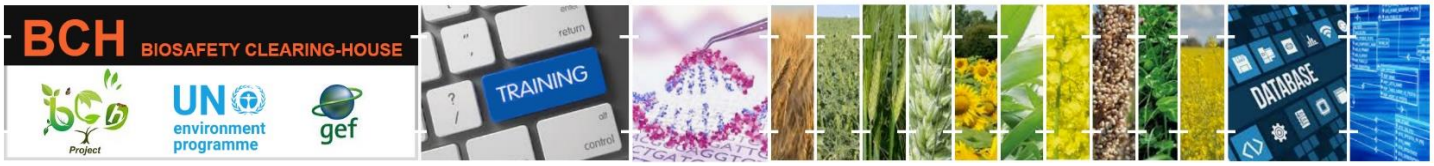

A User's Guide to the Central Portal of the Biosafety Clearing House

An introduction to the Biosafety Clearing House

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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 addresses the requirements in the Cartagena Protocol on Biosafety (CPB) and Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress (NKLSP) for a Party to make specific kinds of information available to the Biosafety Clearing House (BCH). It seeks to explain:

- The purpose and functioning of the BCH,
- The various categories of information available in the BCH, with particular emphasis on the information that a Party is required to submit to the BCH,
- What information is required, and when must it be available in the BCH by providing basic definitions?

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 guide users of the Biosafety Clearing House (BCH). It is developed for a non-technical audience with little or no knowledgeof the Cartagena Protocol and the BCH. Still, it needs to understand the requirements of the Biosafety Clearing House.

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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/

Purpose:

This module presents the various categories of information that a Party to the Cartagena Protocol and Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress:

- Must make available to the BCH,
- Can access it through the BCH.

This module explains the decision-making and communication processes involved and describes the different categories of information in the BCH and obligations and opportunities under the Protocols. It also aims to encourage non-parties to make information available in the BCH.

1. The Biosafety Clearing House – Definition and Context

1.1. What is a Clearing House Mechanism?

Expertise in managing information and technology varies enormously from country tocountry. For this reason, the Convention on Biological Diversity has established a "Clearing House Mechanism" (CHM) to ensure that all governments have access to the information and technologies they need for their work on biodiversity.

The term "clearing house" originally referred to a financial establishment wherechecks and bills were exchanged among member banks so that only the net balances need to be settled in cash. Today, its meaning has been extended to include any agency that brings together seekers and providers of goods, services, or information, thus matching demand with supply.

A Clearing House Mechanism serves to:

- Promote and facilitate technical and scientific cooperation within and between countries,
- Develop a global mechanism for exchanging and integrating information on biodiversity, and
- Develop a human and technological network.

The mechanism's key characteristics are:

- Compatibility with different levels of national capacity,
- Needs-driven,
- Structurally decentralized,
- Provides access to information,
- Supports decision-making,
- Has no vested interest in controlling the expertise or information,

- Created for the mutual benefit of all participants.

The BCH is an information exchange mechanism established by the Cartagena Protocol on Biosafety as part of the CHM[5]. It assists Parties in implementing the provisions of the Protocol and facilitates the sharing of information on and experience with living modified organisms (LMOs).

1.2. What is the role of the BCH?

Article 20[6] of the Cartagena Protocol establishes the Biosafety Clearing House (BCH) in order to:

- Facilitate the exchange of scientific, technical, environmental, and legal information on and experience with LMOs, and
- Assist Parties to implement the Protocol.

1.3. What is the purpose of the BCH, and why is the BCH important?

The information to be made available through the BCH is vital for enabling governments to implement the Cartagena Protocol. Suppose *CPB, Article 20* and subsequent decisions of the governing body of the Protocols are implemented effectively. In that case, the BCH will provide an important repository of up-to-date information on LMOs and biosafety that will assist decision-makers worldwide, as well as civil society and the biotechnology industry.

1.4. How does a Party benefit from the BCH?

While all Parties have **obligations** under the Cartagena Protocol to make information available through the BCH, they can also derive important **benefits** from using the BCH. For example, they can:

- Access information about the national laws, regulations, and guidelines of other Parties and information about the decisions and assessments of other countries relating to specific LMOs,
- Ensure, by submitting up-to-date information in the BCH, that all potential exporters of LMOs to their country, or those who wish to transport LMOs across their territory, are aware of their national regulatory requirements,
- Access information about capacity-building and other assistance available to support the implementation of the Cartagena Protocol, and
- Ensure that the relevant authorities in other countries can quickly find out who to inform in the event of an accidental movement of LMOs into their territory.

