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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
Fifth meeting
Nagoya, 11-15 October 2010
Item 13 of the provisional agenda*

DRAFT TRAINING MANUAL ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

1. At its forth meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol requested the Executive Secretary to: (i) coordinate and facilitate, along with other relevant United Nations bodies and other international organizations, the development of training on risk assessment and risk management in relation to living modified organisms; (ii) convene prior to the fifth meeting of the Parties, regional or subregional training courses to enable countries to gain hands-on experience in preparing and evaluating reports of risk assessments in accordance with the Protocol; and (iii) convene a workshop on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms in the Pacific subregion.

2. In response to that request, the Secretariat coordinated a multi-stakeholder process for the development of training in collaboration with United Nations organizations (Aarhus Convention of the United Nations Economic Commission for Europe, Food and Agriculture Organization of the United Nations, International Plant Protection Convention and the United Nations Environment Programme), other international organizations (Global Industry Coalition and Third World Network) and the academic sector (University of Canterbury and University of Minnesota).

3. The result of the process described below is the draft training manual as attached hereto (annex I) and available online through the Biosafety Clearing-House (BCH) for consideration by the Parties at their fifth meeting.[1]

* UNEP/CBD/BS/COP-MOP/5/1.

[1] The online version of the draft training manual on risk assessment of LMOs is available through the BCH at: http://bch.cbd.int/cpb_art15/training.shtml .

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In order to minimize the environmental impacts of the Secretariat's processes, and to contribute to the Secretary-General's initiative for a C-Neutral UN, this document is printed in limited numbers. Delegates are kindly requested to bring their copies to meetings and not to request additional copies.

4. In the development of the training manual, the Secretariat first prepared an outline and invited collaborators to provide inputs and comments. Thereafter, on the basis of the various feedbacks, the Secretariat prepared a draft training manual and invited the collaborators for a peer-review process. The draft manual was then revised by the Secretariat on the basis of the feedback and comments provided during the peer-review process.

5. While using the provisions of the Cartagena Protocol on Biosafety, particularly its Annex III, as a basis for drafting and reviewing the emerging training manual, the Secretariat also attempted to incorporate experience and current practice from number of national regulatory frameworks and international organizations in a comprehensive manner.

6. The draft training manual was subsequently used as a teaching tool during two capacity-building activities:

(a) The Pacific subregional workshop on capacity-building and exchange of experiences on risk assessment (Nadi, Fiji, 4–7 July 2010); and

(b) The Asian subregional training course on risk assessment of living modified organisms (Siam Reap, Cambodia, 12–16 July 2010).[2]

7. With a view to assessing the usefulness of the draft training manual, participants in the Pacific workshop and Asian training course were invited to answer a questionnaire. The results of this questionnaire are summarized in annex II. These results indicated that, *inter alia*, the majority of participants agreed that this manual (i) is a useful tool for training on risk assessment; (ii) is easy to understand and follow; (iii) comprises an adequate overview of the risk assessment process, and (iv) is useful for a wide range of users.

8. In providing further feedback, participants considered the draft training manual as a very good teaching tool that provides a well-structured and comprehensive introduction to the risk assessment process and is considered useful to Parties as well as to other countries and relevant organizations. With the view to improving its usefulness, participants recommended that the training manual should be:

(a) Further improved by, *inter alia*, adding a glossary of terms, list of acronyms, flowcharts, diagrams, examples of other non-crop living modified organisms, etc;

(b) Linked to the elements of the "Guidance on Risk Assessment of Living Modified Organisms" developed by the AHTEG;

(c) Presented through a more user-friendly learning tool (e.g. as an interactive software); and

(d) Published in all United Nations languages.

9. On the basis of the feedback provided by the participants to the Pacific workshop and Asian training course and within the limited time available, the draft training manual was revised by the Secretariat and subsequently reviewed by an external scientific editor.

10. The outcome of this process is the draft training manual entitled "Risk Assessment of Living Modified Organisms", which comprises four modules: (i) Overview of biosafety and the Cartagena Protocol on Biosafety; (ii) Preparatory work – Understanding the context in which a risk assessment is carried out; (iii) Conducting the risk assessment; and (iv) Preparing a risk assessment report.

[2] The reports of these activities have been distributed as information documents UNEP/CBD/BS/COP-MOP/5/INF/13 and UNEP/CBD/BS/COP-MOP/5/INF/15 and are available at http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3018.

Annex I

DRAFT TRAINING MANUAL ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

Risk Assessment of Living Modified Organisms

Training manual

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Preamble

This training material was developed by the Secretariat of the Convention on Biological Diversity (CBD) in cooperation with other United Nations bodies and international organizations in response to a request by the Parties to the Cartagena Protocol on Biosafety, in their decision BS-IV/11, paragraphs 13 and 14, to develop training on risk assessment of living modified organisms (LMOs) and to convene training courses to enable countries to gain hands-on experience in preparing and evaluating risk assessment reports in accordance with the Protocol.

The purpose of this material is to provide basic training for environmental risk assessment, taking into account the provisions of the Cartagena Protocol on Biosafety and in particular Annex III of the Protocol. To this end, the training modules attempt to incorporate experience from a variety of national regulatory frameworks and international organizations in a comprehensive manner.

The training material is divided into four modules: (i) Overview of biosafety and the Cartagena Protocol on Biosafety; (ii) Preparatory work – Understanding the context in which a risk assessment is carried out; (iii) Conducting the risk assessment; and (iv) Preparing a risk assessment report.

Although this material applies to all types of LMOs and their intended uses within the scope and objective of the Protocol, it has been developed based largely on LM crop plants because of the extensive experience to date with environmental risk assessments for these organisms.

This training material may be further developed, as appropriate, as new information and experience become available.

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Acknowledgements

This training material was developed through a collaborative multi-stakeholder process. The Secretariat of the Convention on Biological Diversity wishes to express its appreciation to the following organizations for their valuable inputs and comments: Aarhus Convention of the United Nations Economic Commission for Europe, Food and Agriculture Organization (FAO), International Plant Protection Convention (IPPC), United Nations Environment Programme (UNEP), Global Industry Coalition (GIC), Third World Network (TWN), University of Minnesota and University of Canterbury. Moreover, the Secretariat would like to thank Paul Keese (Office of Gene Transfer Regulator, Government of Australia) and Ulrich Ehlers (Federal Office of Consumer Protection and Food Safety, Germany) for their help in developing the initial outline of the training manual.

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Module 1:

Overview of biosafety and the Cartagena Protocol on Biosafety

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Using this module

This module contains introductory sections explaining basic concepts in biosafety and an introduction to the Cartagena Protocol on Biosafety and other international biosafety-related bodies and organizations. An overview of modern biotechnology and its techniques are included in the section on biosafety. The section on the Cartagena Protocol on Biosafety explains the scope and objective of the Protocol, and provides an overview of Article 15, Annex III, the Biosafety Clearing-House (BCH) and the precautionary approach.

This module also includes a section on other international bodies involved in risk assessment in the context of biosafety, such as the Food and Agriculture Organization of the United Nations (FAO), the Codex Alimentarius, the International Plant Protection Convention (IPPC), the World Organisation for Animal Health (OIE), the World Trade Organization (WTO), the Organisation for Economic Co-operation and Development (OECD), as well as bilateral and multilateral agreements.

1. Introduction to biosafety and the Cartagena Protocol on Biosafety

1.1 History of the Protocol

The United Nations Conference on Environment and Development (also known as the "Earth Summit"), held in Rio de Janeiro in 1992, marks a significant achievement in the overall policy of the United Nations on the environment. In particular, several documents resulting from that meeting today constitute the basis of international law on biosafety: Agenda 21, the Rio Declaration on Environment and Development, and the United Nations Convention on Biological Diversity (CBD).

Agenda 21 is a comprehensive programme for action in social and economic areas, and for conserving and managing natural resources. Its chapter 16 addresses the "Environmentally sound management of biotechnology" (see Example 2) and outlines the need for international agreement on principles to be applied to risk assessment and management, and to set out the implementation of safety mechanisms on regional, national and international levels.

The Rio Declaration on Environment and Development is a series of principles defining the rights and responsibilities of States. Principle 15 addresses the possibility of harm from actions or decisions when extensive scientific knowledge on the matter is lacking.

Example 1 – Agenda 21, Chapter 16, Paragraph 29

"There is a need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology, which should build upon those developed at the national level. Only when adequate and transparent safety and border-control procedures are in place will the community at large be able to derive maximum benefit from, and be in a much better position to accept the potential benefits and risks of, biotechnology."

Source: UNCED (1992a).

Example 2 – Principle 15 of the Rio Declaration on Environment and Development

"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Source: UNCED (1992b).

The CBD was inspired by the world community's growing commitment to sustainable development. It represents a dramatic step forward in the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources. The issue of safety in biotechnology is addressed in Articles 8(g) and 19(3) of the CBD.

More specifically, in Article 8(g), Parties to the CBD are called upon to establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse impacts on the conservation and sustainable use of biological diversity. In Article 19(3), the Parties are called upon to consider the need for and modalities of a protocol for the safe transfer, handling and use of LMOs resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

Example 3 – CBD Article 8. In-situ Conservation

"Each Contracting Party shall, as far as possible and as appropriate:

Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health."

Source: Convention on Biological Diversity (1992).

Example 4 – CBD Article 19. Handling of Biotechnology and Distribution of its Benefits

"The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."

Source: Convention on Biological Diversity (1992).

Taking into account the provisions above, the Conference of the Parties to the CBD decided, at its second meeting, to develop a protocol on biosafety, specifically focusing on transboundary movement of LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account human health.

UNEP then drafted the International Technical Guidelines for Safety in Biotechnology to serve as interim guidance for biosafety and these Guidelines were adopted by the Global Consultation of Government-designated Experts in Cairo in December 1995.

In 1996, the Conference of the Parties for the CBD established an Open-ended *Ad Hoc* Working Group on Biosafety to develop a draft protocol. This Working Group met six times between 1996 and 1999 and, as the conclusion of its last meeting, a draft protocol was submitted for consideration by the Conference of the Parties at an extraordinary meeting in February 1999, in Cartagena, Colombia. The Conference of the Parties was not able to finalize its work in Cartagena. As a result, the Conference of the Parties suspended its first extraordinary meeting and agreed to reconvene as soon as possible.

The Conference of the Parties reconvened and adopted the Cartagena Protocol on Biosafety on 29 January 2000 in Montreal, Canada. The Protocol entered into force on 11 September 2003 upon ratification by the fiftieth Party. As of June 2010, 159 Parties had acceded/ratified the Protocol.

1.2 What is biosafety?

In its broad sense, the term biosafety refers to the protection of human health and the environment from potential harm due to biological agents.

Under the CBD, and more specifically under the Cartagena Protocol on Biosafety (hereinafter "Protocol" 1/), the term biosafety essentially refers to safety procedures aimed at regulating, managing or controlling the risks associated with the use and release of living modified organisms (LMOs) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, also taking into account the risks to human health. Biosafety comprises multidisciplinary scientific fields, including, but not limited to, biology, ecology, microbiology, molecular biology, animal and plant pathology, entomology, agriculture and medicine as well as other considerations such as legal, socio-economic and public awareness.

Figure 1 – Biosafety

1/ The text of the Cartagena Protocol on Biosafety is available at http://bch.cbd.int/protocol/text/.

1.3 What are living modified organisms?

According to the Cartagena Protocol on Biosafety: 2/

(a) "Living modified organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(b) "Modern biotechnology" means the application of:

i. *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

ii. fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

An LMO is, therefore, an organism that results from the use of modern biotechnology through (i) *in vitro* modification of nucleic acid (DNA or RNA) molecules; or (ii) cell fusion between organisms of different taxonomic families.

Modern biotechnology techniques include, but are not limited to, *in vitro* DNA and RNA techniques for the modification of genetic material (e.g. by insertion, modification or deletion of genes or other nucleic acid sequences) in all types of organisms, such as plants, animals, microbes and viruses.

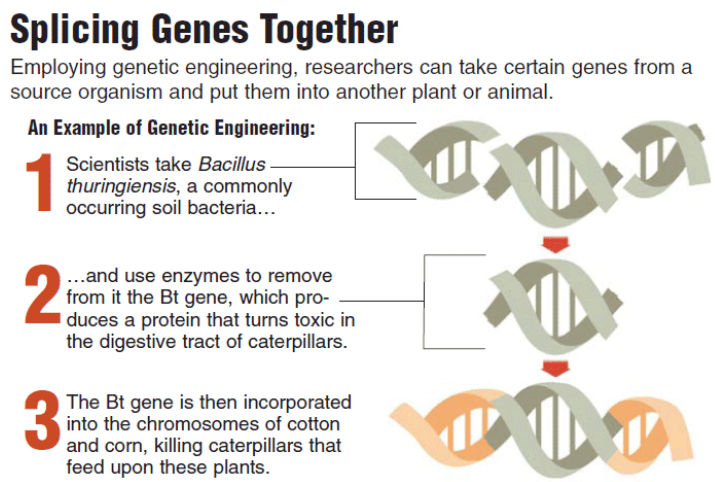
1.3.1 Overview of the techniques used in modern biotechnology

LMOs are most commonly developed through the use of *in vitro* nucleic acid techniques by inserting, deleting or modifying a gene or DNA/RNA sequence in a recipient or parental organism.

The terms genetic modification, genetic engineering, recombinant DNA and DNA manipulation are terms that apply to the direct modification of an organism's genes. The terms genetically modified organism (GMO) as well as genetically engineered or transgenic organism are often used interchangeably for LMOs. The Cartagena Protocol emphasizes the "living" nature of the organism and products thereof, namely processed materials that are of LMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

2/ Article 3, Paragraphs (g) and (i).

Figure 2 – In vitro nucleic acid techniques



Source: North Carolina State University (website).

LMOs can also be produced through cell fusion where cells from two different organisms that do not belong to the same taxonomic family are fused, resulting in an organism containing genetic information from both parental cells. The resulting LMO may contain the complete genomes of the parental organisms or parts of their genomes. Cell fusion can be applied to bacterial, fungal, plant or animal cells, using a variety of techniques to promote fusion.

1.3.2 Commonly used methods for genetic modification of plants

The production of LMOs through genetic modification is a multi-stage process that can be achieved through a variety of methodologies. Methods commonly used in the development of LM plants may be summarized as follows. 3/

Once a gene of interest has been identified and isolated from a donor organism, it is manipulated in the laboratory so that it can be inserted effectively into the intended recipient organism. The manipulation may, for example, include changes to the nucleotide sequence so as to enhance or modulate the expression of the gene once it is introduced into the intended recipient organism.

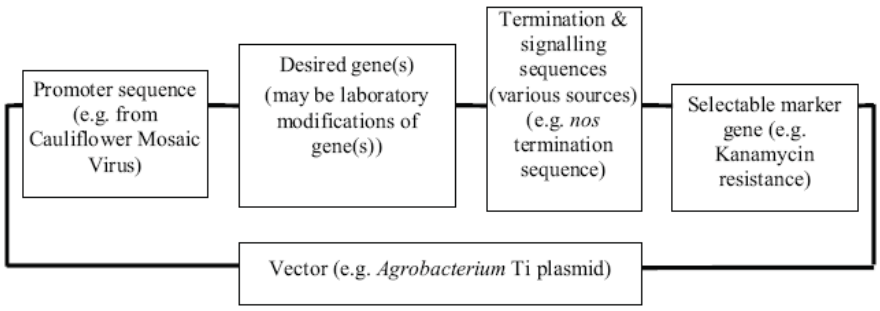
One or more genes of interest, as well as other nucleotide sequences needed for the proper functioning of the gene(s) of interest, may then be built in an orderly sequence into a “gene construct”. The gene construct typically includes a “promoter sequence” and a “termination sequence” which are necessary to ensure that the gene is expressed correctly in the recipient organism. Different promoter sequences control gene expression in different ways — some allow continuous expression of the gene, while others switch expression of the gene on or off at different stages of the life cycle of the organisms or as a reaction to other external influences, as well as control the particular tissues or organs in which the gene will be expressed.

3/ Adapted from IUCN (2003).

A "marker gene" 4/ is often incorporated into the gene construct to help in identifying which individuals of a recipient organism have been modified by the introduction of the gene construct.

Gene constructs currently used may include multiple elements — for example, several promoter sequences and desired genes. Finally, the gene construct may be incorporated into a larger DNA molecule to be used as a vector (e.g. plasmid, virus, etc.). The purpose of the vector is to assist the transfer of the gene construct into the recipient organism.

Example 5 – Scheme of a gene construct and vector



Note: Gene constructs currently used may include multiple elements — for example, several promoter sequences and desired genes.

Source: IUCN (2003).

