Note by the Bureau of the ICCP on technical issues associated with the implementation of the Pilot Phase of the Biosafety Clearing-House

A. Background

At its first meeting, held in Montpellier, France, from 11 to 15 December 2000, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) recommended the development of a pilot phase of the Biosafety Clearing-House (BCH) established by Article 20 of the Protocol. The ICCP identified a number of elements and steps to guide the development of this pilot phase whose objectives were defined by the Committee as follows: i) to build experience and provide feedback for the development of a functional and accessible internet based BCH, and to identify alternatives to the electronic system; ii) to identify and address capacity needs of countries with respect to the BCH (see report of the ICCP meeting as contained in document UNEP/CBD/ICCP/1/9, annex 1).

The ICCP mandated the Bureau to provide management oversight of the development and implementation of the pilot phase of the BCH and to draw upon appropriate technical advisory expertise to facilitate this development and implementation.

The present note contains recommendations made by a liaison group meeting of technical experts on the BCH convened at the initiative of the Executive Secretary from 19 to 20 March 2001 to provide advice on technical issues associated with the implementation of the pilot phase of the BCH. At its meeting held on 21 March 2001, the Bureau endorsed these recommendations and requested the Secretariat to convey them (as information note) to all Governments and invite feedback in order to ensure transparency in the development of the pilot phase of the BCH.

B. Recommendations

I. Guiding Principle

The prototype should be scalable and flexible so as to be able to accommodate future needs. The BCH should also include a disclaimer regarding the information it provides during the pilot phase.

II. Establishment of Central Portal

- Make the central portal available to users as soon as possible
- In the design of the central portal, use the elements referred to in Attachment 1

III. Central Database

- Associate all data in the system with comprehensive set of metadata
- Use a controlled vocabulary for the metadata descriptors
- Where possible draw descriptors from multi-lingual thesauruses to assist in future use of all six official UN languages
- Use information exchange protocols to allow interoperability among databases
- Continue to develop common formats along the lines of those attached (Attachment 2, Attachment 3) for review by the ICCP
- Bureau and make them available to countries for submission of information
- Develop a tool-kit to assist in the establishment of national databases, based on the common formats

IV. Partnerships

Partners with mandatory information (e.g. OECD/UNIDO)

In order to become partners with the BCH, these partners must follow specific guidelines for information sharing:

- Countries must indicate the partner institution which is responsible for hosting the specific information
- Partner institution must conform to the BCH interoperability standards including the "availability" of a "minimum" set of data fields/data sets
- Partners must guarantee maintenance, 24 hour/7 day availability and open access
- If availability "standards" are not reached or if partner does not wish to continue to provide information to BCH, all data/information subject to this partnership will be transferred to BCH/Secretariat

Partners with "non-mandatory" information (e.g. ICGEB)

- Partnership will be sought to "add value"
- Partners must follow specific guidelines for information sharing such as interoperability standards

V. Non-Electronic Access

- Options should address both provider and user
- Options should be country-driven (i.e. respond to country needs)
- First priority should focus on mechanisms to input data
- Prepare guidelines and templates to assist in the input of data (see Section II)

VI. Review

The attached indicators (Attachment 4) are a good basis for evaluation. They will be kept open for the independent review.

Biosafety Clearing-House: Central portal

Introduction to the BCH
- Background information
- Site map
- Glossary
- Frequently Asked Questions

National Focal Points

Competent National Authorities

National laws, regulations and guidelines
- Summary of regulatory system
- Links to laws, regulations and guidelines
- Bilateral and multilateral agreements

Decisions
- Decisions taken under the Advance Informed Agreement procedure
- Decisions on living modified organisms for food, feed and for processing
- Domestic decisions on environmental releases

Risk assessments

Biosafety research
- Link to ICGEB Biosafety bibliographic database and others

Biosafety Roster of Experts

Capacity-building projects

Search facilities
- Search by country or region
- Search by organism and trait
- Advanced search

Related web sites
- Links to OECD/UNIDO and other relevant national, regional and international databases and resources
- Cartagena Protocol on Biosafety
- Link to Protocol home page

