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COLLATION OF CONTRIBUTIONS SUBMITTED BY PARTIES, GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STAKEHOLDERS ON COMPLIANCE, FAIR AND EQUITABLE BENEFIT-SHARING AND ACCESS

Note by the Executive Secretary

CONTENTS

INTRODUCTION..... 5

COLLATION OF CONTRIBUTIONS SUBMITTED BY PARTIES, GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STAKEHOLDERS ON COMPLIANCE, FAIR AND EQUITABLE BENEFIT-SHARING AND ACCESS..... 6

INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING..... 6
BIO and PhRMA..... 6
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)..... 6

III. MAIN COMPONENTS..... 9

A. FAIR AND EQUITABLE BENEFIT-SHARING..... 9

BIO and PhRMA..... 9
1) Linkage of access to the fair and equitable sharing of benefits..... 10

Mexico..... 10
BIO and PhRMA..... 10
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)..... 10
2) Benefits to be shared on mutually agreed terms..... 10

Mexico..... 10
BIO and PhRMA..... 11
3) Monetary and/or non-monetary benefits..... 11

Mexico..... 11
BIO and PhRMA..... 12
4) Access to and transfer of technology..... 12

/...

Mexico 12
BIO and PhRMA 12
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 13
5) Sharing of results of research and development on mutually agreed terms 13
Mexico 13
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 14
6) Effective participation in research activities, and/or joint development in research activities 18
Mexico 18
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 18
7) Mechanisms to promote equality in negotiations 19
Mexico 19
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 20
8) Awareness-raising 20
Mexico 20
9) Measures to ensure participation and involvement of indigenous and local communities in mutually agreed terms and sharing of benefits with traditional knowledge holders 21
Mexico 21
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 22
10) Mechanisms to encourage benefits to be directed toward conservation and sustainable use of biodiversity and socio-economic development, in particular the Millennium Development Goals (MDGs) in accordance with national legislation 23
Mexico 23
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 23
11) Development of international minimum conditions and standards 24
Mexico 24
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 24
12) Benefit-sharing for every use 24
BIO and PhRMA 24
13) Multilateral benefit-sharing options when origin is not clear or in transboundary situations 25
Mexico 25
BIO and PhRMA 25
14) Establishment of trust funds to address transboundary situations 25
Mexico 25
15) Development of menus of model clauses for potential inclusion in material transfer agreements 26
BIO and PhRMA 26
16) Enhanced utilization of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization 26
B. ACCESS TO GENETIC RESOURCES 26
BIO and PhRMA 26
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 26
1) Recognition of the sovereign rights and the authority of Parties to determine access 26
Mexico 26

2) Linkage of access to fair and equitable sharing of benefits 27
Mexico 27
BIO and PhRMA 27
3) Legal certainty, clarity and transparency of access rules 28
Mexico 28
4) Non-discrimination of access rules 28
Mexico 28
5) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions 28
Mexico 28
6) Internationally developed model domestic legislation 29
Mexico 29
7) Minimization of administration and transaction costs 30
8) Simplified access rules for non-commercial research 30
Mexico 30
C. COMPLIANCE 30
BIO and PhRMA 30
1) Development of tools to encourage compliance 31
Colombia 31
(a) Awareness-raising activities 31
Mexico 31
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 32
(b) International understanding of misappropriation/misuse 33
Mexico 33
BIO and PhRMA 33
(c) Sectoral menus of model clauses for material transfer agreements 33
Mexico 34
BIO and PhRMA 34
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 34
(d) Codes of conduct for important groups of users 35
Mexico 35
BIO and PhRMA 36
(e) Identification of best-practice codes of conduct 36
Mexico 36
(f) Research funding agencies to oblige users receiving research funds to comply with specific access and benefit-sharing requirements 36
Mexico 36
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 37
(g) Unilateral declaration by users 37
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 37
(h) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions 37
2) Development of tools to monitor compliance 38
Mexico 38
(a) Mechanisms for information exchange 38
Colombia 38
Mexico 38
BIO and PhRMA 39

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 40
(b) Internationally recognized certificate issued by a domestic competent authority 40
Colombia 40
Mexico 41
BIO and PhRMA 43
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 44
(c) Tracking and reporting systems 45
Mexico 45
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 45
(d) Information technology for tracking 46
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 46
(e) Disclosure requirements 46
Colombia 46
BIO and PhRMA 47
(f) Identification of check points 48
Mexico 48
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 48
3) Development of tools to enforce compliance 48
Colombia 48
Mexico 50
BIO and PhRMA 51
(a) Measures to ensure access to justice with the aim of enforcing ABS arrangements 51
Mexico 51
(b) Dispute settlement mechanisms: 52
(i) Inter-State 52
(ii) Private international law 52
(iii) Alternative dispute resolution 52
Mexico 52
(c) Enforcement of judgments and arbitral awards across jurisdictions 52
Mexico 52
(d) Information exchange procedures between national focal points for access and benefit-sharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements 53
Mexico 53
(e) Remedies and sanctions 53
Mexico 53
4) Measures to ensure compliance with customary law and local systems of protection 53
Mexico 53
ESRC Centre for Economic and Social Aspects of Genomics (Cesagen) 54

INTRODUCTION

1. At the closing of the seventh meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, it was agreed that the annex to the report of the meeting would follow the same format as annex I to decision IX/12 and that it would be the basis for further negotiation on the issues of compliance, fair and equitable benefit-sharing and access at the eighth meeting of the Working Group. It was also agreed that any submissions on these components should build on the annex to the report of the seventh meeting of the Working Group (document UNEP/WG-ABS/7/8).

2. In accordance with the above, in notification 2009-050 of 11 May 2009, the Secretariat indicated that any submissions related to the main components of the Regime taken up at the seventh meeting of the Working Group, and which will again be taken up at the eighth meeting (e.g. compliance, fair and equitable benefit-sharing, access), should build on the annex of the report of the Working Group's seventh meeting (UNEP/CBD/WG-ABS/7/8).

3. Against this background, this document contains a collation of submissions received by the Secretariat on fair and equitable benefit-sharing, access and compliance.

COLLATION OF CONTRIBUTIONS SUBMITTED BY PARTIES, GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STAKEHOLDERS ON COMPLIANCE, FAIR AND EQUITABLE BENEFIT-SHARING AND ACCESS[1]

INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING [2]

BIO and PhRMA

***Proposal applicable to multiple sections of the Annex to document UNEP/CBD/WG-ABS/7/8 (the "Paris Annex")*:**

Proposal for Amendment of text:

All bracketed references to "biological resources," "derivatives" and "products" should be deleted.

Related explanations and rationale

BIO and PhRMA have indicated a strong view that the International Regime must be within the scope of the CBD and must be consistent with the mandate from the COP. The International Regime should only regulate "genetic resources" consistently with the scope of the relevant CBD provisions (e.g., Article 15).
Derivatives, products, and other items should only be included if they fall within the definition of a "genetic resource" under the Convention.

Specific suggestions for consolidation of repetitive text in the Paris Annex:

There are a number of similar or identical topics currently addressed in different sections of the text. As the text evolves, there is a substantial risk that these sections could become inconsistent. This could result in a number of unintended consequences, including inconsistent approaches to a particular desired result. Also, if there are differences in the final text, it would be presumed that the drafters intended different results, even though this may not be the case. In sum, each of the different sections addressing the items listed below should be consolidated, preferably in a single section.

- Awareness-raising activities: Section III.A.8 and Section III.C.1.a. of the Paris Annex
- International access standards to support compliance: Section III.A.11, Section III.B.5, and Section III.C.1.h. of the Paris Annex
- Development of model clauses for potential inclusion in material transfer agreements: Section III.A.15 and Section III.C.1.c of the Paris Annex and Section III.E.5 of COP Decision IX/12
- Link between access and equitable benefit-sharing: Section III.A.1 and Section III.B.2 of the Paris Annex
- Access to and transfer of technology: Section III.A.4 of the Paris Annex and Section III.E.3 of COP Decision IX/12

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[1] For ease of reference, the headings in annex I to decision IX/12 reproduced in this document have been shaded. In addition, the structure follows the annex to the report of the seventh meeting of the Working Group (document UNEP/WG-ABS/7/8).

[2] Reference to the International Regime on Access and Benefit-sharing in this text is without prejudice to the nature of the International Regime.

The suggestions for operational text provided below are directed towards introducing the possibility of *access and benefit-sharing commons licences* into the international regime for further elaboration following adoption of the regime at Nagoya in 2010. The suggestions are based on the growing popularity of commons/open source licensing models in relation to software, creative works and biological material transfer agreements. Full details of the proposal are provided in the discussion paper entitled *An ABS Commons? The Role of Commons/Open Source Licenses in the International Regime* as submitted to the CBD Secretariat.[3] The aim of this document is to stimulate thinking and discussion on possible options for the introduction of access and benefit-sharing commons licences for elaboration after COP10.

The proposals below focus on the enablement of provisions of the international regime for the three categories of utilization of genetic resources and traditional knowledge falling under "Sectoral menus of model clauses for material transfer agreements" under Compliance (III.C.1.c option 2).[4] The three categories of utilization are:

a) research and development not aiming at commercialization (non-commercial research) (III.C.1.c option 2, para. 4. a);
b) research and development aiming at commercialization (commercial research) (III.C.1.c option 2, para. 4. b);
c) commercialization (III.C.1.c option 2, para. 4. c).

These three categories of utilization could be enabled through the introduction *modular access and benefit-sharing licenses.* The aim of the licences would be to give providers choices on the terms and conditions under which genetic resources and traditional knowledge are made available in each category and provide sufficient certainty regarding respect for rights to promote sharing of resources and knowledge. Basic choices would include:

a) non-exclusive and non-commercial licensing terms for non-commercial research;
b) separate and additional agreements for non-exclusive commercial licenses based on PIC and MAT directed towards the promotion of collaborative open innovation networks for the generation of public goods (i.e. realization of the objectives of the Convention, research and development on neglected diseases, adaptation to climate change);
c) commercialization (products) through the application and/or further elaboration of fair trade certification and labelling schemes.

As noted above, the aim of this document is not to argue that the proposed access and benefit-sharing commons licenses should be fully elaborated in the existing negotiating text. Rather, its purpose is to identify the key components of the existing text that may require further elaboration or amendment to enable the elaboration of access and benefit-sharing licenses following adoption of the regime at COP10 in 2010.

Two main approaches are possible for the introduction of licenses within the negotiating text. The first, as a minimalist approach, is to a) introduce reference to licenses in conjunction with model clauses, and; b) to introduce reference to licenses in conjunction with the customary laws and community protocols of indigenous peoples and local communities. As a contribution to wider discussion this document outlines an expanded approach consisting of a series of steps. Those steps are:

1) Include specific references to licenses or licensing with respect to model clauses for material transfer agreements (III.C.1.c option 2);
2) Import the three categories of utilization of genetic resources and traditional knowledge under model clauses into benefit-sharing under "Sharing of results of research and development on mutually agreed terms (III.A.1.5). This would link to "Effective participation in research

[3] This document is available as UNEP/CBD/WG-ABS/8/INF/3.

[4] The three categories are also located in III.A.15 option 2 entitled "Development of menus of model clauses for potential inclusion in material transfer agreements."

activities, and/or joint development in research activities" (III.A.1.6) and enabling technology transfer (III.A.1.4);[5]

3) Section III.A.1.5 would be re-elaborated to provide some specific details of forms of benefit-sharing to be enabled under each category of utilization with particular emphasis on access to results of research and development through the use of access and benefit-sharing commons licenses. Section III.A.1.6 would undergo modification to enable the possibility of collaborative research networks. Section III.A.1.4 on technology transfer would undergo adjustment to include reference to open source and access and benefit-sharing licenses to link with the main research provisions;
4) In Section III.C.2.b for an internationally recognized certificate, references could be inserted to licenses. A new paragraph could be added or incorporated to make reference to licenses and the three categories of utilization of genetic resources and traditional knowledge. The intended effect would be to enable the proposed certificate and add flexibility;
5) It is anticipated that indigenous peoples and local communities would be primary beneficiaries of access and benefit-sharing commons licenses elaborated within the context of the international regime. This would be achieved by linking references to customary law and community protocols with licenses under "Measures to ensure compliance with customary law and local systems of protection" (C.III.4) through a text formula such as "customary laws, community protocols and licenses". The use of such a phrase elsewhere in the text is also likely to be desirable. References to indigenous peoples and local communities could be inserted into the sections on technology transfer and research from which they are presently absent to enable benefit-sharing and participation in research networks (III.A.1 4, 5 and 6);
6) Proposed tracking and reporting systems in the section on Compliance would be enabled through this process with additional suggestions relating to the use of standardized classification systems (the International Patent Classification - IPC - and the UN International Standard Industrial Classification of All Economic Activities - ISIC) being included to facilitate visibility to the international patent system, national accounting systems and the development of statistical indicators. These proposals are directed to enhancing the capacity to know whether misappropriation is occurring and statistical measurement of the effectiveness of the international regime.
7) The section on awareness raising (III.C.1.a) could be further elaborated to open up possibilities for wider public awareness activities arising from the use of an online system for license generation, dissemination and display;
8) Proposals for simplified access rules for non-commercial research (III.B.8 option 1) and a unilateral declaration by users (III.C.1.g) could be enabled by licenses where a potential user signals advanced acceptance of the terms of a non-exclusive non-commercial licence (as a binding contract) for research purposes.

The above summary outlines the main options that could be pursued to include access and benefit-sharing commons licenses in the international regime for further discussion. The main thrust of the proposal is directed towards enablement of existing components of the international regime and the proposal does not seek to remove or replace existing provisions.

The remainder of this document sets out suggestions for potential operational text based on the steps outlined above. For ease of reference the suggestions begin with brief general remarks and then follow the structure of the negotiating text.