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[5] "Clearing House Mechanism," https://chm.cbd.int/.

[6] "Cartagena Protocol on Biosafety", Article 20. https://bch.cbd.int/protocol/text/

The Biosafety Clearing House also plays an important role related to the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress (NKLSP) as it:

- Maintains data on activities involving LMOs and operators,
- Maintains criteria for monitoring and evaluation of damage to biological diversity and human health,
- Maintains a mechanism for notifying and consulting with affected or potentially affected states in the event of incidents,
- Informs operators of their obligations and available remedies as well as laws and regulations,
- Makes information on incidents of damage to biological diversity and appropriate response measures taken or to be taken available,
- Makes available information on incidents of illegal transboundary movements,
- Promotes public awareness and education concerning damage to biological diversity resulting from LMOs and acts as a Source for information on the likelihood of occurrence of damage (*Article 5.3* of the supplementary Protocol).

1.5. What are the obligations of a Party regarding submitting and updating information on the BCH?

A Party has obligations under the Cartagena Protocol to make some information availablethrough the BCH. *Article 20* of the Cartagena Protocol lists the specific information a Party must submit to the BCH. This is described in the section below.

In addition, the COP-MOP[7] may well adopt further decisions in the future regarding the operational and technical aspects of the BCH, including additional information that should be made available through the BCH. Accordingly, Parties to the Protocol will also need to monitor any future decisions of the COP-MOP that require or request additional information to be made available through the BCH.

1.6. What are the types of information that a Party needs to make available?

The various types of information that a Party needs to make available to the BCH through an ongoing process are described in the "Modalities of operation of the Biosafety Clearing House" (*Annex to Decision BS-I/3*: Information sharing and the BCH)[8] as follows:

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[7] The Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Protocol (COP-MOP) is the governing body of the Cartagena Protocol on Biosafety.

[8] The "Modalities of operation of the Biosafety Clearing-House" (Annex to Decision BS-I/3: Information sharing and the BCH) are available at https://bch.cbd.int/protocol/decisions/?decisionID=8284 .

(1) Information that should be made available on the BCH **as soon as the Cartagena Protocol enters into force for a country** (i.e., as soon as it becomes a "Party" to theProtocol:

- The Party should inform the Secretariat of its Cartagena Protocol National Focal Point, BCH National Focal Point, Competent National Authority (or authorities), and point of contact for emergency measures[9]. This information will then be registered in the BCH.
- The Party should also make available, through the BCH, information on existing laws, regulations, guidelines, or any existing bilateral, regional, or multilateral agreement or arrangement regarding the transboundary movement of LMOs.

Information that must be made available to the BCH **when a country** modifiesits regulatory framework:

- If a Party enters into a bilateral, regional, or multilateral agreement or arrangement regarding the transboundary movement of LMOs, or
- If the Party adopts or amends laws, regulations, or guidelines relevant to LMOs.

Information that must be made available on the BCH **when a country takes certain decisions**:

- If a Party takes a final decision on the importation or release of LMOs (e.g., under the Advance Informed Agreement (AIA) procedure), or
- If the Party takes a final decision regarding domestic use, including placing on the market, of an LMO that may be subject to transboundary movement for direct use as food or feed or for processing.

Information that must only be made available **if certain events occur**:

- Information concerning cases of illegal transboundary movement of LMOs, or
- Notification of an occurrence under the Party's jurisdiction resulting in a release that leads to, or may lead to, an unintentional transboundary movement of an LMO.

While the Cartagena Protocol and the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress only impose legal obligations on Parties, non-parties are encouraged to contribute appropriate information to the BCH.

If the BCH is to work effectively, the required information should be registered as soonas possible. Such a step, among other things, will ensure that other BCH users know their relevant national authorities and laws and regulations relating toLMOs.

[9] As for the Cartagena Protocol text in Articles 17 and 19 and Decision BS-I/3.

Note: A Party should not make confidential information available through the BCH.

2. How does the BCH work?

The establishment and upkeep of the BCH is an ongoing process. To supplement and implement *Article 20* of the Cartagena Protocol, the COP-MOP has adopted a decision[10] regarding the modalities of operation of the BCH – i.e., how it will work.

