

Preserving International Access to Genetic Resources for Non-commercial Biodiversity Research

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The non-commercial research sector is speaking up as Parties to the Convention on Biological Diversity negotiate an International Regime for Access to Genetic Resources and Benefit Sharing

For the past few years, a Working Group formed under the Convention on Biological Diversity (CBD) has been developing an International Regime for Access to Genetic Resources and Benefit Sharing (IR-ABS) (1). If the CBD Conference of the Parties approves an overly restrictive IR-ABS in October 2010, then researchers could lose access to biological specimens and materials that are critical to their research. The Consortium for the Barcode of Life, together with the German Research Foundation (Deutsche Forschungsgemeinschaft - DFG) and other science organizations held an international workshop in Bonn, Germany in November 2008 on the subject of “Access and Benefit Sharing in Non-commercial Research”. Participants represented a balance between industrialized and developing countries and a mixture of researchers, policy-makers, lawyers and economists. As described here, the participants identified key issues and outlined a rational solution that serves research, protects national property rights of genetic resources, and generates important non-monetary benefits such as enhanced ability to monitor and preserve national biodiversity. (2)

The CBD is a legally binding international agreement administered under the UN Environment Programme which entered into force in late 1993, to which more than 190 countries are a Party. The CBD’s aims are “the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from the utilization of genetic resources.” (3) The IR-ABS is expected to substantially help in implementing the third objective but there is a controversy over what, specifically, is meant by

“the utilization of genetic resources”. Interpreted narrowly, it could mean the use of organisms or biological specimens for the purpose of cultivation, selective breeding, genetic modification, or gene splicing. That is, a narrow reading of the phrase would restrict the focus of an IR-ABS to activities using genetic resources only to produce more organisms based on their heritable traits. Many countries and Parties to the CBD, however, support a much broader interpretation of the CBD’s definition of “genetic resource” which includes “genetic material ... containing functional units of heredity”, and "their derivatives ... and products". (3) Since "functional units" of DNA and RNA can be found in wood, wool, soil, water, airborne particles, as well as in all agricultural and many pharmaceutical products, this broader interpretation would cover essentially the entire biosphere and many commodities, including anything a biologist might want to touch or sample.

This ambiguity is deeply rooted in the language of the CBD but there is a practical solution. Genetic resources are utilized in different ways and these uses generate different types of benefits. In December 2008, the CBD convened a Group of Legal and Technical Experts to study the issue of definitions in the treaty (and other issues), and they defined seven categories of uses (4). Five of these categories involve making organisms, new varieties, compounds or products for commercial purposes from genes or the metabolic pathways they control. One category is the use of “genetic resources” to conserve endangered species through captive breeding programs or repositories of living organisms (e.g., seedbanks, zoos, botanical gardens, culture collections). The seventh category, “characterization and evaluation”, includes the study of organisms for the purpose of generating knowledge of biodiversity and its functional characteristics. Non-commercial biodiversity research fits within this category of utilization.

Within these confines, a discussion of access and benefit sharing related to non-commercial may be much less controversial.

Non-commercial research may be linked or lead to research and development of commercial products, but in many cases it does not. Non-commercial and commercial research can use the same methods and facilities and be pursued by the same researchers, making it difficult to distinguish intent. Nevertheless, at the practical level at which international agreements for access to specimens and genetic resources are negotiated, it is possible to separate non-commercial projects and activities from their commercial counterparts. Participants in the Bonn workshop compiled a list of tangible indicators that separate non-commercial from commercial research (e.g., restrictions on dissemination of research results, restrictions on access to reference specimens, patent applications). Distinguished in this way, non-commercial research generates new knowledge and collections of reference specimens that generate benefits through the public domain, without generating proprietary benefits. Countries that provide access to their biodiversity for non-commercial research derive a range of non-monetary benefits, including training, a better understanding of their genetic resources, and an improved basis for managing, conserving, and developing their biodiversity.

The concerns of provider countries were important components of discussions at the Bonn workshop, and three emerged as central: (A) changes of intent from non-commercial to commercial research; (B) use of sample materials by third parties in ways that were not approved by a provider country in legal agreements; and (C) the commercial use of research results in the public domain without sharing benefits with the provider country. The workshop produced suggestions for specific measures, described below, that could be built into legal agreements between researchers and provider countries and would manage the risk of lost benefits associated

with these concerns. In the terminology of CBD, these legal ABS agreements include “Prior Informed Consent” to enter into an access arrangement, “Mutually Agreed Terms” of the agreement, and “Material Transfer Agreements” that stipulate the terms of international movement of specimens. The IR-ABS would be highly relevant in developing national legislation that would govern legal agreements to access to genetic resources in both provider and user countries.

(A) *Changes of intent.* Research projects that begin with purely non-commercial intent can make serendipitous discoveries with commercial potential. This is both reasonable and desirable, as long as the mutually agreed terms of the project between provider countries and researchers are followed and the provider country receives its agreed upon share of the benefits. If the terms of a project assumed no commercial intent, then new terms should be negotiated if commercial intent emerges during the project. The indicators of commercial intent, mentioned above, could serve as operational criteria for determining when new terms must be negotiated.

