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Convention on Biological Diversity

Distr. GENERAL

UNEP/CBD/WG-ABS/9/2 10 March 2010

ORIGINAL: ENGLISH

AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING Ninth meeting Cali, Colombia, 22-28 March 2010

COLLATION OF SUBMISSIONS PROVIDED IN RELATION TO PREAMBULAR TEXT, DEFINITIONS AND TEXT FOR INCLUSION IN ANNEX II TO THE REPORT OF THE EIGHTH MEETING OF THE WORKING GROUP ON ACCESS AND BENEFIT-SHARING

Note by the Executive Secretary

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INTRODUCTION

- 1. At its eighth meeting in November 2009, the Working Group on Access and Benefit-sharing built a consolidated text, including all the main elements of the international regime, to serve as a basis for further negotiations. This consolidated text is found in annex I to the report of the meeting (UNEP/CBD/WG-ABS/8/8). Annex II of the same report contains operative text related to institutional issues, implementing provisions and final clauses relevant for the consolidation of the international regime.
- 2. At the same meeting, the Co-Chairs indicated that no further submissions on main components contained in annex I were requested. However, new submissions would be allowed for preambular text, definitions and text for inclusion in annex II (Proposals for operational texts left in abeyance for consideration at the next meeting of the Working Group).
- 3. In light of the above, in preparation for the ninth meeting of the Working Group, Parties, other Governments, international organizations, indigenous and local communities and relevant stakeholders were invited to submit views and proposals, including operational text, by notification 2010-008 dated 19 January 2010.
- 4. In response to this notification, the Secretariat received submissions from: Canada; Switzerland; Berne Declaration, Church Development Service, Ecoropa, and the Third World Network and the Quebec Native Women Inc.
- 5. These submissions are being circulated herewith.

I. SUBMISSIONS FROM PARTIES

CANADA

Canadian submission on definitions, preambular text and operational text left in abeyance for ABSWG-9

Preambular text

Recalling the sovereign rights of States over their natural resources and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation

Further recalling decision VI/24 of the Conference of the Parties adopting the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization

Further recalling that each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not impose restrictions that run counter to the objectives of the Convention

Further recalling that Article 15(5) of the Convention provides that access to genetic resources shall be subject to the prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party; and in this context recognizing that each Contracting Party may determine that access to its genetic resources will not be subject to prior informed consent in the context of Article 15 of the Convention on Biological Diversity

Further recalling that Article 15(4) of the Convention provides that Contracting Parties shall take measures to ensure that access, where granted, is on mutually agreed terms

Further recalling that in accordance with Article 15(7) of the Convention the fair and equitable sharing of benefits arising from the commercial and other utilization of genetic resources shall be upon mutually agreed terms as decided between the provider and user.

Noting that Parties have differing legal systems, and accordingly have chosen to implement the access and benefit-sharing provisions of the Convention according to their national conditions.

Recognizing that the fair and equitable sharing of benefits can only be realized after access to genetic resources has been granted and when they have been used to generate benefits.

Recognizing that benefit-sharing on mutually agreed terms may include monetary and/or non-monetary benefits

Recognizing that benefit sharing measures under this regime are effective tools contributing to the eradication of poverty and the promotion of economic and social development

Recognizing the importance of providing legal certainty to the various stakeholders involved in the conservation, sustainable use and the fair and equitable sharing of benefits derived from the use of genetic resources and associated traditional knowledge

Recognizing that intellectual property rights play an important role in the fair and equitable sharing of benefits arising from the use of genetic resources and associated traditional knowledge, and that these rights need to be supportive of and do not run counter to the objectives of the Convention

Recognizing the importance of promoting equality in negotiations of mutually agreed terms between providers and users of genetic resources

Taking into account the need to ensure compliance with access and benefit-sharing national legislations, regulations and requirements, with the aim of ensuring the fair and equitable sharing of benefits arising from the commercial and other utilization of genetic resources and associated traditional knowledge

Noting that customary law provides a sub-set of existing rules related to access and benefit-sharing of genetic resources, and measures to comply with such rules

Emphasizing that both providers and users of genetic resources benefit from the availability of model clauses for potential inclusion in material transfer agreements and inventories/catalogues of typical utilizations of genetic resources since the use of such clauses and inventories will raise legal certainty, may lower transaction costs and will

contribute to creating a level playing field between provider and user when negotiating mutually agreed terms.

