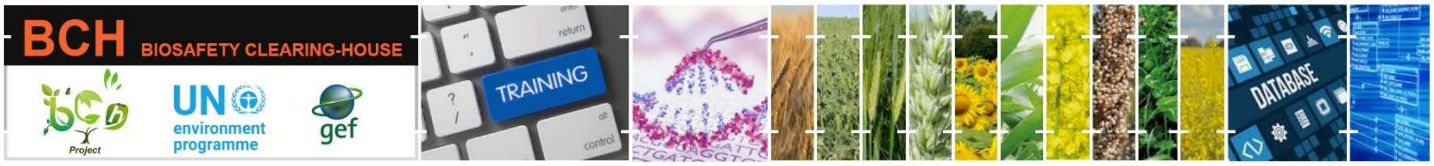

A User's Guide to the Central Portal of the Biosafety Clearing House

Information-sharing Obligations on Becoming a Party to the Cartagena Protocol

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Part of the UNEP-GEF BCH III Project Training Material package.

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

List of Abbreviations

AIA	Advanced Information Agreement
BCH	Biosafety Clearing-House
BCH-NFP	Biosafety Clearing-House National Focal Point
CBD	Convention on Biological Diversity
CBD-NFP	Biosafety Clearing-House National Focal Point
CNA	Competent National Authority
COP-MOP	Conference of the Parties Serving as the Meeting of the Parties
CPB	Cartagena Protocol on Biosafety
CPB-NFP	Cartagena Protocol on Biosafety National Focal Point
GEF	Global Environment Facility
LMO	Living Modified Organism
MC	Management Centre
nBCH	National node of the Biosafety Clearing-House
NBF	National Biosafety Framework
NFP	National Focal Point
SCBD	Secretariat of the Convention on Biological Diversity
UNEP	United Nations Environment Programme

1. Introduction to the Module

What you will learn in this module:

This module addresses the information-sharing obligations faced by a Party on entry into force of the Protocol. It seeks to explain:

- The information-sharing responsibilities of the BCH National Focal Point,
- The information that must be made available by a Party through the BCH immediately on entry into force of the Protocol,
- An overview of ongoing information-sharing obligations.

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 was designed to guide users of the Biosafety Clearing-House. It was developed mainly for government representatives, including National Focal Points (NFPs).

Purpose

This module examines the information-sharing obligations outlined by the Cartagena Protocol and relevant decisions by the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP). It also aims to incentivize a non-party to

[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/

consider making information available to the BCH even before a country completes its ratification process.

2. Becoming a Party to the Protocol

OVERVIEW

To become a Party to the Cartagena Protocol on Biosafety, States may ratify, accede to, approve, or accept the Protocol. At this point they take on certain obligations.

2.1. Becoming a Party

Various terms are used to indicate that a State or regional economic integration organization (e.g., the European Union (EU)) has consented to be bound by an international treaty, including "ratification", "accession", "approval", and "acceptance". The legal implications of these consent forms are the same to the extent that the treaty becomes legally binding.

All States that have ratified acceded to, approved, or accepted the Protocol are, therefore, legally Parties to the Protocol.

2.1.1. Ratification and Accession

The primary distinction in becoming a Party is between ratification and accession. Only those States that signed the Protocol when it was open for signature (i.e., between its adoption and the closing date for signature, 4 June 2001) can proceed to ratify it. In signing the Protocol, States only indicated general support for its objective and provisions and their intention to become Parties and be legally bound by it. However, the signing did not establish consent to be bound by the Protocol. Therefore, a further act of *ratification* is required before the State becomes a Party.

The instrument of ratification is signed by the Head of State, Government or Minister for Foreign Affairs and deposited with the Depositary – the Secretary-General of the United Nations. Once a State has deposited this instrument, the Protocol enters into force forthat State ninety days later. At this point, the State is bound by the provisions of the Protocol and must comply with its obligations.

States that *did not sign* the Protocol when it was open for signature cannot ratify it – they may only accede to it. These States, therefore, deposit an instrument of *accession* to become a Party. (Note: These States have the same rights and obligations as those ratified the Protocol.)

2.1.2. Acceptance and Approval

The terms "acceptance" and "approval" are of more recent origin and apply under the same conditions as those that apply to ratify. Certain countries use

"acceptance" or "approval" to participate in treaties. The terms are also used in cases where organizations (e.g., the EU) rather than States become Parties to an international treaty. While the uses of these terms relate to the diversity of legal systems, the legal effect is the same as ratification.