General Remarks:

1. Linkage of access to the fair and equitable sharing of benefits (III.A.1)

[5] Decision IX/14 concerning technology transfer makes reference to the need for "More in-depth analysis of new open-source-based models of innovation, as well as other additional options to intellectual property rights". Decision IX/14 para. 11(a).

Reference to access and benefit-sharing licences could be inserted into III.A.1 to make the relationship between access and benefit-sharing explicit through the use of licenses as forms of contract.

2. Linkage of access and benefit-sharing licences with community protocols and customary laws

A linkage could be established between indigenous and local community protocols and customary laws throughout much of the negotiating text using the following text formula or minor variations:

"**customary laws, community protocols, and licences…**" of indigenous peoples and local communities

Rationale:

The introduction of licensing options is directed towards building on proposals for access and benefit-sharing arrangements based on customary laws and community protocols by addressing the question of:

a) enduring recognition of ILC contributions over time;
b) providing ILCs with choices on the terms and conditions under which knowledge and resources are made available;
c) enabling contract based approaches through the use of licenses as a form of contract;
d) making terms and conditions visible to the wider intellectual property regime.

The proposed inclusion of references to licenses is not intended to replace references to customary laws or community protocols but addresses the wider question of what happens when knowledge and resources go mobile and begin to circulate within the context of the international regime.

3) Linkage of references to model clauses with access and benefit-sharing licences

References to model clauses could be combined in the following formula "**model clauses and licensing terms**" or minor variations throughout much of the text (i.e. III.A.15 option 2 and III.C.1.c option 2.

Rationale:

References to licensing terms/licenses in relation to model clauses would make the purposes of model clauses clearer and enable the development of menus of modular licensing terms for the three categories of utilization of genetic resources and traditional knowledge. The menus of modular licensing terms could then be used by providers in an online environment to automate generation of licenses as with existing Creative Commons and Science Commons models.

III. MAIN COMPONENTS

A. FAIR AND EQUITABLE BENEFIT-SHARING

BIO and PhRMA

BIO and PhRMA support fair and equitable benefit-sharing as set out in the CBD. The CBD is clear, however, that the benefit-sharing "shall be on mutually agreed terms" (*see, e.g.*, Article 15.7). Thus, any provisions in the International Regime relating to fair and equitable benefit-sharing must permit providers and users to decide the terms freely. Such terms will normally be embodied in a contract or other agreement that represents a meeting of the minds of the provider and the user of the genetic resources at issue. Typical rules for contracts should be applied to those contracts and agreements involving benefit-sharing. Specific mandatory benefit-sharing terms would appear to be both inconsistent with CBD principles and unworkable.

1) Linkage of access to the fair and equitable sharing of benefits [6]

Mexico

3. Each Contracting Party shall take legislative, administrative, or policy measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of [genetic resources][biological resources][, their derivatives][and products] with the Contracting Party and/or indigenous peoples and local communities providing such resources[, their derivatives][and products]country of origin or Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be subject to prior informed consent of the Contracting Party and/or indigenous peoples and local communities providing such resources[, their derivatives][and products]country of origin or Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party and on mutually agreed terms.

BIO and PhRMA

Operative text

"Parties may require that prior informed consent for access to genetic resources shall be obtained based on mutually agreed terms between the provider and the user in accordance with the Convention."

Related explanations and rationale

BIO and PhRMA support linking fair and equitable sharing of benefits to access to the genetic resources. Benefit-sharing should be handled at the point of access through mutually agreed terms embodied in an appropriate ABS agreement to reduce any uncertainties as to the status of genetic resources and benefits arising from their use. The current text contained in the Paris Annex does not clearly articulate the importance of mutually agreed terms.

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References to access and benefit sharing licences could be inserted at various points in the text to establish the linkages between access and benefit-sharing

2) Benefits to be shared on mutually agreed terms

Mexico

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 {*preambular paragraph*}

Recognizing that benefit-sharing on mutually agreed terms may include monetary and/or non-monetary benefits {*preambular paragraph*}

1. Each Party shall stipulate measures to ensure the fair and equitable sharing of the benefits arising out of the use of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge.

[6] There is also a section on linkages of access to the fair and equitable sharing of benefits under section III.B.1.2 of annex I to decision IX/12.

2. The conditions for the equitable sharing of the benefits arising out of the use of traditional knowledge, innovations and practices associated with [genetic resources][biological resources][, their derivatives][and products] shall be stipulated in mutually agreed terms, in accordance with national legislation, and customary laws of indigenous peoples and local communities These shall include *inter alia*:

a) between the indigenous or local communities and the users; or

b) between users and the national authority of the provider country, with active involvement of concerned indigenous and local communities.

3. Parties shall take measures for ensure providers and users of [genetic resources][biological resources][, their derivatives][and products], when establishing mutually agreed terms to include:

(a) The obligation to share monetary and non monetary benefits shall survive the termination of the agreement contained in mutually agreed terms and shall be included in any material transfer agreement.

b) The effective participation of the country of origin of the [genetic resources][biological resources][, their derivatives][and products] in research activities and/or to facilitate the joint development of research activities between the country of origin and the user;

c) model clauses and relevant inventories/catalogues of typical utilizations of [genetic resources][biological resources][, their derivatives][and products] and related monetary or non-monetary benefits.

BIO and PhRMA

Operative text

"Parties should require that, where mutually agreed terms have been reached between provider and user in accordance with national law, the user shall not be subject to additional claims relating to those genetic resources from parties other than the provider."

Related explanations and rationale

Consistent with principles of legal clarity and transparency, once a user has reached mutually agreed terms with the appropriate provider in accordance with the national access and benefit-sharing regime, the user should not be subject to additional claims by third parties, e.g., other communities or entities, which claim some relation to the genetic resources at issue. For example, if there are competing claims to particular genetic resources grown in *in-situ* conditions within a particular jurisdiction, such claims should be properly directed to the national competent authority. The appropriate hierarchy between claims should be resolved in the national law.

3) Monetary and/or non-monetary benefits

Mexico

1. Parties shall take measures to encourage that benefit-sharing includes, all forms of utilization of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge.

2. The International Regime on Access and Benefit-sharing will include an indicative list of mutually agreed terms. Mutually agreed terms shall identify the types of monetary and/or non-monetary

benefits to be shared for the utilization of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge, innovations and practices.

3. Parties shall subject to Article 16 of the Convention, take measures to share the benefits of research and technology linked to conservation and sustainable use, irrespective of access to [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge.

4. Parties shall establish a financial mechanism for the International Regime on Access and Benefit-sharing.

Option 2

3. The benefits to be shared may include, but are not limited to:

(a) Monetary and non-monetary benefits listed in Appendix II of the Bonn Guidelines; and

(b) Non-monetary benefits in accordance with Articles 15(6), 16(3), 16(4) and 19 of the Convention.

BIO and PhRMA

Operative text

"The benefits to be shared may include, but are not limited to the monetary and non-monetary benefits listed in Appendix II of the Bonn Guidelines."

Related explanations and rationale

The International Regime should not seek to pre-determine or influence the content of mutually agreed terms on behalf of providers and users, which would be inconsistent with the Convention. Rather, providers and users should freely choose the benefits in light of the specific circumstances surrounding the transfer of genetic resources. These benefits can include, inter alia, those listed in Appendix II of the Bonn Guidelines.

4) Access to and transfer of technology

Mexico

In accordance with Article 16 of the Convention, Parties shall take measures when establishing mutually agreed terms, to ensure access to and transfer of technology which makes use of those resources.

BIO and PhRMA

Operative text

"Parties may provide incentives for users and providers of genetic resources to consider, when negotiating mutually agreed terms for access to genetic resources, access to and transfer of technology which makes use of those genetic resources."

"Parties may provide incentives to enterprises and institutions in their territories for the purposes of promoting and encouraging voluntary transfer of technology that is relevant to the conservation and

sustainable use of biological diversity or make use of genetic resources to least-developed country Parties."

Related explanations and rationale

BIO and PhRMA support measures that promote effective technology transfer and cooperation. However, it should be understood that effective technology transfer generally cannot be coerced. Rather, it is often a very complicated process that requires good will and commitment by the transferor and the transferee that can only be obtained in a voluntary, cooperative and mutually supportive arrangement. Technology transfer also requires an enabling environment provided by an effective legal and policy framework including, e.g., effective protection of intellectual property rights, a legal framework to support market-based licensing of those rights, regulations favoring investment and trade, funding incentives for research, and appropriate policies in other areas. Parties also can provide incentives, such as tax incentives or other benefits, to entities in their jurisdiction to engage in technology transfer arrangements.

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Option 1

Under option 1, reference could be made to the use of access and benefit-sharing licences to facilitate technology transfer to providers and developing countries.

Operative text

Access to and transfer of technology on fair and favourable terms will, inter alia, be facilitated through promotion of the use of existing open source licenses and access and benefit-sharing licenses to be elaborated within the context of the international regime.

Related explanations and rationale

Recognition of licenses would promote recognition of the increasing emergence of freely available open source software for biology (i.e. European Molecular Biology Open Software Suite or EMBOSS) and the growing application of open source approaches to material transfer agreements (Science Commons Biological Material Transfer Agreement Project). Reference to existing open source licenses reflects reference to open source in Decision IX/15 para. 11 while reference to ABS licenses refers to future developments under the regime to address ABS issues.

5) Sharing of results of research and development on mutually agreed terms

Mexico

1. Parties shall establish, taking into account Article 15, paragraph 7, Article 16, paragraph 2, 3 and 4, Article 19, paragraph 1 and 2, and Article 20, paragraph 4, of the Convention, measures to ensure the fair and equitable sharing of benefits from the results of research and development, including through facilitating access to the results of such research and development and through access to and technology transfer, and other utilization of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge, including technology protected by patents and other intellectual property rights on concessional and preferential terms to developing countries, taking into account prior informed consent and mutually agreed terms and respecting national legislations of the country of origin of such resources or the parties that have acquired the resources in accordance with the Convention.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

5) Sharing of results of research and development **within the context of the international regime** on mutually agreed terms

[1. Parties [shall][should] establish, taking into account Article 15, paragraph 7, Article 16, paragraph 3 and 4, Article 19, paragraph 1 and 2, and Article 20, paragraph 4, of the Convention, measures to ensure the fair and equitable sharing of benefits **arising** from the results of research and development~~,~~. **Such measures will be enabled through the use of access and benefit-sharing licenses to be elaborated within the context of the international regime applicable to the three categories of utilization of genetic resources and traditional knowledge addressed by the international regime.**[7] **Such measures will promote and facilitate compliance with the terms under which access is provided for the three categories of utilization of genetic resources and traditional knowledge addressed by the international regime:**

a) Research and development not aiming at commercialization (non-commercial research)

Access to the results of non-commercial research and development will be facilitated through the use of non-exclusive and non-commercial access and benefit sharing licences elaborated within the context of the international/this regime. In accordance with the terms under which access to genetic resources and the traditional knowledge of indigenous peoples and local communities was granted, access to the results of non-commercial research and development will be facilitated for non-exclusive and non-commercial purposes. Facilitated access to research results will include;

i) Access to results of non-commercial research and development on non-exclusive and non-commercial terms;

ii) Access to and transfer of technology arising from non-commercial research and development on non-exclusive and non-commercial terms;

iii) Access to results of non-commercial research and development arising from utilizations of [genetic resources][biological resources][, their derivatives][and products] and traditional knowledge unforeseen at the time a non-exclusive and non-commercial licence was granted;

iv) Access to biological materials for research purposes under non-exclusive and non-commercial licensing terms for purposes determined by providers under material transfer agreements developed for this purpose;

iv) Promotion of the use of open-source journals and open-source repositories for biological data that provide access on non-exclusive and non-commercial terms directed towards facilitating sharing of resources provided within the context of the international regime by the non-commercial research community and indigenous peoples and local communities;[8]

[7] The three categories of utilization are identified in C.1.c option 2 and A. 15 option 2.

[8] The use of the term biological material encompasses genetic resources as defined under Article 2 and reflects the outcomes of the expert group on definitions.

v) Promotion of the timely use of open access online repositories for copies of publications in proprietary journals that utilize material made available within the context of the international regime on non-exclusive and non-commercial terms.[9]

Genetic resources and traditional knowledge made available under the terms of a non-exclusive, non-commercial licence will be clearly identified using access and benefit-sharing identifiers to facilitate search, retrieval and monitoring of compliance with the terms under which access was provided;[10]

Research aiming at commercialisation that seeks to make use of research results provided under non-exclusive non-commercial access and benefit-sharing licenses will require new PIC and MAT of the original providers, including indigenous peoples and local communities, under a separate and additional agreement to the original non-commercial licence;

b) Research and development aiming at commercialization (commercial research)

Sharing of the results of research and development aiming at commercialisation will be determined in accordance with the prior informed consent of participating providers, including indigenous peoples and local communities, and mutually agreed terms established between providers and users;

Sharing of results of research and development aiming at commercialization may take place on exclusive or non-exclusive terms as determined by providers. Parties [to the international regime] will take measures to promote the use of non-exclusive licenses directed to the objectives/purposes of the international regime and the generation of public goods;

Sharing of research results aiming at commercialization for genetic resources and traditional knowledge will promote the use of non-exclusive commercial licences to foster the creation of collaborative open innovation networks directed towards, *inter alia*:

i) the conservation and sustainable use of biodiversity;

ii) research and development on neglected diseases;

iii) research and development on adaptation to climate change;

iv) other public goods involving the utilization of genetic resources and traditional knowledge that are poorly served by standard innovation models with particular reference to priorities identified by providers;

Parties will encourage access to patented technologies arising from the utilization of genetic resources and traditional knowledge made available under the terms of access and benefit-sharing licenses through the use of tools including, *inter alia*:

a) Licenses of right;

b) Open patents;

[9] The central idea is that proprietary peer review journals should be required to permit authors to deposit pre-print copies of publications and that post-print copies (which will be of higher quality) should be made publicly available within a reasonable period where they include material made available under an ABS license. This will benefit researchers, developing countries and indigenous peoples and local communities.

