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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
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Item 6.2 of the provisional agenda *

INFORMATION-SHARING AND THE BIOSAFETY CLEARING-HOUSE (ARTICLE 20)

Note by the Executive Secretary

I. INTRODUCTION

1. The Biosafety Clearing-House (BCH) was established in accordance with Article 20, paragraph 1, of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to (i) facilitate the exchange of information on, and experience with, living modified organisms, and (ii) to assist Parties to implement the Protocol.

2. The present note was prepared by the Executive Secretary and includes a short introduction to the development of the Biosafety Clearing-House (Section I); a status report of the progress in the implementation of the Biosafety Clearing-House (Section II); a synthesis of views on the transition between the pilot phase and the fully operational Biosafety Clearing-House (Section III); an update on activities undertaken to identify and address the capacity needs of countries to access and use the Biosafety Clearing-House (Section IV); and a draft decision with regard to the modalities of the operation of the Biosafety Clearing-House, including reports on its activities, in accordance with paragraph 4 of Article 20 of the Protocol (Section V).

3. Since the Biosafety Protocol entered into force on 11 September 2003, Parties to the Protocol are obliged to fulfil their obligations pursuant to the Protocol's provisions. The Biosafety Clearing-House is one of the key mechanisms that will be used by Parties to implement the provisions of the Protocol.

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

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4. The role of the Biosafety Clearing-House in the provision and exchange of information in support of implementation of the Protocol, is clearly articulated in the Protocol. At a minimum, the Biosafety Clearing-House has a role in providing access to information relating to:

(a) Existing national legislation, regulations and guidelines for implementing the Protocol, as well as information required by Parties for the advance informed agreement procedure (Article 20 paragraph 3 (a));

(b) National laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11 paragraph 5);

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

(d) Contact details for competent national authorities (Articles 19.2 and 19.3), national focal points (Articles 19 paragraph 1 and 19 paragraph 3), and emergency contacts (Article 17 paragraph 3 (e));

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

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

(g) Occurrence of unintentional transboundary movements that are likely to have significant adverse effects on biological diversity (Article 17 paragraph 1);

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

(i) Final decisions regarding the importation or release of LMOs (i.e. approval or prohibition, any conditions, requests for further information, extensions granted, reasons for decision) (Articles 10 paragraph 3 and 20 paragraph 3(d));

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

(k) Final decisions regarding the domestic use of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing (Article 11 paragraph 1);

(l) Final decisions regarding the import of LMOs intended for direct use as food or feed, or for processing that are taken under domestic regulatory frameworks (Article 11 paragraph 4) or in accordance with annex III (Article 11 paragraph 6) (requirement of Article 20 paragraph 3(d));

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

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

(o) LMOs granted exemption status by each Party (Article 13 paragraph 1);

(p) Cases where intentional transboundary movement may take place at the same time as the movement is notified to the Party of import (Article 13 paragraph 1); and

(q) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (Article 20 paragraph 3 (c)).

5. In its decision EM-I/3, paragraph 13, the Conference of the Parties requested the Executive Secretary to commence preparatory work on the functioning of the Biosafety Clearing-House. Issues of relevance to the Biosafety Clearing-House were also included in the work plan for the Intergovernmental Committee for the Cartagena Protocol (ICCP) approved by the Conference of the Parties in decision V/1 whereby the ICCP was requested to consider the following issues regarding information-sharing:

(a) Determination of needs of Parties;

(b) Overview of existing activities/systems and possibilities for cooperation;

(c) Design of data-input systems;

(d) Development of common formats for reporting, e.g., decisions, national legislations, points of contact, focal points, summaries of risk assessments, etc.;

(e) Development of operational systems, information-management policies and procedures for receiving and making information available, including quality-assurance procedures;

(f) Means to ensure confidentiality of information;

(g) Financial and technological resource requirements;

(h) Other issues (such as Article 5).