Attachment 2

Draft Common Format for Movement of LMOs for direct use as food, feed or for processing (LMO-FFPs) (information required under article 11 from Annex II)

a) Applicant details:	Name	<text entry>
	Organization	<text entry>
	Postal address	<text entry>
	Country	<text entry>
	Telephone	<text entry>
	Facsimile	<text entry>
	Email	<text entry>
b) Responsible authority details:	Name	<text entry>
	Organization	<text entry>
	Postal address	<text entry>
	Country	<text entry>
	Telephone	<text entry>
	Facsimile	<text entry>
	Email	<text entry>
c) Identity of living modified organism:	Name	<text entry>
	Identity	<text entry>
d) Description of living modified organism:	Description of gene modification	<text entry>
	Technique used for modification	<controlled vocabulary for common techniques: plasmid carried by Agrobacterium tumefaciens, biolistic methods, electric shock (poration), osmotic shock, other> and <text entry - for further detail>
	Resulting characteristics of the living modified organism	<controlled vocabulary for common characteristics: agronomic properties, antibiotic resistance, bacterial resistance, fungus resistance, herbicide tolerance, insect resistance, marker gene, nematode resistance, product quality, virus resistance, other> and <text entry - for further detail>
e) Unique identification of the living modified organism:	Unique identifier	<controlled vocabulary: agreed international standards>
f) Recipient and/or parental organism:	Taxonomic status	<controlled vocabulary: agreed international standards>
	Common name	<controlled vocabulary with thesaurus>
	Point of collection or acquisition	<geographic coordinates> or <text entry>
	Characteristics of recipient and/or parental organism related to biosafety	<text entry>
g) Centres of origin and centres of genetic diversity:	Centres of origin of recipient and/or parental organism	<controlled: country/region name>
	Centres of genetic diversity of recipient and/or parental organisms	<controlled: country/region name>

	Description of the habitats where the recipient and/or parental organisms may persist or proliferate	<text entry>
h) Donor organism(s):	Taxonomic status	<controlled vocabulary: international agreed standards>
	Common name	<controlled vocabulary with thesaurus>
	Point of collection or acquisition	<geographic coordinates> or <text entry>
	Characteristics of donor organism related to biosafety	<text entry>
i) Approved uses:	Approved uses of the living modified organism	<text entry >
j) Risk assessments	A previous and existing risk assessment report consistent with Annex III	<link: see separate format>
k) Handling, storage, transport and use (include packaging, labelling, documentation, disposal and contingency procedures, where appropriate)	Suggested methods for safe handling	<text entry>
	Suggested methods for safe storage	<text entry>
	Suggested methods for safe transport	<text entry>
	Suggested methods for safe use	<text entry>

Attachment 3

Draft Common Format for Biosafety Laws, Regulations & Guidelines (Article 20.3a)

1) Country:	<controlled vocabulary from CBD: country list>
2) Jurisdiction:	<controlled vocabulary from CBD: country list> and <text entry, e.g. Scotland and Wales>
3) Title of document:	<text entry, e.g. Ugandan National Gene Technology Act>
4) Type of document:	<controlled vocabulary from Protocol: national law / national regulation / national guideline>
5) Subject area:	<controlled vocabulary from Protocol: Pharmaceuticals / Transit and contained use / LMOs for intentional introduction into the environment / LMOs for use as food or feed or for processing / Handling, transport, packaging and identification, etc.> or <controlled vocabulary from other sources: Contained use / Field trial / Placing on the market / Transit / Other>
6) Objective:	<Text entry e.g. "The objective of this Act is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.">
7) Scope:	<text entry e.g. "These regulations apply to the transboundary movement, transit, handling and use of all living modified plants that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.">
8) Date of entry into force:	<standard date format: YYYY-MM-DD>
9) Amendments:	<text entry and cross-reference link>
10) Official languages available:	<controlled vocabulary: e.g. English, French, Urdu>
11) Other translations and their status:	<text entry>
12) Location of document texts:	<specific types of entry: e.g. html or pdf or hyperlink or street address and/or official Gazette reference>
13) Regulatory contact:	<Standard contact address details: name, address, phone, fax, email>
14) Any other relevant information:	<text entry>