2.1.3. Succession

Succession occurs when one State replaces another for responsibility over international relations of the State's territory. Generally, a newly independent State which makes a notification of succession is considered a Party to the Protocol from the date of the succession of the State, or from the date of entry into force of the treaty, whichever is the later date.

2.2. Benefits of becoming a Party to the Cartagena Protocol

There are several benefits in becoming a Party to the Cartagena Protocol, including the following:

- Ability to influence the implementation of the Protocol and shape its further development through participation in the decision-making processes of the Conference of the Parties serving as the meeting of the Parties to the Protocol,
- Developing country Parties and Parties with economies in transition are eligible for financial support from the Global Environment Facility (the financial mechanism for the Protocol) for capacity-building as well as other support for implementation of the Protocol and participation in its processes,
- Enhanced visibility and credibility of national systems for regulating biosafety within the global community,
- Contribution to harmonized rules, procedures, and practices in managing the transboundary movement of LMOs,
- Facilitation of mechanisms and opportunities for governments to collaborate with other governments, the private sector and civil society on strengthening biosafety,
- Improved access to relevant technologies and data and benefiting from a regular exchange of information and expertise, and
- Demonstrating commitment to conservation and sustainable use of biological diversity through implementing biosafety measures.

2.3. Obligations on becoming a Party to the Cartagena Protocol

Becoming a Party to the Cartagena Protocol also confers several obligations that should be in place as soon as the Protocol enters into force for that Party. This module elaborates the primary information-sharing obligations, including the role of the BCH focal point, information that must be made available no later than

entry into force of the Protocol for a Party and ongoing information reporting requirements.

Given the central role of the BCH in the operation of the Protocol, the availability, accuracy, and accessibility of relevant information through the BCH is crucial. Early administrative tasks (i.e., during preparation before entry into force) typically include putting into place the necessary infrastructure and personnel at the domestic level to collect, classify, make available, use, access, and disseminate relevant information to and from the BCH. The BCH Focal Point is responsible for ensuring that information flow to and from the BCH is done in a timely manner.

3. Role of the BCH Focal Points

OVERVIEW

BCH National Focal Points are responsible for validating information, liaising with the CBD Secretariat, and developing a network of information partners to assist in implementing the BCH.

3.1. Function of the BCH Focal Points

BCH National focal points are nominated by each Party or government to liaise with the Secretariat regarding issues of relevance to the development and implementation of the BCH.

Their role and responsibilities are set out in the Modalities of Operation of the BCH (*COP-MOP decision BS-I/3*), including:

- Active clearance for publishing information registered on the Biosafety Clearing House, including validation at a national level of records to make them publicly available through the central portal,
- Liaison with the Secretariat regarding the technical aspects of national participation in the Biosafety Clearing House, as well as provision of advice on further technological development, including, among other things, suggestions for improvements to the layout and system specifications of the central portal and central databases, and
- Facilitation of developing a network of multi-sectoral and interdisciplinary partners, as appropriate in the Biosafety Clearing- House implementation process.

3.1.1. Active clearance for publishing information ('validation')

BCH National Focal Points are authorized by their countries to use the BCH Management Centre to create, delete, or modify information about competent national authorities, national biosafety websites or databases, laws and regulations, decisions on living modified organisms (LMOs), risk assessments, biosafety experts, capacity-building needs and priorities, capacity-building activities, and news items for their country. Only the BCH National Focal Point has the authority to "validate" information for that country (i.e., verify the accuracy of a record and make it public) and register authorized users for the country.

This means that the role of the BCH National Focal Point is to ensure the quality, accuracy, and completeness of the information that is made available through the BCH. To assist in this process, most countries will implement local management procedures to ensure that information providers have verified that their information is correct and complete before it is provided to the BCH focal point.

Records registered or validated by BCH National Focal Points are published immediately.

BCH National Focal Points may also register additional National Authorized Users who can submit information in all the information categories. However, before publication, the BCH National Focal Point must verify the accuracy of any record and validate it before it is made public. This means that it is essential that BCH Focal Points to monitor pending records in the BCH because they will not be made available through the BCH until the Focal Point has validated the information for publishing.

Registered Biosafety Experts can be permitted by their BCH National Focal Point to modify any information about their own Expert Records in the Roster of Experts. As with other Authorized Users that modify information under national jurisdiction, these changes must be validated by the BCH National Focal Point before they are published.