[10] This proposal links the access and benefit-sharing licenses with the main components of the international certificate.

c) Patent pools;

d) Peer Review Patent projects.

In accordance with Article 16 of the Convention, access to results of research and development arising from the utilization of genetic resources and traditional knowledge protected by patents and plant variety protection in force prior to the date of establishment [entry into force] of the international regime will be made available on concessional and preferential terms to developing countries and indigenous peoples and local communities;

Parties will provide applicants for patent rights and plant variety protection utilizing genetic resources and traditional knowledge with outstanding applications at the time of the establishment [entry into force] of the international regime with opportunities to enter into compliance with the terms of the regime through the use of incentive measures including, inter alia: patent fee schedules, the tools identified above, discontinuation of applications, or other measures deemed appropriate by Parties.

c) Commercialization (commercial use)

Parties will take measures to promote the application and, as appropriate, further elaboration of fair trade certification and labelling schemes for the utilization of genetic resources and traditional knowledge in commercialization (commercial products) for resources made available under the terms of the international regime. The promotion and, as appropriate, further elaboration of fair trade schemes for genetic resources and traditional knowledge will be respectful of the customary laws, community protocols and human rights of indigenous peoples and local communities.

2. Parties requiring prior informed consent for access to their [genetic resources][biological resources][, their derivatives] [and products] [shall][should] take measures to encourage providers and users of [genetic resources][biological resources][, their derivatives][and products], when establishing mutually agreed terms, to consider sharing of results of research and development **under the terms of access and benefit-sharing commons licences to be elaborated within the context of the international regime for this purpose.**

Related explanations and rationale

The central idea in the text provided above is that the use of access and benefit-sharing licences could generate, and be directed towards, particular types of benefits.

a) Non-commercial research:

For non-commercial research the primary benefits arise from access to the results of research to advance knowledge and understanding of biodiversity and problems confronting human societies. However, concerns have been expressed regarding whether material made available to the public domain will become readily appropriable for commercial purposes. The proposed licenses address this through the use of licensing contracts setting out the terms of use (i.e. non-exclusive, non-commercial). As such knowledge and resources would not fall into the public domain but may be publicly accessible.

A second concern regarding access for non-commercial purposes has been the lack of access to resources and publications that become enclosed in proprietary databases or journals using pay per view business models. The proposal seeks to address this through the promotion of open source repositories and journals and provision that material that forms the basis for a closed pay

per view/subscription journal publications are deposited in an freely accessible online repository within a reasonable period (i.e. pre-print or post-print).

A third concern addressed by this proposal is change of use i.e. for commercial purposes. This is addressed through a requirement for sharing of results on utilizations that were unforeseen at the time a license was provided under the same terms (i.e. non-exclusive and non-commercial terms). Where the change of use is directed to commercial research or commercialization a separate and additional agreement involving new PIC and MAT is envisaged (dual licensing).

b) Commercial research

This proposal recognizes the utility of commercial research but seeks to direct attention to the desirability of providing incentives for commercially oriented research in areas that are presently poorly served by models of innovation focusing on exclusive licensing arrangements. Specifically, the proposal directs attention to the desirability of promoting non-exclusive commercial licensing to facilitate the creation of collaborative open innovation networks for research and development in relation to issues such as conservation, sustainable use, research on neglected diseases and adaptation to climate change that are of key relevance to developing countries and indigenous peoples and local communities.

It should be noted that this proposal does not preclude exclusive licensing (business as usual) at the discretion of providers. However, an emphasis on non-exclusive commercial licensing would bring the international regime into line with the emerging emphasis on open innovation within 21st Century business models and provide incentives for collaborative innovation in areas poorly served by exclusive "cathedral" models of innovation i.e. neglected diseases and pharmaceuticals.

Proposals in relation to intellectual property considerations arising from commercial research are intended to highlight the existing flexibilities within the system (i.e. fee schedules, licenses of right, and patent pools) and emerging developments (i.e. open patents and peer review projects to improve patent quality). It should be noted that the individual flexibilities possess strengths and weaknesses and for this reason are listed as "inter alia" optional tools.

Proposals relating to patent and plant variety protection certificates that are in force at the time of the adoption/entry into force of the international regime are intended to promote conformity with the provisions of the Convention under Article 16 and related provisions. Proposals relating to *outstanding applications* for such rights at the time of adoption/entry into force of the international regime are based on recognition of the large backlogs of applications confronting intellectual property offices (notably for patents) and the desirability of providing opportunities for applicants to enter into compliance with the international regime through the use of differential incentives (i.e. fee schedules). This could have the additional advantage of contributing to improving the quality of patent portfolios in relation to genetic resources and traditional knowledge in jurisdictions where this is a significant concern (i.e. Europe). These proposals do not require modification to existing patent laws but would exploit the possibilities of existing flexibilities. Proposals regarding disclosure of origin and licenses are addressed below.

c) Commercialization.

The rise of Fair Trade (ethical trade) certification and labelling schemes directed towards establishing fair conditions for communities of producers participating in commodity production (i.e. coffee and tea) is an increasingly important niche in western markets. The application, and potential further elaboration, of Fair Trade schemes to products developed under the terms of the international regime could contribute to promoting equitable benefit-sharing with producers (i.e. indigenous peoples and local communities) and reward participating companies with competitive advantage through market differentiation. Fair Trade style certification and labelling under ABS

would be most obviously applicable for botanical medicines and cosmetics but could extend to the marketing of pharmaceuticals developed under access and benefit-sharing licenses using open innovation models (i.e. for neglected diseases).

The overall intention of these proposals is to introduce flexibility into the international regime in terms of the sharing of the results of research and development as the *primary generator* of benefits under the international regime. These proposals are directly linked to effective participation in research activities and the establishment of collaborative research networks as set out below.

6) Effective participation in research activities, and/or joint development in research activities

Mexico

1. Parties shall agree to strengthen research capability and ensure effective involvement of national counterparts, taking into account the special needs of developing country Parties in particular the least developed among them, small island developing States and countries with economies in transition.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

6) Effective participation in research activities, ~~**and/or**~~ joint development in research activities **and establishment of collaborative research networks**

[1. Parties [shall][should] agree to strengthen research capability and **promote the establishment of collaborative research networks between partner countries, institutions and indigenous peoples and local communities directed towards the objectives of the Convention and the generation of mutually agreed public goods. Strengthening of research capability and establishment of collaborative research networks will be directed towards the identified research needs of developing countries, in particular the least developed among them, small island developing States, countries with economies in transition, and indigenous peoples and local communities participating in the international regime.** ~~ensure effective involvement of national counterparts, taking into account the special needs of developing country Parties in particular the least developed among them, small island developing States and countries with economies in transition.~~]

[2. Parties [requiring prior informed consent for access to their genetic resources][biological resources][, their derivatives][and products] [shall][should] take measures to [ensure][encourage the [providers][countries of origin] and users when establishing mutually agreed terms, to [consider][ensure] the effective participation of [providers][countries of origin] of the [genetic resources][biological resources][, their derivatives][and products] [in research activities and/or to facilitate the joint development of research activities **including collaborative research networks** between ~~the~~ [providers[country of origin] and ~~the~~ **users within the context of the international regime.] To this end, Parties will elaborate access and benefit-sharing commons licenses to support effective participation in research activities, joint research and development and establishment of collaborative research networks between providers and users.**

[3. Parties [shall][should] take measures to ensure that the private sector facilitates joint development of technologies relevant to the conservation and sustainable use of biodiversity or make use of [genetic resources][biological resources][, their derivatives][and products] for the benefit of both government institutions and the private sector of developing countries in accordance with Article 16 of the Convention.] **Such measures may include promotion of the use of non-exclusive commercial access and benefit-sharing licenses to be elaborated within the context of the international regime.**

[4. Parties [shall][should] in accordance with Article 18 of the Convention promote the establishment of joint research programmes, ~~and~~ joint ventures **and collaborative research networks** for the development of technologies relevant to the objectives of the Convention.]

Related explanations and rationale

These proposals are directed towards opening up the possibility of collaborative research networks directed towards purposes identified by providers through the use of licenses. International research collaborations, notably for non-commercial research purposes, are an increasing feature of research in the biosciences (i.e. genome sequencing for neglected diseases) and a major feature of initiatives such as the European Union Framework research programme. The promotion of collaborative research networks enabled by the certainty provided by access and benefit-sharing licensing would enable benefit-sharing under the international regime. Reference to non-exclusive commercial research licenses reflects the desirability of non-exclusive licensing for collaborative commercial research and research and development in areas poorly served by exclusive or "cathedral" models of innovation.

7) Mechanisms to promote equality in negotiations

Mexico

Recognizing the importance of promoting equity in negotiations of mutually agreed terms between providers and users of genetic resources {*preambular paragraph*}

1. Parties shall take measures such as:

a) Developing consultative arrangements with relevant stakeholders and indigenous and local communities holding traditional knowledge associated with [genetic resources][biological resources][, their derivatives][and products];

b) Supporting the capacity of countries of origin or indigenous and local communities and users of [genetic resources][biological resources][, their derivatives*][* and products] to negotiate mutually agreed terms and, prior informed consent.

2. Contracting Parties shall:

(a) Take measures to ensure appropriate participation by the indigenous peoples and local communities involved in access procedures where their rights are associated with the [genetic resources][biological resources][, their derivatives][and products] being accessed or where traditional knowledge associated with these [genetic resources][biological resources][, their derivatives][and products] is being accessed;

(b) Establish mechanisms to ensure that decisions are made publicly available subject to provisions related to confidential information.

(c) The effective involvement of indigenous and local communities should be promoted by providing information especially regarding scientific and legal advice in order for them to be able to participate effectively and to be actively engaged in various stages of access and benefit-sharing arrangements such as in the development and implementation of mutually agreed terms and contractual arrangements.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

2 [(c) The effective involvement of indigenous and local communities should be promoted by:

(iii) **Providing clear and transparent licensing options to allow indigenous peoples and local communities to make informed decisions regarding appropriate options in making knowledge and resources available in a manner consistent with their customary laws, community protocols, and respectful of their rights;**

(iv) **Providing online tools for access to model community protocols, ethical guidelines, toolkits, menus of licensing options and sources of advice to inform decision-making by indigenous peoples and local communities in entering into access and benefit-sharing agreements;**

(v) **Providing capacity-building in the use of tools for tracking and monitoring compliance with the terms of access and benefit-sharing agreements including compliance with licensing terms.**

Related explanations and rationale

These proposals build on existing elements of the text and are directed towards providing indigenous peoples and local communities with a range of tools for use in entering into access and benefit-sharing agreements. Reference to licenses and capacity-building in tracking and monitoring is intended to establish a linkage to more detailed provisions of the regime under compliance.

8) Awareness-raising [11]

Mexico

Parties shall take measures to raise awareness of access and benefit-sharing issues in support of mandatory compliance measures to ensure benefit-sharing. Such measures may include inter alia:

(a) Making available up to date information about their domestic access and benefit-sharing framework, national laws, policies and procedures;

(b) Steps to promote the International Regime on Access and Benefit-sharing, including the promotion of a wider understanding among the public on the concepts of misappropriation, misuse, and biopiracy as well as for the recognition of the contribution made by indigenous and local communities to biological diversity and the benefits generated by that contribution];[12]

(e) Information dissemination through a website and/or an access and benefit-sharing clearing house;

[11] There is also a section on awareness-raising under section III.C.1.1.(a) of annex I to decision IX/12.

[12] Mexico considers that this paragraph shall incorporate not only the mentioned concepts (misappropriation, misuse, and biopiracy) but all the concepts and definitions as revised by the *Group of Legal and Technical, Experts on Concepts, Terms working Definitions and Sectoral Approaches (Namibia, december 2008.*

Documents UNEP/CBD/WG-ABS/7/2 and UNEP/CBD/WG/ABS/4/7.

(f) Promotion of codes of conduct and best practice measures in consultation with stakeholders;

(g) Promotion of regional exchange of experiences related to access and benefit-sharing;

(h) Communication, education and awareness-raising of access and benefit-sharing-related issues to the relevant sectors and stakeholders.

9) Measures to ensure participation and involvement of indigenous and local communities in mutually agreed terms and sharing of benefits with traditional knowledge holders

Mexico

1. The elements of Traditional Knowledge associated to the International Regime on Access and Benefit-sharing shall be developed and implemented in accordance with Article 8(j) of the Convention:

(a) Parties shall adopt and recognize, in consultation with the relevant indigenous and local communities, sui generis systems for the protection of traditional knowledge, innovations and practices associated to genetic resources[biological resources][, their derivatives][and products];

(b) Parties shall respect, recognize and protect the rights of indigenous and local communities to their knowledge, innovations and practices and ensure the equitable sharing of benefits arising from the utilization of the knowledge, innovations and practices associated with genetic resources [biological resources][, their derivatives][and products], subject to the national legislation, regulations and requirements of the countries where these communities are located;

2. Contracting Parties shall in accordance with Article 8(j) of the Convention ensure fair and equitable sharing of benefits arising from the utilization of knowledge, innovations and practices associated with genetic resources of indigenous and local communities. The benefits referred to here are benefits to indigenous and local communities in particular:

(a) Promote the wider application of traditional knowledge associated to genetic resources, [biological resources][, their derivatives][and products] innovations and practices of indigenous and local communities upon their voluntary approval and involvement in accordance with Article 8(j) of the Convention;

(b) Further the customary use of biological resources in line with traditional customary practices that are compatible with conservation and sustainable use of biological diversity in accordance with Article 10(c) of the Convention;

(c) Take into account the customs, decision-making processes and systems integral to indigenous and local communities in the process of seeking access to their genetic resources[biological resources][, their derivatives][and products] and/or associated traditional knowledge, and also in negotiating mutually agreed terms;

(d) Encourage and develop methods of cooperation for the development and use of indigenous and traditional technologies in furtherance of the objectives of the Convention by the training of personnel and provision of expertise by representatives of indigenous and local communities in accordance with Article 18(4) of the Convention.

