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MEETING OF TECHNICAL EXPERTS ON
THE BIOSAFETY CLEARING-HOUSE
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Item 3.1 of the provisional agenda*

# ESTABLISHMENT OF THE BIOSAFETY CLEARING-HOUSE

*Note by the Executive Secretary*

*Contents*



## I. INTRODUCTION

1. The purpose of the present note is to assist the Meeting of Technical Experts in its consideration of the item in the work plan of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) on information-sharing regarding determination of needs of Parties with respect to establishing the Biosafety Clearing-House. It provides an overview of the role of the Biosafety Clearing-House in implementing the information-exchange requirements under the Protocol, an analysis of the interactions between the Biosafety Clearing-House and the clearing-house mechanism of the Convention on Biological Diversity, and a discussion of the special needs of developing countries and countries with economies in transition.

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### A. *The Cartagena Protocol on Biosafety*

2. The Cartagena Protocol on Biosafety ("the Protocol"), adopted by the Conference of the Parties to the Convention on Biological Diversity on 29 January 2000, seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology, and focuses specifically on transboundary movements. It establishes a procedure ("advance informed agreement" or AIA) for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The Protocol also establishes a Biosafety Clearing-House to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol.

### B. *Role of the Biosafety Clearing-House*

3. According to Article 20, paragraph 1, of the Protocol, the Biosafety Clearing-House has two main objectives, namely:

(a) To facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms (LMOs); and

(b) To 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.

4. The Biosafety Clearing-House will serve as a means through which information is made available to achieve these objectives. In accordance with Article 20, paragraph 2, of the Protocol, it will provide access to information made available by the Parties relevant to the implementation of the Protocol and will also provide access, where possible, to other international biosafety information exchange mechanisms.

5. Through their national focal points, and/or their competent national authorities to be designated pursuant to Article 19, paragraphs 1 and 2, of the Protocol, Parties are expected to provide, update and process the information required under the Protocol, and this will be the primary task of the information-exchange system. All levels of government, the private sector, non-government organizations and the general public will also be important users of the system, and it is expected that they will use the Biosafety Clearing-House to retrieve information for inquiry, analysis and decision-making purposes.

6. In addition, in accordance with Article 24, paragraph 2, of the Protocol, non-Parties are to be encouraged to contribute information to the Biosafety Clearing-House on LMOs released, or moved into or out of, areas within their national jurisdiction.

## II. OPERATION OF THE BIOSAFETY CLEARING-HOUSE OF THE PROTOCOL UNDER THE CLEARING-HOUSE MECHANISM OF THE CONVENTION

### A. *The clearing-house mechanism of the Convention*

7. According to Article 20, paragraph 1, of the Protocol, the Biosafety Clearing-House was established as part of the clearing-house mechanism (CHM) under Article 18, paragraph 3, of the Convention on Biological Diversity ("Technical and scientific cooperation"). The clearing-house mechanism of the Convention was established to promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.

8. The clearing-house mechanism is conceived of as a global network of Parties and partners working together to facilitate implementation of the Convention. The priorities and work programme of the clearing-house mechanism are decided by the Conference of the Parties, on the basis of the advice of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA).

9. According to the strategic plan endorsed by the Conference of the Parties at its fifth meeting, in May 2000, the three objectives of the clearing-house mechanism are:

(a) *Cooperation*: the promotion and facilitation of scientific and technical cooperation within and between countries;

(b) *Information exchange*: the development of a global mechanism for exchanging and integrating information on biodiversity within and between countries; and

(c) *Network development:* the development of the clearing-house mechanism focal points and their partners.

10. Guidance from the Conference of the Parties has emphasized that the key characteristics of the clearing-house mechanism are that it should be compatible with national capacities, needs-driven and decentralized in nature, provide access to metadata, provide support to the decision-making process, and to the extent possible involve the private sector.

11. The process of gathering and organizing the information that feeds into the clearing-house mechanism network is in itself decentralized, with national focal points coordinating efforts among themselves. The contribution of each partner is included in the information system of the clearing-house mechanism and is made available to all users by enhancing networking between existing national, regional, subregional and international focal points and centres of relevant expertise, as well as governmental and non-governmental institutions and the private sector. The role of the clearing-house mechanism is that of a facilitator, ensuring the dissemination of experience and knowledge among all partners, so that the system as a whole learns from that shared experience.

12. A more detailed summary of the operation of the clearing-house mechanism is provided in the information note on the subject prepared by the Executive Secretary for the Meeting of Technical Experts (UNEP/CBD/BS/TE-BCH/1/INF/4).

