

WIPO General Assembly

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REPORT ON THE INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE (IGC)

prepared by the Secretariat

I. INTRODUCTION

1. The WIPO General Assembly, at its Forty-Seventh (22nd Ordinary) Session in October 2015, agreed on the mandate for the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) for the 2016/2017 biennium.

2. The IGC's mandate for the 2016/2017 biennium, which was set out in document WO/GA/47/19, provides as follows:

“Bearing in mind the Development Agenda recommendations and acknowledging the progress made, the WIPO General Assembly agrees that the mandate of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (Committee) be renewed, without prejudice to the work pursued in other fora, as follows:

“(a) The Committee will, during the next budgetary biennium 2016/2017, continue to expedite its work, with a focus on narrowing existing gaps, with open and full engagement, including text-based negotiations, with the objective of reaching an agreement on an international legal instrument(s), without prejudging the nature of outcome(s), relating to intellectual property which will ensure the balanced and effective protection of genetic resources (GRs), traditional knowledge (TK) and traditional cultural expressions (TCEs).

“(b) The Committee’s work in the 2016/2017 biennium will build on the existing work carried out by the Committee with a primary focus on reaching a common understanding on core issues, including definition of misappropriation, beneficiaries, subject matter, objectives, and what TK/TCEs subject matter is entitled to protection at an international level, including consideration of exceptions and limitations and the relationship with the public domain.

“(c) The Committee will follow, as set out in the table below, a clearly defined work program, based on sound working methods, for the 2016/2017 biennium. This work program will make provision for 6 sessions of the Committee in 2016/2017, including thematic, cross-cutting and stocktaking sessions. The Committee may decide to establish an expert panel(s) and hold further Ambassadorial/Senior Capital-Based Officials meetings during future Committee sessions.

“(d) The Committee will use all WIPO working documents, including WIPO/GRTKF/IC/28/4, WIPO/GRTKF/IC/28/5 and WIPO/GRTKF/IC/28/6, as well as any other contributions of member states, using an evidence-based approach, including studies and examples of national experiences, including domestic legislation and examples of protectable subject matter and subject matter that is not intended to be protected; and outputs of any expert panel(s) established by the Committee and IGC-related seminars and workshops conducted under Program 4. However, examples, studies, seminars or workshops are not to delay progress or establish any preconditions for the negotiations.

“(e) Taking note of the utility served by the 2015 WIPO seminars on IGC-related subjects, provision shall be made for the Secretariat, under Program 4, to organize inter-sessional seminars and workshops to build regional and cross-regional knowledge and consensus on issues related to IP and GRs, TK and TCEs with a focus on unresolved issues.

“(f) In 2016, the Committee is requested to provide, for information only, a factual report to the General Assembly on its work up to that time, and in 2017, submit to the General Assembly the results of its work on an international legal instrument(s) relating to intellectual property which will ensure the balanced and effective protection of GRs, TK and TCEs. The General Assembly in 2017 will take stock of progress made, and decide on whether to convene a diplomatic conference or continue negotiations. It will also consider the need for additional meetings, taking account of the budgetary process.

“(g) The Committee may also consider the conversion of the Committee into a Standing Committee and, if so agreed, make a recommendation in this regard to the General Assembly in 2016 or 2017.

“(h) The General Assembly requests the International Bureau to continue to assist the Committee by providing Member States with necessary expertise and funding, in the most efficient manner, of the participation of experts from developing countries and LDCs, taking into account the usual formula for the IGC.

Work Program – 6 Sessions

Indicative Dates	Activity
February/March 2016	(IGC 29) Undertake negotiations on GRs with a focus on addressing unresolved issues and considering options for a draft legal instrument Elaborate an indicative list of outstanding/pending issues to be tackled/solved at the next session on GRs Duration 5 days.
May/June 2016	(IGC 30) Undertake negotiations on GRs with a focus on addressing unresolved issues and considering options for a draft legal instrument Duration 5 days.
September 2016	(IGC 31) Undertake negotiations on TK with a focus on addressing unresolved issues and considering options for a draft legal instrument Elaborate an indicative list of outstanding/pending issues to be tackled/solved at the next session on TK Duration 5 days.
September 2016	WIPO General Assembly Factual report
November/December 2016	(IGC 32) Undertake negotiations on TK with a focus on addressing unresolved issues and considering options for a draft legal instrument Duration 5 days.
March/April 2017	(IGC 33) Undertake negotiations on TCEs with a focus on addressing unresolved issues and considering options for a draft legal instrument Elaborate an indicative list of outstanding/pending issues to be tackled/solved at the next session on TCEs Duration 5 days.
June/July 2017	(IGC 34) Undertake negotiations on TCEs with a focus on addressing unresolved issues and considering options for a draft legal instrument Stocktaking session and making a recommendation Duration 5 days.
September 2017	WIPO General Assembly will take stock of and consider the text(s), progress made, and decide on whether to convene a diplomatic conference or continue negotiations. It will also consider the need for additional meetings, taking account of the budgetary process.”