3.1.2. Liaison with the CBD Secretariat regarding the BCH

BCH Focal Points are responsible for interacting with the CBD Secretariat regarding the technical aspects of national participation in the BCH. This includes providing the Secretariat with feedback on their experiences with the operation of the BCH to improve its future development and ability to meet the needs of Parties. The

Modalities of Operation of the BCH specifically request focal points to provide advice on further technical development, including suggestions for improvements to the layout and system specifications of the Central Portal and its databases.

BCH Focal Points may provide such information directly to the Secretariat at any time, or the Secretariat may request feedback through a Notification or questionnaire. In many cases, it will be necessary for the BCH Focal Point to coordinate responses from various national users to provide comprehensive and representative feedback.

3.1.3. Facilitating a network of partners

BCH Focal Points play an essential role in facilitating the development of a network of BCH users at a national (and/or regional) level. For this network to aid in the implementation process of the BCH, they typically come from a variety of institutions, sectors, and disciplines to ensure the needs of all relevant players at the national level.

One of the activities that the BCH Focal Point may carry out in this regard is to advise the relevant national authorities when relevant information is made available through the BCH (e.g. when another Party registers a decision to place on the market an LMO intended for direct use as food). Accordingly, all BCH Focal Points areautomatically subscribed to the BCH Current Awareness Service. This service sends outregular updates summarizing new information that has been added to the BCH. It is sentdirectly to users by email or to a specified fax number (See Module 6, "RegisteringInformation in the BCH Central Portal", section "My Subscriptions" for further details.) Several resources are available in the BCH to assist focal points in networking and sharing information more effectively. For example, the Biosafety Organizations records assist in developing relationships with foreign organizations with similar goals. Also, the Biosafety Virtual Library Resources, Capacity Development Initiatives and online conferences and forums provide greater access to information, training, experience, and fundraising opportunities.

3.2. Responsibilities of Information Partners

Some countries use an interoperable mechanism to make their information available through the BCH. In such instances, information partners must follow specific interoperability guidelines for information-sharing prepared by the Secretariat. Where partner institutions are hosting information that is required under the Protocol to be made available to the BCH, the following minimum standards apply:

- Nomination of an institutional focal point in the partner organization responsible for liaison with the Secretariat,
- Written confirmation by the relevant Party or Government that responsibility for the provision of this information has been conveyed to the institution in question and

- Guaranteed maintenance of their information exchange system, as well as provision of 24 hour/7 day a week availability and open access to the required information.

If these standards cannot be maintained or a partner does not wish to continue providing information to the BCH, all data or information subject to the partnership must be transferred to the BCH website.

4. On Entry into Force of the Cartagena Protocol

OVERVIEW

Information that must be provided no later than the date of entry into force of the Protocol for a Party includes designation of National Focal Points, contact points in case of emergency, and Competent National Authorities.

The Cartagena Protocol contains several provisions that require each Party to take specific administrative measures at a national level as soon as the Protocol enters into force.

4.1. Designation of National Focal Points

Article 19 of the Protocol requires each Party to designate one National Focal Point for the Protocol (CPB-NFP).

The CPB-NFP National Focal Point is the primary contact point between a Party and the Secretariat. This is the person or national institution that receives, for example:

- Notifications from the Secretariat regarding, for example, newly available resources or requests to designate delegates for meetings,
- Invitations to submit views on matters relating to the Protocol and
- Documentation for Biosafety meetings.

The name and address of the CPB National Focal Point must be provided to the Secretariat no later than the date of entry into force of the Protocol for that Party. The registration of National focal points in the BCH can only be done by the Secretariat upon receipt of a *written communication* addressed to the Executive Secretary and endorsed by the *following categories*:

- 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 details of the *Point of contact for receiving notifications under Article 17* (*Emergency Measures*) must be communicated to the Secretariat by the *National Focal Point for the Biosafety Clearing House* (BCH-NFP).

Note: The common format for National Focal Point nominations is available for download at your *Dashboard page*: https://bch.cbd.int/en/register/.

By standard procedure for nomination of all focal points, *written confirmation* of the nomination of a person or institution to the post of any category of *National Focal Point* must be sent to the CBD Secretariat before such records can be created (i.e., they are the only type of national record that a country cannot create through the BCH dashboard).