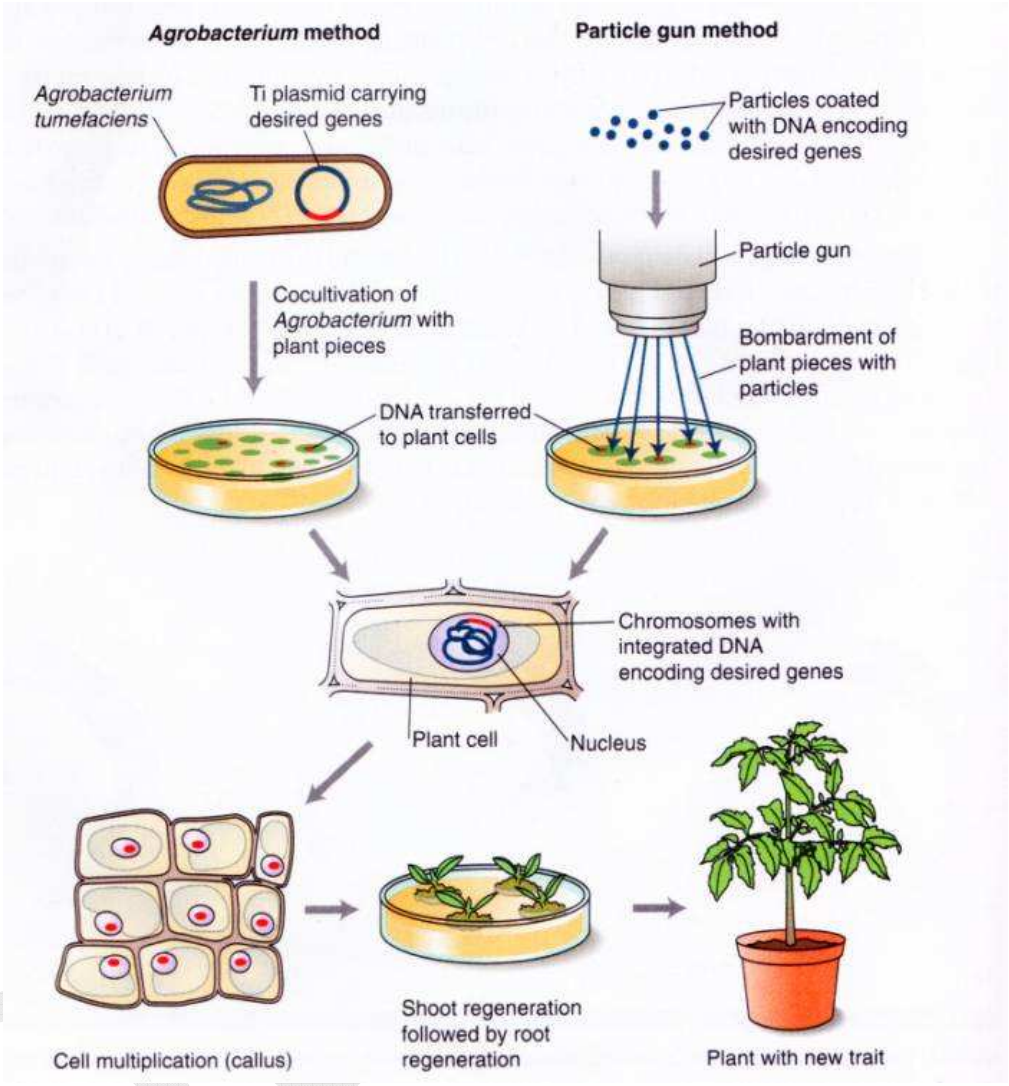
The recipient organism is then transformed by different methods (e.g. via infection using *Agrobacterium*, particle bombardment, injection, etc.) for integration of the gene construct into the genome of the recipient organism.

Transformed cells need to be selected and regenerated into complete LMOs. The following step is the further selection of the LM event(s) that contain the desired transgene(s) and express the desired characteristics. Through selection, many experimental LMOs are discarded and only a few events reach the stage of commercialization.

In the case of LM plants, cross-breeding to introduce the transgene(s) into other recipient varieties is also common.

4/ During genetic transformation, gene constructs are inserted in only a fraction of the cells used in the process. "Marker genes" are typically used to identify or select cells or organisms in which the gene construct(s) was successfully introduced. Marker genes may, in some cases, be removed from the LMOs at a later stage.

Figure 3 – Genetic modification of plants



Source: Mirkov (2003).

1.3.3 Examples of commercialized LMOs

In 1978, the first LMO was produced at the commercial level by the creation of an *Escherichia coli* strain (i.e. a bacterium) producing the human protein insulin. In 1996, the first genetically modified seeds were planted in the United States of America for commercial use. 5/

To date, the most broadly commercialized LMOs introduced into the environment are agricultural crops. According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), the worldwide area cultivated with LM crops has been growing steadily since 1996, and in 2009, the cultivation of LM crops accounted for 134 million hectares (James, 2009). Soy, maize, cotton and rapeseed that are resistant to herbicides and/or are able to produce pesticidal proteins account for the

5/ FLAVR SAVR™ Tomato by Calgene Inc.

majority of LM crops currently being commercialized (see LMO Registry in the BCH at http://bch.cbd.int/database/lmo-registry).

In 2009, a goat that produces an anticoagulant drug for humans was the first LM animal to be approved for commercial production. 6/ Zebra fish containing fluorescent protein genes are another example of LM animals on the market.

Moreover, a number of LM vaccines for humans and animals are being commercialized.

To date, there are no examples of commercialization of LMOs resulting from cell fusion.

1.4 Objective and scope of the Protocol

The objective of the Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

The Protocol establishes rules and procedures for the safe handling, transfer and use of LMOs. The Protocol focuses on the transboundary movement of LMOs to be introduced into the environment and those to be used directly as food, feed or for processing, and seeks to protect biological diversity, taking into account human health, from the potential risks posed by LMOs resulting from modern biotechnology.

All LMOs that may have adverse effects on biodiversity or human health are within the scope of the Protocol. Nevertheless, some types of LMOs may be excluded from some provisions.

Example 6 – Scope of the Cartagena Protocol on Biosafety

- ***LMOs subject to the provisions of the Protocol***

  All LMOs which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 4).

- ***LMOs excluded from the Protocol's provisions on transboundary movements***

  LMOs that are pharmaceuticals for humans that are addressed by other international organizations or agreements (Article 5).

Source: IUCN (2003).

6/ http://www.gtc-bio.com/science.html.

1.5 Living modified organisms for intentional introduction into the environment – Advanced Informed Agreement

The Advanced Informed Agreement (AIA) defines mandatory procedures to be applied to the first transboundary movement of an LMO for introduction into the environment. LMOs intended for direct use as food or feed, or for processing are subject to a different procedure (see below).

The AIA procedure begins with the Party of export or the exporter notifying the Party of import of the proposed transboundary movement of an LMO for intentional introduction into the environment. The notification must contain, at a minimum, the information specified in Annex I of the Protocol including, among other things, the contact details of the exporter and importer, the name and identity of the LMO and its intended use, as well as a risk assessment report consistent with Annex III of the Protocol.

The Party of import has 90 days to acknowledge the receipt of the notification, and 270 days to communicate its decision to the notifier and the BCH. In its decision, the Party of import may approve 7/ or prohibit the import of the LMO, request further information or extend the decision period to a defined period of time. If a Party of import does not communicate its decision within 270 days, it should not be understood that consent was given.

Example 7 – Application of the Advanced Informed Agreement (AIA) procedure

- ***LMOs subject to AIA provisions***

  - LMOs intended for intentional introduction into the environment (Article 7(1)).

- ***LMOs excluded from the Protocol's AIA provisions***

  - LMOs in transit (Article 6(1)).
  - LMOs destined for contained use in the Party of import (Article 6(2)).
  - LMOs intended for direct use as food or feed, or for processing (LMO-FFPs) (Article 7(2)).
  - LMOs identified by the meeting of the Parties to the Protocol as being not likely to have adverse impacts (Article 7(4)).

Source: IUCN (2003).

1.6 Living modified organisms for direct use as food or feed, or for processing

According to Article 11 of the Protocol, a Party that takes a decision regarding an LMO that may be subject to transboundary movement for direct use as food or feed, or for processing (LMO-FFP) shall submit within 15 days to the BCH information specified in Annex II of the Protocol, including, among other things, the name and identity of the LMO and its approved uses, as well as a risk assessment report consistent with Annex III of the Protocol (see Article 11.1).

7/ A decision that approves the use of an LMO may be taken with or without conditions. If there are conditions, the decision must set out the reasons for the conditions.

1.7 Competent national authorities

Each Party should designate one or more competent national authorities (CNAs) who will perform the administrative functions required by the Protocol and are authorized to take decisions on the LMOs for which they are designated (see Module 2).

1.8 Risk assessment (Article 15 and Annex III)

Article 15 of the Protocol sets out the provisions for Parties to conduct risk assessments of LMOs. It requires that risk assessments be carried out in a scientifically sound manner in accordance with Annex III and taking into account recognized risk assessment techniques.

While the Party considering permitting the import of an LMO is responsible for ensuring that a risk assessment is carried out, it has the right to require the exporter to do the work or to bear its cost. This is particularly important for many developing countries (SCBD, 2003).

The Protocol, therefore, empowers governments to decide whether or not to accept imports of LMOs on the basis of risk assessments. These assessments aim to identify and evaluate the potential adverse effects that an LMO may have on the conservation and sustainable use of biodiversity in the receiving environments.

Annex III sets out the general principles and methodology for the risk assessment process.

The general principles for risk assessment under the Protocol are that: (i) it must be carried out in a scientifically sound and transparent manner, and on a case-by-case basis; (ii) lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk; and (iii) risks of LMOs should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

Individual Parties use these general principles to guide the development and implementation of their own national risk assessment process (see Module 2).

The following are considerations about some of the general principles for risk assessment:

Scientific soundness – The Cartagena Protocol explicitly states that risk assessments should be carried out in a scientifically sound manner. The principle of scientific soundness entails that risk assessments are to be undertaken in a systematic way on the basis of verifiability and reproducibility of information by, for example, reporting on methods and data in sufficient detail to enable others to repeat the steps of the risk assessment independently. Some countries have integrated this principle into their own procedures, with specific suggestions about what type of information can be appropriately used in a risk assessment. In many cases, different sources and criteria for scientifically sound information have been set, ranging from scientific literature, studies presented by the notifier, expert opinions, etc. Consultations among scientific experts may also be considered to be an appropriate means of gathering such information.

Transparency – Annex III states that risk assessments should be conducted in a transparent manner.

Most countries with national biosafety frameworks in place have procedures to ensure transparency in the risk assessments. The CNAs often show what transparency mechanism is in place to handle notifications

and how the mechanism is applied in each case. The level of transparency may, however, range from public notification to broad public involvement.

Some countries, for instance, make the necessary requirements for conducting risk assessments available online and, if an approval is granted for release of an LMO into the environment, a public notification is usually made by posting the release online (see also the provisions of Article 23 on "Public Participation" and Section 4.4 in Module 2 on stakeholder participation).

Example 8 – Transparency

"ERMA New Zealand strives to be transparent as is practicable and appropriate in its processes. In general, applications for substances or organisms that can significantly affect the environment must be publicly notified, and anybody can then make a written submission - within 30 working days of public notification - and a hearing will be held if any submitter requests to be heard, or if the Authority thinks it is necessary."

Source: ERMA NZ (website).

Case-by-case – Annex III states that risk assessments should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the LMO concerned, its intended use and the likely potential receiving environment.

The legal frameworks of some countries may also specify other elements to be taken into consideration in each "case".

Example 9 – The case-by-case basis is fundamental to risk assessment of LMOs

A case-by-case approach is one where each release of an LMO is considered relative to the environment in which the release is to occur, and/or to the intended use of the LMO in question. A risk assessment performed for a particular LMO intended to be introduced into one environment may not be sufficient when assessing the possible adverse effects that may arise if that LMO is to be released under different environmental conditions, or into different receiving environments. A risk assessment performed for a particular use of a particular LMO may not be sufficient when assessing the possible adverse effects that may arise if that LMO is to be used in different ways. Because of this, it is important for each case to be addressed separately, taking into account specific information on the LMO concerned, its intended use and its potential receiving environment.

Source: IUCN (2003).

Annex III also states another two general principles to be taken into account when conducting a risk assessment. These are:

- "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk";

- "Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be

considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment."

Considerations on how to apply these two general principles when conducting a risk assessment are included in Module 3.

Annex III also contains a number of steps for conducting the risk assessment as well as points to consider about technical and scientific details regarding, for example, the characteristics of the genetic modification, biological characteristics of the LMO, differences between the LMO and its recipient organism, its intended use, the likely receiving environment, etc.

Module 3 of this training manual explains each of the steps of the risk assessment process according to Annex III of the Protocol.

1.9 Biosafety Clearing-House

The Biosafety Clearing-House (BCH; http://bch.cbd.int) is a mechanism set up under the Cartagena Protocol on Biosafety to facilitate the exchange of information on LMOs and assist countries that are Parties to the Protocol to better comply with their obligations.

The BCH provides open and easy access to a variety of scientific, technical, environmental, legal and capacity-building information provided in all six of the United Nations languages.

The BCH contains information that must be provided by Parties to the Protocol, such as decisions on release or import of LMOs, risk assessments, CNAs and national laws.

Governments that are not Parties to the Protocol are also encouraged to contribute information to the BCH and, in fact, a large number of the decisions regarding LMOs have been registered in the BCH by non-Party governments.

The records of decisions, risk assessments, LMOs, donor and recipient organisms, and DNA sequences are cross-referenced in a way that facilitates data retrieval. For instance, while looking at an LMO record, all the records for the risk assessment that reference that specific LMO can be easily accessed and retrieved.

The BCH also contains other relevant information and resources, including information on national contacts, capacity-building, a roster of government-nominated biosafety experts, and links to other websites, publications and databases through the Biosafety Information Resource Centre.

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1.10 Other provisions under the Protocol

In addition to the provisions above, the Protocol also requires the Parties to the Protocol to consult the public during the decision-making process regarding LMOs (Article 23), make the results of such decisions available to the public (Article 23) and allow the decision-making process to take into account socio-economic considerations arising from the impact of the LMOs on the conservation and sustainable use of biodiversity (Article 26).

2. Other international biosafety-related bodies

Several other international bodies and organizations carry out activities that are relevant to the trade and environmental aspects of LMOs. A brief overview of these bodies is provided below.

2.1 International Plant Protection Convention

The International Plant Protection Convention (IPPC; www.ippc.int) is a multilateral treaty for international cooperation in plant protection. It aims to protect plant health while facilitating international trade. The IPPC applies to cultivated plants, natural flora and plant products, and includes both direct and indirect damage by pests (including weeds). The IPPC was adopted by the Conference of the FAO in 1951. There are currently 173 contracting Parties to the IPPC.

The governing body of the IPPC is the Commission on Phytosanitary Measures (CPM). The CPM has adopted a number of International Standards for Phytosanitary Measures (ISPMs) that provide guidance to countries and assist contracting Parties in meeting the aims of the convention. The IPPC is recognized by the World Trade Organization as the relevant international standard-setting body for plant health. Application of ISPMs is not mandatory; however, under the WTO–SPS Agreement (see below), phytosanitary measures based on international standards do not need additional scientific or technical justification.

ISPM No. 11 (IPPC, 2004) describes the factors to consider when conducting a pest risk analysis (PRA) to determine whether a pest is a quarantine pest. The main text of the standard (indicated with "S2" throughout the text) and particularly Annex 3 of this ISPM includes guidance on conducting a PRA on LMOs.

In order to increase member countries' capacity to conduct PRAs, the IPPC has developed a training course and training materials. 8/

2.2 Codex Alimentarius Commission

The Codex Alimentarius Commission (CAC; www.codexalimentarius.net) is a subsidiary body of the FAO and the World Health Organization (WHO) established in 1961–1963 to protect the health of consumers and ensure fair practices in food trade. It currently has 166 members.

The Codex Alimentarius, which means "food code", is a compilation of standards, codes of practice, guidelines and recommendations on food safety prepared by the Commission. In the area of foods derived from biotechnology, the Codex provides guidance on human health risk analysis in its "Principles for the

8/ The IPPC training materials are available at: https://www.ippc.int/index.php?id=186208.

Risk Analysis of Foods Derived from Modern Biotechnology" (CODEX, 2003) and in its "Working Principles for Risk Analysis for Food Safety for Application by Governments" (CODEX, 2007).

2.3 Food and Agriculture Organization

The Food and Agriculture Organization (FAO; www.fao.org) of the United Nations also carries out activities on biosafety and biosecurity. Among these, the FAO Working Group on Biosafety is responsible for two of the FAO's Priority Areas for Interdisciplinary Action (PAIAs), namely "Biosecurity for Agriculture" and "Food Production and Biotechnology Applications in Agriculture, Fisheries and Forestry".

2.4 World Organisation for Animal Health

The World Organisation for Animal Health (OIE; www.oie.int) is an international intergovernmental organization founded in 1924 for improving animal health worldwide. As of June 2010, the OIE had 176 member countries.

The objectives of the OIE are to: (i) guarantee the transparency of animal disease status worldwide; (ii) collect, analyse and disseminate veterinary scientific information; (iii) provide expertise and promote international solidarity for the control of animal diseases; and (iv) guarantee the sanitary safety of world trade by developing sanitary rules for international trade in animals and animal products.

Within the mandates of the OIE, the principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material.

2.5 World Trade Organization

The World Trade Organization (WTO; www.wto.org) is an international organization responsible for establishing the rules of trade between nations. It has a number of agreements that affect the trade of LMOs. One such agreement is the international treaty of "Agreement on the Application of Sanitary and Phytosanitary Measures", also known as the SPS Agreement.

The SPS Agreement concerns the application of sanitary and phytosanitary measures for food safety and animal and plant health regulations, and may apply to LMOs. Article 5 of the SPS Agreement is of interest in the context of this training material since it addresses risk assessment and the determination of the appropriate level of sanitary or phytosanitary protection.

