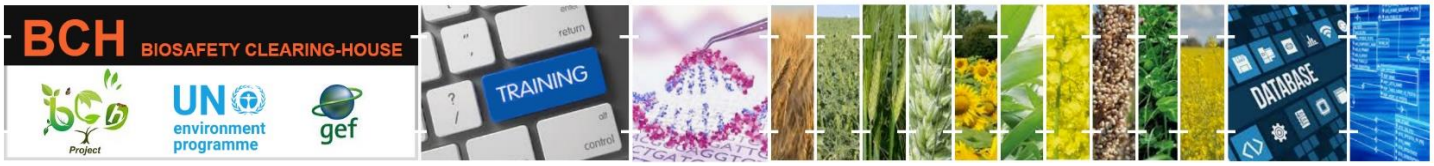

A User's Guide to the Central Portal of the Biosafety Clearing House

An introduction to the Cartagena Protocol on Biosafety

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Reproduction

Disclaimers

Please note that this module has been prepared to assist in understanding the Cartagena Protocol on Biosafety. It is not intended to provide legal interpretation of the Protocol or decisions made by the Conference of the Parties serving as the meeting of the Parties to the Protocol. Please refer to the original text of the Protocol and COP-MOP decisions for any further information.

Module Outline

1. Introduction to the Module

What you will learn in this module:

This module briefly outlines some of the key elements of the Cartagena Protocol that are of importance for the Biosafety Clearing-House. It includes briefs on the background and purpose of the Protocol, working procedures that apply, and institutional and administrative arrangements.

Context:

The UNEP-GEF Project for ***Capacity Building for Effective Participation in the Biosafety Clearing-House*** (BCH-I)[1], in collaboration with the Secretariat of the Convention on Biological Diversity (SCBD), prepared a modular training package aimed at providing a practical "how-to" guide for countries to assist them in learning, understanding, using, and setting up national access to the BCH. The training package was updated in October 2012 within the UNEP-GEF Project for ***Continued Enhancement of Capacity Building for Effective Participation in the BCH*** (BCH-II)[2] and presently in September 2023 within the UNEP-GEF Project for ***Sustainable Capacity Building for Effective Participation in the Biosafety Clearing House*** (BCH-III)[3]. The training package was designed to be flexible and is tailored to meet the diverse needs of different countries, allowing them to select those tools that are most useful to their situation, needs and priorities. The training package is divided into several modules[4], each addressing one element of the BCH.

Audience:

This module is designed to provide guidance to users of the Biosafety Clearing House (BCH). It is developed for a non-technical audience with little or no knowledge of the Cartagena Protocol and the BCH, but with a need to understand the Cartagena Protocol on Biosafety.

Purpose:

As an introduction to the Cartagena Protocol on Biosafety, this module provides the basics:

- To understand the decision-making and communications processes involved in the Cartagena Protocol;
- To introduce the Biosafety Clearing House as the major vector/support for the Protocol's communication process.

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[1] https://www.thegef.org/projects-operations/projects/2581
[2] https://www.thegef.org/projects-operations/projects/3856
[3] https://www.thegef.org/projects-operations/projects/5688
[4] Virtual Learning Environment at https://bch3-vle.unep.org/

This module does not intend to provide a detailed or exhaustive guide on the Cartagena Protocol itself. For this purpose, the IUCN Explanatory Guide to the Cartagena Protocol on Biosafety[5] might provide deeper and more documented information.

2. What is the Cartagena Protocol on Biosafety?

A "**Protocol**" is an agreement adopted within the framework of another international agreement. The **Cartagena Protocol on Biosafety**[6] (the Protocol) to the Convention on Biological Diversity is an international agreement (treaty), concluded and adopted in the framework of the Convention on Biological Diversity (CBD)[7] whose objectives are the conservation and sustainable use of biological diversity and the sharing of benefits arising from the use of genetic resources. The Protocol governs the movements of Living Modified Organisms (LMOs) resulting from modern biotechnology from one country to another[8].

