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Guest Editorial

Bridging the gap between researchers and policy-makers: International collaboration through the Biosafety Clearing-House†

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INTRODUCTION

Most governments have developed, or are developing, national biosafety frameworks to enable them to address known and potential risks associated with the introduction of GMOs into their territories, and these regulatory systems may have a great impact on biotechnology research – not only at the stage of environmental testing, but also during laboratory studies. These national systems are in turn strongly influenced by international agreements, particularly the Cartagena Protocol on Biosafety ('the Protocol').

The Protocol is a legally binding instrument that governs the international movement of living modified organisms resulting from modern biotechnology[1] (broadly equivalent to GMOs), and has an impact on international trade, environmental protection, and human health. The Protocol addresses issues as diverse as well-defined procedures for exporting GMOs that will be introduced into the environment (through the 'Advance Informed Agreement' procedure), to measures that will impact on importing and exporting GMOs that are destined for contained use (under Article 18 on 'Handling, Transport, Packaging and Identification').

Free-flowing dialogue between the policy-makers who set global rules for environmental biosafety protection, and the researchers that will ultimately be responsible for implementing many of these rules at a local level, is a key element in ensuring that the policies produced through the international process are scientifically sensible and practical to implement 'on the ground'. The Biosafety Clearing-House – an information-exchange mechanism established under the Protocol – can play an important role in assisting this exchange of information.

Although the Protocol focuses on addressing concerns of the potential adverse effects of living modified organisms on biological diversity, it is recognized in the text of the Protocol itself that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures. Many researchers are strongly committed to developing GMOs that aim to meet pressing social and economic needs, as well as environmental protection (Cohen, 2005), and the Protocol's parent Convention on Biological Diversity aims to promote both conservation and sustainable use of biodiversity.

THE REGULATORY PROCESS

The main players in the operation of the governing body of the Protocol (known as the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol, or the "COP/MOP") are government officials (with delegations that may be drawn from the trade, environment, or agriculture ministries; although in

† The views expressed in this article are those of the author and do not necessarily represent the views of the Secretariat to the Convention on Biological Diversity.

[1] "Modern biotechnology" is defined in the Protocol to mean the application of *in vitro* nucleic acid techniques, or fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and are not techniques used in traditional breeding and selection (SCBD, 2000, Article 3).

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in many developing countries, it is more likely that one person may be responsible for a gamut of issues that cover anything from risk assessment to liability and redress measures). Traditionally, participation in the intergovernmental negotiating process by non-government representatives has included the use of avenues such as physical access to delegates (roaming the conference halls where official international meetings take place); circulation of policy documents prepared by civil society organizations; and participation in national-level policy-formulation processes. In some (rare) cases, non-government experts may be included in an official delegation and thus participate directly in the decision-making process itself.

Although private sector associations and environmental organisations also participate in the international negotiation process, scientists and academic researchers active in biosafety research have been poorly represented at best. There is therefore a real risk that the researchers who will ultimately be responsible for working within the legislations that arise from these processes are missing out on the opportunity to influence the debate before it becomes law. An indication of growing concern in this area is the increasing participation in initiatives such as the International Project on GMO Environmental Risk Assessment Methodologies, which is driven by public sector scientists (GMO-ERA, 2005), and the Public Research and Regulation Foundation initiative, which aims to involve the public research sector in developing regulations relevant to the development and application of biotechnology (PRRF, 2005).

SHARING RESOURCES AND EXPERTISE THROUGH THE BCH

The Biosafety Clearing-House (BCH) was established under the Protocol with two main objectives: it provides a platform to exchange information on, and experience with, living modified organisms; and, it also assists governments that have ratified to implement the Protocol (SCBD, 2000). The role of this information sharing mechanism in exchanging scientific, technical, environment and legal information on, and experience with, GMOs should prove to be an important one for researchers. The central portal of the Biosafety Clearing-House is available on the Web at http://bch.biodiv.org.

The BCH is intended to function as a central information marketplace. Parties (*i.e.*, governments that have ratified the Protocol; 129 as of 23 November 2005) have a legal obligation to provide many types of information within defined time-frames, and the BCH was created as a distributed system, meaning that information in the BCH is owned and updated by the users themselves to ensure timeliness and accuracy of the information. All information provided by governments is directly validated by each government 'owner' (*i.e.*, verified for accuracy and authenticity by nominated national focal points) before being published on the site, to ensure the highest level of security and reliability of data.

The BCH contains information that must be provided by Parties to the Protocol, such as decisions on release or importation of GMOs, risk assessments, competent national authorities, and national laws; as well as other relevant information and resources, including information on capacity-building, a roster of government-nominated experts in the field, and links to other websites and databases. Governments that are not Parties to the Protocol are also encouraged to contribute information the BCH, and in fact a large number of the decisions in the BCH have been registered by two non-Party governments (Canada and the United States), reflecting the global spirit of goodwill and cooperation that has supported the development of the BCH to date.

One of the main added values provided by the BCH in this field of information-sharing is the use of common formats and standardized terminology or "controlled vocabulary" to categorize the information contained within the databases. This allows the many users of the BCH to use the same terms whether they are registering information or searching for it, including synonyms within a language (a user searching for information about corn will receive the same search results as someone who makes a search using the term maize); relationships between terms (a search using the common name maize can retrieve results registered with the taxonomic name *Zea mays*; *Z. mays* records will also be found when searching for grasses in the Family *Poaceae*); and also – most importantly – between languages (for instance, records registered using the French *maïs* or Spanish *maiz* will also be retrieved when searching in English for maize). The BCH therefore operates in all six UN languages for both reporting and retrieving data (English, French, Spanish, Russian, Arabic and Chinese) – enabling wide access to global information.

