

UNEP-GEF Project for Building Capacity for Effective Participation in the Biosafety Clearing House



United Nations Environment Programme Global Environment Facility

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OPERATIONAL HANDBOOK

For Participating in the UNEP-GEF Project for Effective Participation in the Biosafety Clearing-House (BCH)

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Abbreviations

BCH Biosafety Clearing-House

CBD Convention on Biological Diversity
CPB Cartegena Protocol on Biosafety
GEF Global Environment Facility

GMO Genetically Modified Organism

InWEnt Capacity Building International Organization of Germany

LMO Living Modified Organism

nBCH National BCH

NCA National Competent Authority
NCC National Coordinating Committee

NEA National Executing Agency
NPC National Project Coordinator
NPD National Project Document
NBF National Biosafety Framework

NBSAP National Biodiversity Strategy and Action Plan

SCBD Secretariat of the Convention on Biological Diversity

SIDS Small Island Developing States

TOR Terms of Reference

UNEP United Nations Environment Programme

UNITAR United Nations Institute for Training and Research
COP/MOP Conference of the Parties/Meeting of the Parties

Purpose

The aim of this handbook is to provide a practical "how-to" guide for countries. To assist them in developing and implementing the national project aimed at developing their access to and use of the Biosafety Clearing-House (BCH). The project will enable countries to fulfill their obligations towards the Cartagena Protocol by entering the required information in the BCH in a timely fashion, it will also enable countries to use and benefit from the BCH.

This handbook is primarily intended for use by those institutions and staff responsible for the development, use and maintenance of the BCH, namely:

- National Executing Agency (NEA)
- National Executing Agency Focal Point (NEA FP)
- National Project Coordinator (NPC), where already in place under the UNEP-GEF NBF Development project
- BCH Task Force (BCH TF)
- CBD BCH Focal Point
- BCH Regional Advisors

Structure

This handbook is divided into the following five sections:

- I. Project Rationale
- II. Institutional Structure
- III. Project Design
- IV. Regional Experts
- V. Reporting

I. PROJECT RATIONALE

1. Why does a country need a national Biosafety Clearing-House system?

The Cartagena Protocol on Biosafety entered into force on 11 September 2003, 90 days after the deposit of the fiftieth instrument of ratification by the Republic of Palau on 13 June 2003. Entry into Force of the Protocol means it is legally binding internationally and in the legal systems of all consenting states, i.e. Parties to the Protocol. Parties are, therefore, obliged to comply with, and implement, all provisions of the Protocol. The Cartagena Protocol established the Biosafety Clearing-House under Article 20 of the Protocol. As listed in Box 1 below.

Box 1 Article 20 Information Sharing and the Biosafety Clearing-House

- 1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:
 - (a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and
 - (b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.
- 2. The Biosafety Clearing-House shall serve as means through which information is made available for the purposes of paragraph 1 above. It shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international Biosafety information exchange mechanisms.
- 3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:
 - (a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;
 - (b) Any bilateral, regional and multilateral agreements and arrangements;
 - (c) Summaries of its risk assessments or 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 generic material obtained through the use of modern biotechnology;
 - (d) Its final decisions regarding the importation or release of living modified organisms; and
 - (e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure.
- 4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

The Secretariat of the Convention on Biological Diversity (SCBD) manages and hosts the central portal of the BCH. The BCH is comprised of a central portal and a distributed network of external components.

The BCH is critical to the implementation of the Protocol and is intended to be a repository of up-to-date information on LMOs and Biosafety. It assists decision-makers in countries around the world, as well as civil society and the biotechnology industry.

Thus, 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. The Protocol requires that countries enter and manage their own data in the BCH. The notification (*SCBD/BS/RH/jh/38460* attached as Annex 2) from the SCBD gives the requirements that need to be fulfilled as of the date of entry into force of Cartagena Protocol on Biosafety. It is imperative, therefore, that all countries have the basic infrastructure and technical capacity, including equipment, tools and practical know-how, to fulfill their obligations and to take advantage of the benefits of the BCH.

There are several ways by which a country can make information available to the BCH. The SCBD has proposed five such options (the notification from the SCBD SCBD/BS/CS/WD/jh/36477 is attached as Annex 3), and these options are highlighted in Box 2 below:

Box 2

Option 1: Entering and managing country data from a Management Centre, which is part of the BCH.

Option 2: Sending information to the CBD secretariat via the simple nBCH, faxes, CD-Rom, e-mail or any other method.

Option 3: Creating and managing a database of required information that interacts with the central portal through the Internet and allows the central portal to pull information from it. This is referred to as the "pull" option and requires, at the minimum, a schedule to be set-up with the CBD secretariat for the central portal to be able to access the database through the Internet at certain times to be able to pull the information from it.

Option 4: Creating and managing a database of required information that interacts with the central portal through the Internet and pushes information from the database to the central portal either on a schedule determined by the country or with every update to the database. This is referred to as the "push" option and requires, at the minimum, a secure Internet connection to enable the country to send their information

Option 5: Non internet option: sending info by means other than the internet.

The five options mentioned in Box 2 are not mutually exclusive and countries can use these in conjunction with each other or can start with one option and eventually move to another option. For example, to be able to be compliant with the Protocol, countries may wish to start entering the required data using options 1 or 5, while making a decision to develop either options 3 or 4, over the longer term.

2. What will the BCH project provide?

This project is intended to:

A. Assist countries with:

- How to enter the required data into the BCH;
- How to set-up their national BCH system;
- How to use the BCH; and
- B. Assist stakeholders who will either be required to use the BCH to enter country information and/or search information on the BCH to support decision-making.

The UNEP-GEF Biosafety Unit will provide participating countries with easy-to-use training material and access to applications developed by some governments¹. These tools will be widely available to all countries and stakeholders enable them to learn more about the BCH and their obligations. Regional Advisors, as mentioned below in *Section IV*, will be trained to provide assistance in the set-up the different tools and to deliver specific training at a country level, as required.