[+ name of submitter and date of submission to BCH]

Review of the pilot phase of the BCH

Suggested indicators for success:

Elements	*Indicators*
Principles	
Development to be guided by principles of inclusiveness, transparency and equity	• Number and variety (regional balance, access to Internet-based and non-electronic information, etc.) of governments participating in the pilot phase • Number and variety (regional balance, access to Internet-based and non-electronic information, etc.) of governments providing information to the BCH
Objectives	
To build experience and provide feedback for the development of a functional and accessible Internet based BCH	• Number and regional balance of governments participating in the pilot phase • Internet usage statistics
To identify alternatives to the electronic system	• Identification of alternatives to the electronic system • Effectiveness of the alternative mechanisms implemented
Identify and address capacity needs of countries with respect to the BCH	• Consultation with countries • Identification of capacity needs of countries • Establishment of mechanisms to address capacity needs
Characteristics	
Amenable to rapid development	• Responses to changing requirements
User-friendly, searchable and understandable	• Efficient search facilities • Effective guidelines for use of system • Standard key words / meta-data
Efficient mechanism for implementation of the requirements of the Protocol	• Inclusion of information required to implement the Protocol • Consultation with countries
Information to facilitate decision-making	Inclusion of the following information: • Information under the AIA procedures • Information on focal points • Information of national competent authorities • National legislation • Decisions • Risk assessment reports • Use of scientific information
Information for Article 11, paragraph 1 (LMO-FFPs)	• Inclusion of information specified in Annex II of the Protocol
Access to the roster of experts	• Availability of roster of experts • Searchability of roster of experts
Elements required to implement the pilot phase	
Central portal	• Establishment of central portal • Consultation with countries

Central database	• Establishment of the central database • Information from countries without a national database • Information sent from countries without an electronic infrastructure • Information required to implement Article 11, paragraph 1 • Searchable indexes of information to facilitate decision-making, including that required under the Advance Informed Agreement procedure
Linkage of central portal to national, regional and international databases/nodes	• Number and regional distribution of national, regional and international databases/nodes identified and linked • Level of interoperability between databases
Common formats for information	• Creation of common formats for data reporting for major categories of information • Consultation with countries
Recommendations in the Annex	
Administrative	• Creation of appropriate administrative arrangements with relevant international organizations • Use of existing information systems as models for implementing the obligations under Article 10 and 11, paragraph 1 of the Biosafety Protocol
Access of all countries to existing databases	• Use of best practices
Oversight and management	• Consultation with Bureau
Technical implementation	• Use of appropriate technical advisory expertise • Number and regional balance of Governments facilitating establishment of linkages to the BCH
Monitoring and review	• ICCP-2 report on the progress of the pilot phase • Outcome of independent review of the pilot phase • Outcome of technical experts meeting to review the pilot phase
Capacity building	• Number and regional balance of governments who have submitted their priority needs to the Executive Secretary regarding capacities • Identification of capacity-building needs of those countries to be linked to the Biosafety Clearing-House • Identification of measures to establish a capacity-building programme addressing those needs • Preparation of report analyzing identified capacity-building and financial requirements of countries in the specified categories • Circulation of the above information to the appropriate organizations with a role in capacity-building
Languages	• Ability of pilot phase to enable the use of all six official United Nations languages at a later stage
Resources	• Amount of financial support and appropriate technical assistance received from developed country governments and other donors

Project plan	Inclusion of the following elements in the pilot phase: • Establishment of the central portal • Creation of appropriate administrative arrangements and partnerships with other international organizations and governments • Identification of relevant databases and resources, and links established where appropriate • Establishment of central database(s) • Identification and development of appropriate common information formats and search mechanisms • Incorporation of mechanisms for adapting existing systems to conform to BCH requirements • Preparation of a report assessing the capacities of all interested governments • Development of a mechanism for non-electronic information-sharing
Timing	• Initiation of all elements of the project plan within one month of availability of resources
Work plan	• Development of a work plan for completion of all tasks in a timeframe that allows for relevant consideration by ICCP-2
Government submission of appropriate information	• Time taken for governments to submit appropriate information (no later than three months after ICCP-1)