Other WTO agreements, such as the Technical Barriers to Trade (TBT) Agreement, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), and the General Agreement on Tariffs and Trade (GATT) may also apply to LMOs.

2.6 Organisation for Economic Co-operation and Development

The Organisation for Economic Cooperation and Development (OECD; www.oecd.org) provides a setting where governments compare policy experiences, seek answers to common problems, identify good practice, and coordinate domestic and international policies.

With regard to risk assessment, the OECD has published the "Recombinant DNA Safety Considerations" (OECD, 1986) and consensus documents, which focus on the biology of the recipient organisms or introduced traits and are useful in background preparation for an LMO risk assessment. 9/

2.7 Bilateral, regional and multilateral agreements

In addition to international treaties and standards, countries may engage in bilateral, regional and multilateral agreements, such as free-trade agreements (FTAs), provided they are consistent with the objective of the Protocol and do not result in a lower level of protection than that provided for by the Protocol. Such agreements could also be used to undertake shared responsibilities in assessing risks to facilitate decisions on LMOs. 10/

3. References

CODEX (2003) Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. Organisation for Economic Co-operation and Development (OECD). Available at: http://www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf (access June 2010).

CODEX (2007) Working Principles for Risk Analysis for Food Safety for Application by Governments. Organisation for Economic Co-operation and Development (OECD). Available at: www.codexalimentarius.net/download/standards/10751/CXG_062e.pdf (access June 2010).

Convention on Biological Diversity (1992) Available at: http://www.cbd.int/doc/legal/cbd-un-en.pdf (access June 2010).

ERMA NZ (website) Environment Risk Management Authority New Zealand. New Organisms FAQs. Available at: http://www.ermanz.govt.nz/help/faq-no.html (access June 2010).

IPPC (2004) ISPM No. 11: Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks and Living Modified Organisms. Available at: https://www.ippc.int/file_uploaded/1146658377367_ISPM11.pdf (access June 2010).

IUCN (2003) An Explanatory Guide to the Cartagena Protocol on Biosafety. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=41476 (access June 2010).

James C (2009) Global Status of Commercialized Biotech/GM Crops: 2009. ISAAA Brief No. 41, ISAAA: Ithaca, NY.

Mirkov TE (2003) The molecular basis of genetic modification and improvement of crops. In: Chrispeels MJ, Sadava DE (eds.) Plants, Genes and Crop Biotechnology. Jones and Bartlett Publishers, 2nd edition.

9/ Available at: http://www.oecd.org/document/51/0,3343,en_2649_34387_1889395_1_1_1_1,00.html.

10/ According to the WTO (http://www.wto.org/english/tratop_e/region_e/region_e.htm), the overall number of Regional Trade Agreements (RTAs) in force has been increasing steadily, a trend likely to be strengthened by the many RTAs currently under negotiation. Of these RTAs, FTAs and partial scope agreements account for 90%, while customs unions account for 10%. The Regional Trade Agreements Information System (RTA-IS; http://rtais.wto.org/UI/PublicMaintainRTAHome.aspx) contains information on those agreements that have either been notified or for which an early announcement has been made to the WTO.

North Carolina State University (website) Available at: http://www.ces.ncsu.edu/resources/crops/ag546-1 (access July 2010).

OECD (1986) Recombinant DNA Safety Considerations. Available at: http://www.oecd.org/dataoecd/43/34/40986855.pdf (access June 2010).

SCBD-UNEP (2003) An Introduction to the Cartagena Protocol on Biosafety. Secretariat of the Convention on Biological Diversity (SCBD) and United Nations Environment Programme (UNEP). Available at: http://www.cbd.int/doc/press/presskits/bs/cpbs-unep-cbd-en.pdf (access June 2010).

UNCED (1992a) Agenda 21. United Nations Conference on Environment and Development (UNCED), Rio de Janerio, Brazil, 3–14 June 1992. Available at: http://www.un.org/esa/dsd/agenda21 (access June 2010).

UNCED (1992b) Rio Declaration on Environment and Development. United Nations Conference on Environment and Development (UNCED), Rio de Janerio, Brazil, 3–14 June 1992. Available at: http://www.unep.org/Documents.Multilingual/Default.asp?documentid=78&articleid=1163 (access June 2010).

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Module 2:

Preparatory work – Understanding the context in which a risk assessment is carried out

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Using this module

This module aims at assisting risk assessors in setting the stage for a risk assessment to be carried out in a scientifically sound and transparent manner, and on a case-by-case basis.

It highlights the importance of understanding how national policies provide overarching guidance for the process. A risk assessor should be familiar with national regulatory and administrative frameworks, including national risk assessment practices, general principles and various obligations, since they establish the legal context for any risk assessment conducted by a national authority.

This module describes the relationship between national policies that establish protection goals, regulatory requirements and risk assessment processes that would be compliant with the Cartagena Protocol on Biosafety.

It also provides elements to facilitate the understanding of the mandate of risk assessors and the multi-disciplinary nature of the risk assessment process.

1. Introduction

Prior to receiving a living modified organism (LMO) notification, risk assessors 1/ may need to be familiar with issues such as environmental protection goals, regulatory requirements and compliance of a national framework with the Protocol, and have an understanding of the general framework within which the risk assessment must be carried out to comply with national laws and administrative procedures.

The biosafety framework of each country may address administrative matters by establishing mechanisms for, for example: (i) the selection of risk assessors and/or establishment of advisory bodies; (ii) handling confidential information (Article 21); (iii) public awareness and participation (Article 23); and (iv) whether and how socio-economic considerations will be taken into account in the decision-making process (Article 26). A risk assessor may also wish to be familiar with all these mechanisms before undertaking a risk assessment.

The following sections of this module provide an overview of how some issues might be considered by risk assessors prior to undertaking a risk assessment.

2. The broad national context

Most countries have overarching environmental and public health strategies as well as national and international obligations that provide the broad context within which the risk assessment of LMOs is carried out.

1/ For the purposes of this training material, the term “risk assessor” refers to an individual mandated by a competent national authority (CNA) to conduct and manage the risk assessment process.

2.1 National protection goals and assessment endpoints

Countries are sovereign in setting their own goals such as the protection of the environment, biodiversity or the health of their citizens. In so doing, they often adopt environmental and public health strategies as part of their national policy and legislation. These strategies, in turn, are often derived from, or compliant with, broader internationally agreed instruments.

Environmental and health policies and laws often define sets of "protection goals" or values to be protected. Some protection goals are defined broadly, e.g. conservation of biodiversity, while others are more specific, e.g. protection of a threatened or endangered species. Regardless of whether they are broad or specific, protection goals set the context for all (environmental) risk assessments.

Example 1 – Biodiversity protection goal in the European Union

"To halt the loss of biodiversity and the degradation of ecosystem services in the EU by 2020, restore them in so far as feasible, while stepping up the EU contribution to averting global biodiversity loss."

Source: Council of the European Union (2010).

In addition to the protection goals, national legislations sometimes also define "assessment endpoints". Assessment endpoints are valued biological or ecological entities that need to be protected and have some attribute that is measurable.

Ecological assessment endpoints, for instance, are most easily expressed in terms of impacts on a valued species (e.g. survival and reproduction of yellow fin tuna). Any component from virtually any level of biological organization or structural form that is recognized as an entity that needs to be protected can be considered as an assessment endpoint.

Example 2 – Assessment endpoints

"An assessment endpoint is an explicit expression of the environmental value to be protected, operationally defined as an ecological entity and its attributes."

Source: US Environmental Protection Agency (1998).

Once a risk assessment has been triggered, the risk assessor(s) will need to identify the relevant protection goals and assessment endpoints if these are available. The risk assessor(s) then determines which assessment endpoints are meaningful to the specific case at hand to ensure that the protection goals will be adequately protected. For example, the regulatory framework of a country may identify "agricultural biodiversity" as one of its protection goals and the risk assessor(s) may be asked to consider, as an assessment endpoint, the abundance of a valued species, e.g. an insect pollinator in the environment where the LMO may be released.

Selecting endpoints is among the most critical aspects when preparing a conceptual model for the risk assessment as it contributes to setting the stage for the risk assessment and the remaining steps of the process (see Module 3).

In conclusion, before undertaking a risk assessment for an LMO, risk assessors and other biosafety officers must understand national protection goals and the importance of deciding upon relevant assessment endpoints in order to plan a risk assessment.

2.2 Other national and international obligations

A country may have national laws and international obligations, e.g. trade agreements that are not directly related to biosafety or to the environment but may influence how the risk assessors will proceed once a risk assessment of an LMO is triggered. Some such obligations may, for instance, affect the scope of the risk assessment (see Module 3).

For examples of relevant international treaties and agreements, see Module 1.

3. National biosafety context

3.1 National biosafety framework

Many countries address biosafety-related issues through a large process that includes the development and implementation of a national biosafety framework (NBF). An NBF consists of a combination of policy, legal, administrative and technical instruments that are set in place to address safety for the environment and human health in relation to modern biotechnology.

In most cases, the administration of biosafety responsibilities is either shared by several government departments (e.g. environment, agriculture, health, science) or centralized and managed by one office which is responsible for the coordination of biosafety issues over a number of government departments.

The choice of framework most often reflects existing regulatory structures and the resources available at the national level for implementing biosafety regulations.

There has been a significant increase in the number of countries that possess NBFs. A global initiative funded by the Global Environment Facility (GEF) and its implementing agencies helped this process by providing administrative and technical assistance to countries in developing and implementing their NBFs in accordance with their obligations under the Cartagena Protocol.

Individual country's choices in developing national biosafety policies resulted in a variety of forms, depending on national priorities. Some chose to develop a standalone policy on biosafety, while others formulated combined policies on biotechnology and biosafety. Some policies were part of wider policies on biodiversity conservation and environmental protection, trade-related issues, biosecurity and quarantine, or established within the overall context of sustainable development or Agenda 21 (UNCED, 1992).

As of July 2009, through the GEF-funded initiatives, 111 developing countries had completed the development phase of their NBFs and made them available online. 2/

2/ http://www.unep.org/biosafety/National%20Biosafety%20frameworks.aspx.

3.2 Competent national authorities

While NBFs consist of policy, legal, administrative and technical instruments, the institutional responsibility for decision-making and for risk assessments of LMOs usually lies within competent national authorities (CNAs). According to the Cartagena Protocol, each Party is to designate one or more CNAs to perform the administrative functions required by the Protocol.

Furthermore, each Party is obliged to clearly indicate, through the Biosafety Clearing-House (BCH), any existing laws, regulations or guidelines for implementation of the Protocol, as well as the names and addresses of its CNA(s). 3/

The NBFs usually set out competencies and procedures depending on the LMO (e.g. the type of LMO or its intended use). As such, risk assessments may be assigned to different CNAs within the same country.

Example 3 – Competent National Authorities in Mexico

In Mexico, for instance, depending on the LMO and its intended use, one or more of its CNAs (Ministry of Health, Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food, and Ministry of Environment and Natural Resources) may be responsible for the risk assessment.

Source: Biosafety Clearing-House.

The options chosen by countries for the institutional set-up of CNAs in the different NBFs include: (i) a single CNA receiving and processing all requests regarding LMOs; or (ii) more than one CNA, each with different responsibilities and with either a single or multiple windows for the receipt of requests regarding LMOs.

In cases when a Party designates more than one CNA, information on the respective responsibilities of those authorities should be clearly stated and made available to the BCH. This information may include, for instance, which CNA is responsible for which type of LMO.

In most of the draft NBFs developed by countries assisted by the United Nations Environment Programme (UNEP) as a GEF-implementing agency, the responsibility of risk assessment was assigned to the CNA(s) or the overall biosafety body, with or without advice from either an *ad hoc* scientific advisory body or an established advisory committee.

3/ Laws, regulations and guidelines, as well as CNAs' contact details and other national information requested by the Cartagena Protocol can be accessed through the menu "Country Profiles" available from the BCH at: http://bch.cbd.int.

Example 4 – Competent National Authorities and National Biosafety Frameworks

While the competent national authority (or authorities) is responsible for carrying out administrative functions under the Protocol vis-à-vis other Parties, the decision-making process under a Party's national biosafety framework for reaching a decision on the proposed import of an LMO is likely to involve a wide range of national authorities. The national biosafety framework should set out the domestic level procedure, including any necessary consultations, by which any decision on a proposed import will be taken.

Source: IUCN (2003) An Explanatory Guide to the Cartagena Protocol on Biosafety.

Upon receiving a request that triggers a risk assessment, the CNA takes several actions as part of a process to ensure that a scientifically sound risk assessment is carried out by risk assessors. These may include the following:

(a) Reviewing the LMO notification for completeness against a pre-determined list of information; 4/
(b) Specifying the terms of reference for the risk assessment and expected information to be included in the final report;
(c) Identifying one or more risk assessors who will conduct and manage the risk assessment.

Example 5 – Institutional responsibilities for risk assessment

Albania – the National Biosafety Committee makes decisions, being advised by the Scientific Commission of the National Biosafety Committee. The scientific committee shall consist of seven members. The members of the scientific committee will be experts from the field of microbiology, genetics, medicine, biochemistry and molecular biology, pharmacy, agriculture, veterinary science, biotechnology and safety at work.

Caribbean – The CNA is assisted in its work by a Scientific Advisory Committee, which is responsible for conducting risk assessment. In Grenada and the Bahamas, risk assessment is done by the national biosafety coordinating body. In addition to the Scientific Advisory Committee, St. Lucia's CNA is supported in its work by a legislated entity called the Biosafety Unit. Staffing of the unit is also legally constituted and is comprised of the following: biosafety coordinator, information technology specialist, biosafety appraisal officer, public education specialist, administrative secretary and inspectors.

Gambia – An inter-sectoral National Biosafety Technical Working Group will be established with primary responsibility for risk assessment; decision making will be through the National Biosafety Technical Committee.

4/ In the case of a notification for transboundary movement to countries that are Parties to the Cartagena Protocol, this list shall contain, at a minimum, the information specified in Annex I (in the case of an application for the intentional introduction into the environment) or in Annex II (in the case of a decision regarding LMOs intended for direct use as food or feed, or for processing).

Tajikistan – Risk assessment will be the responsibility of an Expert Board under the National Biodiversity and Biosafety Center (NBBC). It will consist of experts from research institutions of the Academy of Science, Tajik Academy of Agricultural Science and Ministry for Healthcare. All these subdivisions have the relevant capacity, technical equipment and work experience.

Tonga – The Director for Department of Environment (the CNA) can specify the means by which scientifically-based risk assessments are to be carried out and appoint appropriate bodies to undertake risk assessments.

Source: UNEP (2006).

3.3 Risk assessment practices and principles

The risk assessment process includes practices and principles that may differ between countries.

As seen in Module 1, Annex III of the Protocol lists the general principles for risk assessment. Individual Parties use these general principles to guide the development and implementation of their own national risk assessment process. As such, the general principles for risk assessment may be incorporated into the country's laws or be included in guidelines adopted by the country.

Example 6 – Risk assessment practices in various countries

In **Argentina**, once an LM plant has been sufficiently field-tested, the applicant may request that the crop be 'flexibilized' that is, be approved for unconfined (usually large-scale) planting for certain specified uses. These are: (i) for regulatory purposes — to provide material for analytical, toxicological and other required tests; (ii) for export; (iii) for off-season seed increase — not to be sold in the country; (iv) for tests to be later presented (after approval for commercialization is granted) in support of new variety registration; or (v) for pre-commercial multiplication pending variety registration.

In **Canada**, the risk assessment audits for plants with novel traits (PNTs, which includes LMOs) are undertaken in offices of the Plant Biosafety Office of the Canadian Food Inspection Agency (CFIA; http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml).

In **Mexico**, a group of scientists, together with authorities from the Ministry of Agriculture, analyse the applicant's risk assessment on the basis of national legislation. This group may request help from other experts to decide on an application. When the Ministry of Agriculture has become familiar with an LM crop, it may allow the applicant to increase the area planted for the crop but the applicant will have to continue to present the risk assessment as was done for the first application. Any biosafety measures for a semi-commercial release would also have to be maintained.

In **New Zealand**, responsibility for risk assessment lies with the applicant based on the criteria in the legislation. Forms and guides assist applicants understand the intent of the legislative criteria. The Environmental Risk Management Authority (ERMA) evaluates the information provided and if required can seek further expert information or reports as appropriate. Low risk activities that conform to the requirements of the regulatory regime are not publicly notified. Some activities are discretionary for public notification while there are others for which there is a mandatory requirement for public notification (see ERMA's website: http://www.ermanz.govt.nz).

In the **Philippines**, the National Committee on Biosafety for the Philippines audits the risk assessment on LMO activities and calls on the expertise of the Scientific and Technical Review Panel to provide an independent safety audit and recommendations.

In **South Africa**, as a general guideline, if scientific reviewers consider a repeat activity of assessed risk to be one that does not differ from an earlier approved activity in terms of the nature of the LMO (host and modified DNA), the applicant, the release environment, the size of the release and the confinement conditions, they will consider a fast track procedure for approval.

In the **United Kingdom**, the United Kingdom Advisory Committee on Releases to the Environment (ACRE) reviews the safety of LMO activities at the request of Ministers and makes recommendations on whether activities should proceed and what minimum risk management conditions are needed to minimize harm to the environment and human health (http://www.defra.gov.uk/environment/acre/about/index.htm).