To fully participate in the BCH, Governments need to put in place lines of communication and information exchange to ensure that information is made available through the BCH in a timely and appropriate fashion. To assist Parties in doing so, some basic principles of the operation of the BCH, as established by the COP-MOP, are set out briefly here.

The development of the BCH is to be guided by the principles of inclusiveness, transparency, and equity and is to be open to all governments.

A Party must nominate a National Focal Point for the BCH whose responsibilities include:

- Clearance for publishing information registered in the BCH, including validating national records created by authorized users before publication.
- Liaison with the Secretariat of the Convention on Biological Diversity regarding technical aspects of national participation in the BCH.
- Liaison with the Secretariat of the Convention on Biological Diversity regarding issues of relevance to the development and implementation of the BCH.

2.1. Who can access the BCH?

Information in the BCH is open and accessible to all users, and therefore, **confidential information**[11] (under *Article 21* of the Protocol) should not be submitted to the BCH.

2.2. Who can register information in the BCH?

Information that must be made available through the BCH might originate in different government departments or agencies. Registering and updating national information in the BCH is restricted to BCH National Focal Points and National Authorized Users (NAUs). When NAUs submit information, it must be validated by the BCH National Focal Point before publication.

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[10] https://bch.cbd.int/protocol/decisions/?decisionID=8284 .

[11] "Cartagena Protocol on Biosafety," article 21 on Confidential information. https://bch.cbd.int/protocol/text/ .

(1) Information that cannot be registered directly in the BCH by BCH account holders.

The Secretariat of the Convention on Biological Diversity **registers CBD, CPB, and BCH National Focal Points (NFPs)** once a request has been made to the CBD Executive Secretary by:

- A government minister for the appointment of a CBD NFP,
- The country's CBD NFP for the appointment of a CPB NFP, and
- The country's CPB NFP for the appointment of a BCH NFP.

National Information can be published directly in the BCH only by BCH NFPs:

- National Authorized Users (NAUs) – NAUs have the same rights as BCH NFPs, except that their respective NFP must validate any national record they submit before publication in the BCH.

Information that can be submitted only by BCH NFPs or NAUs:

- Competent National Authorities (CNA),
- Supplementary Protocol Competent Authorities (SPCA),
- Biosafety Laws, Regulations, Guidelines and Agreements (LAW),
- Countries' Decisions or any other Communications (DEC),
- Risk Assessments generated by a regulatory process (RA),
- National Biosafety Websites or Databases (NDB),
- National Reports on the Implementation of the Cartagena Protocol (NR)
- Biosafety Experts (EXP), and
- Country Profiles for Biosafety Clearing House (BCP)

Note: None of the information above will be published in the BCH until the BCH NFP has validated it. Validation of national information is under the exclusive control of the BCH NFP.

Information that can be submitted by all BCH-registered users:

- Biosafety Virtual Library Resources (VLR),
- Biosafety Organizations (ORG),
- Laboratories for detection and identification of LMOs (LAB),
- Living Modified Organisms (LMO),
- Genetic elements (GENE),
- Organisms (ORGA),
- Risk Assessments generated by an independent or non-regulatory process (IRA)

- Submissions (SUB),
- Capacity Development Initiatives (CDI),
- BCH News (BCHN), and
- Contacts (CON)

Note: Except for contact details records, none of the information above will be published in the BCH until the SCBD has validated it.

Note: The SCBD reserves the right to review and verify, before publication, all information submitted by BCH-registered users.

2.3. Language requirements of the BCH

The COP-MOP has decided that information should be submitted to the BCH in an official language of the United Nations (Arabic, Chinese, English, French, Russian, or Spanish). However, for BCH users to fulfill their needs and obligations at both the national and international levels, they may also submit their information in the BCH in one or more additional languages.

In addition, although the information in the body of each record in the BCH must be at least in one of the six UN languages, complete information sources and documents linked to BCH records may be made available in any language.

To minimize the burden of translation, the COP-MOP has also encouraged Parties and other governments to provide courtesy translations of information in the BCH into one or more languages commonly used internationally.

3. What information can be found in the BCH?

Article 20 of the Cartagena Protocol sets out specific information that Parties must make available through the BCH. At its first meeting, the COP-MOP adopted a decision that set out the categories of information that Parties must register in the BCH

- Laws and regulations,
- National contacts,
- Decisions and declarations on LMOs,
- Risk assessments,
- Unique identification,
- Capacity building,
- Roster of experts, and
- Decisions and declarations on the BCH.

