



## Convention on Biological Diversity

Distr.  
GENERAL

UNEP/CBD/ BS/COP-MOP/5/3  
23 June 2010

ORIGINAL: ENGLISH

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### CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY

Fifth meeting

Nagoya, 11-15 October 2010

Item 5 of the provisional agenda\*

#### **OPERATION AND ACTIVITIES OF THE BIOSAFETY CLEARING-HOUSE**

*Note by the Executive Secretary*

#### **I. INTRODUCTION**

1. The Biosafety Clearing-House (BCH) is established by Article 20 of the Cartagena Protocol on Biosafety as part of the clearing-house mechanism of the Convention on Biological Diversity (CBD), 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”. The Biosafety Clearing-House is accessible online at <http://bch.cbd.int/>.

2. The Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), in past meetings, provided two main guidance documents regarding the functioning and implementation of the Biosafety Clearing-House: the modalities of operation of the Biosafety Clearing-House<sup>1</sup> and the multi-year programme of work for the operation of the Biosafety Clearing-House.<sup>2</sup>

3. At their fourth meeting, the Parties to the Protocol, in decision BS-IV/2, emphasized “the importance of facilitating ease of access to the Biosafety Clearing-House to all Parties as well as the need for Parties to make the results of their decisions available to the public, *inter alia* through the Biosafety Clearing-House”. The Parties also emphasized “the need to ensure sustainability of capacity-building to enable developing countries to effectively use the Biosafety Clearing-House”.

4. In the same decision, the Parties to the Protocol also urged Parties and invited all other Governments to: “provide relevant information to the Biosafety Clearing-House, including information pertaining to decisions regarding the release or import of living modified organisms and risk assessments

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\* UNEP/CBD/BS/COP-MOP/5/1.

<sup>1</sup> BS-I/3, annex at <http://bch.cbd.int/about/operation-modalities>

<sup>2</sup> BS-II/2, annex at <http://bch.cbd.int/about/mypow>

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taken prior to entry into force of the Protocol” and invited all stakeholders of the Biosafety Clearing-House to continue to make relevant biosafety information and resources available through the Biosafety Information Resource Centre (BIRC).

5. In the same decision, the Parties to the Protocol requested the Executive Secretary to:

(a) Improve the structure of the common formats and simplify the registration procedure, for instance by increasing the use of metadata in addition to free text entry;

(b) Implement a procedure for the validation of information in the Central Portal of the Biosafety Clearing-House which establishes a timeframe for the confirmation or updating of information by Parties;

(c) Continue assisting national nodes for the Biosafety Clearing-House that are interlinked and interoperable with the Central Portal through the maintenance and improvement of the two applications: *Hermes* and the *BCH Ajax Plug-in*;

(d) With the view to facilitating the ease of access to the Biosafety Clearing-House to:

(i) Improve the electronic tools available for the analysis of search results (e.g. different sorting options);

(ii) Include electronic links to national reports in the country profile pages; and

(iii) Undertake additional activities, such as the introduction of online tools for statistical analysis and graphic representations of data;

(e) Commission a study of users and potential users of the Biosafety Clearing-House in order to:

(i) Assess what information users and potential users of the Biosafety Clearing-House would find useful; and

(ii) Prioritize the work programme of the Biosafety Clearing-House in order to focus the efforts of the Secretariat on making the Biosafety Clearing-House a useful tool;

6. In the same decision, the Parties to the Protocol also “urged the Global Environment Facility to extend the UNEP-GEF Biosafety Clearing-House project, in its current form as a global project with a view to ensuring sustainability of national Biosafety Clearing-House nodes and providing more capacity-building support, with special attention to targeted stakeholders (e.g., customs departments and phytosanitary inspectors), and to provide additional funding for these activities from sources other than the Resource Allocation Framework (RAF) taking into consideration the global nature of the project”.

7. Accordingly, section II of the present document contains a progress report on the programme elements identified in the multi-year programme of work for the Biosafety Clearing-House,<sup>3</sup> section III provides a synthesis of the study on users and potential users of the Biosafety Clearing-House and section IV provides elements for a decision on the operation of the Biosafety Clearing-House. The annex to the document contains a breakdown of records submitted to the Biosafety Clearing-House as of March 2010.

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<sup>3</sup> BS-II/2, annex, at <http://bch.cbd.int/about/mypow>

## II. **PROGRESS REPORT ON THE MULTI-YEAR PROGRAMME OF WORK FOR THE BIOSAFETY CLEARING-HOUSE**

### A. *Programme element 1: Structure and function of the Central Portal*

8. The objective of this programme element is to “improve ease of reporting and accessing information in the Biosafety Clearing-House in response to identified needs of users”.

#### *New common formats and revamped Management Centre*

9. Common formats are standard forms for the submission of information to the Biosafety Clearing-House. They are made available in both offline (e.g. for gathering information) and online (e.g. for the submission) formats through the Biosafety Clearing-House Management Centre.

10. In response to a direct request of the Parties to the Protocol at its fourth meeting, the structure of the common formats for the submission of information to the Biosafety Clearing-House has been improved and simplified. Additional metadata have also been added to the different formats in order to simplify data search and increase the capacity of cross-links among different categories of data.

11. The mandatory fields have been clearly identified in all common formats in order to guarantee a minimum level of information in all records registered in the Biosafety Clearing-House and a note on the review page is available to identify all missing information. A timeframe procedure for the validation of information has been also introduced and a deadline for the confirmation or updating of information is now either required or optional depending on the category of record.

12. Two sets of common formats are now available in the revamped *Registering Information* section of the Biosafety Clearing-House: (i) National records and (ii) Reference records (see table 1). The submission of national records is restricted to Biosafety Clearing-House national focal points (BCH-NFPs) and National Authorized Users (NAUs). All records submitted by NAUs will have to be reviewed for accuracy and completeness by the BCH-NFP prior to validation and publication. Reference records may be submitted by all registered users and are subject to review for accuracy and completeness by the Secretariat prior to validation and publication.