In addition, and where required, the project will also provide the equipment (hardware and software) for countries to set-up their national BCH System. This will be based <u>solely</u> on the decision countries make for their national BCH system, based on the options described in Box 2. Also, if countries have already received equipment for the setting up of their national BCH from the *UNEP-GEF project for Development of National Biosafety Frameworks*, an assessment will be made to determine whether there is a need for additional equipment or software.

To assist countries more effectively, the UNEP-GEF Biosafety Unit has recruited and is providing the services of regional experts to countries, on a retainer basis. UNEP-GEF, CBD Secretariat, InWEnt and UNITAR have trained the Regional Advisors to enable them to provide the best assistance possible to countries.

Countries can request the services of a Regional Advisor by providing a short description of the work required by the Advisor. Countries may require the services of different Advisors at different times. *Section IV* provides a more complete description of the kinds of services a country may request from Advisors and how to access them.

¹ The governments of Canada, Switzerland and USA are currently providing applications for countries to use. These explained in more detail in Annex 6.

II. INSTITUTIONAL STRUCTURE

In setting up institutional structures for the BCH and for participating in the project, some points need to be considered.

The core institutional structure for setting up a national BCH and for participating in the project consists of five components:

- 1. National Executing Agency (NEA)
- 2. NEA Focal Point (NFP), responsible for BCH Project
- 3. Biosafety Clearing-House Task Force (BCH TF)
- 4. Biosafety Clearing-House Focal Point (BCH FP)
- 5. National Data Entry and/or an Information Technology staff

Each of these components must have clearly defined roles and project responsibilities for the national BCH processes to be effective.

1. The National Executing Agency (NEA)

The National Executing Agency (NEA) is the legal entity responsible for managing the execution of the activities related to the BCH project at a national level, and to UNEP at the international level. In some cases, this may be the NEA of the UNEP-GEF *Project for the Development of a National Biosafety Framework*. However, a country may also decide that a National Competent Authority (NCA), which is directly related to the setting-up of and managing the BCH, would be the NEA for the BCH project.

The role of the NEA is considered to be central to the effective management and successful completion of the Project. Its main task consists of coordinating the full participation of all governmental agencies with mandates relevant to the Biosafety Clearing House as well as the private and public sectors as related to the management of the national BCH.

The following criteria should be taken into consideration in the identification of the most appropriate organization to serve as the NEA²:

- NEA should be a body with a central role in managing the information for the BCH.
- The NEA should have the capacity to manage administrative functions as well as to coordinate other agencies.
- The NEA may have a possible continuing role within the future National Competent Authority.
- The NEA should display full transparency in all its decision processes.
- NEA should have experience in communicating with other agencies as well as the private and public sectors.

² If an NEA already exists for the UNEP-GEF project for the *Development of the NBF*, you may wish to skip this section. This section is only relevant if there is a need to appoint a new NEA.

• There should be a clear acknowledgement from other relevant agencies and organizations of its role as a coordinator.

In many aspects, as mandated by the Cartagena Protocol on Biosafety, the functions of the NEA include a coordinating role as required for the management and reporting of national-level information to the BCH.

Roles and Responsibilities of a National Executing Agency

The Name of the Agency, acting as the 'National Executing Agency' (NEA), will be the legal entity responsible for executing the BCH Project. The NEA will be appointed by the National Government after consultation with the GEF and CP focal points. The draft Terms of Reference (TOR) for the NEA would include the following functions:

- Establish the Biosafety Clearing-House Task Force (BCH TF), where possible, as a subcommittee of the National Coordinating Committee (NCC) of the Development project;
- Appoint a person within the Agency (NEA Focal Point) who would have full
 responsibility for ensuring that the activities required to set-up, use and access the BCH
 project are fulfilled;
- Provide the necessary scientific, technical, financial and administrative support to the work of the BCH TF, working in close cooperation with relevant government agencies, the scientific community and the public and private sectors;
- Ensure that regular reports, financial accounts, and requests are submitted to UNEP as set out in Annex 3;

2. NEA Focal Point (NFP)

The NEA Focal Point is the individual responsible for the management, coordination and oversight of the UNEP-GEF BCH Project, as well as the monitoring and reporting on the progress of the BCH set-up in his/her country. The person assigned by the NEA will have full responsibility for the activities relating to the set-up of the BCH within his/her country, but may not be assigned full-time to the project. This work would be likely to be part of other duties already being undertaken by the person. NB: *The project will not provide funds for this position and the government's contribution would be treated as co-financing to the project.*

As the Secretary of the BCH TF, the NFP will act as the link between the BCH TF (the consultative body of the institutional structure) and the NEA (the executive body of the institutional structure), as well as the liaison between the overall national institutional structure and the UNEP-GEF Biosafety Team. The role of the NFP is therefore catalytic to the effective and efficient operation of the various activities conducted under the Project.

As Secretary to the BCH TF and link to the NEA, the main tasks of the NFP include the following activities:

- Organizing BCH Task Force meetings, including manage the travel and the payment of subsistence allowance to Task Force members;
- Overseeing the progress of the BCH Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Fostering, establishing and maintaining links with other related national and international programmes and National Projects;
- Preparing and overseeing the development of Terms of Reference as well as supervise the performance of the Regional Advisors being provided by the project;
- Ensuring that all relevant information is available to the BCH Task Force about the state of IT in the country and the requirements and options for setting up a national BCH system;

As the liaison point to the UNEP-GEF team, the NFP will:

- Prepare a detailed needs assessment and budget for the national BCH system under the guidance of the BCH Task Force;
- Manage the finances, oversee overall resource allocation and where relevant submit proposals for budget revisions to the BCH Task Force and UNEP.
- Ensure that all the activities are carried out on schedule and within budget to achieve the stated outputs;
- Prepare and submit forms as required.

