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INTERGOVERNMENTAL COMMITTEE FOR THE
CARTAGENA PROTOCOL ON BIOSAFETY
First meeting
Montpellier, France, 11-15 December 2000
Item 4.1 of the provisional agenda*

INFORMATION-SHARING (ARTICLE 20, ARTICLE 19)

Outcome of the meeting of Technical Experts on the Biosafety Clearing-House

Note by the Executive Secretary

INTRODUCTION

1. In paragraph 13 of its decision EM-I/3, the Conference of the Parties to the Convention on Biological Diversity requested the Executive Secretary to commence preparatory work on the functioning of the Biosafety Clearing-House (BCH) referred to in Article 20 of the Protocol. At its fifth meeting, the Conference of the Parties requested the Executive Secretary to convene, prior to the first meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), the meeting of technical experts on the Biosafety Clearing-House referred to in decision EM-I/3 (decision V/1, para. 3).

2. In compliance with that request, the Meeting of Technical Experts on the Biosafety Clearing-House was held in Montreal at the seat of the Secretariat from 11 to 13 September 2000. Experts were drawn from a roster of Government-nominated experts qualified in the fields of management of biosafety-related issues, information-sharing systems and database management, establishment of clearing-houses and/or the clearing-house mechanism of the Convention on Biological Diversity. In addition to the Government-nominated experts, the following were also invited to participate in the meeting:

(a) The Chairman and members of the Bureau of the Intergovernmental Committee for the Cartagena Protocol on Biosafety;

(b) Representatives from the following intergovernmental organizations active in biosafety and/or information-exchange issues: Global Environment Facility (GEF), International Centre for Genetic Engineering and Biotechnology (ICGEB), European Commission Joint Research Centre, Organisation for Economic Co-operation and Development (OECD), Third World Academy of Sciences (TWAS), United Nations Industrial Development Organization (UNIDO), and United Nations Environment Programme (UNEP); and

* UNEP/CBD/ICCP/1/1.

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(c) Representatives of the Global Industry Coalition and the NGO community.

3. The Meeting considered issues relevant to information-sharing requirements and the Biosafety Clearing-House as reflected in the work plan of the ICCP endorsed by the Conference of the Parties to the Convention (decision V/1, annex). These included:

(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 resources requirements;

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

4. The report of the Meeting of Technical Experts, including its conclusions and recommendations, is attached as annex I to the present note. The report has already been distributed in English only under the symbol UNEP/CBD/BS/TE-BCH/1/5.

5. Also attached to the present note are the working documents prepared for the meeting, namely, the notes by the Executive Secretary on:

(a) Establishment of the Biosafety Clearing-House (see annex II);

(b) Operation of the Biosafety Clearing-House (see annex III); and

(c) Partnership opportunities (see annex IV).

These documents were originally circulated for the meeting, in English only, under the symbols UNEP/CBD/BS/TE-BCH/1/2, UNEP/CBD/BS/TE-BCH/1/3 and UNEP/CBD/BS/TE-BCH/1/4, respectively.

6. In paragraph 37 of the report, the Meeting of Technical Experts recommended that the Secretariat prepare an estimate of resources that would be required to establish the pilot phase of the Biosafety Clearing-House, taking into account the other recommendations of the Meeting, for consideration by the ICCP. This estimate, currently being prepared by the Executive Secretary, will be circulated as an addendum to the present note.

7. The ICCP may wish to consider the conclusions and recommendations of the Meeting of Technical Experts on the Biosafety Clearing-House, as they appear in paragraphs 17-39 of its report, and make recommendations for the launching of the Biosafety Clearing-House, taking into account the priority accorded to this activity by the Conference of the Parties at its first extraordinary meeting (decision EM-I/3, para. 13) and at its fifth meeting (decision V/1).

ANNEXES

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Annex I

REPORT OF THE MEETING OF TECHNICAL EXPERTS ON THE BIOSAFETY CLEARING-HOUSE*

Introduction

1. On 29 January 2000, the Conference of the Parties to the Convention on Biological Diversity adopted the Cartagena Protocol on Biosafety at its first extraordinary meeting. It also adopted decision EM-I/3, in paragraph 13 of which it requested the Executive Secretary to commence preparatory work on the functioning of the Biosafety Clearing-House referred to in Article 20 of the Protocol. At its fifth meeting, in May 2000, the Conference of the Parties requested the Executive Secretary to convene, prior to the first meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP), the meeting of technical experts on the Biosafety Clearing-House referred to in the table at the end of decision EM-I/3 (decision V/1, para. 3).

2. Accordingly, the Meeting of Technical Experts on the Biosafety Clearing-House was held in Montreal from 11 to 13 September 2000 at the office of the Secretariat of the Convention to consider issues relevant to information-sharing requirements and the Biosafety Clearing-House as reflected in the work plan of the ICCP endorsed by the Conference of the Parties to the Convention (decision V/1, annex).

I. OPENING OF THE MEETING

3. The Meeting was opened by Mr. Hamdallah Zedan, Executive Secretary of the Convention at 9 a.m. on Monday, 11 September 2000. He welcomed the participants and reminded them of the mandate of the meeting. He also thanked the Governments that contributed financially to ensure a large participation in the meeting and to its successful organization: Austria, Norway, the United Kingdom and the United States of America.

II. ORGANIZATIONAL MATTERS

2.1. ATTENDANCE

4. A list of participants in the meeting is annexed to this report.

2.2. ELECTION OF OFFICERS

5. The following officers were elected by acclamation at the opening session of the Meeting:

Chair: *Mr. François Pythoud (ICCP Bureau member, Switzerland)*

Rapporteur: *Ms. Eliana Fontes (Brazil)*

2.3. ADOPTION OF AGENDA

6. The Meeting adopted the following agenda on the basis of the provisional agenda that had been circulated under the symbol UNEP/CBD/BS/TE-BCH/1/1:

* Originally circulated under the symbol UNEP/CBD/BS/TE-BCH/1/5.

1. Opening of the meeting.
2. Organizational matters:
   - 2.1. Election of officers;
   - 2.2. Adoption of the agenda;
   - 2.3. Organization of work.
3. Issues for in-depth consideration:
   - 3.1. Establishment of the Biosafety Clearing-House;
   - 3.2. Operation of the Biosafety Clearing-House;
   - 3.3. Partnership opportunities.
4. Other matters.
5. Conclusions and recommendations.
6. Adoption of the report.
7. Closure of the meeting.

2.4. ORGANIZATION OF WORK

7. The Meeting adopted the proposed programme of work as contained in annex II to the annotations to the provisional agenda (UNEP/CBD/BS/TE-BCH/1/1/Add.1).

III. ISSUES FOR IN-DEPTH CONSIDERATION

3.1. ESTABLISHMENT OF THE BIOSAFETY CLEARING-HOUSE

8. In considering agenda item 3.1, the Meeting had before it a note by the Executive Secretary on the establishment of the Biosafety Clearing-House (UNEP/CBD/BS/TE-BCH/1/2). A representative of the Secretariat provided an overview of the objectives and development of the clearing-house mechanism of the Convention on Biological Diversity to assist the meeting in its consideration of how the Biosafety Clearing-House and the clearing-house mechanism could fit together conceptually.

9. The conclusions and recommendations of the Meeting under this item are contained in section V below.

3.2. OPERATION OF THE BIOSAFETY CLEARING-HOUSE

10. In considering agenda item 3.2, the Meeting had before it a note by the Executive Secretary on the operation of the Biosafety Clearing-House (UNEP/CBD/BS/TE-BCH/1/3).