### B. *Interactions between the Biosafety Clearing-House and the clearing-house mechanism of the Convention*

13. There is a high degree of complementarity between the purposes and mandates of the Biosafety Clearing House and the clearing-house mechanism. Although the clearing-house mechanism is envisaged as a cooperative network that will come to include all Parties, and the Conference of the Parties has encouraged all Parties and other potential partners to play a full role in its development, two factors should be considered:

(a) The clearing-house mechanism is not yet a universal and symmetrical network of partners, notwithstanding the increasing number of Parties that have designated focal points or who have established clearing-house mechanism websites. As discussed in the above-mentioned information note by the Executive Secretary, there are a number of key issues to be resolved before this ideal state is reached;

(b) The fact that some Parties have incipient or non-existent clearing-house mechanism structures does not *a priori* impede the ability of other Parties to proceed with national implementation of the Convention. However, the nature of the Protocol and the objectives of the Biosafety Clearing-House imply a relationship of mutual dependence between Parties of import and Parties of export in respect of the data to be processed by the Biosafety Clearing-House. If the necessary information is not available

via the Biosafety Clearing-House the purposes of the Protocol are likely to be defeated. This raises issues that have not yet had to be addressed by the clearing-house mechanism.

14. An additional consideration is related to different processes of developing the two clearing-houses. At its second meeting, the Conference of the Parties determined that the clearing-house mechanism should be developed by gradually building up its functions in response to clear and identified demand based on experience gained and resources available (decision II/3, paragraph 4 (c)).

15. In contrast, the Biosafety Clearing-House needs to operate a minimum set of key functions from the outset in order to allow countries to meet their legally binding commitments to provide certain categories of information immediately upon the entry into force for them of the Protocol and to permit Parties to make the informed decisions about the import of LMOs, a matter that is at the heart of the Protocol.

### C. *Implications*

16. Many of the categories of data to be processed by the Biosafety Clearing-House are similar in nature to the categories of data Parties are expected to provide through the clearing-house mechanism in accordance with decisions of the Conference of the Parties. The differences lie in the nature of the obligation and the implications of non-performance.

17. Experience gained through the pilot phase of the clearing-house mechanism suggests that the development of a universal and symmetrical decentralized global network requires substantial investments of time, financial resources and capacity development. Where possible, the Biosafety Clearing-House should use existing publicly available information, such as that posted on national websites (e.g., national legislation and summaries of risk assessments). However, at least in the early stages, it is probable that only a restricted range of Parties will have such data already available in a useable format (e.g., accessible via the Internet). It is therefore likely that the resources and effort expended by the Secretariat on collecting and posting data will be proportionally greater than is currently the case with the clearing-house mechanism.

18. As elaborated further in the note by the Executive Secretary on the operation of the Biosafety Clearing-House (UNEP/CBD/BS/TE-BCH/1/3), the question of whether to maintain a decentralized global network or instead to centralize some of the functions of the Biosafety Clearing-House will also have to be addressed.

## III. INFORMATION-EXCHANGE REQUIREMENTS AND THE ROLE OF THE BIOSAFETY CLEARING-HOUSE IN IMPLEMENTING THE PROTOCOL

### A. *Facilitating information exchange*

19. In order to achieve the first objective for the Biosafety Clearing-House under Article 20 of the Protocol (namely, facilitating the exchange of information on biosafety), the Biosafety Clearing-House will need to receive, process, and/or provide access to a number of types of information. Article 20, paragraph 3, of the Protocol specifically requests each Party to make available the following types of information to the Biosafety Clearing-House:

(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of LMOs generated by its regulatory process, and carried out in accordance with Article 15 ("Risk assessment"), including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of LMOs; and

(e) Reports submitted by it pursuant to Article 33 ("Monitoring and reporting"), including those on implementation of the advance informed agreement procedure.

20. It is possible that the Biosafety Clearing-House will also need to provide access to other types of information of relevance for the implementation of the Protocol, such as:

(a) International laws regarding the sovereignty of States over their territorial sea, and the sovereign rights and the jurisdiction that States have in their exclusive economic zones and their continental shelves, and international laws and instruments that provide navigational rights and freedoms for ships and aircraft of all States (Article 2, paragraph 3);

(b) Available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health (Article 2, paragraph 5); and

(c) LMOs that are pharmaceuticals for humans that are addressed by other international organizations or agreements (Article 5).