13. Both the *Registering Information* section and all of its common formats have been translated and made available through the Biosafety Clearing-House in all six official United Nations languages. As a result, the entire Biosafety Clearing-House is now available in all six official United Nations languages.

#### *Improved analysis of search results*

14. The grouping and sorting options by the main components of records have been added as part of the output of search result pages. For example, the output of a search result for *Country's decisions and other communications* may be now grouped and/or sorted by country, LMO, novel trait, taxonomic status and type of decision. For a more detailed analysis, the output of search results is also available for download in CSV format, readable with any spreadsheet application (e.g. MS Excel).

*Table 1. Overview of the new BCH common formats*

Category and type of record	Minimum number of mandatory fields	Timeframe for confirmation or updating
<b>a) National records</b>		
National focal points	13	Mandatory, 1 year
National biosafety websites or databases	4	Mandatory, 1 year
Competent National Authorities	8	Mandatory, 1 year
Biosafety laws, regulations, guidelines and regional and international agreements	6	Optional, 2 years
Country's decisions or other communications	7	Optional, 2 years
Risk assessments generated by a regulatory process	6	Optional, 2 years
Biosafety experts	28	Mandatory, 1 year
Reports on biosafety expert assignment	9	No expiration
<b>b) Reference records</b>		
Contact details	6	Mandatory, 1 year
Capacity-building activities, projects and opportunities	11	Mandatory, 1 year
Capacity-building needs assessment	3	Mandatory, 1 year
Biosafety organizations	8	Mandatory, 1 year
Biosafety Information Resource Centre (BIRC)	7	No expiration
BCH News	3	No expiration
Risk assessments generated by an independent or non-regulatory process	6	Optional, 2 years
Living modified organisms (LMOs)	6	No expiration
Genes and DNA sequences	4	No expiration
Organisms	1	No expiration

*Roster of experts*

15. In decision BS-IV/4, the Parties to the Cartagena Protocol requested the Executive Secretary “to remove all existing records in the roster within three months and refill the roster with those experts who are nominated or re-nominated by Parties and Governments”. In the same decision the Parties approved a new format for the submission of expert nominations and authorized the Secretariat “to check all nomination forms for completeness and return to the nominating Governments any nomination forms that are incomplete and/or do not meet the criteria and minimum requirements”.

16. Accordingly, the content of the roster was removed completely in September 2008 and the Executive Secretary invited all national focal points for the Cartagena Protocol to make new nominations to the roster of experts in accordance with the updated guidelines.<sup>4</sup> Expert records are now maintained in the roster for a period of four years from their last update. At the expiry of this period, they are deleted from the roster until the experts are re-nominated by their Governments.

<sup>4</sup> Notification 2008-107 at <http://www.cbd.int/doc/notifications/2008/ntf-2008-107-cpb-en.pdf>

*Interoperability of the Biosafety Clearing-House with other websites and databases*

17. The Biosafety Clearing-House is an open system and instructions for making other websites/databases interoperable are available from its pages.<sup>5</sup> However, only few countries have decided to make their databases interoperable with the Biosafety Clearing-House and the online submission of information through the Central Portal remains the most used option by the majority of the countries.

18. An important contribution towards meeting the specific needs of the Parties in using their biosafety data in combination with other national information continues to be offered by the two applications: *Hermes* and the *BCH Ajax plug-in*. Both applications which were developed by the Secretariat allow national data submitted to the Biosafety Clearing-House to be immediately available to biosafety websites maintained at the national level without involving elaborate procedures. In addition, the developers of regional Biosafety Clearing-House nodes have taken keen interest in both applications because of their simplicity of use that does not require any further development of additional infrastructure. Furthermore, a wide variety of country data may be easily made available with the use of either application.<sup>6</sup>



*Cross-references among different categories of information stored in the Biosafety Clearing-House*

19. In order to make browsing easier among related records, cross-reference links have been added to the “Country profile” page (e.g. new link to national reports). Also, there are now record layouts with cross-reference links through the use of “tabs”. For example, figure 1 below shows an LMO record with its three tab-links that provide access to “LMO information”, as well as to all “Decisions” and “Risk Assessments” records that have been published on that LMO.

**Figure 1. “Tab-links” providing cross-references among BCH data.**

 Modified Organism

ACS-BN007-1 - Liberty-Link™ Innovator Canola

LMO Information	Decisions on the LMO						Risk Assessments	
Country	Domestic Use			Import			Environmental Release	Other
	Food	Feed	Processing	Food	Feed	Processing		
<a href="#">Australia</a>								
<a href="#">Canada</a>								
<a href="#">China</a>								
<a href="#">European Union</a>								
<a href="#">Japan</a>								
<a href="#">Republic of Korea</a>								
<a href="#">Mexico</a>								
<a href="#">New Zealand</a>								
<a href="#">United States of America</a>								

<sup>5</sup> BCH Interoperability Services 3.0 at <http://bch.cbd.int/help/interoperability/webservice3/>

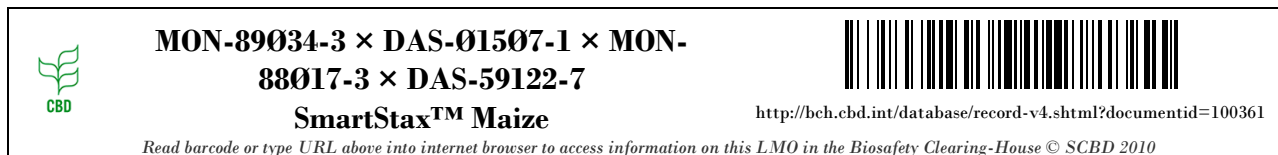
<sup>6</sup> Hermes and BCH Ajax Plug-in manuals, as well as a list of examples of BCH National Nodes realized through the use of Hermes are available at <http://bch.cbd.int/resources/solutions/>