11. An introduction to information management issues, system architecture and confidentiality considerations was provided by experts from the International Centre for Genetic Engineering and Biotechnology (ICGEB) and the European Commission.

12. The conclusions and recommendations of the Meeting under this item are contained in section V below.

3.3. PARTNERSHIP OPPORTUNITIES

13. In considering agenda item 3.3, the Meeting had before it a note by the Executive Secretary on partnership opportunities (UNEP/CBD/BS/TE-BCH/1/4).

14. Representatives from OECD and UNIDO gave a presentation to highlight the opportunities for possible cooperation between their existing information exchange resources and the Biosafety Clearing-House.

15. The conclusions and recommendations of the Meeting under this item are contained in section V below.

IV. OTHER MATTERS

16. Two issues were raised under this item: (i) the role of an advisory/steering committee to assist the Secretariat in the setting up of the Biosafety Clearing-House; and (ii) a review mechanism for the Biosafety Clearing-House. The recommendations reached on these issues are elaborated below.

V. CONCLUSIONS AND RECOMMENDATIONS

17. The Meeting considered the types of information to be processed by the Biosafety Clearing-House identified in paragraphs 25-28 of document UNEP/CBD/BS/TE-BCH/1/2.

18. The Meeting adopted the following conclusions and recommendations for consideration by the Intergovernmental Committee for the Cartagena Protocol on Biosafety at its first Meeting.

19. The Meeting recognized that the clearing-house mechanism and the Biosafety Clearing-House have distinctly different roles; the clearing-house mechanism is for information exchange and to promote scientific and technical cooperation, whereas the Biosafety Clearing-House is also central to the actual implementation of the Protocol.

20. Given the need for the Biosafety Clearing-House to be operational by the time the Protocol enters into force, the Meeting recommended that the Biosafety Clearing-House should be implemented in a phased manner, beginning with a pilot phase.

21. This pilot phase should extend at least until the second meeting of the ICCP, and should have as its objectives:

(a) Incorporation of the information necessary for implementing the Protocol in a timely manner;

(b) Ready availability of information to Parties through the Biosafety Clearing-House; and

(c) Efficient functioning of the Biosafety Clearing-House.

22. Future development of the Biosafety Clearing-House will ensure that all types of information to be processed by the Biosafety Clearing-House are effectively incorporated.

23. This pilot phase should concentrate on:

(a) Information to facilitate decision-making, including that required under the advance informed agreement (AIA) procedure, such as national focal points and competent national authorities; regulations; and summaries of risk assessments and other decisions,

(b) Those requirements for which the Biosafety Clearing-House is part of the procedure for living modified organisms intended for direct use for food or feed, or for processing (LMO-FFPs) (i.e. Article 11, paragraph 1).

24. In discussing the operation of the pilot phase of the Biosafety Clearing-House, the following elements were considered: storage, data submission, validation, indexing and access. Issues related to partnership and resources were also considered by the Meeting.

25. The Meeting recommended using a combination of centralized/decentralized information systems to offer the Biosafety Clearing-House the necessary flexibility for better coordination of the submission of data while ensuring timeliness and links to complementary distributed information.

Information to facilitate decision-making, including that required under the advance informed agreement (AIA) procedure

26. The Meeting recommended the development of a central portal to assist users to access information. The web-page structure used by BIO-BIN may serve as a model.

27. The Meeting recommended a distributed approach to storage of information falling outside of Article 11, paragraph 1. This will consist of a central portal providing the basic information with links directing users to specific information on national and other data sources. The central portal should also be available in the interim for countries without the technological capabilities to host their own information.

28. The Meeting recommended the use of metadata (i.e. descriptive identifiers such as name, author, date, etc.) to facilitate the submission, searching, location and retrieval of information.

29. With regard to submission and validation of information, the Meeting recalled that Parties should ensure the accuracy of the information provided by them through the Biosafety Clearing-House.

Information related to procedures for LMO-FFPs (Article 11, paragraph 1)

30. The Meeting recommended a centralized approach to storage and management of information relating to procedures for LMO-FFPs provided to the Biosafety Clearing-House.

31. The Meeting recommended the development of standard formats/templates and use of metadata to facilitate the submission, searching, location and retrieval of information.

32. With regard to submission and validation of information, the Meeting recalled that Parties are responsible for the accuracy of the information provided to the Biosafety Clearing-House.

33. The Meeting considered that the use of all six United Nations official languages for the submission of information in the standard formats/templates would have resource implications. The Meeting recommended that limiting the number of languages during the pilot phase may facilitate establishment of the Biosafety Clearing-House, and facilitate usability and more efficient administration of the system.

Capacity building

34. The Meeting recommended that emphasis be placed on strengthening the capacities of all Parties to access the Biosafety Clearing-House, particularly with reference to electronic access capabilities. The Meeting considered that the development of regional nodes or networks would facilitate the capacity of Parties to access and provide information to the Biosafety Clearing-House.

35. The Meeting also emphasized the important role of the Biosafety Clearing-House for capacity-building, especially for developing countries and countries with economies in transition, in relation to information-exchange for risk assessment and risk management.

Partnerships

36. The Meeting recommended that partnerships with relevant initiatives be established.

Resources

37. The Meeting recommended that the Secretariat prepare an estimate of resources that would be required to establish the pilot phase of the Biosafety Clearing-House, taking into account the other recommendations of the Meeting, for consideration by the ICCP.

Confidential information

38. The Meeting recommended that all information provided to the Biosafety Clearing-House should be information that is not considered confidential.

Follow-up and evaluation

39. The Meeting recommended that the development of the pilot phase be monitored and reviewed, as a basis for future planning and development of the Biosafety Clearing-House.

VI. ADOPTION OF THE REPORT

40. The present report was adopted on the basis of the draft report that had been circulated as document UNEP/CBD/BS/TE-BCH/1/L.1, on the understanding that the Rapporteur would be responsible, with the assistance of the Secretariat, for its finalization to reflect the proceedings of the closing session and to incorporate the conclusions and recommendations adopted by the Meeting.

VII. CLOSURE OF THE MEETING

41. The Chair declared the Meeting of Technical Experts on the Biosafety Clearing-House closed at 3:30 p.m. on Wednesday, 13 September 2000.

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Annex II

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.

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).*

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);

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

(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.

Annex III

OPERATION 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 items in the work plan of the Intergovernmental Committee for the Cartagena Protocol (ICCP) required to make the Biosafety Clearing-House operational, with a focus on design features of an electronic processing unit at the core of the system. A short analysis is provided of information management issues (including common formats, data-input systems, and quality-assurance procedures), considerations in designing the system architecture, means to protect confidential data, and security issues.

II. INFORMATION MANAGEMENT ISSUES

A. *Information requirements*

2. The information-exchange system of the Biosafety Clearing-House will need to meet the information needs of a wide and diverse audience, including competent national authorities and national focal points of Parties and other Governments, international governmental organizations, national regulatory agencies, industry developers, non-governmental organizations, members of the public, and the Convention Secretariat.

3. The note by the Executive Secretary on the establishment of the Biosafety Clearing-House (UNEP/CBD/BS/TE-BCH/1/2) describes the types of information that will be processed by the Biosafety Clearing-House. The communication of information required to operate the advance informed agreement procedure and procedures for processing living modified organisms for direct use for food, feed or processing (LMO-FFPs) through the Biosafety Clearing-House will be its most important function in the early stages. Thus, the main characteristics of the Biosafety Clearing-House information-exchange system will be:

(a) To allow validated data to be submitted to the system;

(b) To store and/or provide access to this data;

(c) To present the data so that it can be easily found;

(d) To control access to confidential data in the system; and

(e) To protect the data submitted to the system.