6. At its first meeting, ICCP considered these issues and made recommendations regarding the development of the Biosafety Clearing-House. 1/ ICCP recommended that the Biosafety Clearing-House be administered by the Secretariat on a pilot phase basis. The two objectives for the pilot phase, identified at the first meeting of ICCP, were: (i) to build experience and provide feedback for the development of a functional and accessible Internet based Biosafety Clearing-House, and to identify alternatives to the electronic system; and, (ii) to identify and address the capacity needs of countries with respect to the Biosafety Clearing-House. At its first meeting, ICCP also requested the Executive Secretary to develop a work plan for completion of all tasks in a timeframe that would allow for relevant consideration by the second meeting of ICCP. At its second meeting, ICCP, noting the progress report on the development and implementation of the Biosafety Clearing-House, 2/ made recommendations for the further development of the pilot phase of the Biosafety Clearing-House. 3/ Similarly, at its third meeting, ICCP noted the progress on the development and implementation of the Biosafety Clearing-House in the inter-sessional period, 4/ and made recommendations for the continued development of the pilot phase of the Biosafety Clearing-House. 5/

7. ICCP mandated its Bureau to provide management oversight of the development and implementation of the pilot phase, and to draw upon appropriate technical advisory expertise to facilitate the development of the pilot phase of the Biosafety Clearing-House. Accordingly, the Bureau produced three notes on technical issues associated with the implementation of the pilot phase of the Biosafety

1/ UNEP/CBD/ICCP/1/9, annex I.

2/ UNEP/CBD/ICCP/2/9.

3/ UNEP/CBD/ICCP/2/15, recommendation 2/8 para.1.

4/ UNEP/CBD/ICCP/3/5.

5/ UNEP/CBD/ICCP/3/10, recommendation 3/3.

Clearing-House, which were incorporated into the recommendations of each ICCP meeting, and the pilot phase was developed and implemented by the Secretariat in line with these recommendations. The three notes from the Bureau are compiled in an information document (UNEP/CBD/BS/COP-MOP/1/INF/13).

8. In addition to direct management oversight from the Bureau, the development of the pilot phase of the Biosafety Clearing-House has benefited from the inputs of several meetings of Liaison Groups and technical expert groups, in response to decision V/1 (paragraph 3) of the Conference of the Parties and the recommendations of ICCP (UNEP/CBD/ICCP/1/9, annex I). Specifically, a technical expert meeting was held in September 2000, and Liaison Group meetings were convened by the Executive Secretary in March 2001, September 2001, April 2002, and April 2003. These meetings provided advice on technical issues associated with the implementation of the pilot phase of the Biosafety Clearing-House. Reports of the meetings are available at http://www.biodiv.org/doc/default.aspx.

9. It should also be noted that at the request of the ICCP, the Executive Secretary commissioned an independent review of the pilot phase of the Biosafety Clearing-House, using feedback from participating countries and indicators to measure success against the objectives of the pilot phase. The results of this review were considered at the third meeting of the ICCP, and the ICCP recommendations for further development of the Biosafety Clearing-House took into account the strengths and weaknesses that were identified in conducting the independent review.

10. The pilot phase of the Biosafety Clearing-House was launched on 5 April 2001. Version 2.0 of the website was released on 1 February 2003. The Biosafety Clearing-House website is available online at http://bch.biodiv.org. Discussion of the transition from the pilot phase to the fully operational and functional Biosafety Clearing-House is found in section III below.

11. The ICCP, at its third meeting, urged Governments to submit their views on the transition between the pilot phase and the fully operational and functional Biosafety Clearing-House. As of 22 October 2003, the Executive Secretary had received submissions on the operation of the Biosafety Clearing-House from: Australia, the European Union, Paraguay, Switzerland and the United States of America. The International Centre for Genetic Engineering and Biotechnology (ICGEB), the Organisation for Economic Co-operation and Development (OECD) and WWF International also provided submissions. The submissions are compiled in an information document on information sharing and the Biosafety Clearing-House (article 20, para.4), (UNEP/CBD/BS/COP-MOP/1/INF/1).

12. The ICCP, also at its third meeting, recommended that the OECD report to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol on interoperability between the OECD product database, including on the use of the OECD unique identifiers for transgenic plants. This report has been made available as part of the compilation of views (UNEP/CBD/BS/COP-MOP/1/INF/1).

