any potential environmental stress i.e. they are not specific to plants, microorganisms, or animals.

Limitations in Applicability: None

Notes: Appropriate adaptation of the EPA Guidelines could be a challenge in some countries using them for LMOs. First, EPA has regulatory oversight for a subset of genetically engineered organisms with

pesticidal properties. Second, application of the guidelines requires a certain level of capacity, which is dependent on the experience of country experts with ecological risk assessment and knowledge of the guidelines. Finally, triggers for ecological risk assessment under the US EPA Guidelines are product-based, while the process-based trigger for risk assessment under the Protocol could create some challenges in using these guidelines appropriately.

F. Food and Agriculture Organization of the United Nations (FAO)

1. International Code Of Conduct On Plant Biotechnology As It Affects The Conservation And Utilization Of Plant Genetic Resources (DRAFT 1995)

Description/Purpose: In 1991, the FAO's Commission for Genetic Resources for Food and Agriculture (CGRFA) requested the preparation of a draft Code of Conduct on Biotechnology, with the aim of maximizing the positive effects and minimizing the possible negative effects of biotechnology. The Code contains five modules, including biosafety and other environmental concerns.

In 1993, noting that the Convention on Biological Diversity was considering the development of a Biosafety Protocol, the CGRFA recommended that the biosafety component of the draft Code of Conduct for Biotechnology be forwarded to it, so that it might be incorporated into this work. It also postponed further work on the draft Code until the completion of the negotiations for the revision of the International Undertaking on Plant Genetic Resources.

Relevance to Annex III: The Code provides only general principles and requirements for risk assessment, and it does not address the details in Annex III. For example, it advocates establishing a National Biosafety Committee and suggests that risk assessments be conducted on a scientifically sound basis (incorporating consideration of possible negative consequences for human and animal health and the environment, including agro-ecosystems, and possible erosion of plant genetic resources and biodiversity.) However, it does not provide detailed points to consider or a particular methodology, but advocates a case-by-case, step-by-step approach, and states that the details and depth of required information should be proportional to the estimated degree of risk (a positive approach to risk assessment). Information provided by the Code appears to be similar to that of Annex III of the Protocol.

Limitations in Applicability: This document is still only a draft.

Notes: This Code applies to GM plants and to micro-organisms and other organisms modified by biotechnologies in cases where they might have adverse affects on plant genetic resources.

II. GUIDANCE MATERIALS APPLICABLE TO PRODUCTS NOT WITHIN THE SCOPE OF THE PROTOCOL (FOOD SAFETY CONSIDERATIONS)

A number of documents that deal with food safety issues can provide guidance on general principles for risk assessment and risk management of LMOs under the Protocol. They include:

A. Codex Alimentarius

1. Risk Analysis of Foods Derived from Modern Biotechnology (2003)

Description/Purpose: The Principles were developed within a task force of the Codex Alimentarius, and agreed by consensus, to provide a framework for undertaking risk analysis on safety and nutritional aspects of foods derived from modern biotechnology. The Principles do not address environmental,

ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods, and are designed to be consistent with the Codex Working Principles for Risk Analysis (adopted 2003 for the framework of Codex Alimentarius).

Relevance to Annex III: The definition of "modern biotechnology" is taken from the Biosafety Protocol. The Principles cover risk assessment, risk management and risk communication and management constraints because of "other factors." They do not cover how to manage scientific uncertainty, because that issue is addressed in a separate section within Codex. The use of precaution in risk management is a topic that lacks consensus within Codex.

Limitations in Applicability: The document was designed to address principles for human food only.

2. Food Safety Assessment of Foods Derived from Recombinant DNA Plants (2003)

Description/Purpose: The Safety Assessment document was developed to support the Principles for Risk Analysis of Foods Derived from Modern Biotechnology. The Guideline document addresses safety and nutritional aspects of foods derived from plants with a history of safe use as food, and those that have been modified to exhibit new traits.

The Assessment document describes the recommended approach to safety assessment for foods derived from recombinant DNA plants where a conventional counterpart exists, identifies the data and information generally applicable to making such assessments, and takes into consideration intended and unintended effects.

Relevance to Annex III: This Guideline does not address environmental risks. The concept of substantial equivalence does not imply absolute safety of a new product, but rather focuses on assessing the safety of any identified differences so that the safety of the new product could be considered relative to its conventional comparator.

Limitations in Applicability: This process does not address modified animal feed or animals fed that feed.

3. Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (2003)

Description/Purpose: The Guideline supports the Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. The Guideline addresses safety and nutritional aspects of foods produced through the actions of recombinant-DNA microorganisms and describes recommendations for safety assessment of foods produced using recombinant-DNA microorganisms, using comparison to a conventional counterpart.

Relevance to Annex III: The document does not address risks related to environmental releases of recombinant-DNA microorganisms used in food production.

Limitations in Applicability: The Guideline focuses on safety of the recombinant DNA microorganism used in food production, and where appropriate on metabolites produced by action of recombinant-DNA microorganisms on food.

4. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (2003)

Description/Purpose: The Principles are intended to provide guidance to Codex and joint FAO/WHO expert bodies and consultations, to ensure that food safety and health aspects of Codex standards and related texts are based on risk analysis.

Relevance to Annex III: According to these Principles, risk analysis should be applied consistently, be open, transparent and documented, and conducted in accordance with both the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Statements of Principle Relating to the Role of Food Safety and Risk Assessment. Risk analysis should follow a structured approach comprising three distinct components (assessment, management and communication).

Limitations in Applicability: Relates specifically to Codex work which is consensus driven, and includes principles for conduct of risk analysis generally (full documentation, functional separation between risk assessment and risk management; relevance of precaution; role of science; and needs of developing countries).

Other Documents of Interest:

Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account

Work will be based on sound scientific analysis, taking into account other legitimate factors relevant for consumer health protection and promotion of fair practices in food trade.

Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle (above)

When health and safety are concerned, the Statements of Principle Concerning the Role of Science and the Statements of Principle Relating to the Role of Food Safety Assessment should be followed. Other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process; the risk manager should indicate how these factors affect selection of risk management options and development of standards, guidelines and related texts. Consideration of other factors should not affect the scientific basis of risk analysis, with separation between assessment and management to ensure scientific integrity of the risk assessment.

Consideration of other specific other factors in development of risk management recommendations should be clearly documented, including the rationale, on a case-by-case basis.

The feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered. Concerns related to economic interests and trade issues in general should be substantiated by quantifiable data. The integration of other legitimate factors in risk management should not create unjustified barriers to trade. Attention should be given to the impact on developing countries of inclusion of such factors.

Statements of Principle Relating to the Role of Food Safety and Risk Assessment

Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances. Food safety assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, and should be documented in a transparent manner.

B. Food and Agriculture Organization of the United Nations (FAO)

1. FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from GM Animals, including Fish (2003)

Description/Purpose: A joint FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from GM Animals was held from 17-21 November 2003 with the objective to provide scientific advice to the FAO/WHO on the safety assessment of such foods.

Relevance to Annex III: The document has some links with Annex III, but is too general in nature to be used as a step-by-step model for risk assessment under the Protocol. It advocates a case-by-case basis for risk assessment and concludes that safety assessments for food derived from GM animals can be largely performed along the lines that have already been established for GM plants (ie: Codex standards). In other words, it suggests completing a comparative safety assessment of the GM animal with its conventional counterpart.

Limitations in Applicability: This document only applies to food derived from animals and only offers recommendations that have yet to be finalized.

C. World Health Organization (WHO)

General Description: The WHO administers several groups that perform risk assessments of chemical and microbiological hazards as they relate to human health, and specific assessments of chemical risk in specific foods for Codex guidance and Member States.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) perform chemical risk assessments. Through the GEMS/Food program, WHO also promotes the collection, collation and evaluation of data on chemicals in foods and the total diet at regional and international levels.

The WHO and FAO perform microbiological risk assessment via the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA). The JEMRA "takes the form of a series of meetings of experts, reviews and interprets existing microbiological risk assessments on a number of pathogen/commodities combinations identified, and evaluates the likely impact of different risk management options." (from WHO site)

FAO/WHO have also issued more general guidance on risk assessment as applied to food standards issues. Among the reference documents for the latter is the report of the 1995 FAO/WHO "Expert Consultation on the Application of Risk Analysis to Food Standards Issues," (see http://www.who.int/foodsafety/publications/micro/march1995/en/.)

The WHO is currently in the process of preparing a study on "Modern Biotechnology, Human Health and Development," which is expected to be complete at the end of 2005.

Relevance to Annex III: If specific products of modern biotechnology that contain LMOs are the subject of either chemical or microbiological risk assessment by JECFA, JMPR or JEMRA, this work would be relevant to Annex III with respect to human health. Such risk assessments could be incorporated by Protocol Parties in their own risk assessments of the human health aspects of products containing particular LMOs, or adopted and used as a basis for risk management measures. Expert panels generally complete relatively neutral science-based analyses, but have on occasion been criticized as biased in favor of a particular approach. The provision of scientific advice was recently examined by a FAO/WHO Task Force.