B. *Common formats*

4. In order to allow for proper data browsing and querying of the database, it is essential that all reports submitted should share a common format—either a single common format or common open formats where the tools to read the documentation are freely available over the Internet. A lack of common standards will stunt the growth of an effective information-exchange mechanism, and the ability of the Biosafety Clearing-House to further develop and exploit information-exchange opportunities.

5. Therefore, agreement must be reached on common formats for sharing and exchanging information and data for inclusion in the Biosafety Clearing-House. Samples of common formats for data exchange, based on the requirements of the Protocol, will be presented to the Meeting of Technical Experts for further consideration.

C. *Data input*

6. Metadata (i.e., information about the data, such as the owner and content) will be required as part of the Biosafety Clearing-House to inventory what information is available in the system and where it is located. The content provider would supply the initial metadata that describes the information. It would then be valuable if automatic analysis of the information submitted through the database could allow some metadata to be created automatically (for example: dates of submission; keyword indexing). However, since the machine interpretation of data cannot as yet reliably answer common questions that users are likely to ask, the validation process will probably also need to allow a human operator to enter additional information.

7. In order to facilitate entry into a database, documents should be submitted in electronic format as far as practicable. The geographic extent of the interested area, the enormous differences in computer technology and the different organizations and regulatory frameworks that exist among countries suggest the implementation of a flexible system accessible to all users.

8. A few standard, widely used file formats, are discussed below. At the simplest level of data-exchange, ASCII (American Standard Code for Information Interchange) is the most common format for encoding text files in computers and on the Internet, although standard ASCII does not allow for complex formatting or use of diacritics. RTF (Rich Text Format) is a file format that enables the exchange of text files between different word processors, while Unicode is a relatively new system for interchanging written text in 24 supported language scripts.

9. HTML (Hypertext Markup Language) is a “presentation”, or “formatting” language—a set of “markup” symbols or codes inserted in a file intended for display on a World Wide Web browser—and is a standard recommended by the World Wide Web Consortium (W3C). The current version of HTML is HTML 4, but HTML 3.2 is the most widely supported version. However, the major Web browsers (Microsoft's Internet Explorer and Netscape's Navigator) implement some features differently and provide non-standard extensions for the language.

10. XML (Extensible Markup Language) is a “data description” language and is currently a formal recommendation from W3C. XML is similar to the language of today's Web pages, HTML. Both XML and HTML contain mark-up symbols to describe the contents of a page or file. HTML describes the

content of a Web page (mainly text and graphic images) only in terms of how it is to be displayed and interacted with. In contrast, an XML file can be processed purely as data by a program or it can be stored with similar data on another computer or, like an HTML file, can be displayed and therefore be used to exchange information with a database.

11. Proprietary file formats are also often used for documents such as those produced using popular word processors like Microsoft Word and WordPerfect. Also produced by a specific commercial application, but widely used on Internet, are PDF (Portable Document Format) files, produced by Adobe through Acrobat applications; its main commercial advantage consists in the free distribution via Internet of the "Reader" application.

D. *Common language*

12. An important issue in accepting submissions to the Biosafety Clearing-House will be the language of submission. The simplest solution for exchanging information through the Biosafety Clearing-House system would be the adoption of a compulsory unique language to be used in all information submitted to the Biosafety Clearing-House. (This may have resource implications for many regions, particularly with regard to the time-limits required under the Protocol for submission of certain types of information to the Biosafety Clearing-House.)

13. A functional alternative, but one that would be more limited for search and retrieval functions, would be to allow the submission of exhaustive documents in a common language, synthesizing and referring to original documents provided as annexes. More limited again would be to provide only abstracts and metadata in a common language.

14. Further consideration could be given to the use of a controlled vocabulary for keyword indexing of information to be processed by the Biosafety Clearing-House in a number of different languages. In the absence of a standard vocabulary it would be very difficult to compile meaningful datasets and information products, let alone exchange them in an efficient and harmonized manner. However, use of publishing reference tools may facilitate activities in this regard, for example, by using the UNEP multilingual thesaurus of environmental terms, EnVoc (Environmental Vocabulary). EnVoc is published in all six official United Nations languages (Arabic, Chinese, English, French, Russian and Spanish), and a number of other Governments have undertaken the translation of the thesaurus into their national languages.

E. *Content validation and quality assurance*

15. To be effective in an increasingly large-scale information-exchange service, content validation must proceed with minimal manual intervention. It is unlikely to be economically feasible for every piece of content submitted to the Biosafety Clearing-House to be checked manually. Therefore, metadata information will be needed to describe both the content and the validation criteria.

16. There are likely to be a number of parts to a validation service, for example:

(a) Syntactic validation checks the technical correctness of the content, for example that all links in a Web page are valid;

(b) Semantic validation determines if the content matter is correct in its current use context, for example, that this is the correct risk assessment for the LMO concerned. The answers to these questions are supplied by the content metadata, either generated automatically or else supplied by a human user. (It is to be hoped that intelligent media processing can replace the human user.)

(c) Additional metadata can be added to the content to record the results of the syntactic and semantic validation. (This may be particularly important if a human user has contributed to validation, since the same questions can then be answered automatically in future.)

(d) Finally, the content can be secured so that if it is transferred to another organization or process, the metadata can be trusted and potentially the content used without any further need for validation.

17. Nevertheless, each Party should be considered totally responsible for its own submissions.

F. *Data-reporting*

18. The reporting role of the Biosafety Clearing-House will be to:

(a) Make its information accessible to all users,

(b) Facilitate the process of both integrating and summarizing the information to the extent desired by decision makers and the public;

(c) Sift through this information to find that information specifically requested by decision-makers and facilitate getting the information to them; and

(d) Ensure presentation in a format that is clear and understandable to decision makers.

19. The reporting system should be characterized by transparency, accessibility, objectivity, reliability, high quality and rapid reporting of results.

III. SYSTEM ARCHITECTURE

20. A first important issue to consider in designing the system is related to whether information is maintained in a decentralized network or a central database.

A. *Decentralized network*

21. One option for the operation of the Biosafety Clearing-House would be to implement a decentralized information-exchange system, based on new and existing autonomous systems for storing and distributing data. If such an approach were to be adopted, the most important consideration would be technical inter-operability between the systems. It is likely that data would need to be both exchanged between different information systems, and also shared or "pooled" at a central location in order to achieve synergy and added value.

22. Ensuring technical inter-operability places detailed demands at multiple levels, which range from physical interconnection to correct interpretation by applications of data that is provided by other applications. For two information systems to inter-operate effectively, they must be able not only to exchange relevant information but also to interpret the information they exchange according to consistent definitions—merely providing information in digital form does not necessarily mean that it can be readily shared between systems. Inter-operability would also require that systems be inter-operable at the data level—that the format and semantics of the data are also coordinated so as to permit interoperation.