*Recent developments not implemented to date*

20. One important addition to the Biosafety Clearing-House still “in progress” at the time of publication of this document is due to be released in the third quarter of 2010. Following a specific request of the Parties to the Protocol at their fourth meeting to “undertake additional activities, such as the introduction of online tools for statistical analysis and graphic representations of data”, the Secretariat has started the implementation of a data-mining tool through *online analytical processing* (OLAP) in order to answer multi-dimensional analytical queries. Biosafety Clearing-House users will be able to display the results of queries obtained through this tool in different ways according to their choice, e.g. rough data, statistics, graphic or geographic representations (through GIS). A side-event at the fifth meeting of the Parties to the Protocol is scheduled to present an overview of this latest Biosafety Clearing-House tool.

21. A minor project is also currently under development at the time of publication of this document on the implementation of quick-links to the BCH pages that provide information on LMOs (identification, country’s decisions, risk assessment etc.). The quick-link appears as a small image, downloadable from the Biosafety Clearing-House and easy to copy to documents identifying LMOs (figure 2). The image contains the LMO’s unique identifier, the trade name and the link to the relevant BCH page where information on the LMO is available. In the example below the link to the BCH page is presented in both its alphabetic and barcode representations and provides a quick and direct access to the LMO information shown in figure 1 above.

**Figure 2. Draft of a “quick-link” to the BCH page providing information on a specific LMOs**



**B. Programme element 2: Information content and management**

22. The objective of this programme element is to “increase the amount of information that is currently being reported to the Biosafety Clearing-House, and ensure it is provided in a timely manner”.

23. During the intersessional period, the Biosafety Clearing-House underwent a systematic reorganization of its records. This reorganization was done by introducing new common formats as well as identifying incomplete or empty records and updating them. The following are the specific changes that were undertaken:

(a) As noted earlier, in August 2008, following up a request from the Parties to the Protocol,<sup>7</sup> all experts previously registered in the Roster were removed;

(b) In September 2009, following a revision of the common format for the submission of information, more than 2000 incomplete risk assessment records were removed because they were not specifying the LMOs that were the objects of the risk assessments;

(c) In September 2009, after an ambiguity was identified in the former common format for the submission of information on decisions under Article 11.1 (LMO-FFPs), a remedial action taken by the Secretariat also rendered visible hundreds of decisions submitted earlier under both Article 11 and Advanced Informed Agreement - AIA (introduction into the environment).

24. A full review of Biosafety Clearing-House records in the capacity-building databases was also undertaken. Records were reviewed for accuracy and completeness. They were also checked to verify if they were up to date. An extensive review was made on the status of the Academically Accredited Course

<sup>7</sup> BS-IV/4 at <http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11683>

database and an updated list of institutions offering courses or research opportunities in Biosafety education/training and GMO/LMO assessment is now available.

25. Similarly, the content of the *LMO*, *Organism* and *Gene and DNA sequence* registries was extensively reviewed and improved by cross-references among registries and to their related decisions and risk assessment documents. It is noted that, as of March 2010, only approximately 50 per cent of the LMOs listed in the Biosafety Clearing-House have a unique identifier. As a result, a specific request for assistance on this issue has been addressed to the Global Industry Coalition (GIC) to promote, among their associated companies, better identification of commercialized LMOs.

26. A breakdown of records submitted to the Biosafety Clearing-House as of March 2010 is set out in the annex to this document. It reflects more accurately the current details of the submissions received by countries and allows a more accurate analysis of the data available. It is however noted that there is still only a limited number of decisions on the intentional introduction of LMOs into the environment and a significant absence of the summary reports of their risk assessments related to the decisions submitted. In particular:

(a) Of the over 300 LMOs commercialized worldwide, only 489 decisions have been submitted to the Biosafety Clearing-House by 22 Parties and a total of 705 decisions have been submitted by 26 countries (see table 2 of the annex);

(b) Of the 489 decisions by Parties, only 266 (i.e. 54 per cent) have a risk assessment attached. Similarly, of 216 decisions submitted by non-Parties, only 54 (25 per cent) have a risk assessment attached. The Secretariat has sent detailed notes to the relevant BCH National Focal Points drawing attention to the issue.

27. A risk assessment report consistent with Annex III of the Protocol must be made available to the Competent National Authority in notifications for the AIA procedure for intentional introduction into the environment (Art. 7-10) and directly to the Biosafety Clearing-House in decisions on LMOs for direct use as food or feed, or for processing (LMOs-FFP, Art. 11) as part of the information requirements specified in annexes I and II of the Protocol, respectively.

28. National approaches to the interpretation of the Protocol may have had an impact on the number of decisions submitted by the Parties to the Biosafety Clearing-House regarding intentional introductions into the environment. The AIA procedure under the Cartagena Protocol does not apply to the transboundary movement of LMOs destined for contained use. Once an LMO has been imported for contained use, any subsequent application for approval for the intentional introduction of the LMO into the environment is not a transboundary movement and thus it does not trigger the AIA procedure. Parties may therefore not have considered that they need to communicate a decision on such an application to the Biosafety Clearing-House because the procedure is not triggered.

29. Subparagraphs (c) and (d) of paragraph 3 of Article 20 of the Protocol apply here, however, and they require each Party to make available to the Biosafety Clearing-House its final decisions regarding the release of LMOs as well as summaries of risk assessments generated by its regulatory processes. These subparagraphs provide that all decisions and risk assessments be made available to the Biosafety Clearing-House whether they are triggered by a transboundary movement or by an internal request.