The Protocol is called the '**Cartagena'** Protocol on Biosafety after the city in Colombia where it was originally scheduled to be concluded and adopted. The final text of the Protocol was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003.

States and regional economic integration organizations[9] that join the Protocol and agree to be legally bound by its provisions are called 'Parties' to the Protocol. An updated list of Parties to the Protocol can be found on the **Cartagena Protocol website**[10]. Only states or regional economic integration organizations that are Parties to the Convention on Biological Diversity may become Parties to the Cartagena Protocol.

3. What is the purpose of the Cartagena Protocol on Biosafety?

In accordance with the **precautionary approach** contained in Principle 15 of the Rio Declaration on Environment and Development (see Box 1), the objective of the

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[5] IUCN (2003), An Explanatory Guide to the Cartagena Protocol on Biosafety, https://portals.iucn.org/library/efiles/documents/eplp-046.pdf

[6] 'Cartagena protocol on Biosafety' https://bch.cbd.int/protocol/text/

[7] The convention on biological Diversity' CBD https://www.cbd.int/

[8] Article 19.3 of the Convention on Biological Diversity (CBD) (https://bch.cbd.int/protocol/text/) invites Parties to 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.

[9] 'Use of terms' IUCN (2003), An Explanatory Guide to the Cartagena Protocol on Biosafety, https://portals.iucn.org/library/efiles/documents/eplp-046.pdf , Pg 41 (j)

[10] "Status of ratification and entry into force », CBD, CPB https://bch.cbd.int/protocol/parties/

Protocol (*Article 1* 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** (**LMOs**) 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.

Box 1. Principle 15 of the Rio Declaration on Environment and Development states[11]:

"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."

Elements of the precautionary approach find reflection in a number of the provisions of the Cartagena Protocol, such as:

- The preamble[12], reaffirming "the precautionary approach contained in *Principle 15* of the Rio Declaration on Environment and Development";
- *Article 1*[13], indicating that the objective of the Protocol is "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development";
- *Article 10.6*[14] and *11.8*[15] stating « Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on biodiversity, taking into account risks to human health, shall not prevent a Party of import from taking a decision, as appropriate, with regard to the import of the LMO in question, in order to avoid or minimize such potential adverse effects."
- *Annex III*[16] on risk assessment, stating "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."

[11] Principle 15, Rio Declaration on Environment and Development (1992): https://documents-dds-ny.un.org/doc/UNDOC/GEN/N92/836/55/PDF/N9283655.pdf?OpenElement
[12] « Preamble CPB», CBD, CPB https://bch.cbd.int/protocol/text/
[13] « Objective », CBD, CPB, Art 1. https://bch.cbd.int/protocol/text/
[14] « Decision procedure», CBD, CPB, Art 10, https://bch.cbd.int/protocol/text/
[15] Procedure for LMO's intended for direct use as FFP, CBD, CPB, Art 11.8, https://bch.cbd.int/protocol/text/
[16] « Risk assessment», CBD, CPB, Annex III, https://bch.cbd.int/protocol/text/

4. How does the Cartagena Protocol work?

The Cartagena Protocol promotes biosafety by establishing practical rules and procedures for the safe transfer, handling and use of LMOs, with a specific focus on regulating **transboundary movements** of all LMOs (i.e., movements of LMOs across borders, from one country to another) that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. LMOs that are pharmaceuticals for humans are excluded from the provisions of the Protocol on transboundary movement if they are covered by other international agreements or arrangements. In general terms, the Protocol:

a) *Sets out general obligations and principles that are applicable to all LMOs;*

b) *Establishes specific rules and procedures that are applicable to the transboundary movement of specific categories of LMOs;*

c) *Establishes institutional arrangements for the administration, oversight and future evolution of the Protocol; and*

d) *Makes provision for capacity building and financial resources to assist developing countries and countries with economies in transition to implement the Protocol.*

4.1. The Advance Informed Agreement (AIA) procedure. LMOs for intentional introduction into the environment

Under the Protocol, the Advance Informed Agreement (AIA) procedure applies to the first intentional transboundary movement of an LMO for intentional introduction into the environment of the Party of import.