23. If desired, there are a number of approaches by which current autonomous systems, not designed up-front for inter-operability, could be made to inter-operate to exchange information:

(a) *The data "bus" approach.* Each system uses its own data definitions internally. However, exchanges of data with other systems are conducted through a "bus", that is, a common data standard into which data must be translated before being transmitted to another system. Any system

wishing to use this data then downloads it from the "bus" and retranslates the data into locally meaningful terms before that data is used;

(b) *The data-dictionary approach.* Each system has a published data dictionary and a simple query-response mechanism to access the data with published message formats. Given a later need to inter-operate, another supplier could build to that embedded base interface and access the system's data. A system with this capability may cost more than a closed system, and additional security issues may need to be addressed with this approach;

(c) *The data-translator approach.* Two systems that need to inter-operate have a translator that converts one set of data definitions into the other. This approach preserves the internal integrity of the data, but the translators may be slow and, more importantly, may not preserve the original semantics of the underlying data;

(d) *The data-server approach.* Data and processing are separated. When a system requires data, it connects to a data server that provides the data. Enforcement of definitions can thus be limited to just a few servers rather than a myriad of applications. By moving the data into a system separate from the individual applications, this approach facilitates reuse of data in new, unanticipated ways.

24. Benefits of the decentralized model would include more timely data-sharing, as the original data providers would not have to go through this extra step of circulating data to a central repository. The result would be a need for fewer resources.

25. However, the establishment of such a system would involve major trade-offs between inter-operability and security. Inter-operability can promote an attacker's access to diverse systems, thus facilitating the rapid spread of attacks. In addition, ad hoc work-arounds to overcome a lack of inherent inter-operability could introduce many hard-to-manage security problems. Another trade-off is the potential for inter-operability problems posed by the introduction of new security features into part of a larger system of systems.

26. Apart from technical challenges involved in ensuring inter-operability, other disadvantages with establishing a decentralized system may be exclusive availability to Internet users, limits in access to strategic data where parts of the network have less reliable telecommunications infrastructure, and a significant increase in the time to carry out data queries. A decentralized system may also suffer from a lack of coordination in data reporting, quality assurance, and database management, making it difficult to combine data across systems and make regional information available quickly.

B. *Centralized database*

27. An alternative strategy to overcome limitations such as lack of coordination in data-reporting, and to increase data-quality assurance, could be to create a centralized database that contains all the core data submitted under the Protocol.

28. In addition to storing essential and official information in a central repository, it would perhaps be desirable to include, in the searchable data, all the relevant references (and links) to other optional information available on other systems. The synergy of the core database with the other information systems, maintained by the Parties or other international stakeholders, would contribute to develop a neutral, transparent, cost–effective, efficient, accessible and decentralized system, in harmony with the design of the clearing-house mechanism of the Convention (as discussed in the note by the Executive Secretary on the establishment of the Biosafety Clearing-House (UNEP/CBD/BS/TE-BCH/1/2)).

29. Problems could be encountered with such a system because of the need for data providers to turn over their data to a centralized database, a process that can be time-consuming. The process of making

corrections to the centralized database is likely to be slower and may result in multiple versions of the same data set—one set on the data provider's computer system and a second in the centralized database.

30. These problems may be overcome by the use of a database-management system that would allow individual data collectors and data providers to manage their own data locally, while providing a centralized means of uploading the data into a larger database. These data could be fully protected by the data-management structure, and only the data provider would be permitted to make changes. Data in the centralized database would then be available for comprehensive analysis and reporting.

C. *Combination model*

31. A combination of systems may also be considered. Depending on its sophistication and design, a combined model may offer the Biosafety Clearing-House the necessary flexibility for better coordination of the submission of data while ensuring timeliness and links to complementary information distributed. Once the issues of security and validation of information are resolved, the system could be designed to deal with different types of data having different levels of confidentiality and validation needs. In this manner, through a combined model, it may be easier to target, administer and make available the data that is required for the development of the Biosafety Clearing-House.

IV. CONFIDENTIALITY CONSIDERATIONS

32. Article 21 of the Protocol provides for the notifier to identify information submitted under the procedures of the Protocol that is to be treated as confidential, and Parties are required to ensure that they have procedures to protect such information.

33. Article 21, paragraph 6, of the Protocol clearly defines the type of information that shall not be considered confidential:

(a) The name and address of the notifier;

(b) A general description of the living modified organism or organisms;

(c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(d) Any methods and plans for emergency response.

34. Any other information therefore, could potentially be classified as confidential (with appropriate justification) and would need to be sufficiently protected when being circulated through the Biosafety Clearing-House.

35. In order to allow for maximum transparency of the Biosafety Clearing-House, and to ensure that only a minimal amount of information is classified as confidential, such information should not be mixed with non-confidential information and could be contained exclusively in separate files annexed to the main document.

A. *A sample approach for dealing with confidential information*

36. One example of confidential data being circulated through an information clearing-house is that relating to experimental field trials of genetically modified organisms conducted in the European Union under directive 90/220/EEC. A demonstration of the system will be given at the Meeting of Technical Experts.

37. The main operational procedures of the system are as follows:

(a) The competent authorities submit a notification to the Commission by registered mail. A fax or an electronic mail is addressed to the Commission from the competent authority as evidence that the notification has been sent;

(b) On receiving the notification, the Commission records the date of receipt on the document and also numbers the pages received. The competent authority submitting the document is informed by the Commission (by fax) of the date of receipt and the date of circulation to other competent authorities;

(c) The circulation will, as a rule, be carried out once a week.

38. The system allows for greater security if confidential business information is being distributed to the member States. Firstly, member States must comply with the general requirements for receiving confidential business information, namely, that all individuals (within the member States and within the European Commission) handling such information must have received clearance to do so and that dossiers must be stored in secure places and distributed by diplomatic bag rather than by post or courier. Finally, mail must be registered at all stages of circulation to allow the security officer of the European Commission to be informed of the whereabouts of the confidential information at all times.

39. An overview of the content of the database can be found at http://food.jrc.it/gmo/. When the project was established in 1991, it consisted solely of a system for the exchange of printed dossiers. In 1996, an electronic system was developed and implemented in all member States of the European Union. However, information was exchanged exclusively through the distribution of diskettes and not through electronic mail, while confidential business information continued to be distributed on paper in line with the original distribution mechanism.

40. As with Article 21 of the Protocol, article 19 of directive 90/220/EEC clearly defines the type of information in notifications that may or may not be kept confidential. At present, only a limited amount of information in the database (144 out of 1569 notifications (9.2 per cent)) is labelled as confidential business information. In most cases, the confidential business information is restricted to the molecular characterization of the insert. The fact that so little information is confidential does not necessarily mean, however, that all of the non-confidential information is readily accessible. The availability of this information is dependent upon national decision-making processes.

41. The member States of the European Union have expressed an interest in having not only electronic access to the information relating to small-scale field trials, but also dossiers submitted for authorization of commercial releases under part C of the directive. These dossiers very often contain confidential business information and, therefore, a special system had to be set-up to allow for secure on-line access.

42. The two biggest security threats to this system are possibly unauthorized access to corporate assets (both from outside the network and from within), and the threat of damage and loss through viral infection. The following methods as a means to secure the system are currently being considered.

B. *Extranets*

43. One option for facilitating secure transfer of confidential information is to limit its exposure through use of an extranet*. An extranet is a private network that uses Internet protocols and the public telecommunication system to securely share part of an organization's information or operations with key stakeholders. An extranet can be viewed as part of an organization's intranet that is extended to specified users outside the organization.

44. An extranet requires security and privacy. These require firewall-server management, the issuance and use of digital certificates or similar means of user authentication, encryption of messages, and the use of virtual private networks (VPNs) that tunnel through the public network.

45. When considering secure data transfer via the network, it is important to understand that there are a number of security issues and risks associated with extranets. The keyword for all extranet applications is "sharing": sharing databases, sharing information, sharing documents, etc. It is also a tool for efficient collaboration, since extranet users can actively participate in the process of sharing information.