**C. *Programme element 3: Sharing information on and experience with living modified organisms***

30. The objective of programme element 3 is to “make a broader range of biosafety information accessible to users of the Biosafety Clearing-House”.

*Electronic forums, real-time conferences, surveys and collaborative portals*

31. As a part of its mandate to assist Parties to implement the Protocol, the Biosafety Clearing-House is often requested to provide tools for promoting the exchange of ideas as well as scientific and technical information on biosafety issues. During the past intersessional period a number of electronic forums, collaborative portals and electronic surveys were launched with a significant level of appreciation from various users.

32. The Open-ended Online Expert Forum on Risk Assessment and Risk Management was established by decision BS-IV/11 and launched in November 2008.<sup>8</sup> As of March 2010 it was attended by a total of 228 experts.<sup>9</sup> In the course of 16 months, the forum hosted 18 different discussion groups and 8 regional real-time online conferences on different topics with the view to identifying major issues relating to specific aspects of risk assessment and risk management relevant to the mandate of the AHTEG on Risk Assessment and Risk Management, as established by decision BS-IV/11.

33. A special module for the real-time online conferences was developed in-house by the Secretariat and allows for running electronic meetings to simulate the real face-to-face meetings with specific agenda for the virtual meeting. Registered users are presented with a screen interface where they can (i) follow the flow of the written interventions, (ii) request the floor and (iii) post their own written interventions. The module allows for one or more chair-persons who can manage the list of requests for the floor and post interventions on the main screen. There is also a help-desk function which allows the organizer of the conference to contact participants individually in the event of technical problems.

34. The Real-time Conference module is supported by all main operating systems, completely managed by the BCH server. It only requires the availability of a simple piece of software which is easily available for download on the internet and compatible with the vast majority of internet browsers. Special attention has been dedicated to making the module easily usable even when internet connections are slow or intermittent. The module is now an integral part of the BCH system and it is also available to all national nodes based on the platform developed by the Secretariat (*Hermes* instances). Upon request, it may be made available to Parties for national or regional electronic biosafety conferences.

35. Other forums held in the intersessional period include an Online Forum on Capacity-Building (3-28 November 2008 and 19 January - 6 February 2009) and an Online Forum on Standards for LMO Shipments (18 May - 5 June 2009). The detail analysis of participation in all of the above forums and to the real-time conferences, as of March 2010, is provided in table 2 and table 3 below.

**Table 2. Participation to electronic forums (2008-2010)**

Forum	Duration	Registered participants	No. of discussion groups	Total number of interventions
Open-ended Online Expert Forum on Risk Assessment and Risk Management <sup>10</sup>	23 months	228	18	315
Online Forum on Capacity-Building	7 weeks	117	8	88
Online Forum on Standards for LMO Shipments	3 weeks	81	11	104
<b>Total</b>	<b>-</b>	<b>426</b>	<b>37</b>	<b>507</b>

<sup>8</sup> The Open-ended Online Expert Forum on Risk Assessment and Risk Management is available at [http://bch.cbd.int/onlineconferences/forum\\_ra.shtml](http://bch.cbd.int/onlineconferences/forum_ra.shtml)

<sup>9</sup> 153 experts were nominated by 48 Parties, 11 experts by 5 Non-Parties and 64 experts by 47 observer groups including representatives from the private sector, academic institutions, NGOs, research foundations and other government institutions. The updated list of experts nominated for the forum is available at [http://bch.cbd.int/onlineconferences/participants\\_ra.shtml](http://bch.cbd.int/onlineconferences/participants_ra.shtml)

<sup>10</sup> Data do not include participation to the real time conference.

**Table 3. Expert participation to the regional real-time online conferences on risk assessment and risk management**

Regional Conferences <sup>11</sup>	No. of experts 1 <sup>st</sup> series of conferences			No. of experts 2 <sup>nd</sup> series of conferences			Total number of interventions
	Parties	Non-Parties	Observers	Parties	Non-Parties	Observers	
Africa	7	1	4	8	0	5	421
Asia and the Pacific	14	3	3	11	2	3	383
Central and Eastern Europe + WEOG	9	2	2	13	2	8	513
Latin America and the Caribbean	13	0	3	6	0	6	537
<b>Total</b>	<b>43</b>	<b>6</b>	<b>12</b>	<b>38</b>	<b>4</b>	<b>22</b>	<b>1854</b>
<b>Total number of experts per series</b>	<b>61</b>			<b>64</b>			<b>-</b>

36. Several surveys were also conducted as a follow up to decisions from the Parties to the Protocol or for receiving feedback on previous experiences. In particular, the following online surveys were launched on the Biosafety Clearing-House during the intersessional period:

- (a) Feedback on online BCH forums (November 2008 - February 2009);
- (b) Application of and experience in the use of socio-economic considerations in decision-making on living modified organisms (14 October - 13 November 2009);
- (c) Study of users and potential users of the BCH (21 December 2009 - 15 February 2010).

37. Results of the above surveys are available both through the Biosafety Clearing-House and in the relevant documents of the Conference of the Parties serving as the meeting of the Parties to the Protocol<sup>12</sup>

38. In addition to forum discussions, some specific groups of stakeholders have requested dedicated areas, or *Collaborative Portals*, on the Biosafety Clearing-House in order to discuss specific topics, coordinate activities and share work material. While all of these collaborative portals are listed in the Biosafety Clearing-House,<sup>13</sup> access to some of them may be limited to the members of a specific group. The following Collaborative Portals were in use as of March 2010:

- COP-MOP Bureau
- Compliance Committee
- Capacity-Building Network
- BCH Informal Advisory Committee (IAC)
- AHTEG on Risk Assessment & Risk Management
- UNEP-GEF BCH Regional Advisors (RAs)
- University of Minnesota & SCBD Joint Practicum on Risk Assessment
- Handling, Transport, Packaging and Identification of Living Modified Organisms (including the Collaborative Portal for Customs Officers)

<sup>11</sup> In several cases participants were offered to participate in regional conferences different from their geographical origin (e.g. English speaking Caribbean countries joined conferences in the English language).