3.1. Laws and Regulations

Article 2, paragraph 1, of the Cartagena Protocol stipulates that Parties "shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol."

A Party is responsible for registering information in the BCH regarding its relevant laws and regulations. This category of information may be registered and updated on the BCH directly by the BCH NFP.

⇒ Existing national legislation, regulations, and guidelines for implementing the Protocol, as well as information required by Parties for the AIA procedure

- This is an ongoing obligation. A Party needs to ensure that up-to-date versions of its relevant laws, regulations, and guidelines for LMOs are available through the BCH.
- The purpose is to ensure that other users of the BCH, especially those that may export LMOs, can find out each country's relevant regulatory requirements.
- Accordingly, if laws, regulations, or guidelines are amended, or new ones are adopted, they should be registered promptly in the BCH.

⇒ National laws, regulations, and guidelines applicable to the import of LMOs intended for direct use as food or feed or for processing (LMOs-FFP *Article 11(5)*)

- This ongoing obligation requires Parties to ensure up-to-date information about relevant national laws, regulations, etc., is available through the BCH.
- This is particularly important concerning LMOs-FFP since there is no obligation in the Protocol itself for Parties of export or exporters to notify the Party of import before the first transboundary movement of LMOs-FFP.
- A Party of import may establish this obligation in its national regulations.

⇒ Bilateral, multilateral, and regional agreements and arrangements (*CPB, Article 14*)

- Each Party must make available through the BCH any bilateral, regional, or multilateral agreements or arrangements regarding the transboundary movement of LMOs, including those they entered into before or after the date of entry into force of the Protocol[12].

[12] Source: "An Explanatory Guide to the Cartagena Protocol on Biosafety", Bilateral, regional and multilateral agreements and arrangements, IUCN, Article 14 Para 395. https://www.cbd.int/doc/books/2003/B-01669.pdf .

3.2. National Contacts

The Cartagena Protocol requires the designation of a number of national institutions to fulfill various functions. Information about these institutions is made available through the BCH.

No later than the date of entry into force of the Protocol, a Party is responsible for communicating to the Secretariat the nominations of relevant Competent National Authority/ies, and National Focal Points (Cartagena Protocol NFP, BCH NFPs, and the contact point for emergency measures under *CPB, Article 17*). Only Competent National Authorities and contact points for emergency measures may be registered andupdated in the BCH directly by the BCH NFP.

⇒ Contact details for notification in the event of unintentional transboundary movement (*CPB, Article 17*)

- Each Party shall, no later than the date of entry into force of the Cartagena Protocol, make available to the BCH the relevant details setting out its point of contact for the purposes of receiving notifications of releases that may lead to an unintentional transboundary movement of LMOs that are likely to have adverse effects on biological diversity or human health.
- This information may be registered and updated in the BCH directly by the BCH NFP.

⇒ Contact details for Competent National Authorities (*CPB, Article 19*)

- This information is critical for the proper functioning of the Cartagena Protocol. It tells Parties of export or exporters to which authority in the Party of import they should address notification of a proposed import of an LMO.
- If a Party designates more than one CNA for different types of LMOs, it must identify which authority is competent for specific categories of LMOs.
- This information may be registered and updated in the BCH directly by the BCH NFP.

⇒ Contact details for National Focal Point (*CPB, Article 19*)

- The Cartagena Protocol's national focal point is responsible for liaising with the Secretariat on behalf of a Party.
- This information is notified by the Party's Government to the Executive Secretary and cannot be changed or updated directly in the BCH by the BCH NFP.

⇒ **Contact details for national focal points for the BCH**

- In its *Decision BS-I/3*, the COP-MOP calls upon each Party to designate an appropriate national focal point for the BCH. The names and addresses of the BCH National Focal Point are made available through the BCH.
- This information is notified by the Cartagena Protocol National Focal Point to the Executive Secretary and cannot be changed or updated directly in the BCH by the BCH NFP.

Under the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress (NKLSP), competent authorities are to take a number of actions in the event of damage or where there is sufficient likelihood that damage will result if timely response measures are not taken (*NKLSP. Article 5*).

In decision CP-9/15, Parties to the NKLSP were requested to designate a competent authority to perform the functions set out in *Article 5* of the NKLSP and make its competent authority's contact information available in the Biosafety Clearing House.

If there is more than one Supplementary Protocol Competent Authority (SPCA) in the country, each SPCA should be published as a separate record with its specific responsibilities clearly explained. It is important to keep the contact information up-to-date and the description of responsibilities clear and concise to provide accurate information.

