Independent Evaluation of the Biosafety Clearing-House Pilot Phase Implementation

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Summary

The Pilot Phase Implementation of the Biosafety Clearing-House has achieved an admirable state of advance to provide an information base for the Biosafety Protocol. The technology employed represents state-of-the-art distributed database approaches, which are now sufficiently stable, efficient, and accepted to serve as the basis for an Internet-based Biosafety Clearing-House. Shortcomings of the Pilot Phase implementation of the Biosafety Clearing-House include the need for greater focus on user needs, particularly related to help facilities, ergonomics, download speed, and content oriented at the needs of all users. The assessment of capacity needs and preliminary training efforts connected with the Pilot Phase have been somewhat less successful, lacking seriously in careful design oriented at assessing and meeting the capacity needs of countries involved, particularly with regards to longer-term needs, immediate needs of seed-funding and training, and pedagogy.

1. Introduction

The Intergovernmental Committee for the Cartagena Protocol (ICCP) decided that the Biosafety Clearing-House would be established in a phased manner, beginning with a Pilot Phase¹. Their recommendation was that this pilot phase be guided by principles of inclusiveness, transparency, and equity, be open to all governments, and would address mechanisms for information-sharing by means both electronic and non-electronic. In particular, two objectives were identified²:

- 1. To build experience and provide feedback for the development of a functional and accessible Internet-based Biosafety Clearing-House; and to identify alternatives to the electronic system.
- 2. To identify and address the capacity needs of countries with respect to the Biosafety Clearing-House

The ICCP also requested that the Executive Secretary commission an independent and transparent review of the pilot phase implementation; hence, at the request of the Executive Secretary, the purpose of this report is to provide said review for the third meeting of the ICCP.

In preparing this report, I organized my consideration around the indicators suggested by the ICCP as indicative of a successful Pilot Phase implementation³. I based my opinions and findings on four principal sources of information, as follows (not ranked in any particular order of importance):

- Interviews, queries, and discussions with the Secretariat.
- Testing and inspection of the Pilot Phase website⁴.
- Attendance and observation of the CEE and Asia-Pacific regional meetings to determine capacity-building needs for implementation of the Pilot Phase.
- Communications (via personal interview, e-mail, and telephone) with delegates from numerous countries to four capacity-building meetings (Africa, GRULAC, CEE, and Asia-Pacific regions), as well as with WEOG representatives and relevant nongovernmental organizations and industry representatives

Based on impressions formed from these investigations, I have assembled the report that follows. The overall purpose of the report is to provide an independent evaluation of the Pilot Phase implementation of the Biosafety Clearing-House, in the hope of identifying both positive and negative points in its design and presentation. Although the report is designed principally to identify these positives and negatives. I have at numerous points in the report made suggestions as to possible remedies for negatives: These points are highlighted with an 'action arrow' ► ... in this way, the reader may choose to focus on these recommendations, or ignore them as he or she chooses.

¹ Annex 1, UNEP/CBD/ICCP/1/3. ² Annex 1, UNEM/CBD/ICCP/1/9.

³ http://bch.biodiv.org/doc/NoteBureauattachment4.pdf.

⁴ http://bch.biodiv.org.

2. The Internet as a Solution to the Clearing-House Challenge

General considerations.—It has been said that the Biosafety Clearing-House represents the first instance in which new information technologies are used towards the fulfillment of major international treaty obligations. Caveats could be given both to the idea of "first instance" and to the idea that the Internet is the *only* basis for the Biosafety Clearing-House. However, that the Internet is likely to be a critical element in fulfillment of countries' obligations under the Biosafety Protocol is enormously clear.

In this sense, contemplating implementation of the Biosafety Protocol across a great diversity of countries, at least five considerations become critical: (1) *access*, (2) *speed*, (3) *reliability*, (4) *security and information integrity*, and (5) *information interchange policies*. Each of these considerations is a *sine qua non* for implementation of the Biosafety Clearing-House: without an effective solution to all, the Biosafety Clearing-House as presently implemented will not prove an effective medium for fulfilling obligations under the Biosafety Protocol. These considerations are, to provide a bit more detail, as follows:

Access – Internet access is considerably more feasible and more universal each year. New technologies such as satellite-mediated access make conceivable the idea of universal access. Nevertheless, the expense involved, as well as the practicalities of installing and maintaining new and unfamiliar equipment, make it clear that access among potential parties of the Biosafety Protocol will not be universal, at least in the initial years of the Protocol (Figure 1, Box 1). Indeed, almost 14% of delegates to the Biosafety Clearing-House capacity-building sessions did not provide e-mail addresses in the participant listsalthough some may simply

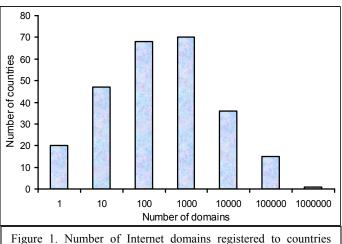


Figure 1. Number of Internet domains registered to countries worldwide. Note that the International domains (e.g., com, edu) are excluded, as are countries for which no domains are registered. Source: <u>http://www.domainstats.com/</u>, updated 2001.

Box 1. Africa Connectivity Statistics (August 2000)

- 54 countries and territories
- All have public local dialup service in capital city
- Only 9 have only one public access full service ISP
- 35 have no local ISPs or POPs for dialup access in cities other than capital

• 44 lack any Advanced Data Services Source: http://www3.sn.apc.org/africa/partial.html.

not have had the information at hand, this number nonetheless suggests that e-mail is

not a feature of everyday life for all of the countries involved in the Biosafety Clearing-House.

• *Speed* – The first-level requirement of access, of course, is but part of the challenge. To be able to use complex web pages and search engines, and (still worse) to be able

to *serve* data effectively, a connection that is sufficiently fast to permit efficient movement of information into and out of a country becomes critical. Files of just a few megabytes can be prohibitively large if connections are slow, making a modern web facility (such as the Biosafety Clearing-House pilot implementation) all but useless.

- *Reliability "24/7"* Although the Internet has seen impressive improvements over the past decade, its service is still not guaranteed. Of course, whereas this same criticism can be levelled at other technologies (e.g., mail, telephone, fax), the potential for problems ("our connection is down") still exists and is probably greater with the relatively novel Internet. Indeed, during the preparation of this report, the Biosafety Clearing-House website was 'down' at one point at which I needed access! This potential for problems is particularly significant in developing countries.
- Security An additional consideration is that of the security of the information served over the Internet. This consideration really splits into two parallel concerns—one that the website may be attacked by hackers or infected by viruses, and the other that the information could be corrupted or amended without authorization. Regarding the first concern, for example, the *Species Analyst* website (another international distributed database concerning biodiversity) was hit and at least partially disabled by viruses twice in 2001 alone! Malicious corruption of Biosafety Clearing-House data for some motivation is perhaps the darker of the possibilities, and yet is not inconceivable.
- Information interchange policies A final consideration is that of countries' policies regarding information exchange and intellectual property rights. This issue is potentially a serious one, in which certain countries may have legistlation that makes free and open access to certain types of information difficult or impossible. Although this issue was frequently mentioned to me and mentioned in documents⁵, none of the countries' delegates with whom I talked or interchanged e-mails mentioned any such problem. Indeed, the answer to my specific question regarding such complications was, without exception, negative. Hence, this issue does not appear to be a serious challenge for the implementation of the Biosafety Clearing-House.

These considerations, taken all together, suggest that the Internet *can* serve as the critical technology for an international agreement like the Biosafety Clearing-House. However, a number of challenges will remain to be solved before this technology can pass from prototype to final product. In particular, \blacktriangleright funds must be invested in Internet access at appropriate speeds, \blacktriangleright security and failsafe procedures must be tested and implemented and \blacktriangleright replicate webservers (mirror sites)⁶ established so that information is always available in appropriate condition when needed.

Making information come alive – true *interoperability.*—The issue of interoperability is critical to making information useful. That is, a simple list of Web links indeed provides access to diverse information sources, but that access is very inefficient. A user would potentially have to visit each link, and develop a query for each

⁵ UNEP/CBD/BCH/LAC.Reg/1/2 p. 4.

⁶ UNEP/CBD/BCH/Afr.Reg/1/2 p. 10.

appropriate information source. A much better solution is to use a technology that permits a single query to sweep through all of the information sources, and encounter all items that are relevant.

Three considerations must be weighed, if this true interoperability is to be achieved:

- <u>Distributed nature of information</u> Information is best kept where it is generated or curated: that institution or those individuals that generate or care for a data set are likely to be the best long-term caretakers of that information. In this way, updates can be made, information can be edited, errors can be corrected, and no 'disconnect' ever arises between versions of the dataset. Hence, an ideal system is distributed in nature, with information sources spread worldwide, and not (or rarely) centralized, with information distant and disconnected from those who generate and curate it.
- <u>Transparency of information among classes</u> Information often consists of different classes with very different characteristics. For example, information to be served in the Biosafety Protocol includes legal documents, taxonomic information, DNA or RNA sequences, and human contact information, among other items. This diversity requires careful attention to connections that exist among information classes, and making certain that information is presented in formats that are mutually compatible and intertransparent.
- <u>Controlled vocabulary</u> Finally, controlled vocabularies provide a 'taxonomy' of ideas and elements that permits efficient data entry and efficient data retrieval, ready translation among the six official United Nations languages, and efficient linking of information sources. We might imagine a legal document linked to a contact person via a name, and to taxonomic information via a Latin binomial chosen from a worldwide taxonomic database, which in turn permits linking taxonomic information with a DNA or RNA sequence. This interoperability truly comes alive when links among classes of information are chosen from controlled vocabularies that keep efficiency high and redundancy nil. The controlled nature of the vocabulary makes translation among the six United Nations languages straightforward.

If all of these considerations are effectively implemented, new classes of results become possible. These new classes have been referred to as 'emergent properties': insights that were impossible with single information sources, but that become attainable once diverse information sets are integrated. In the case of the Biosafety Clearing-House, these emergent properties will include profoundly informed decisions and proposals regarding movements of LMOs among countries by all parties involved.

The Pilot [Internet] Implementation of the Biosafety Clearing-House.—In general, the implementation of the Pilot Phase of the Biosafety Clearing-House provides an excellent technological solution to these challenges. That is to say, the set of protocols and formats that were selected as the technological basis for an Internet-mediated, distributed biosafety information resource are completely appropriate, and appear to be the best solutions available at the present time.

The considerations listed above that are not a function of national infrastructure (i.e., access and connection speed) or the Internet in general (i.e., reliability) include security and information integrity, interoperability, distributed design, intertransparency of information types, and a controlled vocabulary. The RDF/SOAP combination as a means of serving, linking, and integrating the diverse information types that come within the purview of the Biosafety Clearing-House is as ideal as can be: now relatively stable and broadly accepted as a worldwide standard, and provides the interoperable, distributed, intertransparent, controlled-vocabulary environment that is needed for the Clearing-House. Indeed, not only several other biodiversity-related efforts with which I am familiar, but also the excellent Bulgarian national biosafety effort, have arrived at quite similar solutions. This coincidence not only suggests that the one chosen by the Biosafety Clearing-House team is the best available, but also that new levels of integration may be possible via connecting and integrating these large-scale projects.

An important measure not in the present implementation of the Pilot Phase is that of \blacktriangleright 'light' download options. For example, documents presently available only in HTML format could also be served as text-only (of course, at cost of any graphics that might be embedded) ... the savings in a few tests that I did were 25-50%, which would translate into 2-4 times faster downloads (comparing the HTML files served with simple ASCII text). Another possibility is that of serving zipped files (using WinZip), which again yields considerable space savings, which translate into faster information transfer. Although of course these options will not function for all document types (e.g., extraction of text from Adobe Acrobat pdf files), nevertheless they can serve to reduce restrictions imposed by slow Internet connections.

Alternatives to the Internet in the Biosafety Clearing-House.—Although the Internet-based implementation developed by the Biosafety Clearing-House team is indeed an excellent one, the initial considerations of access and speed of access to the Internet suggest that alternative solution to the Internet should be considered, and implemented to the extent that countries so require.

Two sides exist to the non-Internet challenge: providing and receiving data. On the data provider side, the Pilot Phase of the Biosafety Clearing-House has made ample provisions for accepting, computerizing (if necessary), and serving data from countries unable to use the Web interface or serve their information directly. Possibilities include transfer of information by telephone (perhaps risky owing to potential for errors in transcription), fax, or e-mail. Presumably, hard copies submitted via regular mail would also be accepted.

On the receiving end of the information, the challenge is more varied. Users may not *know* what information they require without interacting with the dataset first: that is, a user may wish to browse the information to encounter what information is genuinely useful to him or her. Hence, a diversity of solutions may prove necessary.

Among the solutions that the Toolkit lists as available (although presumably not all are fully implemented) are (1) printed summaries or CD-ROMs to be circulated at regular intervals; (2) response to requests via phone, fax, or post; regional help desks and other online information centers; and document distribution systems (implemented via phone, fax, email). Of these possibilities, a perhaps-optimal combination might prove to be \triangleright regular "publication" of at least the nucleus of the Biosafety Clearing-House to CD-ROMs for countries that so require (to provide for everyday reference), along with a system for immediate delivery (fax, email) of specifically requested documents (to provide for specific, immediate, and up-to-the-minute needs. Of course, publication of CDs from a distributed database system will require \triangleright development of some sort of broad scan harvesting module to create a temporary centralized database (modules of this sort have been developed as part of the LifeMapper application⁷ at the University of Kansas Natural History Museum and Biodiversity Research Center). Printed summaries, although mentioned as desirable by several countries, would likely prove an unsatisfactory solution, given the difficulty of indexing and connecting items of information.

General commentary and conclusions regarding Internet solutions.—This first section of this report has covered a diversity of questions related to the Internet as an appropriate medium by which Biosafety Protocol commitments can be fulfilled. In general, with the advent of new technologies for Internet connectivity, no reason other than financial considerations should impede full Internet connectivity for any country around the world. In this sense, to the extent that international cooperation under the aegis of the Biosafety Clearing-House can result in financial assistance for developing economies, no excuse should exist for anything but full connectivity for each party in the agreement. Nevertheless, given more practical considerations, Internet access, or at least sufficiently rapid Internet access, may not be universal, and so the alternative steps discussed above may be quite helpful.

3. Website Implementation of the Pilot Phase of the Biosafety Clearing-House

The site that has been established as the manifestation of the Pilot Phase of the Biosafety Clearing-House⁸ is in general attractive, well-designed, and functional. That is, in general, a user can enter the site, and find what he or she seeks with little problem. Overall, the site as constructed is also scalable and flexible, meaning that it will be able to grow and adapt as technologies and data structures evolve. This attention to design considerations, combined with the appropriate underlying technology (see above), makes for a useful and functional facility.

A few details, however, merit comment, to fix a few last and relatively minor problems. Most are oriented at making the site more user-oriented and user-friendly. First, regarding the general make-up and design of the page:

• ► From the standpoint of providing a complete picture of the thematic material to be treated, the Biosafety Protocol site⁹ needs to be placed *within* the Clearing-House, at least virtually. That is, more obvious links to the Protocol site would provide users of the Biosafety Clearing-House site with a richer picture of the overall topic.

⁷ <u>http://beta.lifemapper.org/</u>.

⁸ http://bch.biodiv.org.

⁹ <u>http://www.biodiv.org/biosafety/</u>.

- ► "BCH" as a link reference to the Biosafety Clearing-House on the Biosafety Protocol website is not enough. It must be borne in mind that acronyms are most difficult for persons who are not native speakers of a language. Even for native speakers, myself included, confusion may stem from the "Biodiversity Clearing-House" or "Biosafety Clearing-House", either of which could be the "BCH." Adding more explicit tags on the links would solve this problem.
- ► The help and comment facilities seem to be adequate. Discussions with the Secretariat suggest that the design is actually quite nice (any messages arriving go to four persons, of whom the most appropriate responds). All the same, I sent a query as to where would I find a copy of the Biosafety Protocol on 6 February 2002, and did not receive a response ... unless my email was recognized, and for that reason not responded to, it may be worth checking to make certain that the system works. Eventually, with the Biosafety Protocol in full implementation, a full-time "help desk" staff member may prove necessary.
- ▶ While the content of the Toolkit is really quite excellent (see comments below), I worry that it may not be referred to sufficiently. The Toolkit really serves two very different purposes: (1) as a technical reference toolkit and manual, and (2) as a background document for many important issues ("What is Metadata?" for example). Hence, I think that this excellent resource might be much more useful if certain portions were assembled into a "short background course," others into a "technical manual," etc. Indeed, the Bureau¹⁰ has already suggested that the tool-kit be adapted with a search engine, that the intended audience of each module be elucidated, that links be constructed between specific sections of the BCH and appropriate sections of the tool-kit, and that the tool-kit be made interactive whenever possible. That is, this same information resource, virtually reassembled into a series of different resources, can be maximally useful to users.
- ► Speed of response of the website sometimes seems rather slow. Assessment of the connection speed and server capacity at the Secretariat may be a useful step. Also, providing a stripped-down 'light' version of this website would allow those with slower connections to avoid frustrating delays.
- ► Security and data integrity are not presently assured via running checks on data stability. Perhaps a functionality of caching a version of critical data weekly could provide the possibility of comparing this week's version against last week's version to detect any unauthorized changes. This functionality, which is not presently implemented, could flag data that might be either corrupted or altered in some way. Such a feature is at the very least worthy of exploration.

Again, these details are minor in nature. Fixing, or at least reexamining, them would only make an excellent web facility better.

Data queries.—On the 'user' side, in general, finding things on the Biosafety Clearing-House website is quite easy. The website is logically constructed, and the query

¹⁰ 10 Oct 2001 *Notes from the Bureau*.

facilities are obvious, usable, consistent in structure and use, and largely self-explanatory. The search engines work rapidly, and return results in a highly usable format. Standard keywords are provided from nicely prepared picklists, so that idiosyncratic terms are difficult to insert.

On the negative side, not many issues need to be mentioned. As mentioned above, \blacktriangleright a help section could be developed from the existing tool-kit. Perhaps needed would be more immediate 'help' items: e.g., in the query-building screens, it is unclear as to how one would construct boolean queries (X and Y). \blacktriangleright Overall, the search facilities could be rethought with an idea to user needs ... what are the questions that users will ask? Also, \blacktriangleright if search results could be ranked by importance (e.g., national biosafety frameworks above specific risk assessments above non-official information), search results may be more generally useful. Finally, \blacktriangleright an option for a second search at the end of a particular document that would provide 'related links' might encourage more in-depth research and reading.

Data-sharing.—As detailed above, the technology underlying this website and query facilities is excellent, providing an interoperable, efficient, and stable platform for integrating diverse information sources over the Internet. Of course, these technologies require a fair amount of expertise with computer applications, so a variety of tactics were adopted to make the site usable to all potential parties wishing to share data.

The array of options for data-sharing available is appropriate. It ranges from lowtechnology solutions that are available to every party worldwide to high-technology implementations that are more complex to put into function. The toolkit appropriately describes each of three distinct technological solutions that permit parties to share data via the Biosafety Clearing-House: (1) submission by fax, hard copy, or e-mail, for processing and integration by the Biosafety Clearing-House; (2) submission via a webbased form; and (3) full interoperability via the Simple Object Access Protocol (SOAP) version 1.1. Clearly, the lowest-technology solution is also the least flexible, and keeps the data remote from the party, whereas the highest-technology solution is much more flexible, and keeps the data in the possession of the party.

Descriptions of steps necessary for each level of technology are appropriate. Certainly, the low-technology approach is attainable by any party anywhere, and instructions are sufficient. For more complex solutions, instructions are [correctly] geared to those with expertise in those fields that is, the purpose of the tool-kit is *not* to get untrained people working with XML technology (much better courses exist for that); rather, the tool-kit must function to let XML-trained people connect data sets to the Biosafety Clearing-House. Indeed, I queried a capable database programmer at the University of Kansas as to the appropriateness of the tool-kit's instructions for the RDF/SOAP solution; his response indicated that the instructions could indeed be followed by an appropriately trained technician.

4. Content of the Pilot Phase of the Biosafety Clearing-House

experts.

The thematic content of the Biosafety Clearing-House is a critical point: why create an information Clearing-House if the information content is not of interest or use to potential users. Careful thought must go into the thematic content of the site, the ways in which users will wish to use it, and the types of users that will be using the site. For instance, users who are working towards new national legislation will wish to review laws from countries around the world that deal with parallel topics, whereas users doing risk assessments may wish to see information regarding the behavior and impacts of a particular LMO in past introductions around the world, and users focused on national biosafety strategies may wish to see exact DNA sequances by which to monitor for a particular gene (see in particular GRULAC #7, Appendix I). This consideration of user needs should provide a critical guide to the development of the Biosafety Clearing-House.

| Information Type Existing laws, regulations, and | Appropriately served in Pilot Phase? |
|--|---|
| Existing laws, regulations, and | |
| guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure | Yes |
| Any bilateral, regional and multilateral agreements and arrangements | Yes |
| Summaries of risk assessments or environmental reviews of living modified organisms generated | Yes |
| Final decisions regarding the importation ore release of living modified organisms | Yes |
| Reports submitted pursuant to Article 33, including those on implementation of the advance informed agreement procedure | No |
| | the Protocol, as well as information required by the Parties for the advance informed agreement procedure Any bilateral, regional and multilateral agreements and arrangements Summaries of risk assessments or environmental reviews of living modified organisms generated Final decisions regarding the importation ore release of living modified organisms Reports submitted pursuant to Article 33, including those on implementation of the advance |

Mandatory information.— Within the context of an appropriate technology

Table 1. List of information types that are mandatory as part of the Biosafety Clearing-House, Article 20.

Other information sets mentioned in the Biosafety Protocol are not included in the Pilot Phase at all. For example, Article 25.3 states that parties will make available information concerning cases of illegal transboundary movements; Article 26.2 encourages parties to cooperate and exchange information on socioeconomic considerations; and Article 17.2 lays out information content regarding notifications of unintentional transboundary movements of living modified organisms. These information sets, while specified in the Protocol, are not included in the Pilot Phase implementation.

Population of the basic data content of the Pilot Phase implementation of the Biosafety Clearing-House by countries has been uneven (Table 2). That is, with the basic information, for instance, such as national focal points, an impressive 89 countries have provided information to the Clearing-House. For other information types, however, such as laws, regulations, and guidelines, only 29 countries have supplied information. Finally, several information types (e.g., decisions under AIA, risk assessment summaries) remain unpopulated.

Nevertheless, it should be borne in mind that the Clearing-House remains in a Pilot Phase, and countries are not yet required to provide information. the Biosafety Once Protocol takes effect, broader population of the Clearing-House is to be expected.

| Data type | Number of | Number of |
|---------------------------------------|--------------|--------------|
| | countries | records |
| National focal point | 89 | 112 |
| National competent authority | 26 | 74 |
| National biosafety database | 9 | 18 |
| Laws, regulations, and guidelines | 29 | 35 |
| Regional and international agreements | 0 | 0 |
| Decisions under AIA | 0 | 0 |
| Decisions under Article 11.1 | 1 | 1 |
| Risk assessment summaries | 0 | 0 |
| Capacity-building projects | | 57 |
| Roster of experts | | 411 |

Table 2. Current status of Biosafety Clearing-House in terms ofpopulation of data by countries.

Non-mandatory information.—Article 20.1(a) states that Parties should "Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms." This exchange, to the extent that it should be mediated by the Biosafety Clearing-House, has been emphasized less in the Pilot Phase. Although links to other biosafety-related sites are included, they are just hyperlinks, and not integrated fully into the interoperable search and query mechanism.

Although some may (and have, in the course of my research) suggest that the Protocol's mandate is unclear on the need for such information sets, the ICCP was indeed clear¹¹: partners with "non-mandatory" information will be sought to "add value" to the information facility (the example given was ICGEB). Indeed, the ICCP later suggested¹² allowing organizations undertaking biosafety-related activities to register relevant websites on the BCH, adding the opportunity for still more content to the Pilot Phase. Potential information sources are manifold:

¹¹ 30 March 2001 Notes from the Bureau.

¹² 10 Oct 2001 Notes from the Bureau.

- ► *Bibliography* at present, only a hyperlink to ICGEB is available. This connection could easily be made much more vibrant via a live XML link. Moreover, the ICGEB database is relatively small, and is not up-to-the-minute, so connection to additional bibliographic sources would be desirable.
- ► *Related web-sites* rich sources of information related to biosafety are available at sites such as those of UNIDO and OECD, which are hyperlinked to the Biosafety Clearing-House. Again, exploration of the possibility of a live XML link would greatly enhance the functionality and utility of this linkage. Communications with the Secretariat indicate that such explorations of full interoperability are presently under discussion
- ► *Taxonomic information* the ICCP called for linkages with existing initiatives such as the Global Taxonomic Initiative to provide common names¹³ for organisms referred to in the Biosafety Clearing-House. I would suggest that this idea be amplified greatly. Linkage with taxonomic (e.g., GTI, ITIS¹⁴, Species2000¹⁵), phylogenetic (e.g., Tree of Life¹⁶), and biodiversity information (e.g., REMIB¹⁷, TSA¹⁸) (see comments by GRULAC #2, CEE #1) databases, allowing new functionalities: free movement between common and scientific names, examination of effects of close phylogenetic relatives, analysis of geographic distributions of related species, etc.
- ► Web search engines Although information is less controlled, and must be appropriately filtered. Web search engines can provide a rich source of information regarding issues of interest. For example, using Google¹⁹, I found 123,000 links related to biosafety and 1.9×10^6 links related to biotechnology, and on Yahoo²⁰, I found 89,700 links related to biosafety, and 769 for biotechnology. This information, appropriately qualified given its provenance, can serve excellently to enrich the overall information resource.
- ► Funding opportunities The current implementation includes a section entitled "Biosafety Capacity Building Projects and Other Initiatives" within a Capacitybuilding link. This section, nevertheless, does not distinguish well between opportunities for parties to seek funding, and the projects that are already funded or even completed. While both types of projects appear to emerge in the results, and one can search by project status, the elements served are quite different both in content and in expected audience. It would be quite a service to the less-developed Parties to provide a more specific funding opportunities portal.
- ► Training opportunities Similar to Funding opportunities ... a specific (virtual, distributed) compendium of training opportunities would constitute an important

 ¹³ 10 Oct 2001 Notes from the Bureau.
¹⁴ http://sis.agr.gc.ca/pls/itisca/taxaget?p_ifx=plglt.

¹⁵ http://www.sp2000.org/.

¹⁶ http://tolweb.org/tree/phylogeny.html.

¹⁷ http://www.conabio.gob.mx.

¹⁸ http://speciesanalyst.net.

¹⁹ http://www.google.com.

²⁰ http://www.yahoo.com.

improvement to the site. These last two suggestions may require some adjustments to the controlled vocabularies that underlie this sector of the information facility.

Other.—Finally, several other elements requested by the ICCP are implemented, and are to varying degrees in acceptable condition. For example, the disclaimer about the preliminary, non-binding nature of the Pilot Phase implementation is okay, as is the site map (= "Table of Contents") that can be used as an introductory page. A help desk and help facility is basically not present ... to some degree, the Tool-kit helps, but is not structured as "I am lost, help me" but rather "I need to read up on" ... the actual wording in one example is "Please consult Module 1 of the Pilot Phase of the Biosafety Clearing-House Toolkit for further information on using this function." As detailed above, minor modifications to the structure of the Toolkit can create an effective help desk facility without too much difficulty.

5. Capacity-building: Small- and Large-scale, Short- and Long-term

The Regional Meetings on Capacity Building for the Biosafety Clearing-House included introductory workshops intended to identify needs for capacity-building. As such, these meetings focus principally on identifying needs, and not on actual capacitybuilding; still, a thorough introduction to the Pilot Phase implementation is provided, and participants are helped to explore the work done to date. Hence, below, I comment on the overall design and content of these capacity-needs-identification sessions under the general rubric of 'capacity-building.'

Capacity-building is a most difficult challenge, as it has many and diverse dimensions, and very different meanings for different people or institutions. In a short-term view, it may mean learning how to use a particular software tool, whereas in the long term, it may include assuring financial stability or appropriate staffing for an entire institution. Whereas both of these manifestations of 'capacity-building' are important, the critical step is that of bridging the gap between the two. If a connection is not built, the delegate learning the software tool sits and thinks, "yes, but back in my country, I still have no staff, no computer, no Internet connection, and no future funding!" and does not pay full attention. Although both extremes of the spectrum (short *versus* long term) are treated in the current sessions (e.g., the Nitra and Beijing meetings that I attended), the short term is overemphasized, the two are not adequately connected, and indeed neither is particularly well designed.

The critical need is careful pedagogical design. That is, a training course must be designed with the needs, interests, and skill levels of those to be trained in mind. One does not just stand up in front of a group and say, "here is the tool and here is how to use it." Rather, needs of the trainees must be integrated with activities and challenges that are interesting and stimulating to the participants. Lesson plans would help greatly help, as would planned, applied activities, as well as a framework for discussing longer-term needs and action items. ► Take-home handouts (not just printouts of PowerPoint presentations) that are packed with useful information would be enormously useful (one delegate actually wrote me to ask for the URL of the Biosafety Clearing-House after the

regional meeting!). \blacktriangleright Presentations by NGOs and delegates from other regions should be integrated components in these sessions, rather than add-ons without a clear purpose—in particular the former were seriously distracting from the central purposes of the meetings. Without a doubt, \blacktriangleright addition of discussions of biological issues related to the BCH by a biologist well-versed in issues related to LMOs would add helpful dimensions. In addition, \blacktriangleright separation of the 'training' side of these capacity-building efforts from the needs-assessment side would reduce the emphasis on report-writing, as opposed to real training and operational capacity-building. As it is, the training for both trainees and trainers.

Short-term capacity-building.—This part of the Pilot Phase implementation—that of providing a basic introduction to the BCH Internet facility—is that which needs the most drastic reworking. As it is at present (e.g., Nitra and Beijing courses), it is carried out at the end of a long meeting, some trainees are bored because material is much below their abilities, and the training is more rote process learning than anything designed to excite and engage the trainees. Watching, and talking with a number of the delegates, I have a number of suggestions.

- ► Stand-alone training session The Nitra and Beijing training sessions were implemented back-to-back with other meetings. Although certainly economies of scale were achieved in the financing of this combined meeting, the function of both was clearly compromised, as delegates were already tired by the beginning of the meeting.
- ► Appropriate trainee groups If training sessions can be separated from political meetings, then it becomes possible to focus more closely on the most appropriate individuals for training. In particularly small and less developed countries, a single person might be both national biosafety focal point and data-entry technician and reporter to the Clearing-House. However, in most countries, the national biosafety focal point may have a trusted assistant who is in charge of the informatics end of the challenge. Training should be focused on these persons ... the people who will actually carry out the work.
- ▶ Divide by skill level Even within the appropriate trainee groups, marked variation will exist in the skill levels of different participants. Some are true beginners, needing help with the basics of using a Web-based software package, whereas others have ample expertise in informatics-related work. As implemented in Nitra, teaching the use of the Biosafety Clearing-House to all of these people together serves only to bore the experienced participants. I would suggest that the trainees be divided up into at least two groups: experienced people for advanced discussions of XML, RDF, and SOAP technologies, and beginners for a more basic introduction. In this way, all of the trainees would come away with a tangible set of new experiences.
- ► Activities and challenges Training courses must do more than just show the use of a tool. In fact, training should give general concepts (e.g., how to use the search tools in general), rather than repeating similar tasks (e.g., here is how to use the national focal point search tool, now here is how to use the national competent

authority search tool, etc.). Even more importantly, though, trainees must be interested ... that is, some manner of grabbing their attention must be sought out and developed.

One possibility may be the use of applied challenges. For instance, for trainees with the Biosafety Clearing-House, it may be possible to develop a series of training exercises that simulate real-life situations in which they would use the tools. For instance, industry representatives from the region could be invited to come and mock-propose an importation of a LMO, and participants could use the Biosafety Clearing-House facility to gather information and prepare a response. The point is that of *using* the tool for something engaging, rather than simply to learn the basic function of the tool.

• ► Framework for future – Although a major component of the Biosafety Clearing-House capacity-building effort is that of identifying future needs, the group effort towards this end is quite unorganized. Of course, in a U.N.-sponsored setting, this sort of needs-identification effort must be impulsed by the delegates. However, if they are asked to achieve this without an appropriate framework, then each product will be idiosyncratic, little comparable, and less useful overall. I would suggest that brainstorming ideas be developed, within an appropriate structure, that help people think of their needs. I have seen excellent exercises of this sort in the United States, in which a professional 'facilitator' guides a group through a priority-setting exercise. Drawing on some of these techniques could be quite productive.

Bridging short- and long-term goals.—The training course, as presently implemented, offers no concrete connection between short-term and long-term objectives. Because of this 'disconnect,' trainees can come away with a sort of hopelessness ... using the tool worked fine in Nitra or Beijing, but may be hopeless in their own offices. One ends up not seeing much hope, other than that long-term goals

may see funding within a few years. This attitude is not positive, and does not promote sustained interest and activity by delegates.

From my conversations with delegates (see Box 2 and Appendix I), the critical bridge is that of immediate funding opportunities. Both the training course and the website implementation neglect this point. The training course could easily include components of 'funding opportunities' and 'training opportunities.' and present the delegates with a list of possibilities and contacts for obtaining small-tomedium-scale resources with which to

Box 2. Longer-term priorities mentioned repeatedly by delegates:

- Computer hardware and software
- Internet connectivity with appropriate speed of connection
- Personnel to implement informatics activities
- High-level training (both intense courses and graduate training at the Ph.D. level) for biosafety personnel in informatics activities
- Sustained funding for national participation in the Biosafety Clearing-House
- Promotion of subregional and regional integration of biosafety-related activities
- Ability to assess potential risks in LMO importations autonomously ... e.g., facilities, funding, staff, and training for risk assessment activities

'get started.' (The website could use some reorganization to emphasize this point as well, see above.) This step would also give delegates something to take home that is immediately useful to them.

Long-term goals.—Long-term goals are simultaneously easy and difficult to address. As assessed in the training courses and in the UNEP/GEF workshops, countries know quite well what their longer-term priorities are (see Box 2), and the comments of delegates with whom I spoke were remarkable uniform. The coincidence of ideas and needs among regions and among countries is close, suggesting that, in general, similar concerns apply across the world.

That is, of course, the hard part as well. Countries around the world will require ample funding in order to participate fully in the Biosafety Clearing-House. Countries do not wish just to send off their data for serving from Montreal, to be able to fulfill their legal responsibilities under the Biosafety Protocol. Rather, they wish to be able to be full participants, serving and using information freely. This goal is, of course, a major challenge, and will require enormous investment of time and resources. \blacktriangleright Incorporation of idea-generating regarding long-term sustainability of Biosafety Clearing-House – related activities into the capacity-building efforts would round out the thematic content—how can a developing nation turn seed-funding and training into a long-term sustainabile and self-sustaining effort?

6. Recommendations and Conclusions

Above, I have reviewed the entire body of information, activity, and participation that is the Pilot Phase of the Biosafety Clearing-House. I organized my comments into several categories: the Internet as a viable solution to the Biosafety Clearing-House challenge, the Pilot Phase website implementation, the thematic content of the website, and the capacity-building efforts towards the goal of implementing the Biosafety Clearing-House. Nevertheless, several broader commentaries and thoughts come to mind, which I will treat here.

Achieving success with indicators suggested by the ICCP.—As stated above, I organized my consideration around the indicators suggested by the ICCP as indicative of a successful Pilot Phase implementation²¹. Although I structured this report thematically rather than by the schema used by the ICCP in its list of indicators, returning to that list is a useful step. Hence, the following table summarizes my evaluation of the degree to which the ICCP's indicators were met in the Pilot Phase implementation.

²¹ <u>http://bch.biodiv.org/doc/NoteBureauattachment4.pdf</u>.

Table 3. General summary of indicators suggested by the ICCP as signaling a successful Pilot Phase implementation of the Biosafety Clearing-House. Ratings are $\textcircled{}{}$ = satisfactory to excellent, \approx = difficult to tell, $\textcircled{}{}$ = unsatisfactory, ? = not relevant or not yet available.

| Element | Indicator | Rating | Comments |
|---|--|--------|---|
| Principles of inclusiveness, transparency, and equity | Number and variety of governments participating in Pilot Phase | ٢ | |
| | Number and variety of governments providing information to BCH | ٢ | |
| Build experience and provide feedback for development of BCH | Number and regional balance of governments participating in the Pilot Phase | ٢ | |
| | Internet usage statistics | ٢ | |
| Identify alternatives to the electronic system | Identification of alternatives | ٢ | |
| | Effectiveness of alternative mechanisms implemented | 8 | Alternatives on data provider side only |
| Identify and address capacity needs of countries | Consultation with countries | ٢ | |
| | Identification of capacity needs of countries | ٢ | |
| | Establishment of mechanisms to address capacity needs | 8 | Addressing true capacity needs of countries will be difficult and expensive |
| Amenable to rapid development | Responses to changing requirements | ٢ | |
| User-friendly, searchable and understandable | Efficient search facilities | ٢ | |

| Element | Indicator | Rating | Comments |
|---|--|--------|---|
| | Effective guidelines for use of system | ٢ | |
| | Standard keywords and metadata | ٢ | |
| Efficient mechanism for implementation of requirements of Protocol | Inclusion of required information | ٢ | Does not yet include information from reports pursuant to Article 33 |
| | Consultation with countries | ٢ | |
| Information to facilitate decision- making | Provide information under AIA procedures | ٢ | |
| | Information on focal points | ٢ | |
| | Information on national competent authorities | ٢ | |
| | National legislation | ٢ | |
| | Decisions | ٢ | |
| | Risk assessment reports | ٢ | |
| | Scientific information | 8 | Incomplete or inefficient ties to some sources, no ties to some of most useful sources |
| Information for Article 11, Paragraph 1 | Inclusion of information specified in Annex II of Protocol | ٢ | |
| Access to the roster of experts | Availability of roster | ٢ | |
| | Searchability of roster | ٢ | |

| Element | Indicator | Rating | Comments |
|--|--|---------|--|
| Central portal | Establishment of central portal | : | |
| | Consultation with countries | ÷ | |
| Central database | Establishment of the central database | ٢ | To the extent that a central database is desirable, it has been established (the hope is that someday, it would be completely distributed) |
| | Information from countries without a national database | \odot | |
| | Information sent from countries lacking an electronic infrastructure | Ü | |
| | Information for Article 11.1 | Ü | |
| | Searchable indexes | \odot | |
| Linkage of central portal to distributed databases/nodes | Number and regional distribution of databases/nodes linked | ٢ | In general, good, but concerns again follow linkage of sources of additional information beyond the mandatory information sets |
| | Level of interoperability | 0 | Again, 'other' information sources, including a number of critical information sources, are not fully interoperable at present |
| Common formats for information | Creation of common formats | :: | |
| | Consultation with countries | Û | |

| Element | Indicator | Rating | Comments |
|--------------------------|--|--|---|
| Administrative | Creation of appropriate administrative arrangements with relevant international organizations | 8 | Discussions to this end are apparently underway with groups such as ICGEB, UNIDO, and OECD |
| | Use of existing information systems as models | information systems as | |
| | Access of all countries to databases | ٢ | Note, however, concerns regarding Internet access and speed |
| | Use of best practices | \odot | |
| Oversight and management | Consultation with Bureau | ? | |
| Technical implementation | Use of appropriate technical advisory expertise | ٢ | |
| | Number and regional balance of governments facilitating establishment of linkages | balance of governments Gacilitating establishment | |
| Monitoring and review | ICCP-2 report on progress of Pilot Phase | ٢ | |
| | Outcome of independent review | ? | |
| | Outcome of technical experts meeting | | |
| Capacity building | Number and regional balance of governments submitting priority needs to Executive Secretary | ~ | Apparently, response was minimal, yet this need has been addressed via regional meetings |
| | Identification of capacity- building needs of countries | ٢ | |

| Element | Indicator | Rating | Comments |
|--------------|--|---------------------|---|
| | Identification of measures to establish a program towards addressing those needs | | Little progress towards addressing long-term capacity needs |
| | Preparation of report analyzing identified capacity-building and financial requirements of countries | 8 | No synthesis of regional reports that I have seen |
| | Circulation of above information to appropriate organizations | ⊗ See previous item | |
| Languages | Ability to scale to all 6 UN languages | | |
| Resources | Amount of financial support and appropriate technical assistance received from developed country governments and other donors | 8 | Countries universally identified financial support and technical assistance as ongoing major needs |
| Project plan | Establishment of central portal | ٢ | |
| | Creation of appropriate administrative arrangements and partnerships | ~ | Mixed success, with fully interoperable links still to be established with some of the most important organizations |
| | Identification of relevant databases and resources \approx Establishment of central database $\ensuremath{\textcircled{o}}$ | | Need to emphasize provision of other scientific information more |
| | | | |

| Element | Indicator | Rating | Comments |
|---|--|--------|---|
| | Identification and development of appropriate common information and search formats© | | |
| | Mechanisms for adapting existing systems to BCH © requirements | | |
| | Preparation of report assessing the capacities of all interested governments | | No synthesis prepared from regional assessments |
| | Development of a mechanism for non- electronic information- sharing | | Provider side implemented, user side not implemented |
| Timing | Initiation of all elements of project plan within one ? month | | Unknown to me |
| Work plan | Work plan for completion of tasks for ICCP-2 | | Unknown to me |
| Government submission of appropriate information | Time taken for submission | ? | Unknown to me, although the information content appears reasonable for a Pilot Phase implementation |

Achieving critical mass for an information base.—The transition phase between a Pilot Phase and a production-quality information facility like the Biosafety Clearing-House is critical. In the first place, in general, it is unclear that a Pilot Phase *necessarily should* translate directly into a final product ... rather, it should be an experiment that educates one regarding what should be the dimensions of the final product. Still, the Pilot Phase implementation of the Biosafety Clearing-House is an effective solution to the challenges proposed to it by the ICCP and by the Protocol in general, and so may indeed serve an effective role as an information facility once the Cartagena Protocol goes into effect.

Nevertheless, it is important to consider how to get the Biosafety Clearing-House 'off the ground,' so to speak. If the information facility is relatively devoid of information

content, then development of a faithful and active user group will be difficult. Rather, countries may fulfill their obligations as to information-sharing, but may not look to the Biosafety Clearing-House as a vital source of information ... in this sense, the terms of Article 20 of the Cartagena Protocol ("Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms") would not be fulfilled.

So, an important consideration is that of how to populate the Biosafety Clearing-House with useful information *before* it officially comes into existence. Although the countries' information sets should arrive relatively promptly, as part of their Protocol commitments, careful attention should be paid to making the Biosafety Clearing-House an information-rich environment from the outset – bibliography, risk assessments served on other sites, etc. The point is to make a first visit to the Clearing-House a rewarding occasion, because it takes only a single disappointing visit to turn a visitor off to an idea.

Funding and training opportunities.—The "needs" emphasized by every needsassessment document produced, and every interview or e-mail response that I had, were of funding and training. Moreover, training and funding opportunities can provide a vital bridge between short-term activities (e.g., learning software tools) and long-term activities (e.g., strategic planning towards eventual broad and abundant funding. Hence, these two components were so dominant in every dimension that I strongly suggest that they see much-increased emphasis in the remainder of the development of the Pilot Phase, and beyond.

As discussed above, funding and training opportunities can be emphasized quite a bit on both the web-site and in the training courses. On the web-site, the point is that of taking the 'search for capacity-building projects' and split it into more functional pieces, one of which would be 'funding opportunities,' another would be 'training opportunities,' and a final (and less important) one could be 'examples of already-funded projects. In the training courses, a 30-60 minute module could emphasize these opportunities, and leave the delegates with some concrete strategies for initiating activities in their respective countries. (One CEE delegate, upon being urged to participate actively in the priority-setting exercise, responded ... "It is just a document!") Emphasizing a middle ground – between the short-term training and longer-term capacity-building – could make an impressive impact on the enthusiasm of the delegates.

Relationship between the Biosafety Clearing-House and the Biodiversity Clearing-House Mechanism.—In the course of my interviews, I heard much discussion of the odd position of the Biosafety Clearing-House as one component of the Biodiversity Clearing-House Mechanism. While this debate is beyond the scope of the present report, having to do with the Cartagena Protocol in general, it nevertheless is an issue looming in the background of what I am investigating. One comment or opinion is clear, however ... that the oddity of having one autonomous entity within another is striking.

Several of the delegates (see, e.g., *GRULAC #2* and *GRULAC #7*, Appendix I) commented on the need to integrate the biosafety-type data with information resources

regarding distributions, taxonomy, legal status, phylogeny, etc., of vulnerable species or the distribution of centers of diversity and endemism. In this sense, more intimate integration with the Biodiversity Clearing-House would make good sense. It would certainly provide a richer information environment in which to investigate biosafety issues as they relate to natural environments (permitting questions such as, "what are the wild relatives of this LMO that may be imported , where are they found, what is their conservation status, etc.?").

Pilot Phase in relation to the Cartagena Protocol.—Again, I will make a comment on a matter that would seem to be peripheral to the purppose of this report. Nevertheless, I consider this particular point to be extremely important to the development of the Pilot Phase. This perception is based on both my own impressions and on input from many concerned delegates, particularly from the smallest and most economically challenged governments. The question is, basically, whether the Pilot Phase as presently designed serves well the needs of *all* parties equally.

The Biosafety Protocol includes considerable verbage that emphasizes that the Biosafety Clearing-House should be a facility designed to meet the needs of both exporting and importing countries²². Exporting countries need a stable and consistent mechanism for proposing exportations, and the Pilot Phase of the Biosafety Clearing-House fulfills these needs amply. However, importing countries have very different needs: whereas a stable and consistent mechanism for receiving and processing importation proposals is needed, also needed is a rich information base upon which informed decisions can be based. This should, according to the Biosafety Protocol²³, be one of the important functions of the Biosafety Clearing-House.

Nevertheless, the focus of the Pilot Phase has been focused on the needs of the exporting parties. For example, the Bureau of the $ICCP^{24}$ stated that "First priority should focus on mechanisms to input data." Indeed, of the information sources included in the Pilot Phase implementation, only a rather tenuous hyperlink would be available to lead a Party to data sources other than the mandatory documents. Note particularly the comments of *CEE* #2 and *GRULAC*#2 (Appendix I) ... Importing Parties badly need access to diverse information sources that at present they lack.

Comments on tracking or predicting LMO behavior in ecosystems.—To continue the reasoning begun in the preceding section, I believe that several comments are in order. As is well known, LMOs represent novel assemblages of genes, and prediction of their behavior in ecosystems is indeed a complex challenge. Nevertheless, we can take some lessons from the broad literature on the behavior of invasive alien species in new regions and ecosystems.

²² See, e.g., Article 20, section 1b.

 $^{^{23}}$ See, e.g., Article 20, section 1a.

²⁴ Notes from the Bureau, 30 March 2001.

A large body of literature on invasive species²⁵ emphasizes and reemphasizes a single theme: the best indicator of invasiveness is *past behavior*. That is, rich sources of information regarding past introductions and importations *and subsequent monitoring regarding success or failure* will provide the best indicator of potential invasiveness. In this sense, to the extent that the alien species – LMO analogy works, a critical step for importing countries wishing to understand the potential behavior of an LMO in a novel region would be rich sources of information about the past known behavior of that organism ... the best source of such information is doubtless the scientific literature.

This perspective can be extended even further, to involve Importing Parties in the data-gathering and monitoring process. *GRULAC#2* proved to be a particularly rich source of ideas that summed up the ideas of many other delegates: importers wish to be data providers as well as data users. That is, whereas exporting countries can focus on the development and improvement of LMOs, importing countries could be the laboratory in which the behavior of these new organisms is studied and understood. These experiences—good or bad—need to be shared among importing countries in order for this Clearing-House to bring this importer-to-importer component of the Clearing-House to life. This potential, of course, then serves to emphasize the need for funding, training, and infrastructure in the countries that will likely be predominantly on the side of importers rather than exporters of LMOs.

Conclusions.—Referring again to the two objectives stated in the Introduction, the Pilot Phase implementation of the Biosafety Protocol has been variably successful. The first objective—that of gaining experience towards Internet- and non-electronic Clearing-House solutions—has doubtless been amply achieved. Indeed, the solution that has been developed is quite elegant, and has the capacity to meet the needs of a fully-implemented Biosafety Clearing-House.

On the other hand, the second objective—that of identifying and addressing the capacity needs of participating countries—has been met with less success. Identification of needs has been handicapped by what appears to be minimal forethought regarding *how* to go about identifying needs. The process has been further complicated by an overly intensive focus on report-writing (when does the tail begin to wag the dog?). More generally, the idea of identifying and addressing capacity needs requires careful planning, attention to the situation of countries and delegates, and good pedagogical design.

In general, then, the Biosafety Protocol has seen a successful pilot phase implementation. A technological solution is in place that is adequate (even excellent) to meet the needs of most countries, and that can facilitate efficient information interchange among all parties involved. Although adjustments can be made regarding how participants' needs are assessed, these needs nevertheless appear to be quite uniform across the world—ample long-term funding, training opportunities, and the like dominate the results of needs assessments.

²⁵ E.g., Brown, A. G. 2000. Invasive species: Responses needed to an accelerated national problem. National Invasive Species Council, <u>http://www.crie.org/ncseconference/bp/background9.htm</u>.

Appendix I. Extracts from Selected Delegate Responses

In all, inquiries (see Appendix II) were sent to 204 delegates who had attended Biosafety Clearing-House training courses, in Lima (September 2001), Nairobi (January 2002), Nitra (February 2002), and Beijing (March 2002), as follows:

| Region | Number of delegates contacted | Number responding | Subregions represented |
|---------------------------------------|-------------------------------------|----------------------|---|
| Latin America and the Caribbean | 28 | 10 | South America, Central America |
| Africa | 41 | 6 | West Africa, East Africa |
| Central and Eastern Europe | 63 | 12 | Central Europe, Eastern Europe, Former Soviet Republics |
| Asia and Pacific | 72 | 15 | Middle East, South Asia, East Asia, Pacific Islands |
| Western Europe and Others | 7 | 1 | Western Europe |

In general, my first contact with delegates was via email or in person at the regional meetings, and in some cases I followed up by telephone. I also communicated with 7 representatives of industry and non-governmental organizations regarding the Pilot Phase implementation of the Biosafety Clearing-House. In the pages that follow, I have translated (to the best of my ability) and summarized (eliminating comments not directly relevant to this report and some repetitive themes) selected delegates' commentaries for the illustration of points made in the main report. Although all of the points raised that I consider critical are treated in the main report, I nevertheless felt that it was important to provide the 'primary data' so that my motives in some of my points become clear.

GRULAC #1

On Content: Yes, in the context of the Biosafety Clearing-House, the information contained in the databases is indeed useful. However, information from the countries—including mine—is quite precarious. I consider that lacking is a broader niche for scientific information and technical information that refers directly to the LMOs.

On Capacity-building: The course that I took should have been done in a context that was exclusively for training, not within the framework of a political meeting. It was quite short, and many of the people attending were political in orientation, rather than technical—the people who should be the object of the training. Also, the process of capacity-building and training should be an ongoing process, that is renewed at regular intervals, so that the trainees are kept up-to-date. Since my participation in the Lima meeting, I have heard nothing more on the subject. The course should be longer, so that trainees emerge able to teach these techniques to others.

On the Toolkit: I think that badly needed is a module that treats issues of confidentiality and intellectual property rights as related to the information requests regarding LMOs.

GRULAC #2

On Content: The Pilot Phase implementation of the Biosafety Clearing-House feels much more oriented towards the potential exporter and its needs than to the needs of all users. Fails particularly in providing a broad information source to potentially importing countries, who need a diversity of information sources that go far beyond the simple legal requirements that are the minimum specification of the Protocol. The full breadth of the information resources outlined in the Protocol needs to be implemented before the Biosafety Clearing-House can be genuinely useful. Desperately needed for potentially importing countries is information on centers of origin and biodiversity, longterm impacts on ecosystems, detailed reasons why use of a particular organism has or has not been successful elsewhere, confidential information (released only to competent national authorities?) that may reflect importantly on a particular risk assessment, and socio-economic data that assess lateral impacts on natural systems.

On Capacity-building (the Biosafety Clearing-House training courses): Courses must focus on groups of appropriate trainees. Training senior delegates who are primarily political in focus is of little use, as they return to their political jobs, and never have anything to do with the day-to-day information management tasks. Also, doing the training as pure Powerpoint presentations, without hands-on experience, is not helpful. The Lima meeting was pretty well oriented as to participants

On Course Content: A critical lack in the Biosafety Clearing-House training team is someone with expertise in the *biology* of Biosafety issues. That is, they presently include persons very knowledgeable in the informatics, as well as in the legal aspects of the Protocol, yet no one with expertise in the biological underpinnings, and what issues or data types are critical to its implementation.

On TRUE Capacity-building: True capacity in Biosafety and biotechnology issues is assuring that parties are able to *use and produce* information. That is, "capacity" goes far beyond the simple idea of knowing how to use the tools and data that are developed elsewhere. Rather, "capacity" includes the full capacity to manage *and produce* data within a particular country. I see no true real interest in north-to-south technology transfer in biotechnology or biosafety: usually it is just bioengineered products that are transferred, but not the actual technology or knowledge. The true capacities that are needed are trained human resources, an academic system capable of feeding capable people into those jobs, and an industrial sector that also is strengthened by collaboration and cooperation from industries wishing to export biotech materials. On a shorter term, yes, offices, computers, personnel, training, and connectivity are all important, yet most important is the development of a value system that places biodiversity and environmental concerns on a par with other issues in national governments.

GRULAC #3

On Help Facilities: The help facilities were not sufficiently clear to permit use of the facility.

On Capacity-Building: The limitations of some countries were not taken into account, in comparison with other countries that are already more advanced.

GRULAC #4

On several occasions, the system did not get positive results in a search, but after a few tries, I would get results. The system does not give the reason behind a negative result. Critical search fields are not distinguished from those that might be optional. Arriving at the site, it could be good to guide the user to the Toolkit, where much more information exists regarding the structure, the logic, and the content of the site.

In my country, most public institutions possess the basic necessary electronic infrastructure and sufficient technical expertise to build a national informationmanagement system. Nevertheless, our institutions lack hardware (computers): this lack could complicate our participation in the short term, and its maintenance could complicate things in the long term.

GRULAC #5

The implementation of this information interchange mechanism requires a lot of technical support or help from technicians who have special capacity and preparation with these techniques. This support would be convenient and welcome on the part of the countries which we find ourselves very much behind in this respect.

GRULAC #6

Sometimes I could find the information that I was looking for, although it appeared that there was not much information there for Latin America and the Caribbean. The training efforts were not really well oriented to my country's needs ... it was more of a demonstration of how to navigate the site. What would be more useful would be if each country representative had data (even mocked-up data) to work with and explore the process of entering data into the BCH on his/her own.

GRULAC #7

I see three broad areas for interoperability. (1) One is in the "documents" part of the BCHM. I should think those are already interoperable by things like Google. (2) Another area is the reports about LMOs introductions. Those are very useful from our perspective. Knowing the precise whereabouts of the introductions (when available), the species, the tests, the results (permit granted or denied), etc. would be quite useful. Now, you must realize that countries report those cases in different ways. So before interoperability you must have a modicum of standardization and agreement, but this would be a truly useful thing to do. (3) The last area where interoperability would be extremely useful is in the biological, ecological, genetical, pollination, etc. data about LMOs and their wild relatives. If all of us could put our databases with the data about say, Carica papava, name, localities, biological features of major populations, etc. in a standardized or semistandardized format, searching for the data, which now is difficult, would be much easier. Now getting the dna sequences, any population information, etc. requires major literature searches. We are building a database of such biological data, but why not build it collectively over the web, using the BCH? This area will require some technical designing. Now also notice that those three areas do not have to talk to each other much.