<sup>12</sup> At <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3018>

<sup>13</sup> At <http://bch.cbd.int/onlineconferences/>

*The Biosafety Information Resource Centre (BIRC)*

39. The BIRC, the virtual library hosted by the Biosafety Clearing-House, is continuously growing in size (41 per cent increase since the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol) as a result of the contributions from all Biosafety Clearing-House registered users and other biosafety stakeholders. The primary purpose of the BIRC is to increase the accessibility and utilization of available biosafety information and resources.

*Technical documentation*

40. To fulfil a specific request from the Informal Advisory Committee (BCH-IAC), the Secretariat initiated a project for the organization of all Biosafety Clearing-House documentation and release notes in order to better track all changes to the system since its inception. The aim of this project is to provide the Biosafety Clearing-House with an archive that describes and explains all codes in use.

**D. Programme element 4: Capacity-building and non-Internet accessibility**

41. The objective of programme element 4 is to “ensure that countries have the necessary capabilities to access the Internet-based central Portal and are able to access information through the Biosafety Clearing-House in a timely manner”.

*The UNEP-GEF Biosafety Clearing-House project*

42. Capacity-building for the Biosafety Clearing-House was addressed by the Parties to the Protocol at their fourth meeting in decision BS-IV/2, in which Parties urged the Global Environment Facility (GEF) “to extend the UNEP-GEF Biosafety Clearing-House project, in its current form as a global project”. The project development phase between UNEP, as the implementing agency and GEF on the extension of the previous Biosafety Clearing-House project had not yet been finalized as at May 2010. The project “concept” was approved by the GEF Council in November 2009. This concept allowed for the extension of the project to cover a maximum of 50 eligible countries. Eligibility has been extended to those countries that had completed the previous project or had initiated a project on the implementation of their National Biosafety Frameworks (NBFs) through a prior or ongoing GEF project. As a follow-up to the concept approval, UNEP informed the Secretariat that the full project document was under preparation and subject to the final endorsement by the GEF Chief Executive Officer, the project is expected to commence in the second half of 2010. It is noted that GEF support is yet to be available for further capacity-building on the Biosafety Clearing-House. However, in order to assist Biosafety Clearing-House users and, in particular, BCH national focal points in their daily use of the Biosafety Clearing-House, several tools were developed in-house within the limited resources of the Secretariat.

*Tutorial modules and Frequently Asked Questions*

43. A set of five tutorial modules was developed on the use of the main sections of the BCH Central Portal. They were made available in three languages (English, French and Spanish) and in several audio-video formats in the Biosafety Clearing-House.<sup>14</sup> The tutorial video-clips were also made available on the BCH channel of YouTube<sup>15</sup> to allow users to benefit from the advanced capacity of this network to smoothly “stream” video files. The modules developed to date are as follows:

- (a) Common features - features that can be found on all of the BCH web pages;
- (b) Text pages - features that can be found on the BCH homepage as well as in “The BCH” and “The Protocol” sections;

<sup>14</sup> At <http://bch.cbd.int/help/tutorials/>

<sup>15</sup> At <http://www.youtube.com/user/bchcpb>

- (c) Finding information - how to search for information through the Finding Information section;
- (d) Registering information - how to register information through the Management Centre;
- (e) Resources - features designed to help you better use and understand the Biosafety Clearing-House.

44. In parallel with the tutorial modules, a new set of “Frequently Asked Questions (FAQs)” was developed and published in the Biosafety Clearing-House.<sup>16</sup>

#### *Help section*

45. As a follow-up to the revamping of the “Registering Information” section of the Biosafety Clearing-House, a module for help on registering information was also developed and made available in the BCH Help section along with the previous modules developed in collaboration with the UNEP-GEF project. The entire Help section has also been updated and it is available in all six official languages of the United Nations.<sup>17</sup>

#### *Off-line versions of the Biosafety Clearing-House*

46. During the intersessional period, the Secretariat continued the quarterly shipment of off-line copies of the BCH on DVD to the BCH national focal points of countries that have limited Internet connections. There are currently 29 countries that are benefitting from this service. Previously, the off-line version of the Biosafety Clearing-House was only available on CD-ROM and in English only. However, starting with June 2010, the off-line copies will be shipped in DVD format and will have texts in all six United Nations languages.<sup>18</sup>

#### *Training activities*

47. Several training activities at the national and regional level were held during the intersessional period. The staff of the Secretariat participated in some of these events (i.e. when funding and time limitations allowed). As of March 2010, the following countries have posted on the BCH news of their training activities:

- Belize, August and September 2008: National Workshops on Cartagena Protocol and the BCH.
- Bhutan, March 2009: 1st National Biosafety Clearing-House Workshop.
- Croatia, 2008 - 2009: Five National BCH Workshops; First and Second National Workshop for the members of the BCH Task Force Group; Handling applications for release of GMOs into the environment and placing GMOs on the market.
- Dominican Republic, December 2008: VIII BCH Training Workshop.
- Egypt, August 2008: 1st National BCH Workshop.
- Fiji, May and September 2008: first and second national workshop.
- Iran (Islamic Republic of): December 2008 and February 2009 - Three National BCH workshops.
- Kiribati, December 2008: BCH second national workshop.