Considering the wide range of the envisioned activities for the NFP, the following criteria may help in the identification of the appropriate candidate:

- A degree in Science or Law
- An in-depth knowledge of the Cartagena Protocol
- Ability to command some influence and respect among stakeholders in all biosafety activities at the national level.

NB: The NPC of the Development Project may, if possible, also be the NEA FP for this project.

3. BIOSAFETY CLEARING-HOUSE TASK FORCE

A BCH Task Force should be established, which could be set up as part of other biosafety committees or as a sub-committee of the National Coordinating Committee (NCC). The NCC was established under the UNEP-GEF project for *the Development of the National Biosafety Framework* by the National Executing Agency (NEA) to advise and guide the preparation of a National Biosafety Framework.

This Task Force needs to be multi-disciplinary and multi-sectoral as it will be the major decision making body to be involved in the practical development of the BCH project.

The Task Force may need to adapt itself to external events and to change its composition and functions as the project develops. It is important not to be directive in its definition at the start. The Task Force can respond to changing circumstances and widen its membership as the process of stakeholder consultation goes on and brings out key players that also need to be involved in the process.

The Task Force may establish sub-working groups as necessary, with appropriate Terms of Reference. These might look at specific issues at a more technical level (e.g. which option to use for the national BCH system, what should be the structure of the national BCH system, etc.).

a. Who should be members of the Biosafety Clearing-House Task Force?

The membership of the BCH Task Force may include:

- 1. National CP Focal Point;
- 2. BCH Focal Point;
- 3. An IT person and a data entry person from each of the competent national authorities;
- 4. Representatives of the National Executing Agency; and
- 5. The National Project Coordinator of the UNEP-GEF project for Development of National Biosafety Frameworks, where possible.

b. Who chairs the BCH Task Force?

The question of who chairs the meetings is an issue to be considered carefully. This role will have a major influence on the development of the Task Force. The Chair of the Task Force should possess the following qualities:

- Be a recognized authority in the country on issues related to biosafety, the Cartagena Protocol or an IT-expert who has experience in working with international agreements.
- Be able to listen to all different views and help find appropriate and workable solutions.
- Be decisive, incisive and able to tackle the large array of questions that will arise.
- Be experienced in chairing public meetings.
- Be able to deal with the media on a number of contentious and difficult issues which are likely to be raised.
- Be able to execute leadership that enables the BCH Task Force to work effectively in making decisions and setting up the national BCH access.

Whether the Task Force chooses a permanent chairman or a rotating position is the choice of the country. However, continuity in the position through the life of the project will be likely to be valued highly by all parties.

c. How does the National Executing Agency Focal Point (NFP) relate to the BCH Task Force?

The NFP is appointed by the National Executing Agency. The NFP will act as a secretary to the BCH TF and is a non-voting member of the group.

d. How to organize BCH TF meetings?

The role of the BCH TF will be most successful when there is continuous follow up of issues during the start-up. Most countries would benefit from regular meetings held every month, at a minimum. Upon the establishment of the national BCH system, meetings can be held once every three months.

Invitations to BCH TF members should be sent out by the NFP with enough time for members to arrange to attend. All arrangements for the venue and the dissemination of papers for a meeting, etc will need to be done by the NEA and NFP.

Costs of travel to the meetings, at the most economical and reasonable rates, should be provided for relevant BCH Task Force members. Basic costs of convening the TF will be covered through the initial MOU signed by the NEA, at the most economical and reasonable rates. A payment to cover meal costs may be seen as a necessary part of the arrangements, if refreshments are not provided by the hosting organization. It is not be acceptable to pay any other type of allowances to BCH TF members for their attendance (i.e. honorarium). The NFP and his assistants would normally manage the travel and subsistence payments.

e. What does the BCH Task Force do?

The BCH Task Force has the following specific tasks:

- i. Analyze, relevant information available in the country related to the establishment of an appropriate national BCH system to enable the country to fully participate and benefit from the BCH and comply with its obligations under the Cartagena Protocol. The following documents can be consulted to enable the country to make choices:
 - Guidelines for national participation in the Biosafety Clearing House attached as Annex 2.
 - Requirements that need to be fulfilled at the date of entry into force of the Cartagena Protocol on Biosafety attached as Annex 3.
 - Submission of information to the Biosafety Clearing-House (BCH) on existing decisions related to (i) import of living modified organisms (LMOs) for intentional introduction into the environment and (ii) domestic use of LMOs intended for direct use as food or feed, or for processing that may be subject to transboundary movement is attached as Annex 4.
 - A full bibliography of reference documents that the BCH Task Force may wish to consult is attached as Annex 5.
- ii. Identify how information should be stored, managed and made available to the BCH.

- iii. Analyze and send to the UNEP-GEF Biosafety Unit a document outlining the current status of the BCH in the country and existing needs (form 3).
- iv. Develop a training plan strategy (form 5).
- v. Develop an overall longer-term strategy for the continued sustainability and use of the national BCH system and the regional obligations to be fulfilled relating to the central BCH portal.
- vi. Provide guidance in the over-all implementation of this project.

The UNEP-GEF Biosafety Unit has prepared forms, which are attached at the end of this document. The BCH Task Force should use or adapt these forms to assist in making their decisions and in corresponding with the UNEP-GEF Biosafety Unit.

4. Biosafety Clearing-House Focal Point (BCH FP)

COP7-MOP1 decision *BS-I/3 calls upon* each Party that has not yet done so to designate an appropriate national focal point for the Biosafety Clearing-House and further *invites* all Governments, organizations and other users interested in entering into a partnership with the Biosafety Clearing-House to nominate an appropriate focal point to carry out this role and it further details the role of the BCH FP as is elaborated in Box 3 below.

