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Windhoek, 2-5 December 2008
Item 3 of the provisional agenda*

CONCEPTS, TERMS, WORKING DEFINITIONS AND SECTORAL APPROACHES RELATING TO THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING

Submission from the international workshop on the topic of "Access and Benefit-sharing in Non-Commercial Biodiversity Research", Bonn, 17-19 November 2008

Note by the Executive Secretary

1. As envisaged in paragraph 12 of the revised annotated agenda of meeting (UNEP/CBD/ABS/GTLE/1/1/Add.1/Rev.1), the Executive Secretary is circulating herewith, for the information of participants in the Group of Technical and Legal Experts on Concepts, Terms, Working Definitions and Sectoral Approaches in the Context of the International Regime on Access and Benefit-Sharing, a submission from the international workshop on "Access and Benefit-sharing in Non-Commercial Biodiversity Research", which was held in Bonn from 17 to 19 November 2008.

2. The submission is being circulated in the form and language in which it was received by the Convention Secretariat.

* UNEP/CBD/ABS/GTLE/1/1.

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SUBMISSION FROM AN INTERNATIONAL WORKSHOP

"ACCESS AND BENEFIT SHARING IN NON-COMMERCIAL BIODIVERSITY RESEARCH"

I. INTRODUCTION

This document provides responses to four questions addressed to the Ad Hoc Technical Experts Group (AHTEG) on Concepts, Terms, Working Definitions, and Sectoral Approaches that were contained in the Conference of the Parties (COP) decision IX/12, annex II, section B. The responses were prepared during an international workshop by 51 researchers and representatives of national and international organizations from 24 countries.

Governments and researchers in both industrialized and developing nations agree that non-commercial research contributes to the Convention on Biological Diversity's (CBD) objectives of conservation and sustainable use of biodiversity. Non-commercial research can generate non-monetary benefits which help narrow the gap in science and technology capacity between industrialized and developing countries. In some cases, non-commercial research can also lead to commercial developments that will produce economic benefits for both provider and user countries. Access to biological material is critical to non-commercial research and for this reason the members of the non-commercial research community are eager to participate in the development of the International Regime for Access and Benefit Sharing (ABS).

II. BACKGROUND

With this goal in mind, ten national agencies and international scientific organizations[1] convened a workshop on "Access and Benefit Sharing in Non-Commercial Biodiversity Research" at the Museum Koenig in Bonn, Germany, on 17-19 November 2008[2]. The organizers gathered nominations for biological scientists, policy specialists, representatives of NGOs and government agencies, and others who are interested and knowledgeable in matters concerning the CBD and ABS. Fifty-one participants[3] were selected to provide the following balanced representation among geographic regions and perspectives. The researchers were primarily drawn from the community of taxonomists, systematic biologists, museum and herbarium scientists, ecologists, and genome scientists. This emphasis on whole-organism research (as opposed to biochemistry, biophysics, or developmental biology, for example) is closer to the original objectives of CBD and the missions of the workshop's sponsors. They were asked to provide their personal perspectives and they did not participate as official representatives of their respective agencies, institutions, or research communities.

Sector			**Geographic Region**				
Research	**Agency**	**Other**	**OECD Countries**	**Africa**	**Latin America**	**Asia**	**Pacific**
29	10	12	28	8	4	9	2
56.9%	19.6%	23.5%	54.9%	15.7%	7.8%	17.6%	3.9%

Prior to and during the workshop, participants were provided with CBD documents including those related to preparations for the upcoming meetings of the AHTEGs in Namibia and Japan. Participants were asked to prepare three documents: (1) a workshop report on the overall topic of the relationship

[1] The workshop was sponsored by: The Consortium for the Barcode of Life (CBOL); the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation); Museum Koenig, Bonn; the Swiss Federal Office for the Environment (FOEN); the International Barcode of Life Project (iBOL); the European Distributed Institute of Taxonomy (EDIT); the Moorea Biocode Project of French Polynesia; Muséum National d'Histoire Naturelle (MNHN, Paris); DIVERSITAS/bioGENESIS; and UNESCO's Natural Sciences Sector.

[2] For workshop prospectus, agenda, and documents, see http://barcoding.si.edu/ABSworkshop.html.