B. *Summary of data to be processed by the Biosafety Clearing-House*

21. As its central operative mechanism, the Protocol sets out an advance informed agreement (AIA) procedure, applicable prior to the first intentional transboundary movement of LMOs for intentional introduction into the environment. In brief, the basic AIA requirement of the Protocol gives importing Parties the right to receive from the exporter information on any LMO intended for introduction to the environment, prior to first import, and to approve, prohibit or restrict imports of that LMO. The decision of the Party of import must be communicated to the Biosafety Clearing-House.

22. The Protocol also contains specific exemptions for a number of categories of transboundary movement of LMOs, to which the AIA procedure does not apply. These include LMOs that are pharmaceuticals for humans that are addressed by other relevant international agreements or organizations (Article 5), LMOs in transit and destined for contained use (Article 6), LMOs identified by a decision of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity (Article 7) and living modified organisms for direct use for food, feed or processing (LMO-FFPs) (Article 11).

23. LMO-FFPs are subject to a modified form of the AIA procedure where, rather than setting out detailed notification and consent procedures for this category, the Protocol requires Parties to give notice through the Biosafety Clearing-House, of final decisions regarding domestic use of LMO-FFPs. Parties are also required to make available through the Biosafety Clearing-House copies of relevant national laws and regulations applicable to the import of LMOs falling into this category.

24. A summary of data to be processed by the Biosafety Clearing-House is elaborated below, with reference to the relevant Article of the Protocol. The technical considerations for exchange of this information will be addressed under item 3.2 of the provisional agenda (Operation of the Biosafety Clearing-House).*

* See the note by the Executive Secretary prepared under this item (UNEP/CBD/BS/TE-BCH/1/3).

25. Information relating to *actions taken by Parties* will include:

(a) National legislation, regulations and guidelines for implementing the Protocol (Article 20) and laws, regulations and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (Article 11);

(b) A register of domestic legislation applying to imports of LMOs (Article 11, Article 14);

(c) Bilateral, multilateral and regional agreements and arrangements (Article 14);

(d) Information regarding means of public access to the Biosafety Clearing-House (Article 23).

26. Information relating to the *operation of the Protocol* will include:

(a) Information provided to the Secretariat to be disseminated to all Parties (Article 20);

(b) Contact details for competent national authorities, national focal points, and emergency contacts (Article 17, Article 19);

(c) Reports submitted by the Parties on the operation of the Protocol (Article 33);

(d) Decisions by a Party on regulating the transit of specific LMOs (Article 6, paragraph 1);

(e) Information on unintentional transboundary movements and points of contact (Article 17);

(f) Information on illegal transboundary movements (Article 25);

(g) A register of Parties without access to the Biosafety Clearing-House (Article 11).

27. Information relating to the operation of the *AIA and LMO-FFP procedures* (Articles 7-13) will include:

(a) A register of LMOs identified by a decision of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 7, paragraph 4)

(b) 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) (Article 10);

(c) Information relating to the operation of the procedure for LMO-FFPs (Article 11);

(d) Reviewed decisions and relevant information if required (Article 12);

(e) Registers of organisms granted exemption status by each Party (Article 13);

(f) Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and relevant information regarding products thereof (i.e. the information set out in Annex II and Annex III to the Protocol).

28. Information on operations that will facilitate the *exchange of information* on, and experience with, LMOs that may be of use in capacity-building (Article 22), such as:

(a) Access to the roster of experts on biosafety;

(b) Access to other international biosafety information exchange mechanisms; and

(c) Coordination of capacity-building projects on biotechnology and biosafety, initiated by governmental, non-governmental and international organizations and related to implementation of the Protocol.

C. *Assisting in the implementation of the Protocol*

29. In order to achieve the second objective under Article 20 (namely, that of assisting Parties to implement the Protocol), the Biosafety Clearing-House will provide improved and integrated access to information sources that already exist, and promote the exchange of information, knowledge, experience and best practices.

30. The Biosafety Clearing-House may be able to provide a forum for the exchange of views and information on biosafety by countries, the scientific community, relevant non-governmental and intergovernmental organizations and the private sector. This would allow direct feedback from the users regarding their needs and views, and would aid in identifying needs of Parties and other users, and also in developing and promoting opportunities for collaboration in this area.

31. The Biosafety Clearing-House also has a role in enhancing international cooperation and communication on scientific research, legislation, and training in the field of biosafety. In addition to providing a forum for discussion of these issues, the Biosafety Clearing-House will also provide access to a roster of experts in biosafety. When it adopted the Protocol, the Conference of the Parties also decided, by paragraph 15 of its decision EM-I/3, to establish a regionally balanced roster of experts in the field of biosafety. Experts are to be nominated by Governments, in fields relevant to risk assessment and risk management related to the Protocol, to provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of living modified organisms. The role of the roster of experts will be developed further at the first meeting of the ICCP.