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<sup>16</sup> At <http://bch.cbd.int/help/faq/>

<sup>17</sup> At <http://bch.cbd.int/help/topics/en/webframe.html>

<sup>18</sup> The latest version of the off-line copy of the BCH is also made available on line for download at <http://bch.cbd.int/resources/downloads/#offline>

- Republic of Korea, December 2008: Subregional Workshop for Capacity-Building on The BCH and Information Sharing.
- Libyan Arab Jamahiriya, November and December 2008: Two training workshops on using and updating Biosafety Clearing House.
- The former Yugoslav Republic of Macedonia, June 2009: National workshop for inspectors and customs officers.
- Montenegro, January 2009: National Workshop for Inspectors.
- Saint Lucia, March 2009: BCH training workshops for: (a) farmers; (b) members of the National Coordinating Committee (NCC); and (c) secondary school teachers.

#### ***E. Programme element 5: Review of activities***

48. The objective of programme element 5 is to “ensure that the programme of work is achieving the goals of the Biosafety Clearing-House effectively”.

##### *The Informal Advisory Committee*

49. In accordance with decision BS-I/3, the Secretariat periodically seeks assistance from an Informal Advisory Committee (BCH-IAC) with a focus on providing guidance to the resolution of technical issues associated with the development of the Biosafety Clearing-House.

50. During the intersessional period, the BCH-IAC held two meetings in Montreal and discussed and assessed the progress of work on the Biosafety Clearing-House. The following list provides an overview of the main issues discussed by the committee during these meetings:

- (a) Current status of the Biosafety Clearing-House and general progress in the multi-year programme of work;
- (b) Assessment and review of the new Management Centre, new registration pages and common formats for off-line registration;
- (c) Assessment and review of the Biosafety Clearing-House forum, activities and tools;
- (d) Assessment and review of the new “Help” section in the Biosafety Clearing-House;
- (e) Assessment of national and regional nodes;
- (f) Pending requests from the decisions of the Parties to the Protocol;
- (g) Status of the UNEP-GEF BCH project extension, related training activities and collaboration;
- (h) Biosafety Clearing-House component of the draft Strategic Plan of the Cartagena Protocol;
- (i) Future developments and challenges.

51. The summary outcomes of the meetings, including reports, conclusions and recommendations made to the Executive Secretary for consideration in the implementation of the programme of work for the Biosafety Clearing-House are available in the Biosafety Clearing-House.<sup>19</sup>

52. The next meeting of the BCH-IAC is scheduled for the end of 2010. In order to continue its work of providing technical assistance to the Secretariat. It is expected that the Committee will be invited to consider the ongoing implementation of the programme of work as well as other relevant issues raised by the fifth meeting of the Parties.

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<sup>19</sup> At <http://bch.cbd.int/about/iac/>

### *Implementation of security audit recommendations*

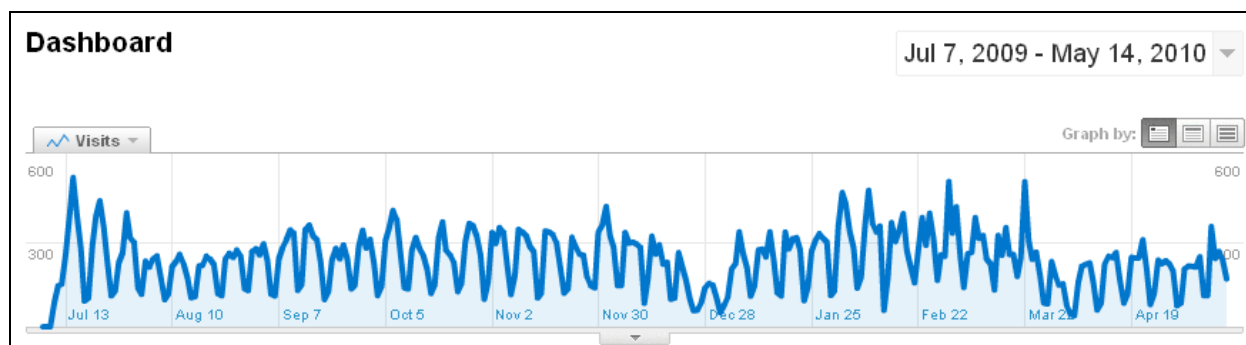
53. In accordance with decision BS-III/2, in March 2008, with the generous contribution of the Government of Switzerland, the Secretariat undertook an external security audit of the central portal and its infrastructure.<sup>20</sup> The recommendations of the security audit have been fully implemented during the intersessional period.

### *Monitoring Biosafety Clearing-House activity*

54. The activity of the Biosafety Clearing-House is constantly monitored in-house to ensure the maximum reliability of the system. In 2009, the Biosafety Clearing-House web server received over 30 million requests (“hits”) and approximately 400,000 files were downloaded by users. In the same year, the BCH up-time (i.e., the time the server was available to the public) was 99.97 per cent.

55. Since July 2009, the Biosafety Clearing-House has also been monitored daily by an external engine, Google Analytics, which provides insights into the website traffic and network effectiveness. Figure 3 below provides an overview of the reported Biosafety Clearing-House traffic in the period from 7 July 2009 to 14 May 2010.

**Figure 3. BCH traffic overview provided by Google Analytics**



## **III. STUDY OF USERS AND POTENTIAL USERS OF THE BCH**

56. As mandated by decision BS-IV/2, a study of users and potential users of the BCH<sup>21</sup> was conducted, as outlined in paragraph 5 above. This study was designed to determine what information users and potential users of the Biosafety Clearing-House find helpful and gather feedback from the users. This feedback is to enable the meeting of the Parties to focus its efforts, prioritize its programme of work and maximize the usefulness of the Biosafety Clearing-House.

57. The Informal Advisory Committee of the Biosafety Clearing House (BCH-IAC), at the fifth meeting, further elaborated on the elements of the study and made recommendations as set out in document UNEP/CBD/BS/BCH-IAC/5/2.<sup>22</sup>

58. The study took place in the first quarter of 2010, using three main sources of information: (i) an online survey, (ii) targeted, semi-structured interviews and (iii) an analysis of existing materials.