13. The ICCP, also at its third meeting, requested the Executive Secretary to invite relevant national and international organizations to provide views on the development of unique identification systems for classes of LMOs and their harmonization. The OECD submission noted in the previous paragraph was the only submission received in this regard. Further discussion of unique identification is taken up in the note by the Executive Secretary on handling transport, packaging and identification of living modified organisms (UNEP/CBD/BS/COP-MOP/1/7). In accordance with paragraph 4 of Article 20 of the Protocol, 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 at its first meeting, and kept under review thereafter.

II. PROGRESS REPORT ON THE DEVELOPMENT AND IMPLEMENTATION OF THE PILOT PHASE OF THE BIOSAFETY CLEARING-HOUSE

14. The Secretariat has endeavoured to implement the pilot phase of the Biosafety Clearing-House according to the recommendations made by the Intergovernmental Committee and under the close guidance of its Bureau. During its first meeting, ICCP recommended that the pilot phase have the following characteristics:

(a) Must be amenable to rapid development;

(b) Must be user-friendly, searchable, and understandable;

(c) Provide an efficient mechanism for implementation of the requirements of the Protocol;

(d) Incorporate on a priority basis:

(i) Information to facilitate decision-making, including that required under the Advance Informed Agreement procedure: information on focal points, national competent authorities, national legislation, decisions and risk assessment reports;

(ii) Information for Article 11, paragraph 1, on living modified organisms intended for direct use as food or feed, or for processing (LMO-FFPs)

(iii) Access to the roster of experts, following final decision on the operation of the roster.

15. Further, ICCP-1 recommended that the following elements were required to implement the pilot phase of the Biosafety Clearing-House:

(a) A central portal;

(b) Central database(s) that contain(s) at a minimum:

(i) Information from countries without a national database (e.g. information in accordance with Article 20, paragraph 3 (a), of the Protocol);

(ii) Information sent from countries without an electronic infrastructure (e.g. information in accordance with Article 10, paragraph 3, and Article 20, paragraphs (c) and (d) of the Protocol);

(iii) Information required to implement Article 11, paragraph 1;

(iv) Searchable indexes of information to facilitate decision-making, including that required under the Advance Informed Agreement procedure;

(c) Linkage of central portal to national, regional and international databases/nodes;

(d) Common formats for information, which can incorporate linked information through appropriate search engines.

16. The following paragraphs review the progress and current status of implementation of the key elements identified by ICCP for the development of the pilot phase.

A. Central portal and central databases

17. The pilot phase of the Biosafety Clearing-House has been designed to consist of: a central portal, with linkages to a distributed network of national, regional and international nodes/databases. The central portal underpins all activities on the Biosafety Clearing-House, including finding information in, and registering records with, the Biosafety Clearing-House databases. The central portal functions essentially as an interactive site map to assist in the use and navigation of the Biosafety Clearing-House website.

18. Furthermore, the pilot phase of the Biosafety Clearing-House contains an information management centre, which is used to register information with the Biosafety Clearing-House central database. The management centre is an electronic, web-based mechanism by which national focal points for the Biosafety Clearing-House can manage all information relating to their country. National focal points are provided with an account and password to enable them to add, modify and/or delete records. National focal points may delegate responsibility for entering data to other authorized personnel, but remain responsible for validating each record for their government before it can be made publicly available through the website of the Biosafety Clearing-House. Users without access to the Internet may also submit information directly to the Secretariat for inclusion in the central database.

B. Linkage of central portal to national, regional and international databases/nodes

19. The operational framework of the pilot phase of the Biosafety Clearing-House has been developed as a decentralized system for information gathering and retrieval. In this way, updating the information in the Biosafety Clearing-House is not the sole responsibility of the Secretariat or any one institution. It is a decentralized activity, undertaken by active partners in the Biosafety Clearing-House network, and supervised by a network of national focal points.

20. The pilot phase is also designed to be interoperable with other databases, so it offers Governments the option of registering information with the central Biosafety Clearing-House database, or with another (interoperable) database of their choice. The location of the information makes no difference to the user, who is able to retrieve all information through the central portal of the Biosafety Clearing-House.

21. In addition, the Secretariat has developed guidelines for simple interoperability, which enables the Biosafety Clearing-House to search registered national website nodes for information, as well as national databases.

