Access and Benefit Sharing: Understanding the Rules for Collection and Use of Biological Materials

CARL-GUSTAF THORNSTRÖM, *Senior Research Advisor, Agriculture, Sida/SAREC; Docent-Associate Professor, Guest Researcher and Advisor on Genetic Policy, Swedish Biodiversity Center, Swedish University of Agricultural Science, Sweden*

ABSTRACT

The rules that govern the collection and use of biological matter have changed dramatically in the last 15 years. Arising out of the Convention on Biological Diversity (CBD), the Access and Benefit-Sharing (ABS) project applies to research carried out for either purely scientific or commercial reasons, for which organisms or parts thereof and/or related traditional knowledge are obtained from countries that are party to the CBD and their local and indigenous communities. Other agreements have added new ABS legislation to govern the acquisition and use of biological material and related information. Everyone—including tourists, nature conservationists, scientists, photographers, and journalists—is subject to these new regulations. But scientists and researchers who seek to access and use proprietary genetic resources, biological matter, and related information (such as traditional knowledge and farming know-how) are especially affected by the ABS project. It is essential for scientists and researchers to understand the fundamental principles of ABS. This includes knowing the relevant rules, regulations, laws, customs, and conditions for benefit sharing in the country where one intends to conduct research and/or collect samples. One must carefully plan ahead for any such activities by contacting key organizations and filing the proper documentation. Lack of planning may lead to unfortunate and undesired outcomes, including fines, imprisonment, deportation, and denied future access. Planning is critical.

1. INTRODUCTION

According to the Convention on Biological Diversity (CBD), biological resources belong to the states in whose territory the resources are found. So, with regard to ownership, biological resources are no different from mineral resources, oil, or timber. However, in recent years there have been times when this principle of ownership has not been respected. Resources were exported, developed, and commercialized without the consent of the countries that provided them and without enabling those countries to partake in the benefits that resulted from these activities. In order to prevent this *biopiracy* and create a climate of mutual trust, the community of states undertook to regulate the handling of genetic resources in a binding international agreement referred to as the CBD.

CBD implementation is not only a moral obligation, but also a legal one that binds member states. The goal of the CBD is to conserve biological diversity and to promote its sustainable use in conjunction with the fair and equitable sharing of benefits. Responsibility for implementing the agreement is given to the state in which the biological material originates. However, all states have a responsibility to cooperate in implementing and enforcing the agreement. For industrialized countries, this means supporting biodiversity-rich, but often economically poor countries in their efforts to conserve and manage biodiversity. The keys to these collaborative efforts are technology transfer and cooperative research. The CBD contains rules that clarify the rights and responsibilities of all of the parties involved in these efforts.

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To advance its mission, the Conference of the Parties (COP) of the CBD decided in 2004 to create the Access and Benefit-Sharing (ABS) project, an international program overseeing access to genetic resources and the sharing of benefits arising out of their utilization. Negotiations over ABS began in 2005. It is anticipated that it will take up to ten years for it to be completely established.

Correspondingly, over the last decade a number of new legally binding agreements regarding biological material/related information have been signed and ratified by United Nations member countries. Examples are the CBD, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), treaties of the International Union for the Protection of New Varieties of Plants (UPOV, particularly the 1991 treaty), the International Treaty on Plant Genetic Resources for Food and Agriculture (the Treaty), the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (ICGTK) that meets under the World Intellectual Property Organization (WIPO), the Cartagena Protocol on Biosafety under the CBD, and the nonbinding Global Crop Diversity Trust, among others.

All these agreements add new legal dynamics to ABS legislation that addresses the acquisition and use of biological material and related information (such as ethnobiology and traditional knowledge). Indeed, there is a new world order emerging in relation to biological matter, a fact that changes the nature of public and private sector research and development efforts.

Everyone, including tourists, nature conservationists, scientists, photographers, and journalists, are subject to these new regulations. Particularly targeted are scientists and researchers who make significant use of proprietary genetic resources, biological matter, traditional knowledge, and farming know-how. Such knowledge may, in national legislation, be considered intellectual property (IP) or trade secrets, and, as such, neither in the public domain nor available for unauthorized appropriation.

Violation of the new access laws (for example, by scientists conducting unauthorized collection activities) can result in fines, imprisonment, and denial of future visits to the collection area. A violation may result in increased transaction time for obtaining formal access permits. A violation may also result in a prohibition on other scientists working in a country.