The Advance Informed Agreement or AIA procedure is designed to ensure that before an LMO is imported into a country for the first time for intentional introduction into the environment, the Party of import:

a) *Is notified about the proposed import;*

b) *Receives full information about the LMO and its intended use;*

c) *Has an opportunity to assess the risks associated with that LMO and to decide whether or not to allow the import.*

The AIA procedure includes (1) communication and (2) decision-making processes between the Parties:

(1) Communication process:

a) *The Party of export or the **exporter must notify** the Party of import of the proposed transboundary movement in advance of the first shipment, providing detailed, written information about the LMO and its intended use.*

b) *The Party of import is to acknowledge receipt of this information within 90 days.*

c) *Then, within 270 days of the date of receipt of notification, the Party of import must **make a decision and communicate it to the notifier and the BCH** either: (i) approving the import, (ii) prohibiting the import, (iii) requesting additional relevant information, or (iv) extending the 270 days by a defined period of time. Unless unconditional consent is given, the Party of import must give reasons for its decision.*

(2) Decision-making process:

a) *The decision of the Party of import must be based on a **risk assessment**;*

b) *Parties may also take into account certain **socio-economic considerations** in making a decision whether or not to allow the import of an LMO;*

c) *The Protocol allows Parties to take decisions based on the **precautionary approach** where there is a lack of scientific certainty due to insufficient scientific information and knowledge regarding the extent of possible adverse effects of an LMO.*

d) *The Protocol also contains provisions on **public participation** and on the treatment of **confidential information** (see Box 2).*

Box 2. Public participation

The Protocol requires Parties to promote and facilitate public awareness, education and participation on biosafety and to ensure that the public has access to information on LMOs that may be imported. In accordance with their laws and regulations, Parties are to consult the public in the decision-making process regarding LMOs, make the public aware of the results of decisions, and inform the public about access to the Biosafety Clearing-House.

Priority area 3 of the Programme of Work on public awareness, education and participation regarding LMOs[17] recommends that parties make use of relevant tools, guidelines and other related resources in developing training activities and materials related to public awareness, education and participation regarding LMOs. Parties are also encouraged to develop resources and make them available[18]. A pocket guide on access to information and public participation regarding LMOs has been developed jointly by CBD and Aarhus Convention[19] in May 2021.

[17] https://bch.cbd.int/protocol/cpb_art23_pow.shtml
[18] https://bch.cbd.int/onlineconferences/portal_art23/resources.shtml#tab=2
[19] https://bch.cbd.int/protocol/outreach/Pocket%20Guide.pdf

Confidential information

Under the AIA procedure and other procedures specified by the Protocol, the Party of import will require information on LMOs and intended uses of LMOs to allow its regulatory authorities to make an informed decision on whether to allow the import of the LMO in question. The notifier must make all required information available to the regulatory authorities, but it may identify certain information that should be treated as confidential - i.e., that should not be divulged to third parties, including the public. Where the Party of import and the notifier disagree as to which information should be kept confidential, the party of import should consult the notifier prior to disclosure and the notifier may decide to withdraw the application. The Protocol specifies that the following information may never be treated as confidential: (a) the name and address of the notifier; (b) general description of the living modified organism; (c) summary of risk assessment; and (d) methods and plans for emergency response.

Once information is made available to the BCH in accordance with *Article 20* and other provisions of the Protocol, it will not be considered confidential as the objective is to make this information publicly available.

Exceptions to the AIA procedure:

The Protocol's AIA procedure does not apply to:

- LMOs in **transit**[20];
- LMOs destined for **contained use**[21] in the Party of import;
- LMOs intended for direct use as Food or Feed or for Processing (**LMOs-FFP**)[22].

Nonetheless, Parties do have the right to regulate such transboundary movements if they wish. A Party should make available to the BCH any decision it takes regarding the transit through its territory of a specific LMO.

