An introduction to the Biosafety Clearing House

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1 Introduction to the Module

What you will learn in this module:

This module briefly addresses the requirements in the Protocol 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 regard to information that a Party is required to register in the BCH**
- **what information is required, and when it may need to be made available in the BCH, through the provision of basic definitions**

Context:

The UNEP-GEF Project for Capacity Building for Effective Participation in the Biosafety Clearing House (BCH) is preparing a modular training package that aims to provide 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 is designed to be flexible and is tailored to meet diverse needs of different countries, allowing them to select those tools and ideas that are most useful to their situation, needs and priorities. The training package is divided into four modules, each addressing one element of the Biosafety Clearing House (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 requirements of the Biosafety Clearing House.

Purpose:

This module presents the various categories of information that a Party to the Protocol:

- must make available to the BCH;
- can access through the BCH

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

2 The Biosafety Clearing House – Definition and context

This section defines and set a context for the Biosafety Clearing House.

2.1 What is a Clearing House Mechanism?

Expertise in managing information and technology varies enormously from country to country. 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 where checks 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 which was established by the Cartagena Protocol on Biosafety as part of the **(CHM).**[1] It assists Parties to implement the provisions of the Protocol and to facilitate sharing of information on, and experience with, living modified organisms (LMOs).

2.2 What is the role of the BCH?

Article 20[1] 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
- Assists Parties to implement the Protocol.

2.3 What is the purpose of the BCH and why is the BCH important?

The information that is to be made available through the BCH will be vital for enabling governments to implement the Protocol. If Article 20 and subsequent decisions of the governing body of the Protocol are implemented effectively, the BCH will provide an important repository of up-to-date information on LMOs and biosafety that will assist decision-makers in countries around the world, as well as civil society and the biotechnology industry.

2.4 How a Party benefits from the BCH?

While all Parties have **obligations** under the 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 registering 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 implementation of the 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.

2.5 What are the obligations of a Party regarding registering and updating information on the BCH?

A Party has **obligations** under the Protocol to make some information available through the BCH. Article 20 of the Cartagena Protocol lists the **specific information** [1] that a Party must provide to the BCH. This is described in the section below.

In addition, the COP-MOP[2] 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 which require or request additional information though be made available to the BCH.

2.6 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)[1] as follows:

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

- 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[2]. 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.

(ii) Information that must be made available to the BCH ***when a country*** modifies its 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.

(iii) 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 and food or feed, or for processing.

(iv) 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 Protocol only imposes legal obligations on Parties, non-Parties are also encouraged to contribute appropriate information to the BCH

If the BCH is to work effectively, required information should be registered as soon as possible. Among other things, such a step will ensure that other BCH users are aware of their relevant national authorities and laws and regulations relating to LMOs.

Note:

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

3 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[1] regarding the modalities of operation of the BCH – i.e. how it will work.

In order 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 the validation of national records created by authorized users prior to publication..
- Liaison with the Secretariat regarding technical aspects of national participation in the BCH.
- Liaison with the Secretariat regarding issues of relevance to the development and implementation of the BCH.

3.1 Who can access the BCH?

Information in the BCH is open and accessible to all users and therefore **confidential information**[1] (under Article 21 of the Protocol) should not be registered in the BCH.

3.2 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 information is registered by NAUs, it must be validated by the BCH National Focal Point prior to publication.

Information that cannot be registered directly in the BCH by BCH account holders

CBD, CPB and BCH National Focal Points (NFPs) are registered by the Secretariat 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.

Information that can be registered directly in the BCH only by BCH NFPs:

- National Authorized Users (NAUs) – NAUs have the same rights as BCH NFPs except that any national record they register must be validated by their respective NFP prior to publication in the BCH.

