

ESRC Centre for Economic and Social Aspects of Genomics (Cesagen)¹

Access and Benefit-Sharing Commons Licenses

Suggestions for operational text for consideration at WG-ABS8 Annex to UNEP/CBD/WG-ABS/78

Introduction:

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. 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).² 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

¹ Cesagen is a publicly funded non-profit Research Centre of the UK Economic and Social Research Council (ESRC) and is a joint collaboration between Cardiff University and Lancaster University. This document was prepared by Dr. Paul Oldham, Research Fellow, Cesagen, Lancaster University.

² 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.”

- 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 activities, and/or joint development in research activities” (III.A.1.6) and enabling technology transfer (III.A.1.4);³
- 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

³ 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).

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)

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.

A: Fair and Equitable Benefit Sharing

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

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) Access to and transfer of technology (III.A. 4)

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.

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.

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 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.⁴ 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

⁴ The three categories of utilization are identified in C.1.c option 2 and A. 15 option 2.

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;⁵

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.⁶

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;⁷

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;

⁵ 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.

⁶ 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.

⁷ This proposal links the access and benefit-sharing licenses with the main components of the international certificate.

- b) Open patents;
- 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.

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 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.]

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

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.**

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.

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

[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, customary 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.]**

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

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.**

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

(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

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.

B. ACCESS TO GENETIC RESOURCES ^{g/}

Note: The text proposals provided in this document 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.

C. COMPLIANCE

1) Development of tools to encourage compliance

(a) Awareness-raising activities

Additional paragraphs to existing 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,

^{g/} The title is without prejudice to the eventual scope of the International Regime on Access and Benefit-sharing.

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;

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 Commons⁹ and Science Commons licenses.¹⁰ 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.

(c) Sectoral menus of model clauses for material transfer agreements ^{11/}

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**

⁹ <http://creativecommons.org/license/>

¹⁰ 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>

^{11/} There are also sections on sectoral menus of model clauses in section III.A.15 and in section III.E.1.5 of annex I to decision IX/12.

regional and national equivalents. Details of indicators are provided in **the** Annex {...} of the International Regime on Access and Benefit-sharing.]

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.

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

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.

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

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;

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.

(a) Mechanisms for information exchange

(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 licences;**]

[(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 {...}.]

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

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~~]

(a) 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.

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

[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

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;

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.

(f) Identification of check points

[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**.]

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.

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

*[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**.

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.