3. Parties shall provide timely guidance, legal representation, monitoring, information and assistance in prior informed consent and mutually agreed terms of traditional knowledge of indigenous

and local communities at the request of indigenous and local communities seeking the recognition and/or enforcement of their rights.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

[1. The elements of the International Regime on Access and Benefit-sharing [shall][should] be developed and implemented in accordance with Article 8(j) of the Convention:

(a) [In consultation with the relevant indigenous and local communities,] Parties [may][shall][should] consider developing, adopting and/or recognizing, as appropriate, [**customary laws,** community protocols **and access and benefit-sharing licences** ~~and/or other] sui generis systems~~ for the [protection][and/or promotion] of traditional knowledge, innovations ~~and~~ practices and associated ~~to~~ [genetic resources][biological resources][, their derivatives][and products];

(b) Parties [shall][should] [respect,] recognize and protect the rights of indigenous and local communities to their knowledge, innovations and practices and ensure the equitable sharing of benefits arising from the utilization of the knowledge, innovations and practices associated with [genetic resources][biological resources][, their derivatives][and products], **through respect for their customary laws, community protocols and the terms of access and benefit-sharing licenses under which knowledge and resources are made available**~~; subject to the national legislation[, regulations and requirements] of the countries where these communities are located~~;

(c) [When access to traditional knowledge associated with [genetic resources][biological resources][, their derivatives][and products] is sought,] Users [shall][should] obtain the prior informed consent of indigenous and local communities holding [that] traditional knowledge associated with [genetic resources] in accordance with Article 8(j) of the Convention, [subject to][in accordance with] national legislation[, regulations and requirements] of the country where these communities are located[, **customary laws,** community protocols**, the terms of access and benefit-sharing licenses** and **consistent with** relevant international law].]

[2. *(a) Benefits to humanity:*

[All Contracting Parties [shall][should]:

(a) Promote the wider application of knowledge, innovations and practices of indigenous and local communities with their [voluntary] approval and involvement in accordance with Article 8(j) of the Convention**, in a manner consistent with customary laws, community protocols, the terms of access and benefit-sharing commons licences, and respectful of their rights**;

[(c) Take into account the **community protocols,** custom**s**ary **laws**, decision-making processes and systems integral to indigenous and local communities in the process of seeking access to their [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge, ~~and also~~ in negotiating mutually agreed terms **and take measures to promote compliance with the terms of access and benefit-sharing licences developed to ensure respect for the rights of indigenous peoples and local communities in the context of the international regime**;]

[(b) Benefits to indigenous and local communities:

[3. (e) Prior informed consent of indigenous peoples and local communities and the approval and involvement of the holders of traditional knowledge, innovations and practices, in

accordance with their **customary laws, community protocols, and access and benefit-sharing licensing terms** ~~traditional practices, national access policies and subject to national legislation~~;

(f) Documentation of traditional knowledge, innovations and practices, [shall][should] be subject to the prior informed consent of indigenous peoples and local communities**, [and be] consistent with the customary laws, community protocols, and access and benefit-sharing licensing terms under which indigenous peoples and local communities participate in documentation of their traditional knowledge, innovations and practices;**

(g) Providing support for capacity-building, in order for them to be actively engaged in various stages of access and benefit-sharing arrangements, such as in the development and implementation of mutually agreed terms, ~~and~~ contractual arrangements **and selection of appropriate access and benefit-sharing licensing terms with respect to their knowledge, innovations, practices and resources.]**

Related explanations and rationale

This proposal is directed towards enabling *choices* for indigenous peoples and local communities on the terms and conditions and purposes for which they make knowledge and resources available for wider use. In particular, the proposal links respect for customary laws and community protocols with licenses, as a form of contract, to facilitate sharing of knowledge and resources in conditions of sufficient legal certainty to promote widespread participation in what could be characterised as a "protected commons" for access to genetic resources and benefit-sharing.

10) Mechanisms to encourage benefits to be directed toward conservation and sustainable use of biodiversity and socio-economic development, in particular the Millennium Development Goals (MDGs) in accordance with national legislation

Mexico

Parties shall encourage users and providers, in their mutually agreed terms, to consider directing benefits arising from the utilization of genetic resources[biological resources][, their derivatives] [and products] towards the conservation and sustainable use of biological diversity in accordance with the objectives set out in Article 1 of the Convention, and to contribute to national sustainable development strategies.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

Parties [shall][should] encourage users and providers, in their mutually agreed terms **and licensing provisions**, to consider directing benefits arising from the utilization of [genetic resources][biological resources][, their derivatives] [and products] towards the conservation and sustainable use of biological diversity in accordance with the objectives set out in Article 1 of the Convention, [and] to contribute to [domestic] sustainable [socio-economic] development [strategies]. **Parties [shall][should][will] elaborate and promote the use of access and benefit-sharing licenses directed towards the pursuit of the realisation of the Millennium Development Goals following adoption of the international regime.**

Related explanations and rationale

This proposal directs the international regime towards contributions to the public goods identified in the text of the Convention and the Millennium Development Goals through the use of licenses as set out in the section on research.

11) Development of international minimum conditions and standards

Mexico

1. Parties should take measures and establish minimum conditions and standards for ensuring fair and equitable sharing of results of research, and of benefits arising from every commercial and other form of utilization of genetic resources[biological resources][, their derivatives][and products] and/or associated traditional knowledge, upon mutually agreed terms.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

(a) Contribute to strengthening the situation of the less powerful party/parties at all levels in the sharing relation, including by enabling:

(i) Equal access to information;

(ii) Effective participation by all relevant stakeholders;

(iii) Capacity building;

(iv) **Participation in international collaborative research networks**;

(v) Preferential access to markets, new technology and products;

(d) Respect value and legal systems across cultural borders, including customary laws, **community protocols, and access and benefit-sharing licences of indigenous peoples and local communities** and ~~indigenous intellectual property systems~~

Related explanations and rationale

This proposal emphasises the importance of the participation of less powerful parties (as providers) in all aspects of sharing with a particular emphasis on participation in international collaborative research networks as set out in the research section. In addition greater clarity is provided in relation to indigenous intellectual property systems through reference to community protocols and licenses.

12) Benefit-sharing for every use

BIO and PhRMA

Operative text

"Parties may encourage that providers and users consider, when negotiating mutually agreed terms, the potential uses for the genetic resources."

Related explanations and rationale

BIO and PhRMA support the concept of providing for mutually agreed terms for access and benefit-sharing for both commercial and non-commercial uses. However, the concept of benefit-sharing "for every use" may be interpreted to encompass mandatory benefit-sharing for uses that are not subject to mutually agreed terms (e.g., uses of a genetic resource made freely available or other uses exempted

from such requirements in the national law, e.g., taxonomic uses). This is outside the scope of the CBD and should not be included in the International Regime. However, Parties may want to encourage providers and users to take any potential uses into account when negotiating access and benefit-sharing terms.

13) Multilateral benefit-sharing options when origin is not clear or in transboundary situations

Mexico

Contracting Parties should facilitate the inclusion of the different indigenous and local communities, within and across their boundaries that share a particular knowledge, innovation or practice in the negotiation of relevant access and benefit-sharing agreements and support the fair and equitable sharing amongst these indigenous and local communities of the benefits arising from such agreements.

BIO and PhRMA

Operative text

"Where genetic resources are shared by different countries of origin, Parties that are countries of origin may enter into agreements with other countries of origin for that resource that include mutually agreed terms for the sharing of benefits between the Parties concerned when that resource is provided by one of the Parties concerned. Such agreements between Parties shall not impose additional restrictions on granting prior informed consent in any one Party and shall have no effect on the rights and obligations of providers and users established in the mutually agreed terms governing the access of the relevant genetic resources in particular access and benefit-sharing agreements."

Related explanations and rationale

When multiple countries hold the same genetic resource, these countries may agree to share benefits received for transfer of a specimen of a genetic resource from one country or local or indigenous community with the other countries. Such agreements should be separate from the ABS agreement between the provider and the user and should not have any effect on the liabilities or obligations of a user of genetic resources that is not party to that agreement. Permitting claims of third countries not party to an ABS agreement would add great uncertainties to the process and discourage the transfer of genetic resources. As noted, if there are competing claims to particular genetic resources grown in *in-situ* conditions within a particular jurisdiction, the appropriate hierarchy between claims should be resolved in the national law.

14) Establishment of trust funds to address transboundary situations

Mexico

In cases where the origin of the knowledge, innovations and practices associated to genetic resources are unclear, a fund should be established which should be administered by representatives of indigenous and local communities who shall ensure that it is used to further the rights of indigenous and local communities.

15) Development of menus of model clauses for potential inclusion in material transfer agreements [13]

BIO and PhRMA

Comment:
BIO and PhRMA comments on sectoral menus of model clauses for material transfer agreements are provided below in respect of Section III.C.1.c.

16) Enhanced utilization of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization

B. ACCESS TO GENETIC RESOURCES [14]/

BIO and PhRMA

BIO and PhRMA support the concept of access to genetic resources being linked to fair and equitable sharing of benefits on the basis of mutually agreed terms, as envisioned in the CBD. However, national laws governing the terms of access, e.g., in national ABS regimes, should be non-discriminatory and should thereby treat domestic and foreign researchers on similar terms. In addition, access terms should be transparent and "facilitative" in nature and should not be burdensome or punitive in nature.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

The text proposals provided in this document[15] are directed towards enabling the compliance and benefit-sharing components of the international regime. However, in relation to access it may be noted that researchers seeking access for non-commercial purposes could signal advanced acceptance of a non-exclusive non-commercial access and benefit-sharing agreement as part of the application process. Advanced acceptance of non-commercial licensing terms could enable facilitated access for the purposes specified in the license. The effect would be to enable non-commercial research activity. See also the unilateral declaration under C below.

1) Recognition of the sovereign rights and the authority of Parties to determine access

Mexico

Recalling the sovereign rights of States over their natural resources, and that the authority to regulate access to genetic resources rests with national governments and is subject to national legislation *{preambular paragraph }*

Recalling furthermore that each Contracting Party shall endeavour to create the conditions to facilitate access by other Contracting Parties to genetic resources for environmentally sound uses, and refrain from imposing restrictions contrary to the objectives of the Convention *{preambular paragraph}*

Recalling furthermore that access to genetic resources will be subject to the prior informed consent of the Contracting Party supplying such resources, unless said Party decides otherwise.

[13] There are also sections on sectoral menus of model clauses in section III.C.2.1.b and in section III.E.1.5 of annex I to decision IX/12.

[14] The title is without prejudice to the eventual scope of the International Regime on Access and Benefit-sharing.

[15] "this document" refers to the submission from CESAGEN.

1. The Contracting Parties have sovereign rights over their natural resources, and the authority to regulate access to genetic resources [biological resources][, their derivatives] [and products], rests with national governments. Wherever access to [genetic resources] [biological resources] [, their derivatives] [and products] involves the knowledge, innovations and practices of indigenous and local communities, said indigenous and local communities will have a voice in regulating access, subject to national legislation.

2. Access to genetic resources [biological resources][, their derivatives] [and products] and/or related traditional knowledge will be subject to the prior free and informed consent of indigenous and local communities. Access to genetic resources and related traditional knowledge of indigenous peoples and local communities will be subject to their prior informed consent.

6. Each Party will communicate to the Secretariat, at the latest on the date of entry into force of this International regime on access and benefit-sharing for said Party, the names and addresses of their coordination center and competent national authority or authorities.[16] [17]

2) Linkage of access to fair and equitable sharing of benefits [18]

Mexico

Recognizing that fair and equitable benefit-sharing can be achieved only after access to genetic resources has been granted *{preambular paragraph }*

Recalling that Article 15.5 of the Convention stipulates that access to genetic resources will be subject to the prior informed consent of the Contracting Party supplying the genetic resources, unless said Party decides otherwise *{preambular paragraph}*

Recalling furthermore that Article 15.4 of the Convention stipulates that the Contracting Parties will take steps to ensure that, when access is granted, it shall be under mutually agreed conditions *{preambular paragraph}*

1. The Parties will take all necessary steps to establish a national regulatory framework to regulate access to genetic resources [biological resources][, their derivatives][and products], and/or related traditional knowledge, as well as the rights of indigenous peoples and local communities, and guarantee that the ensuing benefit-sharing shall take place under mutually agreed conditions.

3. The Contracting Parties will adopt legislative and administrative measures to regulate those cases in which there is a modification in the original purpose for which access was granted to genetic resources [biological resources][, their derivatives] [and products] [and/or related traditional knowledge].

4. The non-fulfilment of the mutually agreed conditions of access may result in the revocation of fulfilment certification.

BIO and PhRMA

[16] The placement of paragraphs 4 to 6 *supra* should be given further consideration.

[17] There is also a section on competent national authorities, in accordance with paragraphs 4 to 6 *supra*, in section III.C.1.2.b of annex I to decision IX/12.

[18]/ There is also a section on the linkage of access to fair and equitable sharing of benefits under section III.A.1.1 of annex I to decision IX/12.

Comment:
This topic should be consolidated with the section of the identical name in III.A.1.

