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MEETING OF TECHNICAL EXPERTS ON THE
BIOSAFETY CLEARING-HOUSE
Montreal, 11-13 September 2000
Item 3.3 of the provisional agenda*

PARTNERSHIP OPPORTUNITIES

Note by the Executive Secretary

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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.

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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.