Box 3 Decision BS-I/3 Role of the Biosafety Clearing-House focal points

National focal points (or, where appropriate, Institutional Focal Points) for the Biosafety Clearing-House shall be nominated to liaise with the Secretariat regarding issues of relevance to the development and implementation of the Biosafety Clearing-House, whose functions shall include the following roles and responsibilities:

- a) 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;
- b) Liaison with the Secretariat regarding the technical aspects of national participation in the Biosafety Clearing-House, as well as provision of advice on further technical development including, *inter alia*, suggestions for improvements to the lathe countryt and system specifications of the central portal and central databases; and
- c) Facilitation of the development of a network of multi-sectoral and interdisciplinary partners, as appropriate in the implementation process of the Biosafety Clearing-House.

Thus the role of Biosafety Clearing-House Focal Point is to liaise with the Secretarial of the Convention on Biological Diversity (SCBD), which is also the Secretariat for the Cartagena Protocol on Biosafety. In addition, the BCH FP will be responsible for ensuring validation of information that a country wishes to include in the BCH.

Currently, the Management Centre on the central portal of the BCH, which is managed by the SCBD, only accepts information that has been validated by the national BCH FP. Thus, all countries are encouraged to nominate a BCH FP and to officially forward this information to the SCBD.

5. National Data Entry and/or an Information Technology staff.

The National Data Entry / IT staff is the person who will be updating the country information required by the BCH. This function may be the responsibility of the BCH FP or it may be another member of the NEA staff member who performs this role.

Each country will have to decide for itself whether the roles of the BCH FP, a data entry person and an IT specialist should be undertaken by three different people or by a simple person.

NOTE: It is important to note that whatever institutional structures a country chooses in terms of data entry and the role and responsibility of the BCH FP, the BCH FP is the ONLY person who can validate data that is to appear on the BCH using the Management Centre on the CP. This role may be devolved to others using web services. However, the SCBD has to be notified to for the information to appear on the BCH.

a. Roles And Responsibilities of national data entry/IT staff

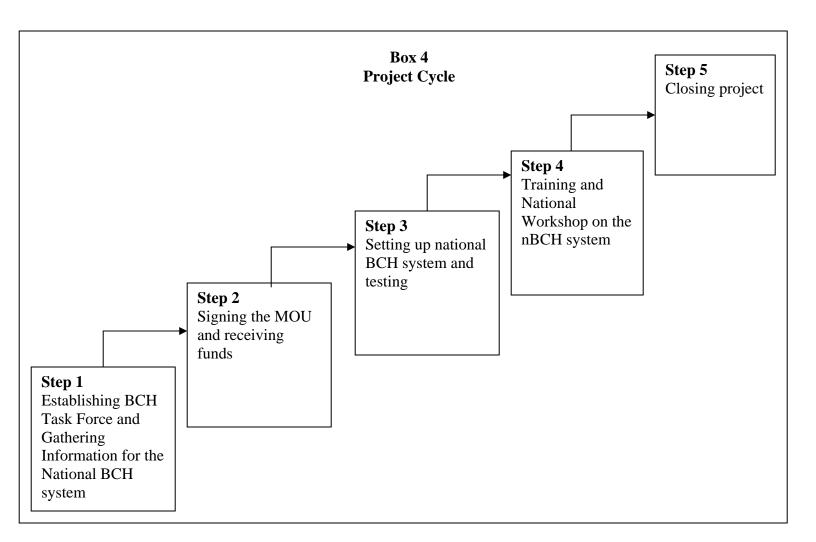
The draft Terms of Reference (TOR) may be:

- Ensure the overall set up and functionality of the national BCH;
- Ensure that any changes mandated by the MOP decisions are incorporated into the national BCH;
- Ensure that interoperability, if that option is chosen, is functional every time there is new information;
- Ensure that the national BCH system is continuously working. Manage any functionality problems; and
- Enter and continuously update national data in to the BCH;

III. PROJECT DESIGN

Countries have been provided with a sample Memorandum of Understanding, which they need to adapt and tailor to their own national needs, priorities and situation. This is one of the first management tasks of the NFP. Actions set out in the sample work plan must be taken. These should be translated into specific actions and the strategies required to set up and manage the national BCH. These actions should take into account the existing opportunities and consider existing constraints within their country, as well as their priorities.

The different stages of the project cycle for setting up and promoting the national BCH access are part of a continuous process. Each step builds on the preceding one. A sample project cycle is elaborated below in Box 4. Typically, the following process should be followed:



- 1. Step 1: To complete Step 1, a country will need to establish its BCH Task Force as mentioned in the section above. In the initial stage, the BCH Task Force will need to identify, analyze and assess a number of issues as detailed below. After this has been done, UNEP-GEF Biosafety Unit and the country will prepare an MOU. This MOU will indicate the resources required for the country to set-up, access and promote the country national BCH system, and will be negotiated and signed by the NEA and the UNEP-GEF Biosafety Unit. In addition, countries will be required to submit a sustainability strategy outlining the continued operation of the nBCH, after the end of the project, as required by the Cartagena Protocol.
- **2.** <u>Step 2:</u> Upon completion of the negotiation mentioned in step 1, the MOU will be signed between the country and the UNEP-GEF Biosafety Unit. At this time, 75% of the negotiated funds will be released to the country for purchase of equipment and training, as needed.
- **3.** <u>Step 3:</u> During this phase, the choice of nBCH will be made operational and the set-up of the nBCH system completed. The nBCH will also be tested during this step.
- **4.** <u>Step 4:</u> Training for the national focal points will be carried out during this phase and any other national workshops will be conducted, as required, with the assistance of the Regional Advisors.
- 5. <u>Step 5:</u> Finally, at its completion, the country will assess whether the project has achieved its original goal, and what the lessons are for the future in terms of further steps. The country will have to report back to the Biosafety Unit on the project to receive the residual 25% of the negotiated costs of setting up the BCH.

Note: At any time during the life of the project, a country may wish to access Regional Advisors, using Form 9, who have been trained and are on contract with the Biosafety Team.