C. *Firewalls and proxy servers*

46. The most common method of securing an extranet system is through use of "firewalls". Firewalls are hardware/software combinations configured to control the information that can flow in and out of the extranet. All data passing in and out of the Internet is transmitted through "routers" and these play a major role in firewalls. Routers act as packet filters (i.e. filtering units of data) and, based on a set of rules established by the system administrator, the router will allow certain packets in but will reject the input of others.

47. Proxy servers are another important tool for the maintenance of extranet security. The proxy server acts as an intermediary between the extranet and the Internet. It evaluates all requests for information from an authorization database and, if the request is acceptable, the proxy contacts the Internet. The returning page also passes through the proxy server from the Internet. In this way, the proxy server can keep a record of all transactions, and provides a trail to track any kind of attack. The proxy server also shields the extranet from the Internet given that the only Internet Protocol (IP) address transmitted to the Internet is that of the proxy server. Against this background, individuals pretending to be legitimate clients and trying to capture IP addresses for a "spoofing" attack (pretending to be a legitimate client) are not able to "see" the originating IP addresses, which are hidden inside the network.

48. Firewalls and proxy servers are an effective "barrier" method of controlling the passage of information in and out of an extranet, but do not address the issue of maintaining data integrity before or after transmission. They also cannot address the integrity of the individuals sending or receiving information although encryption and authentication systems are available for this purpose.

D. *Encryption*

49. Encryption is a sophisticated method of encoding or "scrambling" data so that the data can only be decoded or unscrambled by the party for whom the message is intended. While encryption is a very

* **Intranets** are secured areas that utilize Internet and WWW standards and technologies to conduct internal communication and collaboration activities. Adopted by companies at a phenomenal rate, intranets have produced efficiencies for businesses that allow users to manage their organizations more efficiently and effectively "behind the firewall". **Extranets** represent the bridge between the public Internet and the private corporate intranet. Extranets connect *multiple* and diverse organizations on-line behind virtual firewalls, where those who share in trusted circles can network in order to achieve commerce-oriented objectives.

powerful method for securing data, it neither offers positive proof of the identity of the sender nor verifies whether or not information has been tampered with or somehow altered in transmission.

E. *Authentication*

50. Authentication adds another layer of security to the system by providing positive identification of the sender of the information. Traditional authentication systems include the widely used password authorization methods. However, in today's robust computing environment, more sophisticated methods of authentication are necessary to ensure the integrity of data and to eliminate or reduce the possibility of fraud.

51. Digital signatures or “digital IDs” have brought this level of sophistication to the computing arena. Digital IDs incorporate a public/private key pair that is generated and bound to a user's name (and other identifying information) by a trusted third party certification authority, which issues the digital ID to the user. This ID can be attached to an encrypted message to assure the recipient of the correct identity of the sender. It can also be installed in a Web browser to be used in place of a password dialogue for information and services that require membership or restrict access to particular users. Since the slightest change in a “digitally signed” document will cause the digital signal verification process to fail, this method of authentication also allows people to check the integrity of signed documents.

E. *Viruses*

52. Viruses are a major concern for the integrity of an extranet. An appropriate way to deal with this problem is to run virus-checking software specifically designed for extranets. This software operates on a server, and checks files for viruses as they are sent to the extranet. Files are only accepted if they are virus-free and are blocked if they appear to be contaminated.

53. There are at present a number of available hardware/software packages that provide extremely high levels of security. The ultimate choice depends upon a number of factors including the type of operating system, the cost, the number of users, the speed of access required, etc.

F. *Implications for the Biosafety Clearing- House*

54. It is technically possible to bring together a large number of users under a secure extranet, and this option could be considered for the exchange of confidential information through the Biosafety Clearing-House. The cost for the design, development and maintenance of a system for exchange of information is very high, particularly in terms of human resources, and it is therefore imperative to design a system that is both functional and sufficiently flexible.

55. It is also essential for any information-exchange system to have a clear structure defined at the outset. This should include precise knowledge of the fields of information needed and the details of the information required. It is also important to design a streamlined system for the import of data and to train that all users in its operation. The system must also be functional and user-friendly and should clearly meet the expectations of the user.

56. The amount of confidential information should be limited to the minimum in line with existing legal requirements. Eventually, a layered system could be developed that limits the number of authorized people who have access to all layers. The second layer would contain no confidential information and would be intended for personnel who need to work with the system without necessarily requiring knowledge of all the data.

V. ESTABLISHMENT OF A PILOT PHASE OF THE BIOSAFETY CLEARING-HOUSE

57. In its decision V/1, adopting the work plan of the Intergovernmental Committee for the Cartagena Protocol, the Conference of the Parties emphasized that it was a matter of priority to launch the Biosafety Clearing-House no later than the entry into force of the Protocol. However, the complexity associated with designing an information-exchange system to achieve a grand universal solution must not be underestimated.

58. Given the need for the Biosafety Clearing-House to be operational as soon as possible, the scope of the initial establishment phase will need to be smaller in scale and less complex, and should concentrate on implementing core activities of the Protocol. Consideration could be given to developing a pilot phase of the Biosafety Clearing-House, similar to that developed by the clearing-house mechanism of the Convention. The clearing-house mechanism's long-term programme of work and strategic plan (adopted by the fifth meeting of the Conference of the Parties, in May 2000) were based on the results of the independent review of the pilot phase.

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

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

(a) System architecture design issues: for example, centralized versus decentralized systems, including the possible establishment of a central database for the Biosafety Clearing-House, receiving official submissions by Parties and other stakeholders and allowing references (and links) to other external, accessible information exchange mechanisms;

(b) Mechanisms for data input and validation, including control and development of metadata; election of standard electronic formats for documents submission compatible with the platform of choice; election of authorized methods of submissions; and definition of validating methods according to defined security standards;

(c) Authentication of contributions: such as definition of a list of acknowledged contributors, and the inclusion of a clearly labelled, public board for unacknowledged, relevant contributions;

(d) Issues associated with data-browsing and querying, such as selection of common language for submissions (and definition of the core information that must be provided in this language) and a classification system and document layout for standard submissions;

(e) Handling of confidential data: definition of security standards to protect the integrity of the system and definition of procedures to prevent unauthorized access to classified data.

Annex IV

PARTNERSHIP OPPORTUNITIES

Note by the Executive Secretary

CONTENTS

I. INTRODUCTION

1. According to Article 20, paragraph 2, of the Protocol on Biosafety, in addition to serving as a means through which information is made available by the Parties relevant to the implementation of the Protocol, the Biosafety Clearing-House shall also provide access, where possible, to other international biosafety information exchange mechanisms.

2. The present paper provides an overview of the major international biosafety information exchange mechanisms currently in operation and considers a sample of other available resources, with a view to assisting the Meeting of Technical Experts in its consideration of possibilities for cooperation with other biosafety information exchange mechanisms.

3. Representatives from intergovernmental organizations (IGOs) active in biosafety and/or information-sharing activities will also be invited to give a presentation under this item on the opportunities for cooperation between these existing information-exchange resources and the Biosafety Clearing-House.

II. INTERGOVERNMENTAL ORGANIZATIONS

4. The present section outlines the main activities related to global information exchange being coordinated by intergovernmental organizations active in the exchange of biosafety-related information.