In the **United States of America**, the US Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS; http://www.aphis.usda.gov) identifies specific activities where notification only is needed before an activity commences. The regulators review all of these notifications and can request full risk assessment review if they believe the activity differs sufficiently from the familiar to warrant this additional regulation. Risk assessments are audited within APHIS, the Environmental Protection Agency (EPA; http://www.epa.gov) and the Food and Drug Administration (FDA; http://www.fda.gov) depending on the nature of the LMO and its use.

Source: UNEP-GEF (2005).

4. Expert advice and the role of the risk assessor(s)

4.1 Scientific advisory body

In some countries, the necessary expertise to carry out risk assessments of LMOs resides in the regulatory agencies and the risk assessments are carried out internally. In such cases, these agencies typically have the option of requesting additional expert input if deemed necessary.

On the other hand, the regulatory frameworks of many other countries call for the establishment of scientific expert panels on an *ad hoc* basis once a risk assessment has been triggered. In such cases, a CNA assesses which expertise is needed for each specific case and pools together an external team of risk assessors consisting of experts in the relevant scientific fields.

Such an advisory body may contain a pool of experts at the national, regional or international levels, who can be called upon to assist the mandated risk assessor(s) when a need arises. A scientific advisory body allows the CNAs to quickly engage the appropriate expertise for a particular risk assessment.

In cases when a CNA establishes a team or panel of risk assessors, it typically designates one of the risk assessors to be in charge of the overview and coordination of the risk assessment process.

Example 7 – How scientists are involved in the risk assessment process

National institutions responsible for a biosafety framework may include, for instance, a scientific advisory body that carries out or reviews a risk assessment and recommends what, if any, risk management measures may be needed to protect the environment and human health.

In **Belarus**, experts who will conduct risk assessment will be chosen from a roster of experts that will be adopted by Government. In every case, experts will be selected separately.

In **Mexico**, the Ministry of Agriculture, one of the CNAs for Biosafety, consults a group of scientists for advice on each request. The Inter-Secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM; http://www.cibiogem.gob.mx) also has a database of 350 experts in different disciplines from whom they can seek advice.

In **New Zealand**, in addition to the in-house expertise of ERMA, an expert science panel of eminent researchers has been established and a roster of experts including overseas experts is maintained and is used as appropriate.

In **South Africa**, the regulatory office has a database of over 60 scientists and experts used in risk assessment. However, not all of these experts are needed for every review. The reviewers all sign a confidentiality agreement with the regulators.

Source: UNEP-GEF (2005).

4.2 Responsibilities of the risk assessor(s)

National frameworks establish different types of responsibilities for the risk assessors. These responsibilities are usually specified in the terms of reference for the risk assessment and may include, for example:

- Review of the information provided in the LMO dossier, and in particular the information in the risk assessment provided by the applicant, if available;
- Identification of any other relevant scientific information on the subject at hand, including previous risk assessments or new information that has come to light;
- Consideration of information gaps and scientific uncertainties, and possible ways to address them;
- Conducting the risk assessment and preparing a report.

These actions are performed in a process that can be iterative. For example, it is possible that while the risk assessment is being conducted a new piece of scientific information comes to light and reveals some information gaps that had not been identified previously. In such a case, it may be necessary to identify and engage additional sources of scientific expertise that should be added to the initial risk assessment panel or scientific advisory body.

In reviewing the LMO dossier or at any subsequent step of the risk assessment, the CNA(s) or the risk assessor(s) may decide that further documentation is needed and may choose to request it from the applicant or to conduct or commission their own testing.

The risk assessor(s) in charge of leading the process is often responsible for the coordination of the expert panel or risk assessment team, as well as for reporting the findings and disseminating relevant documents among other parties involved, including other stakeholders (see below), as appropriate, to ensure that information is properly shared and in a timely manner.

Parties to the Protocol shall ensure that they have procedures to protect confidential information (see Article 21). As such, the risk assessor(s) is also required to respect any confidential business information indicated by the CNA, taking into account that, according to the Protocol, the following information cannot be considered confidential: (i) the name and address of the notifier; (ii) a general description of the LMO(s); (iii) a summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health; and (iv) any methods and plans for emergency response.

Once a scientific risk assessment is completed, the risk assessor(s) prepares a risk assessment report in accordance with the terms of reference established by the CNA. The report should be sufficiently detailed to provide the necessary scientific information to the decision makers (see Module 4).

4.3 Roster of Experts on Biosafety

To facilitate countries' access to relevant expertise when needed, the Parties to the Cartagena Protocol on Biosafety established the "Roster of Experts on Biosafety". The aim of this Roster is to "provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of living modified organisms".

Information on the experts of the Roster of Experts on Biosafety is accessible through the BCH at: http://bch.cbd.int/database/experts. As of June 2010, the Roster of Experts on Biosafety had 77 experts from 28 countries.

4.4 Stakeholder participation

In the context of risk assessments of LMOs, stakeholders are those with an interest or stake in biosafety, i.e. in the safe transfer, handling and use of LMOs in the country (UNEP-GEF, 2003).

While there is no direct mention of stakeholder participation in Article 15 on Risk Assessment of the Protocol, Article 23 requires that Parties consult the public in the decision-making process regarding an LMO.

Determining the extent to which the public and other stakeholders may be involved in the decision-making process is a prerogative of each regulatory framework.

Some countries have a mechanism to enable public participation during the risk assessment and/or decision-making process. For example, one of the CNAs in New Zealand, ERMA (http://www.ermanz.govt.nz), opens LMO notifications for public consultation on its website.

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5. References

Council of the European Union (2010) Press release: 3002nd Council meeting – Environment. Brussels, 15 March 2010. Available at: http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/envir/113373.pdf (access June 2010).

IUCN (2003) An Explanatory Guide to the Cartagena Protocol on Biosafety. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=41476 (access June 2010).

UNCED (1992) Agenda 21. Rio Declaration on Environment and Development, United Nations Conference on Environment and Development (UNCED), Rio de Janerio, Brazil, 3–14 June 1992. Available at: http://www.un.org/esa/dsd/agenda21 (access June 2010).

UNEP (2006) A Comparative Analysis of Experiences and Lessons from the UNEP-GEF Biosafety Projects. Available at: http://www.unep.org/biosafety/Documents/UNEPGEFBiosafety_comp_analysisDec2006.pdf (access May 2010).

UNEP-GEF (2003) A Biosafety Framework Development Toolkit - Phase 0: Starting the Project. Available at: http://www.unep.ch/biosafety/old_site/development/devdocuments/TOOLKIT%202006%20Phase0.pdf (access May 2010).

UNEP-GEF (2005) A Biosafety Framework Development Toolkit - Phase 3: Drafting the NBF - Designing the Administrative Systems for Handling Applications and Notification. Available at: http://www.unep.ch/biosafety/old_site/development/devdocuments/TOOLKIT%202006%20Phase3b.pdf (access May 2010).

US Environmental Protection Agency (1998) Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F. Available at: http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=36512 (access June 2010).

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Module 3:

Conducting the risk assessment

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Using this module

This module provides an overview of the risk assessment methodology. It is structured in four sections. The first section provides an overview of the general methodology for environmental risk assessment and reviews some of the terms used. The second section provides elements that form the basis of a scientifically sound risk assessment conducted on a case-by-case basis. For each of these elements, this section also includes the points to consider from Annex III of the Protocol, along with a short rationale as to how this information may be useful. The third section explains some common actions that are undertaken when setting the context and scope of the risk assessment. The final section discusses the process of conducting the risk assessment *per se*, and follows the methodology and steps of Annex III of the Protocol along with a short description on how risk assessors may proceed in each of these steps. It is noted that this module does not replace Annex III but rather aims at assisting risk assessors in the practical use of the concepts contained therein.

Any methodology or terminology that is used in this module but that is not included in Annex III or in the Protocol does not reflect a particular regulatory approach to risk assessment of living modified organisms (LMOs), but rather draws on a variety of academic and regulatory experiences. As in the other modules, examples from various approaches to risk assessment are provided.

Although many of the principles included in this module are broadly applicable, taking into consideration the experience available, this module focuses primarily on risk assessment of LM plants produced through the application of *in vitro* nucleic acid techniques.

1. Introduction

Risk assessment is a process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system (WHO, 2004).

The risk assessment process involves a critical review of available data for the purpose of identifying and possibly quantifying the risks resulting from, for example, natural events (flooding, extreme weather events, etc.), technology, practices, processes, products, agents (chemical, biological, radiological, etc.) and any activity that may pose threats to ecosystems, animals and/or people.

The objective of a risk assessment under the Cartagena Protocol “is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health” (Article 1).

The results of risk assessments of living modified organism (LMOs) are typically used by decision makers to make informed decisions regarding the approval, with or without conditions (e.g. requirements for risk management and monitoring strategies), or the prohibition of a certain use of the LMO.

Figure 1 – Assessing risks

Source: http://www.scienceinthebox.com/en_UK/safety/riskassessment_en.html.

This module provides an introduction to risk assessment and considerations that may assist risk assessors in conducting risk assessments of LMOs that are consistent with Article 15 and Annex III of the Protocol. 1/

2. Overview of the risk assessment methodology

In order to understand what is meant by risk assessment, it is important to be familiar with the concepts of ***risk*** and ***hazard***, and how these terms differ. The term "risk" does not have a single unambiguous definition but is often defined as "the probability of harm". Risk is broadly understood as the likelihood that a harmful consequence will occur as the result of an action or condition.

Risk is often described as the combined evaluation of hazard and exposure.

- "*Hazard*" is defined as the potential of a stressor to cause harm to a biological system (e.g. a species) (UNEP/IPCS, 1994).
- "*Exposure"* means the contact between an agent and a receptor. Contact takes place at an exposure surface over an exposure period (WHO, 2004).

The pathway leading to the exposure of the receptor to the hazard forms the third element in risk. Ascribing the probability of exposure to the hazard by a receptor characterizes the risk. All three elements must be evaluated to form an effective and useful risk assessment for specific scenarios (UNEP Division of Technology, Industry and Economics, website).

1/ Taking into consideration the experience available, the focus of this training module will be LMOs produced through the application of *in vitro* nucleic acid techniques (i.e. produced through genetic transformation) and not on LMOs produced through cell fusion beyond the taxonomic family (see Article 3 of the Protocol).

A simple example can be used to distinguish hazard from risk: acids may be corrosive or irritant to human beings (=hazard). The same acid is a risk to human health only if humans are exposed without protection to it. The degree of harm caused by the exposure will depend on the specific exposure scenario. 2/ If a human only comes into contact with the acid after it has been heavily diluted, the risk of harm will be minimal but the hazardous property of the chemical will remain unchanged (EEA, 1998).

Example 1 – What is risk? What is risk assessment?

Risk = the combination of the magnitude of the consequences of a hazard, if it occurs, and the likelihood that the consequences will occur.

Risk assessment = the measures to estimate what harm might be caused, how likely it would be to occur and the scale of the estimated damage.

Source: UNEP (1995).

According to WHO (2004), a risk assessment process can be divided into four main phases:

(a) *Hazard identification* – The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system or (sub)population;
(b) *Hazard characterization* – The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties;
(c) *Exposure assessment* – Evaluation of the exposure of an organism, system or (sub)population to an agent (and its derivatives);
(d) *Risk characterization* – The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or (sub)population, under defined exposure conditions.

If risks are identified during the last step above, risk management strategies may be identified which may effectively prevent, control or mitigate the harm from happening. As such, the risk assessment process often includes an additional step on the identification of a range of possible risk management strategies that could reduce the level of risk.

It is worth noting, however, that it is only during the decision-making process that a choice is made as to whether or not risk management strategies should be implemented (see more details on the identification of risk management strategies in Module 4).

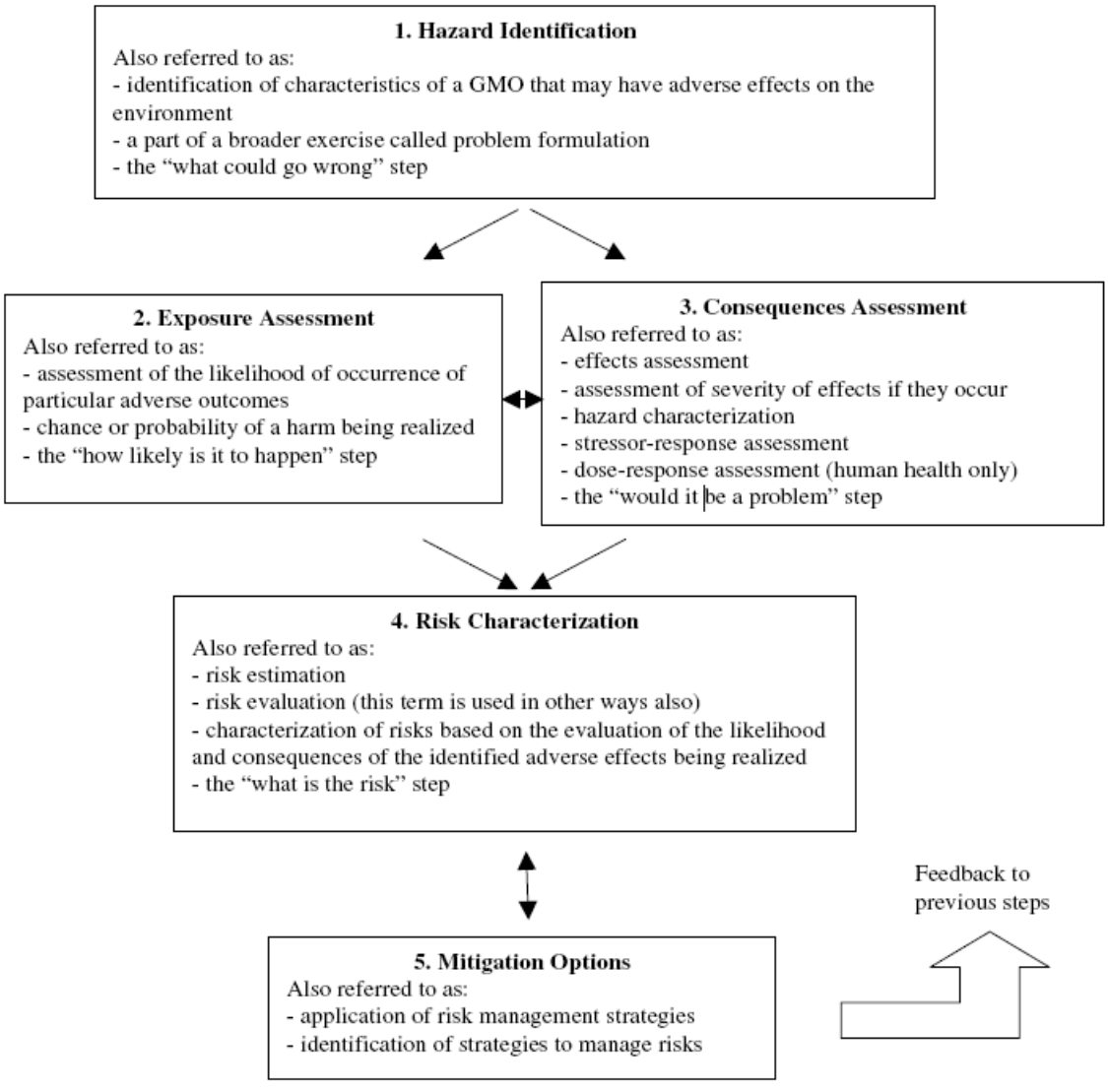
As a whole, the risk assessment process can be highly iterative, in which one or several steps may need to be re-evaluated when, for instance, new information becomes available in an attempt to increase the level of certainty.

2/ *"Exposure scenario"* is a set of conditions or assumptions about sources, exposure pathways, amounts or concentrations of agent(s) involved, and exposed organism, system or (sub)population (i.e. numbers, characteristics, habits) used to aid in the evaluation and quantification of exposure(s) in a given situation.

The methodologies for risk assessment of LMOs have evolved over the last several years. At a conceptual level, the methodologies have been adapted from the existing paradigms for environmental risk assessment developed for chemicals and other types of environmental stressors (Hill, 2005). As a result, the terminology used in the different methodologies may vary.

Being familiar with the different terms used in risk assessment enables a more direct comparison between the terminology used in Annex III and different risk assessment frameworks, and facilitates the interpretation of results from different risk assessments, for instance, for the same LMO.

Example 2 – Variation in terminology used to describe methodological components common to many risk assessment frameworks



Source: Hill (2005).

3. Context and scoping of the risk assessment

Protection goals for the conservation and sustainable use of biodiversity may be defined in national, regional and international policies. In setting the context of a risk assessment, these goals may be relevant for the identification and selection of appropriate assessment endpoints and for determining which methodology will be used in the risk assessment process. Understanding the contribution of national, regional and regulatory policies in setting the context of the risk assessment is part of the preparatory work for a risk assessment as seen in Module 2.

After consideration of the protection goals, the risk assessment of a particular LMO proceeds to the scoping phase in order to define the extent and the limits of the risk assessment process. This phase usually consists of at least three main actions: (i) selecting relevant assessment endpoints or representative species on which to assess potential adverse effects; (ii) establishing baseline information; and (iii) when possible, establishing the appropriate comparator(s).