22. To date, a number of relevant national, regional and international databases have been identified and linked to the central portal of the Biosafety Clearing-House. Interoperability with international nodes such as the Organization for Economic Co-operation and Development (OECD), the United Nations Industrial Development Organisation (UNIDO) and the International Centre for Genetic Engineering and Biotechnology (ICGEB) has been implemented and is being further developed.

23. In September 2003, the Secretariat issued guidelines to Parties and other Governments on the options available related to national participation in the Biosafety Clearing-House (UNEP/CBD/BS/COP-MOP/1/INF/14). The intent of the guidelines is to assist Parties and other Governments in selecting one or more options to make national information required under the Protocol available through the central portal of the Biosafety Clearing-House, that are appropriate to their needs and capacities. The Biosafety Clearing-House is currently interoperable to varying degrees with biosafety databases maintained by a few governments.

C. Common formats for information

24. At its first meeting, the ICCP requested the Secretariat to develop common formats for information as an element of the pilot phase of the Biosafety Clearing-House. A number of common formats for reporting information through the Biosafety Clearing-House were then developed by the Secretariat. At its second meeting, the ICCP requested the Secretariat to revise the common formats to enhance user-friendliness. The formats have been developed and adapted on a continuing basis during the pilot-phase, incorporating feedback received from countries, the ICCP and its Bureau, and are available on the Biosafety Clearing-House (http://bch.biodiv.org/Pilot/Related/GettingStarted.aspx).

25. Where possible, the data structure for the common formats is modular in design (for example, the same set of fields is used to describe a living modified organism whether it appears in a decision reported under the advance informed agreement procedure, a decision under Article 11 paragraph 1, or in a risk assessment summary). Additionally, the information in many fields is described through the use of a "controlled vocabulary" (i.e. the information must be entered by selecting from a pre-defined list of terms). This vocabulary is then translated into the six official United Nations languages, using established international multilingual thesauri where possible, to facilitate the ability to search for records in all languages, regardless of the language in which the record was initially entered.

III. TRANSITION FROM THE PILOT PHASE TO THE FULLY OPERATIONAL AND FUNCTIONAL BIOSAFETY CLEARING-HOUSE

26. The pilot phase of the Biosafety Clearing-House, in its current form, provides the means for Parties to make information available as required by the provisions of the Protocol. It is expected, however, that refinement of the Biosafety Clearing-House will be a continuous process, and that Parties may wish to add additional functionality to the Biosafety Clearing-House over time.

27. It appears that Governments have been pleased with the progress of development of the pilot phase of the Biosafety Clearing-House, and generally consider that the central portal, in combination with a distributed network of interoperable databases, currently provides for a useful and reliable Internet-based system for efficient information exchange under the Biosafety Protocol (see UNEP/CBD/BS/COP-MOP/1/INF/1).

28. Several Governments have established their own national nodes for provision of information to the Biosafety Clearing-House, and/or have contributed information directly through the use of the management centre of the central portal. Items noted in the submissions as developments that could assist governments and organizations in making their information available through interoperable national nodes and local websites include:

(a) Clear delineation of the roles and responsibilities of the national focal point for the Biosafety Clearing-House;

(a) Use of common formats and controlled vocabularies to report information, that are flexible enough to reflect the various types of regulatory structures used in different countries;

(b) Development by the Secretariat of flexible standards and technical guidance for establishing interoperability; and

(c) Establishment of mechanisms to support the provision of technical guidance and a flow of information between the Secretariat, experts, and focal points for the Biosafety Clearing-House and partner organizations.

29. The use of the OECD's unique identifiers for transgenic plant lines as a key to access records in the Biosafety Clearing-House, as recommended by the ICCP at its third meeting, 6/ was welcomed.

30. The development of an "instant Biosafety Clearing-House" database template, including to the extent possible the development of self-standing templates for national web sites, was also noted as a useful initiative to facilitate storage and organization of data at national level and to assist in exporting these data to the central portal.

31. Although the implementation of the Biosafety Clearing-House must focus primarily on information requested under the Protocol, one submission noted that it should also serve as a means to provide access to more general scientific information about biosafety.

32. A number of the submissions on the transition between the pilot phase and the fully operational and functional Biosafety Clearing-House stressed that Governments and organizations should continue to contribute information to the Biosafety Clearing-House during the time between entry into force of the Protocol and the first meeting of the Parties, in order to continue to build sufficient national experience.