[3] The list of workshop participants is available at http://barcoding.si.edu/ABSworkshop.html.

between non-commercial research and the International ABS Regime[4], (2) responses to two of the questions addressed to the AHTEG on Compliance, and (3) responses to the four questions, presented below, that were addressed to the AHTEG on Concepts, Terms, Working Definitions, and Sectoral Approaches in COP IX/12 Annex IIB. These four questions were:

A. What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?

B. Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;

C. Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;

D. What are [*sic*] the range of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?

III. RESPONSES TO QUESTIONS ADDRESSED TO THE AHTEG

In considering the questions posed by the COP, participants in the workshop understood that the AHTEG would consider the full range of sectors involved in CBD and ABS. The workshop focused on non-commercial research and therefore could not respond to the questions precisely as posed by the COP. The workshop participants agreed to modify the questions slightly in order to answer them from their perspective as scientists devoted to non-commercial research and officials involved in ABS matters related to non-commercial research. In doing so, the workshop participants hoped that their perspective will be of interest to the AHTEG members, even though the questions addressed by the workshop are not identical to the questions posed in COP IX/12 to the AHTEG.

A. What are the different ways that the non-commercial research sector and its subsectors understand and treat biological resources[5], genetic resources[6], derivatives, and products?

The workshop participants recognized that the CBD contains definitions for the terms "biological resources" and "genetic resources" and that the term "functional units of heredity" are core concepts in the discussion of ABS regulations. Nevertheless, these terms, and the terms "derivative" and "product" are not recognized as clear, unambiguous concepts across the biological sciences. Biologists commonly use the terms "specimen", "material" or "samples" when referring to physical items. Biological properties and processes are commonly viewed on the different hierarchical levels of molecules, genes, cells, tissues/organs, individuals, populations, species, communities and ecosystems. To researchers, the term "biological resources" is non-specific and could reasonably be interpreted to mean anything from an individual nucleotide to a bacterium to an entire forest. Similarly, the term "genetic resources" that have "functional units of heredity" could be understood as a segment of DNA, a population of organisms, an entire species, or anything in between.

For example, researchers describe and study the characteristics and functions of cells, tissue, organisms, species, communities, and ecosystems. Most of this study involves observations of "phenotype" – the morphology, behaviour, functionalities, and interrelationships of the objects of study. Phenotype results from the interaction of genotype (information in the functional units of heredity) and the environment. In recent years, characterizing the genotype itself, through gene sequencing technologies, has become

[4] The full workshop report will be released in December 2008 at http://barcoding.si.edu/ABSworkshop.html

[5] Defined in CBD Article 2: "includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity."

[6] Defined in CBD Article 2 as "genetic material of actual or potential value; 'genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity."

another approach to characterizing organisms and species. Strictly speaking, the "biological resources" that make up the living world are much more than the information in "genetic resources".

A "derivative" can be the result of a natural metabolic process or it can be the end-product of a synthetic procedure, depending on the scientific context. A "product" in biological science can be a natural or man-made substance. Some workshop participants noted that in their specific research areas, "derivatives" could be interpreted and understood as "genetic resources" if they are the result of developmental pathways controlled by genes, which provide the information in the functional units of heredity. However, most of the workshop's participants agreed that "derivatives" and "genetic resources" could be interpreted as separate and distinct concepts. For them, "genetic resources" includes the information contained in the functional units of heredity. "Derivatives" are the functional outcomes of the expression of that information, mitigated by the environment, and are therefore not a "genetic resource", strictly speaking.

Participants agreed that whatever meaning is attached to these terms, Article 15 of the CBD should be interpreted to include only "the utilization of genetic resources" in its ABS provisions, not the broader category of "biological resources". For purposes of regulating access and sharing benefits under the terms of Article 15, the focus should be on the proposed utilization of genetic resources, the information in the functional units of heredity. In the context of non-commercial research, it makes sense to apply article 15 of the CBD to "biological resources" only when access to that resource is being requested with the clear purpose of looking at it as a carrier of genetic material and for the objective of utilizing the genetic information that it contains.

It may be necessary to refer to "biological resources" in Prior Informed Consent agreements (PICs), Mutually Agreed Terms (MATs) and benefit sharing arrangements (BSAs), but this term could be viewed as all-inclusive, reaching beyond the scope of applicability of the CBD. National and international regulations applicable to "biological resources" would therefore be independent of the regulation of the utilization of genetic resources based on Article 15. This interpretation is in agreement with the current practise by most countries of regulating food products and commodities which contain biological material (such as wood, organic clothing, etc.) without reference to CBD or its ABS provisions.

B. What are various forms of utilization of genetic resources in the sub-sectors within the non-commercial biodiversity research sector?