<sup>20</sup> The report of the external security audit of the Central Portal of the Biosafety Clearing-House and its infrastructure is available at <http://www.cbd.int/doc/meetings/bs/mop-04/information/mop-04-inf-19-en.pdf>

<sup>21</sup> Available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3018>

<sup>22</sup> Available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3303>.

59. The online survey was designed to take into account the extent of the experience of respondents in the use of the Biosafety Clearing-House as well as in their participation in online forums and/or real-time conferences. The survey was made available through a notification to all BCH focal points and by email to registered users and regional advisors as well as to a list of potential BCH users, generated from the participant lists of meetings and training workshops organized by the Secretariat and other organizations.

60. The targeted, semi-structured interviews were conducted with an audience from twenty stakeholder groups, taking into account geographical balance.

61. The existing materials that were analyzed were (i) mission reports from the UNEP-GEF Biosafety Project “Building Capacity for Effective Participation in the Biosafety Clearing House (BCH) of the Cartagena Protocol”, (ii) the final report of UNEP-GEF Biosafety Project and (iii) an academic report titled “Effective participation in the Biosafety Clearing House: Participation options and impediments to information provision”.<sup>23</sup>

62. The study revealed that most of the users expressed satisfaction with the Biosafety Clearing-House and especially with the recent changes the Biosafety Clearing-House has undergone. It also revealed that the UNEP-GEF project *Building Capacity for Effective Participation in the Biosafety Clearing-House (BCH) of the Cartagena Protocol* has contributed effectively to the present level of awareness of the functioning of the Biosafety Clearing-House.

63. However, the study identifies several key issues that limit the total fulfilment of the mandate of the Biosafety Clearing-House and recommends actions to be taken by different stakeholders in order to overcome these limitations.

64. In particular the study emphasizes the following needs:

(a) Continuation of capacity-building projects with special emphasis on the Biosafety Clearing-House in the programme of work of the Protocol;

(b) Enhancement of synergies and avoidance of duplications of activities between relevant United Nations agencies and organizations;

(c) Capacity-building activities to take place at the global, regional and subregional level rather than at solely the national level;

(d) Ensuring, at the national level, the sustainability of BCH nodes/websites, compliance with the information-sharing obligations under the Protocol, awareness among key stakeholders and the commitment of Governments to addressing important biosafety issues;

(e) Inclusion in the BCH programme of work a component dedicated specifically to further improvements to the BCH Central Portal;

(f) Ensuring the availability of the necessary human and financial resources.

65. Specific recommendations are also made in the study to address, *inter alia*: (i) the need for financial support in capacity building projects; (ii) the need for specific guidance material for government officials; (iii) the need to provide information and guidance in multiple languages; (iv) the usefulness of using the Biosafety Clearing-House as a platform for online forums and conferences with a prioritized list of topics; (v) the need for translation of selected documents into languages other than the official United

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<sup>23</sup> The [user](http://bch.cbd.int/about/reports-and-reviews/#feedback) survey, feedback and other publications on the Biosafety Clearing-House are available at <http://bch.cbd.int/about/reports-and-reviews/#feedback>

Nations languages; (vi) the usefulness of involving BCH national focal points in the improvement of the Biosafety Clearing-House; (vii) the possibility of organizing regional and subregional meetings for the exchange of experience and lessons learned on the Biosafety Clearing-House; and (viii) the need to periodically review the common formats.

#### **IV. ELEMENTS OF A DRAFT DECISION ON THE MODALITIES OF OPERATION OF THE BIOSAFETY CLEARING-HOUSE**

66. At their fifth meeting, the Parties to the Protocol are invited to consider the general operation of the Biosafety Clearing-House and the ongoing implementation of its programme of work so as to further give direction to future Biosafety Clearing-House activities.

67. On the basis of: (i) the progress report on the implementation of the multi-year programme of work for the operation of the Biosafety Clearing-House; and (ii) the study of users and potential users of the Biosafety Clearing-House, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) may wish to adopt a decision on:

(a) Activities aimed at further improving the Biosafety Clearing-House as a central facility for information sharing;

(b) Submission of relevant information to the Biosafety Clearing-House. The Parties to the Protocol may wish to put a mechanism in place to ensure that Parties submit complete information pertaining to decisions on living modified organisms and their associated risk assessments; and also invite other Governments to submit the same;

(c) Addressing the need for capacity-building for the use of the Biosafety Clearing-House. Parties may wish to request the GEF to extend the ongoing project for continued enhancement of building capacity for effective participation in the Biosafety Clearing-House (BCH-II), currently limited to 50 participants, to all eligible Parties;

(d) Ensuring the sustainability of national BCH nodes. The Parties to the Protocol may wish to request Parties and invite other Governments to clearly identify their needs on this subject through the Biosafety Clearing-House and request the UNEP-GEF project and the Secretariat to accordingly intensify the support provided;

(e) Introducing changes in the Biosafety Clearing-House. The changes introduced in common formats, registration procedure, tools for the analysis of search results and graphic representations of data may request some time to be fully assessed by BCH users, the Parties to the Protocol may wish to request the Secretariat to assess usefulness of the changes to the BCH users and to report to the next meeting of the Parties;

(f) Need for easy access among cross-related information in the Biosafety Clearing-House. Parties may wish to consider the usefulness of the “quick-link” tool (see paragraph 21 above) to facilitate coordination among relevant national agencies for references to information in the Biosafety Clearing-House;

68. In further consideration of the recommendations of the BCH study, Parties may wish to:

(a) Invite relevant United Nations agencies and international organizations to enhance synergies and avoid duplications of activities in the provision of information on living modified organisms;

(b) Invite the UNEP-GEF project to promote capacity building activities at the global, regional and in particular at the subregional level in order to increase the exchange of experiences among different countries;

(c) Request the UNEP-GEF project and the Secretariat to produce further guidance to the Biosafety Clearing-House with special attention to targeted stakeholders (e.g. government officials, media, general public, members of civil society organizations, etc.);

(d) Request the Secretariat to organize online forums and conferences on topics relevant to biosafety and the implementation of the Cartagena Protocol;

(e) Request the Secretariat to explore innovative ways to make BCH information available in other languages than the official United Nations languages.