4.2. LMOs for direct use as Food or Feed, or for Processing (LMOs-FFP)

LMOs intended for direct use as food or feed, or processing (LMOs-FFP)[23] (*Article 11*) include a large category of agricultural commodities - these might be, for example, bulk shipments containing genetically modified corn, soybeans or other agricultural

[20] « Transit and contained use», CBD, CPB, Art 6(1) https://bch.cbd.int/protocol/text/

[21] « Use of terms», CBD, CPB, Art 3 and Art 6(2) https://bch.cbd.int/protocol/text/

[22] « LMOs-FFP» UNEP-GEF Biosafety projects, An introduction to the Cartagena protocol on Biosafety, para. 4.2 below.

[23] « Procedure for LMO's intended for direct use as food or feed or for processing », CBD, CPB, Art 11. https://bch.cbd.int/protocol/text/

commodities that are intended for direct use as Food or animal Feed or for Processing, but are not intended for use as seeds.

The Protocol does not apply the AIA procedure to these LMOs. Instead, the communication and decision-making processes are as follows:

- When a Party makes a final decision at the domestic level regarding the commercial growing or placing on the market (but not field trials) of an LMO, that might be exported for direct use as food or feed or for processing, then that Party must notify the BCH (thereby notifying other Parties) within 15 days of making the decision.
- Where such a decision has been taken, the Protocol specifies in its Annex II[24] the minimum information that should be provided to the BCH.

Parties of import can decide whether and how to subject LMOs-FFP to notification, risk assessment and approval procedures prior to first import, in accordance with their domestic regulatory framework and consistent with the objectives of the Protocol. The Protocol recognizes that some developing countries or countries with economies in transition may not have a domestic regulatory framework for LMOs-FFP in place. It allows such Parties to declare through the BCH that decisions on the first import of LMOs-FFP will be taken in accordance with risk assessment as set out in the Protocol and within a 270-day timeframe for decision-making[25].

In contrast to the bilateral AIA procedure, which is based on direct communication between Parties, the procedure for LMO-FFPs in the Protocol is essentially a multilateral information exchange mechanism centered on the BCH.

4.3. Unintentional transboundary movements of LMOs

The Protocol recognizes that, because of their characteristics, there may be circumstances in which LMOs will cross national boundaries accidentally. Therefore, when a Party knows of an occurrence in its jurisdiction that leads, or may lead, to an unintentional transboundary movement of LMOs that is likely to have significant adverse effects on biodiversity and human health, it must:

a) notify affected or potentially affected States, the BCH and relevant international organizations with information on the unintentional release.

b) initiate immediate consultation with the affected or potentially affected States to enable them to determine response and emergency measures.

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[24] « Information required concerning LMO's intended for direct use as food or feed or processing under Art 11», CBD, CPB, Annex II, https://bch.cbd.int/protocol/text/

[25] « Procedure for LMO's intended for direct use as food or feed or for processing», CBD, CPB, Art 11.6.

4.4. Handling, packaging and identification requirements for LMOs

Parties are required to take measures for the safe handling, packaging and transportation of LMOs[26]. The Protocol invites Parties and other Governments[27] to use existing guidance for handling, transport and packaging of LMOs as referred to in relation to operational objective 1.6 of the Strategic Plan for the Cartagena Protocol on Biosafety;

Each Party is required to take measures ensuring that LMOs subject to intentional transboundary movement are accompanied by documentation identifying the LMOs and providing contact details of persons responsible for such movement. The details of these requirements vary according to the intended use of the LMOs[28].

The first meeting of COP-MOP adopted a decision outlining identification requirement for different categories of LMOs[29]. Ultimately, the Secretariat of the Convention on Biological Diversity (SCBD) issued the "Biosafety Technical Series 05: Training Module on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety »[30].

In its *decision CP-10/11* the COPMOP recognizes the importance of the Network of Laboratories for the Detection and Identification of Living Modified Organisms and encourages Parties to continue to cooperate to develop regional networks of laboratories to facilitate the exchange of experience, sharing of information and building of expertise in the field[31]

4.5. The Biosafety Clearing-House

The Protocol establishes the Biosafety Clearing-House[32].