Limitations in Applicability: JECFA, JMPR and JEMRA risk assessments are relevant only to the human health effects of LMOs, and therefore do not address the environmental issues that form the basis of biodiversity concerns. This is not to say that a “JECFA-like” process to assess environmental risks would not be useful.

III. GENERAL GUIDANCE ON RISK ASSESSMENT AND RISK MANAGEMENT

A. International Organization for Standardization (ISO)

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

Description/Purpose: These standards address implementing environmental management systems, conducting environmental audits and other related investigations, evaluating environmental performance, using environmental declaration and claims, conducting life cycle assessments, and addressing environmental aspects of products and product standards.

2. Guide 73, Risk Management (2002)

Description/Purpose: This document provides definitions for terms associated with risk management.

3. ISO 22000 (2004)

Description/Purpose: The ISO 22000 is a new standard in development intended to address food safety using the principles of Hazard Analysis Critical Control Point (HACCP). There is a step in developing the HACCP wherein a risk assessment is performed, which is why this standard may be of interest to Parties in the risk assessment discussions under the Protocol. In a food system, risks are defined as chemical (e.g. lubricants, sanitizing agents), biological (micro) or physical (wood, glass, etc).

ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD) [22 DECEMBER 2004] [SUBMISSION: ENGLISH]

In reference to item 6.10 *Consideration of other issues for the effective implementation of the Protocol* and the request that the Executive Secretary collect and collate existing guidance materials regarding risk assessment and risk management of LMOs.

OECD has been active in the area of risk assessment for nearly 20 years and there are quite a number of outputs of this work which will be of interest to the SCBD. Fortunately, the attached document, an ***Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology***, was recently declassified by OECD. Although this introduction was drafted mainly as an explanation for the use of consensus documents in risk/ safety assessment, it also includes a comprehensive description of a number of background concepts and principles which are important to risk assessment and are explained in previous OECD guidance. There is also a description of the types of information used in risk assessment. Based on this previous work, the attached introduction explains the origin of OECD's Working Group for Harmonisation in Biotechnology and shows why biosafety consensus documents were included as part of its core activities. There is also a complete list of references. As such, it is a useful introduction to the past and current work of OECD on risk/ safety assessment.

Currently, the environmental biosafety consensus documents are one of the main outputs of the Working Group. They focus on specific crops (or other organisms) which have been genetically modified. They address issues concerning the biology of specific crops which are addressed in risk assessment, for example, the potential for gene transfer within a crop species and among closely related species, or the potential of the crop for weediness. Some other consensus documents address traits used in genetic modifications such as herbicide tolerance. To date, OECD's Working Group has published over 20 such documents. The attached introduction includes text on the use of consensus documents in risk/ safety assessment. There is also a full list of published consensus documents as well as those in preparation.

Finally, the attached introduction makes reference to the consensus documents of OECD's Task Force for the Safety of Novel Foods and Feeds. They are complementary to those of the Working Group, as they deal with food/ feed safety issues associated with major crops.

The Working Group is undertaking other projects which are relevant to risk assessment and will be of interest to the SCBD, though they are at an earlier stage of development. The first is a project on molecular characterisation, which is joint project between OECD's Working Group and Task Force. It has the objective (amongst other things) of identifying the scientific basis underlying the use of data from molecular characterization in the risk assessment of transgenic plants. The second is a project which is entitled *Parameters for Environmental Risk/ Safety Assessment*. This Working Group is still planning the details of this project.

Progress on all of the above activities will be discussed at the 16th meeting of the Working Group which will be held at OECD Headquarters, Paris, 23-25 February 2005. As on previous occasions, the SCBD has been invited to this meeting and is welcome to participate in the discussions. The 16th meeting of the Working Group will also be the opportunity to make progress with our co-operation on issues related to the BCH and the OECD databases. In this connection, one of the most important issues will be a discussion on unique identification for micro-organisms.

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Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

09-Jul-2004

English - Or. English

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

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Working Group on Harmonization of Regulatory Oversight in Biotechnology

AN INTRODUCTION TO THE BIOSAFETY CONSENSUS DOCUMENTS OF OECD'S WORKING GROUP FOR HARMONISATION IN BIOTECHNOLOGY

English - Or. English

JT00167337

An earlier version of this document entitled *"Why Consensus Documents?"* was prepared for the Workshop on Consensus Documents and Future Work in Harmonisation, which was held in Washington DC, 21-23 October 2003. Its aim was to explain the reasons for the Working Group on Harmonisation of Regulatory Oversight in Biotechnology including work on consensus documents in its original programme of work. It also described the intended uses of the documents as tools for use in environmental risk/ safety assessments of transgenic organisms.