Information on the functional units of heredity is used across the full range of non-commercial research activities. For example, DNA sequencing is now widely used as a way to characterize and document biological diversity at the genetic level. In some research areas such as taxonomy (and the CBD's Global Taxonomy Initiative, GTI[7]) and systematic biology, selected gene sequences are used as diagnostic characters for distinguishing and identifying species (through DNA barcoding, for example) and for understanding evolutionary relationships (through phylogenetic analysis). Other research activities study gene sequences in order to understand their expression through developmental pathways and responses to the environment.

These types of utilization are aimed at creating new knowledge and a better understanding of the living world. They produce results for use by other practitioners in that research area and for use in other fields of research and application. For example, taxonomy produces inventories of species that live in a country or region, and systems for species identification. These identification systems can be used by researchers in ecology or ecosystem studies and by border inspectors responsible for preventing the introduction of agricultural pests or illegal trade of endangered species. The utilization of genetic resources in these ways is not aimed at modifying or propagating organisms for commercial purposes.

Many of the genetic research techniques used by non-commercial researchers (*e.g.*, DNA sequencing) are also used by researchers with commercial intent. It is not the techniques themselves which distinguish

[7] The Global Taxonomy Initiative is a cross-cutting initiative of the CBD that has been put in place to facilitate attainment of CBD goals in other thematic areas and cross-cutting initiatives.

commercial from non-commercial research activities. Rather, it is the intent for which the techniques are used which separates the classes of commercial and non-commercial research projects.

C. Should there be different approaches to access and benefit sharing for communities with and without commercial intent?

The workshop participants concluded that the overall structure of PICs, MATs, and BSAs should apply to non-commercial research as well as commercial research. Non-commercial research is, in principle, also subject Material Transfer Agreements (MTAs) and other contracts required by national legislation.

Access to genetic resources for research is regulated by a permitting process in many countries, especially those that have not yet implemented ABS legislation and regulations. Collecting permits or general research permits are not good substitutes for more specific PICs and MATs that are designed to authorize access to genetic resources for research.

Participants also concluded that the non-commercial nature of research in this sector should make it possible to use standardized ABS documents and procedures. There are examples of such standardized approaches that provide important good practices and lessons learned that may be relevant to development of the International Regime for ABS. These models indicate ways that a standardized approach to ABS agreements could promote the security of commercial benefits to provider countries while also:

- Reducing the time, effort, and transaction costs currently needed to develop ABS agreements in many countries;
- Promoting non-commercial research in provider countries; and
- Increasing the non-monetary benefits that accrue to provider countries, especially those that increase their capabilities in science and technology through research collaboration and training opportunities.

This suggestion for a standardized, simplified system of PICs, MATs, and ABS agreements for non-commercial research is based on a single premise: non-commercial research is devoted to generating new knowledge and other research results that are shared openly with the global research community and society in general. Provider countries are therefore assured access to all the benefits of the research.

The workshop's participants recognized three challenges associated with this proposal:

1. It can be difficult to distinguish non-commercial from commercial research;
2. Non-commercial research produces information and samples that can be used by third parties for commercial purposes; and
3. Non-commercial research projects can develop into commercial projects.

1. Distinguishing non-commercial from commercial research. Non-commercial research adheres strictly to a basic principle in science: results of research must be made public so that other members of the research community can test and confirm the results, and can use the results as a basis for future research. Commercial research often produces results that are also shared openly, but some of its results are protected as intellectual property to which access can be restricted.

In most cases, it should be possible to separate non-commercial from commercial research projects during discussions leading to agreements based on PIC and MAT. Proposers of non-commercial research projects should be willing to accept the terms of standardized documents that require the open dissemination of research results and prohibit patenting or other retention of intellectual property rights over the research results that are not acceptable to the provider country. The workshop participants recognized that open dissemination of results can be distinct from free access. For example, publishers often charge subscription fees for scientific journals, and books with non-commercial research results are sometimes sold for profit by publishers. Research samples that are curated in reference collections (*e.g.*, museums, botanical gardens, culture collections) are available to qualified researchers but

requesters of these samples can be asked to cover the cost of preparation and shipment. Access to these public research results can be negotiated under the terms of the BSA.