Definitions

Misappropriation

Misappropriation of a genetic resource means to acquire a genetic resource in violation of the provisions of domestic access and benefit-sharing legislation of a Party providing the genetic resource by failing to:

- a. obtain prior informed consent of the Party or any competent authority designated by the Party to provide such consent, OR
- b. enter into mutually agreed terms on access and benefit-sharing arising from the commercial or other utilization of genetic resources.

The submission of this definition is without prejudice to whether a definition will be necessary in the regime and whether Canada would ultimately be in a position to agree to a compliance measure associated with any definition of misappropriation.

Operational Texts Left in Abeyance for Consideration at the Next Meeting of the Working Group

Article XX Relationship to Other Instruments

Nothing in the international regime/protocol shall be interpreted as implying any change in the rights and obligations of a party under any existing international agreement.

Nothing in the international regime/protocol will prevent the development, recognition and accommodation of intergovernmental agreements relating to access and benefit sharing that achieve the objectives of the Convention and are consistent with the provisions of the international regime.

Article XX Financial Mechanism and Resources

- 1. In considering financial resources for the implementation of this international regime, the Contracting Parties [shall][should][will] take into account the provisions of Article 20 of the Convention.
- 2. The financial mechanism established in Article 21 of the Convention [shall][should][will], through the institutional structure entrusted with its operation, be the financial mechanism for the international regime.
- 3. Regarding the capacity-building referred to elsewhere in the international regime, the governing body of the [international regime][Protocol] will provide guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, and [shall][should][will] take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

- 4. In the context of paragraph 1 above, the Contracting Parties [shall][should][will] take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this international regime.
- 5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this [Protocol][international regime], [shall][should][will] apply, *mutatis mutandis*, to the provisions of this section.
- 6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this [international regime][Protocol] through bilateral, regional and multilateral channels.

SWITZERLAND

Bern 18.02.2010

Submission by Switzerland for WG-ABS 9 regarding the need for definitions in the ABS-IR

General considerations

Switzerland is of the view that the draft operative text of the ABS-IR (Annex I of UNEP/CBD/WG-ABS/8/8) should first be further elaborated and negotiated and only then work should be undertaken to define certain terms to be included in the ABS-IR. This seems particularly important in order to make the most efficient use of the remaining negotiating time to finalize the operative provisions of the ABS-IR, and to avoid negotiating these provisions in the exercise of defining certain terms.

The decision on what definitions the ABS-IR should contain might be based on the following:

A: Terms that are already defined in the CBD could be included in the ABS-IR but should not be newly defined, as this could lead to inconsistency with the provisions of the CBD and the existing practice under the CBD;

B: Specific terms which are unique in the context of ABS might be additionally defined in the ABS-IR in order to facilitate its implementation and to enhance legal certainty in ABS transactions and compliance mechanisms;

C: Certain terms might become sufficiently clear through further elaborating on and negotiating of the operative text of the ABS-IR and therefore no specific definition might be needed;

D: Some terms are best to be defined in mutually agreed terms between providers and users of genetic resources and associated TK. Thus no need might arise to include them as definitions in the ABS-IR.

Considerations on specific terms based on the current status of the ABS-IR

A: The following terms are defined in the CBD and could be referenced in the ABS-IR:

"Biological diversity", "Biological resources", "Biotechnology", "Country of origin of genetic resources", "Country providing genetic resources", "Genetic material", "Genetic resources", "Sustainable use"

B: The following terms are not defined in the CBD but could be defined in the ABS-IR:

"Utilization of genetic resources" means the modification, biosynthesis, breeding and selection, propagation and cultivation, conservation, characterization and evaluation, or any biotechnological application involving genetic resources in activities of research not aiming at commercialization, research and development aiming at commercialization, and commercialization.