3.3. Decisions and Declarations on LMOs

A Party is responsible for registering its decisions and declarations in the BCH. This category of information may be registered and updated in the BCH directly by the BCH NFP.

⇒ **Decisions regulating the transit of LMOs (*CPB, Article 6(1)*)**

- If a Party decides to regulate the transport of living modified organisms through its territory, this information should be notified to the BCH.

⇒ **Decision on Contained use of LMOs (*CPB, Article 6.2*)**

- "**Contained use**" is defined by the Cartagena Protocol to mean "any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment" (*Article 3(b)*).

⇒ Decisions regarding the first import of LMOs for intentional introduction into the environment (*CPB, Articles 7-10 and 14(4)* or domestic regulatory framework)

- This refers to decisions adopted by a Party of import (under the AIA procedure or a domestic regulatory framework) for the first intentional transboundary movement of living modified organisms for intentional introduction into the environment. The decision (including approval or prohibition, any conditions attached to approvals, requests for further information, extensions granted, reasons for the decision, etc.) will be communicated to the notifier by the relevant Competent National Authority of the Party of import and to the BCH by the BCH NFP.
- Intentional introduction into the environment can include introduction both for experimental or commercial purposes. A field trial, confined field trial, or experimental introduction is regarded as an intentional introduction into the environment when the conditions specified in *CPB, Article 3, paragraph b*, are unmet *(decision CP-9/12)*.
- Making these decisions available through the BCH is important as it notifies other Parties and potential exporters of LMOs:
    - Which LMOs a Party of import has approved for intentional introductioninto the environment (and subject to what conditions, if any)?
    - Which LMOs a Party of import has refused and why?
- Notifications under *CPB, Article 10 or 14(4)* may specify how the decision will applyto subsequent imports of the same LMO.

⇒ Decisions regarding the domestic use of LMOs intended for direct use as food or feed or for processing (LMOs-FFP) that may be subject to transboundary movement (*CPB, Article 11(1)*)

- This is a key obligation in relation to the regulation of LMOs-FFP.
- If a Party makes a final decision regarding the commercial growing or placing on the market of an LMO that might be exported for direct use as food or feed or for processing, this information (including approvals and prohibitions) should be made available through the BCH within 15 days of making the decision. The Cartagena Protocol sets out in its Annex II[13] the information that must be provided to the BCH.
- The timely provision of such information to the BCH is important as other Parties rely on the BCH to find out what LMOs-FFP might be exported.

[13] "Cartagena Protocol on Biosafety" CBD, Annex II. https://bch.cbd.int/protocol/text/.

- Where the Party concerned approves the LMO in question only for field trials and the same LMO was to be sent to another Party for field trials, it would be subject to *CPB, Article 7* (AIA) provisions.

⇒ Decisions regarding the import of LMOs intended for direct use as food or feed or for processing (LMOs-FFP) (*CPB, Article 11(4)*)

- If a Party takes a decision on the import of LMOs-FFP under its domestic regulatory framework, this information (including approvals and prohibitions) should be made available through the BCH.

⇒ Review and change of decisions (*CPB, Article 12(1)*)

- A Party of import may, on its own initiative or upon request, review a decision it has made regarding the import of an LMO on the basis of new information or where there has been a change of circumstances.
- Reviews or changes of previous decisions should be promptly made available through the BCH.

⇒ LMOs subject to simplified procedures (*CPB, Article 13(1)*)

- In some circumstances, the Protocol allows a Party of import to indicate that certain imports of LMOs may take place on the basis of notification only (rather than explicit prior approval). A Party of import may also decide to exempt certain imports of LMOs from the AIA procedure.
- If a Party decides to utilize these simplified procedures, it should make available through the BCH the LMOs to which the simplified procedures will apply.

⇒ Information on the application of domestic regulations to specific imports of *LMOs* (*CPB, Article 14(4)*)

- The Protocol allows a Party to decide that its domestic regulations will apply with respect to specific imports to it.
- If a Party decides to adopt such an approach, it must notify the BCH of its decision.

⇒ Occurrence of unintentional transboundary movements of LMOs (*CPB, Article 17*)[14]

- 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

[14] Source: "An Explanatory Guide to the CPB," IUCN, p. 119 https://www.cbd.int/doc/books/2003/B-01669.pdf

significant adverse effects on biodiversity and human health, it must notify affected or potentially affected States (through their point of contact for emergency measures under *CPB, Article 17*), the BCH, and, where appropriate, relevant international organizations with information on the unintentional release.