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

- Biosafety Experts
- Competent National Authorities
- Country Needs and Priorities
- Decisions on LMO for FFP under Article 11
- Decisions on LMO under Advance Informed Agreement
- Laws
- National Biosafety Websites or Databases
- Other Decisions or Declarations
- Regional or International Agreement
- Regulations or Guidelines
- Reports on Biosafety Expert Assignment
- National Risk Assessment reports

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

Information that can be registered by all BCH registered users

- Biosafety Courses

- Capacity Building Projects & Opportunities
- Biosafety International Organizations
- BCH News items
- Contact Information
- General Risk Assessment reports
- LMO / Gene / Parent or Donor Organism Registries items
- Biosafety Information Resource Centre (BIRC) items
- Scientific Bibliographic Biosafety Database (SBBD) items

Note: None of the information above will be published in the BCH until it has been validated by the SCBD (with the exception of the SBBD items that are subject to ICGEB validation).

The SCBD reserves the right to review and verify, prior to publication, all information submitted by BCH registered users

3.3 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, in order for BCH users to fulfil their needs and obligations, at both the national and international level, they may also register 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 that are linked to BCH records may be made available in any language.

In order to minimise 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 that are commonly used internationally.

4 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
- Decisions and declarations on the BCH

4.1 Laws and Regulations

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 what each country's relevant regulatory requirements are.
- Accordingly, if laws, regulations or guidelines are amended, or new ones 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 is an ongoing obligation requiring Parties to ensure that up-to-date information about relevant national laws etc., are available through the BCH.
- This is particularly important in relation to LMOs-FFP since there is no obligation in the Protocol itself for Parties of export or exporters to notify the Party of import in advance of 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 (Article 14)**

- Each Party is required to make available through the BCH any bilateral, regional or multilateral agreements or arrangements regarding the transboundary movement of LMOs, including those that they entered into before or after the date of entry into force of the Protocol.[1]

4.2 National Contacts

The Protocol requires the designation of a number of national institutions to fulfil 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 Art. 17). Only Competent National Authorities and contact points for emergency measures may be registered and updated in the BCH directly by the BCH NFP.

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

- Each Party shall, no later than the date of entry into force of the 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 (*Article 19)***

- This information is critical for the proper functioning of the Protocol. It tells Parties of export or exporters to which authority in the Party of import they should address a 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 *(Article 19)***

- The Cartagena Protocol national focal point is responsible for liaising, on behalf of a Party, with the Secretariat.
- 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.

4.3 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 (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.

⇒ **Decisions regarding the first import of LMOs for intentional introduction into the environment (Articles 7-10 and 14(4))**

- This refers to decisions adopted by a Party of import (under the AIA procedure or a domestic regulatory framework) for 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 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..
- 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 introduction into the environment (and subject to what conditions, if any);
    - Which LMOs a Party of import has refused and why.
- Notifications, under Article 10 or 14(4) may specify how the decision will apply to 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 (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 Protocol sets out in its Annex II[1] 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.
- Where the Party concerned approves the LMO in question only for field trials, the submission of information to the BCH about this decision is not mandatory under the Cartagena Protocol. However, if the same LMO were to be sent to another Party for field trials then it would be subject to the provisions of Article 7 (AIA).

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

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

- The Protocol recognises 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.[2]
- 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.

⇒ **Review and change of decisions (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 *(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 utilise 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 (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(Article 17)[3]**

- 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 notify affected or potentially affected States (through their point of contact for emergency measures under Article 17) the BCH and, where appropriate, relevant international organisations 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 (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.

4.4 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 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. 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.

4.5 Other Information Available on the BCH

There are numerous other types of information that are registered in the BCH. This information originates from various sources, including Parties, governments and organisations.