(B) *Third party use of samples.* International transfer of samples is often necessary because many developing provider countries lack taxonomic expertise for identification and the resources to create and maintain repositories for long-term curation of reference collections of biological samples (e.g., museums, herbaria, culture collections) as well as the instrumentation for important analytical techniques (e.g., DNA sequencing, electron microscopes). Provider countries are concerned that once samples of their genetic resources are stored abroad, they could be lent to third parties who will use them for commercial purposes without sharing benefits. New IT systems and codes of conduct that enable the tracking of loaned specimens are becoming more common among repositories and communities of repositories (e.g., IPEN (5), ITPGRFA (6) and MOSAICC (7)). Creative Commons licensing (8) is also gaining acceptance

as a mechanism for improving access, documenting ownership, and giving attribution to providers while prohibiting commercial use. Through these systems, provider countries will have access to information on the downstream use of their genetic resources (9).

(C) *Data in the public domain.* Developing countries may have limited capacity for commercial development based on research results in the public, including the results of research on their own genetic resources. In the long-term, capacity building and training will reverse this inequality of capabilities – two key benefits of many non-commercial research projects. In the short term, provider countries should be given the opportunity to protect their property rights before they are published and lead to commercial development by others. This could be accomplished by including a standard element in non-commercial ABS agreements -- a requirement that users must provide copies of manuscripts to provider country authorities when they are submitted for publication. Provider countries would not have the right to block, delay, or edit the publications, but they would have an opportunity to protect property rights before publication.

Ensuring the fair and equitable sharing of the monetary benefits of commercial research is a complicated legal challenge. The CBD's ABS Working Group has labored over this issue for years. In contrast, ensuring the open sharing of the benefits of non-commercial research may be relatively straightforward. As the deadline for submitting the text for an International Regime approaches, Parties to the Convention may wish to harvest this 'low-hanging fruit'. At the April 2009 meeting of the ABS Working Group, the notion of a simplified system of access to genetic resources for non-commercial research seemed to be gaining support. Specific proposals were put forward by several Parties in the negotiation and, relative to other ABS topics, these generated no heated discussion. The next rounds of ABS negotiations will be in November 2009

in Montreal and in March 2010 in Colombia. Participants in the Bonn Workshop will be submitting documents that support the proposal for a simplified access regime for non-commercial research, such as the following.

An operational definition for non-commercial research. Research with the goal of adding knowledge to the public domain, without restrictions or proprietary ownership, is non-commercial in nature. The research specimens collected during this research should either remain in the country of origin or should be maintained in *ex situ* collections under terms of usage that are mutually agreeable to the provider country and stewards of the specimens.

Simplified, standardized access procedures. Countries such as Australia have implemented procedures that minimize the transaction costs, bureaucracy, and delays associated with granting access to genetic resources for non-commercial research. By using standardized documents, provider countries can promote international research collaborations without compromising control of the use of their genetic resources. Examples of such documents are the Standard Material Transfer Agreement of the ITPGRA (6) and Creative Commons licenses (8).

Proactive measures that promote trust. The research community can be active in building trust with provider countries, thereby reinforcing the mutual benefits of simplified access procedures. A consortium of botanical gardens has developed guidelines for ethical access to and use of plant genetic materials (10) and these guidelines form the basis of institutional policies. The Swiss Academy of Sciences has compiled good practices for non-commercial research that provide detailed guidance to institutions and their researchers (11). The German Research Foundation has produced obligatory Guidelines for grant applications in the scope of the CBD regulations (12). Provider countries can have more confidence in long-term relationships with institutions that adopt these policies than they can with individual

researchers who may have no established relationships of trust with a provider country.

Repositories of *ex situ* collections can modernize their systems for documenting their specimens, linking them to the ABS agreements under which they were obtained from provider countries and documenting their subsequent use in more transparent ways. Research funding agencies can begin to require adherence to ethical practices, as they do for research involving human and animal subjects.

The most important next step is for researchers, their institutions and professional societies to become aware and involved. Without a concerted effort, an International ABS Regime may make no distinction between commercial and non-commercial research. Taxonomists, ecologists, and many other biologists will then be viewed in the same light as bio-prospectors from pharmaceutical and agribusiness companies (12). The time remaining before the CBD's July 2010 deadline is getting shorter, and the doors to international non-commercial biodiversity research could soon be closed.

References and Notes

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2. Report of a workshop on Access and Benefit Sharing in Non-commercial Biodiversity Research; <http://barcoding.si.edu/PDF/BonnABSWorkshopReport-FINAL.pdf>
3. For the complete CBD text see <http://www.cbd.int/convention/convention.shtml>
4. Report of the meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions, and Sectoral Approaches; <https://www.cbd.int/doc/meetings/abs/abswg-07/official/abswg-07-02-en.pdf>

5. IPEN, International Plant Exchange Network, is a consortium of botanical gardens that share a database and data management protocols for the exchange of plant samples; see <http://www.bgci.org/resources/ipen>
6. ITPGRFA, the International Treaty for Plant Genetic Resources for Food and Agriculture, is a system of exchange of living samples of 64 crop species from international research centers. A distributed database system with a web-based interface provides access to information on the movement of samples; see <http://www.planttreaty.org/>
7. MOSAICC, Micro-Organisms Sustainable use and Access regulation International Code of Conduct, is a set of guidelines for the negotiation of access to microbial samples and their handling after international transfer; see <http://bccm.belspo.be/projects/mosaicc/>
8. <http://creativecommons.org>
9. CBD commissioned “Study on the Identification, Tracking and Monitoring of Genetic Resources”; see Executive Summary, Standards in Genomic Sciences 1 (2009) doi:10.4056/sigs.1491; full text at <http://www.cbd.int/doc/meetings/abs/abswg-07/information/abswg-07-inf-02-en.pdf>
10. “Principles on Access to Genetic Resources and Benefit-sharing for Participating Institutions” have been endorsed by 22 botanical research institutions; see <http://www.kew.org/conservation/principles.html>
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