Regional Advisors may be used for any or all of the following tasks (Section IV explains how the country can request the services of a regional experts):

- Assisting in making the choice for type and style of national participation in the BCH;
- Delivering training activities including a training workshop, where required, with national counterparts to train approximately 20 participants in the use and access of the BCH; and
- Assisting in making the choice of national BCH access operational.
- Sustainability strategy
- Training National Focal Points
- Negotiating costs of setting up the BCH

Following is a step-by-step guide for the NFP. The steps will enable the NFP to get the MOU signed, the money released for you to buy equipment, set-up and operationalise the nBCH and plan a national workshop, if required. The UNEP-GEF Biosafety Unit has prepared a list of forms, which are attached; to assist country's with the decision-making processes while deciding on their choices for a national BCH system.

A country may access a Regional Advisor at any time to assist the country in making decisions on any of the following steps:

Step 1: Establishing BCH Task Force and Gathering Information

- 1) Establish a BCH Task Force and forward the names of the task force to the Biosafety Team in Geneva using *Form* 1, as attached.
- 2) The BCH Task Force will assess all the options and relevant information available in the country in order to establish an appropriate national BCH infrastructure to enable the country to fully participate and benefit from the BCH and comply with its obligations under the Cartagena Protocol.
- 3) The BCH Task Force will also identify how information should be stored and managed for input into the central BCH portal. The Task Force may wish to consult the Guidelines prepared by the CBD secretariat, attached as Annex 2.
- 4) The BCH Task Force will analyze and send to the UNEP-GEF Biosafety Unit a set of documents outlining the current status of the BCH in the country and its needs. Each country will need to use the three forms: *Forms 2, 3 and 4* as attached. These documents should be returned to the UNEP-GEF Biosafety Unit within **2-3 months** of receiving this handbook in order to facilitate the start of the project.
- 5) The BCH Task Force will also have to develop an overall longer-term strategy for the continued sustainability and use of the national BCH and the obligations that are required to be fulfilled relating to the central BCH portal. This will also be forwarded to the UNEP-GEF Biosafety Team. The sustainability strategy should include how the country will continue to support the national BCH as per the requirements of the Cartagena Protocol.
- 6) The BCH Task Force will need to assess the training needs required to get the BCH set up and running, using the *Form 5*, as attached.
- 7) A work plan will also need to be sent to the Biosafety Team and attached to the MOU. A sample work plan is attached, for the country's information, as Annex 1. Adjustments will need to be made by each country to this basic plan depending on their specific needs.

- 8) Upon receipt of **Forms 1-5**, a sustainability strategy and a proposed work plan for the set-up and use of the BCH, the UNEP-GEF Biosafety Unit will start preparing an MOU for the country as a basis for negotiation between the NEA and the UNEP-GEF Biosafety Unit.
- 9) At any time, during the life of the project, the country may wish to request the services of a Regional Advisor, using *Form* 9, to help the country set-up the country national BCH systems as well as use their services for delivering training to people who are required to use the BCH.

Step 2: MOU Signature and Receipt of Money

- 10) Upon completion of the negotiation between countries and the UNEP-GEF Biosafety Unit, an MOU, with a detailed cost estimate, will be signed between the country and the UNEP-GEF Biosafety Unit.
- 11) After the MOU has been signed, the NEA will receive 75% of the funds, as requested and agreed upon in the MOU for purchase of equipment, for BCH Task Force meetings and for a national workshop, if so required.

Step 3: Setting up nBCH System and Testing

- 12) After the purchase of the equipment, *Forms 6 and 7* detailing the inventory of equipment, and operation of the equipment will have to be completed and forwarded to the UNEP-GEF Biosafety team in Geneva.
- 13) The country may wish to request the services of a Regional Advisor, using *Form 9*, to help the country set-up the country national BCH systems as well as use their services for delivering training to people who are required to use the BCH.

Step 4: Training

- 14) Upon the set-up of the national BCH system and the completion of the operational tests, the country may wish to hold a training workshop for the national focal points and any other national workshops that may be required.
- 15) After the execution of the training workshop, *Form 8*, which quantifies the progress made in BCH training, will need to be sent to the UNEP-GEF Biosafety Team.
- 16) In addition, a country may wish to use the Regional Advisors, using *Form 9*, to train the people who will be directly responsible for the information requirements of the BCH.

Step 5: Closure of Project

- 17) Upon receipt of the completed *Forms 6, 7 and 8* the residual 25% of the negotiated costs will be forwarded to the NEA. Once the residual money is transferred to the country, the project will be considered completed and the process to close the project be undertaken by the UNEP-GEF Biosafety Unit.
- 18) Countries will be requested to submit an evaluation of Regional Advisors, using *Form* **10**, each time a Regional Advisor completes a task requested by the country.

IV. REGIONAL ADVISORS

1. How can countries request the service of Regional IT and CPB Advisors?

Countries will be offered and provided hands-on assistance by Regional Advisors in assessing and analyzing their training needs in using and benefiting fully from the national BCH.

Countries will be able to select from a pool of regional IT and Cartagena Protocol training Advisors for the professional expertise required to assist with the development and implementation of a national capacity building programme tailored to the technical needs of a country. Two groups of regional experts will have in-depth knowledge and therefore be able to provide targeted and tailored expertise to countries in the fields of IT and the CPB.

All Regional Advisors have been chosen by UNEP in a peer-review process and given extensive training in the work to be undertaken in a country and are on-call to countries. The CVs and experience of each Advisor will be made openly available and the choice of Regional Advisor will be left to the country, and their services will then be provided according to country needs, within the scope of the project and subject to availability.

Note: Advisors are not substitutes for local resources or expertise, but are meant to be complimentary. You are encouraged to team your resources in order to maximize the impact of setting up, using and training for the BCH. A maximum number of 15 days of Regional Advisor services per country is available throughout the duration of the project.