This revised draft has taken into account a number of comments that were made at the time of the workshop including those from non-member countries. It has been slightly expanded to include some additional background material on the Working Group. It also includes two new sections: one which describes the process by which consensus documents are drafted and brought to final publication; and the second, which summaries current and future trends within the Working Group.

This text was prepared because there has been an increasing interest in the Consensus Documents, including from non-member countries. For this reason, it is important to have a clear and authoritative explanation on the role of Consensus Documents in risk/ safety assessment, as well as a description of how they are developed.

At the 15th meeting of the Working Group (held 16-18 June 2004) it was agreed that the document be forwarded to the Joint Meeting with a recommendation that it be declassified.

1. This text describes the origin of OECD's Working Group for Harmonisation in Biotechnology and explains why Consensus Documents were included as part of its core work. It also addresses the purpose of these documents and their intended use as a practical contribution to the risk/ safety assessments of transgenic organisms.

About OECD's Working Group

2. OECD's Working Group comprises delegates from the 30 Member countries of OECD and the European Commission. Typically, delegates are from those government ministries and agencies, which have responsibility for the environmental risk/ safety assessment of products of modern biotechnology. The Working Group also includes a number of observer delegations and invited experts who participate in its work. They include: Argentina; Russia; Slovenia; the United Nations Environment Programme (UNEP); the Secretariat of the Convention on Biological Diversity (SCBD); the United Nations Industrial Development Organisation (UNIDO); and the Business and Industry Advisory Committee to OECD (BIAC).

Regulatory Harmonisation

3. The Working Group was established in 1995 1/ at a time when the first commercial transgenic crops were being considered for regulatory approval in a number of OECD Member countries. From the beginning, one of its primary goals was to promote international harmonisation in biotechnology among member countries. Regulatory harmonisation is the attempt to ensure that the information used in risk/ safety assessments, as well as the methods used to collect such information, are as similar as possible. It could lead to countries recognising or even accepting information from one anothers' assessments. The benefits of harmonisation are clear. It increases mutual understanding among member countries, which

1/ The original title of the Working Group was the Expert Group for the Harmonisation of Regulatory Oversight in Biotechnology. It became an OECD Working Group in 1998.

avoids duplication, saves on scarce resources and increases the efficiency of the risk/ safety assessment process. This in turn improves safety, while reducing unnecessary barriers to trade (OECD 2000). Many delegates have said that the process of working towards harmonisation, and the resulting discussions among member countries, is almost as important as the products produced.

The need for harmonisation activities at OECD.

4. The establishment of the Working Group and its programme of work followed a detailed analysis by member countries of whether there was a need to continue work on harmonisation in biotechnology at OECD, and if so, what that work should entail. This analysis was undertaken by the Ad Hoc Group for Environmental Aspects of Biotechnology (established by the Joint Meeting2), which was active, mainly during 1994.

5. The Ad Hoc Group took into consideration, and built upon, the earlier work at OECD, which began in the mid-1980s. Initially, these previous activities at OECD concentrated on the environmental and agricultural implications of field trials of transgenic organisms, but this was soon followed by a consideration of their large-scale use and commercialisation. (A summary of this extensive body of work is found in Annex I.)

Key background concepts and principles

6. The Ad Hoc Group took into account (amongst other things) previous work on risk analysis that is summarised in *Safety Considerations for Biotechnology: Scale-up of Crop Plants* (OECD 1993a). The following quote gives the flavour: *"Risk/safety analysis is based on the characteristics of the organism, the introduced trait, the environment into which the organism is introduced, the interaction between these, and the intended application."* This body of work has formed the basis for environmental risk/ safety assessment that is now globally accepted. So in considering the possibilities for harmonisation, the attention of the Ad Hoc Group was drawn to these characteristics and the information used by risk/ safety assessors to address them.