- The information to be provided to the BCH in such circumstances should include:
    - Available relevant information on the estimated quantities and relevant characteristics/traits of the LMO,
    - Information on the circumstances and estimated date of the release and on the use of the LMO in the originating Party,
    - Any available information about the possible adverse effects on the conservation and sustainable use of biodiversity, taking also into account risks to human health,
    - Available information about possible risk management measures,
    - Any other relevant information, and
    - A point of contact for further information.

⇒ Illegal transboundary movements of LMOs (*CPB, Article 25(3)*)

- The Protocol provides that transboundary movements of LMOs carried out in contravention of a ' 'Party's domestic laws and regulations should be considered illegal. A Party must make available to the BCH information about any cases of illegal transboundary movement of LMOs pertaining to it.

⇒ Declarations regarding the framework to be used for LMOs intended for direct use as food or feed or for processing (LMO-FFPs) (*CPB, Article 11(6)*)

- 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 a risk assessment as set out in the Protocol and within a 270-day timeframe for decision-making[15].
- A Party wishing to take advantage of this provision should submit a declaration to the BCH. For practical purposes, if a Party makes such a declaration, it should also indicate the Competent National Authority to which notification of any proposed import of an LMO-FFP should be made.

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[15] Source: "An Explanatory guide to the CPB" IUCN, Article 11, Pg 85
https://www.cbd.int/doc/books/2003/B-01669.pdf

⇒ **Notification that a Party does not have access to the Biosafety Clearing House (*CPB, Article 11.1*).**

⇒ **Communication of information on 'Handling, Transport, Packaging and Identification' (*CPB, Article 18*) See *decision BS-III/10*.**

⇒ **Declaration made upon ratification of or accession to the Protocol.**

3.4. Risk Assessment

Decision-making on imports of LMOs under the Protocol is to be based on risk assessments. The Protocol requires Parties to register in the BCH report or summaries of risk assessments and environmental reviews of living modified organisms generated by its regulatory process and carried out in accordance with *CPB, Article 15*, including, where appropriate, relevant information regarding products thereof, namely, processed materials of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through modern biotechnology. This information provides a useful resource for other Parties that may need to conduct their own risk assessment of the same LMO in the future.

Risk assessment reports are mandatory for all decisions regarding the first import of LMOs for intentional introduction into the environment or regarding the domestic use of LMOs intended for direct use as food or feed or for processing (LMOs-FFP) and should be consistent with *Annex III* of the Cartagena Protocol.

A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, cannot be considered confidential information and should always be made available through the BCH when generated by regulatory processes.

In addition to national records for "Risk assessments generated by a regulatory process," a risk assessment or environmental review of living modified organisms, if carried out in accordance with *Annex III* of the Cartagena Protocol, can be submitted as "Risk Assessment generated by an independent or non-regulatory process (IRA)" reference records.

3.5. Other Information Available in the BCH

There are numerous other types of information that are submitted to the BCH. This information originates from various sources, including Parties, governments, and organizations.

⇒ **LMOs, genes, and organisms' registries**

- The BCH contains databases providing the following registries:

- The **LMO-Unique Identifiers Registry (LMO-UIds)** provides summary information on all living modified organisms registered in the BCH, including transformation events, genetic modifications, and the unique identification code (if available) for each record. Links to all decisions that refer to these organisms are provided at the bottom of each LMO record, accessible through the registry,
- The **Gene Registry** provides summary information on gene inserts and characteristics of the genetic modifications of LMOs, and
- The **Organism Registry** provides summary information on parental, recipient, or donor organisms related to the LMOs registered in the BCH.

- Each registry can be accessed through the link at the bottom of the left column (compiled information) or searched through a common search interface.

⇒ **Capacity Development Initiative (CDI)**

- *Article 22* of the Cartagena Protocol states that "Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement. "
- Having all information on capacity development projects and initiatives, including activities and outcomes, available in one database can provide opportunities for coordination among actors involved in capacity development in the same geographical area or covering similar thematic issues to learn from each other experiences. It can also help identify and address gaps and overlaps in the coverage of different capacity activities.

⇒ **Biosafety Experts (EXP)**

- The COP-MOP decided that the BCH will maintain a **Roster of Experts**[16] (see *Decision EM-I/3, 14*)[17] to provide advice and other support, as appropriate and upon request, to developing countries and countries with economies in transition, to conduct risk assessments, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movement of LMOs.