Written confirmation may be sent by fax or postal mail to the Secretariat on institutional letterhead, such as that of the appropriate ministry, agency, etc.

4.2. Designation of Cartagena Protocol Competent National Authorities

Article 19 of the Cartagena Protocol requires each Party to designate one or more Competent National Authorities (CNAs) for the Protocol. CNAs are responsible for exercising the administrative functions required by the Protocol. The functions of the CNA suggest that the designated institution(s) should have the authority to make decisions about imports of LMOs at the domestic level.

The functions of the CNA are addressed in *Article 19* of the Protocol and may include, for example:

- Receiving notification of a proposed transboundary movement of an LMO that falls within the scope of the Advance Informed Agreement (AIA) procedure (*Article 8*),
- Acknowledging receipt of the notification (*Article 9*),
- Requesting further information from the notifier, if necessary (*Articles 9* and *10*),
- Communicating the decision of the Party of import to the notifier and the BCH, withreasons, when required (*Article 10(3)*),
- Responding to requests by the Party of export or notifier to review decisions (*Article 12*) and

- Consulting with the notifier, where necessary, on treating confidential information (*Article 21*).

> The exact entity may be designated to act as both a National Focal Point and a CNA. The names and addresses of the NFP and the CNA or authorities must be provided to the BCH no later than the date of entry into force of the Protocol for that Party.

In some countries, a single CNA (e.g., the Ministry of Environment) is designated to address all functions pursuant to the Protocol. Others are designated to address, for example, a specific LMO or its intended use. For instance, the Agriculture Ministry may be responsible for imports of genetically modified crops or seeds; the Fisheries Ministry may be responsible for imports of transgenic fish; and a specialized agency may be responsible for all other LMO imports.

If a Party chooses to designate more than one CNA, it must inform the Secretariat for the information to be made available to Parties through the BCH. This allows a notifier to find out which CNA in the Party of import it should contact regarding a proposed transboundary movement of an LMO.

Although the CNA is responsible for carrying out administrative functions under the Protocol, the decision-making process under a Party's national biosafety framework may involve a broader range of national organizations and/or other authorities. The procedure for making decisions at the domestic level (including any necessary consultations) should be set out in the national biosafety framework.

The information that should be provided to register a CNA is contained in the *Competent National Authority Common Format*, which can be downloaded from the BCH common formats page on your *Dashboard page*: https://bch.cbd.int/en/register/.

4.3. Identification of a contact point for unintentional transboundary movements and emergency measures

Article 17 of the Protocol requires each Party to make available to the BCH, no later than the date of entry into force of the Protocol for the Party, details of its point of contact to receive notifications concerning any occurrence that leads or may lead to unintentional transboundary movement of an LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health in such States.

Because an incident of this nature may happen at any time, countries must be prepared for emergency measures and make their contact point's details available

through the BCH. The information that should be provided to register the contact point for unintentional transboundary movements and emergency measures is in the *National Focal Point Common Format*, available for download from your *Dashboard page*: https://bch.cbd.int/en/register/.

Checklist 1: No later than entry into force of the Protocol

- Designate a National Focal Point for the Protocol (*Article 19.1*).
- Provide the name and address of the CPB National Focal Point to the CBD Secretariat (*Article 19.2*).
- Designate one or more Competent National Authorities (*Article 19.1*). Provide the name and address of the Competent National Authorities to the CBD Secretariat (*Article 19.2*). In cases where more than one competent national authority has been designated, also convey to the Secretariat relevant information on the responsibilities of each authority (including, at a minimum, the type of LMOs that each authority is responsible for).
- Identify an *Article 17* point of contact to receive notification concerning any occurrence that may lead to unintentional transboundary movement of an LMO.
- Provide the name and address of the *Article 17* focal point to the CBD Secretariat (*Article 17.2*).
- Designate a BCH Focal Point to be able to fulfil information-sharing obligations (COP-MOP *decision BS-I/3*).

5. Information to be shared following entry into force of the Cartagena Protocol

OVERVIEW

Information that must be shared following entry into force of the Protocol includes changes of Competent National Authorities functions or contact details, laws and regulations, decisions on LMOs, risk assessment reports, any other decision, declaration, notification or report relevant to the Protocol, appointment and contact details of biosafety experts, capacity-building needs and priorities and capacity-building activities.