In order to implement the Protocol, Parties, and other entities (e.g., exporters; importers) dealing with LMOs, need access to information about applicable laws and regulations affecting LMOs, and about LMOs themselves.

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[26] «Handling, Transport, packaging and identification» CBD, CPB, Art 18, https://bch.cbd.int/protocol/text/

[27] Decision BS-VII/8(3) https://bch.cbd.int/protocol/decisions/?decisionID=13355

[28] «Handling, Transport, packaging and identification» CBD, CPB , Art 18.

[29] https://bch.cbd.int/protocol/decisions/?decisionID=8288

[30] Biosafety Technical Series 05: Training Module on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety https://bch.cbd.int/en/database/VLR/BCH-VLR-SCBD-260177

[31] COPMOP Decisions 10th meeting https://www.cbd.int/decisions/mop/?m=cp-mop-10

[32] « Information sharing and the BCH », CBD, CPB, Art 20, https://bch.cbd.int/protocol/text/

The BCH is the primary mechanism through which this information will be available, and is therefore a cornerstone of the Protocol's biosafety regime. The BCH will be particularly important with regard to the transboundary movement of **LMOs-FFP**[33].

Parties to the Protocol are obliged to make certain information available through the BCH. But the BCH also gives countries access to important information provided by others: for example, about relevant national laws and regulations; about decisions other countries have made regarding specific LMOs and about biosafety-related capacity-building initiatives and assistance.

The Protocol sets out some specific requirements regarding the categories of information to be made available through the BCH. Further specific requirements may also be established in the future by the COP-MOP[34].

Specific requirements and opportunities related to the BCH are explained in more detail in Module **2: « An Introduction to the BCH ».**

5. What are the institutional arrangements established by the Protocol?

5.1. National institutional arrangements

Upon ratification and entry into force of the Protocol in a country, each Party must:

a) *designate one **National Focal Point** (NFP) to be responsible on its behalf for liaison with the **Protocol Secretariat** (Article 19).*

b) *designate one **National Focal Point for the Biosafety Clearing House** (BCH-NFP) to liaise with the Secretariat regarding issues of relevance to the development and implementation of the Biosafety Clearing House and to validate national records for publication in the BCH (decision BS-I/3, annex)*[35].

c) *designate one or more Competent National Authority (CNA), to be responsible for performing the administrative functions required by the Protocol and authorised to act on the Party's behalf with respect to those functions. Where a Party designates more than one competent national authority, it must inform the Secretariat which authority is responsible for dealing with different types of LMOs.*

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[33] «Procedure for LMO's intended for direct use as food or feed or for processing»UNEP-GEF Biosafety projects, An introduction to the Cartagena protocol on Biosafety, pg 9.

[34] « Governing body of the CPB » UNEP-GEF Biosafety projects, An introduction to the Cartagena protocol on Biosafety, p 12.

[35] BS-I/3.7 https://bch.cbd.int/protocol/decisions/?decisionID=8284

d) *provide the BCH with details of its point of contact for receiving notifications from other Parties of unintentional transboundary movements of LMOs (Article 17).*[36]

e) *notify the Secretariat of the names and addresses of its NFP(s) and CNA(s).*

Nomination of National Focal Points

Information on focal points can *only* be registered in the BCH by the Secretariat upon receipt of an official written communication addressed to the Executive Secretary and endorsed by the relevant authorities.

The rules and procedures for nominating a focal point are as follows:

- The designation of a **National Focal Point for the Cartagena Protocol on Biosafety (CPB-NFP)** must be endorsed by the *National Focal Point for the Convention on Biological Diversity (CBD-NFP)* or by a *direct expression of the Government* (i.e. a Minister of State).
- The designation of a **National Focal Point for the Biosafety Clearing-House (BCH-NFP)** must be endorsed by the *National Focal Point for the Cartagena Protocol on Biosafety (CPB-NFP)*.
- The designation of a **Contact Point for unintentional transboundary movements and emergency measures (***Article 17***)** must be endorsed by the *National Focal Point for the Biosafety Clearing-House (BCH-NFP)* or by the *National Focal Point for the Cartagena Protocol on Biosafety (CPB-NFP)*.