Unfortunately, it can take a lot of time to get the requisite permissions for collecting biological specimens. In Brazil, approximately 400 applications to use biological materials are received annually. The processing rate for these applications is 25–50 per year. This is due to strict ABS legislation. A similar situation prevails in Colombia, which has received some 50 access applications over the last five years. Of the 50 applications, 22 were denied due to improper access behavior, and one application (for biological research on dolphins) was approved. The remaining applications are still being processed.

2. THE NEW GENETIC-POLICY LANDSCAPE

Below is a brief summary of each agreement in the new genetic-policy landscape, with regard to use of biological matter.

- The CBD, adopted in 1992 at Rio de Janeiro, provides national sovereignty over genetic resources and access conditions for other sovereign parties.
- TRIPS, adopted in Marrakesh in 1994, provides a minimum IP protection standard for biological matter such as plant varieties, microorganisms, and microbiological processes.
- ICGTK was set up in 2001 by WIPO to discuss IP issues relating to access to genetic resources and the protection of traditional knowledge, including disclosure requirements in patent applications.
- UPOV provides legal protection for plant varieties fulfilling the NDUS criteria (new, distinct, uniform, and stable), while including a breeder's exemption and farmer's privilege.
- The International Treaty on Plant Genetic Resources for Food and Agriculture, adopted in Rome in 2001, provides a multilateral system of access and benefit sharing under a

revised material transfer agreement (MTA) in relation to some 35 defined crops.

- The Global Crop Diversity Trust, set up in 2002, is an attempt by the Food and Agriculture Organization (FAO) of the United Nations and the World Bank to establish a trust fund for global *ex situ* collections of germplasm of relevance for food and agriculture.
- The Cartagena protocol, adopted in Montreal in 2000, provides rules for the transfer of genetically modified living organisms across borders.
- In 2002, the CBD adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization. A voluntary supplement to the CBD, the Bonn guidelines offer basic information about the rules on access and concrete procedures (or protocols) to follow. The objectives of the Bonn guidelines in relation to academic research are:
  - to promote awareness of the implementation of relevant provisions of the CBD
  - to provide parties to the CBD and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits
  - to provide information about the practices and approaches to be adopted by users and providers in the context of access and benefit sharing
  - to promote capacity building and the transfer of appropriate technology to providing parties

3. IP RIGHTS

IP rights are temporary, exclusive ownership rights to the *application* of an idea. Such rights may be granted in the form of patents, trademarks, industrial designs, copyrights, geographical indications, or trade secrets. Given the breakthroughs in biotechnology and information technologies in the last few decades, intellectual property has expanded considerably into the area of biological matter. For example, in the area of agricultural research the following biological matter falls under various IP regimes:

- plant seeds or other propagative plant parts collected after 1994
- plant and animal cell lines
- plasmids
- other recombinant vectors
- gene promoters
- gene markers
- transformed bacteria
- isolated plant DNA
- plant cDNAs
- isolated animal DNA
- bacteria (other than the transformed bacteria)
- isolated/purified proteins (other than those obtained by purchase of laboratory reagents)
- equipment for specialized laboratory purposes
- information regarding laboratory methods
- genomic sequence database(s)
- other nucleotide sequence database(s) such as PCR primer databases, cDNA sequences

Traditional and farming knowledge is also protected under the CBD and the Treaty, subject to national legislation. In general, researchers in the public sector, using proprietary biological materials and related information owned by private sector companies, may have to sign agreements stipulating further use and confidentiality conditions. Furthermore, public research products using proprietary materials and methods may be required to sign license and royalty agreements with those who hold the relevant IP rights.

It should always be remembered that IP protection is territorial; it may be recognized in some countries and not in others. This territoriality of intellectual property has implications for scientists' freedom to operate: what they may be able to do in one country may not be possible in another country without an appropriate license.

4. THE EMERGING NEW WORLD ORDER REGARDING BIOLOGICAL MATTER

The new national sovereignty over biological and genomic matter mandates new rules for the access and use of biological matter and related information. Examples of recent legislation in Latin America include the Andean Pact Decision 391/96: Common Regime on Access to Genetic Resources.[1] Peru, in accordance with its National Strategy on Biological Diversity (Decreto Supremo No. 102-2001-PCM), recently added legislation relating to traditional knowledge (Law 27.811, August 2002), and a special national authority (INRENA) has been established to deal with ABS issues. In Africa, the Organization for African Unity (OAU, now the African Union) Model Law for the Protection of the Rights of Local Communities Farmers and Breeders and the Regulation of Access to Biological Resources (adopted in Addis Abeba, December 2001) has been used by some nations as a model for regulating access to biological material. In 2001, India adopted a bill to protect plant varieties and farmer's rights (Bill No. 123 of 1999) and, in 2000, a biodiversity bill (Bill No. 93 of 2000).