[16] Decisions adopted by COP-MOP 1. UNEP/CBD/BS/COP-MOP/1/15, BS –I/4, Annex I, Para. C. https://bch.cbd.int/protocol/decisions/?meeting=mop-01 .
[17] "COP decision EM-I/3", CBD, section III. https://www.cbd.int/decisions/?m=excop-01

- *Decision BS-IV/4*[18] sets out the criteria and minimum requirements for experts to be nominated to the roster of experts (*Annex I*) and the guidelines for the roster (*Annex II*). According to *decision BS-IV/4*, experts' records are maintained on the roster for four years from their last information update. Afterward, they will be deleted from the roster unless re-nominated.

⇒ National Reports submitted by Parties (NR)

- The Protocol requires each Party to submit a periodic report on its implementation of the Protocol to the Secretariat. These reports are made available in the BCH.

⇒ Biosafety Virtual Library Resource (VLR)

- The Biosafety Virtual Library Resource (VLR) is an electronic catalog of publications and information resources relevant to the Cartagena Protocol on Biosafety. This includes literature on biosafety, reports and case studies, awareness-raising materials, videos, and capacity-building resources. The core objective of this catalog is to make biosafety information and resources more accessible to policymakers, educators, researchers, and the general public.
- The VLR record may be submitted online by any registered BCH user, but its accuracy and completeness must be validated by the Secretariat before its publication.
- Various decisions of the COP-MOP have expanded the range of scientific, technical, environmental, and legal information available through the BCH.

⇒ BCH training materials and assistance

- There is a variety of information in the BCH itself about the technical aspects of operating the BCH, including an **FAQ**, **BCH Training** Modules, **a guide to the BCH**, and **a training site**. Common formats for posting information on the BCH can be downloaded. In addition, the BCH hosts online conferences for information sharing and networking.

[18] https://bch.cbd.int/protocol/decisions/?meeting=mop-04

4. Support Tools 1, 2 and 3

[Support Tool – 1, List of information to be posted on BCH]

a) *Existing national legislation, regulations, and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (CPB, Art. 20 para. 3 (a)),*

b) *National laws, regulations, and guidelines applicable to the import of LMOs intended for direct use as food or feed or for processing (CPB, Art. 11, para. 5),*

c) *Bilateral, multilateral, and regional agreements and arrangements (CPB, Art. 14, para. 2 & CPB, Art. 20 para. 3 (b)),*

d) *Contact details for competent national authorities (CPB, Art. 19.2 and 19.3),*

e) *Contact details for NKLSP competent authorities (Decision CP-9/15; NKLSP, Art. 5),*

f) *Contact details for national focal points (CPB, Art. 19, para. 1& 3 & decision BS-1/3),*

g) *Contact details for an emergency contact point for receiving notifications of unintentional transboundary movements of LMOs (CPB, Art. 17, para. 2),*

h) *Reports submitted by the Parties on the operation of the Protocol (CPB, Art. 20 para. 3 (e));*

i) *Decisions by a Party on regulating the transit of specific living modified organisms (LMOs) (CPB, Art. 6 para. 1),*

j) *Decisions by a Party on contained use of of specific living modified organisms (LMOs) (CPB, Art. 6 para. 2),*

k) *Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity and related information, including contact point for further information (CPB, Art. 17 para. 1 & 3),*

l) *Illegal transboundary movements of LMOs (CPB, Art. 25 para. 3),*

m) *Final decisions regarding the importation or release of LMOs (i.e., approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (CPB, Art. 10 para. 3 & CPB, Art. 20 para. 3(d)),*

n) *Decisions on field trial, confined field trial, or experimental intentional introduction when the conditions specified in CPB, Art. 3, para b, are unmet (Decision CP-9/12).*

o) *Information on the application of domestic regulations to specific imports of LMOs (CPB, Art. 14 para. 4),*

p) *Final decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed or for processing (CPB, Art. 11 para. 1),*

q) *Final decisions regarding the import of LMOs intended for direct use as food or feed or for processing that are taken under domestic regulatory frameworks (CPB, Art. 11 para. 4) or in accordance with annex III (CPB, Art. 11 para. 6) (requirement of CPB, Art. 20 para. 3(d)),*

r) *Declarations regarding the framework to be used for LMOs intended for directuse as food or feed or for processing (CPB, Art. 11 para. 6),*

s) *Review and change of decisions regarding intentional transboundary movementsof LMOs (CPB, Art. 12 para. 1),*

t) *LMOs subject to simplified procedures regarding intentional transboundary movement and exempted by a Party from the AIA procedure (CPB, Art. 13, para 1),*

u) *Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and 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 (CPB, Art. 20 para. 3 (c)),*

v) *Communication of information on 'Handling, Transport, Packaging and Identification' (CPB, Art. 18 & decision BS-III/10)*