3. Paragraph (f) of the mandate for this biennium (quoted above) requests the IGC, in 2016, “to provide, for information only, a factual report to the General Assembly on its work up to that time”. This document is prepared pursuant to this decision.

II. IGC SESSIONS IN 2016

4. Pursuant to the mandate for the 2016/2017 biennium and the work program for 2016 thus far, the IGC held three sessions in 2016, as follows:

- (a) IGC 29, from February 15 to 19, 2016, on the subject of GRs;
- (b) IGC 30, from May 30 to June 3, 2016, on the subject of GRs; and
- (c) IGC 31, from September 19 to 23, 2016, on the subject of TK.

5. As required by the IGC's mandate, IGC 29 developed an "Indicative List of Outstanding/Pending Issues to be Tackled/Solved at the Next Session", which was transmitted to IGC 30. IGC 30 developed a "Second Revision of the 'Consolidated Document Relating to Intellectual Property and Genetic Resources'" (annexed to the present document as "I"), and decided that this text, as at the close of the session on June 3, 2016, be transmitted to the Thirty-Fourth session of the IGC, in accordance with the Committee's mandate for 2016-2017 and the work program for 2017, as contained in document WO/GA/47/19.

6. IGC 31 developed a further text "The Protection of Traditional Knowledge: Draft Articles Rev. 2" (annexed to the present document as "II"), and decided that this text, as at the close of the relevant agenda item on September 23, 2016, be transmitted to the Thirty-Second session of the IGC, in accordance with the Committee's mandate for 2016-2017 and the work program for 2017, as contained in document WO/GA/47/19. As required by the IGC's mandate, IGC 31 also developed an "Indicative List of Outstanding/Pending Issues to be Tackled/Solved at the Next Session", which was transmitted to IGC 32.

7. Certain Member States submitted documents for consideration by one or more of the three IGC sessions held so far in 2016. These documents, as well as the decisions adopted at each of those sessions, are available online at <http://www.wipo.int/tk/en/igc/>.

III. SEMINAR IN 2016

8. Paragraph (e) of the mandate takes "note of the utility served by the 2015 WIPO seminars on IGC-related subjects" and requests the WIPO Secretariat "to organize inter-sessional seminars and workshops to build regional and cross-regional knowledge and consensus on issues related to IP and GRs, TK and TCEs with a focus on unresolved issues".

9. Pursuant to this decision, a *Seminar on Intellectual Property and Genetic Resources* was organized on May 26 and 27, 2016, prior to IGC 30. The Program and all the presentations made are available online at http://www.wipo.int/meetings/en/details.jsp?meeting_id=39823.

IV. CONTRIBUTION TO THE IMPLEMENTATION OF THE DEVELOPMENT AGENDA RECOMMENDATIONS

10. Further to the 2010 WIPO General Assembly decision "to instruct the relevant WIPO Bodies to include in their annual report to the Assemblies, a description of their contribution to the implementation of the respective Development Agenda Recommendations", IGC 31 also discussed the contribution of the IGC to the implementation of the Development Agenda (DA) Recommendations.

11. In this regard, the following statements were made at IGC 31. These will also appear in the initial draft report of IGC 31 (WIPO/GRTKF/IC/31/10 Prov.), which will be made available, as requested by the IGC, by October 28, 2016:

The Delegation of Nigeria, speaking on behalf of the African Group, acknowledged the various technical assistance and capacity-building activities undertaken by the Traditional Knowledge Division and WIPO in general, to provide regulatory advice and other development-oriented assistance to developing and least developed countries. It emphasized Development Agenda Recommendation 18, which, when adopted in 2007, urged the IGC to “accelerate the process on the protection of genetic resources, traditional knowledge and folklore, without prejudice to the outcome, including the possible development of an international instrument or instruments.” In that context, a resounding and unassailable contribution of the IGC to the implementation of the Development Agenda recommendations was a conclusion of the three-subject IGC negotiations with an outcome of a minimum standard, functional international legally binding instrument that enhanced the transparency and efficacy of the international IP system, promoted and protected tradition-based knowledge, creation and innovation in the modern IP framework (whether commercialized or not), and ensured equitable economic benefits, and as appropriate, moral rights, for the owners of such knowledge. The assistance provided by WIPO in the sphere of IGC-related topics had to be demand driven, development oriented, transparent, and respond to the specific priorities and/or development needs of the demanding country. It was also crucial that such engagements take into account the existing flexibilities in the international IP system. The African Group remained committed to achieving the Group’s objective desire within the IGC and would continue to engage constructively.