32. In addition, the global electronic platform for scientific and technical cooperation under the clearing-house mechanism, referred to in annex II, item (j) of decision V/14 of the Conference of the Parties, is currently at an early stage of development, but will in future offer opportunities for facilitating the transfer of technology and knowledge to assist Parties in the implementation of the Protocol.

33. At present, information being gathered for inclusion in the Biosafety Clearing-House includes:

(a) The name and coordinates of each Government's focal point(s) for the ICCP

(b) Information on existing programmes in each country for regulating living modified organisms, and possibilities of providing related technical assistance, including training, to interested Parties and States; and

(c) Names and coordinates of national experts in fields relevant to risk assessment and risk management related to the Protocol who could be included in the roster of experts.

## IV. SPECIAL NEEDS OF DEVELOPING COUNTRY PARTIES AND COUNTRIES WITH ECONOMIES IN TRANSITION

34. The use of electronic media and tools is increasingly playing an increasingly important role in communications between Governments, authorities and the public. It is clear that the electronic transfer of data, information and documents can dramatically increase the capacity to handle and process information of both the users and suppliers of that information, and increasing amounts of information are stored and transferred electronically. Information on biosafety issues is no exception, and there are currently a large number of very useful online information resources freely accessible through the Internet that address topical concerns and information needs relating to the LMOs into the environment. While the lack of access to personal computers and reliable telecommunications networks is still an obstacle to Internet-based information-exchange, the emergence of wireless application technologies and third-

generation mobile telephony may significantly broaden the possibilities of accessing data posed online via cellular phones.

35. Nevertheless, the success of information transfer depends entirely on the ability of the system to deliver the information where it is needed and in a form that can be used by those requiring the information. Article 20, paragraph 1 (b), of the Protocol places special emphasis on 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.

### A. *Telecommunications infrastructure and Internet access*

36. It is readily apparent that there is a huge disparity in resources and telecommunication infrastructures between countries and, although the Internet is widely used in some regions, it is not a viable medium for information-exchange in all areas. Effective use of Internet-based resources requires a relatively good telecommunications infrastructure, and the cost of access tends to be inversely proportional to the per capita income of the population, remaining prohibitively expensive in some parts of the world. Capacity building for information exchange is a key necessity in these areas.

37. In addition to the hardware and access issues, it is unlikely in early stages that all developing country Parties and countries with economies in transition will be able to make information available in electronic format. Setting up electronic databases requires systems design, standards, maintenance, publicity and training. The main problems likely to be faced in this regard are funding (for developing human resources) and gaining access to the required technology. Following the initial investment required for establishment of such a system, maintenance of a good information system will then require the training and support of technical people, administrators and users. There will also be a need to assess other local requirements, such as language translation.

38. The Biosafety Clearing-House needs to be accessible to all users whatever the state of technological development in their country. Therefore, along with the development of electronic data-exchange systems, equal efforts will need to be made with regard to traditional information-exchange mechanisms to both implement the Protocol, and to facilitate knowledge acquisition in the practical application of biosafety assessment and management. Efficient information exchange can be assured only with the establishment and maintenance of communication linkages, making data accessible and facilitating knowledge development.

### B. *Diverse means of access to information*

39. Firstly, there is a need to incorporate into the system non-Internet ways of accessing the Biosafety Clearing-House, such as postal distribution of printed material; diskettes or CD-ROMs containing the biosafety roster of experts and/or smaller electronic databases made into executable files; introduction of a quarterly Biosafety Clearing-House newsletter to publicize available information, etc. Information can also be made available electronically via Internet protocols other than Web technologies, such as FTP, e-mail and telnet.

40. However, there are a number of other approaches that could be explored with regard to supporting efficient information exchange, particularly with regard to enhancing access to information exchanged via electronic media. A selection of these approaches is discussed below.

### C. *Strengthening regional data networks*

41. The connective nature of databases through regional and subregional networks would help speed access to information and avoid unnecessary traffic on Internet. For example, the Asian Pacific

Advanced Network (APAN) has been established with headquarters in Singapore and a secretariat at the Singapore National University. In the past year or two, Japan, the Republic of Korea, Taiwan, Australia and Singapore have been connected through a fast Internet backbone. The Asian Pacific Bioinformatics Network has also been established with India as one of the nodes. Such regional data networks provide a reasonable speed of communication among scientists of this region.