A. *Inter-Agency Network for Safety in Biotechnology (IANB)—Safety in Biotechnology News* (http://www.oecd.org/ehs/biobin/IANB.htm)

5. A number of intergovernmental organizations have projects related to safety in biotechnology. In November 1999, eleven of these organizations formed the Inter-Agency Network for Safety in Biotechnology (IANB) to enhance the exchange of information and facilitate cooperation between members.

6. Participating organizations are the Secretariat of the Convention on Biological Diversity (CBD), the Consultative Group on International Agricultural Research (CGIAR), the Food and Agriculture Organization of the United Nations (FAO), the International Centre for Genetic Engineering and Biotechnology (ICGEB), the Office International des Epizooties (OIE), the Organisation for Economic Co-operation and Development (OECD), the United Nations Conference on Trade and the Environment (UNCTAD), the United Nations Development Programme (UNDP), the United Nations Industrial Development Organization (UNIDO), the World Health Organization (WHO), and the World Trade Organization (WTO). As one of its first steps, the IANB has started to publish a six-monthly newsletter *Safety in Biotechnology News*. The target audience for this network is:

(a) The secretariats of member intergovernmental organizations (to keep one another informed of their activities);

(b) Delegates from member States who participate in the work; and

(c) Any other interested parties.

B. *Organisation for Economic Co-operation and Development (OECD)—BioTrack* (http://www.oecd.org/ehs/service.htm; http://www.olis.oecd.org/bioprod.nsf)

7. OECD has a number of projects related to biosafety, for example, those organized by the Working Group for the Harmonization of Regulatory Oversight in Biotechnology, the Task Force for the Safety of Novel Foods and Feeds and the Working Party on Biotechnology.

8. OECD has been developing information resources, related to the use and regulation of GMOs, since the late 1980s. Today, most of its information resources are found in the information system, BioTrack Online. This has been developed in such a way to be compatible with the websites of national authorities, as well as the UNIDO Biosafety Information System and Advisory Service (BINAS) (see paras. 15-20 below).

9. BioTrack is managed by the OECD Working Group for the Harmonization of Regulatory Oversight in Biotechnology (comprised of delegates from member countries) to ensure that it meets the needs of national regulatory authorities.

10. BioTrack includes information on regulatory developments in OECD member countries. This information is provided by designated national contact points and is formatted under the following headings:

(a) Responsible ministry/agency;

(b) Contact points;

(c) Relevant laws/regulations/rules;

(d) Commercialized products.

11. This format was devised by the OECD Working Group, and is managed in such a way to ensure that linkages between national web servers, OECD and other resources such as BINAS are easily maintained and improved. Two important challenges are to ensure non-duplication of information, and to ensure that the information remains up to date.

12. A major component of BioTrack is the Product Database, which includes those products of biotechnology that have been approved in member countries. The information is formatted in the following way:

(a) Information about the product:

(i) OECD record number;

(ii) Organism common name;

(iii) Organism scientific name;

(iv) Trait;

(v) Gene(s);

(vi) Company/institute;

(vii) Company/institute contact name;

(b) Information about the product approval process:

(i) First country where notified;

(ii) Year;

(iii) Countries where unconfined planting has been authorized;

(iv) Countries where marketing has been authorized;

(v) Countries where food use has been authorized;

(vi) Countries where animal feed use has been authorized;

(vii) Additional information.

13. The format of the Product Database provides for links from the database to national safety/ risk assessment documents. In this way, it is possible to organize a large amount of information concerning one product from a number of different authorities. BioTrack Online also includes a database of field trials of genetically modified organisms (GMOs) that contains thousands of records.

14. OECD and UNIDO have been working together for a number of years on BINAS and BioTrack. The objective is to maintain links between the two systems and to avoid non-duplication of effort.

C. *United Nations Industrial Development Organization (UNIDO)—Biosafety Information System and Advisory Service* (BINAS) (http://binas.unido.org/binas; http://binas.unido.org/dt)

15. UNIDO is the task manager within the United Nations system for the follow-up to chapter 16 of Agenda 21, on the environmentally sound management of biotechnology. UNIDO has been developing information resources related to the use and regulation of GMOs since 1994. These resources are managed under the Biosafety Information System and Advisory Service (BINAS).

16. BINAS is managed by the Biodiversity Unit of UNIDO and responds to requests from member countries for the provision of technical assistance in the formulation of biosafety guidelines and setting-up of capacities for regulatory oversight.

17. BINAS maintains databases on:

(a) Competent biosafety authorities in member countries;

(b) Contact points

(c) Relevant laws/ regulations/ rules;

(d) Field trials.

18. The focus of the information content is non-OECD countries. For information on regulatory developments in OECD countries, users are referred to BioTrack. The structure of the databases is identical to the OECD's BioTrack to ensure contextual complementarity and easy navigation between the two sites.

19. BINAS is the repository of technical biosafety-related documents (reviews, monographs, manuals) and publishes a quarterly newsletter *BINASNews*.

20. BINAS has developed a computerized decision-support system for risk assessment. The system is intended as a tool to preserve, disseminate and interpret available data and information regarding releases of genetically modified crop plants into the environment. It is also intended to enhance familiarity with environmental introductions of transgenic crops and provide information support to regulatory authorities, researchers and biosafety officers of public institutions and commercial enterprises. The system, known as "dtree", contains a considerable body of information deriving from the OECD's Biosafety Consensus Documents. Work is under way to further enhance the system.

D. *International Centre for Genetic Engineering And Biotechnology (ICGEB)—Biosafety Bibliographic Database* (http://www.icgeb.trieste.it/biosafety/bsfdata1.htm)

21. The International Centre for Genetic Engineering and Biotechnology (ICGEB) is dedicated to advanced research and training in molecular biology and biotechnology. Its mandate is to promote the safe use of biotechnology world-wide with special regard to the needs of the developing countries. The Centre has a Biosafety Unit dedicated to information-dissemination and training in biosafety. It organizes annual workshops for scientists in biosafety and manages a bibliographic database of all the main scientific articles and books in biosafety and risk assessment for the environmental release of GMOs.

22. The ICGEB website contains the following three sections:

(a) *Biosafety database:* a scientific, bibliographic, searchable database on biosafety studies. This database is updated monthly and contains scientific articles (full reference and abstract), that have been published in international, peered reviewed, scientific journals since 1990 (currently about 2000). All the records have been extracted from the international applied life sciences database CAB ABSTRACTS, and AgBiotechNet, the online service for Agricultural Biotechnologists from CABI Publishing. These are selected and classified by ICGEB scientists in accordance with identified "topics of concern" for the environmental release of genetically modified organisms (GMOs) as follows:

(i) Risks for animal and human health: Toxicity & Food quality/safety; Allergies; Pathogen drug resistance (antibiotic resistance);

(ii) Risks for the environment: Persistency of gene or transgene (volunteers, increased fitness, invasiveness) or of transgene products (accumulative effects); resistance/tolerance of target organisms or susceptibility of non target organisms; increased use of chemicals in agriculture; unpredictable gene expression or transgene instability;

(iii) Risks for agriculture: weeds or superweeds; alteration of nutritional value (attractiveness of the organism to pests); reduction of cultivars (increase of susceptibility) and loss of biodiversity;

(iv) General concerns (loss of familiarity; higher cost of agriculture; field trials not planned for risk assessment; ethical issues (labelling);

(v) Risks of interaction with non target organisms (genetic pollution through pollen or seed dispersal; horizontal gene transfer (transgene or promoter dispersion); transfer of foreign gene to micro-organisms (DNA uptake); generation of new live viruses by recombination (transcapsidation, complementation, etc.);

(vi) Genetically modified micro-organisms;

(vii) Aquaculture;

(b) *Biosafety library*: a collection of selected documents on biosafety, including all the official documents issued by the main international organizations operating in this field, scientific finding (articles, proceedings and workshops) published on the Web and some indications on the regulations presently in force in a number of countries;

(c) *Biosafety links*: a list of links to world-wide national, United Nations, international organisation and governmental agency websites related to biosafety. An e-mail newsletter, *ICGEB Biosafety News*, which disseminates information regarding the activities of the Centre on this issue, provides interaction with Web users, updates of the ICGEB biosafety web pages and all major events related to biosafety.