These examples illustrate the different kinds of regulations now facing foreign parties, whether scientists, commercial prospectors, or nature conservationists, who seek access to biological material and information. The examples suggest a need for a coherent understanding of researchers' obligations under TRIPS and the International Treaty on Plant Genetic Resources for Food and Agriculture.

5. OBTAINING RESEARCH PERMITS WITH ABS PROVISIONS

The following issues should be addressed before collection leading to R&D begins:

- Under which conditions may I, as a scientist, *enter* another sovereign state in my scientific capacity?
- Under which conditions may I, as a scientist, *collect* biological material and related information?
- Under which conditions may I, as a scientist, *carry out or export* biological material and related information from that sovereign state?
- Under which conditions may I, as a scientist, *make further use* of collected biological material and related information?

Before collecting for purposes of research, contact your counterpart in the country to find out which rules apply. It is useful to also contact that country's embassy/consulate/legation in your own home country. Information on the following topics would be useful:

- requirements for foreign parties to access biological material and information
- conditions of benefit sharing
- conditions regarding applying IP rights
- national focal point for handling ABS issues
- ABS conditions (are written instructions available to foreign parties?)

6. PREPARING YOUR RESEARCH PERMIT APPLICATION

After having checked with your counterpart or the relevant embassy, fill in any research permits provided by relevant authorities in the country you plan to visit. If ABS issues are not specified, then do the following:

- Present briefly the scientific objectives, refer to your national counterpart, and include specifics about what biological matter and related information is planned for collection.
- Indicate how you will collect the material and with whom, and state if duplicates will be deposited in the country where collection is carried out.
- Indicate that, if necessary according to the country's laws, you will apply for an export permit.
- Indicate how further use of the collected material will be made upon your return, such as:
  - showing material and sharing information at seminars and lectures

  - sharing collected material and information with other scientists, botanical gardens, and/or private companies
  - using the collected materials and/or information in the R&D of products that may eventually be commercialized
- Indicate, in case of possible commercialization, what steps you have taken to comply with relevant national ABS provisions in the country concerned.

7. IF YOU GET INTO TROUBLE

Should you encounter difficulties, or just have questions related to ABS, consult the clearinghouse or the legal department of your research institution, university, or college for specific advice and information about the policies and guidelines your home institution has implemented to comply with the CBD and other agreements.

If the answers you get are inadequate, then consult your country's ABS focal point or ask research funding agencies about colleagues who have contacts in the country concerned. Contact the embassy of the country concerned in case their national authorities do not answer; try direct contact by telephone. Remember that it is usually far easier to be cautious and proceed correctly than it is to fix a problem after it has happened.

8. ISSUES OF UNCERTAINTY

Unfortunately, there is still uncertainty concerning the potential restrictions of accessing, using, and transferring biological material and related information. These include, but are not necessarily limited to:

- **international seas and arctic areas, which are not covered by national laws.** ABS issues regarding these areas are not fully regulated in international conventions
- **protection of traditional/indigenous knowledge, which is still being established.** Such protection is possible under CBD Article 8 (j), subject to national legislation. At present there are some 20 national legislations in place using the sui generis provisions. However, these have not yet been tested by the TRIPS Council and are still under discussion in the Intergovernmental Committee.
- **global consensus on Access and Benefit Sharing for all genetic resources, which is still being developed.** This initiative, following the CBD Bonn guidelines on ABS, is mainly discussed in the Intergovernmental Committee. Today access and exchange of the Treaty through the Treaty will be multilateral, according to a standardized Prior Informed Consent/Mutually Agreed Terms and a standardized MTA agreed by the governing body of the Treaty. Access to and exchange of all other genetic resources and material (excluding human material) is presently subject to bilateral provisions set in national legislation. Some 35 countries have legislation in place, including India, Brazil, and the Andean Community. The ABS project under CBD and the Intergovernmental Committee is an attempt to try to standardize ABS for non-Treaty material.[2]
- **legal protection of plant varieties inside/outside UPOV.** Landraces and farmer varieties/primitive cultivars are protected, subject to national legislation under CBD Article 8 (j) and the Treaty Article 9. The NDUS criteria of UPOV do not normally cover landraces and farmer varieties/primitive cultivars, but these are still the result of intellectual innovation, mainly by local farmers. In TRIPS Article 27.3 (b) provisions are given to introduce sui generis protection of such plant material. India's plant variety protection and farmer's rights bill provide such protection.
- **Certificate of Origin / Disclosure of Origin (CO) in IP applications.** Discussions are ongoing in CBD and in the Intergovernmental Committee regarding a compulsory requirement in IP/patent law that applicants must provide a Certificate of Origin that verifies bona fide access (CBD's Prior Informed Consent/Mutually Agreed Terms) of genetic resources used. Controversy exists with regard to CO