2. **Use of information and samples from non-commercial research by third parties for commercial purposes.** Once the results of non-commercial research have been released in the public domain, they can be used by third parties for commercial ventures as well as non-commercial research. Participants in the workshop recognized that provider countries will want to obtain the monetary and other benefits associated with all commercial developments that result from the access to genetic resources they have granted under an ABS agreement for non-commercial research. A standard PIC, MAT, and MTA for non-commercial research projects could serve this goal by including:

- Requirements for the involvement of a recognized research institution in the user country (or countries), as well as cognizant researchers, in the ABS agreement;
- Requirements for the involvement of research institutions and/or researchers in the provider country, with the understanding that these institutions and researches will represent the provider country's interests in identifying and protecting the potential commercial opportunities that may result from the research project;
- Assurances that any manuscripts that result from the research and submitted for publication will also be provided to the provider country in advance of publication. Pre-publication access to these manuscripts will allow the provider country with the opportunity to file patent applications to protect any intellectual property prior to its release in the public domain; and
- Restrictions on the supply of samples of the genetic resource to third parties. Standard clauses in ABS documents will need to accommodate international codes of taxonomic nomenclature which do not allow for restriction of access by third parties[8]. The CBD's Global Taxonomy Initiative is one example of a broad activity that involves codes of nomenclature and unrestricted access to reference collections[9].

[8] This happens for example in the taxonomy of bacteria & viruses For example the International Code of Nomenclature of Bacteria, now International Code of Nomenclature of Prokaryotes, currently published by the International Committee on Systematics of Prokaryotes (ICSP); or the International Code of Virus Classification and Nomenclature. This is due to the fact that the sample supporting the classification must be viable and deposited in two collection institutions in different countries. Botany and zoology taxonomies have similar rules but they do not disallow restriction of commercial uses by third parties since the specimen is usually dead. So refinements might be needed to amend either the classic ways these Societies use to operate although there might be scientific difficulties on manners to deal with these existing requirements and practices or the content of a standard non-commercial research MTAs concerning third party access restrictions. In practice, such bodies have more or less well-documented tracking systems to document where specimens have been sent, which might be built upon.

[9] The CBD Conference of the Parties Decision III/10 endorsed the recommendation by SBSTTA II/2 that the Global Environment Facility should support a Global Taxonomy Initiative that should, among other things, "[*strengthen*] reference collections in countries of origin including, where appropriate, the exchange of paratypes on mutually agreed upon terms; and [*make*] information housed in collections worldwide and the taxonomy based on them available to the countries of origin." It also, within the GTI Programme of Work set out in Decision VI/8, called for "*inter alia*, improved access by taxonomists of all Parties to the taxonomic reference material itself, particularly type specimens and material presently held outside countries of origin [since this is] is important in developing work within the GTI." In addition, COP IX/22, in para 3. "*Acknowledges* the role and importance of natural history collections and taxonomic institutions for fulfilling the goals of the Convention."

3. **Development of non-commercial research projects into commercial research projects.** In principle, access to genetic resources could be requested and approved using standard ABS documents that are appropriate for a non-commercial research project, but the research process uncovers unanticipated commercial opportunities. As a result of these new opportunities, researchers from either the user and provider countries (or both) may develop intents to restrict the distribution of some research results and to obtain intellectual property right. If the standard ABS documents are based on the premise of open sharing of all research results, then restricted access and proprietary ownership of research results will not be covered. The parties to the ABS agreement would therefore need to renegotiate an ABS agreement to cover the new commercial intent of the research project.

D. Identify and describe the characteristics of access and benefit-sharing arrangements for non-commercial research.

The basic contents of a standard ABS agreement for non-commercial research are described above. A model agreement with PIC, MAT, and MTA for non-commercial research could include the following standard elements:

1. Specification of the proposed non-commercial research and its objectives;
2. Declaration of non-commercial intent;
3. Information on the national authority responsible for ABS agreements;
4. Information on the local authority and local communities involved in the specific ABS agreement;
5. Information about and role of scientific institutions and researchers from the provider country in the proposed research activities, including any acknowledgement or co-authorship in publications;
6. Specification of the non-monetary benefits which might be generated by the project and shared with the provider country, including, for example:
    a) activities and contributions that build elements of the biodiversity research capabilities of the provider country; and
    b) pre-publication access by the provider country to research results;
7. Methods, equipment/research tools, and technologies that will be used;
8. Uses of research results and materials that are restricted;
9. Deposition of genetic resources and other research materials, and possible restrictions of subsequent use;
10. Conditions of transfer of samples to third parties;
11. Reporting requirements; and
12. Provisions concerning changes from non-commercial intent to commercial intent.