Countries, who wish to get use the technical expertise of either an IT and/or CPB Regional Advisors, will need to fill in the attached *Form 9* (*Request for Regional Training Advisors*) and accompany it with an official request specifying the advisory and training needs, and forward it to the UNEP-GEF Biosafety Unit. A typical request for a Regional Advisor will follow the steps listed below:

- 1. Upon receipt by the UNEP-GEF Biosafety Unit of a request from a country for a Regional Advisor, using *Form 9*, accompanied by TOR, the Biosafety Unit will contact the Regional Advisor chosen by the country and make the travel and other associated administrative arrangements for the Advisor to visit the country or provide expertise from their base country;
- 2. Countries are advised to choose, whenever geographical possible a Regional Advisor from their region;
- 3. Each country is provided free of charge by UNEP-GEF Regional Advisor services for up to 15 days through the MoU duration;

- 4. The Regional Advisor will be in contact with the country and complete his/her tasks according to the TOR specified by the country;
- 5. Upon completion of the specified tasks, the Regional Advisor will submit, to the UNEP-GEF Biosafety Unit a report on the activities conducted and services rendered;
- 6. The recipient country will be also requested to forward to the UNEP-GEF Biosafety Unit a completed evaluation of the Expert, using *Form 10*.

Note: In the case that countries wish to contract Regional Advisors directly without passing through the UNEP-GEF BCH Project, all above-mentioned costs would have to be covered by the country.

- 2. How can Regional IT and CPB Advisors assist countries?
 - During Step 1 and 2?
 - During Steps 3 through 5?
 - 1) Regional IT Advisors
 - a) Steps 1 and 2

Throughout Steps 1 and 2, the Regional IT Advisors can provide technical advice and assistance to the respective country in order to identify and assess the current status of the IT equipment with the BCH Task Force, and technical requirements in regard to:

- Information and system support;
- Needs for in-depth national capacity building in the usage of BCH; and
- Additional training needs related to the aspects of data entry and knowledge management.

Additionally, the Regional IT Advisors can advise the BCH Task Force:

 With the installation and use of the chosen model of national BCH components in accordance with the respective country needs, and in consistency with guidelines for national governments that have been developed by the CBD Secretariat in order to evaluate the various options available for developing national components of the BCH.

In providing their assistance, the Regional IT Advisors will liaise with the BCH Task Force, the Regional CPB Advisors and the BCH Project Task Manager to analyze requests for IT equipment (hardware and software) submitted by participating countries to ensure they are in line with the countries' capacity and technical requirements for national BCH.

b) Steps 3 through 5

During Steps 3 through 5, the Regional IT Advisors can:

- Continue to provide advice, technical assistance and training to national BCH staff on the usage of selected IT systems;
- Discuss, identify and assess in close cooperation with the country and the UNEP-GEF Biosafety Unit, options for sources of information, information technology software and hardware, and techniques for processing information and storing data;
- Be at the disposal of the BCH Task Force to assist with the evaluation of national strategies to ensure continuity and sustainability of fulfillment of obligations related to the BCH, and to advise on the use of technical applications related to the installation and manning of the national BCH component;
- Advise the BCH Task Force with design and operation of the respective national BCH Website;
- Assist in building national capacity on accurate usage and data entry for the nBCH; and
- Train & assist national experts with the construction and maintenance of Websites and linkages between Websites.

Based on established mission TORs, the Regional IT Advisor will be responsible for ensuring compatibility between IT systems and other relevant databases and information systems. Throughout the project cycle, the Regional IT Advisor will conduct, carry out, and evaluate the effectiveness of IT systems & equipment installed and report to the country and the UNEP-GEF Biosafety Unit on accomplished tasks, on-going capacity building activities, and specific training requirements.

2) Regional CPB Advisors

The second group of Regional CPB Advisors is specialized on substance-related issues of the Cartagena Protocol on Biosafety, with an emphasis on Article 20. Their services are complementary to the work of the Regional IT Advisors, and the two sets of experts are always delivered in coordination with each other. For this reason, full documentation of all inputs and results is essential throughout the consultancy process.

a) Steps 1 and 2

During Steps 1 and 2, the Regional CPB Advisors will combine and supplement identified and formulated IT capacity building needs with substance-related in-depth training components on the provisions and obligations under the Cartagena Protocol on Biosafety (CPB). In preparation for steps 3 and 4, Regional CPB Advisors will also be able to help to identify and assess countries' training needs for national capacity building relevant to knowledge management and obligations relating to the Biosafety Clearing-House (BCH).

b) Steps 3 through 5

During the project execution phase the Regional CPB Advisors will be at the disposal of the NBCH Task Force to advise on all aspects of design and implementation of national capacity building programmes in order to assist national BCH staff in fully understanding the provisions of, and national obligations to the CPB, with particular emphasis on Article 20. Regional CPB Advisors will assist a country, in cooperation with the IT Advisor, in adapting their national BCH system to be consistent with the rights and obligations of the CPB.

In that context the Regional CPB Advisors will assist, in close cooperation with the relevant Regional IT Advisors:

- With the development and coordination of thematic national training workshops, thus
 providing continuous advice and tailored capacity building to national BCH staff
 throughout the project life.
- With advise to the respective BCH Task Forces, the Regional IT Advisors, and the UNEP-GEF Biosafety Unit, to analyze national requests on specific CPB capacity building requirements, and to develop, upon request of the respective BCH Task Force, adequate training components for national-level workshops or to help the focal points understand the requirements of the CPB.