⇒ **LMOs, genes and ornganisms registries**

The BCH contains databases providing the following registries:

(i) The **LMO-Unique Identifiers Registry (LMO-UIds)**, which 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;

(ii) The **Gene Registry**, which provides summary information on gene inserts and characteristics of the genetic modifications of LMOs; and

(iii) The **Organism Registry**, which 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 Building**

Through the BCH, Parties and others can access important information about capacity-building and other assistance for implementation of the Cartagena Protocol. The following databases are provided:

(i) **Biosafety Capacity Building Projects**, which contains information on project status and location, lead organization(s) and contacts, objectives and activities, lessons learned, a brief description of each project and web links for detailed information;

(ii) **Capacity-Building Opportunities**, which includes information on one-time, short-term capacity building opportunities, such as: funding grants, scholarships and fellowships, technical assistance, training workshops, internships/apprenticeships, study tours, partnerships, discussion forums and others;

(iii) **Compendium of Academically-Accredited Biosafety Courses**, which includes a listing of recurrent academically-accredited biosafety education and training programs offered around the world; and

(iv) **Capacity-Building Needs and Priorities**, which includes national and regional necessities for the implementation of the Biosafety Protocol, identified and categorized in line with the elements of the Capacity-building Action Plan.

⇒ **Roster of Experts**

The COP-MOP decided that the BCH will maintain a **Roster of Experts** [1] (see **Decision EM-I/3** [2]) 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.

The COP-MOP also encourages Parties to provide the Secretariat with an **evaluation of any advice** [3] given by experts from the Roster as well as results achieved. The evaluations are made available through the BCH. This assists other Parties in making decisions about use of the roster of experts.

⇒ **National Reports submitted by Parties**

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 resources**

Various decisions of the COP-MOP have expanded the range of scientific, technical, environmental and legal information available through the BCH.

- The **Biosafety Information Resource Centre (BIRC)** allows the BCH users to search for electronic catalogues of biosafety-related publications and information resources including: news services; e-mail list servers; online databases and search engines; reports and case studies; journals, newsletters and teaching materials (manuals, toolkits and presentations). Its objective is to increase the accessibility and utilization of available biosafety information and resources for policymakers, educators, researchers, and the general public. BIRC contributions are welcome from all BCH registered users.

- The **Scientific Bibliographic Database on Biosafety,** maintained by the International centre for Genetic Engineering and Biotechnology (ICGEB), provides access to a bibliographic collection of scientific studies relevant to biosafety and risk assessment of biotechnology. This searchable database is updated monthly and contains records of scientific articles (full reference + abstract) published in national and international scientific periodicals from 1990 onwards. Each record is vetted by ICGEB scientists for its contribution to the numerous scientific debates concerning Genetically Modified Organisms (GMOs).

⇒ **BCH training materials and assistance**

There is a variety of information inn the BCH itself about 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.

5 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 (Article 20 paragraph 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 (Article 11 paragraph 5);

c) Bilateral, multilateral and regional agreements and arrangements (Articles 14 paragraph 2 and 20 paragraph 3 (b));

d) Contact details for competent national authorities (Articles 19.2 and 19.3);

e) Contact details for national focal points (Articles 19 paragraph 1 and 19 paragraph 3);

f) Contact details for emergency contact point for receiving notifications of unintentional transboundary movements of LMOs (Article 17 paragraph 2;

g) Reports submitted by the Parties on the operation of the Protocol (Article 20 paragraph 3 (e));

h) Decisions by a Party on regulating the transit of specific living modified organisms (LMOs) (Article 6 paragraph 1);

i) 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 (Article 17 paragraphs 1 and 3);

j) Illegal transboundary movements of LMOs (Article 25 paragraph 3);

k) 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) (Article 10 paragraph 3 and Article 20 paragraph 3(d));

l) Information on the application of domestic regulations to specific imports of LMOs (Article 14 paragraph 4);

m) 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 (Article 11 paragraph 1);

n) 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 (Article 11 paragraph 4) or in accordance with annex III (Article 11 paragraph 6) (requirement of Article 20 paragraph 3(d));

o) Declarations regarding the framework to be used for LMOs intended for direct use as food or feed, or for processing (Article 11 paragraph 6);

p) Review and change of decisions regarding intentional transboundary movements of LMOs (Article 12 paragraph 1);

q) LMOs subject to simplified procedures regarding intentional transboundary movement and exempted by a Party from the AIA procedure (Article 13, paragraph 1);

r) 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; (Article 20 paragraph 3 (c)).