Although these actions are described here as separate activities, in practical terms, the scoping phase is an iterative process where the risk assessors will usually draw on the results of each action to inform the subsequent actions until all their elements have been considered sufficiently to enable the risk assessment to proceed.

3.1 Selecting relevant assessment endpoints or representative species

The purpose of an assessment endpoint or of representative species is to provide a measure that will indicate whether or not the LMO may cause an adverse impact on a protection goal. In order to be useful, the selected assessment endpoints or characteristics of the representative species should be specific and measureable.

Assessment endpoints or species representative of important ecological functions or roles should be selected on a case-by-case basis. The complexity of the ecosystems and the large number of potential candidates add to the challenges in selecting the appropriate assessment endpoints in ecological systems. Some important criteria for the selection of assessment endpoints to be used in the risk assessment of LMOs may include, for example: (i) their relevance to the protection goals; (ii) a well-defined ecological function; (iii) accessibility to measurement; and (iv) level of potential exposure to the LMO.

Identifying assessment endpoints or representative species that are relevant within the context of the likely potential receiving environment allows the risk assessor(s) to focus on interactions that are likely to occur. However, if, for example, the preservation of a certain species is a primary protection goal and a risk scenario that the LMO could have a negative impact on that species can be formulated, risk assessors may need to assess whether the LMO has the potential to cause an adverse effect even if the habitat or the geographical distribution areas of the protected species do not overlap with the likely potential receiving environment of the LMO. This could occur, for example, if a third species is sexually compatible with the LMO and the protected species, and has a distribution area that overlaps with the distribution areas of the LMO and the protected species, thereby providing an indirect exposure pathway between them.

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Example 3 – Questions asked when selecting representative species for assessing effects of Bt plants on non-target organisms

- Which variant of the Bt protein are we dealing with?
- Where is it expressed (in the leaves, pollen or only in the roots)?
- Is it produced in the plant throughout its life or only during particular growth phases?
- Which insects come into contact with the Bt protein?
- Is this contact direct and long-term or only occasional?
- Which insects ingest the Bt protein through their prey?

Source: GMO Safety (website).

Example 4 – Common problems in selecting assessment endpoints

- Endpoint is a goal (e.g. maintain and restore endemic populations);
- Endpoint is vague (e.g. estuarine integrity instead of abundance and distribution of a species);
- Ecological entity may not be as sensitive to the stressor;
- Ecological entity is not exposed to the stressor (e.g. using insectivorous birds for avian risk of pesticide application to seeds);
- Ecological entities are irrelevant to the assessment (e.g. lake fish in salmon stream);
- Importance of a species or attributes of an ecosystem are not fully considered;
- Attribute is not sufficiently sensitive for detecting important effects (e.g. survival compared with recruitment for endangered species).

Source: US Environmental Protection Agency (1998).

3.2 Establishing the baseline

In simplified terms, the baseline for the risk assessment of an LMO is a snapshot of the environment prior to the introduction of an LMO. In risk assessment, the baseline information describes the conditions existing prior to the introduction of the factor whose potential adverse effect is being assessed. Baselines can refer, for instance, to a particular environment or health conditions of a population.

The baseline should be established with the aim of having measurable information on any element of the likely potential receiving environment that is considered relevant in assessing the impacts from the introduction of the LMO, including considerations on possible impacts on human health.

3.3 Establishing the appropriate comparator(s)

As seen above, comparative risk assessment is one of the general principles of risk assessment as set out in Annex III to the Protocol, whereby risks associated with the LMO "should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment".

Using a comparator may help a risk assessor in identifying the novel characteristics of the LMO and assessing whether the LMO presents greater, lesser or equivalent risk than the non-modified organism being used in a similar way and in the same environment.

Depending on the context, a risk assessor may also choose to consider similar or related non-modified organisms as useful comparators, such as for instance (near-)isogenic lines. Related management practices and experience with similar non-modified organisms may also be helpful. For example, when considering the risk assessment for an insect-resistant LM crop, a risk assessor may wish to consider, among other things, the available experience with pest control practices applied to non-modified organisms of the same species as the recipient or parental organism(s) (e.g. use of spores from *Bacillus thuringiensis* as pesticides).

In some circumstances, choosing appropriate comparator(s) could be a challenge. This could happen, for example, in the case of LM crops resistant to abiotic stresses if the non-modified recipient or parental organism(s) were not able to grow in the receiving environment. Under extreme stress conditions, when a comparator may not be available to provide for a meaningful comparison, a characterization of the abiotic stress-tolerant LM crop as a novel genotype in the receiving environment may provide relevant information to the risk assessment.

4. Elements of a case-by-case risk assessment of LMOs

The case-by-case approach in risk assessment is based on the premise that risks that may arise from the release of an LMO depend on three main elements: the LMO itself, the likely potential receiving environment and the intended use of the LMO in question. In order to identify and assess risks, each of these elements needs to be characterized in a concerted manner and as appropriate for the specific risk assessment. Moreover, it is noted that while these three elements may be sufficient to establish the boundaries of a risk assessment, potential adverse effects may extend beyond these elements to, for instance, unintended receiving environments and uses.

The information required for each of these elements in a risk assessment may vary in nature and level of detail from case to case. The following sections (4.1–4.3) provide examples of information that may be relevant for the characterization of each element above. These sections include several of the "points to consider" as indicated in paragraph 9 of Annex III of the Protocol.

A large portion of the information listed here is usually included in the LMO request triggering the risk assessment. The risk assessors may determine whether or not the information provided is sufficient and adequate for conducting a scientifically sound risk assessment and, if needed, obtain additional information by, for instance, carrying out their own investigation or requesting it from the applicant.

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Example 5 – The case-by-case approach

"A risk assessment performed for a particular LMO intended to be introduced to one environment may not be sufficient when assessing the possible adverse effects that may arise if that LMO is to be released under different environmental conditions, or into different receiving environments. A risk assessment performed for a particular use of a particular LMO may not be sufficient when assessing the possible adverse effects that may arise if that LMO is to be used in different ways. Because of this, it is important for each case to be addressed separately, taking into account specific information on the LMO concerned, its intended use, and its potential receiving environment."

Source: IUCN (2003).

4.1 Living modified organism

4.1.1 Characterization of the recipient organism or parental organisms

In order to identify whether there are characteristics associated with an LMO that may cause potential adverse effects (see Section 5.1), it is first necessary to have information about the recipient or parental organism(s). 3/ For many LMOs, the biology of the recipient or parental organism(s) will strongly influence the potential interactions of the LMO in the receiving environment.

Information on the recipient or parental organism(s) is, therefore, essential as it will help the risk assessor identify the exposure and its scenarios, and, ultimately, whether a risk is posed by an LMO.

The information that is needed for the characterization of the recipient or parental organisms will vary depending on each case. It normally includes biological and reproductive characteristics of the recipient/parental organism(s) that could be important for determining potential exposures of other organisms to the LMO in question in the likely potential receiving environment, such as possible interactions with predators, prey, competitors, pathogens, etc.

In many cases, information on the recipient or parental organism can be found in biology documents, such as those published by the Organisation for Economic Co-operation and Development (OECD) 4/ and Canadian Food Inspection Agency (CFIA) 5/ for many species of LMOs currently under commercialization.

The LMO will, in most cases, share more genetic identity with the actual recipient or parental organism(s) than with other members of the parental species. Thus, it is also important to consider, whenever possible, comparative data from the actual non-modified recipient or parental organism(s).

Information about recipient or parental organism(s) to be considered may include:

Taxonomic status – This information is useful for identifying the recipient or parental organism(s) and for ensuring that information provided and cited during the assessment pertains to the organism for which

3/ For the purposes of this training material, "recipient organism" will be considered to be the non-transformed organism that was subject to genetic modification through *in vitro* nucleic acid techniques. Similarly, "parental organisms" will refer to the donor organisms of either cells, when used in cell fusion, or genetic material when used for *in vitro* nucleic acid techniques.

4/ See http://bch.cbd.int/database/record-v4.shtml?documentid=48496.

5/ See http://www.inspection.gc.ca/english/plaveg/bio/dir/biodoce.shtml.

the assessment is being carried out. Typically, the taxonomic status includes the scientific name (i.e. genus and species, for example, *Zea mays*) and information about the taxonomic family (e.g. Poaceae). This may also include other information used to further classify (e.g. sub-species, variety, strain) or differentiate the recipient or parental organism(s) (e.g. ploidy level or chromosome number).

Common name – The familiar or colloquial names for the parental organism that may be commonly used in the country of introduction and in international trade may be useful for finding information relevant to the biology of the organism. Caution is, however, recommended when using information about recipient or parental organism(s) where only common names (versus the scientific name) are used as the same common name may be applied to more than one species.

Biological characteristics – Information on the biological characteristics of the recipient or parental organism(s), such as the production of endogenous toxins and allergens, its reproductive biology, seed dispersal and growth habit, are also important points for consideration.

Origin – The origin of the recipient or parental organism(s) refers to its place of collection and may be important because populations within a species (e.g. variety, strain, isoline, etc.) may have significantly different characteristics. For domesticated species, this may be supplemented with a pedigree map where available.

Centres of origin and centres of genetic diversity – Knowing the centre(s) of origin and genetic diversity can provide information on the presence of sexually compatible species and the likelihood of ecological interactions in the receiving environment. In the absence of more specific information, the centre of origin can also offer insight into the biology of the species (e.g. habitats to which the species is adapted).

Habitat where the recipient or parental organism(s) may persist or proliferate – Information about the ecosystems and habitats (e.g. temperature, humidity, altitude, etc.) where the recipient or parental organism(s) is known to be native and where it may have been introduced and is now naturally established provides baseline information for understanding the range of habitats in which the species exists, the range of behaviours exhibited in those habitats, and how characteristics of the species determine the range of habitats where it occurs. This information can provide the basis for estimating other habitats, in which the species may persist or proliferate, and can be very valuable in determining the likely potential receiving environment and, consequently, the level of exposure to the LMO. For more details on the type of information that may be useful, see Section 4.2 on the "Likely potential receiving environment(s)".

The history of use can be very valuable as well. For example, if an LMO persists in heavily managed environments (e.g. agriculture, silviculture or recreationally managed land), this will provide information about the conditions necessary for its survival. It may also provide direct indications of how the LMO will behave in other managed environments.

4.1.2 Description of the genetic modification

Information on the genetic material that was introduced or modified, as well as the method used for the genetic transformation is useful in identifying novel properties of the LMO, such as what new gene products are expressed and which of the endogenous genes of the recipient or parental organism(s) may be affected by the genetic modification.

Typically, the description of the genetic modification includes information on: (i) the "donor organism(s)" or source from which the inserted genetic element(s) originates; (ii) characteristics of each introduced or

modified genetic element, including their intended and known biological function(s); (iii) the vector used, if applicable; and (iv) the transformation method. Each of these points is explained briefly below:

Donor organism(s) – The relevant information about the donor organism(s) includes its taxonomic status, common name, origin and relevant biological characteristics.

Modified genetic elements or insert(s) – The relevant information on the inserted or modified genetic elements includes the name and characteristics of the inserted or modified nucleic acid sequence(s), including the marker genes or non-coding DNA, and their function(s). If available, a history of use may be important with regards to potential toxicity or allergenicity of the gene products derived from the donor organism. If the genetic elements originate from a donor organism that is known to be a pest or pathogen, it is also relevant to know whether and how these elements contribute to the pest or pathogenic characteristics.

Vector – In molecular biology, a vector is a nucleic acid molecule used as a vehicle to transfer foreign genetic material into another cell. If a vector, for example a plasmid, was used for the transformation, relevant information includes its identity, source or origin, and its host range.

Transformation method – Specifying the method that was used in the transformation (e.g. *Agrobacterium*-mediated, particle gun, etc.) is also relevant when describing the genetic modification.

Characteristics of the modification – This refers to information about the inserted or modified genetic elements and whether they are present and functioning as expected in the LMO. Normally, this involves confirming that the DNA insert or modified genetic element is stable in the genome of the LMO. Information such as the insertion site in the genome of the recipient or parental organism(s), cellular location of the insert (e.g. chromosomal, extrachromosomal or chloroplast DNA), its mode of inheritance and copy number may also be relevant.

4.1.3 Identification of the LMO

With regard to the identification of the LMO, the following are important points to consider:

Unique identifiers – A unique identifier is a code corresponding to a transformation event derived from recombinant DNA techniques provided by the LMO developer to enable the unequivocal identification of the LMO. Each unique identifier is made up of a sequence of 9 alphanumeric digits such as, for example, MON-89788-1 assigned according to the OECD guidance document (OECD, 2006). 6/

Detection and identification methods – The availability of methods for detection and identification of the LMO may be considered as well as their specificity, sensitivity and reliability. This information may be relevant not only in assessing the risks but also, for example, in considering possible monitoring and risk management strategies (see Module 4). Some regulatory frameworks require a description of such methods as a condition for regulatory approval in order to ensure that the tools for assisting with monitoring and risk management are available.

6/ For more details, see OECD (2006).

Example 6 – CFIA detection and identification method criteria

According to the Canadian Food Inspection Agency (CFIA), acceptable methods for detection and identification of LMOs must address the following:

Test type – Methods must be suitable and may be protein, RNA- or DNA-based. Phenotypic-based methods will not generally be considered suitable.

Limit of detection – Methods must meet the following sensitivity and accuracy requirement:

> For those methods that are grain-based, the method must be able to detect 0.2% modified grain (2 grains in 1000) with a 95% confidence interval.
> For those methods that are not grain-based (e.g. single ingredient feed), the method must be able to detect 0.2% modified material in a sample with a 95% confidence interval.

Procedural clarity – The method must be complete and laid out in a stepwise fashion that may be easily followed by a person unfamiliar with the method. Detailed descriptions of sample size, replicates, extraction procedure, expected results (figures/sequences), interpretation and acceptance criteria must be included.

Cross-reactivity – The method must be shown to be specific to the PNT of interest. Any potential for cross-reactivity must be clearly stated. Cross-reactivity data must be provided demonstrating that the method does not cross-react with other commercially available PNTs of the same species with similar traits/modifications that are currently available on the Canadian market.

Reference material – The company must provide appropriate reference materials to the CFIA upon request. Appropriate reference material will be determined by the CFIA based on the method provided.

Contact information – The company must provide contact information for a technical support person.

Source: CFIA (website).

4.2 Likely potential receiving environment(s)

The receiving environment of an LMO encompasses both the area where the LMO will be intentionally introduced into the environment as well as any potential receiving environment(s) which will likely be exposed to the LMO.

As such, when characterizing the receiving environment, in addition to the area where the LMO will be intentionally introduced, the likely potential receiving environment of an LMO should also be thoroughly examined during a risk assessment, with particular attention given to areas where exposure levels to the LMO will be highest.

The characterization of the likely potential receiving environment takes into account its ecological characteristics, including physical location/geography, climate, and its biological entities and their interactions. The characterization of the likely potential receiving environment will help in selecting appropriate assessment endpoints for the risk assessment (see Module 2, Section 2.1) and will also affect the assessment of the potential interactions of the LMO with other organisms.

To determine the likely potential receiving environments, risk assessors may consider potential pathways for dispersal of the LMO as well as the habitats where the recipient/parent organism(s) may persist or proliferate.

An analysis of possible dispersal routes and mechanisms is also important in establishing the likely potential receiving environments. Different dispersal mechanisms may exist and could be inherent either to the LMO (e.g. altered seed characteristics), its intended use (e.g. shipment practices) or the receiving environment (e.g. proximity to a river). The risk assessment should take into consideration all possible dispersal mechanisms, keeping in mind the biology of the LMO and non-modified recipient or parental organism(s), in a concerted manner for each case.

Information about the likely potential receiving environment can include considerations of both large-scale (e.g. climate) and small-scale characteristics (e.g. microclimate) depending on the complexity of the environment. The type of information about the likely potential receiving environment and the level of detail depend on, in accordance with the principle of case-by-case, the nature of the LMO and its intended use (see Section 4.3).

It may not be possible or practical to consider every possible interaction between the LMO and the receiving environment. Such challenges and limitations should be acknowledged during the risk assessment process.

Some physical and biological characteristics of the likely potential receiving environment(s) that may be considered in the risk assessment of LMOs are described below. This is an indicative list and the information required to satisfy the needs of the assessment will vary depending on the nature of the LMO and its intended use.

4.2.1 Physical characteristics

The physical or “abiotic” characteristics of the likely potential receiving environment may have a great impact on the ability of an LMO to survive and persist.

Geography and climate – Geography encompasses characteristics such as latitude, which will influence day length and altitude. Climate encompasses temperature, precipitation, humidity, wind and other meteorological measures over long periods of time. For the purposes of environmental risk assessment, geography and climate are among the most important factors that impact on the ability of an LMO to survive and persist. For LM plants, temperature and precipitation are likely to be key determinants. Seasonality (variations in climate with an annual cycle) can also be an important consideration in the potential survival and persistence of an LMO.

Soil – The type and quality of soil can greatly influence the ability of an LM plant to survive or persist without land management. The type and quality of soil are heavily influenced by the organisms living in its proximity, but abiotic factors such as climate, geography and its topology will also play a role in determining its characteristics (e.g. mineral content, moisture level, texture, etc.).

Management status – The management status of an environment is a measure of how much human intervention takes place in order to maintain a particular condition. A separate but related concept is “disturbance” which can be considered as the amount of human activity that affects the environment but without the intention of maintaining a particular condition. Management and disturbance may greatly influence the ability of an LMO to survive and persist in the environment. Receiving environments can be highly managed or unmanaged, and highly disturbed or undisturbed.