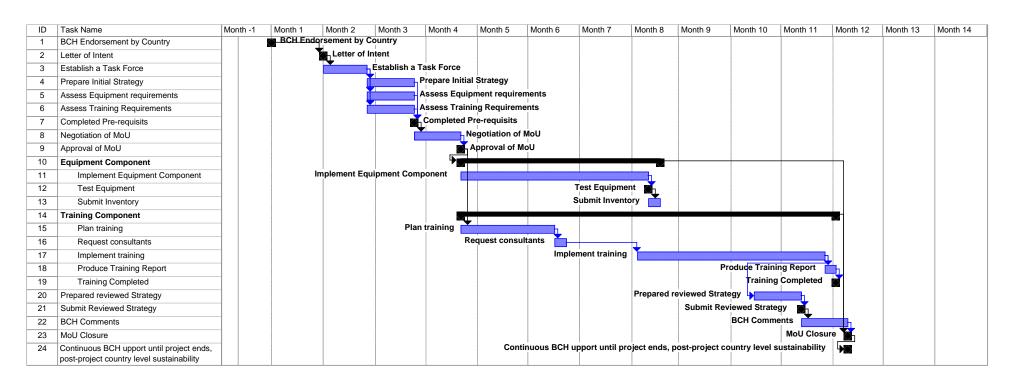
V. REPORTING TO UNEP-GEF BIOSAFETY UNIT

After the projects starts, all countries will be required to report to the BCH Project Task Manager as follows:

- 1. Send a completed *Form 6* after the purchase of the equipment;
- 2. Send a completed *Form 7* on operating the nBCH; and
- 3. Send a report of the workshop, if held, using *Form 8* to describe training objectives, inputs and results;
- 4. In addition, countries are requested to submit *Form* **10**, to evaluate the services rendered by a Regional Advisor for each assignment conducted.

After completion of steps 1-3 and the submission of final report clearly indicating sustainability of the national BCH system beyond the life of the project.

Annex 1 Sample work plan



Annexes 2-6

2	3	4	5
"Guidelines for Nat. Part in BCH 2003-en.	"Notification 2003-en.pdf"	"Submisstion of info to BCH 2003-en.pdf"	4-bibliography.doc
6			
"ANNEX 6.doc"			

Form 1 Notification of the Nomination of the BCH Task Force

Country: MoU Code No.:				
National Executing A	gency:			
I am pleased to inforn BCH Task Force:	n of the following	individuals, who hav	ve been nominated as	part of the
Name	Profession/Title	MINISTRY / AGENCY	BIOSAFETY RELATED FUNCTION	DATE OF INITIAL APPOINTMENT
The above list superse list provided prior to here, and is effective a	the date listed			
Signature by the Head	l of the NICA.			
•	Tor the NEA. [ame and Title:			
Dat	e of Signature:			
Seal of	the institution:		S	tamp

Form 2 Choice of National BCH System

Country:
National Executing Agency (NEA):
Which option has been chosen by your country? Please check one of the following options. Option 1: Using the BCH Central Portal Option 2: Non Internet, sending information by Post, Fax, E-mail, CD-ROM Option 3: "PULL" - BCH Central Portal crawls your data on your web server Option 4: "PUSH" - Your data are pushed from your server to the BCH Central Portal
Why has this option been chosen? Please explain in a few words what are the main criteria that have been considered to make your choice: technical skills are available, a web server is already running, a Biosafety database is already used, no internet is available in my office.
How will sustainability of the chosen option in the long-run be achieved? Will you organize training workshops? Will you train technical skills to several people to run and manage your database, your web server? Have you planned to produce specific user guide and technical guide of your application? Are you going to train several data input persons? Have the security aspects been considered (firewalls, backups, updates)?
Signature by the Head of the NEA: Name and Title:
Date of Signature:
Seal of the institution:

Form 3

National Assessment of locally available BCH Assets and Requirements Section to be signed by the NEA

Country:	
National Executing Agency (NEA):	

Note: The country may wish to consider the following when making their assessments and reviewing their requirements.

- 1. The institutional infrastructure of BCH operations
 - a. The NEA and the project setup
 - b. Government network of institutions relating to the BCH

In this section you would describe the network of institutions and their role relating to the BCH. It is also recommended to describe the information flow from the creation of a new data (new decision on LMO, new national law, new National Competent Authority, etc.) to the publication of this data onto the BCH. For example identify, when a new decision or law has been adopted, who is responsible to communicate it, who will enter the information into the BCH system, who will validate the content of this new data (must be the NEA NFP).

- 2. Today's national technology level and its support system
 - a. Computing equipment and services locally available
 - b. Operation and maintenance capabilities of local technology
 - c. Communication technology and infrastructure service providers

Please describe what is the actual technical infrastructure of the institutions involved locally in the National BCH: equipment already available, computers, servers. Do you have any Internet connection? Do you connect to Internet with a Modem on a telephone line? Is Internet available 24 hours/24, 7 days/7 (for NEA, for the other partner institutions)? Do you have a person who is responsible of local computers/servers maintenance? Etc.

- 3. Mobilization of assets and their status regarding the BCH
 - a. Detailed description of the national BCH setup you want to implement in your country following the decided option in **Form 2**.
 - b. Equipment from national sources (Items list and values in Form 4)
 - c. Equipment from donors and third party sources (c.f. Form 4)
 - d. HR assets available for BCH operations
 - e. Equipment and services to be procured with UNEP-GEF BCH Funding (c.f. Form 4)
 - f. Other resources available
 - g. Sustainability considerations

In this section please report Human Resources and equipment your institution and/or country will allocate to the National BCH. Also describe how you are going to run the BCH on a long term (Training of persons, Workshops). The following **Form 4** will allow you to detail the items and values of the different equipment and services you described.

Prepared by Name and Title:	
On Behalf of the National	
Executing Agency Signature by the	
Head of the NEA:	
Date of Signature:	
Seal of the institution:	Stamp

Form 4

Detailed Costing of proposed national BCH System

Section to be signed by the NEA

A. Equipment to be procured with UNEP-GEF BCH Funding

Ітем	Qтү	VALUE IN USD	INTENDED LOCATION AND RESPONSIBLE PERSON	ESTIMATED AMORTIZATION PERIOD
Subtotal A				

B. Services to be procured with UNEP-GEF BCH Funding, this could include BCH Task Force Meetings, the National Workshop set-up and any other services that may be required, not including the services of Regional Experts.