33. Additionally, several of the submissions stressed the importance of meeting capacity needs of countries to access and use the Biosafety Clearing-House. Specific suggestions included ensuring that the Central Portal is designed to facilitate online access for Governments with poor Internet connectivity; making the website easy to navigate and to read; and making the Central Portal fully available in all official United Nations languages. Additional information on identifying and addressing the capacity needs of countries to access and use the Biosafety Clearing-House is provided in section IV below.

IV. IDENTIFYING AND ADDRESSING THE CAPACITY NEEDS OF COUNTRIES TO ACCESS AND USE THE BIOSAFETY CLEARING-HOUSE

34. In the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety (see document UNEP/CBD/BS/COP-MOP/1/6) , the ICCP identified information exchange and data management, including full participation in the Biosafety Clearing-House as a key element requiring concrete action.

35. Recognizing the need for capacity-building related to the Biosafety Clearing-House, and in accordance with the request from the ICCP at its first meeting, the Secretariat is, on a continuing basis, analysing the identified capacity-building and financial requirements of the developing countries, 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, to enable their active participation in the pilot phase of the Biosafety Clearing-House.

36. To this end, a series of regional workshops on the Biosafety Clearing-House was held between February 2001 and March 2002 in order to provide countries with the opportunity to express their needs and expectations with regard to the establishment of the pilot phase. Financial support for these meetings was provided by the Governments of the United States of America, the United Kingdom of Great Britain and Northern Ireland, and Japan. Following the completion of this round of regional meetings, the ICCP considered a synthesis of capacity-building needs identified by the regions, with a view to considering the possibility of establishing a capacity-building programme addressing those needs. Further information on capacity-building needs, and on the proposed Coordination Mechanism for the Implementation of the Action Plan on Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety, is available in the notes from the Executive Secretary on

6/ UNEP/CBD/ICCP/3/10, recommendation 3/3, paragraph 2.

Capacity-building (UNEP/CBD/BS/COP-MOP/1/6) and on operationalization of the roster of experts on biosafety (UNEP/CBD/BS/COP-MOP/1/6/Add.2).

37. With the kind assistance of funds provided by the Government of the United States of America, the Secretariat has developed a tool-kit to illustrate and simulate the pilot phase of the Biosafety Clearing-House, to facilitate learning of the Biosafety Clearing-House information-sharing tools. The tool-kit also includes the interoperability standards and guidelines for the pilot-phase database. (The toolkit is available online at http://bch.biodiv.org/Toolkit_homepage/home.html).

38. The Secretariat has also developed and distributed two prototype CD-ROM versions of the pilot phase that can be used for training purposes.

39. Some countries, especially the least developed and small island developing States, have emphasized the need for the continued development of non-Internet-based mechanisms to access the Biosafety Clearing-House. Unreliable telecommunications systems and high cost of access to the Internet have been cited as being of particular concern for these countries. Alternative methods of access, including the use of fax and telephone, and the provision of CD-ROMs and hard copies of documents, have been made available by the Secretariat to enhance equitable participation in the Biosafety Clearing-House.

40. In collaboration with UNEP, the Secretariat has assisted in the development of a proposal on Building Capacity for Effective Participation in the Biosafety Clearing-House of the Cartagena Protocol, which has been submitted to the Global Environment Facility (GEF) as an add-on project to the current GEF project on development of national biosafety frameworks. The project aims to enable developing country Parties to the Protocol to participate fully in the Biosafety Clearing-House, through the strengthening of core human resources and the establishment of appropriate infrastructure. The project will be considered at the GEF Council meeting in November 2003.