The Protocol relies heavily on sharing appropriate and timely information for its effective operation and implementation. The BCH is the Protocol's primary information-sharing system and an essential tool for implementation. Therefore, many initial tasks that must be taken after entry into force are related to making information available to the BCH. Because the BCH plays such an important role in the operation of the Protocol for all Parties, it is essential to make any relevant information available and accessible as soon as possible.

5.1. Information-sharing under *Article 2*

Each Party is required to make available to the BCH information specified under paragraph 3 of *Article 20* as follows:

a) *Any existing laws, regulations, and guidelines for implementation of the Protocol, as well as information required for the Advance Informed Agreement (AIA) procedure under the Protocol,*

b) *Any bilateral, regional, and multilateral agreements and arrangements,*

c) *Summaries of risk assessments or environmental reviews of LMOs, including relevant information regarding processed products of LMO origin,*

d) *Final decisions regarding the importation or release of LMOs,*

e) *Reports submitted by it pursuant to* Article 33*, including those on implementing the AIA procedure.*

In addition to *Article 20*, various other articles in the Protocol directly or indirectly reference information that must be shared through the BCH.

5.2. Information required for the Advance Informed Agreement (AIA) procedure

Article 20(3)(a) refers to information required by Parties for the AIA procedure, some ofwhich must be made available through the BCH as follows:

- Any Decision by the Party of import on whether to approve, prohibit or restrict the import (Article 1) and the reasons on which it is based (*Article 10(4)*),
- Where relevant, information on the domestic regulatory framework governing the import of LMOs from the Party of import (*Articles 9* and *10*),
- Information on risk assessment (*Articles 10(1)* and *15* and *Annex III*),
- Information on review of decisions (*Article 12*), and
- Information on simplified procedures (*Article 13*).

Not all information generated by the AIA procedure is reported to the BCH; for example, the notification of intended export from the Party of export or exporter (*Article 8*) and acknowledgement of receipt (*Article 9*) is materially a bilateral process.

Under *Article 10*, the Party of import must communicate its decision to the BCH (and to the notifier) within 270 days of receiving the notification on whether or notto allow the proposed transboundary movement. The 270-day period specified in the Protocol is a maximum – i.e., Parties may inform the notifier and the BCH of their decision in a shorter timeframe if they can do so.

In certain circumstances, the 270-day period may be extended. These circumstances include:

- Cases where additional information has been requested from the notifier. In such instances, the time the Party of import waits for the additional relevant information is effectively "added" to" the 270-day period. (*Article 10(3)(c)*), and
- Cases where the Party of import informs the notifier that an additional defined period is required (*Article 10(3)(d)*).

The decision on whether or not to allow the import of LMOs is communicated to the BCH to allow Parties, governments, exporters, importers and other stakeholders to find out which LMOs have been approved or prohibited for import for intentional introduction into the environment by a Party to the Protocol, and under what conditions (if any).

A Party of import may review and change a decision regarding an intentional transboundary movement in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health. In such a case, the Party must

inform the BCH (and the notifier)**within 30 days of taking the decision**, including setting out its reasons (*Article 12*).

Article 13 provides that Parties can address certain LMO importsdifferently. Under *Article 13.1(a)*, a Party may indicate that certain transboundarymovements of LMOs may occur at the same time as the movement is notified to it, i.e.,without waiting for further decision procedures. A Party may also exempt (*Article 13.1(b)*) certain LMO imports from the AIA procedure. In either case, Parties who intend to use these provisions make available through the BCH the list of LMOs or information onthe specific circumstances to which such procedures will apply.

Article 14.4 allows for a general application of domestic regulations to specific imports rather than using the AIA procedure and requires advance notification through the BCH.

5.3. LMOs intended for direct use as food or feed or for processing(Article 11)

Under *Article 11(1)*, a Party making a final decision regarding the release (domestic use and placing on the market) of an LMO at the domestic level, which may be exported for direct use as food or feed or for processing (LMO-FFP), must make it available through the BCH **within 15 days of reaching the decision**.

Parties to the Protocol that usually import agricultural commodities for food, feed or processing may respond to such information regarding the commercialization of LMO-FFPby taking a decision under their domestic regulatory frameworks, which must be consistent with the objective of the Protocol. Each Party is required to make copies of any laws, regulations, and guidelines, if any, applicable to the import of LMOs-FFP available through the BCH (*Article 11.5*). This requirement is intended to promote transparency and predictability by allowing a person who intends to export an LMO-FFP to a Party to the Protocol to find out through the BCH what national regulations of the importing Party will apply to the proposed export.