4.2.2 Biological characteristics

The biological characteristics of the likely potential receiving environment consist of all the living organisms present in the environment, its biological communities and the interactions among them.

Both managed and unmanaged environments contain complex biological characteristics that pose challenges for environmental risk assessments.

As any other organism, an LMO released into the environment is expected to have many interactions with other organisms. For the purposes of environmental risk assessment, it is critical to develop verifiable risk scenarios and identify the appropriate species that may be impacted by the presence of the LMO in the environment. For example, gene flow and, possibly, introgression are more likely to occur when sexually compatible species are present in the likely potential receiving environment.

Risk assessors should strive to identify criteria to characterize representative species in the likely receiving environment since their interactions with the LMO are informative for the assessment endpoints.

4.3 Intended use

The intended use of an LMO can provide valuable information and context for the risk assessment process. Understanding the intended use also allows a risk assessor to structure the exposure assessment by starting with the environment where the LMO will be deliberately introduced, and then considering whether or not the LMO is likely to disseminate or persist outside of this environment.

To illustrate how the intended use can affect the likelihood of a risk posed by an LMO, a hypothetical case of an LM tree being used for wood production could be considered, in which the first flowering would occur after 15 years of planting, but logging would takes place after only 10 years. As such, the intended use would result in the LM tree being logged before its first flowering. Consequently, in this hypothetical case, the intended use would influence the likelihood of potential outcrossing of this LM tree.

Information regarding the intended use of the LMO may also take into account any new or changed use in comparison to the recipient or parental organism(s), for example, in cases where the recipient or parental organism(s) is a crop for human consumption but the intended use of the LMO is the production of a compound for pharmaceutical or industrial use.

The scale and type of the introduction into the environment, for example, field trials or commercial releases, and whether a risk management strategy is proposed, may also be relevant when considering the intended use. Many regulatory frameworks, for instance, require that submissions for field trials be accompanied by information on risk management strategies to reduce exposure to the LMO.

Considerations on the intended use may also take into account national and regional experiences with similar organisms, their management and exposure to the environment.

5. Conducting the risk assessment

Conducting the risk assessment involves synthesizing what is known about the LMO, its intended use and the likely potential receiving environment to establish the likelihood and consequences of potential

adverse effects to biodiversity and human health resulting from the introduction of the LMO. Risk assessors need to identify the information needed and understand how it will be used. Using and interpreting existing information, as well as identifying information gaps and understanding how to deal with scientific uncertainty are crucial during the risk assessment.

Some risks can be assessed based on existing scientific literature and available information alone. Others may require laboratory experiments (e.g. early tier toxicology testing), confined field experiments or other scientific observations. Scientifically sound methodologies should be determined and documented for testing any identified risk scenario. When assessment methods are well described, risk assessors and subsequent reviewers are better equipped to determine whether the information used was adequate and sufficient for characterizing the risk.

Example 7 – Data acquisition, verification and monitoring

"The importance of the data acquisition, verification, and monitoring process in the development of accurate risk assessments has been emphasized. Models, no matter how sophisticated, are simply attempts to understand processes and codify relationships. Only the reiteration of the predictive (risk assessment) and experimental (data acquisition, verification, and monitoring) process can bring models close to being a true picture of reality."

Source: UNEP/IPCS (1994).

Considerations of uncertainty are undertaken throughout the whole risk assessment process. The risk assessment methodology as set out by the Cartagena Protocol states that "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". 7/

Although uncertainty can be often addressed by requesting additional information, the necessary information may not always be available or new uncertainties may arise as a result of the provision of additional experimental data. As uncertainty is inherent in the concept of risk, it is important to consider and analyse, in a systematic manner, the various forms of uncertainty (e.g. types and sources) that can arise at each step of the risk assessment process. The source(s) of uncertainty may originate from the lack of data/information and/or the choice of experimental design. The nature of uncertainty may be described for each identified source of uncertainty arising from: (i) lack of information, which may be reduced with more research/testing; (ii) limitations of the current state of knowledge; and (iii) inherent variability among, for example, different populations in the receiving environment.

If the level of uncertainty changes during the risk assessment process (e.g. by provision of new information), an iteration of parts or the entire risk assessment process may be needed.

It is important to note that while scientific uncertainty is taken into consideration during the various steps of the risk assessment process and the results of uncertainty considerations may be included in the risk assessment report, ultimately, it is the responsibility of the decision-makers to decide how to take into account the precautionary approach when making a decision on an LMO.

7/ Paragraph 7(f) of Annex III.

Example 8 – Scientific uncertainty

"There is no internationally agreed definition of 'scientific uncertainty', nor are there internationally agreed general rules or guidelines to determine its occurrence. Those matters are thus dealt with – sometimes differently – in each international instrument incorporating precautionary measures."

Source: IUCN (2003).

The following sections address the steps of the risk assessment methodology described in paragraph 8 of Annex III to the Protocol.

These steps describe a structured and integrated process, whereby the results of one step are relevant to subsequent steps. The risk assessment process may also need to be conducted in an iterative manner, where certain steps may be repeated or re-examined to increase or re-evaluate the reliability of the risk assessment. If, during the process, new information arises that could change the outcome of a step, the risk assessment may need to be re-examined accordingly.

5.1 Identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects

The first formal step of the risk assessment is "an identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects on biological diversity in the likely potential receiving environment, taking into account risks to human health". 8/

What constitutes an "adverse effect" will depend on the context and scope of the risk assessment, taking into account, as appropriate, the specific protection goals as seen above.

Example 9 – Potential adverse effects

"With every new emerging technology, there are potential risks. For LMOs, the potential risks include:

- The danger of unintentionally introducing allergens and other anti-nutrition factors in foods;
- The likelihood of transgenes escaping from cultivated GM crops into wild relatives;
- The potential for pests to evolve resistance to the toxins produced by GM crops;
- The risk of these toxins affecting non-target organisms."

Source: GMAC Singapore (website).

The molecular and phenotypic characterization of an LMO provides the basis for identifying differences, both intended and unintended, between the LMO and its recipient or parental organism(s). Molecular analyses may be performed to characterize the products of the modified genetic elements, as well as of other genes that may have been affected by the modification. Data on specific expression patterns may be relevant for risk assessment in order to determine exposure, and may also include data confirming the absence of unintended products (e.g. in the case, for instance, where the gene product is intended to function only in a specific tissue, data may be used to confirm its specificity in that tissue and demonstrate its absence in other tissues).

8/ Paragraph 8(a) of Annex III.

Other phenotypic data are often presented to indicate that the LMO is behaving as anticipated. This could include data on reproductive characteristics, alterations in susceptibility to pests and diseases, tolerance to abiotic stressors, etc.

Once the potential adverse effects have been identified, the risk assessment proceeds to estimating the likelihood and consequences of these effects. To this end, developing risk scenarios may, in some cases, provide a useful tool.

A risk scenario may be defined as "a sequence of events with an associated consequence" (Transport Canada, 2004). In the context of risk assessment of LMOs, a risk scenario may be explained as a scientifically supportable chain of causal events through which the LMO might have an adverse effect on an assessment endpoint.

Example 10 – A risk scenario

"The possibility that growing Bt corn may kill ladybird beetles due to ingestion of the Bt protein when preying on insects feeding on the GM corn, thereby reducing the abundance of coccinellids in the agroecosystem and increasing the incidence of pests."

Source: Hokanson and Quemada (2009).

A well defined risk scenario should be scientifically plausible and allow the assessor to identify information that is necessary for assessment of risks.

Although some risk scenarios may appear to be obvious (e.g. potential for insect-resistant plants to affect insect herbivore populations), it is always useful to identify the risk scenarios fully.

Clear and well-defined risk scenarios can also contribute to the transparency of risk assessment because this allows others to consider whether or not the subsequent steps of the risk assessment have been adequately performed, and also facilitates the consideration of possible strategies to manage the identified risks.

A common challenge in generating a well-defined risk scenario is to choose representative species that would be exposed to the LMO. This is why an exposure assessment should be considered when selecting assessment endpoints.

When establishing risk scenarios, several considerations may be taken into account. These include, for example: (i) gene flow followed by undesired introgression of the transgene into species of interest; (ii) toxicity to non-target organisms; (iii) allergenicity; (iv) tri-trophic interactions and indirect effects; and (v) resistance development. The following paragraphs explain some of these considerations in more detail:

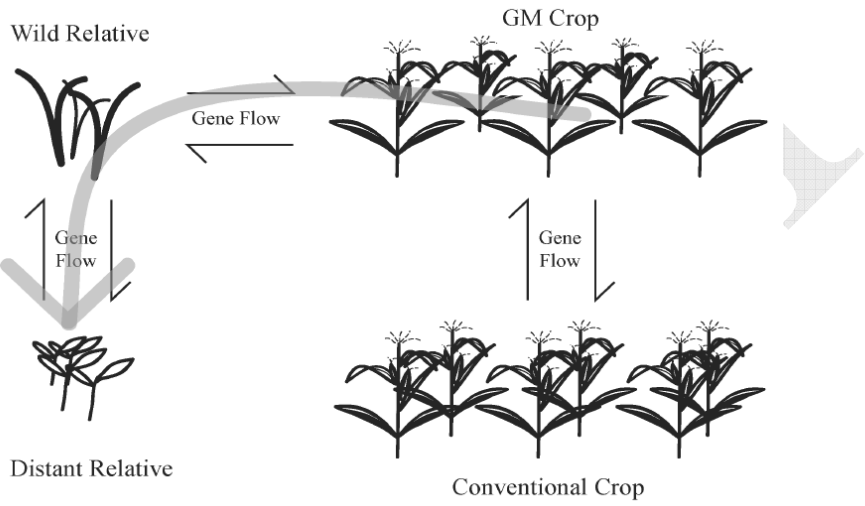
Gene flow followed by undesired introgression of the transgene in species of interest – Gene flow is a term used to indicate the transfer of genetic material from one population or species to another. Gene flow may be horizontal (i.e. without involvement of sexual crossing) or vertical (e.g. via pollen).

In the case of plants, vertical gene flow may occur even between organisms that are located fairly far away from each other since pollen can be carried large distances by the wind or insects, for instance.

The potential for gene flow from an LMO to non-modified organisms is first evaluated by investigating whether sexually compatible species are present in the receiving environment.

If sexually compatible species are present in the receiving environment, there is a potential for gene flow from the LMO to these species. Whether or not the transgene can potentially introgress into the population of the sexually compatible species will be largely determined by the biology of the recipient or parental organism(s) and of the LMO itself (see considerations regarding the likelihood and consequences of gene flow and introgression in Sections 5.2 and 5.3).

Figure 2 – Gene flow to conventional crops and distant relatives through "genetic bridges"



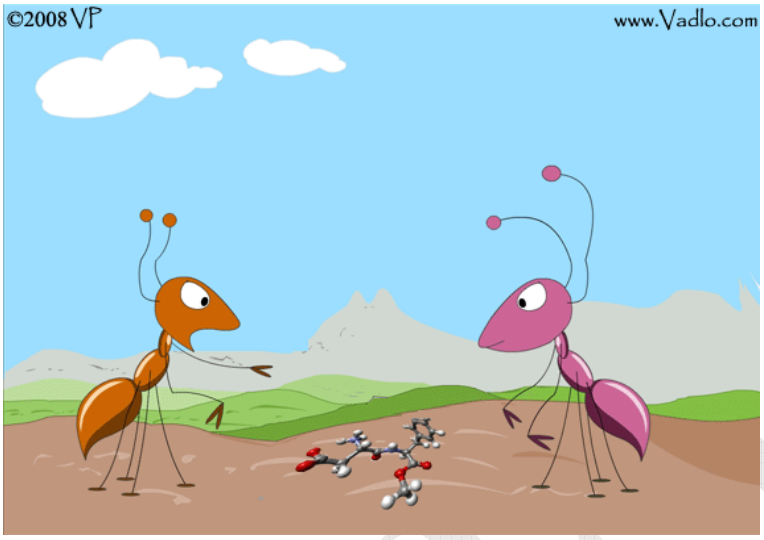
Source: Heinemann (2007).

Toxicity to non-target organisms – The potential for an introduced gene product to be toxic to organisms in the environment is typically addressed by controlled exposure in the environment or by direct toxicity testing, or by a combination of the two. Non-target organisms may include, for instance, herbivores, natural enemies (e.g. parasitoids and predators), pollinators and pollen feeders, soil ecosystems and weeds.

If toxicity testing is needed, it typically follows a sequential series of tiered tests. Early tier studies involve highly controlled laboratory environments where representative or surrogate test species are exposed to high concentrations of the gene product being studied (i.e. worst case exposures) to determine whether there are any toxic effects. If toxic effects are observed in early tier tests or if unacceptable uncertainty exists, more realistic conditions representative of field-level exposures can be tested to determine the extent of the risk.

The gene products of transgenes in LMOs may be produced in very small quantities and may be difficult to isolate in the amounts required for toxicity testing. If this is the case, and it is determined that toxicity tests are required, the risk assessor may consider results from tests using gene products obtained from alternate sources (e.g. bacterial expression systems or the organism from which the transgene was derived), provided that these gene products are chemically and functionally equivalent.

Figure 3 – Exposure to non-target organisms



Source: VADLO (website).

Allergenicity – Allergies are a type of adverse immunological response that affects individuals who are predisposed to certain types of substances (i.e. allergens). Allergens are often proteins or peptides.

In considering allergenicity caused by LMOs, it is important to take into account the exposure to proteins newly expressed in the LMO and novel forms of these proteins that are unique to the LMO. This may, in some cases, only be possible using techniques that isolate all variants of the protein from the LMO, and not obtained from alternate (surrogate) sources (e.g. bacterial expression systems). In addition, the possibility that allergens known to exist in the recipient/parental organism may be produced in greater amounts, for example by over-expression of a gene that encodes for a protein that is known to be a common allergen, may also be taken into account.

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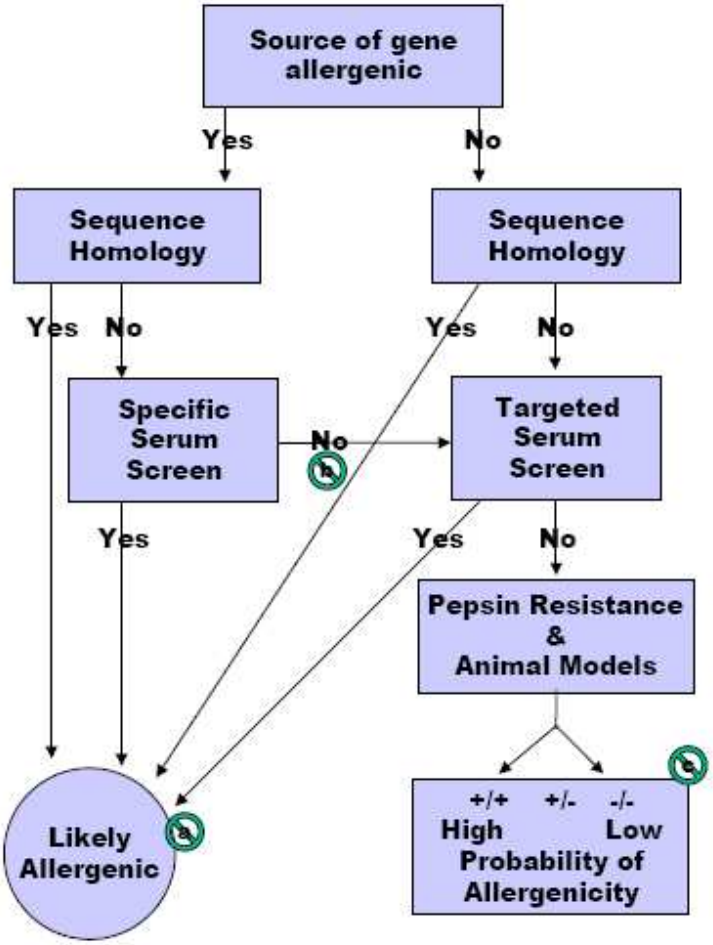
Example 11 – Assessment of the allergenic potential of foods derived from modern biotechnology



Footnotes:

(a) Any positive results obtained from sequence homology comparisons to the sequences of known allergens in existing allergen databases or from serum screening protocols, both conducted in accordance with the guidelines established in Sections 6.1, 6.2 and 6.3 of FAO/WHO (2001) indicate that the expressed protein is likely allergenic.

(b) The degree of confidence in negative results obtained in the specific serum screen is enhanced by the examination of larger numbers of individual sera as explained in Section 5.3 of FAO/WHO (2001). Conducting the specific serum screen with small numbers of individual sera when larger numbers of such sera are readily available should be discouraged.

(c) When positive results are obtained in both the pepsin resistance and animal model protocols, the expressed protein has a high probability to become an allergen. When negative results are obtained in both protocols, the expressed protein is unlikely to become an allergen. When different results are obtained in the pepsin resistance and animal model protocols, the probability of allergenicity is intermediate, although rational explanations may be possible in some situations.

Source: FAO/WHO (2001).

Tri-trophic interactions and indirect effects – "Tri-trophic interaction" is an important concept in ecology and occurs when a change at one trophic level indirectly affects trophic levels which are more than one step away. Consideration of tri-trophic interactions and indirect effects may be relevant to biodiversity protection goals.