V. DRAFT DECISION ON THE MODALITIES OF OPERATION OF THE BIOSAFETY CLEARING-HOUSE

41. The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol may wish to adopt a decision along the following lines:

The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol,

Having examined the note by the Executive Secretary, (UNEP/CBD/BS/COP-MOP/1/5), reviewing the progress in the development and implementation of the pilot phase of the Biosafety Clearing-House;

Taking note of the recommendations made by the ICCP on the development of the pilot phase of the Biosafety Clearing-House;

Taking note that the progress made and experience gained during the implementation of the pilot phase has produced valuable insights as to the future development of the Biosafety Clearing-House;

1. *Adopts* the modalities of operation of the Biosafety Clearing-House that are contained in the annex to this decision;

2. *Welcomes* the participation in the pilot phase of governments and international organizations that have provided information to the Biosafety Clearing-House, either directly through the

Management Centre of the Central Portal, or through the development of nodes that are interoperable with the Central Portal of the Biosafety Clearing-House,

3. *Encourages* Parties, governments and other users to develop national, regional, sub-regional and institutional nodes that are interlinked with the Central Portal, in accordance with minimum standards for partnership that will be set for this purpose. It is suggested that these nodes and/or partnerships would focus initially on:

(a) Providing searchable access to information to facilitate decision-making, particularly that required under the Advance Informed Agreement procedure and information required to implement Article 11 on the procedure for living modified organisms intended for direct use as food or feed, or for processing.

(b) Providing searchable access to any other information required by the Protocol to be made available to Parties through the Biosafety Clearing-House as summarized in paragraph 4 of the note by the by the Executive Secretary on information sharing and the Biosafety Clearing-House (UNEP/CBD/BS/COP-MOP/1/5); and

(c) Facilitating access to and dissemination of scientific, technical, environmental and legal information on, and experience with, living modified organisms.

4. *Invites* relevant international, regional, subregional and national organizations and entities willing to offer their cooperation as active partners in the implementation of the Biosafety Clearing-House to communicate the details of their offer and *requests* the Executive Secretary of the Secretariat to enter into collaborative arrangements and to report to its second meeting on the results of such arrangements;

5. *Calls upon* each Party that has not yet done so to designate an appropriate national focal point for the Biosafety Clearing-House;

6. In this regard, *invites* 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;

7. *Requests* the Executive Secretary to continue analysing the identified capacity-building and financial requirements of developing countries Parties to the Protocol, in particular the least developed and small island developing States among them, and Parties with economies in transition, as well as Parties that are centres of origin and centres of genetic diversity, to enable their active participation in the Biosafety Clearing-House. This information will be provided to Governments, intergovernmental and non-governmental organizations with a role in capacity-building;

8. *Calls upon* the international community to make additional voluntary contributions to meet the capacity-building needs of countries with respect to the implementation of national components of the Biosafety Clearing-House;

9. *Decides* to review the implementation of the Biosafety Clearing-House at its second meeting serving as the meeting of the Parties to the Cartagena Protocol, and requests the Executive Secretary to submit a progress report to that meeting, with a view to developing a longer-term programme of work for the Biosafety Clearing-House.

Annex

MODALITIES OF OPERATION OF THE BIOSAFETY CLEARING-HOUSE

A. Characteristics of the Biosafety Clearing-House

1. The Biosafety Clearing-House shall be developed in a manner consistent with the following characteristics:

(a) Guided by the principles of inclusiveness, transparency and equity, and open to all Governments;

(b) Making use of a central portal to assist in the use and navigation of the Biosafety Clearing-House website;

(c) Containing a central database for making information available through the Biosafety Clearing-House, that stores, at a minimum, information from countries without a national database, as well as incorporating information provided by interoperable information-exchange systems;

(d) Providing access to information to assist countries in capacity-building for implementation of the Protocol, as well as providing support to the Coordination Mechanism for the Action Plan for Building Capacities for the Effective Implementation of the Protocol (which includes databases on capacity-building activities; identified national needs and priorities), should it be established by the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety;

(e) Providing access to the roster of experts on biosafety established by decision EM-I/3, paragraph 14, of the Convention of the Parties;

(f) As a decentralized mechanism where appropriate, making use of the Internet as a delivery mechanism, as well as other mechanisms to ensure the participation of Parties without Internet access;

(g) Making use of common formats to report information, such as decision information, laws and regulations, and national contact details, using a modular data structure where possible;

(h) Making use, where appropriate, of a controlled vocabulary to describe records, which can be translated into the official United Nations languages, to facilitate the ability to search for records in all languages;

(i) Making use of metadata about each record (i.e., descriptive identifiers such as name, date, author, etc.), to facilitate the submissions, searching, location and retrieval of information;