This 15-day reporting window applies when, for example, a Party decides to permit the commercial marketing of a genetically modified maize plant within its territory that could subsequently be exported for animal feed or for processing for food or other use. By wayof another example, it would also apply to a decision permitting the growing of domestically developed genetically modified cassava, which may be exported for direct use as food or for processing. (Note that if this cassava were then exported to another Party tobe planted, it would fall under their AIA procedure since it would then be intended for introduction into the environment of the importing Party.)

Article 11 also applies to LMOs for direct use for processing. Examples of such LMOs mayinclude those used in industrial processes to produce plastics or oils.

Note: A field trial, confined field trial, or experimental introduction is regarded as an intentional introduction into the environment when the conditions are specified in CPB, Article 3, paragraph b, are unmet (decision CP-9/12).

In contrast to the AIA procedure, *Article 11* of the Protocol does not require a Party exporting an LMO-FFP or an exporter of an LMO-FFP to provide any notification or information directly to the importing Party. Any such obligation will only be triggered by the domestic regulations of the importing Party. In practice, however, the domestic requirements of the importing Party often result in the first imports of an LMO-FFP being subject to procedures similar to AIA. For example, the importing country 's biosafety framework may require prior notification of the first import of an LMO-FFP, a risk assessment, and explicit approval.

In the absence of a domestic regulatory framework, a developing country Party or a Party with an economy in transition may declare that it will make a decision about the first import of an LMO-FFP following the procedures specified under *paragraph 6 of Article 11*. This is to ensure that any such Parties that do not yet have a domestic regulatory framework in place to address imports of LMO-FFPs may nonetheless subject LMO-FFP imports to prior notification and approval procedures in a manner consistent with the Protocol's objective. Any Party with no domestic regulatory framework for LMO-FFP imports in place but wishes to subject such imports to prior assessment and approval should indicate this by declaring this effect through the BCH.

Article 14 addresses the situation where Parties to the Protocol have concluded, or intend to conclude, a separate agreement or arrangement on the intentional transboundary movement of LMOs. For example, two neighboring countries that trade actively in LMOs may decide to conclude an agreement that is more specific than the Protocol and is tailored to those countries' particular situation and needs. An example of such an agreement could be the case of the European Union and its member States. As Parties to the Protocol, the European Community and its members may wish to apply, in precedence over the provisions of the Protocol, relevant EU legislation within the EU's internal market and to imports of LMOs from third-party States into the EU.

Checklist 2: Initial information must be submitted to the BCH to implement the AIA procedure, imports of LMO-FFPs and other releases.

- Existing national legislation, regulations and guidelines for implementing the Protocol and information required by Parties for the AIA procedure (*Article 20.3(a)*).
- Any bilateral, regional and multilateral agreements and arrangements regarding biosafety (*Article 20.3(b)*).
- Notification on applying domestic regulations to specific imports of LMOs (*Article 14.4*).
- Imports of LMOs are exempted from the AIA procedure (*Article 13.1(b)*).
- Cases in which intentional transboundary movement may co-occur as the movement is notified to the Party of import (*Article 13.1(a)*).
- In the absence of a national regulatory framework, a declaration regarding the framework will be used for the first import of LMO-FFPs (*Article 11.6*).
- Final decisions regarding the importation or release of LMOs (*Article 20.3(d)*) within 15 days of deciding on LMO-FFPs and within 270 days of receiving the notification for the AIA procedure.
- Summaries of risk assessments generated by the national regulatory process (*Article 20.3(c)*).
- Information on review and decision change (*Article 12.1*) within 30 days of taking the decision.
- Notification of a release that leads, or may lead, to an unintentional transboundary movement of an LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health (*Article 17.1*).
- Information concerning illegal transboundary movements of LMOs (*Article 25.3*).

5.4. Protecting commercial information (*Article 21*)

Each Party is required to protect confidential information received under the Protocol and as identified by the notifier. It must put in place procedures to protect and treat such information in no less favorable manner than it treats confidential information in connection with domestically produced LMOs. Confidentiality must also be respected if thenotifier withdraws the notification. Confidential information should not be made available through the BCH.

However, the following information shall not be considered confidential: (a) the name and address of the notifier, (b) a general description of LMO, (c) a summary of risk assessment and (d) methods and plans for emergency response.