Observations and experimentation to identify such effects are challenging because of the complexity of ecological interactions, the difficulty of establishing causality between observed variation and treatment effects (e.g. the presence of the transgene or gene product), and natural variability in populations over time. Moreover, in a food chain (or food web), effects at the trophic levels may become observable only at a later stage.

Example 12 – A tri-trophic interaction

"Suppose that there were a grassland where the major herbivore was a species of vole (n.b. a small rodent) which eats grass seeds and that this vole was able to reach population levels which allowed the vole to eat nearly all of the seeds. Further suppose that the main predator of this vole was a species of hawk and that this hawk was capable [of] eating enough voles to reduce the voles population to nearly zero (at least to the point that voles could no longer eat very many of the seeds). So, if the population of hawks is high, the population of voles is low and the grass produces lots of seeds. However, if the population of hawks is low, the vole population will be high, and the grass will disperse few seeds."

Source: Abrahamson (website).

Resistance development – The extensive use of herbicides and insect-resistant LM crops has the potential to result in the emergence of resistant weeds and insects. Similar breakdowns have routinely occurred with conventional crops and pesticides. Several weed species have developed resistance to specific herbicides which are extensively used in combination with herbicide-resistant LM crops. Insect-resistant Bt-crops similarly could lead to the emergence of Bt-resistant insects (FAO, 2004).

The extent of the adverse effect and possible consequences of the insurgence of resistant weeds and insects should be thoroughly considered in a risk assessment. Some regulatory frameworks require that risk management strategies be identified in order to lower the risk of resistance development.

Example 13 – Topics of concern

According to the International Centre for Genetic Engineering and Biotechnology (ICGEB), the main issues of concern derived from the deliberate introduction of LM crops (and their derived products) into the environment or onto the market have been classified as:

Risks to animal and human health – Toxicity and food/feed quality/safety; allergies; pathogen drug resistance (antibiotic resistance); impact of selectable marker;

Risks to the environment – Persistence of gene or transgene (volunteers, increased fitness of LM crop, invasiveness) or of transgene products (cumulative effects); susceptibility of non-target organisms; change in use of chemicals in agriculture; unpredictable gene expression or transgene instability (gene silencing); environmentally-induced (abiotic) changes in transgene expression; ecological fitness; changes to biodiversity (interference of tri-trophic interactions); impact on soil fertility/soil degradation of organic material;

Gene transfer – Genetic pollution through pollen or seed dispersal and horizontal gene transfer (transgene or promoter dispersion); transfer of foreign gene to microorganisms (DNA uptake); or generation of new live viruses by recombination (transcapsidation, complementation, etc.);

Risks for agriculture – Resistance/tolerance of target organisms; weeds or superweeds; alteration of nutritional value (attractiveness of the organism to pests); change in cost of agriculture; pest/weed management; unpredictable variation in active product availability; loss of familiarity/changes in agricultural practice.

Source: ICGEB (website).

5.2 Evaluation of the likelihood

This step entails an evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the LMO.

After the potential adverse effects of the LMO have been identified, the risk assessment proceeds to a formal analysis of the likelihood and consequence of these effects with respect to the identified assessment endpoints.

Although the steps of evaluating likelihood and consequences are dealt with separately in Annex III of the Protocol, some risk assessment approaches consider these steps simultaneously or in reverse order.

The likelihood of an adverse effect is dependent upon the probability of one or a series of circumstances actually occurring.

It is difficult to describe in detail an evaluation of likelihood or consequence without using an example because the evaluation is dependent on the nature of the LMO, the receiving environment and, if appropriate, on the risk scenario used. Some examples are given below.

For instance, if it is determined that undesired outcrossing of the transgene with a non-modified organism is possible (i.e. the two species are sexually compatible), in the evaluation of likelihood, the risk assessment may consider both the likelihood of the outcrossing and, if relevant, the likelihood of the establishment of the LMO progeny. Considerations of the latter may be based, for example, on assessing whether or not the transgene would affect the fitness level of the progeny (i.e. the capability of individuals to compete and reproduce in a given environment). If, for example, the transgene may induce a positive fitness effect, the likelihood that the population resulting from the outcrossing would increase is high. On the other hand, transgenes that have a negative fitness effect would result in a low likelihood that the population resulting from the outcrossing would increase. Transgenes that have a neutral impact on fitness may persist in populations at low levels depending on the rate of outcrossing or introgression as well as on the overall population dynamics of the species.

Example 14 – Likelihood of introgression

"To evaluate a possible ecological effect of an inserted gene being introgressed into a natural population it is important to estimate the probability of introgression. Such a probability estimate can be obtained from measurements of hybridisation rates, assumed selective advantage of inserted gene, and fitness measurements of parent plants, hybrid plants, and plants from the first and second back-cross generations.

If hybrids are formed and it is likely that these hybrids are able to survive the consequences should be discussed."

Source: Ministry of Environment and Energy Denmark (1999).

In another example, in a case where the risk scenario involves the toxicity of an LMO plant (or a substance produced by an LMO plant) to an insect herbivore, the analysis of likelihood may consider the probability that the insect will be present, that the insect will feed on the LMO and that the insect will ingest a sufficient quantity of the LMO to suffer an adverse effect. Likelihood may consider probabilities on an individual level (e.g. what the chances are that an individual herbivore might consume the LM plant) or on a population level (e.g. what percentage of the population of herbivores will come into contact with the LMO) or both.

5.3 Evaluation of the consequences

The consequences of the adverse effects, should these occur, may be severe, minimal or anywhere in between. The evaluation of the consequences may consider the effects on individuals (e.g. mortality, reduced or enhanced fitness, etc.) or on populations (e.g. increase or decrease in number, change in demographics, etc.) depending on the adverse effect being evaluated.

The risk assessment should consider the consequences of each adverse effect based on a concerted analysis of what is known about the LMO, the likely potential receiving environment and the assessment endpoints, as well as the likelihood assessment.

Example 15 – Consequences of effects to non-target organisms

When the inserted trait causes the plant to produce potentially toxic compounds, or if flower characteristics are changed, i.e. colour, flowering period, pollen production, etc., then effects on pollinators have to be measured. A test of effects on honeybees (*Apis mellifera*) is obligatory because of the importance of honeybees as pollinators of both wild and crop species and because standardized test protocols testing for effects of conventional pesticides exist for this pollinator. These tests include exposure through nectar and pollen.

Source: Ministry of Environment and Energy Denmark (1999).

Furthermore, using an example where gene flow and introgression could lead to a potential adverse effect, what impact the presence of a transgene will have on biodiversity will depend on its effect on individual fitness as well as on the importance of that species relative to the protection goals. For instance, if a sexually compatible species, present in the receiving environment, is directly relevant to a biodiversity protection goal (e.g. it is a protected species), then the impact on biodiversity can be assessed by looking directly at the impact of the transgene on the population. If the sexually compatible species is not directly related to a biodiversity management goal, then the impact of the expression of the transgene will be

dependent on indirect interactions. Indirect effects may be challenging to assess (see Section 5.1) and are dependent on the ecological importance of the species.

5.4 Estimation of the overall risk

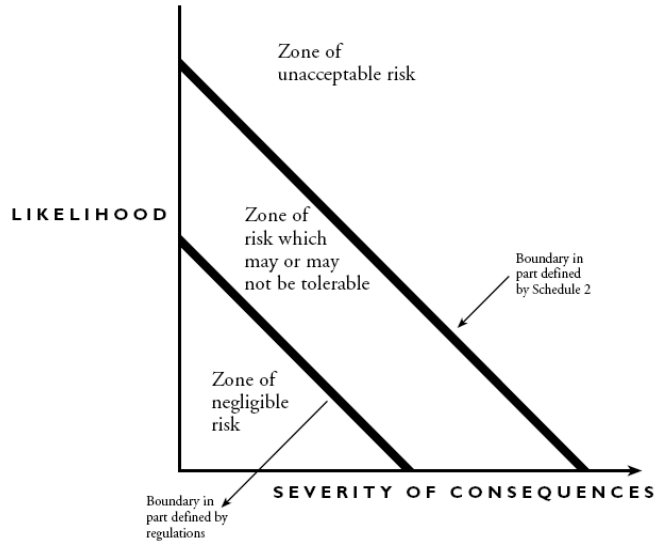
This step consists of the integration of likelihood and consequence of each of the individual risks identified through the preceding steps, and takes into account any relevant uncertainty that emerged, thus far, during the process. In some risk assessment approaches, this step is referred to as "risk characterization".

To date, there is no universally accepted method to estimate the overall risk but a variety of guidance materials are available that address this topic (see for instance, documents under "Scientific and technical issues/risk assessment" in the Biosafety Information Resource Centre (BIRC). 9/

In rare instances, the risk characterization results in a quantitative value (e.g. 6% of a population will be exposed to a stressor, and of that percentage half will experience mortality). More frequently, the risk characterization for an LMO will be qualitative. In such cases, a description of the risk characterization may be expressed as, for instance, 'high', 'medium', 'low', 'negligible' or 'indeterminate due to uncertainty or lack of knowledge'.

The outcome of this step is the assessment of the overall risk of the LMO. Once this is achieved, it is helpful to determine, as an internal quality control, whether the risk assessment has met the criteria established at the beginning of the process, also taking into account those criteria established in the relevant policies in practice with regard to the protection goals, assessment endpoints and thresholds.

Figure 4 – Estimation of overall risk



Source: ERMA NZ (1998).

9/ http://bch.cbd.int/database/resources.

5.5 Identification of risk management and monitoring strategies

Annex III of the Protocol states that the risk assessment methodology may entail "a recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks" and "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". 10/

5.5.1 Risk management

Risk management strategies refer to measures that may be implemented after the LMO is introduced into the environment (or placed on the market, if applicable) and aim at reducing the risks identified during the assessment to a level that are considered to be acceptable. Risk management strategies can be useful to increase confidence when dealing with uncertainty or, in the case where risks have been identified, to reduce the likelihood or impact of the potential adverse effect.

Example 16 – Application of management strategies for risks from the deliberate release or marketing of LMO(s)

"The risk assessment may identify risks that require management and how best to manage them, and a risk management strategy should be defined."

Source: The European Parliament and the Council of the European Union (2001).

Risk management strategies may aim at reducing the likelihood or consequences of potential adverse effects. These types of risk management strategies may be referred to as "*preventive measures*" and "*mitigation measures*", respectively. Some approaches to risk assessment may also include the identification of measures to control an adverse effect should it occur.

For LMOs, common risk management strategies have typically been designed to reduce the likelihood of exposure, but depending on the specific case, management options might include a variety of measures that are directly or indirectly related to the LMO. Some examples of risk management strategies for LMOs include: minimum distances from sexually compatible species if there is evidence that gene flow could cause adverse effects, destruction of seeds remaining in the field or of volunteer plants after harvest, restrictions from introduction into specified receiving environments, etc.

Certain risk assessment steps, particularly the evaluation of likelihood and consequences may need to be re-evaluated to take into account each of the identified risk management strategies, since these may affect the estimation of the overall risks.

10/ Paragraphs 8(e) and (f) of Annex III.

5.5.2 Monitoring

Some biosafety frameworks may request a plan for monitoring the receiving environment for adverse effects that may arise after the introduction of the LMO.

Monitoring after the release of the LMO aims at detecting changes (e.g. in the receiving environment(s) or in the LMO) that could affect the likelihood or consequences of one or more potential adverse effects.

Example 17 – Post-market monitoring

"Post-market monitoring may be an appropriate risk management measure in specific circumstances. Following the safety assessment, the need and utility for post-market monitoring should be considered, on a case-by-case basis, during risk assessment and its practicability should be considered during risk management."

Source: Health Canada (2006).

Monitoring strategies may be designed on the basis of the protection goals identified by national legislation and regulation, if available, and those parameters relevant to the indication of any increasing risk to the assessment endpoints. The strategies may include "general surveillance", designed to identify unexpected long-term effects of the LMOs or traits, or be "case-specific", where potential adverse effects identified during the risk assessment are investigated. Monitoring for the development of resistance in insect pests following introduction of pesticide-producing LM crops would be an example of a "case-specific" scenario. Monitoring for the abundance of species in an environment would be an example of "general surveillance".

Example 18 – Case-specific monitoring and general surveillance of LM plants

"The environmental monitoring of the GM plant will have two focuses: (1) the possible effects of the GM plant, identified in the formal risk assessment procedure, and (2) to identify the occurrence of adverse unanticipated effects of the GM plant or its use which were not anticipated in the environmental risk assessment. […] Appropriate case-specific monitoring measures should be developed on a case-by-case approach depending upon the outcomes of the risk assessment. Possible risks identified in the environmental risk assessment should be studied in hypothesis-driven experiments and tests.

The objective of general surveillance is to identify the occurrence of unanticipated adverse effects of GM plants or their use on human health or the environment that were not anticipated in the environmental risk assessment. Since no specific risk is identified, no hypothesis of risk can be tested, so it is difficult to propose specific methods to carry out general surveillance."

Source: EFSA (2006).

Where it is appropriate, other potential adverse effects such as delayed, cumulative, synergistic or indirect effects resulting from the LMO, the trait or the inserted or modified genes may be considered in the post-release monitoring strategies.

Since risk management and monitoring strategies will be highly specific for the LMO and its intended use in the likely potential receiving environment, it is essential that a detailed methodology for each identified

strategy also be identified. The methodology may include, for example, the frequency, locations and methods of sampling, as well as methods of analysis (e.g. laboratory testing).

Example 19 – Various types of monitoring according to the Australian Government

Routine monitoring inspections – these are based on risk profiling and sampling of a range of dealings, locations where dealings are undertaken, and organisations who are conducting dealings;

Follow-up visits – these are undertaken to follow-up on issues or to check the implementation of remedial action;

Review visits – monitoring of premises may be focused on a specific issue that is being reviewed by the Monitoring and Compliance Sections and visits are selected on that basis;

Audit visits – a comprehensive examination of an organisation's activities that includes specific visits to inform the audit process;

Investigation visits – these visits are based on inquiries into allegations of a breach of the Gene Technology Act 2000; and

Unannounced 'spot checks' – these are undertaken as a subset of the routine monitoring activities or as part of follow-up checks, incident reviews, or investigations.

Source: OGTR (2007).

6. References

Abrahamson WG (website) The *Solidago Eurosta* Gall Homepage – A Resource for Teaching and Research. Ecology and Evolution. Available at: http://www.facstaff.bucknell.edu/abrahmsn/solidago/gallresearch.html (access June 2010).

CFIA (website) Detection and Identification Method Criteria. Canadian Food Inspection Agency (CFIA). Available at: http://www.inspection.gc.ca/english/plaveg/bio/detecte.shtml (access May 2010).

EEA (1998) Environmental Risk Assessment - Approaches, Experiences and Information Sources. Environmental Issue Report No. 4, European Environmental Agency (EEA). Available at: http://www.eea.europa.eu/publications/GH-07-97-595-EN-C2/riskindex.html (access July 2010).

EFSA (2006) Opinion of the Scientific Panel on Genetically Modified Organisms on the Post Market Environmental Monitoring (PMEM) of genetically modified plants (Question No. EFSA-Q-2004-061). European Food Safety Authority (EFSA). Available at: http://www.efsa.europa.eu/en/efsajournal/doc/gmo_op_ej319_pmem_en,0.pdf (access June 2010).

ERMA NZ (1998) Annotated Methodology for the Consideration of Applications for Hazardous Substances and New Organisms under the HSNO Act 1996. Environmental Risk Management Authority of New Zealand (ERMA NZ), 30 pp. Available at: http://www.ermanz.govt.nz/help/faq-no.html (access June 2010).

FAO (2004) The State of Food and Agriculture: 2003–2004. Part I: Agricultural biotechnology: meeting the needs of the poor? Section B: The evidence so far. Food and Agriculture Organization of the United Nations. Available at: http://www.fao.org/docrep/006/Y5160E/y5160e00.htm (access May 2010).

FAO/WHO (2001) Evaluation of Allergenicity of Genetically Modified Foods. Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO), 29 pp. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=41976 (access June 2010).

GMAC Singapore (website) Genetically Modified Organisms. Genetic Modification Advisory Committee (GMAC) Singapore. Available at: http://www.gmac.gov.sg/Index_FAQs_Genetically_Modified_Organisms.html (access August 2010).

GMO Safety (website) Available at: http://www.gmo-safety.eu (access August 2010).

Health Canada (2006) Guidelines for the Safety Assessment of Novel Foods. Food Directorate Health Products and Food Branch, Health Canada, June, 2006. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=101221 (access June 2010).

Heinemann JA (2007) A Typology of the Effects of (Trans)gene Flow on the Conservation and Sustainable Use of Genetic Resources. Food and Agriculture Organization (FAO), Background Study Paper No. 35, Rev. 1, 100 pp. Available at: ftp://ftp.fao.org/ag/cgrfa/bsp/bsp35r1e.pdf (access July 2010).

Hill RA (2005) Conceptualizing risk assessment methodology for genetically modified organisms. Environ. Biosafety Res. 4:67–70. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=41660 (access June 2010).

Hokanson K, Quemada H (2009) Improving risk assessment – problem formulation and tiered testing. Presented at SEARCA Agriculture and Development Seminar Series, 28 April 2009. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=101212 (access June 2010).

