

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

Practice Exercises on Submitting National Records to the BCH Central Portal

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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.

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List of Abbreviations

BCH	Biosfaety Clearing-House
BCH-NFP	BCH National Focal Point
CBD	Convention on Biological Diversity
CNA	Competent National Authority
COP-MOP	Conference of the Parties Serving as the Meeting of the
GEF	Parties
LMO	Global Environment Facility
NAU	Living Modified Organism
NFP	National Authorized User
SCBD	National Focal Point
UNEP	Secretariat of the Convention on Biological Diversity
	United Nations Environment Programme

1. Introduction to the Manual

In this manual you will learn the detailed steps needed to submit records in the different types of BCH national records through practical exercises.

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 BCH* (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 modules⁴, each addressing one element of the BCH.

Audience

This manual is designed to guide specifically BCH National Focal Point and National Authorized users of the Biosafety Clearing House (BCH) who need to submit national records to the BCH. It is developed for a non-technical audience with little or no knowledge of the Cartagena Protocol and the BCH. Still, it needs to understand the requirements of the BCH Central Portal.

Purpose

This manual demonstrates the process of submitting national information to the BCH Central Portal using the online submission forms in the BCH Submit Dashboard. The web-based BCH allows governments to administer their BCH information directly online, helping them implement the Cartagena Protocol on Biosafety.

BCH users with limited internet access may also submit information offline by completing the common formats and submitting them, duly signed, to the SCBD (Secretariat of the Convention on Biological Diversity).

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/

- By Email: Filled in common formats can be emailed to the Secretariat at bch@cbd.int
- By Fax: Filled in common formats can be faxed to the Secretariat at +1 514-288-6588

As an example, you can refer to the instructions for submitting information within this guide, as much of the procedure is similar. More information on common formats can be found in the Manual "Submitting Information in the BCH Central Portal", and in the BCH online help documentation - <u>https://bch.cbd.int/en/kb/tags/submitting-information/What-are-common-formats-/619c55464f1f30000140eec8</u>

Because of possible delays, postal mail may not be a viable solution for certain categories of information that must be submitted according to strict timelines (e.g. final decisions regarding domestic use of LMOs for food or feed, or final decisions for processing under Article 11.1 of the Protocol, which must be made available through the BCH within fifteen days of making the decision).

1.1. BCH Training Site

To aid in learning and understanding how to submit BCH records, the BCH has a training site, mirroring the actual BCH Central Portal.

BCH Website: <u>https://bch.cbd.int</u>

BCH Training Site: https://bch-training.cbd.int/en/

The training site, which includes the same functionality as the actual BCH, allows for entry of sample records, training on website navigation, validation of records, and overall familiarity of the website. It allows country personnel to become familiar with entering and managing data, without the implications of making public "real" data that may not be complete.

Warning: You should always make sure you are logged in to the BCH Training Site if you want to practice in submitting test records.

Please refer to the "Submitting Information in the BCH Central Portal" Manual for more details about how to use the BCH Training site.

2. Submitting New National Information to the BCH

OVERVIEW: National Records include information shared by Parties following entry into force of the Protocol.

The submission of National Records is restricted to Biosafety Clearing-House National Focal Points (BCH-NFPs) and National Authorized Users (NAUs). BCH BCH-NFPs are authorized by their countries to use the BCH Submit Dashboard to create and modify information required by the Protocol and COP-MOP decisions. BCH-NFPs can

register NAUs for the country to organize submitting national information. However, only the BCH-NFP has the authority to "validate" information for that country, i.e. verify the accuracy of a record and make it public. This means that the role of the BCH National Focal Point is to ensure the quality, accuracy and completeness of the information that is being made available through the BCH. To assist in this process, most countries will put in place 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.

National Records include the following types of records:

- National Focal Point (NFP)
- Competent National Authority (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 Cartagena Protocol on Biosafety (NR4, NR3, NR2, NR1, NRI)
- Biosafety Experts (EXP)
- Country Profiles for Biosafety Clearing-House (BCP)

2.1. National Focal Points

National Focal Points are the primary point of contact for all information about a particular issue within a country. They are provided to the BCH in accordance with various articles of the Protocol:

- In addition to their role in validating all national records for publication through the BCH, BCH Focal Points are responsible for liaison with the CBD Secretariat on technical issues related to the BCH, provided in accordance with the BCH Modalities of Operation, adopted in accordance with Article 20 of the Protocol.
- National Focal Points for the Protocol are responsible for liaison with the CBD Secretariat on Protocol issues and details are provided in accordance with Article 19 of the Protocol.

• The point of contact for notifications on unintentional transboundary movements and emergency measures is provided in accordance with Article 17 of the Protocol.

In accordance with 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 cannot be created directly through the BCH Submit Dashboard).

Written confirmation may either be sent by fax or postal mail to the Secretariat on Ministry letterhead, signed by a Focal Point for the Protocol or Convention, or responsible Minister. Email confirmation may be used, as long as the email originates from an account that has previously been validated by the Secretariat (i.e. an existing focal point).

The information that should be provided to register a National Focal Point is contained in the National Focal Point and Contact Details Common Formats, which can be downloaded (in the six UN languages) from the BCH common formats page at https://bch.cbd.int/en/kb/tags/submitting-information/What-are-common-formats-/619c55464f1f30000140eec8.

2.2. Important! Accessing the correct BCH Submit Dashboard

For all the solutions in the next sections, it is assumed that you have done the following:

- If you are <u>practicing</u> how to submit BCH information
 - Log in the "Training Site" of the BCH
- If you are not practicing, that is, you are submitting directly to the BCH
 - Log in the BCH
- After logging in, go to the BCH Submit Dashboard.

Please refer to the manual entitled "Submitting Information in the BCH Central Portal" for more details about how to login the BCH or use the BCH Training site.

2.3. Competent National Authorities

One or more Competent National Authorities should be designated by a government to have the responsibility of performing the administrative functions required by the Protocol. Relevant information on the functions of these authorities is made available to the BCH in accordance with Article 19 of the Protocol. Where more than one competent national authority is designated, the information provided through the BCH should, at a minimum, specify which competent national authority is responsible for which type of LMO.

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EXERCISE: Submit a new Competent National Authority (CNA)



In the "Submit Dashboard," click on "+" found in the same row as "Competent National Authority" from the list of National Records. This will open the online submission form which has four (4) arrow/tabs, i.e., Introduction, Submission form, Review, and Publish. It always opens the first arrow/tab "Introduction" which describes the BCH record type you are planning to submit, along with instructions on how to submit such a record.

Introduction arrow/tab

• Read the description and instructions and click "Submission form" arrow/tab to continue.

Submission form arrow/tab

General Information

Select which language(s) you wish to submit this record: *

• Select: English (or your local language if data is in local language)

Country *

• Nothing to do. This is fixed and defaults to your country. Name of the Competent National Authority *

• Type in the name of the competent national authority.

Contact Details

Address

• Type in the street address of the competent national authority, e.g., 413 Saint-Jacques Street

City *

• Type in the city of the CNA, e.g., Montreal State or Province • Type in the State/Province of the CNA, e.g., Quebec Postal Code or Zip • Type in the postal/zip code of the CNA, e.g., H2Y 1N9 Country of Contact * • Select the country address of the CNA Phone number(s) * • Type in the phone number/s of the CNA, e.g., +1 514 288 2220 Fax number(s) ٠ Type in the fax number/s of the CNA if any, e.g., +1 514 288 6588 Email(s) * • Type in the email address/es of the CNA, e.g., secretariat@cbd.int Website address(es) • Click "+ Add link" – "Editing link" dialog box shows up Editing link Url* Type in the URL of the website of the CNA, e.g., (i) https://bch.cbd.int Name Type in the name of the website, e.g., BCH Central Portal (ii) Language * (iii) Select the language used in the CNA's website, e.g., English • Click "Save" to add the CNA's website Additional Contact Information Contact person • Click "+ Add record(s)" – list of contacts shows up in a dialog box Please select from the list of published records below: Type in name of contact person in search box, and click "Search", or Scroll through the names to find the contact person • If found In the list, tick the checkbox beside the contact person of the CNA, to select it. (iv) Click "Select" to continue and add the ticked contact as CNA

- contact person.
 - If not found in the list, you can add a new contact person

"reference record" by clicking "Create Contact". The "Create new Contact" dialog box appears which contains the online submission form for "Contacts."

Create new Contact/Introduction

- (v) Read "Introduction" page.
- (vi) Click "Submission form" arrow/tab

Create new Contact/Submission form

- (vii) Type in all the details of the new contact person to be added
- (viii) Once all are typed in and correct, click "Review" arrow/tab.Create new Contact/Review
- (ix) Check that the document is valid and all details are correct and complete.
- (x) If all are correct, click "Publish" arrow/tab.
- (xi) If need correction, click "Submission form" arrow/tab to go back to editing the contact's details.

Create new Contact/Publish

- (xii) Do a final check of all contact's details.
- (xiii) If all are correct, click "Publish." The new contact will be added to the BCH and also added as Contact Person to your CNA record.
- (xiv) If corrections are needed, click "Submission form" arrow/tab to go back to editing the contact's details.

Responsibilities

Administrative functions *

• Tick the function/s of this CNA. You can tick as many as needed.

Types of organism(s) under its responsibility *

• Tick the appropriate organism/s, as many as needed.

Detailed description of the regulatory functions

• If needed, type in details for this CNA

Timeframe for confirmation or updating of information

• Read the instructions.

Additional Information

Additional Information

- Type in any additional information for this CNA (if needed) Any other relevant documents
 - Click "+ Add file" to upload a file document about the CNA (if needed)
 - Click "+ Add link" to add an online document about the CNA

(if needed)

Notes

- Type in any notes about this record (if needed)
- Click "Review" arrow/tab to continue.

Review arrow/tab

- Top of the page shows whether the entered data is complete or lacking any mandatory data fields.
- Lower part of the page shows all the data you have entered about the CNA.
- Check for completeness and correctness.
- If document is valid and complete, click "Publish."
- If there are data that needs correcting, click "Submission form" arrow/tab to go back to editing the CNA's details.
- Publish arrow/tab
- The lower part of the page shows all CNA details you have entered. Do a final check for correctness and completeness.
- If correction is needed, click "Submission form" arrow/tab to go back to editing the CNA's details.
- If all information is correct and complete, click "Publish" (for BCH-NFP); "Request publish" (for NAUs)
- If you are a BCH-NFP, the new CNA record will now be published on the BCH; If you are an NAU, the new CNA record will be pending approval by your BCH-NFP.

2.4. Biosafety Laws, Regulations, Guidelines and Agreements (LAW)

Any existing laws, regulations, and guidelines for implementation of the Protocol, as well as information required by Parties for the Advance Informed Agreement procedure, must be submitted to the BCH in accordance with Article 20.3(a). Any bilateral, regional, and multilateral agreements and arrangements must be submitted to the BCH in accordance with Article 20.3(b).

Typically, a national law is a law that has been passed by the national legislative body of a country's government. In most jurisdictions, a national regulation is "subordinate legislation," usually of an administrative nature, that is authorized by a national law. A national guideline is intended to assist with providing ways of complying with national laws, and national regulations.

Your country can also have BCH-related Agreements with other entities like: other countries, regions, organizations, private entities, etc., that are also required to be submitted to the BCH.

EXERCISE: Submit a new Biosafety Law, Regulation, Guidelines, or Agreement (LAW)



In the "Submit Dashboard," click on "+" found in the same row as "Biosafety Laws, Regulations, Guidelines, or Agreements" from the list of National Records. This will open the online submission form which has four (4) arrow/tabs, i.e., Introduction, Submission form, Review, and Publish. It always opens the first arrow/tab "Introduction" which describes the BCH record type you are planning to submit, along with instructions on how to submit such a record.

Introduction arrow/tab

• Read the description and instructions and click "Submission form" arrow/tab to continue.

Submission form arrow/tab

• General Information

Select which language(s) you wish to submit this record: *

• Select: English (or your local language if data is in local language)

Country submitting a law, regulation, guideline or agreement *

• Nothing to do. This is fixed and defaults to your country.

Is this an amendment to a law, regulation, guideline or agreement already published on the BCH? *

• Toggle "Yes" or "No" to indicate if this is an amendment or not. Title of document *

• Type in the title of the law/regulation/guideline/agreement

Legislative details

Type of Law / Regulation *

• Toggle the radio button corresponding to the document being submitted (i.e., law, regulation, policy, guidelines, regulatory framework, agreement, etc.)

Area of jurisdiction *

• Select from the drop-down menu the area of jurisdiction of the law or regulation (i.e., Regional, National, Sub-national, Other)

Subject areas *

• Tick the checkbox/es that applies to the law / regulation Types of organisms addressed *

• Tick the checkbox/es that applies to the law / regulation Brief description of the document including objective and scope

• Type in a description of the document, if needed.

Date of entry into force

• Select the date, if needed.

Document details

Document text

- If the law / regulation has its text in a file, click "+ Add file" to upload.
- If the law / regulation has online text available, get its URL and click "+ Add link" to link it here.

Unofficial Documents (or courtesy translations)

- If there are unofficial documents whose text is in a file, click "+ Add file" to upload the file.
- If there are unofficial documents whose text is online, get its URL and click "+ Add link" to link it here.
- If it is available as text, copy-and-paste the text into the provided textarea input field.

Relationship with other laws/regulations

• If this law / regulation has relations with other law / regulation that is published in the BCH or you want to publish it in the BCH, link it here by clicking "+ Law, Regulation or Guideline"

Please select from the list of published records below:

- (xv) If the related law / regulation is already published in the BCH > Search the published related law / regulation > Tick its checkbox to select it > Click "Select" to link it as related to this law / regulation
- (xvi) If the related law / regulation is not yet published in the BCH > Click "Create Biosafety Law..." > Add the related law / regulation

as discussed in this section.

• If the related law / regulation has text already available but you don't want to publish yet on the BCH, you can just copy-and-paste the text into the provided textarea input field.

Regulatory contact information

Competent National Authority(ies) and/or Supplementary Protocol Competent Authority(ies) *

• Click "+ Add records" to link the "reference record" of the CNA's contact information.

Timeframe for confirmation or updating of information

Should this information be confirmed or updated after two years from the date of submission? *

• Toggle "Yes" or "No" to answer this question

Additional Information

Any other relevant information

• Type in any other relevant information – if not available as a file or published in the BCH.

Any other relevant documents

- If available as a file, click "+ Add file" to upload.
- If available as a published document in the web, click "+ Add link".

Notes

- Type in any notes you have for this document.
- When all input is done, click "Review" arrow/tab

Review arrow/tab

- The top part of the page will indicate whether the data entry is complete or lacking mandatory fields.
- The lower part shows all the data entered for your final checking.
- If there are data needed to be corrected or added, go back to the form by clicking "Submission form."
- If the data entry form is valid and all data are checked to be correct, continue by clicking "Publish" arrow/tab.
- Publish arrow/tab

- The lower part of the page shows all the details you have entered for this record. Do a final check for correctness and completeness.
- If correction is needed, click "Submission form" arrow/tab to go back to editing the entries.
- If all information is correct and complete, click "Publish" (for BCH-NFP); "Request publish" (for NAUs)
- If you are a BCH-NFP, the new law / regulation record will now be published on the BCH; If you are an NAU, the new law / regulation record will be pending approval by your BCH-NFP.

2.5. Country Decision or any other Communications (DEC)

All final decisions regarding the importation or release of LMOs must be submitted to the BCH. These include decisions taken under the Advance Informed Agreement procedure for intentional release into the environment, decisions, and declarations under Article 11 of the Protocol for LMOs for food or feed, or for processing and other decisions. The decisions can be categorized by their subjects in the following types:

- Decision on LMOs for intentional introduction into the environment (according to Article 10 or domestic regulatory framework)
- Decision on LMOs for direct use as food or feed, or for processing (Article 11, LMOs-FFPs)
- Decision under the Simplified Procedure (Article 13)
- Decision on Pharmaceuticals (Article 5)
- Decision on Transit of LMOs (Article 6.1)
- Decision on Contained use of LMOs (Article 6.2)

The Protocol also requires submitting to the BCH the country's notifications, declarations and other communications related with transboundary movements of LMOs or implementation of the Protocol including notifications of illegal or unintentional transboundary movement. The notifications and other communications can be categorized by their subjects in the following types:

- Notification that domestic regulations shall apply with respect to specific imports of LMOs (Article 14.4)
- Notification about the unintentional transboundary movement of LMOs (Article 17.1)
- Notification about illegal transboundary movements of LMOs (Article 25.3)
- Notification that a Party does not have access to the Biosafety Clearing-House (Article 11.1)
- Declaration that, in the absence of a domestic regulatory framework, decisions on LMOs-FFPs will be taken according to Article 11.6
- Communication of information on 'Handling, Transport, Packaging and Identification' (Article 18)
- Declaration made upon ratification of or accession to the Protocol

Countries can also submit to the BCH any other relevant decisions and communications related with LMOs or implementation of the Protocol that

governments wish to make available through the BCH including decisions on import or release of LMOs taken before the Protocol has entered into force for the country.

The COP-MOP 3 meeting also invited Parties to the Protocol and other Governments to make available to the Biosafety Clearing-House the following additional information:

- The transformation events that are commercially produced for each planting cycle in the exporting country;
- The geographical area within the exporting country where each transformation event was cultivated;

If this information is available, it should be provided through the "additional information" field of a decision document.

EXERCISE: Submit a new Country Decision or any other Communications (DEC)



In the "Submit Dashboard," click on "+" found in the same row as "Countries' Decisions or any other Communications (DEC)" from the list of National Records. This will open the online submission form which has four (4) arrow/tabs, i.e., Introduction, Submission form, Review, and Publish. It always opens the first arrow/tab "Introduction" which describes the BCH record type you are planning to submit, along with instructions on how to submit such a record.

Introduction arrow/tab

• Read the description and instructions and click "Submission form" arrow/tab to continue.

Submission form arrow/tab

• General Information

Select which language(s) you wish to submit this record: *

• Select: English (or your local language if data is in local language)

Country submitting the decision or communication *

• Nothing to do. This is fixed and defaults to your country.

Is this an amendment to a decision or communication already published on the BCH? *

• Toggle "Yes" or "No" to indicate if this is an amendment or not. Competent National Authority(ies) responsible for the decision or communication *

• Click "+ Add record(s)" to link the CNA's BCH record that is related to this country decision.

Title / Reference number of the decision or communication * • Type in the title of this decision / communication. Date of the decision * • Select the date the decision / communication was made Is the decision taken prior to entry into force of the Protocol? Toggle "Yes" or "No" to answer the question. **Jurisdiction** Type in the jurisdiction of the decision / communication, if any. • Subject of the decision, notification, communication or declaration Common decisions * • Tick the checkbox/es applicable. Other decisions * • Toggle the radio button applicable. Communications, notifications and declarations * • Toggle the radio button applicable. Timeframe for confirmation or updating of information Should this information be confirmed or updated after two years from the date of submission? * • Toggle "Yes" or "No" to answer the question. Additional Information Any other relevant information • Type in any other relevant information – if not available as a file or published in the BCH. Any other relevant documents • If available as a file, click "+ Add file" to upload. • If available as a published document in the web, click "+ Add link". Notes Type in any notes you have for this document. When all input is done, click "Review" arrow/tab Review arrow/tab The top part of the page will indicate whether the data entry is complete or lacking mandatory fields.

• The lower part shows all the data entered for your final checking.

- If there are data needed to be corrected or added, go back to the form by clicking "Submission form."
- If the data entry form is valid and all data are checked to be correct, continue by clicking "Publish" arrow/tab.
- Publish arrow/tab
- The lower part of the page shows all the details you have entered for this record. Do a final check for correctness and completeness.
- If correction is needed, click "Submission form" arrow/tab to go back to editing the entries.
- If all information is correct and complete, click "Publish" (for BCH-NFP); "Request publish" (for NAUs)
- If you are a BCH-NFP, the new law / regulation record will now be published on the BCH; If you are an NAU, the new law / regulation record will be pending approval by your BCH-NFP.

2.6. Risk Assessment generated by a regulatory process (RA)

All risk assessments and environmental reviews of LMOs must be submitted to the BCH and linked to the appropriate decision. Parties must submit summaries of its risk assessments or environmental reviews of LMO generated by a its regulatory process and carried out in accordance with Article 15 (Risk Assessment), including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of LMO origin, containing detectable novel combinations or replicable genetic material obtained using modern biotechnology.

There are several public sources that address the actual process for developing the Risk Assessment procedures.

The BCH itself contains very valuable specific tools and training materials targeted to Risk Assessments procedures:

- The Online Forum on Risk Assessment and Risk Management (accessible at <u>http://bch.cbd.int/onlineconferences/forum_ra.shtml</u>). This portal has been developed as a response to the Parties decision BS-IV/11. The portal also includes real-time online conferences and discussion groups.
- In the link above are several resources like: "Guidance on Risk Assessment of Living Modified Organisms" (accessible at https://www.cbd.int/doc/meetings/bs/mop-08/official/bs-mop-08-08-add1-en.pdf) that has been welcomed by the Parties at their fifth meeting.

EXERCISE: Submit a new Risk Assessment generated by a regulatory process (RA)



In the "Submit Dashboard," click on "+" found in the same row as "Risk Assessments generated by a regulatory process (RA)" from the list of National Records. This will open the online submission form which has four (4) arrow/tabs, i.e., Introduction, Submission form, Review, and Publish. It always opens the first arrow/tab "Introduction" which describes the BCH record type you are planning to submit, along with instructions on how to submit such a record.

Introduction arrow/tab

• Read the description and instructions and click "Submission form" arrow/tab to continue.

Submission form arrow/tab

General Information

Select in which language(s) you wish to submit this record: *

• Select: English (or your local language if data is in local language)

Country *

- Nothing to do. This is fixed and defaults to your country. Title of the risk assessment*
 - Type in the title of this risk assessment.

Date of the risk assessment *

• Select the date of this record, or, tick the checkbox "Date not available" if date is not available.

Competent National Authority(ies) responsible for the risk assessment *

• Click "+ Add record(s)" to link the CNA's BCH record that is

responsible for this risk assessment.

Please select from the list of published records below:

- (xvii) Type in part of the CNA's name in the Search box to get results of submitted CNAs in the BCH with that name.
- (xviii) Select the correct CNA from the results by ticking its checkbox.
- (xix) Click "Select" to link it to this RA.
- (xx) If the CNA has not yet been added to the BCH, you can do so now by clicking "Create Competent National Authority." Just be sure that you have all the required data to enter in all the mandatory fields.

Contact details of the main responsible risk assessor

• Click "+ Add record(s)" to link the contact record of the risk assessor, if needed.

Please select from the list of published records below:

- (xxi) Type in part of the Contact's name in the Search box to get results of submitted Contacts in the BCH with that name.
- (xxii) Select the correct Contact from the results by ticking its checkbox.
- (xxiii) Click "Select" to link it as the risk assessor of this RA.
- (xxiv) If the Contact has not yet been added to the BCH, you can do so now by clicking "Create Contact." Just be sure that you have all the required data to enter in all the mandatory fields.

Risk assessment details

Living modified organism(s) *

- Click "+ Add record(s)" to link the LMO's BCH record/s. Please select from the list of published records below:
- (xxv) Type in part of the LMO's name in the Search box to get results of submitted LMOs in the BCH with that name.
- (xxvi) Select the correct LMO from the results by ticking its checkbox.
- (xxvii) Click "Select" to link it as the LMO for this RA.
- (XXVIII) If the LMO has not yet been added to the BCH, you can do so now by clicking "Create Living Modified Organism." Just be sure that you have all the required data to enter in all the mandatory fields. Scope of the risk assessment *
 - Tick the checkboxes applicable.

Risk assessment report / summary *

- If available as a file, click "+ Add file" to upload.
- If available as a published document in the web, click "+ Add link".

Please use this field to provide a summary of the risk assessment.

• Type in (or copy-paste) the summary text if available.

Methodology and points to consider (Refer to Annex III, paragraphs 8 and 9 of the Cartagena Protocol on Biosafety.)

Potential adverse effects identified in the risk assessment

• Type in (or copy-paste) the text into the provided textarea input field.

Likelihood that the potential adverse effects will be realized

• Type in (or copy-paste) the text into the provided textarea input field.

Possible consequences

• Type in (or copy-paste) the text into the provided textarea input field.

Estimation of the overall risk

• Type in (or copy-paste) the text into the provided textarea input field.

Recommendation(s) on whether the risks are acceptable/manageable and any management strategies

• Type in (or copy-paste) the text into the provided textarea input field.

Need(s) for further information on specific issues of concern

• Type in (or copy-paste) the text into the provided textarea input field.

Receiving environment(s) considered

• Type in (or copy-paste) the text into the provided textarea input field.

LMO detection and identification methods proposed

• Type in (or copy-paste) the text into the provided textarea input field.

Information sharing with other databases

Is this risk assessment related to an LMO for commercial use?

• Toggle "Yes" or "No" to answer the question.

Timeframe for confirmation or updating of information

Should this information be confirmed or updated after two years from the date of submission? *

- Toggle "Yes" or "No" to answer the question.
- Additional information

Any other relevant information

• Type in (or copy-paste) the text into the provided textarea input field.

Any other relevant documents

- If available as a file, click "+ Add file" to upload.
- If available as a published document in the web, click "+ Add link".

Notes

- Type in any notes you have for this document.
- When all input is done, click "Review" arrow/tab

Review arrow/tab

- The top part of the page will indicate whether the data entry is complete or lacking mandatory fields.
- The lower part shows all the data entered for your final checking.
- If there are data needed to be corrected or added, go back to the form by clicking "Submission form."
- If the data entry form is valid and all data are checked to be correct, continue by clicking "Publish" arrow/tab.
- Publish arrow/tab
- The lower part of the page shows all the details you have entered for this record. Do a final check for correctness and completeness.
- If correction is needed, click "Submission form" arrow/tab to go back to editing the entries.
- If all information is correct and complete, click "Publish" (for BCH-NFP); "Request publish" (for NAUs)
- If you are a BCH-NFP, the new law / regulation record will now be published on the BCH; If you are an NAU, the new law / regulation record will be pending approval by your BCH-NFP.

2.7. National Biosafety Websites or Databases (NDB)

Many governments already have national websites that are relevant to the implementation of the Biosafety Protocol. These can be modified a bit to also display the country's BCH data (using BCH code snippets) and then can be added as a National Biosafety Website or Database in the BCH. Or a government can opt to create a new one for the sole purpose of its BCH activities.

EXERCISE: Submit a new National Biosafety Website or Database (NDB)

SOLUTION:

In the "Submit Dashboard," click on "+" found in the same row as "National Biosafety Websites or Databases (NDB)" from the list of National Records. This will open the online submission form which has four (4) arrow/tabs, i.e., Introduction, Submission form, Review, and Publish. It always opens the first arrow/tab "Introduction" which describes the BCH record type you are planning to submit, along with instructions on how to submit such a record.

Introduction arrow/tab

• Read the description and instructions and click "Submission form" arrow/tab to continue.

Submission form arrow/tab

- Select in which language(s) you wish to submit this record: *
- Select: English (or your local language if data is in local language)

Website or Database details

Country *

• Nothing to do. This is fixed and defaults to your country.

Website or database name *

• Type in (or copy-paste) the name of this website / database. Description *

• Type in (or copy-paste) the text into the provided textarea input field.

Website address *

• Click "+ Add link" to enter the website's URL.

Timeframe for confirmation or updating of information

• Read the information.

Additional information

Any other relevant information

• Type in (or copy-paste) the text into the provided textarea input field.

Any other relevant documents

- If available as a file, click "+ Add file" to upload.
- If available as a published document in the web, click "+ Add link".

Notes

- Type in any notes you have for this document.
- When all input is done, click "Review" arrow/tab

Review arrow/tab

- The top part of the page will indicate whether the data entry is complete or lacking mandatory fields.
- The lower part shows all the data entered for your final checking.
- If there are data needed to be corrected or added, go back to the form by clicking "Submission form."
- If the data entry form is valid and all data are checked to be correct, continue by clicking "Publish" arrow/tab.
- Publish arrow/tab
- The lower part of the page shows all the details you have entered for this record. Do a final check for correctness and completeness.

- If correction is needed, click "Submission form" arrow/tab to go back to editing the entries.
- If all information is correct and complete, click "Publish" (for BCH-NFP); "Request publish" (for NAUs)
- If you are a BCH-NFP, the new law / regulation record will now be published on the BCH; If you are an NAU, the new law / regulation record will be pending approval by your BCH-NFP.

2.8. Biosafety Experts (EXP)

The roster of experts on biosafety was established by the Conference of the Parties to the CBD (COP) in decision EM-I/3 that adopted the Cartagena Protocol on Biosafety in January 2000. The mandate of the Roster is to "provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of living modified organisms".

At its first meeting in February 2004, the Conference of the Parties serving as the meeting of the Parties (COP-MOP), adopted decision BS-I/4 on the roster of experts, including the Interim guidelines for its operation and the Interim guidelines for the Pilot Phase of the Voluntary Fund for the Roster, which was established by the COP in its decision VI/29 to support eligible countries to pay for the use of experts selected from the roster.

At its third meeting in March 2006, the COP-MOP in its decision BS-III/4 outlined a process aimed at strengthening the quality, effectiveness, and level of use of the Roster of Biosafety Experts.

At its fourth meeting in May 2008, the COP-MOP in decision BS-IV/4 adopted several measures for improving the quality, effectiveness, and level of use of the roster of biosafety experts. These included a set of criteria and minimum requirements for experts to be nominated to the roster, updated guidelines for the roster, as well as a revised nomination form. Parties and other Governments were requested to make fresh nominations in accordance with the new criteria and minimum requirements and the Executive Secretary was requested to remove all existing records in the roster within three months and refill the roster with the new nominations. The Parties also decided to revitalize the pilot phase of the Voluntary Fund for the Roster.

At its fifth meeting in October 2010, the COP-MOP considered the report on the status of the Roster of Experts and the Voluntary Fund for the Roster. In decision BS-V/4 it urged Parties and other Governments that had not yet done so to nominate experts to the roster, taking into account the need for gender balance and for balanced coverage of the different areas of expertise in the roster. It also urged Parties and other Governments to facilitate the release of their experts on the roster, and in a timely and flexible manner, when they are selected to undertake assignments by other Parties.

Experts can only be submitted to the roster by BCH National Focal Points, using a form which requires detailed information about the background and specialization of the expert. This information is maintained in the BCH database and can be accessed publicly in the BCH website.

Once a record has been created for a particular expert, BCH National Focal Points may then give permission to the expert to modify his or her own record. If you are an expert and would like to have access to your record, ask the BCH-NFP that registered you to the roster to inform the Secretariat that you have permission to access your record. Once the Secretariat is informed, you will receive a password.

In accordance with the guidance for use of the roster Governments are requested to submit the reports on the assignments undertaken by Biosafety Experts contacted through the roster.

Important: It should be noted that decisions taken by Governments are the sole responsibility of the country taking those decisions, whether or not they have been taken on the basis of advice given by the experts nominated for the biosafety roster of experts. Nominating governments or the Secretariat may, upon request, provide suggestions to governments regarding the selection of experts, but neither shall be liable for the selection of experts decided upon by the requesting country, nor for the use of the roster of experts or the conduct of and the advice given by an expert from the roster.

Up-to-date information about the Roster of Expert, news and nomination process is available at <u>http://bch.cbd.int/protocol/cpb_roster.shtml</u>.

The SCBD has published a "Guide to the Roster of Experts", that can be downloaded from the BCH at <u>http://bch.cbd.int/database/attachment/?id=10937</u>. This is quite old but still a useful guide.





In the "Submit Dashboard," click on "+" found in the same row as "Biosafety Experts (EXP)" from the list of National Records. This will open the online submission form which has four (4) arrow/tabs, i.e., Introduction, Submission form, Review, and Publish. It always opens the first arrow/tab "Introduction" which describes the BCH record type you are planning to submit, along with instructions on how to submit such a record.

Introduction arrow/tab

• Read the description and instructions and click "Submission form" arrow/tab to continue.

Submission form arrow/tab

• NOTE: The form has seven (7) parts separated by tabs: Part I to VII.

PART I

General Information

Select in which language(s) you wish to submit this record: *

• Select: English (or your local language if data is in local language)

Country *

• Nothing to do. This is fixed and defaults to your country.

Notes

- Type in any notes you have for this document.
- When done, click "Part II" tab.