[Support Tool 2 - Unique identification of LMOs]

The BCH modalities of operation require the BCH to use existing unique identification systems for living modified organisms, as appropriate, to facilitate the searching and retrieval of information.

Currently, the only unique identification system to be made available through the BCH is the OECD Unique Identifier for Transgenic Plants (see the Revised 2006: OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants (ENV/JM/MONO(2002)7/REV1), published by the OECD in February 2002 and revised in November 2006).

The OECD Unique Identifier is a simple alphanumeric code given to each living modified plant approved for commercial use, including for use as food or feed. The guidance has been designed so that developers of a new transgenic plant can generate an identifier and include it in the dossiers they forward to national authorities during the safety assessment process. Once approved, national authorities can forward the unique identifier to the OECD Secretariat for inclusion in the OECD's product database, from which the information is automatically shared with the Biosafety Clearing House.

The unique identifier is a nine-digit code comprising three elements separated by dashes (-). These elements are outlined below:

- 2 or 3 alphanumeric digits to designate the applicant;
- 5 or 6 alphanumeric digits to designate the transformation event;
- 1 numerical digit for verification (this is intended to reduce errors by ensuring the integrity of the alphanumeric code).

Two approaches are possible for products created with more than one transformation event (often called "stacked" transformation events), where these transformation events have been previously approved for commercialization. An applicant may choose to generate a novel unique identifier for such products, or they may choose to use a combination of the unique identifiers from products previously approved for commercialization.

Common Applicant Codes

Code	Applicant
ACS	Bayer CropScience (Aventis (AgrEvo (Plant Genetic Systems)))
BPS	Amylogen HB
CDC	University of Saskatchewan
CGN	Calgene (Monsanto)
DAS	Dow AgroSciences and Pioneer Hi-Bred
DD	DuPont
DKB	DEKALB (Monsanto)
FLO	Florigene
KM	KWS and Monsanto
MON	Monsanto
NMK	NatureMark (Monsanto)
PH	Pioneer Hi-Bred
REN	Renessen LLC Netherlands
SEM	Seminis Vegetable Seeds
SYN	Syngenta

[Support Tool 3 – Timeframe for submitting information to the BCH]

Timeframe for submitting information to the Biosafety Clearing House

Related Article	Information content	Timeframe for reporting to the BCH
6-1	Decision of a Party of transit to regulate the transport of living modified organisms through its territory	no specification
11-1	Final decision regarding the domestic use of an LMO that may be subject to transboundary movement for direct use as food or feed or for processing	15 days
11-5	National laws, regulations & guidelines applicable to the import of LMO-FFPs	no specification
11-6	Decision-making process if no domestic regulatory framework exists	270 days
12-1	Review of decision regarding intentional transboundary movements of LMOs	30 days
13-1(a)	Cases in which intentional transboundary movement may take place	no specification
13-1(b)	Imports of LMO exempted from the AIA procedure	no specification
14	Bilateral, regional, and international agreements and arrangements made before and after adhesion to the Protocol	no specification
17-1	Unintentional transboundary movement	as soon as Party knows the situation
17-2	Points of contact for related matters	date of entry into force of the Protocol in the country
19-1	Notification CNA(s) and NFP(s)	date of entry into force of the Protocol in the country
19-3	Secretariat makes information available in the BCH	no specification
20-3(a)	Existing laws, regulations, guidelines, and information on the AIA procedure	no specification
20-3(b)	Bilateral, regional, and international agreements and arrangements made before and after adhesion to the Protocol	no specification

Related Article	Information content	Timeframe for reporting to the BCH
20-3(c)	Summaries of risk assessments, environmental reviews of LMOs	no specification
20-3(d)	Final decision regarding the importation or release of LMOs	no specification
20-3(e)	Reports on the implementation of the AIA procedure	no specification
23	means of public access to BCH	party shall endeavor
25	Information concerning cases of illegal transboundary movements pertaining to it	no specification