The Delegation of Brazil recalled that the IGC had resumed its activities after a hiatus of more than one year. The existence of the IGC was a condition for the implementation of at least one of the Development Agenda recommendations, Recommendation 18. Other recommendations were also involved in the IGC’s work, namely Recommendations 15, 16, 17, 19 and 22. In 2016, there had been two IGC sessions: IGC 29 and IGC 30, dealing with the relationship between GRs and the IP system, which had contributed to accelerating the IGC process towards a legally-binding instrument. The Delegation was hopeful that the current and future sessions would continue to follow Recommendation 18, as well as continue to implement other relevant recommendations.

The Delegation of China appreciated the contributions of the IGC to the implementation of the Development Agenda and aligned itself with the statements made by the Delegation of Nigeria, on behalf of the African Group, and by the Delegation of Brazil. The protection of GRs, TK and TCEs reflected diversified aspirations of all countries, and the balance between creativity and tradition. It hoped to continue to pursue the work so as to realize the aspirations of developing countries, particularly least developed countries, in that area.

The Representative of the Tulalip Tribes, speaking on behalf of the Indigenous Caucus, said that the previous year, the United Nations General Assembly had adopted the Sustainable Development Goals (SDGs), which aimed to eliminate extreme poverty by 2030, and to leave no-one behind in achieving sustainable development. He drew attention to the SDG target under the goal to end extreme poverty, which required States to ensure that all men and women, in particular the poor and the vulnerable, had equal rights to economic resources, as well as access to basic services, ownership and control over land and other forms of property. For indigenous peoples, ownership over “other forms of property” included ownership of TK, TCEs and other community intellectual creations. He recommended that Member States of the IGC take cognizance of that SDG target in the course of the negotiations. In order to comply with the Outcome Document of the World Conference on Indigenous Peoples, the United Nations had adopted the

System-Wide Action Plan for ensuring a coherent approach to achieving the ends of the Declaration on the Rights of Indigenous Peoples (the SWAP). The SWAP ultimately aimed at contributing to the realization of indigenous peoples' rights at the country level through reinforced support by the UN system to Member States in that regard. He urged Member States of the IGC to ensure coherence between the instruments being negotiated and other international legal instruments on the rights of indigenous peoples. Any instrument developed by the IGC should not diminish the rights of Indigenous peoples under other international legal instruments.

The Delegation of India aligned itself with the statements made by the Delegation of Nigeria, on behalf of the African Group, and by the Delegations of Brazil and China. The Delegation had been a major demandeur for addressing the misappropriation of GRs, TK and TCEs. It expected that the work of IGC would result in a legally binding instrument(s) to protect and promote GRs, TK and TCEs, thereby addressing various Development Agenda recommendations. The Delegation appreciated and encouraged the work of WIPO in the mainstreaming of the Development Agenda in its work.

12. The WIPO General Assembly is invited to take note of the "Report on the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)" (document WO/GA/48/9) in accordance with the IGC's mandate for the 2016/2017 biennium and the IGC's work program for 2016.

[Annexes follow]

**Second Revision of the Consolidated Document Relating to
Intellectual Property and Genetic Resources**

(as at the close of IGC 30 on June 3, 2016)

LIST OF TERMS

[Traditional Knowledge Associated with Genetic Resources

Option 1

“Traditional knowledge associated with genetic resources” means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, [that subsist in] [that are associated with] genetic resources.]

Option 2

“Traditional knowledge associated with genetic resources” means substantive knowledge of the properties and uses of genetic resources [and their derivatives] held by [rightful holders, including] indigenous [people[s]] and local communities [and which directly leads to a claimed [invention] [intellectual property]] [and where, but for the traditional knowledge, the invention would not have been made].]

[Biotechnology

“Biotechnology” [as defined in Article 2 of the Convention on Biological Diversity] means any technological application that uses biological systems, living organisms [or derivatives thereof], to make or modify products or processes for specific use.]

[Country of Origin

“Country of origin” is the [first] country which possesses genetic resources in in-situ conditions.]

[[Country Providing] [Providing Country]

“Country providing/Providing country” means, [in accordance with Article 5 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity], a [providing country] [country providing] that is the country of origin [or that has acquired the genetic resources and/or that has accessed the traditional knowledge in accordance with the [Convention on Biological Diversity].]

[Country Providing Genetic Resources

“Country providing genetic resources” is the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from *ex-situ* sources, which may or may not have originated in that country.]

ALT

[“Country providing genetic resources” is the country that possesses the genetic resource and/or traditional knowledge in *in situ* or *ex situ* conditions and that provides the genetic resource and/or traditional knowledge.]

[Derivative]

“Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.]