## Annex

# BREAKDOWN OF RECORDS SUBMITTED TO THE BIOSAFETY CLEARING-HOUSE AS OF MARCH 2010

Table 1. Number of records submitted to the Biosafety Clearing-House

Category of information	Number of BCH records		Increase (%)
	December 2007	March 2010	
Protocol focal points	187	188	0.5%
BCH focal points	191	191	0
Article 17 focal points	63	80	30%
Competent National Authorities	270	351	30%
National biosafety websites and databases	86	106	23%
<b>Total records for national contacts<sup>24</sup></b>	<b>797</b>	<b>799</b>	<b>0.2%</b>
National laws	441	578	31%
Bilateral, multilateral and regional agreements	50	38	-24%
<b>Total records for laws &amp; regulations</b>	<b>491</b>	<b>617</b>	<b>26%</b>
Decisions under AIA (introduction into the environment) <sup>25</sup>	6	309	N/A
Decisions under Article 11.1 (LMO-FFPs)	490	576	17%
Other decisions and declarations	46	144	213%
<b>Total records for Country's decisions and other communications</b>	<b>542</b>	<b>778</b>	<b>43%</b>
<b>Total records for risk assessments reports<sup>26</sup></b>	<b>1,274</b>	<b>416</b>	<b>-67%</b>
Roster of experts members <sup>27</sup>	584	75	-87%
Reports on expert assignments	0	0	0
<b>Total records for the roster of experts</b>	<b>584</b>	<b>75</b>	<b>-87%</b>
<b>Total records submitted by countries</b>	<b>3,688</b>	<b>2,685</b>	<b>-27</b>
LMO registry	171	337	97%
Gene registry	57	234	310%
Parental Organism registry	115	142	23%
<b>Total records for Registries</b>	<b>343</b>	<b>713</b>	<b>108%</b>
Capacity-building opportunities	82	121	48%
Capacity-building projects	134	161	20%
Capacity needs and priorities	52	60	15%
Biosafety-related training and education programmes	33	40	21%
<b>Total records for capacity-building activities</b>	<b>301</b>	<b>382</b>	<b>27%</b>
<b>Total records for international organizations</b>	<b>142</b>	<b>210</b>	<b>48%</b>
<b>Total records for scientific bibliographic database</b>	<b>7,017</b>	<b>7,783</b>	<b>11%</b>
<b>Total records for Biosafety Information Resource Centre (BIRC)</b>	<b>740</b>	<b>1,043</b>	<b>41%</b>
<b>Total number of records in the BCH</b>	<b>12,231</b>	<b>12,816</b>	<b>4.8%</b>

<sup>24</sup> The difference between the sum of the records listed in each category and the total number of records is due to the possibility that one record contains information for more than one category (e.g. a focal point may have more than one role); in this case the same record is listed two or three times in the breakdown.

<sup>25</sup> In September 2009, after an ambiguity was identified in the former common format for the submission of information on decisions under Article 11.1 (LMO-FFPs), a remedial action taken by the Secretariat also rendered visible hundreds of decisions submitted earlier under both Article 11 and Advanced Informed Agreement - AIA (introduction into the environment).

<sup>26</sup> In September 2009, following a revision of the common format for the submission of information, more than 2000 risk assessment records were removed because they did not specify the LMO that was the object of the risk assessment.

<sup>27</sup> In August 2008, following up a request in decision BS-IV/4, all experts previously registered in the roster were removed.

*Table 2. Decisions submitted to the BCH on Advance Informed Agreement (AIA) (Art. 7-10) or LMO-FFPs (Art. 11) and attached risk assessments*

Countries	AIA only	Art.11 only	AIA and Art.11	Total	Risk assessments attached
<i>Parties</i>					
Belgium	0	1	0	1	1
Brazil	0	7	12	19	19
China	0	20	2	22	0
Colombia	13	22	1	36	11
Costa Rica	6	0	0	6	6
Cuba	9	0	0	9	0
Czech Republic	0	3	0	3	0
El Salvador	0	1	0	1	1
European Union	18	43	19	80	5
Germany	10	1	0	11	11
Indonesia	1	0	0	1	1
Japan	50	39	5	94	89
Mexico	12	35	0	47	5
Netherlands	0	2	0	2	2
New Zealand	0	23	0	23	0
Norway	1	0	0	1	0
Philippines	4	46	0	50	46
Republic of Korea	0	69	0	69	68
Romania	2	0	0	2	1
South Africa	3	0	0	3	0
Spain	0	1	0	1	0
Switzerland	0	8	0	8	0
<i>Sub-total: Parties</i>	<i>129 (26%)</i>	<i>321 (66%)</i>	<i>39 (8%)</i>	<i>489 (100%)</i>	<i>266 (54%)</i>
<i>Non Parties</i>					
Argentina	0	9	2	11	0
Australia	0	24	5	29	0
Canada	1	12	44	57	54
United States of America	0	30	89	119	0
<i>Sub-total: non-Parties</i>	<i>1 (0%)</i>	<i>75 (35%)</i>	<i>140 (65%)</i>	<i>216</i>	<i>54 (25%)</i>
<b>Total</b>	<b>130 (18%)</b>	<b>396 (56%)</b>	<b>179 (25%)</b>	<b>705 (100%)</b>	<b>320 (45%)</b>

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