PART II

Profile of the expert

Brief profile *

• Type in (or copy-paste) the text into the provided textarea input field.

Contact details

Click "+ Add record(s)" to link the contacts BCH record of this expert.

Year of birth

• Type in the expert's birth year.

Country of birth

• Select the expert's country of birth from the drop-down menu. Nationality(ies)

• Select the expert's nationality/ies from the drop-down menu.

Notes

- Type in any notes you have for this document.
- When done, click "Part III" tab.

PART III Details of current employment Name of Employer / Organization / Company * Type in the expert's employer name. Iob title * Type in the expert's job title. Department / Division / Unit * Type in the expert's department. Start date * • Select the date the expert started (month and year) Type of organization * • Select from the drop-down menu. Main Areas of Responsibility * • Type in (or copy-paste) the expert's background. **Employment history** Countries or regions where you have worked • Select the country/ies and/or region/s the expert has worked in. Name of Previous Employer / Organization / Company • Type in the name of a previous employer. Department / Division / Unit Type in the department name, if any. Start date • Select the start date. End date • Select the end date. Type of organization • Select the type of organization from the drop-down menu. Main Areas of Responsibility • Type in (or copy-paste) the expert's experience/s. Notes Type in any notes you have for this document. When done, click "Part IV" tab. PART IV Post-secondary education

A. Formal education

First Degree (e.g. B.Sc. in Microbiology)

Title of the Degree or other academic distinction and subject * (xxix) Type in the degree title. Name of academic institution * (xxx) Type in the name. Start date * (xxxi) Select the start date (month and year) End date * (xxxii) Select the end date (month and year) Second Degree Title of the Degree or other academic distinction and subject * (xxxiii) Type in the degree title. Name of academic institution * (xxxiv) Type in the name. Start date * (xxxv) Select the start date (month and year) End date * (xxxvi) Select the end date (month and year) B. Other professional qualifications List a maximum of three other relevant professional qualifications. copy-paste) the expert's (xxxvii) professional Type in (or qualifications. Notes Type in any notes you have for this document.

• When done, click "Part V" tab.

PART V

Areas of expertise

Expertise

• Tick all checkboxes applicable.

Publications

• List your three most important publications related to your main field of expertise.

Professional memberships

Professional memberships

• Type in (or copy-paste) up to three relevant professional societies or organizations of which you are a member.

Technical committees, expert panels or advisory bodies served

• Type in (or copy-paste) up to three relevant technical committees, expert panels or advisory bodies on which you have served and briefly describe your specific responsibilities.

Notes

- Type in any notes you have for this document.
- When done, click "Part VI" tab.

PART VI

Language proficiency

Mother tongue *

- Tick all checkboxes applicable.
- You can also select from the drop-down menu "Add other language".

Other languages

- If the expert uses other language/s, toggle the applicable radio buttons.
- You can also select from the drop-down menu "Add other language".

Notes

- Type in any notes you have for this document.
- When done, click "Part VII" tab.

PART VII

Timeframe for confirmation or updating of information

• Please read the information.

Any other relevant information

Additional information

• Type in (or copy-paste) the text into the provided textarea input field.

Any other relevant documents

- If available as a file, click "+ Add file" to upload.
- If available as a published document in the web, click "+ Add link".

Notes

- Type in any notes you have for this document.
- When all input is done, click "Review" arrow/tab

Review arrow/tab

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- Publish arrow/tab
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2.9. Country Profiles for Biosafety Clearing-House (BCP)

Parties to the Protocol can submit additional information to their "Country Profile" that is being displayed in the BCH. These would be BCH information that the country may want to highlight, or that is not submittable in any of the BCH common formats.





In the "Submit Dashboard," click on "+" found in the same row as "Country Profiles for Biosafety Clearing-House (BCP)" from the list of National Records. This will open the online submission form which has four (4) arrow/tabs, i.e., Introduction, Submission form, Review, and Publish. It always opens the first arrow/tab "Introduction" which describes the BCH record type you are planning to submit, along with instructions on how to submit such a record.

Introduction arrow/tab

• Read the description and instructions and click "Submission form" arrow/tab to continue.

Submission form arrow/tab

General Information

Select in which language(s) you wish to submit this record: *

• Select: English (or your local language if data is in local language)

Country *

• Nothing to do. This is fixed and defaults to your country.

Additional information for the country profile *

Any other relevant information

• Type in (or copy-paste) the text of the additional information you want to show in your Country Profile into the provided textarea input field.

Notes

- Type in any notes you have for this document.
- When all input is done, click "Review" arrow/tab

Review arrow/tab

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- Publish arrow/tab
- The lower part of the page shows all the details you have entered for this record. Do a final check for correctness and completeness.
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A User's Guide to the Central Portal of the Biosafety Clearing House

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