[[Invention] Directly Based On

“[Invention] Directly based on” means that the [invention] [must] make [immediate] use of the genetic resource, and depend on the specific properties of the resource of which the inventor [must] have had [physical] access.]

***Ex-Situ* Conservation**

“*Ex-situ* conservation” means the conservation of components of biological diversity outside their natural habitats.

Genetic Material

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

Genetic Resources

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

***In-Situ* Conditions**

“*In-situ* conditions” means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties [Article 2, CBD].

[Member State

“Member State” refers to a Member State of the World Intellectual Property Organization.]

[Misappropriation

Option 1

“Misappropriation” is the [acquisition] [utilization] of genetic resources, [their derivatives] [and] [or] [traditional knowledge associated with genetic resources] without the [free] [prior informed] consent of [those who are authorized to give [such] consent] [competent authority] to such [acquisition] [utilization], [in accordance with national legislation] [of the country of origin or providing country].]

Option 2

“Misappropriation” is the use of genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources] of another where the genetic resources or traditional knowledge has been acquired by the user from the holder through improper means or a breach of confidence which results in a violation of national law in a provider country. Use of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] that has been acquired by lawful means, such as reading publications, purchase, independent discovery, reverse engineering and inadvertent disclosure resulting from the holders of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] failure to take reasonable protective measures, is not misappropriation.]

[Intellectual Property Office] [Patent Office]

“Intellectual property office” [“Patent office”] means the authority of a Member State entrusted with the granting of [intellectual property rights] [patents].

[[Physical] Access

“[Physical]/[Direct] access” to the genetic resource is its possession or at least contact [which is sufficient enough to identify the properties of the genetic resource relevant for the [invention] [intellectual property]].]

[[Protected] Genetic Resources

“[Protected] genetic resources” means, genetic resources that are protected either pursuant to an intellectual property right or other legal right. Once intellectual property rights in a genetic resource expire, the genetic resource should be in the public domain and not treated as a protected genetic resource.¹

[Source

[Option 1

“Source” refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a resource holder, research centre, [gene bank] [Budapest depository] or botanical garden.]

[Option 2

“Source” should be understood in its broadest sense possible:

- (i) Primary sources, including in particular [Contracting Parties] [Countries] providing genetic resources, the Multilateral System of ITPGRFA, [patent owners, universities, farmers, and plant breeders,] indigenous and local communities; and
- (ii) Secondary sources, including in particular *ex-situ* collections and [scientific literature].]

¹ Several Member States expressed a difficulty in understanding the meaning of this definition. While it is retained in the list of terms, it is requested that the proponents provide greater clarity.

[Source of Traditional Knowledge with Associated Genetic Resources

“Source of Traditional Knowledge Associated with Genetic Resources” means any source from which the applicant has acquired the traditional knowledge associated with genetic resources, including indigenous and local communities, scientific literature, publicly accessible databases, and patent applications, and patent publications.^{2]}

[Unauthorized Use

“Unauthorized use” is the acquisition of genetic resources, [traditional knowledge associated with genetic resources] without the consent of the competent authority in accordance with national legislation of the providing country.]

[Utilization

“Utilization” of Genetic Resources means to conduct research and development, [conservation, collection, characterization, among others,] [including commercialization] on the genetic and/or biochemical composition of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity].]

ALT

[“Utilization” of genetic resources means to conduct research and development [including commercialization] on the genetic and/or biochemical composition of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity] [and to make a new product, or a new method of use or manufacturing of a product.]]]

² This phrase does not appear verbatim in the document, but was introduced contemporaneously with the global deletion of “associated traditional knowledge” from the text. Upon reflection, it was felt that the Member State which introduced the phrase should have the opportunity to clarify its continuing relevance to the text.

[PREAMBLE

[Ensure [encourage] respect for [sovereign rights] [the rights] of [rightful holders, including] indigenous [people[s]] and local communities [as well as [people[s]] partially or entirely under occupation] over their genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources], including the principle of [prior informed consent and mutually agreed terms] and total and effective participation in accordance with international [agreements and] declarations [, in particular the UN Declaration on the Rights of Indigenous Peoples].]

[Contribute to the prevention of misappropriation of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].]

[Minimize the granting of erroneous [IP] [patent] rights.]

[Reaffirming the important economic, scientific, cultural, and commercial value of genetic resources and [traditional knowledge associated with genetic resources].]

[Acknowledging the important contribution of the patent system to scientific research, scientific development, innovation and economic development.]

[Stressing the need for members to ensure the correct grant of patents for novel and non-obvious inventions related to genetic resources and [traditional knowledge associated with genetic resources].]

Encourage respect for indigenous [people[s]] and local communities.

[The [intellectual property] [patent] system shall/should provide certainty of rights for legitimate users and providers of genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources].]

[Recognize the role the [intellectual property] [patent] system plays in promoting innovation, [transfer and dissemination of technology] to the mutual advantage of stakeholders, providers, holders and users of genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources].]

[Promote [transparency and] dissemination of information.]

[A global and compulsory system creates a level playing field for industry and the commercial exploitation of [intellectual property] [patents], and also facilitates the possibilities [under Article 15(7) of the CBD] for the sharing of the benefits arising from the use of genetic resources.]

[Foster [patent] [industrial property] protection and the development of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] and encourage international research leading to innovation.]

[The disclosure of the source would increase mutual trust among the various stakeholders involved in access and benefit sharing. All of these stakeholders may be providers and/or users of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]. Accordingly, disclosing the source would build mutual trust in the North – South – relationship. Moreover, it would strengthen the mutual supportiveness between the access and benefit sharing system and the [intellectual property] [patent] system.]

[[Ensure] [recommend] that no [patents] [intellectual property] on life forms, including human beings, are granted.]

[Recognize that those accessing genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] in a country shall/should, where required, comply with that country's national law providing protection for the genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].]

[[IP][Patent] offices shall/should have a mandatory requirement for disclosure, as elaborated in this international legal instrument, when patenting of genetic resources would cause harm to the interests of indigenous [people[s]] and local communities.]

[Reaffirm, in accordance with the Convention *on* Biological Diversity, the sovereign rights of States over their [natural] [biological] resources, and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.]]

ALT

[Reaffirm, in accordance with the Convention *on* Biological Diversity, the sovereign rights of States over [their] [natural] [biological] [genetic] resources [within their jurisdiction other than those associated with human beings or those associated with intellectual property rights], and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.]]

[I. GENERAL PROVISIONS]

[ARTICLE 1 OBJECTIVE[S]]

1 [The objectives of this instrument are to [enhance the [efficacy] and [transparency] of the [IP] [patent] system; and facilitate mutual supportiveness with international agreements relating to genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].]

ALT 1

1 [The objectives of this instrument are to [enhance the [transparency] of the [IP] [patent] system to facilitate the possibility of ABS through the disclosure of country of origin or source of genetic resources in separate systems such as the CBD.]

ALT 2

1 [The objective of this instrument is to [promote][ensure][the effective protection of] [contribute to the prevention of] [prevent] the [misappropriation of] genetic resources [their derivatives] and [traditional knowledge associated with genetic resources] [through the] [in the context of the] [IP] [patents] system by:]

- (a) Ensuring that [IP] [patent] offices have access to the appropriate information on genetic resources [their derivatives] and [traditional knowledge associated with genetic resources] to prevent the granting of [erroneous] [IP] [patent] rights;
- (b) [Enhancing transparency in the [IP][patent] [and access and benefit sharing] system]; and,
- (c) [Ensuring] [promoting] [facilitating] [complementarity] [mutual supportiveness] with international agreements relating to the protection of genetic resources [their derivatives] and/or [traditional knowledge associated with genetic resources] [and those relating to IP].

[ARTICLE 2] SUBJECT MATTER OF INSTRUMENT

2 This instrument applies to genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].

ALT

[This instrument shall/should apply to patent applications for inventions directly based on genetic resources[, and traditional knowledge associated with genetic resources].]

[II. [MANDATORY] DISCLOSURE]

[ARTICLE 3] [DISCLOSURE REQUIREMENT]

3.1 Where the [subject matter] [claimed invention] within a [IP Rights] [patent] application [includes utilization of] [is directly based on] [is directly based on the utilization of]³ genetic resources [their derivatives] and/or [traditional knowledge associated with genetic resources] each Party shall/should require applicants to:

- (a) Disclose the [providing country that is the country of origin] [country of origin [and]] [or [if unknown],] source of the genetic resources, [their derivatives] and/or [traditional knowledge associated with genetic resources.]
- (b) [Provide relevant information, as required by national law, regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate.]
- (c) [If the source and/or [providing country that is the country of origin] [country of origin] is not known, a declaration to that effect.]

3.2 The disclosure requirement [shall/should/may] [does] not place an obligation on the [IP] [patent] offices to verify the contents of the disclosure. [But [IP] [patent] offices [shall/should] provide guidance to [IP] [patent] applicants on how to meet disclosure requirement [formalities].]

3.3 A simple notification procedure shall/should be introduced by the [patent] [IP] offices that receive a declaration. [It would be adequate to identify in particular the Clearing House Mechanism of the CBD/ITPGRFA as the central body to which the [IP] [patent] offices shall/should send the available information.]

3.4 [Each Party shall/should make the information disclosed[, except for information related to privacy, business secrets, or other lawful confidentiality⁴,] publicly available at the time of application publication [or patent grant].]

3.5 [Genetic resources and [their derivatives] as found in nature or isolated therefrom shall/should not be considered as [inventions] [IP] and therefore no [IP] [patent] rights shall/should be granted.]]

[ARTICLE 4] [EXCEPTIONS AND LIMITATIONS]

4 [In complying with the obligation set forth in Article 3, members may, in special cases, adopt justifiable exceptions and limitations necessary to protect the public interest, provided such justifiable exceptions and limitations do not unduly prejudice the implementation of this instrument.]

ALT

4.1 A [IP] [patent] disclosure requirement related to genetic resources [their derivatives] and [traditional knowledge associated with genetic resources] shall/should not apply to the following:

- (a) [All [human genetic resources] [genetic resources taken from humans] [including human pathogens];]

³ Some members noted a need for a definition for this formulation in the list of terms.

⁴ An alternative formulation from the Nagoya Protocol Art. 14(2) is "without prejudice to the protection of confidential information".

- (b) [Derivatives];
- (c) [Commodities];[/genetic resources when they are used as commodities];
- (d) [Traditional knowledge in the public domain];
- (e) [Genetic resources from areas beyond national jurisdictions [and economic zones]]; and
- (f) [All genetic resources [acquired] [accessed] before [entry into force of the Convention on Biological Diversity] [before December 29th 1993]] [entry into force of the Nagoya Protocol on October 12, 2014].

4.2 [Member States shall/should not impose the disclosure requirement in this instrument on [IP] [patent] applications filed [or having a priority date] before entry into force of this instrument[, subject to national laws that existed prior to this instrument].]

[ARTICLE 5] SANCTIONS AND REMEDIES

5 [Each [Party] [country] shall/should put in place appropriate, effective and proportionate legal and administrative measures to address non-compliance with paragraph 3.1[, including dispute resolution mechanisms]. Subject to national legislation, sanctions and remedies [shall/should] [may] [include, inter alia] consist of:

- (a) Pre-Grant.
 - (i) Suspending further processing of [IP] [patent] applications until the disclosure requirements are met.
 - (ii) A [IP] [patent] office considering the application withdrawn [in accordance with national law].
 - (iii) Preventing or refusing to grant an [IP right] [patent].
- (b) [Post-Grant].
 - (i) Publication of judicial rulings regarding failure to disclose.
 - (ii) [Fines or adequate compensation for damages, including payment of royalties.]
 - (iii) Other measures [including revocation, restorative justice, and economic compensation for holders of genetic resources, their derivatives, and [traditional knowledge associated with genetic resources] including indigenous peoples and/or local communities] may be considered, in accordance with national law.]]

ALT

[5.1 Each Party shall put in place appropriate, effective, dissuasive, and proportionate legal and/or administrative measures to address non-compliance with Article 3, [including preventing further processing of patent applications.]]

[5.2 Material misstatements made with an intent to deceive the patent office regarding compliance with Article 3, shall be deemed perjury, lying to an official, or other similar infraction, and punishable as such in accordance with national law.]

5.3 [[Failure to fulfill the disclosure requirement] [incorrect or incomplete information], [in the absence of fraud], shall/should not affect the validity or enforceability of granted [IP] [patent] rights.]

**[ALTERNATIVES TO ARTICLES 1, 2, 3, 4 & 5
NO NEW DISCLOSURE REQUIREMENT]**

**ALT
[ARTICLE 1]
[OBJECTIVE]**

1 [The objective of this instrument is to prevent the grant of patent rights on inventions that are not novel, non-obvious, and industrially applicable.]

**ALT
[ARTICLE 3]
[NO NEW DISCLOSURE REQUIREMENT]**

3.1 [IP] [patent] applicants may only be required to state where the genetic resource can be obtained if that location is necessary for a person skilled in the art to carry out the invention. Therefore no disclosure requirements can be imposed upon patent applicants or patentees for patents related to genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources], for reasons other than those related to novelty, inventive step, industrial applicability or enablement.]

3.2 [Where the subject matter of an invention is made using genetic resources obtained from an entity having a legal right over the genetic resource [(including a patent owner)], that entity may in the permit agreement or license granting the applicant access to the genetic resource or the right to use the genetic resource, require a patent applicant to:

- (a) Include within the specification of a patent application and any patent issuing thereon a statement specifying that the invention was made using the genetic resource and other relevant information, and
- (b) Obtain consent for uses not encompassed within the permit agreement or license.]

3.3 [Patent offices shall/should publish the entire disclosure of the patent on the Internet, on the date of the patent grant and shall/should strive to make the contents of the patent application publicly accessible over the Internet as well.]

3.4 [Where access to a genetic resource or [traditional knowledge associated with genetic resources] is not necessary to make or use the invention, information regarding the source or origin of genetic resource or the [traditional knowledge associated with the genetic resource] can be provided at any time after the filing date of the application.]

3.5 [Failure to examine a patent application in a timely manner shall/should result in an adjustment of the term of the granted patent to compensate the patentee for delays. Applicants shall/should be provided an opportunity to correct any incorrect or erroneous disclosures.]

[III. DEFENSIVE MEASURES/ DEFENSIVE MEASURES COMPLEMENTARY TO MANDATORY DISCLOSURE⁵]

[ARTICLE 6] [DUE DILIGENCE]

6 Member states shall/should encourage or establish a fair and reasonable due diligence system to ascertain that [protected] genetic resources have been accessed in accordance with [applicable] access and benefit sharing legislation or regulatory requirements.

- (a) A database shall/should be used as a mechanism to allow monitoring of compliance with these due diligence requirements in accordance with national law. However, member states shall/should not be obliged to establish such databases.
- (b) Such databases shall/should be accessible to potential patent licensees [and potential investors] to confirm lawful chain of title of [protected] genetic resources upon which a patent is based.]

[ARTICLE 7] [[PREVENTION OF THE [ERRONEOUS]⁶ GRANT OF PATENTS] [PREVENTION OF THE GRANTING OF PATENTS WHICH DO NOT COMPLY WITH THE REQUIREMENTS FOR PATENTABILITY OF THE INVENTION] AND VOLUNTARY CODES OF CONDUCT]

7.1 Member States shall/should:

- (a) Provide legal, policy or administrative measures, as appropriate and in accordance with national law, to prevent patents from being granted [erroneously] with regard to claimed inventions that include genetic resources [their derivatives] and [traditional knowledge associated with genetic resources] where, under national law, those genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]:
 - (i) Anticipate a claimed invention (no novelty); or
 - (ii) Obviate a claimed invention (obvious or no inventive step).
- (b) Provide legal, policy or administrative measures, as appropriate and in accordance with national law, to allow third parties to dispute the validity of a patent, by submitting prior art, with regard to inventions that include genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].
- (c) [Encourage, as appropriate, the development and use of voluntary codes of conduct and guidelines for users regarding the protection of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources].]
- (d) Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases [information associated with] of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] for use by patent offices.]

⁵ Facilitators Note. Members should note that some members consider Defensive Measures as an alternative option to Disclosure while some other members consider them as a complementary option to Disclosure.

⁶ A Member State requested to change this title to "Protection of the Demand of the Patents". However, the facilitators do not understand the meaning of this proposal and request clarification before such a change is made.

[7.2 As a complement to the disclosure obligation provided for in Article 3, and in the implementation of this instrument, the Contracting State may consider the use of databases on traditional knowledge and genetic resources in accordance with its needs, priorities, and safeguards as may be required under national laws and special circumstances.]

Database Search Systems

7.3 Members are encouraged to facilitate the establishment of databases [information associated with] of genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] for the purposes of search and examination of patent applications, in consultation with relevant stakeholders and taking into account their national circumstances, as well as the following considerations:

- (a) With a view towards interoperability, databases shall/should comply with minimum standards and structure of content.
- (b) Appropriate safeguards [such as filters] shall/should be developed in accordance with national law.
- (c) These databases will be accessible to patent offices [and other approved users].

WIPO Portal Site

7.4 Member States shall/should establish a database search system (the WIPO Portal) that links databases of WIPO members that contain information on genetic resources, [their derivatives] and non-secret [traditional knowledge associated with genetic resources] within their territory. The WIPO portal site will enable an examiner [and the public] to directly access and retrieve data from national databases. The WIPO Portal will also include appropriate safeguards [such as filters].]

[IV. FINAL PROVISIONS]

[ARTICLE 8] RELATIONSHIP WITH INTERNATIONAL AGREEMENTS

8.1 This instrument shall/should establish a mutually supportive relationship [between [intellectual property] [patent] rights [directly based on] [involving] [the utilization of] genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources] and] [with] relevant [existing] international agreements and treaties.

ALT

8.1 [This instrument should be consistent with international IP agreements. Members recognize the coherent relationships between policies that promote the granting of patents involving the utilization of genetic resources and/or [traditional knowledge associated with genetic resources] and policies that promote the conservation of biological diversity, promote access to genetic resources, and the sharing of the benefits of such genetic resources.]

8.2 [This instrument shall/should complement and is not intended to modify other agreements on related subject matter, and shall/should support in particular, [the Universal Declaration on Human Rights, and] Article 31 of the UN Declaration on the Rights of Indigenous Peoples.]

8.3 [No provision in this instrument shall be interpreted as harming, or being to the detriment of the rights of indigenous people enshrined in the United Nations declaration on the rights of indigenous people. In the case of a conflict of laws, the rights of indigenous people enshrined in such declaration shall prevail and any interpretation shall be guided by the provisions of such declaration.]]