### D. *Establishing or enhancing regional information networks*

42. The strengthening and/or development of adequate mechanisms for the supply and exchange of information is seen as an urgent need at both national and regional levels. Accordingly, the development of regional databases would enhance the exchange of information on approvals for releases of LMOs, biosafety experts, biosafety institutions and legislation, among others. These regional databases would help countries to share the financial burden of carrying out risk assessments and enable them to identify external sources of expertise while building up technical capacity as well as harmonizing biosafety efforts within the region.

43. An example of an existing regional network involves Cuba, Ecuador and Colombia. A national system for information exchange was established in Cuba at the instigation of UNEP, aimed at linking national databases and providing public access to information. An exchange network was then set up with Colombia and Ecuador and UNESCO has been requested to provide financial support for the expansion of this network. Other countries have expressed strong interest in forming such subregional networks, and future regional workshops could be held to plan new initiatives.

### E. *"Help desks" and other public online centres*

44. Other lower-cost solutions that may be implemented in those regions where public telecommunications networks and infrastructure are less well developed include regional help desks, and online centres such as administrative and public "information kiosks". Administrative kiosks would be likely to be located at national focal points and or competent national authorities and networked to in a way that enables authorities to share information and access to regional databases, discuss developments or incidents which require immediate action and take rapid decisions.

45. An example of this is the Telecottage Network established in Estonia, which was established in 1993 as a means to provide the public (particularly farmers) with information and consultation opportunities. The "telecottage" is usually little more than a simple room, located in either a shop, school, library, home or village centre. With access usually provided free of charge, the telecottages serve as the main focal point for public access to personal computers and the Internet and provide information on the state of the environment, news, policies and plans, etc., over computer networks, as well as providing a means for local councils to involve the public in decision-making processes.

46. Regional help desks could be established to guide new users of an electronic system, and also to act as a central information-processing and distribution facility for those without connection to the Internet. Regional meetings may be valuable in this regard, as they will enable experts to exchange experiences, to enhance the harmonization of efforts within the region and will also facilitate the implementation of other provisions of the Protocol.

### F. *Partnership arrangements*

47. Implementation of regional networks depends on collaboration — countries and partners working together, learning together, and sharing expertise, knowledge and experiences. Mechanisms are required to support this collaboration, such as a system to identify the needs of countries and partners working to implement the Protocol (including strategies to overcome the barriers that currently limit the participation of indigenous communities) and a system to identify resources available to meet those needs.

48. The development of the clearing-house mechanism of the Convention has benefited from collaborative arrangements, particularly relating to the "parenting or partnering role" of Parties, in which national focal points without connections to the World Wide Web are partnered with national focal points who have access to the Internet and additional space on their server for this kind of bilateral collaboration. Essentially, one Party "parents" on their website some general information for another Party. The kind and amount of information and its presentation is a matter of discussion between the two partners and normally this relationship extends until the "parented" country has established its own access to the Internet. Belgium, for example, currently hosts websites for the Democratic Republic of the Congo, the Niger, Mauritania, Chad and Burkina Faso.

49. It is worth noting that there are a number of different initiatives aimed at increasing international access to information exchanged through the use of electronic tools and media, such as programmes undertaken by the Telecommunication Development Sector of the International Telecommunication Union, whose aim is to facilitate and enhance telecommunication development worldwide by offering, organizing and coordinating technical cooperation and assistance activities; activities under other conventions, for example, under the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, and through INFOTERRA, the UNEP global environmental information exchange network. It is also possible that those industries seeking to export to countries with less developed economies will be prepared to contribute to building technological infrastructure within that country.

## V. POSSIBLE ISSUES FOR FURTHER DISCUSSION BY THE MEETING OF TECHNICAL EXPERTS

50. The Meeting of Technical Experts may wish to further discuss the following issues under this item:

(a) How the Biosafety Clearing-House and the clearing-house mechanism fit together conceptually, how their respective operations can be harmonized and synergies captured, and what specific elements of future Biosafety Clearing-House operations can be identified that are likely to require treatment in ways different from those recommended by the Conference of the Parties for the development of the clearing-house mechanism;

(b) Resource needs and their budgetary implications on the basis of realistic projections of the volume of data and tasks to be performed by the Biosafety Clearing-House;

(c) Implications of operating an electronic Internet-based Biosafety Clearing-House information-exchange system in conjunction with traditional information-exchange mechanisms;

(d) Opportunities for distribution of significant categories of data by non Internet-based means (and resource implications of any proposed mechanisms);

(e) Methods to address special needs of developing country Parties and countries with economies in transition;

(f) Liability implications for information provided in the context of the Biosafety Clearing-House.

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