"when possible" vs. "always required" for granting intellectual property.

- **nonlist material in the Treaty, nonparties, and repatriation of genetic resources.** Questions remain, for example, regarding material that is currently designated under the agreement between the Consultative Group on International Agricultural Research (CGIAR) and FAO of 1994, but that is not on the Treaty crop list (such as groundnuts and soybean). The roles and rights of parties who have not signed/ratified the Treaty still remain open questions, as are provisions in the MTA accompanying repatriation to parties/nonparties of the Treaty.
- **requests for germplasm samples.** The CGIAR genebank collections will form the base of multilateral crop material under the Treaty. The majority of requests for germplasm presently come from developing countries, which increasingly (referring to the Cartagena protocol) require that centers of the CGIAR shall fully guarantee that delivered germplasm does not contain genetically modified crops. Checking every such delivery for a CGIAR center represents significant costs.

9. CONCLUSIONS

The implementation of the ABS system is ongoing, both at the national and international levels. Thus, the relevant authorities may therefore not be clearly designated, and the established procedures may not be transparent and smooth. If the scientists can choose where to carry out research and collection activities, he or she should examine the relevant experience of other researchers and institutes. The national law of the providing countries regulates the ABS procedure. This includes the definition of the competent government agency and of the other stakeholders that must be involved. If relevant national legislation does not yet exist, access permits may be issued on a case-by-case basis, based on general principles of law and similar proceedings and rules.

The ABS procedure may also be combined with other licenses and permits, including for research, collection, and export, as well as Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permits and so forth. However, ABS will not yet apply in most cases and countries. Standardized MTAs and benefit-sharing agreements for similar resources and similar uses may already exist (taxonomy, collection, research, commercialization).

The Bonn guidelines recommend public participation at the local level with regard to all government decisions concerning issues involving resources and permits that affect the public. This may lead to the need for stakeholders at different levels to grant their *prior informed consent*, which may ultimately cause the ABS procedure to become more complex and time consuming. Based on its current complexity, ABS legislation can be divided into four broad categories:

1. **No ABS situation.** The research does not involve any access situation or genetic resources. Thus no ABS contract is necessary. However, other research permits may be required.
2. **Simple ABS situation.** The research involves the collection and transfer (including export) of samples for an inventory. A (standardized) MTA is sufficient.
3. **ABS situation.** The export of samples is required for further analysis and study in a laboratory abroad. No further exploitation is planned. A simple ABS contract is sufficient.
4. **Complex ABS situation.** The proposed research involves various steps, including possible research for commercial purposes or the use of traditional knowledge. A full ABS contract is required.

Whatever the ABS situation turns out to be, in the final analysis the most critical aspect will be to understand the ABS regime; to thoroughly research the laws, rules, regulations, and customs of the country where you intend to conduct research and/or collect; and to *plan ahead* for all foreseeable contingencies. This will make a re-

warding trip far more likely, and your subsequent research activities will have broad benefits that are consistent with the spirit and goals of the ABS project. ■

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CARL-GUSTAF THORNSTRÖM, *Swedish Biodiversity Center, Swedish University of Agricultural Sciences, PO BOX 7007, 750 07 Uppsala, Sweden. Carl-Gustaf.Thornstrom@cbm.slu.se*

1 www.comunidadandina.org/INGLES/normativa/D391e.htm.

2 See, for example, www.wipo.int/tk/en/genetic/proposals/index.html.

3 Thornström CG and L Björk. 2006. Accessing Others Proprietary Biological Matter and Related Information–Towards a Handbook in Access and Benefit Sharing and Related Intellectual Property: Part Three: Entering into Agreements. Unpublished.

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