As the official information-exchange mechanism under the Protocol, the BCH has been created with the intent of providing easy, equitable and international access to relevant biosafety information. This information-exchange mechanism can be used in many ways for different stakeholders. Governments use the BCH to make informed decisions regarding the importation or

release of GMOs through analysis of relevant information, such as decisions on release and risk assessments. Industry and other stakeholders can use the BCH to access information vital to their trade activities, including details of national contacts, relevant laws and regulations with regard to transboundary movement. Scientific and technical cooperation is fostered by allowing users to access or contribute information on capacity-building activities and national priority needs. By providing biosafety regulators independent access to the latest in relevant biosafety research, this will assist in creating practical solutions to negotiations taking place in the international policy-setting arena.

Another feature of the BCH of use to both the regulatory and research communities is the Biosafety Information Resource Centre. This searchable catalogue contains a wide array of biosafety-related publications and other resource materials produced by different organizations and Governments, including: books; research reports; training materials; course catalogues; toolkits or guidebooks; workshop reports; papers and presentations; case-studies; technical publications; newsletters and journals; and CD-ROMs.

USING THE BCH TO FURTHER THE INTERNATIONAL POLICY DEBATE

The BCH has a real potential to bridge the gap between researchers and policy-makers. Conferences have long played a key role in guiding the work of the UN – since its very inception – and the meetings taking place under the Biosafety Protocol are no different. But funding for open-ended international conferences is, of course, a serious issue – not only the costs of running such conferences, but also those of attending them. There are therefore several advantages in fostering debate on international biosafety policy issues through the BCH. In the interest of examining the use of online forums to further promote biosafety information-sharing, the BCH hosted its first online conference on "biosafety considerations in the use of genetically modified organisms for management of animal populations" from 18 October to 15 November 2004[2]. The conference addressed a variety of relevant issues, ranging from particular challenges in developing countries for managing risks, such as implications of poor understanding and education about LMOs, to appropriate timing for international consultation and incorporating frameworks for such consultation in decision-making.

Participant reaction to this pilot initiative was very positive. A total of 495 participants registered for the conference from 104 countries, split fairly evenly between developing and developed country participants. To address issues of equitable access to the conference in the developing world, in addition to web-based access, provision was also made for users to send and receive posts through email only, and participants with limited access to email and Internet were invited to register to receive the daily digest by fax. It is notable that there was also a steady increase in the use of the forum as the debate progressed, both in the number of participants registering, and the traffic accessing the website to read it. This implies that as well as the active (posting) participants, other users felt that they were benefiting from a passive engagement with the online discussion.

In addition to quantitative indicators of participation, there is also considerable qualitative evidence indicating an enthusiastic response of the participants, such as a number of requests to replicate the conference in other subject areas. Several participants from developing countries (particularly those involved in regulatory agencies) noted the benefits of being able to discuss relevant biosafety issues with scientists around the globe, without incurring the (in many cases prohibitive) associated travel and registration costs of a traditional conference. Scientific experts who participated in the conference commented that the conference provided a useful venue to gain an appreciation of what issues are of concern to the regulators, as well as to bring emerging areas of research to their attention.

This case study indicates that conducting such online discussion forums through the BCH may be a useful venue to complement the more traditional UN policy negotiation avenues, by bringing together a wide variety of actors to explore emerging issues. Such a process can encourage fruitful dialogue, and provide an informal venue where scientists and regulators can work together to develop opinions and critiques concerning emerging issues, through actively (or passively) engaging with relevant online debate, as well as bring attention to recent cases or national developments that are relevant to the subject under discussion.

A CALL TO ACTION

Researchers should be using the BCH not only to keep abreast of regulatory developments that may have a

[2] The proceedings of this conference have been archived on the Biosafety Clearing-House and are available on the website at http://bch.biodiv.org/onlineconferences/gmoam.shtml.

future impact on their research, but also to share information with international regulators. The synergistic effect of such interaction between the different players will help participants from different fields to build on one another's perspectives to provide a deeper understanding of the different aspects to issues under consideration.

Naturally, the aim here is not to encourage a proliferation of interest groups to engage in continuing polemic at the international level – far from it, because the workings of representative institutions would likely only be slowed through such congestion. But although nation states are usually the decision-makers, governments do not manage international affairs in isolation – they need to collaborate with others, including civil society, industry and public sector organizations, to ensure sustainable human development policy that can truly be implemented. Involving all the players in the working of the international machinery is essential to ensure that the policies coming out from this process are practical, take into account state-of-the-art research in relevant fields, and are relatively burden-free to implement if possible. The Protocol's Biosafety Clearing-House should be able to fill an important role in bringing together a wide variety of contributors in an open and influential forum.

International law is an evolving phenomenon, and new risk considerations can arise spontaneously and affect a previous risk analysis. It is imperative that researchers consider themselves partners in the international negotiation process, as valuable sources of information, and contributors to ideas and analysis. The magic will happen when the individuals using the BCH come together to focus debate, to stimulate research, and to share information.

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