7. This was reinforced by the concept of familiarity, which is also elaborated in the *"Scale-up"* document (OECD 1993a). This concept *"…is based on the fact that most genetically engineered organisms are developed from organisms such as crop plants whose biology is well understood"*. *"Familiarity allows the risk assessor to draw on previous knowledge and experience with the introduction of plants and micro-organisms into the environment..."* For plants, familiarity takes account of a wide-range of attributes including, for example, knowledge and experience with *"the crop plant, including its flowering/reproductive characteristics, ecological requirements, and past breeding experiences"* (OECD 1993a – see also Annex I for a more detailed description). This illustrates the role of information related to the biology of the host organism as a part of an environmental risk/ safety assessment.

2/ The Joint Meeting was the supervisory body of the Ad Hoc Group and, as a result of its findings, established the Working Group as a subsidiary body. Today, its full title is the Joint Meeting of the Chemicals Committee and the Working Party on Chemical, Pesticides and Biotechnology.

8. The Ad Hoc Group also took into account the document *"Traditional Crop Breeding Practices: An Historical Review to Serve as a Baseline for Assessing the Role of Modern Biotechnology"* (OECD 1993b) which also focuses on host organisms. It presents information on 17 different crop plants, which are used (or are likely to be used) in modern biotechnology. It includes sections on phytosanitary considerations in the movement of germplasm and on current uses of these crop plants. There is also a detailed section on current breeding practices.

A Common Approach to Risk/ Safety Assessment

9. An important additional point for the Ad Hoc Group was to identify the extent to which member countries address the same questions and issues during risk/ safety assessment. If there are big differences it would mean that attempts to work towards harmonisation would be difficult. On the other hand, a high level of similarity would suggest that harmonisation efforts would be more feasible.

10. This point was resolved by two studies, which the Ad Hoc Group was able to consider. The first covered crop plants (OECD 1995a, 1995b) while the second concerned micro-organisms (OECD 1995c, 1996). Both studies involved a survey targeted at those national authorities that are responsible for risk/ safety assessment. The aim was to identify the questions which are addressed by them during the assessment process (as outlined in national laws/ regulations/ guidance documents) in order to establish the extent of similarity among national authorities. Both these studies used the information provided in OECD's *"Blue Book"* (OECD 1986) as a reference point, in particular, the sections of the book (appendices b, c and d) which cover: i) General Scientific Considerations; ii) Human Health Considerations; and iii) Environmental and Agricultural Considerations. Both studies identified a remarkably high degree of similarity among member countries in the questions/ issues addressed in risk/ safety assessment.

The Emergence of the Concept of Consensus Documents

11. So the Working Group was established in the knowledge that national authorities have much in common, in terms of the questions/ issues addressed, when undertaking risk/ safety assessment. It also took into account those characteristics identified as part of risk/ safety assessment (i.e. *the organism*, *the introduced trait* and *the environment*) around which harmonisation activities could focus.

12. It was further recognised that much of the information used in risk/ safety assessment that relates to the biology of organisms (both crop plants and micro-organisms) would be similar or virtually the same in all assessments involving the same organism. In other words, the questions addressed during risk/ safety assessment which relate to the biology of the host organism - for example, the potential for gene transfer within the crop plant species, and among related species, as well as the potential for weediness – remain the same for each application involving the same host species. This also applies to some extent to information related to introduced traits.

13. Consequently, the Working Group evolved the idea of compiling information common to the risk/ safety assessment of a number of transgenic products, and decided to focus on two specific categories: the biology of the host species or crop; and traits used in genetic modifications. The aim of this compilation was to encourage information sharing and prevent duplication of effort among countries by avoiding the need to address the same common issues in each application involving the same organism or trait. It was recognized that biology and trait consensus documents could be agreed upon quickly by the member countries (within one or two years). This compilation process was quickly formalised in the drafting of Consensus Documents.

The Purpose of Consensus Documents

14. The Consensus Documents are not intended to be a substitute for a risk/ safety assessment, because they address only a part of the necessary information. Nevertheless, they should make an important contribution to environmental risk/ safety assessment.

15. As originally stated by the Working Group, Consensus Documents are intended to be a "snapshot" of current information, for use during the regulatory assessment of products of biotechnology. They are not intended to be a comprehensive source of information on everything that is known about a specific host organism or trait; but address – on a consensus basis – the key or core set of issues that member countries believe are relevant to risk/ safety assessment.

16. The aim of the documents is to share information on these key components of an environmental safety review in order to prevent duplication of effort among countries. The documents were envisaged as being used: a) by applicants as information in applications to regulatory authorities; b) by regulators as a general guide and reference source in their reviews; and c) by governments for information sharing, research reference and public information.

17. Originally, it was said that the information in the Consensus Documents is intended to be *mutually recognised* or *mutually acceptable* among OECD Member countries, though the precise meaning of these terms, in practice, is still open for discussion. During the period of the Ad Hoc Group and the early days of the Working Group (1993-1995), the phrase *Mutual Acceptance of Data* was discussed. This is a concept borrowed from OECD's Chemicals Programme which involves a system of OECD Council Decisions that have legally binding implications for member countries. In the case of the Consensus Documents there has never been any legally binding commitment to use the information in the documents, though from time to time, the Working Group has discussed whether and how to increase the level of commitment member countries are willing to make in using the information in the documents. Participation in the development of documents, and the intention by member countries to use the information, is done in "good faith." It is expected, therefore, that reference will be made to relevant consensus documents during risk/ safety assessments.

The Process through which Consensus Documents are Initiated and Brought to Publication

18. There are a number of steps in the drafting of a specific consensus documents. The first step occurs when a delegation, in a formal meeting of the Working Group, makes a proposal to draft a document on a new topic, typically a crop species or a trait. If the Working Group agrees to the proposal, a provisional draft is prepared by either a single country or two or more countries working together. This is often called the "lead country approach". Typically, the lead country(ies) has had experience with the crop or trait which is the subject of the new document and is able to draw on experts to prepare a provisional draft.

19. The provisional draft is first reviewed by the Bureau of the Working Group[3] to ensure that the document addresses range of issues normally covered by Consensus Documents and is of sufficiently high quality to merit consideration by the Working Group as a whole.

3/ The Bureau comprises the Chair and vice-Chairs of the Working Group. The Bureau is elected by the Working Group once per year. At the time of writing, the Chair is from Austria and the vice-Chairs are from Canada, Japan the Netherlands and the United States.

20. Based on the comments of the Bureau, a first draft is then prepared for consideration by the full Working Group. This is the opportunity for each delegation to review the text and provide comments based on their national experiences. The incorporation of these comments leads to a second draft, which is again circulated for review and comment to the Working Group. At this point, the Working Group may be asked to recommend that the document be declassified. Such a recommendation is only forthcoming when all delegations have come to a consensus that the document is complete and ready for publication. Sometimes, however, the text may need a third or even a fourth discussion in the Working Group before a recommendation for declassification is possible.

21. When the Working Group has agreed that a document can be recommended for declassification, it is forwarded to the supervisory Committee, the Joint Meeting, which is invited to declassify the document. Following the agreement of the Joint Meeting, the document is then published.

22. It is important to note that the review of Consensus Documents is not limited to formal meetings of the Working Group. Much discussion also occurs through electronic means, especially via the Working Group's Electronic Discussion Group (EDG). This enables a range of experts to have input into drafts.

23. For a number of documents, it has also been important to include information from non-member countries. This has been particularly true in the case of crop plants where the centre of origin and diversity occurs in a non-member country(ies). In these cases, UNEP and UNIDO have assisted in the preparation of documents by identifying experts from countries which include the centres of origin and diversity. For example, this occurred with the Consensus Document on the Biology of Rice.

Current and Future Trends in the Working Group

24. The Working Group continues its work, not only on the preparation of specific consensus Documents, but also on the efficiency of the process by which they are developed. At the present time, an increasingly large number of crops and other host species are being modified, for increasing number of traits.

25. At the OECD Workshop on Consensus Documents and Future Work in Harmonisation, which was held in Washington DC, 21-23 October 2003, the Working Group was able to consider, amongst other things, how to set priorities for drafting future Consensus Documents among the large number of possibilities. The Working Group is currently considering how best to set priorities in the future.

26. The Workshop also recognised that published Consensus Documents may be in need of review and updating from time to time, to ensure that they include the most recent information. The Working Group is currently considering how best to organise this in the future.

27. For the future drafting of new and updated documents, the Workshop identified the usefulness of developing a standardised structure of Consensus Documents, which is called "Points to Consider". The Working Group is expected to develop, firstly, a Points to Consider document for the biology Consensus Documents and then that of the trait Consensus Documents.

28. The Workshop also recognised the importance strengthening the input of non-member countries into the future development of Consensus Documents. Once again, the Working Group is considering how best to implement this recommendation.

Annex I

OECD BIOSAFETY PRINCIPLES AND CONCEPTS DEVELOPED PRIOR TO THE WORKING GROUP 1986-1994

29. Since the mid-1980s the OECD has been developing harmonised approaches to the risk/ safety assessment of products of modern biotechnology. Prior to the establishment of the Working Group, OECD published a number of reports on safety considerations, concepts and principles for risk/safety assessment as well as information on field releases of transgenic crops, and a consideration of traditional crop breeding practices. This Annex notes some of the highlights of these achievements that were background considerations in the establishment of the Working Group and its development of Consensus Documents.

Underlying scientific principles

30. In 1986, OECD published its first safety considerations for genetically engineered organisms (OECD 1986). These included the issues (relevant to human health, the environment and agriculture) that might be considered in a risk/safety assessment. In its recommendations for agricultural and environmental applications, it suggested that risk/safety assessors:

- "use the considerable data on the environmental and human health effects of living organisms to guide risk assessments;
- ensure that recombinant DNA organisms are evaluated for potential risk, prior to application in agriculture and the environment by means of an independent review of potential risks on a case-by-case basis;
- conduct the development of recombinant DNA organisms for agricultural and environmental applications in a stepwise fashion, moving, where appropriate, from the laboratory to the growth chamber and greenhouse, to limited field testing and finally to large-scale field testing;
- encourage further research to improve the prediction, evaluation, and monitoring of the outcome of applications of recombinant DNA organisms."

The role of confinement in small scale testing

31. In 1992, OECD published its Good Developmental Principles (GDP) (OECD 1992) for the design of small-scale field research involving GM plants and GM micro-organisms. This document, amongst other things, describes the use of *confinement* in field tests. Confinement includes measures, to avoid the dissemination or establishment of organisms from a field trial, for example, the use of physical, temporal, or biological isolation (such as the use of sterility).

Scale-up of crop-plants – "risk/safety analysis"

32. By 1993, the focus of attention had switched to the *scale-up* of crop plants as plant breeders began to move to larger-scale production and commercialisation of GM plants. OECD published general principles for, *scale-up* (OECD 1993a), which re-affirmed that, "*safety in biotechnology is achieved by the appropriate application of risk/safety analysis and risk management. Risk/safety analysis comprises hazard identification and, if a hazard has been identified, risk assessment. Risk/safety analysis is based on the characteristics of the organism, the introduced trait, the environment into which the organism is*

introduced, the interaction between these, and the intended application. Risk/safety analysis is conducted prior to an intended action and is typically a routine component of research, development and testing of new organisms, whether performed in a laboratory or a field setting. Risk/safety analysis is a scientific procedure which does not imply or exclude regulatory oversight or imply that every case will necessarily be reviewed by a national or other authority" (OECD 1993a).

The role of familiarity in risk/safety assessment

33. The issue of *scale-up* also led to an important concept, *familiarity*, which is one key approach that has been used subsequently to address the environmental safety of transgenic plants.

34. The concept of familiarity is based on the fact that most genetically engineered organisms are developed from organisms such as crop plants whose biology is well understood. It is not a risk/safety assessment in itself (U.S. NAS 1989). However, the concept facilitates risk/safety assessments, because to be familiar, means having enough information to be able to make a judgement of safety or risk (U.S. NAS 1989). Familiarity can also be used to indicate appropriate management practices including whether standard agricultural practices are adequate or whether other management practices are needed to manage the risk (OECD 1993a). Familiarity allows the risk assessor to draw on previous knowledge and experience with the introduction of plants and micro-organisms into the environment and this indicates appropriate management practices. As familiarity depends also on the knowledge about the environment and its interaction with introduced organisms, the risk/safety assessment in one country may not be applicable in another country. However, as field tests are performed, information will accumulate about the organisms involved, and their interactions with a number of environments.

35. Familiarity comes from the knowledge and experience available for conducting a risk/safety analysis prior to scale-up of any new plant line or crop cultivar in a particular environment. For plants, for example, familiarity takes account of, but need not be restricted to, knowledge and experience with:

- "the crop plant, including its flowering/reproductive characteristics, ecological requirements, and past breeding experiences;
- the agricultural and surrounding environment of the trial site;
- specific trait(s) transferred to the plant line(s);
- results from previous basic research including greenhouse/glasshouse and small-scale field research with the new plant line or with other plant lines having the same trait;
- the scale-up of lines of the plant crop varieties developed by more traditional techniques of plant breeding;
- the scale-up of other plant lines developed by the same technique
- the presence of related (and sexually compatible) plants in the surrounding natural environment, and knowledge of the potential for gene transfer between crop plant and the relative; and
- interactions between/among the crop plant, environment and trait." (OECD, 1993a)

Risk/safety assessment and risk management

36. Risk/safety assessment involves the identification of potential environmental adverse effects or hazards, and determining, when a hazard is identified, the probability of it occurring. If a potential hazard or adverse affect is identified, measures may be taken to minimise or mitigate it. This is risk

management. Absolute certainty or zero risk in a safety assessment is not achievable, so uncertainty is an inescapable aspect of all risk assessment and risk management (OECD 1993a). For example, there is uncertainty in extrapolating the results of testing in one species to identify potential effects in another. Risk assessors and risk managers thus spend considerable effort to address uncertainty. Many of the activities in intergovernmental organisations, such as the OECD, address ways to handle uncertainty (OECD 2000).