E. *Consultative Group on International Agricultural Research (CGIAR)—System-wide Information Network for Genetic Resources (SINGER)* (http://singer.cgiar.org/)

23. The System-wide Information Network for Genetic Resources (SINGER) is the genetic resources information exchange network of the international agricultural research centres of the Consultative Group on International Agricultural Research (CGIAR). It provides common access to information concerning the collections of genetic resources held by the CGIAR centres. Together, these collections comprise over half a million samples of crop, forage and tree germplasm of major importance for food and agriculture. In addition, CGIAR holds a small collection of fish germplasm for research purposes.

24. SINGER links the genetic resources databases of the CGIAR centres and allows simultaneous searches for information concerning the identity, source, characteristics and transfer of the genetic resources in the collections of individual centres. The website allows on-line searches of the germplasm databases of CGIAR centres available through SINGER by:

(a) *Taxonomy*: taxonomic details for all germplasm found in the accession area. Specific records include: genus (genus, authority names and other relevant details), species (species, subtaxa names, subtaxa epithet). This area consists of a listing of common names of crops (or within organism group) to which a number of species records are linked;

(b) *Collecting missions*: search specific collecting missions carried by the CGIAR centres and their cooperators by centre, collection, taxon, country and year;

(c) *Accession data*: search by CGIAR centre, collection, taxon, country source, source of collection, sample status;

(d) *Cooperators*: names and addresses of the organizations and individuals that have received material, donated material or have collaborated in collecting missions;

(e) *Material transfer or distribution*: details on the transfer of material to requestors. This includes the accession requested, the date of transfer and the information on the cooperator;

(f) Characterization and evaluation data provided by the centres.

F. United Nations Environment Programme (UNEP)—Microbial Strain Data Network (MSDN), Information Resource for the Release of Organisms (IRRO) and the International Register on Biosafety (http://panizzi.shef.ac.uk/msdn/; http://www.unep.org/unep/program/natres/biodiv/irb/)

25. The Microbial Strain Data Network is a non-profit organization providing specialized information and communications services for life scientists worldwide. The network provides access to a unique collection of databases covering microbiology, biotechnology and biodiversity. Many of the databases are derived from the catalogues of microbial culture collections. Several nations are represented, including Russia, Slovenia, the Czech Republic, India, Bulgaria, Argentina and the United Kingdom. All databases are available free on several World Wide Web servers. MSDN is sponsored by the United Nations Environment Programme (UNEP) and other organizations.

26. In 1991, UNEP invited MSDN to organize a workshop to discuss the needs and specifications for a world-wide information system dealing with the environmental release of non-indigenous, novel, or genetically modified organisms. An outgrowth of this workshop was the Information Resource for the Release of Organisms into the Environment (IRRO). IRRO has no regulatory or advisory mission but acts as a neutral information service. This database is a result of a survey undertaken by MSDN in consultation with the IRRO Steering Committee to assess the needs of users for information on releases of organisms into the environment. Part of this study involved the identification of existing resources satisfying these needs. The result is a database of databases holding some information about environmental releases.

27. Records contain the following details: contact information; keywords used to describe resource (including content or scope; introduction of non-modified organisms; releases of genetically modified organisms; type of organisms if information available, e.g. bacteria, *Rhizobium*, nematode, invertebrate, etc; geographical coverage); information covered (including release data, risk assessments, national authority, regulations, experts, taxonomic, genetic research data, patent, bibliographic, abstract, full text, dissertation, grey literature, sequence, catalogue, species, check list, organizations); charges to access information (yes, no or some); organism described (animals, plants, micro-organisms).

28. UNEP also maintains a biosafety website that offers information from many sources on biosafety. It focuses on information useful in establishing a regulatory framework for the safe development, transfer, and application of biotechnology. It also provides links to other websites concerning biosafety, biotechnology, and biodiversity.

III. NATIONAL ENVIRONMENTAL RELEASE DATABASES

29. The present section lists a selection of national initiatives for exchanging information on environmental releases of living modified organisms, with a more detailed outline of three of the more comprehensive Internet sites (in Belgium, Brazil and Switzerland).

A. *Belgian Biosafety Server* (http://biosafety.ihe.be/)

30. The Belgian Biosafety Server is the Web server of the Service of Biosafety and Biotechnology (SBB). It is hosted by the federal Scientific Institute of Public Health under aegis of the Ministry for Consumer Protection, Public Health and Environment.

31. The site primarily aims at providing regulatory and scientific information to the Belgian medical, veterinary, agronomical and biotechnology community. The “Biosafety in Belgium” section of the site gathers legal or administrative data from collaborating partners and scientific information from the SBB. The Belgian Biosafety Server provides information to applicants, groups and the public, and also an

online help service for scientists working in laboratories, greenhouses, animal husbandries and large-scale units or involved in field tests, as well as for investors and those involved in the placing of products on the market in the European Union. Guidelines and forms are available online or as downloads for the regulatory officers, the concerned civil servants concerned and the private regulatory managers and consultants.

32. The "Biosafety in European Union" section of the site gathers regulatory/biosafety/web information related to European biotechnologies and their regulatory framework, mainly based on directives 90/219/EEC, 90/220/EEC and derived or revised European Community directives, products regulations, decisions and guidelines. A "Biosafety in Other Countries" site links to available Web servers publishing similar or complementary regulatory and scientific information in States outside the European Union.

33. Under "regulatory topics" it includes a "European Biosafety Web Ring" with links to specific European Union legislation, as well as legislation in a number of European countries, including Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Norway, Poland, Portugal, Spain, Sweden, Switzerland, the Netherlands, and the United Kingdom. Links to biosafety resources in other countries, including Australia, Brazil, Canada, Japan, New Zealand and the United States of America, are also provided.

B. *Base de Dados Tropical—Brazil (*http://www.bdt.org.br/*)*

34. The aim of the Base de Dados Tropical (BDT) is the dissemination of electronic information as an organizational tool for the Brazilian scientific and technological community. The system disseminates biological information of environmental and industrial interest and provides access to other regional and international databases.

35. The biological control database consists of profiles of researchers throughout the world working on biological control in general and on risk assessment of biocontrol agents in particular. Emphasis is given to studies and tests related to ecotoxicology, epizootiology, ecology, biosafety, legislation, and field release of control agents. The BDT Species Database is a cross-link of all species names stored in the BDT Brazilian databases and the available information related to them. By searching by name, the user receives a list of all databases that contain information related to the given species. Searches can be conducted by genus, species or both.

C. *Swiss Agency for Biosafety Research and Assessment of Technology Impacts (BATS) (http://www.bats.ch/)*

36. BATS is run by the Swiss Priority Programme Biotechnology, Basel, and was founded by the Swiss National Science Foundation. BATS provides expertise in the areas of technology impact research and knowledge management and communication. BATS is active in the acquisition, processing and communication of applications-oriented information and know-how in biotechnology.