CNAs and the point of contact for emergency measures may be registered directly in the BCH by the BCH-NFP.

To nominate a NFP, governments can use the *offline common formats* available in MS Word in the 6 UN languages. An offline common format needs to be completed, duly signed by the respective authority and sent to the Secretariat as a scanned attachment by e-mail to bch@cbd.int, or it can be sent by post or fax.

Offline common formats are available on the Dashboard of the Submit page and can also be downloaded using the links below:

- National Focal Point (NFP): ar | en | es | fr | ru | zh

Upon receipt of a Party's information, the Secretariat will:

a) *maintain lists of designated NFPs and CNAs for the Protocol.*

b) *make this information available to all other Parties, including by posting it on the BCH.*

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[36] « Unintentional transboundary movements » UNEP-GEF Biosafety projects, An introduction to the Cartagena protocol on Biosafety pg 9.

This is to primarily enable potential exporters of LMOs to find out which national authority it should approach in the Party of import to notify, and seek approval for, a proposed transboundary movement of an LMO.

5.2. Governing body of the Cartagena Protocol

The governing body of the Protocol is the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP). The main function of this body is to review the implementation of the Protocol and make decisions necessary to promote its effective operation, including the operation of the BCH. These decisions may give further guidance to Parties on how they should implement the Protocol. The COP-MOP meets regularly, usually every one or two years.

5.3. Administrative body of the Cartagena Protocol

The body that is responsible for the administration of the Protocol at the international level is the **Secretariat of the Convention on Biological Diversity**. Among other functions, the Secretariat is responsible for maintaining the Central Portal of the BCH (see next modules).

From Modern Biotechnology to Biosafety

The term «biotechnology» refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use.

Biotechnology, in the form of traditional fermentation techniques, has been used for decades to make bread, cheese or beer. It has also been the basis of traditional animal and plant breeding techniques, such as hybridization and the selection of plants and animals with specific characteristics to create, for example, crops which produce higher yields of grain.

The difference with modern biotechnology is that researchers can now take a single gene from a plant or animal cell and insert it into another plant or animal cell to confer a desired characteristic on the recipient organism, such as resistance to a specific pest or disease.

In the Cartagena Protocol, modern biotechnology means the application of:

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

b) *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.*

Living organisms that possess a novel combination of genetic material obtained through the use of modern biotechnology are called « **Living Modified Organisms** » in the Cartagena Protocol. This is often abbreviated to « **LMOs** ». Other terms commonly used to describe such organisms are « Genetically Modified Organisms » (GMOs).

Modern biotechnology promises advances in medicine, agriculture, and other fields. These may include new medical treatments and vaccines, new industrial products, and improved crops. Proponents of the technology argue that biotechnology has the potential to promote food security by leading to increases in crop production, decreased pressure on land use, sustainable yield increase in marginal lands or inhospitable environments and reduced use of water and agrochemicals in agriculture.

However, modern biotechnology is a very new field, and much about the interaction of LMOs with various ecosystems is not yet known. Some of the concerns about the new technology include its potential adverse effects on biological diversity, and potential risks to human health. Areas of concern include unintended changes in the competitiveness, virulence, or other characteristics of the LMO; the possibility of adverse impacts on non-target species (such as beneficial insects) and ecosystems; the potential for weediness in genetically modified crops; the possibility of gene flow; and the stability of inserted genes (the possibilities that a gene will lose its effectiveness or will be re-transferred to another host).

Biosafety is a term used to describe efforts to minimize or avoid the potential risks resulting from modern biotechnology and its products. For the purposes of the Cartagena Protocol, this is based on the precautionary approach[37].

[37] See box «Principle 15 of the Rio Declaration» p. 7.