DESCRIPTION OF SERVICES	DURATION	PURPOSE	VALUE IN USD
Subtotal B			

Subtotal B				
C. Total requested UNEP-GE	F BCH Fundi	ng (A+B):	USD	

Form 4 / cont.

D. Equipment procured or made available under Government Contribution

Ітем	QTY	CURRENT VALUE IN USD	INTENDED LOCATION	ESTIMATED AMORTIZATION PERIOD
		_		
Subtotal D				

E. Equipment procured or made available under Donor Contribution

ITEM	QTY	Current	Intended	ESTIMATED
		Value in	LOCATION	AMORTIZATION
		USD		PERIOD
Subtotal E				

F. Staff and services to be procured or made available under Government Contribution

SERVICE DESCRIPTION	DURATION	Conditions	VALUE IN USD
Subtotal F			

G. Total value of Government and		
Donors Contributions (D+E+F):	USD	

H. Total cost of BCH setu USD	Form 4/cont
Prepared by Name and Title: On Behalf of the National Executing Agency Signature by the Head of the NEA:	
Name and Title:	
Date of Signature: Seal of the institution:	Stamp

Form 5 Proposed BCH Training Plan

Country:							
National Exec	National Executing Agency:						
(All analisms to	Part 1: Proposed Training Strategy						
a. Traininb. Resourc. Targetd. Trainin	b. Resource Persons						
		osted Plan					
ACTIVITY No.	ACTIVITY TITLE	No. of Participants	LOCATION (CITY, INSTITUTION)	EXPECTED TOTAL COST (USD)			
			,				
Total estimate	d cost						
Signature							
For the Natior Date:	nal Executing Agency	Stamp					

Form 6

	UNEP-GEF Funded BCH Equipment Inventory								
Country:			NEA:					As of Date:	
	ote: Please include							n the item No. of the	ne inventory entry
tem No.	Description	Make	Model Name and No.	Purchase Price in US \$	Date Purchased	Serial No.	Govt.or Project Inventory No.	Location (Address)	Disposition Recommendation
Subtotal:	Previous Page: US \$		This Pa	ge: US\$		Cumula	tive: US \$		Page of
Name and	d title of NEA Officer:					Signatur	e:		

BCH Equi	Form7 pment Operational Test
Country:	
National Executing Agency:	

Operational test procedure to be provided in due course

Form 8 Post - Training Report

Country:

National Executing Agency:

(All sections to be completed for each type of training activity. If a training report has been produced, it should be attached to this form)

Part 1:

For each activity, using the headings provided below, provide the Training Strategy?

Training objectives, as outlined to the participants
Name of Resource Persons and assessment of their performance
List of participants, with names and titles
Training materials used
Workshop evaluation scores by participants, training objective by objective, and logistics and
management scoring (using a participatory methodology).

Part 2: What activities were carried out?

ACTIVITY No.	ACTIVITY TITLE	NO. OF PARTICIPANTS	LOCATION (CITY, INSTITUTION)	TOTAL COST (US \$)
Total cost against E	BL 3301 of the MoU			

Signature For the National Executing Agency	

Date:	
	Form 9
	Request for BCH Regional Advisors
Country:	<u>-</u>
National Executi	ing Agency:
I. Objective	(s) and Justification for the Regional Advisor
Please state the reasons	s why the country need a consultant, and what problems have to be solved by this assistance
II. Proposed	TORs of the Regional Advisor
The description should	detail the activities to be performed and / or services to be rendered.
III. Duration a	and Timing
	imeframe, i.e. duration of activities/services from start to finish, indicating any factors me, such as seasonal considerations.
IV. Required	Outputs
	t has to be produced by the end of the consultancy and what will be the tangible onal expert will be expected to realize.
V. Partnershi	p, Monitoring / Progress Control
meaningful results i Who will be entrusted	I point and assist the consultant on a daily basis? (Consultants can only provide f they team up with project staff). ed with implementing the Regional Advisor's recommendations? usefulness of the Regional Advisor's activities and results, and how will these be
VI. Potential o	andidates
	of preference, 3 potential Regional Advisors from the BCH pool. Final selection will project on the basis of competency, availability and relative cost.
First Choice	
Second Choice	
Third Choice	

FORM 10 COUNTRY REPORT ON REGIONAL ADVISORS PERFORMANCE

Services Overview

Tasks to be accomplished as stipulated in ToR / Preparation / Participants / Dates / Venue / etc.

Performance of Services					
Performance Area	Performance Analysis	Performance Rating ³			
1. Planning	a) Equipment analysis / needs assessment				
	b) Quality of advice & training provided				
	c) Functionality of I/T software & hardware installed				

³ Rating scale as follows: 1. **Very poor**: does not meet the performance requirements; 2. **Poor**: partially meets performance requirements; 3. **Satisfactory**: meets the performance requirements; 4. **Highly Satisfactory**: Exceeds the requirements in more than one area; 5. **Outstanding**: Exceeds the requirements in all areas.

Performance of Services				
Performance Area	Performance Analysis	Performance Rating ³		
2. Preparation of services provided	Description / explanation on how well the RA was prepared to fulfill the ToR of tasks assigned			
3. On-site advisory support (CP RA) and technical support (IT RA)	a) Advisory support (on country obligations & CP provisions / usage of the BCH / data entry / knowledge management / etc.)			
	b) Technical support (installation / maintenance / improvement of IT soft- and hardware			
	d) Technical support to comply with minimum technical standards to operate NBCH (e.g. if required, upgrading of operating systems, soft- & hardware components, etc.)			
4. Post Mission / Workshop Services	a) Availability of RA to provide advice after completion of assigned tasks (by phone, email, fax)			
	b) Adequate reporting to NBCH upon completion of assigned tasks			

Overall rating and conclusions		
Overall rating:		
	Signatures	
	Signatures	
Prepared by:	Please enter Name & Title	Date:
Reviewed by:	Please enter Name & Title	Date:
Cleared by:	Please enter Name & Title	Date: