The Biosafety Clearing House: Considerations and Caveats

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Introduction

What has been achieved so far with the Biosafety Clearing House (BCH) is remarkable. However, it is clear that, at present, the BCH is NOT sufficient to all the tasks required under the Cartagena Biosafety Protocol, nor does it contain the reliable and comprehensive information necessary for biosafety decision-making.

So what is to be done? The Protocol has come into force, the BCH exists in a pilot form, and the Parties are supposed to have made their appropriate contributions to its various information sections. Yet, looking at its incomplete databases, it is obvious that all is not yet in order at the BCH.

Many suggestions have been made about the BCH -- by the Intergovernmental Committee for the Cartagena Biosafety Protocol(ICCP),(1) by "outside" consultants,(2) by those who designed the BCH, by the Secretariat, by the UNEP-GEF Biosafety Team ,(3) and by those who answered questionnaires about the BCH (4). While all sources of commentary have offered insight into the problems of the BCH, none of their suggestions are binding on the Parties to the Cartagena Biosafety Protocol. **It is up to the Parties themselves to decide which are the useful suggestions for change and what else remains to be done with and to the BCH.**

Despite efforts to the contrary,(5) problems are not likely to be solved quickly nor are current hopes for the BCH to be easily realized. Constraints, including problems of funding, hardware, software, electricity, telephone lines and connections, personnel, technical and scientific know-how, accessibility of data, accessibility of published research, transparency of conflicts of interest, internet reliability and accessibility, and varying levels of ability to comply with all the articles of the Protocol -- to mention just a few of the constraints -- are likely to persist into the foreseeable future.

What is required

Article 20 of the Protocol established a Biosafety Clearing House to

> (a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and
>
> (b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity (6)

While the meaning of and the actors involved in "facilitating" and "assisting" are left to interpretation, Article 20 specifically requires Parties to make available to the BCH:(7)

> -- any information required to be made available under the Protocol,
>
> -- any existing laws, regulations, and guidelines for implementation of the Protocol, as well as information required by the Parties for the advanced informed agreement,
>
> -- any bilateral, regional and multilateral agreements and arrangements,
>
> -- summaries of the risk assessments or environmental reviews of living modified organisms generated by its regulatory process and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof,
>
> -- final decisions regarding the importation or release of living modified organisms,
>
> -- reports submitted pursuant to Article 33 , including those on the implementation of the advanced informed agreement procedure.

In several other places. the Protocol references other information burdens related to specific decision-making circumstances.(8)

Thus it can be seen that, **while the total list of possible tasks related to the BCH may seem daunting, the obligatory list for Parties is not.** Posting laws, regulations, agreements, summaries of risk assessments, final decisions, and reports should not be over-burdensome.

However, doing what has been suggested in some places -- notably, everything possible to make

the BCH the world's database for biosafety decision-making -- would be daunting at this point in time and could siphon off needed resources from more pressing biosafety needs, notably funding and training related to capacity building. Many countries are only now developing the national processes to create the decision-making and generate the data that someday will appear on the BCH. Their needs must be served before those of the exporters of LMOs. (9)

Caveats

Whatever hopes or intention there are for the site, **the most important thing to acknowledge about the Biosafety Clearing House is that it is not, nor should it become, anyone's sole source of information regarding the biosafety of any LMO. Countries of import (and transit) should not be tempted to forgo their right to seek detailed answers to whatever questions they may have about LMOs on the verge of import into or transit through their territories.**

It would be unwise - and potentially costly - to forget that there are inherent limitations already in place on the information found in the BCH. To cite a few of those inherent limitations:

-- Allowances made for Confidential Business Information in the Cartagena Protocol on Biosafety can be expected to *limit* publication of salient details of risk assessments, particularly where results are negative.

-- The country producing the most LMOs and LMO-FFPs (i.e., LMOs for food, feed, or processing) for export is not a Party to the CBD or the Protocol and is by no means required by its own laws to compel its biotechnology industry or its own biosafety regulators to make public all salient details of risk assessments, including the data used to generate decisions.

-- In any case, the Protocol itself requires only *summaries* of risk assessments to be posted on the BCH.

-- Risk assessment as envisaged under the Protocol does not *require* as assessment of socio-economic impacts.

-- Much of the research necessary for biosafety decision-making is not available anywhere because it has not been done. Absent information is to be expected wherever the ecosystems to be accessed (or transited), i.e., the receiving environments, are not the ecosystems in which the original field tests were conducted.

-- The ecosystems of concern may not be well characterized and will require careful description *before* any risk assessment takes place. (10)

-- Not all research results are published, especially in the case of research that produces negative results. Further, not all research is published in a timely way and it can take years before the quality of any research is evaluated in the journals. Still further, not everyone can afford access to or read the language of all the pertinent journals that are published. (11) And finally, not all the pertinent journal articles are translated into all the languages of the United Nations. (12)

-- Not all the information available on or through the BCH may be reliable or up-to-date. The BCH may come to be linked to sites owned or managed by non-Parties. Often, the accuracy or the completeness of the information on such sites is NOT guaranteed.

-- The Protocol does not require Parties to make comparisons among methods for solving the problems particular LMOs may be designed to address. Thus, information about cheaper, faster, less risky solutions to particular problems is unlikely to be found on the BCH. (13)

-- The information required to be posted to the BCH is often not adequate to the task of decision-making. For example, data about those named to the roster of experts does not include information about the listees' stock holdings, board memberships, recent consultations, business, trade, and professional affiliations, etc. In many cases, even details of current and past employment - or close family ties which may present conflicts of interest - are absent. Thus the BCH does not offer sufficient information for those whose might wish to judge the quality of the independence (and lack of conflict of interest) of individual listed experts.

For these and other reasons, it would be rash to expect -- much less, recommend -- the BCH as the sole information source for biosafety decision-making. The BCH could be, at most, a good beginning.

Problems (14)

As more than one report has indicated, even with its accomplishments, the BCH does have its shortcomings - shortcomings beyond those mentioned earlier in this paper. Peterson summarizes the problems in terms of the need for "... greater focus on user [perspectives],(15) particularly related to help [available on the site], ... [greater] download speed, and content oriented at the needs of all users...[as well as sensitivity to and assessment of]... the capacity needs of countries

involved, particularly with regard to long-term needs, immediate needs of seed-funding and training, and pedagogy."(16)

While all these areas require urgent attention, perhaps nothing is more vexing to a current user of the BCH than being required to use particular -- but not easily discoverable -- words from the controlled vocabulary of the BCH, and/or being linked off-site for information only to find that the information is not readily available at the off-site location.

Unfortunately, the help tools available on the BCH are not always helpful for the tasks at hand.There are, for example, problems in using the Tool Kit to find information about the controlled vocabulary.(17) The logic of the structure of the Tool Kit is not necessarily the logic of the beginning BCH user. The modules of the Tool Kit are simply too dense with information, too technical, and written for too many purposes to be of use to a person seeking, for example, the correct word to input into and succeed with the "search" engine. **Either the vocabulary understood by the BCH search engines must be broadened and made more inclusive and intuitive or a separate Tool Kit must be written for (and tested on) BCH beginners in all the language groups.**

Redesigning the Tool Kit or expanding the language understood by the search engine will not solve problems created by linking to other web sites.Other sites are simply not predictable. Sometimes they are "down" or "under construction" or no longer exist. Sometimes they have moved. Sometimes they are difficult to navigate or they contain information that is dated or incomplete. Sometimes their language is different than the language of the BCH version one is using. And whatever the problem may be on another web site, there may be no immediate or even predictable remedy. Further -- and most worrisome of all -- the managers/owners of other sites owe no legal duty of accuracy, completeness, or understandability to those accessing their site from the BCH. Indeed, other web sites are very careful to limit their liability to the user. The OECD web site is a good case in point. (18)

Interoperability was one of the goals and mandates of the BCH, but for users who are confused by restricted vocabularies or who find themselves linked to problematic off-site locations, interoperability amounts to an information barrier. Searches which go nowhere but do so elegantly are only frustrating and off-putting. And where the user may not even be sure of what went wrong or how to describe the problems encountered in the correct words, the possibility of contacting someone for problem resolution is only further frustrating and embarrassing.

This in mind, it should come as no surprise that so few respondents answered the BCH user survey.(19)

At its first meeting, ICCP recommended that the pilot phase of the BCH "be user friendly, searchable, and understandable".(20) It may be that part of the design (and later mandate) of the

BCH are now in conflict with this goal. **Where interoperability and information accessibility clash, it would be better, i.e., more user friendly, if accessibility won. All the information elicited by the Protocol - particularly that required of the Parties -should be on the BCH site and should be easy to access, dated as to last revision, and in easily downloadable files.** Links to other web sites may still be made available for those who want further information. **On a related matter, where information is in flux - as in the case of national biosafety regulations under development - that should be noted. Every Party to the Protocol should fulfill its obligations to the BCH, if only to say specifically that its regulations are "under development" and then to describe the governmental policy in the interim.**

Nothing should appear on the BCH unless it is available *on site* in all the languages of the BCH.

The absence of translations is not a problem restricted to off-site locations. Country biosafety regulations, for example, are often available on the BCH only in the language in which they were written originally. This is not acceptable if the BCH is facilitate "information sharing". Biosafety decision-makers should not be forced to lose time while awaiting translations. **At the moment, it is not clear how much of the BCH will be made available (and on what timeline) in all the necessary languages. Although provision of translations may add cost to the BCH, it would be money well spent if the site is to be at all usable for efficient decision-making by all the Parties.**

Future Considerations

Most urgently, sufficient funding must be found to ensure that Parties can *sustainably* correct whatever biosafety- and BCH-related problems of funding, hardware, software, electricity, personnel, and technical and scientific know-how, etc. they may have at present.

Further, sufficient funding should be found to allow the BCH to become the "user friendly, searchable, and understandable" tool that it was intended to be in the first place. As long as interoperability does not interfere with the diversity-tolerant spirit of the Protocol and its Parties, the BCH may yet become both a trusted information source and an impetus to genuine technology transfer and biosafety regulation.

Lastly, in keeping with the Protocol's concern for public awareness of biosafety, it is to be expected that groups and committees which oversee the BCH and its administration and development will include -- if only for the sake of common sense and transparency -- members of the general public along with Party representatives, website technicians, and relevant others.

End Notes

(1) See for example, the suggestions made in Synthesis of Capacity Building Needs Identified by the Regions for Implementation of the Pilot Phase of the Biosafety Clearing-House. UNEP/CBD/ICCP/3/5/Add 3. 26 March 2002.

(2) A. Townsend Peterson. Independent Evaluation of the Biosafety Clearing-House Pilot Phase Implementation. *In* Information-Sharing (Article 20). Independent review of the pilot phase of the Biosafety Clearing House. Intergovernmental Committee for the Cartagena Protocol on Biosafety. Third Meeting. UNEP/CBD/ICCP/3/INF/10. 2 April 2002.

(3) See for example: UNEP-GEF Projects on National Biosafety Frameworks. Questionnaire on resources and expertise available in countries for the exchange of information with the Biosafety Clearing-House of the Cartagena Protocol. Summary of Results. Available at: <http://www.unep.ch/biosafety/pdf_files/BCH_Questionnaire_Summary.pdf>.

(4) See UNEP-GEF Projects Projects on National Biosafety Frameworks.Questionnaire on resources and expertise available in countries for the exchange of information with the Biosafety Clearing-House of the Cartagena Protocol. Available at <http://www.unep.ch/biosafety/BCHquestionnaire.pdf>.

(5) See for example: Project Brief. Building Capacity for Effective Participation in the Biosafety Clearing House (BCH) of the Cartagena Protocol project. GEF Intersessional Work Program. July 2003. Available at: <http://www.gefweb.org/Documents/Work_Programs/wp_Jul03/wp_jul03.html>.

(6) Cartagena Protocol on Biosafety (CBP) to the Convention on Biological Diversity (CBD). Article 20.1.

(7) CBP. Article 20.3.

(8) The Secretariat of the CBD has made an extensive list available of all the informational requirements set forth in the Protocol. See Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena. First Meeting. Information Sharing and the Biosafety Clearing House (Article 20). Note by the Executive Secretary. UNEP/CBD/BS/COP-MOP/1/5.20 November 2003.

(9) Peterson noted that the pilot BCH better served the needs of exporters than anyone else. See work cited in (2) above.

(10) Peterson, for example, noticed this in his analysis. See work cited in (2) above.

(11) As scientists push to have open publication on the internet, the situation may improve. However, in the interim, it might be wise for the Secretariat to make an arrangements with scientific publishers to allow for group subscriptions to publications for all (or multiple) Parties to the CBP. This may be feasible for journals that publish both in print and on the web.

(12) Language difficulties act as barriers to technology and information transfer. In the case of some countries, such barriers will serve to perpetuate and exacerbate the technology and information transfer barriers erected during the colonial experience.

(13) For discussion of risk assessment paradigms that include comparative solutions, see O'Brien, M. Making Better Environmental Decisions: An Alternative to Risk Assessment. MIT Press. Cambridge. 2000. or Thornton, T. Pandora's Poison: Chlorine, health, and a New Environmental Strategy. MIT Press. Cambridge. 2000.

(14) In all fairness, the discussion in this "Problems" section may be dated. The BCH is a work in progress and much of what is mentioned here may have been corrected by the time this paper circulates. If that is the case, we apologize in advance.

(15) Phrases in brackets have been added by the authors of this paper for the sake of clarity.

(16) See work cited in (2) above.

(17) See work cited in (2) above.

(18) The Biotech Database (for products of biotechnology) found on the OECD website (<http://webdomino1.oecd/ehs/bioprod.nsf>) 3 February 2004, published this "Disclaimer:"

> "1. This prototype Database for products derived using Modern Biotechnology was developed to allow regulatory officials in the OECD Member Countries to share information regarding certain products or regulated articles that have been approved for commercialization, have obtained certain approvals that would allow commercialization of products, or are in the process of being approved for commercialization. It was developed at the request of the Working Group (formerly Expert Group) on Harmonization of Regulatory Oversight in Biotechnology and is in an early stage of development.
> 2. The Information contained in this database is provided to the OECD on a voluntary basis both by authorities in OECD Member countries and by certain institutions that developed these products or are developing products. The information was not necessarily developed for the purposes of this database. It should be emphasized that not all countries or authorities within a country regulate the same products or articles or present the data related to them in similar ways.
> 3. This database is not intended to be comprehensive for the products of Modern Biotechnology nor does it imply that items listed therein have been commercialized. Rather it is intended as an aid to the sharing of information about certain products or articles being approved for potential commercialization.
> 4. While the OECD, authorities in Member Countries, and relevant institutions have made very effort to provide correct information, the correctness of the information in this database cannot be guaranteed. In addition, the items in this database are not intended to represent a complete listing of all products derived using Modern Biotechnology that have been commercialized.
> 5. The OECD is charged with the collection and presentation of the data contained herein. The OECD would greatly appreciate if errors/omissions could be pointed out, so that appropriate measures may be taken to correct them.
> 6. Any other comments on the utility of this Database would be greatly appreciated."

(19) See work cited in (3) above.

(20) This is mentioned as the first ICCP's second goal in the work cited in (8) above.