ICGEB (website) International Centre for Genetic Engineering and Biotechnology. Available at: http://www.icgeb.org/~bsafesrv/introduction/generalintro.html (access May 2010).

IUCN (2003) An Explanatory Guide to the Cartagena Protocol on Biosafety. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=41476 (access June 2010).

Ministry of Environment and Energy Denmark (1999) Ecological Risk Assessment of Genetically Modified Higher Plants (GMHP) – Identification of Data Needs. Ministry of Environment and Energy, National Environmental Research Institute (NERI) Denmark. NERI Technical Report, No. 303, 35 pp. Available at: http://www2.dmu.dk/1_viden/2_Publikationer/3_fagrapporter/rapporter/fr303.pdf (access July 2010).

OECD (2006) Guidance for the Designation of a Unique Identifier for Transgenic Plants. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=101186 (access June 2010).

OGTR (2007) Monitoring protocol in accordance with the Gene Technology Act 2000. Office of the Gene Technology Regulator, Department of Health and Aging, Australian Government, July 2007. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=101222 (access June 2010).

The European Parliament and the Council of the European Union (2001) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0018:EN:HTML (access June 2010).

Transport Canada (2004) TP 13905 Risk Management and Decision-Making Type 2A, Short Process. Available at: http://www.tc.gc.ca/civilaviation/systemsafety/pubs/tp13905/menu.htm (access June 2010).

UNEP (1995) International Technical Guidelines for Safety in Biotechnology. United Nations Environment Programme (UNEP). Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=42114 (access June 2010).

UNEP Division of Technology, Industry and Economics (website) Technical Workbook on Environmental Management Tools for Decision Analysis. Available at: http://www.unep.or.jp/ietc/publications/techpublications/techpub-14/1-EnRA3.asp (access June 2010).

UNEP/IPCS (1994) Training module No. 3. Section C – Ecological risk assessment. United Nations Environment Programme (UNEP)/International Programme on Chemical Safety (IPCS), p 177–222. Available at: http://www.chem.unep.ch/irptc/Publications/riskasse/C2text.pdf (access July 2010).

US Environmental Protection Agency (1998) Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F. Available at: http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=36512 (access June 2010).

VADLO (website) Biomedical and Life Sciences Search Engine. Available at: http://www.vadlo.com (access May 2010).

WHO (2004) IPCS Risk Assessment Terminology. Part 2: IPCS Glossary of Key Exposure Assessment Terminology. World Health Organization (WHO). Available at: http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf (access June 2010).

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Module 4:

Preparing a risk assessment report

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Using this module

This module explains how risk assessors may communicate the outcomes of a risk assessment in a report, structured so as to provide information on: (i) background, context and scoping of the risk assessment; (ii) characterization and estimation of risks; (iii) description of risk management and monitoring strategies; (iv) consideration of remaining uncertainty; and (v) recommendations as to whether or not the risks are acceptable or manageable.

An overview of what type of information could be included under each of these topics is also part of this module.

1. Introduction

The outcomes of a risk assessment are often presented in the form of a written report prepared by the risk assessor(s).

The report is primarily intended to assist the decision makers in making informed decisions regarding the safe use of a living modified organism (LMO).

Presenting the results of a risk assessment could be categorized as a form of risk communication. As in any form of communication, risk assessors should be mindful of the intended recipients, which in addition to decision-makers may also include regulators, risk managers, other risk assessors, the general public, etc.

Example 1 – Risk communication

Risk communication is the interactive exchange of information and opinions among assessors, risk managers, consumers, industry, the academic community and other interested parties throughout the risk analysis process. The information exchange concerns risk-related factors and risk perceptions, including the explanation of risk assessment findings and the basis of risk management decisions. It is vitally important that risk communication with the public comes from credible and trusted sources.

Source: FAO (2001).

It is important that the report is presented in a well-structured form, which not only facilitates the deliberations of decision-makers, but also allows for an easier exchange of information and experience. The context and scope of the risk assessment should be clearly explained as other institutions (e.g. in the same or in different countries) may have an interest in understanding how the risk of a particular LMO was assessed.

With regard to sharing of information, a Party to the Protocol is required to submit to the Biosafety-Clearing House (BCH) all "summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology" (Article 20). This will

include all risk assessments generated to support decisions regarding LMOs for intentional introduction into the environment (Articles 8, 10 and 13) or for direct use as food or feed, or for processing (Article 11) whether they are triggered by a transboundary movement or by an internal request.

The required contents and format of a risk assessment report are generally defined by the competent national authority/authorities (CNA/s) that have the responsibility to make decisions on the LMO(s) in the context of the national biosafety framework.

A risk assessment report typically comprises an analytical synthesis of all the relevant steps and results of the risk assessment process, including an overview of the context and scope of the risk assessment, methodology used and a detailed summary of the results of the overall risk estimation, including the identification of individual risks, as well as the likelihood and consequences of the potential adverse effects.

The report may also contain an evaluation of the availability and quality of the scientific and technical information that were deemed necessary to perform the assessment and characterize the risks, and whether there were gaps in the information.

An analysis of all identifiable uncertainties, including those identified at each step of the risk assessment process as well as the remaining uncertainties at the end of the risk assessment, and how they may impact the overall conclusions of the assessment is also a critical element in the report.

Finally, the risk assessment report also often contains a set of recommendations regarding the acceptability and manageability of the risks posed by the LMO, and the identification of appropriate risk management and monitoring strategies.

The information above may be organized under five broad topics depending on the requirements of the national authority that is responsible for the risk assessment:

(a) Background, context and scoping of the risk assessment;
(b) Characterization and estimation of risks;
(c) Description of risk management and monitoring strategies identified during the risk assessment;
(d) Consideration of remaining uncertainty; and
(e) Recommendations as to whether or not the risks are acceptable or manageable.

An overview of the information which may be included under each of these topics may be found in the following sections of this module.

2. Background, context and scoping of the risk assessment

This part of the report focuses on describing issues that were considered while setting the context and scope of the risk assessment. Basically, this section of the report sets the scene for the reader to follow a clear progression through the subsequent sections of the report.

A risk assessment report usually specifies the mandate that was given to the risk assessor(s) and includes a description of the procedure that was followed in conducting the risk assessment, an indication of which institution carried out the risk assessment, and which, if any, other institutions were consulted or were part of the process. Any other information that helps in understanding the context in which the risk assessment was carried out is also typically included in this part of the report.

Previous approvals or prohibitions of the same LMO, if any, including the regulatory status of the LMO in the country of export or import as well as in any other country may also be included in this section, if appropriate.

The report should describe how the requirements of the national regulatory framework were taken into account, including which protection goals were identified as relevant in the context of the risk assessment and how assessment endpoints were selected.

In summary, the following information may be included in this section of the report:

(a) Contact details of the LMO developer;
(b) Type of approval sought (e.g. introduction into the environment);
(c) Contact details of the institution responsible for the risk assessment;
(d) Relevant regulation;
(e) Relevant protection goals and assessment endpoints;
(f) Previous approvals or prohibitions of the same LMO;
(g) Overview of the terms of reference for the risk assessment; and
(h) Consulted experts or panel of experts, if applicable, and how the involved experts were chosen and how any conflict of interests was managed.

In some cases, the bulk of information presented in this section of the report may be extracted from the request triggering the risk assessment, the national regulatory framework, including environmental and biosafety policies or guidelines, and national biosafety-related databases.

3. Characterization and estimation of risks

This section of the report focuses on the outcomes of the risk assessment steps in accordance with Annex III of the Protocol and as described in Module 3.

Depending on the specific mandate and scope of the risk assessment, the following information may be included in this section of the report:

(a) Description of the LMO (e.g. recipient or parental organism(s), transformation method, inserted or modified sequences, novel traits, purpose of the genetic modification), its intended use and the likely potential receiving environment(s), including considerations on how the baselines were established and appropriate comparator(s) chosen;
(b) Considerations of the availability and quality of information used during the risk assessment;
(c) Methodology used in the risk assessment, explaining, if necessary, the use of terms;
(d) Description of the potential adverse effects and risk scenarios arising from the novel characteristics of the LMO;
(e) Analyses of the likelihood and consequences of each identified potential adverse effect; and
(f) Estimation of the overall risk posed by the LMO.

The information relevant to each of the items above may vary in nature and level of detail on a case-by-case basis, depending on the LMO concerned, its intended use and the likely potential receiving environment.

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While information related to the description of the LMO and its intended use may be obtained in part from the LMO application, the bulk of information to be presented in this section of the report is obtained through the risk assessment process for the specific case at hand.

4. Description of risk management and monitoring strategies

If risk management and monitoring strategies were identified during the risk assessment process (see Module 3), the risk assessment report should contain a section detailing any strategies to minimize the risks identified.

The risk assessment report may include, for instance:

(a) How each identified strategy is expected to contribute to minimizing the likelihood or consequence of potential adverse effects (e.g. by reducing the exposure to the LMO or the consequences of the potential harm);
(b) Details about the methodology for each identified risk management or monitoring strategy, including, for instance, the frequency, locations and methods of sampling, as well as methods of analysis, including laboratory testing when appropriate;
(c) Any uncertainty regarding the effectiveness of any such management or monitoring strategy;
(d) An indication as to whether and how different management strategies can be combined to further minimize uncertainty or identified risks; and
(e) Considerations on unintentional introduction into the environment and emergency measures as appropriate (see Article 17).

5. Consideration of remaining uncertainty

As seen in the previous module (Module 3, Section 5), uncertainty is an inherent component of any risk assessment, and should be considered in a systematic manner at each step of the risk assessment process. Nevertheless, at the end of the risk assessment, uncertainties may still remain with regard to one or more specific steps in the process or about the likelihood or consequences of the potential adverse effects.

Annex III of the Protocol addresses this matter by requiring that “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”. 1/

Considerations of remaining uncertainties should be included in the risk assessment report. These considerations may include:

(a) Identification of major information gaps and, where appropriate, indication of whether gathering additional data (either before the release or after it by monitoring) would significantly increase the overall confidence in the results of the risk assessment;
(b) An analysis of uncertainty, including its types (e.g. gaps in the available information, limitations of the assessment methodology);

1/ Paragraph 8(f) of Annex III.

(c) Discussion of the level of scientific support to issues where there is uncertainty, including an analysis of different scientific views;
(d) Discussion of any assumptions used in assessing the risks, including their strengths and weaknesses;
(e) Discussion of the potential for uncertainties to impact on the overall conclusions of the risk assessment; and
(f) Identification of any threats of serious or irreversible damage to the environment (basis for the adoption of the precautionary approach).

Example 2 – Uncertainty and a precautionary approach

"The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty. Decision-makers need to be aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information. Judging what is an "acceptable" level of risk for society is an eminently *political* responsibility. […] Where possible, a report should be made which indicates the assessment of the existing knowledge and the available information, providing the views of the scientists on the reliability of the assessment as well as on the remaining uncertainties. If necessary, it should also contain the identification of topics for further scientific research."

Source: Commission for the European Communities (2000).

6. Recommendations as to whether or not the risks are acceptable or manageable

Recommendations are one of the most important sections of a risk assessment report as they take into account the outcomes of the risk assessment to provide direct science-based advice to the intended recipients of the report. A recommendation as to whether or not the risks are acceptable or manageable should be kept within the scope of the risk assessment and should be based on its findings.

It is important to note that risk assessor(s) are requested to recommend whether the risks are "acceptable" or not. However, the definition of "acceptability" may not be part of a risk assessment but could be pre-established, for example, in thresholds included in government policies or in the mandate given to the risk assessor. Likewise, the final decision on whether to approve (with or without conditions) or prohibit the specific use of the LMO is taken during the decision-making process, which may take into account, depending on the national regulatory framework and among other things, government policies, public opinion, costs of the risk management measures and socio-economic considerations.

In addition to the issues mentioned above, the recommendations section of the report may also include any relevant information to be considered by the decision-makers prior to making a decision. Some issues that may be relevant include:

(a) A recommendation as to whether or not one or more risk management or monitoring strategies should be implemented and, if so, the specific conditions for each such strategy (see Section 4 above);
(b) Considerations of remaining uncertainties (see Section 5 above); and
(c) A recommendation as to whether and when the risk assessment should be re-visited.

7. References

Commission for the European Communities (2000) Communication from the Commission on the precautionary principle. Commission of the European Communities, Brussels, 29 pp. Available at: http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf (access May 2010).

FAO (2001) Genetically Modified Organisms, Consumers, Food Safety and the Environment. Food and Agriculture Organization (FAO), Rome, 35 pp. Available at: http://bch.cbd.int/database/record-v4.shtml?documentid=41952 (access May 2010).

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Annex II

SUMMARY OF THE RESULTS OF THE ASSESSMENT QUESTIONNAIRE

Participants to the Pacific subregional workshop on capacity-building and exchange of experiences on risk assessment (Nadi, Fiji, 4–7 July 2010) and the Asian subregional training course on risk assessment of living modified organisms (Siam Reap, Cambodia, 12–16 July 2010) were invited to complete a questionnaire to evaluate the workshop/training course and the quality of a draft training manual used as a teaching tool.

Thirty three participants answered the questionnaire. The numbers below indicate the percentage of respondents and their level of agreement to each of the statements on the left column.

A. Objectives of the workshop/training course

Level of agreement	Strongly disagree (%)	Slightly disagree (%)	Neutral / Indifferent (%)	Slightly agree (%)	Strongly agree (%)
The workshop/training course:					
Provided hands-on training in preparing and evaluating risk assessment reports in accordance to the articles and Annex III of the Protocol.	0	0	0	45	55
Provided tools for understanding how an interdisciplinary team can be established in the context of risk assessment	0	3	9	42.5	45.5
Helped develop skills on how to use and interpret existing information, as well as identifying and addressing information gaps	0	0	0	42	58
Helped understand how to establish baseline information relevant for the risk assessment	0	0	0	52	48

B. Quality of the training material

Level of agreement	Strongly disagree (%)	Slightly disagree (%)	Neutral / Indifferent (%)	Slightly agree (%)	Strongly agree (%)
The training material distributed at the beginning of the training course:					
Is a useful tool for training on risk assessment	0	0	3	30	67
Is easy to understand and follow	0	0	15	33	52
Comprises an adequate overview of the risk assessment process	0	0	3	48.5	48.5
Is useful for a wide range of users	0	3	12	45.5	39.5

C. Quality of the training modules

Level of agreement	Strongly disagree (%)	Slightly disagree (%)	Neutral / Indifferent (%)	Slightly agree (%)	Strongly agree (%)
The subjects of the modules listed below were covered adequately:					
Module 1 – Overview of Biosafety and the Cartagena Protocol on Biosafety					
What is biosafety?	0	0	3	18	79
What are living modified organisms?	0	0	0	18	82
History of the Cartagena Protocol on Biosafety	0	3	3	15	79
Objective and scope of the Cartagena Protocol on Biosafety	0	0	0	15	85
LMOs for intentional introduction into the environment - Advanced Informed Agreement (AIA)	0	0	9	15	76
LMOs for direct use as food, feed, or for processing (LMOs-FFP)	3	0	9.5	28	59.5
Competent national authorities	0	0	0	30	70
Risk assessment (Article 15 and Annex III)	0	0	0	27	73
Biosafety Clearing-House	0	0	3	30	67
Other international biosafety-related bodies	0	0	9	33	58
Module 1 (as a whole)	***0***	***0***	***0***	***30***	***70***
Module 2 – Preparatory Work: Understanding the context in which a risk assessment is carried out					
National protection goals and assessment endpoints	0	0	12	21	67
National biosafety framework	0	0	0	33	67
Competent national authorities	0	0	0	30	70
Scientific advisory body	0	0	3	30	67
Responsibilities of the risk assessor(s)	0	0	3	33	64
Roster of experts on biosafety	0	0	6	39	55
Stakeholder participation	0	3	9	30	58
Module 2 (as a whole)	***0***	***0***	***0***	***33***	***67***

Level of agreement	Strongly disagree (%)	Slightly disagree (%)	Neutral / Indifferent (%)	Slightly agree (%)	Strongly agree (%)
The subjects of the modules listed below were covered adequately:					
Module 3 – Conducting the risk assessment					
Selecting relevant assessment endpoints or representative species	0	0	6	33	61
Establishing the baseline	0	0	3	33	64
Establishing the appropriate comparator(s)	0	3	6	39	52
Living modified organism	0	0	0	27	73
Likely potential receiving environment(s)	0	0	6	36	58
Intended use	0	0	9	24	67
Step 1 – Identification of any novel genotypic and phenotypic characteristics associated with the LMO that may have adverse effects	0	0	9	52	39
Step 2 – Evaluation of the likelihood	0	0	3	39	58
Step 3 – Evaluation of the consequences	0	0	3	42	55
Step 4 – Estimation of the overall risk	0	0	3	45	52
Step 5 – Identification of risk management and monitoring strategies	0	0	3	47	50
Module 3 (as a whole)	***0***	***0***	***3***	***41***	***56***
Module 4 – Preparing a risk assessment report					
Background, context and scoping of the risk assessment	0	0	0	27	73
Characterization and estimation of risks	0	0	0	30	70
Description of risk management and monitoring strategies	0	0	0	36	64
Consideration of remaining uncertainty	0	0	3	36	61
Recommendations as to whether or not the risks are acceptable or manageable	0	0	3	36	61
Module 4 (as a whole)	***0***	***0***	***0***	***30***	***70***