5.5. Promoting public awareness and participation (*Article 23*)

The Biosafety Protocol requires and encourages Parties to inform and involve their public in matters relating to LMOs. More specifically, Parties shall:

(1) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs.

Ensure access to information on LMOs, which may be imported.

Consult the public in decision-making regarding LMOs and make the results of decisions available to the public.

Endeavour to inform the public about the means of public access to the BCH.

5.6. Transboundary movements of LMOs between Parties and non-Parties (*Article 24*)

The Protocol does not prohibit transboundary movements of LMOs between Parties and non-parties. Parties may enter bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of LMOs. They can enter into such agreements and arrangements among themselves or with non-parties.

However, the Protocol imposes an obligation on Parties to be consistent with the objective of the Protocol, and it encourages non-parties to adhere to the Protocol and make appropriate information available through the BCH.

5.7. Other requirements

Some measures are not directly required by the Protocol but are necessary for its effective implementation from the date of entry into force. These measures are sometimes prerequisites to achieve full compliance with the Protocol. The following are some practical requirements not directly provided for or authorized by the Protocol.

5.7.1. Assessing Capacity Needs

Most developing countries lack the necessary capacity (e.g., institutional infrastructure, skills, and competence in various fields such as risk assessment, risk management, information management, etc.) to implement the Protocol effectively. Accordingly, a necessary first strategic step is to assess and communicate through the BCH their capacity-building needs to facilitate needs-driven international cooperation in capacity-building activities (as provided for in *Article 22* of the Protocol).

5.7.2. Building and maintaining capacity to use the BCH

Implementing several provisions of the Protocol requires countries to make information available through the BCH. Accordingly, Parties need the capacity to access the BCH.

5.7.3. Preparing for meetings of the COP-MOP

One of the advantages of becoming a Party to the Protocol is the right to participate in making decisions for the COP-MOP. However, not a direct requirement under the Protocol, convening successful COP-MOP meetings is considered each Party's primary and standing requirement. This is because the COP-MOP, by making appropriate decisions, is the principal vehicle to promote and monitor the implementation of the Protocol.

Preparation in advance by Parties to the Protocol contributes enormously towards achieving efficiency in the decision–making process and ensuring the decisions adequatelyreflect each Party’s needs.

Looking at the nature of the various provisions of the Protocol, implementation takes placeat different levels: national, individual, or international by COP-MOP. However, this module's focus has been on information-sharing requirements that need to be fulfilled by each Party.

Like many other international agreements, implementation of the information-sharing requirements of the Biosafety Protocol is a continuous process. The practical implementation of some requirements may be relevant only when and where the situation which gives rise to the requirements exists. However, the translation of the requirements of the Protocol into a specific and comprehensive domestic framework will significantly aid in implementing the provisions of the Protocol.

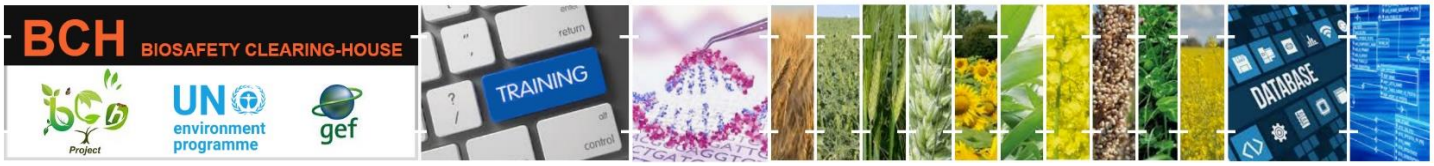
6. Information-sharing for non-Parties

OVERVIEW

All governments are encouraged to both share and access information through the BCH, including non-Parties

The BCH contains information that must be provided by Parties to the Protocol, such as decisions on the release or importation of LMOs, risk assessments, competent national authorities, and national laws. However, governments that are not parties to the Protocol are encouraged to contribute information to the BCH. Many of the decisions currently in the BCH have been registered by non-parties. The information registered in the BCH is freely available to both Parties and non-parties to assist them in achieving the objectives of the Protocol.

Non-Parties are eligible for BCH user accounts with the same registration privileges as Parties. They should also advise the Secretariat of their BCH National Focal Point. Since several of the information-sharing requirements must be notified through the BCH no later than entry into force of the Protocol, it is prudent to ensure all these requirements have been met sometime before the Protocol enters into force.



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