3) Legal certainty, clarity and transparency of access rules

Mexico

1. In order to create conditions to facilitate access to genetic resources [biological resources][, their derivatives] [and products] and contribute to the fulfilment of obligations related to access and benefit-sharing within different jurisdictions, the Parties will adopt the legislative, policy and administrative measures needed, as per *{...}* in order to provide legal certainty, clarity and transparency in their national frameworks regarding access and benefit-sharing.

4) Non-discrimination of access rules

Mexico

Each Party, in implementing its national framework regarding access and benefit-sharing, shall not discriminate in any arbitrary or unjustified way among users from other Contracting Parties or among domestic and foreign users, except if it is in its national interest to do so in accordance with its sovereign right over such resources, which enables it to regulate access in accordance with the recognition of said right in Article 15.1. of the Convention.

5) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

Mexico

Recalling the sovereign rights of States over their natural resources and that the authority to regulate access to genetic resources rests with national governments and is subject to national legislation *{preambular paragraph }*

Recalling furthermore that each Contracting Party will attempt to create the conditions to facilitate access by other Contracting Parties to genetic resources for environmentally sound uses, and to refrain from imposing restrictions contrary to the objectives of the Convention *{preambular paragraph }*

Recognizing furthermore that fair and equitable benefit-sharing can be achieved only after access to genetic resources has been granted *{preambular paragraph }*

1. In order to create conditions to facilitate access to genetic resources [biological resources][, their derivatives] [and products] and contribute to the fulfilment of obligations related to access and benefit-sharing within different jurisdictions, the Parties will adopt the legislative, policy and administrative measures needed, as per *{...}*, in order to provide legal certainty, clarity and transparency in their national frameworks on access and benefit-sharing. These must include:

(General issues)

[b) A [clear] procedure to request prior informed consent from a competent national authority and, if necessary, from indigenous and local communities];]

Subject to the text of heading b) in Section II. Fulfilment of mechanisms for the exchange of monitoring information.[19]

d) Present information about their national frameworks for access and benefit-sharing and facilitate access to them, especially regarding how to request prior informed consent;

e) Provide the information generated in accordance with item d) in the Mechanism for facilitation of the Convention, including information about coordination centers for access and benefit-sharing, and update it on a regular basis;

f) Require that the competent authority provide periodically, as per the Mechanism for facilitation of the Convention, updated information regarding the number of applications processed, including those applications which were granted a prior informed consent, as well as certificates of fulfilment;

[g) [Appropriate] administrative or judicial procedures of appeal regarding prior informed consent, [including cases of omission and [arbitrary and unjustified] discriminatory access practices];]

(*Specific aspects related to requesting decisions on prior informed consent by the competent [national] authority*)

h) Request that decisions by the competent national authorities to grant or deny access should be motivated and well-founded.

(Specific aspects related to the mutually agreed conditions (normally stipulated in contracts)

m) [Clear] rules, within national frameworks for access and benefit-sharing, to establish mutually agreed conditions;

o) Require that mutually agreed conditions should be stipulated in writing;

p) Require that mutually agreed conditions should include a clause on dispute resolution;

q) Require that mutually agreed conditions should reflect that benefit-sharing has been taken into account;

[2. The additional measures established in *{...}* to promote fulfilment in cases of undue appropriation [shall have no relation to] [will be implemented] if the national framework for access and benefit-sharing by a Contracting Party providing a genetic resource [is in accordance with paragraph 1].]

6) Internationally developed model domestic legislation

Mexico

[19] "Each Contracting Party will take the appropriate legislative, administrative or policy measures in order to monitor fulfilment.

b) Facilitate the equitable exchange of scientific, technical, environmental and legal information, as well as the sharing of experiences related to access in the implementation of simplified administrative procedures for access to resources, their derivatives and products for non-commercial research."

Recalling that Article 15.1. of the Convention stipulates that States have sovereign rights over their natural resources, and that the faculty to regulate access to genetic resources rests with national governments and is subject to national legislation *{preambular paragraph}*

Recalling that Article 15.5 of the Convention stipulates that access to genetic resources will be subject to the prior informed consent of the Contracting Party providing the said genetic resources, unless that Party decides otherwise *{preambular paragraph}*

Taking note that the Parties have different legal systems, and have consequently chosen to implement the provisions regarding access and benefit-sharing in the Convention in accordance with their national conditions *{paragraph from the preamble}*

1. Encourages the Parties to provide the Secretariat with examples of provisions for national legislation, and encourages the Secretariat to provide them to the Parties upon request, in order to give assistance and support to said requesting Parties for the implementation of the Convention's provisions regarding access and benefit-sharing on the national level.

2. The Parties will compile examples of provisions for national legislations and examples of frameworks for the adoption of administrative decisions in accordance with the international norms established in *{...}* and will distribute them via the center for information exchange.

7) Minimization of administration and transaction costs

8) Simplified access rules for non-commercial research

Mexico

Option 2

The Contracting Parties which are countries of origin of genetic resources [biological resources][, their derivatives][and products], or other Parties which have acquired genetic resources [biological resources][, their derivatives][and products] in accordance with the text of the Convention, should:

a) Consider simplified rules of access to genetic resources [biological resources][, their derivatives][and products] for non-commercial purposes;

b) Require that new uses of a genetic resource [biological resource] over and beyond what has been established in the mutually agreed conditions should be subjected to a new prior informed consent and mutually agreed conditions, on the part of the supplying country and/or indigenous peoples and local communities involved.

C. COMPLIANCE

BIO and PhRMA

BIO and PhRMA support the incorporation of effective compliance provisions in the International Regime to ensure that the objectives of the CBD can be implemented in a fair and equitable manner that facilitates access and benefit-sharing on mutually agreed terms. In that light, a contract-based approach 6 that includes tools currently used effectively in many international business transactions, such as private international law mechanisms including alternative dispute resolution mechanisms and civil law regarding enforcement of foreign judgments, can ensure effective compliance. In respect of foreign enforcement of

judgments, however, it should be noted that CBD Parties have been generally reluctant to recognize judgments from other jurisdictions.

1) Development of tools to encourage compliance

Colombia[20]

PART 2. GENERAL PROVISIONS

Article 4- Measures to promote and encourage compliance

Establishment of ABS laws

4.3. The Parties agree to make necessary efforts to establish an appropriate national ABS regulatory framework seeking to protect rights on genetic resources, their derivatives and associated traditional knowledge, innovations and practices, in order to ensure the equitable and fair sharing of benefits arising out From the use of those resources and said knowledge, Innovations and practices.

The Secretariat of the CBD will support these activities through the fund created in article four *supra*.

(a) Awareness-raising activities

Mexico

Noting that awareness of domestic access and benefit-sharing regulatory frameworks is important for users and providers to ensure compliance {*preambular paragraph*}

Parties shall take measures to raise awareness of access and benefit-sharing issues in support of [mandatory][voluntary] compliance measures to [ensure][promote] benefit-sharing]. Such measures could include [, but not be limited to]:

(a) Making available up to date information about their domestic access and benefit-sharing framework, in particular national laws, policies and procedures;

(b) Steps to promote the International Regime on Access and Benefit-sharing[, including the promotion of a wider understanding among the public on the concepts of misappropriation, misuse and biopiracy, as well as for the recognition of the contribution made by indigenous and local communities to biological diversity and the benefits generated by that contribution];

(c) Organization of stakeholder meetings;

(d) Establishment and maintenance of a help desk for stakeholders;

(e) Information dissemination through [a specialized website][an Access and Benefit-sharing Clearing House][, as well as hard copies];

(f) Promotion of codes of conduct [and best practice tools] in consultation with stakeholders;

(g) Promotion of regional exchange of experiences related to access and benefit-sharing.

[20] Sections of the submission by Colombia contained in this document are drawn from an unofficial translation provided by Colombia. The original version of the submission by Colombia is in the Spanish language.

2. Parties shall raise awareness in accordance with Articles 8(j) and 10(c) of the Convention to promote the wider application of indigenous knowledge, innovations and practices by actively involving indigenous and local communities with their consent in the planning and implementation of research and training (Article 12), public education and awareness (Article 13), exchange of information (Article 17.2) and technical and scientific cooperation (Article 18.4).]

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Additional paragraphs to existing text

Operative text

(--) Establishment of an online system through which providers and users can register to generate, use, and display access and benefit-sharing licenses for genetic resources and traditional knowledge falling within the scope of the international regime;

(--) Development of publicly visible symbols for genetic resources and traditional knowledge covered under access and benefit-sharing licenses for display in electronic and other formats;

(--) Awareness raising among indigenous peoples and local communities on the availability of access and benefit-sharing licences that provide choices in making traditional knowledge and genetic resources available in a manner that is consistent with customary laws, community protocols and respectful of their rights;

(---) Awareness raising in the use of access and benefit-sharing licences in the non-commercial research sector including in establishing partnerships with providers, the terms and conditions of the use of the materials covered under such licences, and their appropriate uses and display in electronic and other formats;

(---) Awareness raising for research aiming at commercialization on the terms and conditions required to secure a commercial access and benefit-sharing licence, including requirements for renewed PIC and MAT with providers in cases of proposed change of use;

(--) Awareness raising on the availability of fair trade certification and product labelling for producers of commercial products seeking to operate in compliance with the terms and purposes of the international regime;

(--) Guidance to research and development funding agencies on the availability of access and benefit-sharing licences and the terms and conditions of their use;

(--)_ Establishment of an online register of collaborative research networks established under the terms of the international regime using access and benefit-sharing licences and in particular, research networks involving indigenous peoples and local communities or directed towards key public goods;

(--) Establishment of an online register of scientific publications making use of access and benefit-sharing licences;

(--) Publicity for breakthrough scientific publications utilizing materials provided under the terms of access and benefit-sharing licences to promote their wider use and generate public awareness and support;

Related explanations and rationale

The proposals provided above are additions to the existing text and directed towards promoting compliance with the terms of the international regime by making its provisions visible through the use of access and benefit-sharing licenses. The model for this proposal is provided by the human readable, machine readable and lawyer readable integrated Creative Commons[21] and Science Commons licenses.[22] In particular the proposals highlight the importance of the use of online tools for awareness raising of the international regime through the provision of practical tools and visible ABS symbols for materials and products made available in compliance with the terms of the regime.

(b) International understanding of misappropriation/misuse

Mexico

Parties shall take measures aimed at preventing misappropriated and misused genetic resources [, their derivatives] [and products] and asociated traditional knowledge.

BIO and PhRMA

Operative text

"A Party should take measures aimed at ensuring that access to genetic resources is consistent with its national access and benefit-sharing rules.1

1The term "misappropriation" of genetic resources is sometimes used to describe the provision and/or use of genetic resources that is not consistent with national access and benefit-sharing rules."

Related explanations and rationale

A further understanding of the concept of "misappropriation" or "misuse" may be helpful to the dialog among Members of the ABS Working Group.

However, it should be recalled that the terms "misappropriation" and "misuse" are not found in the CBD. A common understanding of these terms should include the notion of a link to compliance with national ABS laws. In other words, if there is no violation of the national ABS law (which should be consistent with the provisions of the CBD), there is no "misappropriation." This type of understanding would ensure that expectations of provider countries are clearly enshrined in national rules and are clearly available and communicated to prospective users. In addition, we believe that a further understanding of these terms will only be possible if there is clarity as to the context in which they are to be used.

This understanding could be reflected in a footnote to operative text.

(c) Sectoral menus of model clauses for material transfer agreements [23]/

[21] http://creativecommons.org/license/

[22] See in particular the MTA license chooser of the Science Commons at http://mta.sciencecommons.org/chooser . For general information see http://www.sciencecommons.org

[23]/ There are also sections on sectoral menus of model clauses in section III.A.2.5 and in section III.E.1.5 of annex I to decision IX/12.

Mexico

[Parties may, in addition to [promoting][ensuring binding] compliance measures:

a) In consultation with users and providers from key sectors, develop sectoral menus of [model] clauses for contracts;

b) Encourage users and providers to use these sectoral menus of [model] clauses when negotiating mutually agreed terms.]

BIO and PhRMA

Operative text

"Parties may, in consultation with users and providers, develop sectoral menus of model clauses for possible use in contracts and make them publicly available for consideration by users and providers when negotiating mutually agreed terms.

"The Secretariat shall establish a central database of model clauses for possible use in access and benefit-sharing agreements that is publicly available, and shall maintain and regularly update the database."

"Parties may submit the sectoral menus of model clauses for possible use in contracts to the Secretariat for inclusion in a central database of model clauses for possible use in access and benefit-sharing agreements. Parties and interested stakeholders may submit clauses used in publicly available access and benefit-agreements to the Secretariat for inclusion in the central database of clauses for access and benefit-sharing agreements."

"Parties may regularly review and, where appropriate, update the menus of model clauses, if any, based on factors including, but not limited to, experiences in successful access and benefit-sharing agreements."

Related explanations and rationale

A sectoral approach to MTAs in the International Regime is appropriate as a general matter because a "one size fits all" approach likely would be unworkable given the vast differences in how genetic resources are utilized by different industries and different non-commercial entities. Thus, the model clauses can be tailored for particular uses of genetic resources and, therefore, be more useful.

Further, the development of model clauses may be helpful to guide ABS negotiations in certain cases. However, if established, any such clauses should not be binding or mandated as the International Regime should permit flexibility in achieving mutually agreed terms for material transfers on a case-by-case basis to better facilitate access. BIO and PhRMA also support providing guidance with respect to certain access principles consistent with the CBD requirement to "facilitate" access in Article 15.2. For example, guidelines that would help ensure transparency and clarity, including identification of specific authorities and points of contact.

In addition, alternatives, such as a database of sample clauses from successful agreements, modeled on the WIPO Database of searchable contract clauses for access and benefit-sharing agreements should be considered.[24]

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

[24] 1http://www.wipo.int/tk/en/databases/contracts/index.html

Operative text

Note: This text also appears in Section A.15

[Option 1

Under option 1, references to menus of model clauses could be extended to use the following formula **"…menus of [model] clauses and licensing terms…"**

[Option 2

Under option 2 references to model clauses could be extended to use the following formula **"…model clauses and licensing terms…**" and minor variants, i.e. "**…clauses, licensing terms…**"

[5. Indicators for the identification of these three categories of utilization of [genetic resources][biological resources][, their derivatives][and products] **will be developed using standardized classification schemes including, *inter alia*: the International Patent Classification, the United Nations International Standard Industrial Classification of All Economic Activities, the Nomenclature of Territorial Units for Statistics and their regional and national equivalents. Details of indicators** are provided in **the** Annex *{…}* of the International Regime on Access and Benefit-sharing.]

Related explanations and rationale

This proposal is directed towards permitting the elaboration of access and benefit-sharing licenses as modular licenses following the adoption of the international regime. Elaboration of the precise terms for the proposed licenses for the three categories of utilization of genetic resources and traditional knowledge would not be required at this stage. The operative text proposals provided under III.A.5 and linked to III.A.4 (technology transfer) and III.A.6 (participation in research activities) are intended to provide the outline of benefit-sharing possibilities that would be enabled through the elaboration of access and benefit-sharing licenses.

Reference to classification systems is intended to enable the generation of international statistics using existing classification schemes established for this purpose. The proposal does not preclude the use of other existing or emerging classification schemes for the purpose of indicators and monitoring. The Nomenclature of Territorial Units for Statistics (NUTS from the French *nomenclature d'unités territoriales statistiques*) is in use in the European Union for geocoding industrial, patent and other activity for statistical purposes. Inclusion of reference to these codes is not intended to preclude use of similar systems in other countries/regions in developing indicators under the regime.

(d) Codes of conduct for important groups of users

Mexico

[*Recognizing* the existence of a range of national and international, sectoral or company specific codes of conduct and best practice guidelines on access and benefit-sharing and their importance in achieving the fair and equitable sharing of benefits arising out of the the utilization of genetic resources, the third objective of the Convention {*preambular paragraph*}]

Parties may, in addition to ensuring binding compliance measures:

(a) Support, as appropriate, the development, review and update of access and benefit-sharing-related [voluntary] codes of conduct [, and best practice standards,] for users of genetic resources [, their derivatives][and products];

(b) Take measures to encourage users to adhere to the codes of conduct [and encourage users to adhere to best practice standards;]

[(c) Ensure the communication, education and awareness of these codes of conduct and best practice standards to the relevant user groups].

BIO and PhRMA

Operative text

"The development, review and update, by relevant users of genetic resources, of voluntary codes of conduct related to access and benefit-sharing may be useful for users and providers of genetic resources."

Related explanations and rationale

Voluntary "Codes of Conduct" for industry or other users of genetic resources may be helpful. Any such code should be established on a voluntary basis by an industry association or group of non-commercial entities representing users of genetic resources with participation from industry and/or other relevant actors. The relevant group itself may monitor compliance. One current example in the biotechnology sector is the BIO Guidelines on Bioprospecting. Another example is the IFPMA Guidelines on Access to Genetic Resources and Equitable Sharing of Benefits Arising Out of their Utilization. As a point of contrast, mandatory "codes of conduct" would be counterproductive and would not be appropriate.

(e) Identification of best-practice codes of conduct

Mexico

[*Recognizing* the existence of a range of national and international, sectoral or company specific codes of conduct and best practice guidelines on access and benefit-sharing and their importance in achieving the third objective of the Convention {*preambular paragraph*}]

Parties may collectively establish a procedure for identifying and regularly reviewing access and benefit-sharing related codes of conduct and guidelines that constitute best-practice

Proposal of Mexico

Mexico suggest that this section could be included as part of the clearing-house mechanism.

(f) Research funding agencies to oblige users receiving research funds to comply with specific access and benefit-sharing requirements

Mexico

Parties shall encourage [research, funding and publishing entities [to] ask for [the unique identifier code referred to in the certificate of compliance][evidence of compliance with relevant national law] as part of their application procedures or research results, as appropriate, when genetic resources their derivatives][and products] and associated traditional knowledge [are] involved.

Proposal of Mexico

Mexico suggests changing the place of this paragraph f) to the section 2 of Monitoring.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

Parties will encourage research, funding and publishing entities to require disclosure of the unique identifier code and accompanying certificate/licensing terms for genetic resources and traditional knowledge provided in accordance with the international regime as part of their procedures for funding applications, project reporting and publication of research results when [genetic resources][biological resources][, their derivatives][and products] and associated traditional knowledge [are] involved.

Related explanations and rationale

This suggestion seeks to simplify the existing text and direct action towards funding agencies and publishing entities. The use of the term licensing is linked to enablement of the international certificate (below). Reference to project reporting refers to the likelihood that genetic resources and traditional knowledge will generally be accessed following the award of funding and cross-links to access to research results under A.

(g) Unilateral declaration by users

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Operative text

Parties may provide users seeking access to [genetic resources][biological resources][, their derivatives][and products] **and associated traditional knowledge with the opportunity to signal advanced acceptance of the terms of a non-exclusive non-commercial access and benefit-sharing licence;**

Related explanations and rationale

This proposal seeks to enable the possibility of a unilateral declaration by users in relation to advanced acceptance of a non-exclusive and non-exclusive licence. Note that the proposed access and benefit-sharing licenses seek to enable the components of the international certificate through the use of contract law. By signalling advanced acceptance of a non-exclusive, non-commercial licence (contract), a potential user could gain facilitated access (i.e. through permitting procedures) for the agreed purposes under the terms of the licence. The advantage for providers, as highlighted in the study on non-commercial research, is that it would overcome the problem experienced by providers in interpreting the intentions of potential users through the use of a licence.

(h) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

2) Development of tools to monitor compliance

Mexico

Each Contracting Party shall take appropriate legislative, administrative or policy measures to monitor compliance;

(a) Mechanisms for information exchange

Colombia

PART 2. GENERAL PROVISIONS

Article 4- Measures to promote and encourage compliance

Information Exchange

4.2 Each Party shall designate a National Focal Point of Coordination of Acces and Benefit Sharing, ABS, which will facilitate access to relevant information on ABS, through a mechanism for the expedite exchange of information. Among other information shall include procedures to verify the prior informed consent - PIC and mutually agreed terms - MAT associated to access to genetic resources, their derivatives or associated traditional knowledge, innovations and practices, including benefit sharing. and possible information on foreign laws.

The Secretariat of the CBD will establish mechanisms to allow access to different National Focal Points through the Clearing·House.

Similarly, the respective National Focal Point of Coordination will keep the information, among others, on filing patent applications and granted patents, and other intellectual property right,. related to genetic resources, their derivatives and/ or associated traditional knowledge, innovations and practices, the information on the procedure at the national offices responsible for approval of production and marketing of food and medical products, including biological and genetic resources and/ or traditional knowledge and procedures for obtaining research funding nationally. National institutions will establish the conditions for which such information is provided to National Focal Points of Coordination.

The National Focal Point of Coordination, shall notify to the National Focal Point of Coordination of the other Party the disclosure made by applicants

Mexico

1. Parties shall collaborate to facilitate information exchange on access and benefit-sharing between Parties, providers and users of genetic resources [, their derivatives][and products] between national access and benefit-sharing focal points, through: An Access and Benefit-sharing Clearing-House as part of the clearing-house mechanism, as well as other means agreed by Parties, including non-internet means, in order to:

[(a) Monitor and Support compliance with national access and benefit-sharing framework and with this International Regime on Access and Benefit-sharing;

(b) Facilitate the equitable exchange of scientific, technical, environmental and legal information on, and experience with, access and benefit-sharing, and on best practices in the application of simplified administrative procedures for access to genetic resources, their derivatives and products for non-commercial research;

Proposal of Mexico

Mexico considers that these two paragraphs c) and d) have to be part of the section III. E. Capacity.

3. Without prejudice to the protection of confidential information, each Party through the national focal point shall make available to the Access and Benefit-sharing Clearing-House inter alia:

(a) Any existing laws, regulations and guidelines for implementing this International Regime on Access and Benefit-sharing;

(b) [Community protocols] and relevant customary laws of indigenous peoples and local communities;

(c) Any bilateral, regional and multilateral agreements and arrangements related to access and benefit-sharing;

(d) Information about national focal point and competent national authority(ies);

(e) List of defaulters of access and benefit-sharing agreements ("name and shame");

(f) Information on model domestic access and benefit-sharing legislation and model clauses for contracts;

(g) Experience in the development of electronic tools for the tracking of genetic resources;

(h) Codes of conduct and best practices in access and benefit-sharing

(i) Information on the certificates of compliance issued at the national level

4. The Access and Benefit-sharing Clearing House shall and inquiry point of certificates of compliance with national legislation issued by the competent national authorities, in accordance with provisions in *{…}*.

5. The modalities of the operation of the [Access and Benefit-sharing] Clearing-House, including reports on its activities, shall be considered and decided upon by the Governing Body of the International Regime on Access and Benefit-sharing at its [first][next] meeting, and kept under review thereafter.]

BIO and PhRMA

Operative text

The following sentence should be added as a new stand-alone sentence to Section III.C.2.a:
"In facilitating information exchange, Parties shall ensure that confidential information is fully protected according to national laws consistent with international agreements."

Related explanations and rationale

BIO and PhRMA support, in principle, mechanisms for information exchange between Parties relating to monitoring compliance with CBD requirements. Such mechanisms may assist collaboration between Parties and increase exchanges of experience with respect to national

implementation of CBD provisions. However, any mechanism for information exchange must be understood to protect confidential information under national laws and international agreements.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

(b) Facilitate the [equitable] exchange of scientific, technical, environmental and legal information on, and experience with, access and benefit-sharing[, and on best practices in the application of simplified administrative procedures for access to [genetic resources][biological resources][, their derivatives][and products] for non-commercial research] **including experience in the use of access and benefit-sharing licences**;

3. Without prejudice to the protection of confidential information, each Party [shall][should] make available to the [Access and Benefit-sharing] Clearing-House[, as appropriate,] [any information required to be made available to the Access and Benefit-sharing Clearing-House under this International Regime on Access and Benefit-sharing,] and:

[(b) **Customary laws,** Community protocols **and access and benefit-sharing licenses;]**

[(f) Information on [model] domestic access and benefit-sharing legislation and [menus of] model clauses **and licensing terms** for contracts;]

[4. The [Access and Benefit-sharing] Clearing House [shall][should] include[, if appropriate,] an international [registration][and inquiry point][database of examples] of certificates of compliance with national legislation[, **customary laws, community protocols and licenses** ~~community protocols and relevant customary laws~~ of indigenous peoples and local communities] and requirements on access and benefit-sharing, issued by the competent national authority(ies), in accordance with provisions in *{...}*.]

Related explanations and rationale

This proposal includes the possibility of exchanging experiences in the use of access and benefit-sharing licenses and a register of licences (as enabling components of certificates) to facilitate search, retrieval and use of material covered under access and benefit-sharing licenses.

(b) Internationally recognized certificate issued by a domestic competent authority

Colombia

PART 2. GENERAL PROVISIONS

Article 5- Measures and tools to monitor ABS compliance

Certificate of compliance

5.1. The Parties agree to establish within their respective jurisdictions a National Certificate of Compliance, which will be a public document issued by the Competent National Authority, and which will state the origin of the genetic resources, their derivatives and/or associated traditional knowledge, innovations and practices and the fulfilment of the ABS laws and requirements, including for those material cover by the ITPGR Treaty under FAO.

This certificate will have international recognition and for this purpose must contain at least the following information:

- Issuing Authority;
- Details of the supplier;
- A unique alpha numeric identifier code and details of the rights of holders of associated traditional knowledge;
- Detailed description of the genetic resources and their derivatives as covered by the respective access authorisation;
- Geographic identification of where access activities are authorised and of the location where genetic resources, their derivatives and associated traditional knowledge, innovations and practices were obtained;
- The assertion that the PIC has been complied with and MAT have been determined;
- Restrictions and authorised uses applicable to the subject matter genetic resource covered by the Certificate;
- Conditions of transfer to third parties and
- The date of issuance of the Certificate.

The Certificate may include non-confidential information related to prior informed consent - PIC - and mutually agreed terms - MAT.

The Certificate must accompany the genetic resource, thus, when the MAT and the PIC will enable the transfer of those resources to others, such transfer should preserve the relation between the Certificate and Mutually Agreed Terms applicable to the resource or knowledge.

The Certificate of Compliance will be required by Parties, in particular National intellectual property authorities, as appropriate, national institutions for funding research, *ex situ* collections, authorities for approval of production and marketing of biological products and customs controls. In the case of genetic materials listed In Annex 1 of the FAO Treaty, when they are used for commercial and research purposes, these requirements will be complied with the presentation of the Material Transfer Agreement.

Parties shall establish sanctions and remedies for the breach of obligations described in the preceding paragraph.

The respective authorities of Intellectual Proprety shall inform the disclosure made to the National Focal Point of Coordination the country, and this one to the National Focal Point of the other Party

The Secretariat of the CBD, will support the establishment of the Certificate of Compliance in developing countries through, *inter alia*, the fund created in article four supra.

5.2. The Parties agree to establish the International Registration of Certificates of Compliance, which will contain digital copies of Certificates, as well as a list of competent national authorities designated by each Party for its issuance.

5.3 The Executive Secretariat shall establish the funds, times and mechanisms to the implementation of the international registration of certificates of compliance.

Mexico

1. Each Party shall designate one national focal point for access and benefit-sharing.

2. Each Party shall also designate one or more competent national authorities, which shall be responsible for and duly authorized to act on its behalf with respect to the following functions:

(a) Performing the administrative functions required by this International Regime on Access and Benefit-sharing, including the issuance of certificates of compliance with national legislation and /or national requirements on access and benefit-sharing;

[(b) The receipt, administration and transfer to the financial mechanism of the funds collected through the enforcement of *{…}*;]

(c) Help providers of genetic resources to obtain relevant information, in relation to prior informed consent and mutually agreed terms, including specific cases of alleged infringements of provider country requirements.

A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

3. Each Party shall, no later than the date of entry into force of this International Regime on Access and Benefit-sharing for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

4. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 3 above, and shall also make such information available through the Access and Benefit-sharing Clearing-House. [25]

Option 1

The International Regime on Access and Benefit-sharing shall establish a system of an internationally recognized certificate of compliance issued by each Party.

The certificate shall be a public document to be issued by the national competent authority and shall be required to be presented at specific checkpoints in user and provider countries established to monitor compliance in relation to a range of possible uses.

(a) The certificate of compliance shall include the following minimum information:
- (i) Issuing national authority;
- (ii) Details of the provider;
- (iii) A codified unique alpha numeric identifier;
- (iv) Details of the rights holders of [associated traditional knowledge;]
- (v) Details of the user;
- (vi) Description of subject matter including genetic resources, their derivatives and products and/or associated traditional knowledge]) covered by the certificate, subject to confidential information as identified in national requirements or by indigenous and local communities providing associated traditional knowledge;
- (ix) Uses permitted and restrictions of use;
- (x) Conditions of transfer to third parties;
- (xi) Date of issuance;
- [(xii) Confirmation of compliance with domestic access requirements]

[25] The placement of paragraphs 1 to 4 above must be further considered.

(xiii) Term of validity

(b) Contracting Parties shall establish checkpoints for the certificate for commercial and non-commercial uses. Checkpoints for commercial uses should include customs controls, intellectual property offices and registration points for other commercial applications not covered by intellectual property rights.

(c) Contracting Parties should facilitate an efficient, easy to use tracking mechanism through the use of new technology and other means agreed to by Parties including capacity building and funding which should include:

(i) Cost efficient publicly searchable certificate databases providing evidence of prior informed consent and mutually agreed terms;
(ii) Recording of progressive compliance on such databases as conditions of prior informed consent and mutually agreed terms are met;
(iii) Searchable application and granted patents and product approval and/or registration databases;
(iv) Integration of genomic and morphological taxonomy to the extent possible to create species certainty ;
(v) Low cost, portable, gene based bar-coding technology to create rapid attack taxonomy;
(vi) Linking unique identifiers to gene-based bar-coding.

[(d) Contracting Parties where viable should:
[(i) Use existing tracking procedures by innovatively reconceptualizing them to track genetic resources, derivatives and products and/or associated traditional knowledge;
(ii) Minimize the creation of new levels of bureaucracy;
(iii) [Where a Party requires prior informed consent,] Promote automatic issuing of certificates upon compliance with specific criteria[, such as completion of material transfer agreements or access and benefit-sharing agreements];
[(iv) Promote consolidation of existing permitting requirements with any new certification system;]
(v) Promote paperless systems;
[(vi) Establish minimum standards for recording of collections, to ensure a link between incoming and outgoing resources, without requiring harmonization of internal recording procedures;]
[(vii) Provide economic support to developing countries, in particular the least developed among them and small island developing States, and countries with economies in transition, to develop online systems to support an international documentation system. (Mover este inciso a la sección de creación de capacidad

Proposal of Mexico

Mexico considers that all the above section d) should be part of the Preamble and not operative text.

(e) Contracting Parties shall ensure that no intellectual property rights based on the utilization of genetic resources, derivatives and products and/or associated traditional knowledge will be granted unless the applications for such intellectual property rights include the disclosure of an Internationally Recognized Certificate of Compliance with the access and benefit-sharing legislation of the provider country.

BIO and PhRMA

Operative text

"Parties shall continue to examine proposals made for internationally recognized certificates issued by a domestic competent authority and the relation of such proposals to the International Regime in a manner to be determined by the Conference of the Parties."

Related explanations and rationale

There are still many outstanding issues regarding the feasibility of establishing such an international certificate system (*see, e.g.*, the Report of the Technical Experts Group in UNEP/CBD/WG-ABS/5/7 (Feb. 20, 2007)). In that light, it is premature to include specific provisions regarding such certificates in the International Regime until a much more thorough discussion has taken place as to the actual use of such certificates. Further, these certificates, if pursued, should not be tied to other laws, e.g., intellectual property laws or regulatory laws.

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Operative text

Option 1
Opening para.

References to "of relevant customary laws of indigenous and local communities" could be harmonised with suggestions provided above through modification to the text following …in accordance with the Convention][, **customary laws, community protocols and licenses**… of indigenous and local communities ~~community protocols and relevant customary laws of indigenous and local communities~~]]

The [voluntary] certificate [shall][should][may] include the following [minimum] information:
[(ix) Uses permitted **~~and,~~** restrictions of use **and licensing terms for**:
a) **Research not aiming at commercialization**
b) Research and development aiming at commercialization; and
c) Commercialization;]
[(x) Conditions of transfer to third parties **including licensing terms**;]

[(b) existing text….. [Checkpoints for non- commercial uses [may][shall][should] include publishing houses of scientific journals, **online data depositories,** grants making bodies and ex-situ collections.]]
[(c) Contracting Parties [shall][should] facilitate an efficient, easy to use [voluntary] certification process through the use of new technology [and other means agreed to by Parties including capacity building and funding] which [may][shall][should] include:
(i) Cost efficient publicly searchable certificate **and licence** databases providing evidence of prior informed consent**,** [**~~and~~** mutually agreed terms**, and licensing provisions**];
(vii) Use of standardized classification schemes including, inter alia: the International Patent Classification (IPC) under the 1971 Strasbourg Agreement and the United Nations International Standard Industrial Classification of All Economic Activities (ISIC) and their regional or national equivalents;

[(d) Contracting Parties where viable [shall][should]:
(iii) [Where a Party requires prior informed consent,] Promote automatic issuing of certificates upon compliance with specific criteria[, such as completion of material transfer agreements, **~~or~~** access and benefit-sharing agreements **or acceptance of the terms of an access and benefit-sharing license]**;

New paragraph.

For tracking access to TK associated with genetic resources, the certificate shall include the following minimum information:

a) Licensing terms, including permitted uses and restrictions of use, for:
   a. Research not aiming at commercialization
   b. Research and development aiming at commercialization; and
   c. Commercialization;

b) Conditions of transfer to third parties including licensing terms.

Related explanations and rationale

The above proposals are intended to enable the international certificate system with respect to the three categories of utilization and to promote flexibility in the choices for which knowledge and resources are made available.

Reference to international classification systems relates to the ability to track and monitor activity and to develop statistical indicators based on classification systems that are already in use worldwide. This is not intended to preclude the use of other classification systems but reflects the desirability of using systems that are already well established with national and regional and international patent offices and national and regional statistical offices.

Reference to traditional knowledge relates to the desirability of enabling choices for indigenous peoples in making traditional knowledge and associated genetic resources available within the context of the international regime.

(c) Tracking and reporting systems

Mexico

1. Contracting Parties should [develop tracking and monitoring systems that identify breaches of contractual obligations or misappropriation of genetic resources, their derivatives and products and/or associated traditional knowledge and bring such breaches to the attention of the rights holders and stakeholders, facilitate exchange of information, including through the clearing house mechanism, related to the development of tracking and monitoring systems of genetic resources, their derivatives][and products, and encourage the further development of information technologies appropriate to that purpose.

Proposal of Mexico for a new paragraph 1.e)

e) Parties shall establish an information exchange framework between Access and Benefit-sharing competent national authority and intellectual property offices to monitor the intellectual property rights based on the utilization of genetic resources and associated traditional knowledge

2. Parties should encourage users and providers to include provisions in access and benefit-sharing contracts to cover monitoring and tracking the use of the [genetic resources][biological resources][, their derivatives][and products] accessed, including measures to monitor compliance with mutually agreed terms.]

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[2. Parties [shall][should] encourage users and providers to include provisions in access and benefit-sharing contracts to cover monitoring and tracking the use of the [genetic resources][biological

resources][, their derivatives][and products] [**and/or associated traditional knowledge**] accessed, including measures to monitor compliance with mutually agreed terms **and licensing provisions**.]

(d) Information technology for tracking

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Operative text

To facilitate tracking Parties may make use of established international classification schemes for [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge] including, inter alia: the International Patent Classification established under the 1971 Strasbourg Agreement, the United Nations International Standard Industrial Classification of All Economic Activities, The Nomenclature of Territorial Units for Statistics and their regional or national equivalents;

Related explanations and rationale

The use of standardized international classification schemes will facilitate the establishment of internationally comparable statistical indicators to provide indicators of activity for genetic resources and traditional knowledge and linkages to economic sectors. The International Patent Classification is in use by patent offices world-wide and the UN International Standard Industrial Classification of All Economic Activities represents the international baseline classification for the development of statistics for activity by economic sector. The Nomenclature of Territorial Units for Statistics is in use in the European Union for geocoding economic and other data and is intended to indicate the types of classification that may be used.

If incorporated within the components of the international certificate/licenses the use of classification schemes would permit the tracking of licenses and international activity for genetic resources and traditional knowledge using electronic means. Specifically, classification of materials covered in certificates/licenses would facilitate their visibility to the international patent system and could include incorporation of unique identifiers into the citation field of patent documents and within patent databases such as the EPO esp@cenet worldwide database. See the discussion paper for further details and practical demonstration.

This proposal does not preclude additional options such as the use of established taxonomies or technologies identified for the tracking of genetic resources in the study prepared for the Secretariat. However, the above classifications will make sense to professionals responsible for developing internationally comparable statistical indicators.

(e) Disclosure requirements

Colombia

PART 2. GENERAL PROVISIONS

Article 5- Measures and tools to monitor ABS compliance

Disclosure of origin

5.4. Parties shall require in their national legislation the explicit obligation to disclose in patent applications the origin of the genetic resource, derivatives and associated traditional knowledge, innovation and practices, when these are used or are part of the invention to be protected.
Similarly, the specific obligation to annex information required to demonstrate that all requirements of PIC and MAT have been complied with in the origin country.

The above requirement may be satisfied with the presentation of Certificate of Compliance issued by the Competent Authority of the country of origin. In Annex 1 of the FAO Treaty, when they are used for commercial and research purposes, these requirements will be complied with the presentation of the Material Transfer Agreement.

5.5. Parties agree that when the country providing the resource or knowledge is not the country of origin, the patent applicant shall disclose the country of origin of the resource and will provide information regarding compliance of the PIC and MAT from that country.

5.6. The parties agree that breach of these conditions or false disclosure shall prevent the granting of the patent[26] or shall revoke or nullify the patent if this was granted, in accordance with the national law.

5.7. In any case, Parties shall establish administrative and criminal measures for non-disclosure of the relevant information and the dissemination of false information to the national authorities.

BIO and PhRMA

Operative text

Current paragraphs III.C.2.e.1 – 3 should be deleted and replaced with the following alternative provision:
"Recognizing that patents and other intellectual property rights may have an influence on the implementation of the Convention in accordance with Article 16(5), Parties may encourage providers and users to include contract clauses relating to intellectual property, as appropriate, in mutually agreed terms."

Related explanations and rationale

BIO and PhRMA reiterate their opposition to proposals made regarding new patent disclosure requirements (e.g., regarding source/origin of genetic resources). BIO and PhRMA are of the view that such requirements will be (a) ineffective in promoting the objectives sought (e.g., compliance with CBD principles) and (b) will introduce uncertainties into the patent system that will inhibit innovation in relevant technologies and will thereby decrease potential benefit-sharing from such efforts. Detailed and lengthy discussions in WIPO and WTO have confirmed this view and, further, have not led to any consensus on such proposals. To the extent further discussion is necessary on these proposals, it should be done at WIPO, which has specialized expertise on matters of intellectual property.

These proposed requirements should not be included in the International Regime. Instead, promoting access and benefit-sharing through "mutually agreed terms," including terms that may address intellectual property issues that may arise in respect of a given transfer of genetic resources, is the best

[26] Concerning with the UPOV, when the national law of the Party does not permit the application of this provision, the Party shall establish monitoring procedures that permit effective, swift and deterrent actions against illegal access to that resource or knowledge.

approach. This approach, and its relationship to intellectual property rights, is reflected in the draft operative text proposal that follows.

(f) Identification of check points

Mexico

1. Parties shall establish other effective supporting mechanisms for compliance at border check points, intellectual property rights offices, etc., including by using certificates of compliance with national legislations, so as to prevent misappropriation of resources.

2. Contracting Parties shall establish check points at, *inter alia*, intellectual property rights offices, market approval authorities and entities, to ensure that the use of [genetic resources][biological resources][, their derivatives][and products] is accompanied by, and is in line with, the relevant international recognized certificate.

3. The check points established by the Contracting Parties shall cover all uses of genetic resources [biological resources][, their derivatives][and products] according to the definition included in the International Regime on Access and Benefit-sharing, in their jurisdiction.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

[1. Parties [shall][should] establish other effective supporting mechanisms for compliance at [border] check points[, intellectual property rights offices, entities funding research, etc., including by using certificates of compliance with national legislations **and/or access and benefit-sharing licenses**, so as to prevent misappropriation of resources].]

[2. Contracting Parties [shall][should] establish check points at, *inter alia*, intellectual property rights offices, market approval authorities and entities funding research, to ensure that the use of [genetic resources][biological resources][, their derivatives][and products] is accompanied by, and is in line with, the relevant international recognized certificate **and/or access and benefit-sharing licenses**.]

Related explanations and rationale

The proposed access and benefit-sharing licenses are intended to build upon and be complementary to the proposed international certificate and to make such provisions visible at checkpoints. To accommodate circumstances in which Parties do not require evidence of prior informed consent the above proposal refers to access and benefit-sharing licenses as an and/or alternative with a view to promoting flexibility. This would also accommodate circumstances where indigenous peoples and local communities located in countries not requiring prior informed consent as a condition of access wished to use access and benefit-sharing licenses in order to make knowledge and resources available under the terms of the international regime.

3) Development of tools to enforce compliance

Colombia

PART 2. GENERAL PROVISIONS

Article 6· Measures to enforce compliance

6.1. The Parties agree that users of genetic resources, their derivatives and associated traditional knowledge, innovations and practices in their jurisdictions, have to comply, with ABS laws and requirements of the country of origin/provider of genetic resources, their derivatives and associated traditional knowledge, innovations and practices, including prior informed consent - PIC and mutually agreed terms - MAT, and provisions under the CBD.

Each Party will take legal, administrative and policy measures, in an effective and transparent manner to comply whit ABS laws and requirements of the country of origin/provider of genetic resources, their derivatives and associated traditional knowledge, innovations and practices, including prior informed consent and mutually agreed terms, and CBD provisions.

Each Party, will establish sanctions and remedies to be applied in the case of alleged breaches of ABS laws and requirements of the country of origin/provider of genetic resources, their derivatives and associated traditional knowledge, innovations and practices, including prior informed consent - PIC and mutually agreed terms - MAT, and provisions under CBD.

6.2. In the case of alleged breaches of ABS laws and requirements of the country of origin/provider of genetic resources, their derivatives and associated traditional knowledge, innovations and practices, including prior informed consent -PIC- and mutually agreed terms - MAT -, and provisions under CBD, the country of origin/provider of genetic resources, their derivatives or the holders of that knowledge, innovation or practices may take legal action in the jurisdiction of the offender user, seeking to remedy the breaches and if necessary obtain the respective redress associated to the benefits arising from such use.

6.3. Parties shall grant non-discriminatory, transparent, expeditious and effective right of entry to its competent authorities, including courts where applicable, as well as alternative dispute resolution mechanisms to countries of origin/provider of genetic resources or derivatives and/or holders of the rights of associated traditional knowledge, innovations and practices, in the case of alleged infringement of ABS laws and requirements of the country of origin/provider of genetic resources, their derivatives and associated traditional knowledge, innovations and practices, including prior informed consent and mutually agreed terms, and provisions under CBD.

6.4. The Parties agree that decisions of national authorities, as well as arbitral awards rendered by panels, with regard to the interpretation or breaches of ABS laws and requirements of the country of origin/provider of genetic resources, their derivatives and associated traditional knowledge, innovations and practices, including prior informed consent and mutually agreed terms, and provisions under CBD, will be immediately enforced within the national jurisdiction of the Party in which they shall be executed.

6.5. The Parties agree to, at the request of any Party, cooperate in the investigation and following up of the cases of alleged infringements of ABS laws and requirements of the country of origin/provider, including prior informed consent - PIC and mutually agreed terms – MAT, and CBD provisions.

6.6. The Parties will establish, as appropriate, mechanisms to provide assistance to countries of origin/providers and holders of associated traditional knowledge, innovations and practices, to exercise and enforce their rights.

6.7. The International Regime will setup a program aimed at to provide, at the request of any developing countries, legal assistance, including eventually representation, and case study support, including evidence gathering, in alleged infringements of ABS laws and requirements of the country of origin/provider, of genetic resources, their derivatives and associated traditional knowledge, innovations and practices, including prior informed consent - PIC and mutually agreed terms - MAT, and CBD provisions.

6.8. The Parties agree to create an International Center for Mediation and Arbitration as a forum to facilitate to solve disputes related to ABS.

Mexico

[1. Each Party shall ensure that users of genetic resources, [biological resources] [their derivatives] [and products] and/or associated traditional knowledge under its jurisdiction comply with the national legislation of the countries of origin of such resources and/or traditional knowledge or of the Parties that have acquired the genetic resources, their derivatives and products in accordance with the Convention, when accessing and/or using such resources, their derivatives and products and/or associated traditional knowledge by taking the following measures *inter alia**:***

(a) Rules requiring that users of genetic resources, [derivatives] [and products] and/or associated traditional knowledge comply with national legislation in the country of origin and the mutually agreed terms on which access was granted, including requirements to equitably share the benefits arising out of the utilization of such resources,[derivatives] [and products] and/or associated traditional knowledge;

(b) Rules requiring that the importation of genetic resources, [biological resources] [derivatives] [and products] and/or associated traditional knowledge comply with domestic requirements regarding prior informed consent.

(c) Measures aimed at preventing the use of misappropriated genetic resources, [biological resources] [derivatives] [and products] their derivatives and products and/or traditional knowledge;

(d) Require that genetic resources, their derivatives and products and/or associated traditional knowledge are only used for purposes consistent with prior informed consent and mutually agreed terms the terms and conditions under which they were acquired;

2. Each Party shall take appropriate, effective and proportionate measures to establish sanctions and remedies when users under their jurisdictions have violated national access and benefit-sharing legislation of the countries of origin of genetic resources, their derivatives and products and/or traditional knowledge of the Parties that have acquired the genetic resources, [biological resources][their derivatives] [and products] in accordance with the Convention. Among others, the Parties should establish the following sanctions and remedies:

(a) The cessation of the acts related to the infraction;

(b) Compensation for damages;

(c) The withdrawal from the market of products resulting from the infringement;

(d) The prohibition on the import or export of goods, materials or any means referred to in the previous paragraph;

(e) The necessary action to avoid continuation or repetition of the offence;

(f) Publication of the judgement and notification to interested persons at the expense of the person(s) who made the infraction

(g) Criminal penalties for use of genetic resources, [biological resources] [their derivatives] [and products] and associated traditional knowledge without compliance with conditions of access and benefit-sharing in the country of origin;

3. Each Party shall, at the request of any interested Party, in accordance with national law and existing agreements or arrangements, cooperate in the investigation and follow up of cases of alleged violations of the national access and benefit-sharing legislation of the country of origin of genetic resources, their derivatives][and products] and/or associated traditional knowledge or of the Party that has acquired the genetic resources, [biological resources][, their derivatives][and products] in accordance with the Convention, including prior informed consent and mutually agreed terms.

4. Each Party shall provide timely guidance and make available information on the types of assistance that are available to nationals of other jurisdictions to assist in the exercise and enforcement of their rights.

5. User Parties may provide financial assistance for the settlement of legal disputes. [27]/

BIO and PhRMA

Operative text

"Parties may encourage providers and users of genetic resources under their jurisdiction to include provisions relating to dispute resolution and other enforcement matters, in mutually agreed terms relating to access and benefit-sharing of those resources in order to facilitate enforcement of the mutually agreed terms."

Related explanations and rationale

Any enforcement system should build on existing systems. In cases involving violations of national access laws, appropriate, effective and proportionate measures (including civil and/or criminal measures) should be considered. However, extraterritorial "enforcement" mechanisms created at the international level under the auspices of the CBD itself, e.g., international CBD tribunals, would be unworkable and should be avoided.

In the case of enforcing ABS agreements, private international law offers many dispute settlement mechanisms that are currently used to enforce contracts relating to international business transactions around the world; *see, e.g.*, paper by the delegation of Canada submitted to the sixth ABS WG meeting (UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008)). Alternative dispute resolution mechanisms and consideration of enforcement of foreign judgments (e.g., based on principles of international comity or under existing agreements such as the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards) should be further considered.

The voluntary use of existing mechanisms in mutually agreed terms, could provide a good starting point for discussion.

(a) Measures to ensure access to justice with the aim of enforcing ABS arrangements

Mexico

1. Access to justice should be in accordance with Principle 10 of the Rio Declaration.

[2. The Governing Body of the International Regime on Access and Benefit-sharing [shall][should][may] [consider][ensure] such [voluntary] measures or mechanisms as appropriate to support effective implementation of the International Regime on Access and Benefit-sharing, including by providing assistance to Parties[, as well assistance that covers issues related to the financial cost of

[27] The placement of paragraphs 1 to 5 above must be further considered.

legal expertise] [and/or indigenous and local communities], upon request, in litigation related to cases of alleged non-compliance [with national access and benefit-sharing laws, regulations and/or requirements and/or breach of access and benefit-sharing agreements]. Such measures/mechanisms [shall][should][may] be considered by the Governing Body of the International Regime on Access and Benefit-sharing not later than at its [first][next] meeting.]

[3. The International Regime on Access and Benefit-sharing [shall][should] establish an international access and benefit-sharing ombudsman's office. The ombudsman's office [shall][should] be responsible for provider countries[, or, where relevant,] [/] countries of origin and indigenous and local communities to identify breaches of their rights and to provide aid in seeking fair and equitable resolution of disputes. The ombudsman's office [shall][should] be empowered to take action on behalf of [provider] countries [of origin/provider countries] and indigenous and local communities through the binding Dispute Resolution Mechanism. The ombudsman's office [shall][should] also where necessary and when requested represent [provider] countries [of origin/provider countries] [and/or] indigenous and local communities in proceedings in foreign jurisdiction, take depositions from indigenous and local communities and provide evidence of customary law and practice as and where appropriate.]

(b) Dispute settlement mechanisms:

(i) Inter-State

(ii) Private international law

(iii) Alternative dispute resolution

Mexico

1.(a) The International Regime on Access and Benefit-sharing shall establish a Dispute Resolution Mechanism accessible to both, countries and other aggrieved stakeholders who include indigenous and local communities, non-governmental organizations, research and commercial interests, and other providers and users of genetic resources, [biological resources][, their derivatives][and products] and/or associated traditional knowledge.

(b) The Dispute Resolution Mechanism should also have regional offices that use local languages and have personnel conversant with the cultural, social, economic and environmental realities of the region.

(c) The Dispute Resolution Mechanism shall be guided in its work by principles of equity, impartiality and independence drawn from a wide range of legal sources including customary law and practices of indigenous and local communities.

(d) The International Regime on Access and Benefit-sharing shall establish mechanisms to provide legal assistance to developing countries and indigenous and local communities.

2. Parties to the Convention shall encourage users and providers to utilize, to the fullest extent possible, existing mechanisms on alternative dispute resolution for contracts.

(c) Enforcement of judgments and arbitral awards across jurisdictions

Mexico

Noting the importance of compliance with ABS agreements/contracts to the international regime *{preambular paragraph}*

Noting also that the existing body of private international law provides a range of options for dispute resolution across national borders {preambular paragraph}

Noting the 1958 United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the New York Convention) and the assistance it provides parties in the enforcement of foreign arbitral awards {preambular paragraph}

1. Contracting Parties shall encourage that their courts will enforce the decisions of the courts of the country of origin/provider countries against unlawful users under the former's jurisdiction subject to basic principles underlying enforcement of foreign judgments under comity in international law.

2. Parties shall encourage access and benefit-sharing users and providers to include provisions in access and benefit-sharing contracts to cover dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

(b) The applicable law;

(c) Options for alternative dispute resolution, such as mediation or arbitration, in the event of contractual disputes.

(d) Information exchange procedures between national focal points for access and benefit-sharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements

Mexico

Proposal of Mexico for a new paragraph:

"National focal points and/or competent authorities shall facilitate, through the international mechanism of compliance, the provision of relevant information on infringement of prior informed consent requirements of providers of genetic resources[, their derivatives][and products] and/or associated traditional knowledge.]"

(e) Remedies and sanctions

Mexico

1. National legislation shall provide for remedies to sanction lack of compliance with the national ABS framework *{…}*

3. Each Contracting Party shall introduce measures to facilitate cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements and misappropriation of [genetic resources][biological resources], [their derivatives][and products,] and/or associated traditional knowledge, such as access to justice and support for claimants in actions of breach of contract or misappropriation.

4) Measures to ensure compliance with customary law and local systems of protection

Mexico

Proposal of Mexico

Mexico eliminates the operative text for considering that deliberations on traditional knowledge under the section on Compliance are not part of the International Regime and are subject of national legislations and policies.

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)

Operative text

[Recognizing that customary law functions within a specific belief system, is dynamic and includes mechanisms to preserve its underlying values and principles **including the fundamental principle of reciprocity in access and benefit-sharing arrangements**{*preambular paragraph*}]

[1. Contracting Parties [shall][should]:

c) Ensure that any acquisition, appropriation or utilization of traditional knowledge in contravention of the relevant **customary laws,** community protocols **and associated access and benefit-sharing licensing terms** constitutes an act of misappropriation;

e) Encourage and support the development of community protocols **and access and benefit sharing licenses** that [shall][should] provide potential users of traditional knowledge with clear and transparent rules for access to traditional knowledge where associated traditional knowledge is shared between: (i) indigenous and local communities spread across national boundaries; and (ii) between indigenous and local communities with different values, customary norms, laws and understandings;

h) Consider relevant customary law and its potential application to access and benefit-sharing transactions in taking measures to raise awareness of access and benefit-sharing issues **including through the use of access and benefit-sharing licenses**.

Related explanations and rationale

It is anticipated that indigenous peoples and local communities would be primary users and beneficiaries of access and benefit-sharing licenses under the international regime. The above proposal is directed towards enabling this possibility with a particular focus on compliance in the creation of a trusted system that can be used by indigenous peoples and local communities.

The reader is also referred to the outcomes of the International Vilm Workshop on Matters related to Traditional Knowledge associated with Genetic resources and the ABS Regime, held 6-10 July 2009 in relation to additional text proposals in this area of negotiating text.