Rationale: The concept of "utilization of genetic resources" is specifically contained in the third objective of the CBD and its Article 15.7 and is crucial in understanding the term "genetic resources" in the context of benefit-sharing. The first part of the proposed definition is based on the results of the technical and legal expert group (TLEG) on concepts, terms, working definitions, and sectoral approaches and lists important categories of typical forms of utilizations of genetic resources based on a technological approach (Para. 13, UNEP/CBD/WG-ABS/7/2). The last category identified by the TLEG has been replaced with "any biotechnological application", which in our understanding is broader and accommodates any missing important category of utilization of genetic resources. The second part of the definition draws on existing operative text in the draft ABS-IR that recognizes three typical forms of utilizations of genetic resources that are found across most sectors and that might trigger different kinds of benefits to be shared on mutually agreed terms.

"Misappropriation of genetic resources" – means access to genetic resources without prior informed consent and/or mutually agreed terms pursuant to the national access legislation of the country providing the genetic resources and the access provisions set out in the ABS-IR in force at the time of access.

Rationale: This definition of misappropriation of genetic resources is based on the submission by Switzerland for WG-ABS 8 that is also included in the draft ABS-IR (Option 2, Alternative A, Annex I of UNEP/CBD/WG-ABS/8/8). The proposal is based on CBD-language and it could work as an important incentive to implement the ABS-IR by connecting the national access legislation of the country providing the genetic resources with the access provisions to be agreed on in the ABS-IR.

- C: The following terms might become sufficiently clear through further elaborating on and negotiating the operative text of the ABS-IR and therefore **no specific definition might be needed**:
 - "Access" This term could become sufficiently clear through the operative text of the access component of the ABS-IR.
 - **"Benefit-sharing"** This term could become sufficiently clear through the operative text of the benefit-sharing component of the ABS-IR.
 - "Traditional knowledge" According to Article 8(j) of the CBD, this term means knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. Should an internationally agreed definition of traditional knowledge be sought, care has to be taken to accommodate the diversity of different forms of traditional knowledge of ILCs relevant for the conservation and sustainable use of biological diversity and existing international understandings.
 - **"Associated traditional knowledge"** This term could become sufficiently clear through further elaborating and negotiating the operative text under the component "traditional knowledge associated with genetic resources".
- D: The following terms seem to be particularly important in the context of benefit-sharing and could be defined between providers and users of genetic resources and associated traditional knowledge in mutually agreed terms. There **might be no need to include an internationally agreed definition in the ABS-IR**:
 - "Derivatives", "Products", "Research not aiming at commercialization", "Research and development aiming at commercialization", "Commercialization"

II. SUBMISSIONS FROM INDIGENOUS AND LOCAL COMMUNITY ORGANIZATIONS, INTERNATIONAL ORGANIZATIONS, RESEARCH INSTITUTIONS, NON-GOVERNMENTAL ORGANIZATIONS AND STAKEHOLDERS

BERNE DECLARATION, CHURCH DEVELOPMENT SERVICE, ECOROPA AND THIRD WORLD NETWORK

Submission of Text on Definitions by Berne Declaration (EvB), Church Development Service (EED), Ecoropa, and Third World Networld Network (TWN)

A legally binding ABS Protocol must be clear and comprehensive in addressing its scope. Since the late 1980s, governments as well as industry and civil society stakeholders advocated numerous cases as "access to genetic resources" and by this way developed a common understanding of what "utilization of genetic resources" means. This includes for example the use of molecules extracted from plants and animals for the devopment and production of drug, genes and enzymes for industrial production processes or the development and production of cosmetics and neutraceuticals from animal or plant extracts. The overall political aim of - and measurement for success for - the ABS Protocol is to bring all these cases under the scope of the future ABS Protocol. This includes the utilization of living organisms and there parts (which all can be characterized as genetic material according to the CBD) eg. for the purposes of breeding; extraction and cloning of genes and extraction of biochemical molecules synthesised by the cells as the result of active "units of heredity" for use in the development and production of above mentioned drugs, cosmetics, nutraceuticals etc..

The ABS Protocol can fulfill this aim either through a specific set of definition or explicit formulation in the operational text or through a combination of both. In its notification 2010-008 from Jan 16, 2010, the SCBD asked for submissions on inter alia text for definitions to be considered at the CIIC and ABSWG-9. For this purpose, the NGOs Berne Declaration (EvB), Church Development Service (EED), Ecoropa, and Third World Network (TWN) have developed text for definitions for the ABS Protocol und would lke to submit it to the SCBD.

According to the CBD definitions, genetic material - "any material of plant, animal, microbial or other origin containing functional units of heredity" - is turned into a genetic resource when "actual or potential value" is added to it. According to our understanding, any access to genetic material is the expression of adding value to this material through the user. Therefore any access to genetic material transforms it into a genetic resource under the CBD. The purpose of the definitions given below is to define the range of use of the genetic resource or associated traditional knowledge that triggers the application of the rules of the future ABS Protocol - specifically access, fair and equitable benefit-sharing and compliance. This approach avoids the renegotiation or additional interpretation of the CBD definitions which was regarded as not practical by the ABS-GTLE-01 and other meetings.

According to this understanding it is already the act of access to genetic resources that triggers the benefit sharing obligation under the CBD and a future ABS Protocol. Any MAT should cover benefit sharing milestones starting at the act of access and throughout the entire chain of creation of non-monetary and monetary profits through the actual use of the genetic resource.

The following definitions are set up in a way that intends to include in the ABS Protocol the access to genetic resources aiming at the use of biochemical molecules synthesised by living organisms and cells as the result of active "units of heredity". For this purpose the term "metabolite" has to be included in the definition section. The majority of all ABS cases put forward by different stakeholders and promoted as best practices are based on the use of biochemicals, eg. all cases related to the development of medicines. The direct use of the genes of organisms covered by the CBD only constitutes a minor case of ABS cases as explained in detail in the various NGO briefing papers made available to the delegates since ABSWG-3.

The following definitions also take into account that utilisation of genetic resources does not necessary mean using the tangible resource but also using the information and knowledge about the genetic

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resource, eg. which has been published as DNA sequence. In this context, the definition of the term "derivative" is of importance, especially with regard to a comprehensive coverage of the benefit-sharing provisions of a future ABS Protocol.

TEXT:

Definitions

"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

[from the CBD]

"Derivative" means any organic compound that is produced by chemical alteration of naturally occuring nucleic acids, proteins and metabolites or by chemical synthesis based on information and knowledge about them.

[based on definitions by biochemistry textbooks as the Oxford Dictionary of Biochemistry and Molecular Biology or Organic Chemistry (McMurray)]

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

[from the CBD]

"Genetic resources" means genetic material of actual or potential value.

[from the CBD]

"Metabolite" means any naturally occurring organic compound produced by processes of biosynthesis or biodegradation in living organisms based on the expression of the functional units of heredity.

[based on definitions by biochemistry textbooks as the Oxford Dictionary of Biochemistry and Molecular Biology or Biochemistry (Lubert & Stryer)]

"Non-commercial research" is characterised by specific mutually terms agreed between the provider and user of the genetic resource or the traditional knowledge associated with a genetic resource with the purpose to exclude their for-profit use and to subject any subsequent access by third parties and the application for any intellectual property rights by the user to a subsequent PIC and MAT with the provider.

[new definition]

- "Utilisation of genetic resources" means adding actual or potential value to living organisms or parts thereof, containing functional units of heredity through, inter alia:
- a) extraction of nucleic acids, proteins and metabolites;
- b) propagation and cultivation with the aim of extracting nucleic acids, proteins and metabolites;
- c) the subsequent use of these isolated nucleic acids, proteins and metabolites in their material form or in the form of information and knowledge about them;
- d) breeding and selection; and
- e) the use for conservation and research

for non-commercial and commercial purposes.

[based on the report of the ABS-GTLE-01 (Windhoek)]

QUEBEC NATIVE WOMEN INC.

To the Chairs of the ABSWG:

Please find below a number of proposals from Quebec Native Women for additional and/or amended language for consideration by the Parties at the 9th meeting of the ABSWG. This note also includes recommendations for consistency of terms through out the text.

Preamble:

The text in **black** indicates existing draft text adopted at ABSWG/8 in November 2009. Text in **red** is proposed new language. The last paragraph dealing with Indigenous rights is intended to consolidate the 8 draft preamble paragraphs in the Montreal Annex addressing Indigenous interests.

Further recalling that in accordance with Article 15(7) of the Convention the fair and equitable sharing of benefits arising from the commercial and other utilization of genetic resources shall be upon mutually agreed terms as decided between the provider and user and recalling Article 15(4) of the Convention, which stipulates that access to resources also must be on the basis of mutually agreed terms;

Emphasizing that both providers and users of genetic resources, their derivatives and products and associated traditional knowledge benefit from the availability of model clauses for potential inclusion in material transfer agreements and inventories/catalogues of typical utilizations of genetic resources since the use of such clauses and inventories will raise legal certainty, may lower transaction costs and will contribute to creating a level playing field between provider and user when negotiating mutually agreed terms:

Recognizing the importance of providing legal certainty to the relevant stakeholders and Indigenous Peoples and local communities involved in the conservation, sustainable use and the fair and equitable sharing of benefits derived from the genetic resources and associated traditional knowledge; Recalling that Article 15(1) of the Convention provides that states have sovereign rights over their resources, and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation, and recalling international commitments to the free, prior and informed consent of Indigenous Peoples and local communities;

Recognizing that patents and other intellectual property rights may have an influence on the implementation of the Convention, and the importance of international cooperation to ensure that such rights are supportive of and do not run counter to the objectives of the Convention;

Affirming respect for the holistic and positive interconnection between biological diversity and traditional knowledge, innovations and practices of Indigenous peoples and local communities particularly *sui generis* customary law and community protocols relevant for the conservation and sustainable use of biological diversity, and the right of Indigenous peoples and local communities to share equitably in the benefits arising from the use of their resources, knowledge, innovations and practices and noting international commitments recognizing the rights of Indigenous Peoples and local communities, including:

United Nations Declaration on the Rights of Indigenous Peoples, GA Res. 61/295 UN GAOR, 61st Sess., Agenda Item 68, UN Doc. A/RES/61/295, (2007);

Convention (No. 169) Concerning Indigenous and Tribal Peoples in Independent Countries, 27 June 1989, 1650 U.N.T.S. (entry into force 5 September 1991);

International Convention on the Elimination of All Forms of Racial Discrimination, U.N.G.A. resolution 2106 (XX) 21 Dec 1965 (entry into force 4 January 1969);

International Covenant on Civil and Political Rights, 19 December 1966, 999 U.N.T.S. 171, Can. T.S. 1976 No. 47 (entry into force 23 March 1976);

Convention On The Protection And Promotion Of The Diversity Of Cultural Expressions 2005, 20 October 2005, U.N. Doc. 2005-138, (entry into force, 18 March 2007);

Vienna Declaration And Programme Of Action, UNGA, World Conference on Human Rights, 1993, UN Doc. A/CONF.157/23 (1993); and

Agenda 21, United Nations Conference on Environment and Development, Annex, Resolution 1, UN Doc. A/conf.151/26/Rev.1 (vol. 1) (1993).

Consistency of Language

The current draft text as adopted at ABSWG/8 is inconsistent in its use of terms leading to confusion and therefore an inability to achieve consensus between Parties. This inconsistency is found in sections dealing with Benefit Sharing, Access, Compliance and Capacity. For the purpose of enhancing clarity and promoting consensus building, it is recommended that the following terms and constructions be used, as appropriate, consistently throughout the text:

- Indigenous peoples and local communities;
- Free, prior and informed consent of Indigenous Peoples and local communities; and
- Genetic resources and associated traditional knowledge.