[End of support tool 1]

[Support Tool 2 - Box 34. Unique identification of LMOs]

The BCH modalities of operation require the BCH to make use of existing unique identification systems for living modified organisms, as appropriate, to facilitate 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 (for further information see https://bch.cbd.int/database/organisms/uniqueidentifiers/about.shtml)

[End of Support Tool 2]

[Support Tool 3 – Timeframe for posting information onto the BCH]

Timeframe for posting information onto 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 domestic use of a LMOP 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, international ageements 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 onto the BCH	no specification
20-3(a)	Existing laws, regulations, guidelines and information on the AIA procedure	no specification
20-3(b)	Bilateral, regional, international ageements and arrangements made before and after adhesion to the Protocol	no specification
20-3(c)	Summarises of risk assessments, environmental reviews of LMOs	no specification
20-3(d)	Final decisionregarding 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 endeavour
25	Information concerning cases of illegal transboundary movements pertaining to it	no specification

[End of Support Tool 3]

6 References

How does the BCH work?

[1] https://bch.cbd.int/about/modalities.shtml.

What is a Clearing House Mechanism?

[1] " Clearing house mechanism", CBD http://www.biodiv.org/chm

What is the role of the BCH?

[1]"Cartagena protocol on Biosafety" CBD, Article 20.

http://www.biodiv.org/biosafety/articles.asp?lg=0&a=bsp-20

What are the obligations of a Party regarding registering and updating information on the BCH?

[1] "An introduction to the Biosafety Clearing House" UNEP-GEF Biosafety project, Training Module 2 page 19
or [support tool 1] at the end of this document

[2] 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.

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

[1]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/about/modalities.shtml#B

[2]As for Cartagena Protocol text in Articles 17 and 19 as well as Decision BS-I/3

Who can access the BCH?

[1]"Cartagena protocol on Biosafety" CBD, article 21 on Confidential information.

http://www.biodiv.org/biosafety/articles.asp?lg=0&a=bsp-21

Laws and Regulations

[1]Source: "An Explanatory Guide to the Cartagena Protocol on Biosafety An Explanatory Guide to the Cartagena Protocol on Biosafety", Bilateral, regional and multilateral agreements and arrangements, IUCN, article 14 Para 395.

http://www.iucn.org/themes/law/pdfdocuments/Biosafety-guide.pdf

Decisions and Declarations on LMOs

[1]"Cartagena protocol on Biosafety" CBD, Annex II.

http://www.biodiv.org/biosafety/articles.asp?lg=0&a=bsp-42

[2]Source: "An Explanatory guide to the CPB" IUCN, Article 11, Pg 85

http://www.iucn.org/themes/law/pdfdocuments/Biosafety-guide.pdf

[3]Source: "An Explanatory Guide to the CPB", IUCN, p. 119

http://www.iucn.org/themes/law/pdfdocuments/Biosafety-guide.pdf

Other Information Available on the BCH

[1]Decisions adopted by COP-MOP 1.UNEP/CBD/BS/COP-MOP/1/15, BS -I/4, Annex I, Para. C. http://www.biodiv.org/biosafety/cop-mop/mop-01-dec-en.pdf

[2]"COP decision EM-I/3", CBD, section III http://www.biodiv.org/decisions/default.asp?lg=0&m=excop-01&d=03

[3]"Decisions adopted by COP-MOP 1." UNEP/CBD/BS/COP-MOP/1/15, BS-I/4, Annex I, Para J.1

http://www.biodiv.org/biosafety/cop-mop/mop-01-dec-en.pdf