(j) Making use of existing unique identification systems for living modified organisms, as appropriate, to facilitate searching and retrieval of information;

(k) Facilitating navigation of the central portal website in all official United Nations languages;

(l) Requiring that all information be submitted to the Biosafety Clearing-House in an official language of the United Nations, while recognizing that full information sources and documents that are linked to records from the Biosafety Clearing-House may be available only in a language of the submitting Government and not in an official language of the United Nations;

(m) Encouraging Parties and other Governments to also provide courtesy translations of information in the Biosafety Clearing-House into one or more languages that are commonly used internationally, in order to minimize the burden of translation;

(n) Not including confidential data as such information shall be exchanged on a bilateral basis;

(o) Building up its functions and activities in response to clear and identified demand, and based on further experience and available resources;

(p) In close cooperation with relevant international organizations to maximize use of existing experience and expertise; and

(q) Enhancing networking between national, regional, sub-regional and international centres with relevant expertise, as well as non-governmental organizations and the private sector, to maximize use of existing experience and to minimize any duplication of work.

B. Administration of the Biosafety Clearing-House

2. The Secretariat of the Convention shall administer the central portal of the Biosafety Clearing-House. These functions will include:

(a) Developing and maintaining the central portal and central databases to ensure the Biosafety Clearing-House is accessible, user-friendly, searchable, and understandable;

(b) Identifying, reviewing and establishing, as necessary, common formats for reporting information to the Biosafety Clearing-House;

(c) Providing hard copies of information available through the Biosafety Clearing-House, as and when requested by Parties;

(d) Assisting governments, on request, in the use of the Biosafety Clearing-House central portal, and coordinating the development of national, regional, subregional and institutional nodes that are interlinked with the central portal;

(e) Entering into administrative arrangements with relevant international, regional, sub-regional and national organizations and entities, as appropriate; and

(f) Performing such other administrative functions as are directed by the Conference of the Parties serving as the meeting of the Parties to the Protocol in other decisions.

C. Role of the Biosafety Clearing-House focal points

3. 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, 7/ 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 layout 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.

D. Technical oversight and advice

4. The Secretariat may seek assistance from an informal advisory committee, constituted and coordinated by the Executive Secretary in a transparent manner, with a particular focus on providing guidance with respect to resolution of technical issues associated with the ongoing development of the Biosafety Clearing-House.

E. Obligations of partner organizations

5. Relevant international, regional, sub-regional and national organizations and entities willing to offer their cooperation as active partners in the operation of the Biosafety Clearing-House shall follow specific interoperability guidelines for information-sharing, to be prepared by the Secretariat for this purpose. Where partner institutions are hosting information that is required by the Protocol to be made available to the Biosafety Clearing-House, the following minimum standards will apply:

(a) Nomination of an institutional focal point in the partner organization, responsible for liaison with the Secretariat;

(b) Written confirmation by the relevant Party or government that responsibility for provision of this information has been conveyed to the institution in question;

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

(d) If these standards cannot be maintained, or if a partner does not wish to continue to provide information to the Biosafety Clearing-House, all data or information subject to this partnership shall be transferred to the central databases maintained by the Secretariat.

F. Reports on activities

6. Once a year, the Quarterly Report prepared by the Secretariat shall include information on the operation of the Biosafety Clearing-House, including information such as the number of and regional distribution of national focal points; the number of records available through the Biosafety Clearing-House; and partnership arrangements that have been entered into. These reports shall also be made available through the Biosafety Clearing-House itself.

7/ For a list of the information required, see paragraph 3 of document UNEP/CBD/COP-MOP/1/5.

7. In addition, Parties and other users of the Biosafety Clearing-House are encouraged to provide the Secretariat with feedback on their experiences with its operation. Such feedback shall be made available to the Conference of the Parties serving as the meeting of the Parties, and may serve as a basis for further development of the Biosafety Clearing-House.

G. Periodic review

8. The implementation and operation of the Biosafety Clearing-House shall be subject to periodic review, which should aim to include consultation with a wide variety of countries and participating organizations. The first review should be undertaken by the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol, with a view to developing a longer-term programme of work. Periodic reviews should then take place in accordance with Article 35 of the Protocol.