AFRICA #1

Since the training course, I have gone into the Portal to familiarize myself with the administration stage. I have not had the opportunity to send live information because my country is now developing it and is in the process of ratifying the Protocol. This information served is useful, but it is hoped that there will be periodic updates of country profiles and useful Internet links to help in serious desktop research and information searches. Links to developments in Biosafety from other sites would be useful. Training efforts should be targetted at professional trainers who would then take care of country training and projects.

Participating countries may have to be assisted to develop their Internet capacity to utilize the Clearing-House. Countries will have to make serious commitment in sustaining Internet accessibility; otherwise, the system would break down. CD-ROM copies of information would be a helpful add-on.

CEE #1

On Information Needs for Decision-making: At present, the only information sources that are used in making decisions regarding importations of LMOs are those provided by the party proposing the exportation/importation. We have no way to prove or confirm these information sources. For example, a proposal has arrived that cites laboratory studies done in Iowa, USA, which support the non-harmful nature of a particular LMO. We do not have any way of knowing how believable this information really is. On Other Information Needs: We badly need access to biodiversity data to permit identification and mapping of wild relatives of LMO species in our risk assessment procedures.

On Capacity-building: Initial funding for developing our information system came from the Council, as well as from the companies proposing the exportationimportation. With the upcoming transfer of funding to state sources, these sources are no longer reliable, particularly those that come from proposing companies. Hence, long-term needs—maintaining and enlarging the information system—will require long-term sustained financial support. Good, capable computer programmers are available, if one has funding.

CEE #2

On Infrastructure: My country has no training, no technical ability, and no financial support. It has no national biosafety framework, nor has it yet ratified the Biosafety Protocol, which it has already signed. We badly need ideas as to where to obtain financial assistance.

On Information Needs: When making a decision regarding importation of LMOs, we have no sources of information. We need information from the scientific literature, as well as on the long-term results of introductions in other countries.

CEE #3

On Infrastructure: We have no funding and no staff for biosafety issues in my country. If we had funding, we would be able to find competent programmers to fulfill the informatics requirements pretty easily. The problem is still funding.

CEE #4

I could not really find the information that I was looking for. But I think that this is mainly because I was not persistent enough. I should learn from the Toolkit first and will do it as soon as possible. During the workshop it would be more useful to spend more time learning how to use the BCH and find information and less time presenting each country's situation.

CEE #5

My country needs additional information sources to be able to use the site effectively. The synthesis of information on risk assessment results, products, transboundary movements including previously approved GMOs could be beneficial in decision making and in preventing illegal traffic of GMOs.

The training efforts were fine in the context of using the central Portal. But further training is needed for the development of national information facilities interoperable with the central portal.

ASIA-PACIFIC #1

I have already provided the Secretariat with several sets of comments that have been followed in the implementation of the present version. I think that the BCH as implemented in the Pilot Phase will prove much more useful to exporting countries than for importing countries ... the data content should be expanded to meet the broader research needs that importing countries have. Perhaps incentives could be considered that would reward industry or NGOs that contribute data voluntarily. "Capacity-building" is *much* more than the basic training sessions that are being done here (Beijing meeting) ... capacity is the ability to participate fully in the BCH, and to sustain that participation in the long-term in a self-sustaining manner.

ASIA-PACIFIC #2

The current implementation could use a section with information on all current LMOs and ones that are being developed, and what uses they have.... I believe that once the BCH goes into effect, as long as countries update their data regularly, it will be the largest source of information, especially for technical experts on specific LMOs.

ASIA-PACIFIC #3

Other types of information that would be useful include information on LMOs/GMOs and new findings, and transboundary movements. Mechanisms for building up regional coordination priorities should have been built. Links between websites could be established.

ASIA-PACIFIC #4

Other types of information that would be useful to my country include information on LMOs/GMOs and new findings, transboundary movements, and products in which GMO materials are involved in the process of finishing the product, even though the raw material may not be of GMOs. More generally, mechanisms for building up regional coordination priorities should have been built—links between websites could be established. If hard copies of important data could be distributed to countries, it would be very useful, as logging in to the Internet is difficult for some countries.

ASIA-PACIFIC #5

The web design is very good and easy to use. However, I am interested in training regarding our participation ... how do we link our own information, and is the website needed for preparing our own metadata? We have a large problem, which is translation into English of our material, and we have no one with a salary to do it.

WEOG #1

Are the contents of the Pilot Phase useful to you and to the needs of your

country? This is a major weakness of the pilot phase of the BCH, because the amount of information given by the countries involved in the implementation of the pilot phase is currently scarce. Therefore it is difficult to make a consistent evaluation on the functionality of the various tools providing by the BCH website, given that the search for information on most topics or fields produce little or no data. The information currently made available is very large. The need for other types of information may arise in the future when the BCH website will fully operational.

NGO #1

Countries that cannot - for whatever reason - use the electronic BCH fully will be disadvantaged, in some cases permanently. It is NOT correct to say that whatever appears on the BCH can be accessed in another form, particularly in the case of data derived from BCH interfaces with other electronic databases. The owners of those interfaced databases have no duty to provide CPB Parties who may be non-electronic users of the BCH with complete copies of whatever is in their databases.

Further, copies of material from other databases would not be "comparable" to what might be found by using the electronic BCH because, at the very simplest level, the paper user would not be able to find the relevant data as quickly as the electronic user. For developing and least developed countries, the costs for acquiring compatible equipment and software, trained personnel, internet, telephone and electricity connection is more expensive or proportionately/comparatively more expensive than in many developed countries. This from the outset already disadvantages the poorer countries. And in many countries, while equipment and software and reasonable access to internet facilities may be available, however, such equipment and software may be incompatible due to not having the latest or reasonably updated/upgraded equipment and software. This may mean that some documents and data are inaccessible, or that also due to the poor internet and telephone connections, the cost of being on-line is expensive or prohibitive, leading to longer periods required for decision-making, higher costs overall and restricted access to documents and data made available on or through the BCH.

Another dimension must be considered: the ongoing need of Parties for up-to-date scientific information about biosafety. Particularly in countries where access to scientific journals is insufficient (for whatever reason - cost, language, etc.), this dimension must be addressed. More place must be accorded to the work of indigenous peoples, communities, NGOs and other groupings of civil society on the BCH.

The objectives of the BCH and all the information that must be included in it are far broader than the priorities of the Pilot Phase. While a Pilot Phase may be necessary, the full operation of the BCH must not be limited in any way due to the precedent-setting of the Pilot Phase, or delayed due to the emphasis given to the Pilot Phase priorities.

All countries must be able to fully use the electronic BCH. This, of course, would mean extensive monies be made available for equipment purchase and maintenance, electricity generation (or provision of equipment that can use solar energy), and hiring and training of personnel. Although it is certainly useful that trainings and CDs are being provided for new users, current CDs and trainings may not help future users. Those being trained now tend to be management and diplomatic personnel and not those who will be entering and retrieving data from the website once the Protocol comes into force. It would seem imperative that the site itself contains an interactive program for new users to go through the site, ask questions, and test their knowledge.

Appendix II. E-mail questionnaire sent to delegates for comment.

1. The Website:

Have you used it since the training course?

Could you find the information that you were looking for?

Was the design easy to use?

Were the instructions and help facilities clear and available?

2. Content

Are the contents of the Pilot Phase useful to you and to the needs of your country?

Are their other types of information that would be useful as well?

3. Capacity-building Efforts

Were the immediate needs of you and your country treated in the training efforts?

Was the teaching and instruction adequate, understandable, and helpful?

Were the facilities adequate for learning the use of this tool?

4. Your Country

Does your country have any information policies that make implementation of the Biosafety Clearing-House over the Internet problematic?

6. General Comments

Please provide any amount or type of commentary that you believe may be helpful to me in my review.