37. Bioweb provides information through full-text search in relevant data banks and documents world wide, with the Eurospider retrieval system; search by categories for institutions and documents with relevant information; and bioweb-Podium — an interactive podium where scientists and members of the general public can discuss current issues.

D. *Other national biosafety sites*

38. Other national biosafety sites include:

(a) Australia (GMAC) http://www.health.gov.au/tga/gene/gmac/piscont.htm;

(b) Argentina (CONABIA) http://siiap.sagyp.mecon.ar/http-hsi/english/conabia/liuk.HTM;

(c) Brazil (CTNBio) http://www.fiocruz.br/cict/oquee/estrut/dect/bis/lib.htm;

(d) Canada (CFIA) http://www.cfia-acia.agr.ca/english/plaveg/pbo/home_e.shtml;

(e) European Union (JRC) http://food.jrc.it/gmo/gmo.asp;

(f) Germany (RKI) http://www.rki.de/GENTEC/GENENG/GENTEC_E.HTM;

(g) New Zealand (ERMA) http://www.ermanz.govt.nz/Applications/index.htm;

(h) Japan (ITD) http://ss.s.affrc.go.jp/docs/sentan/eguide/edevelp.htm;

(i) United States of America (USDA/FDA) http://www.aphis.usda.gov/biotechnology/faqs.html; http://vm.cfsan.fda.gov/~lrd/biopolcy.html.

IV. OTHER POTENTIAL PARTNERSHIPS

39. The Internet offers powerful tools for integrating novel capabilities for biological data analysis with other information that will be contained in the Biosafety Clearing-House. It is possible that future advances in environmental biotechnology informatics may allow the information exchange through the Biosafety Clearing-House to be used to produce mathematical models of system to guide policy makers in their assessments of risk. However, as this type of function is unlikely to be included in early stages of the development of the Biosafety Clearing-House, the sample discussed below is merely intended to be merely indicative, not exhaustive.

A. *Biological Internet databases*

40. Interactive, freely available sequence databases such as the European Molecular Biology Laboratory (http://www.embl-heidelberg.de/Services/index.html) offer free computational services for the scientific community, including sequence search and retrieval, and tools for structural comparisons and predictions. SRS™ (http://srs.ebi.ac.uk/) is a data retrieval system that integrates heterogeneous databanks in molecular biology and genome analysis. There are currently several dozen servers world-wide that provide access to over 300 different databanks via Web interfaces.

41. Taxonomic databases may be also be usefully integrated into the Biosafety Clearing-House system. For example, the International Plant Names Index (IPNI) is a database of the names and associated basic bibliographical details of all seed plants where the data are freely available.

B. *Legal information databases*

42. There are a number of initiatives to provide global access to environmental law information that could be incorporated with the Biosafety Clearing-House. An example of such expertise is ECOLEX (http://www.iucn.org/themes/law/), a joint project of UNEP and IUCN—The World Conservation Union that provides a "gateway to environmental law" to enable access to international and national environmental law information, primarily to assist developing countries.

43. ECOLEX is designed to use the IUCN Environmental Law Information System (ELIS) as its core archival system and link this data to full-text information available with the UNEP Computerized Environmental Law Information Base (CELIB) and other authoritative sources.

44. The project was initiated in 1997. Users can search by subject area, keyword, country, or date. The list of subjects includes, for example: climate/atmosphere; fresh water; marine environment; soils; forests; biodiversity; energy; protected areas; hazardous substances; and wastes. ECOLEX includes

information on multilateral treaties; national legislation; European Union instruments; international "soft law" and related documents; law and policy literature; and judicial decisions.

45. The service is designed to provide users - via two levels of Internet access (general and specialized) - with access to: a locator mechanism; a distributed system of specialized environmental law information databases; products such as CD-ROMs, disk-based information and paper publications; and links to other databases, expertise and more information.

46. Other websites providing access to international legal information specifically relating to biosafety include:

(a) BINAS (http://binas.unido.org/binas/regs.shtml) (see also paras. 15-20 above);

(b) Belgian Biosafety Server (http://biosafety.ihe.be/) (see also paras. 30-33 above);

(c) Biotechnology and Scientific Services (BSS) (http://www.aphis.usda.gov/bbep/bp/);

(d) Colby & Nance Web Site (http://conan.nova.org/welcome.htm);

(e) EUR-Lex—European Union law (http://europa.eu.int/eur-lex/en/index.html);

(f) EUROPARL (http://www.europarl.eu.int/references/en/default.htm);

(g) Food Law (University of Reading) (http://www.fst.rdg.ac.uk/foodlaw/index.htm);

(h) InfoBiotech Canada (IBC) (http://www.ibc.nrc.ca/ibc/);

(i) Official Journal of the European Communities (http://www.europarl.eu.int/basicdoc/en/default.htm)

C. *Patent databases*

47. Public access to text and analysis of DNA patents assessed by various countries is also available on many Internet sites, and often contains information of value to those interested in assessing biosafety applications. Examples of such sites include:

(a) Patent Cooperation Treaty database (http://pctgazette.wipo.int) and Intellectual Property Data Collection (http://ipdl.wipo.int) at the World Intellectual Property Organization (WIPO);

(b) National and regional sites such as the patent information service of the European Patent Office (http://www.european-patent-office.org), the web patent databases at the United States Patent and Trade Mark Office (http://www.uspto.gov/patft/index.html) and the Canadian Intellectual Property Office (http://patens1.ic.gc.ca/intro-e.html) and the Japanese Patent Office (www.jpo-miti.go.jp/homee.htm); and

(c) Joint projects, such as the DNA Patent Database (http://www.genomic.org), a joint project of the Georgetown University's Kennedy Institute of Ethics and the Foundation for Genetic Medicine, that allows free public access to the full text and analysis of all DNA patents issued by the United States Patent and Trademark Office; and the IBM Intellectual Property Network (http://www.patents.ibm.com/home) that allows searching and viewing of patent documents from the United States and Europe as well as patent applications published by WIPO.

D. *News and publication services*

48. Finally, a number of organizations provide up-to-date news services covering biotechnology and biosafety issues.

49. For example, Ag BioTech InfoNet (http://www.biotech-info.net/) covers all aspects of the application of biotechnology and genetic engineering in agricultural production and food processing and marketing.

The goal is to facilitate access to critical, original documents and information, and recognized experts, while the focus is on scientific reports and findings and technical analysis, although the page also covers emerging issues of widespread interest, developments in the policy arena, and major media coverage.

50. Ag BioTech InfoNet offers a road-map to resources on the Internet and provides a forum where people and organizations can raise questions, report new technical findings, and offer conflicting views.

51. *BioSafety Journal* (http://bioline.bdt.org.br/by) is maintained as a free online journal by Bioline International and Science and Technology Letters. The *Journal* presents original research, reviews and discussion papers focused on the effects of novel organisms - genetically manipulated micro-organisms, transgenic plants and animals and unmodified organisms which are alien to an ecosystem - on people and the environment. It will be concerned with the application of science, technology and regulatory processes in monitoring, defining and controlling effects that such organisms may have. So far, only volumes 1-4 (1995-1998) are available online.

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

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

(a) Means to avoid duplication of effort between information-exchange initiatives, and opportunities for collaboration with existing mechanisms for global information exchange on biosafety issues;

(b) Priorities and draft criteria to identify and establish cooperative arrangements with appropriate organizations, and resource implications of such arrangements;

(c) Possibilities for other interactions between the Biosafety Clearing-House and sources of relevant and appropriate information, and realistic timelines for their incorporation into the Biosafety Clearing-House.