Annex II

REFERENCES CITED IN CHRONOLOGICAL ORDER

Recombinant DNA Safety Considerations. Safety considerations for industrial, agricultural and environmental applications of organisms derived by recombinant DNA techniques ("*The Blue Book"*), OECD, 1986.

Field Testing of Genetically Modified Organisms: Framework for Decisions. U.S. NAS - National Academy of Sciences, National Academy Press, Washington DC. USA 1989.

Good Developmental Principles (GDP), OECD 1992.

Safety Considerations for Biotechnology: Scale-up of Crop Plants, OECD, 1993a.

Traditional Crop Breeding Practices: An Historical Review to serve as a Baseline for Assessing the Role of Modern Biotechnology, OECD 1993b.

Commercialisation of Agricultural Products Derived through Modern Biotechnology: Survey Results, OECD 1995a.

Report of the OECD Workshop on the Commercialisation of Agricultural Products Derived through Modern Biotechnology, OECD 1995b.

Analysis of Information Elements Used in the Assessment of Certain Products of Modern Biotechnology, OECD 1995c.

Industrial Products of Modern Biotechnology Intended for Release to the Environment: The Proceedings of the Fribourg Workshop, OECD 1996.

Report of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology to the G8 Okinawa Summit, OECD 2000.

Annex III

CONSENSUS DOCUMENTS PUBLISHED BY THE WORKING GROUP

To date, 20 consensus documents have been published as part of the *OECD Series on Harmonisation of Regulatory Oversight in Biotechnology*.

- 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)

Annex IV

CONSENSUS DOCUMENTS IN PREPARATION

At the time of writing, an additional 18 documents are in preparation.

- 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*

Annex V

LEAD COUNTRIES OF PUBLISHED CONSENSUS DOCUMENTS

Document	Lead Country(ies)
Virus Resistant *Pseudomonas*	Unites States Canada, United Kingdom
Oilseed Rape	Canada
Potato	Netherlands, United Kingdom
Bread Wheat	Germany
Tolerance to Glyphosate Herbicide	United States, Germany, Netherlands
Tolerance to Phosphinothricin Herbicides	United States, Germany, Netherlands
Norway Spruce	Norway
White Spruce	Canada
Rice	Japan
Soybean	Canada
Poplars	Canada
Sugar Beet	Switzerland
Baculovirus	Germany
Sitka Spruce	Canada
Eastern White Pine	Canada
Stone Fruits	Austria
Tolerance to Phosphinothricin Herbicides: Module II	Germany
Maize	Mexico
European White Birch	Finland

Annex VII

CONSENSUS DOCUMENTS OF THE TASK FORCE FOR THE SAFTY OF NOVEL FOODS AND FEEDS: PUBLISHED AND IN PREPARATION

The Task Force for the Safety of Novel Foods and feeds was established in 1999, following a process similar to that of the Working Group. It is a "sister body" to the Working Group and shares the same supervisory committee. The Task Force also publishes Consensus Documents in the series *Safety of Novel Foods and Feeds*. These documents complement those of the Working Group as they deal with issues related to human foods and animal feeds, rather than environmental safety issues.

Published Task Force Consensus Documents:

- Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola)
- Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-Nutrients
- Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-Nutrients
- Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants
- Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea Mays*): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites
- Consensus Document on Compositional Considerations for New Varieties of Bread Wheat (*Triticum aestivum*): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants

Consensus Documents in preparation:

- Consensus Document on Compositional Considerations for New Varieties of Barley
- Consensus Document on Compositional Considerations for New Varieties of Cotton
- Consensus Document on Compositional Considerations for New Varieties of Forage Legumes
- Consensus Document on Compositional Considerations for New Varieties of Mushroom (*Agaricus bisporus*)
- Consensus Document on Compositional Considerations for New Varieties of Rice
- Consensus Document on Compositional Considerations for New Varieties of Sunflower
- Consensus Document on Compositional Considerations for New Varieties of Tomato

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