[8.4 The [PCT] and [PLT] shall/should be amended to [include] [enable Parties to the [PCT] and [PLT] to provide for in their national legislation] a mandatory disclosure requirement of the origin and source of the genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]. [The amendments shall/should also include requiring confirmation of prior informed consent, evidence of benefit sharing under mutually agreed terms with the country of origin.]]

[ARTICLE 9] INTERNATIONAL COOPERATION

9 [[Relevant WIPO bodies shall/should encourage Patent Cooperation Treaty members to] [The PCT Reform Working Group shall/should] develop a set of guidelines for [the search and examination of applications related to genetic resources, [their derivatives] and [traditional knowledge associated with genetic resources]] [administrative disclosure of origin or source] by the international search and examination authorities under the Patent Cooperation Treaty].

ALT

9 [Patent examination authorities should share information related to sources of information related to genetic resources and/or traditional knowledge, especially periodicals, digital libraries and databases of information related to genetic resources and traditional knowledge. WIPO Members should cooperate in the sharing of information related to genetic resources and knowledge, including traditional knowledge, regarding the use of genetic resources.]

[ARTICLE 10] TRANSBOUNDARY COOPERATION

10 [In instances where the same genetic resources [, their derivatives] and [traditional knowledge associated with genetic resources] are found in in-situ conditions within the territory of more than one Party, those Parties shall/should endeavor to cooperate, as appropriate, with the involvement of indigenous [people[s]] and local communities concerned, where applicable, by taking measures that make use of customary laws and protocols, that are supportive of and do not run counter to the objectives of this instrument and national legislation.]

[ARTICLE 11] TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING

11 [Relevant WIPO bodies [shall/should]] [WIPO shall/should] develop modalities for the creation, funding and implementation of the provisions under this instrument. WIPO [shall/should] provide technical assistance, cooperation, capacity building and financial support, subject to budgetary resources, for developing countries in particular the least developed countries to implement the obligations under this instrument.]

[Annex II follows]

The Protection of Traditional Knowledge: Draft Articles

Rev. 2 (September 23, 2016)

PREAMBLE/INTRODUCTION

Recognize value

(i) *recognize the [holistic] [distinctive] nature of traditional knowledge and its [intrinsic] value, including its social, spiritual, [economic], intellectual, scientific, ecological, technological, [commercial], educational and cultural value, and acknowledge that traditional knowledge systems are frameworks of ongoing innovation and distinctive intellectual and creative life that are [fundamentally] intrinsically important for indigenous [peoples] and local communities and have equal scientific value as other knowledge systems;*

Promote awareness and respect

(ii) *promote awareness and respect for traditional knowledge systems; for the dignity, cultural [integrity] heritage and intellectual and spiritual values of the traditional knowledge [holders]/[owners] who conserve, develop and maintain those systems; for the contribution which traditional knowledge has made in sustaining the livelihoods and identities of traditional knowledge [holders]/[owners]; and for the contribution which traditional knowledge [holders]/[owners] have made to the [conservation of the environment] conservation and sustainable use of biodiversity, to food security and sustainable agriculture, healthcare, and to the progress of science and technology;*

Alternative

(ii) *promote respect for traditional knowledge systems, for the dignity, cultural integrity and spiritual values of the traditional knowledge holders who conserve and maintain those systems;*

[End of alternative]

Promote [conservation and] preservation of traditional knowledge

(iii) *promote and support the [conservation of and] preservation [of] [and respect for] traditional knowledge [by respecting, preserving, protecting and maintaining traditional knowledge systems [and providing incentives to the custodians of those knowledge systems to maintain and safeguard their knowledge systems]];*

[Consistency with relevant international agreements and processes

(iv) *take account of, and operate consistently with, other international and regional instruments and processes, in particular regimes that relate to intellectual property and access to and benefit sharing from genetic resources which are associated with that traditional knowledge, [as well as the U.N. Declaration on the Rights of Indigenous Peoples;]]*

[Promote access to knowledge and safeguard the public domain

(v) *recognize the value of a vibrant public domain and the body of knowledge that is available for all to use, and which is essential for creativity and innovation, and the need to protect, preserve and enhance the public domain;]*

[Document and conserve traditional knowledge

(vi) contribute to the documentation and conservation of traditional knowledge, encouraging traditional knowledge to be disclosed, learned and used in accordance with relevant customary practices, norms, laws, and/or understandings of traditional knowledge holders, including those customary practices, norms, laws and/or understandings that require prior informed consent or approval and involvement and mutually agreed terms before the traditional knowledge can be disclosed, learned or used by others;]

[Promote human rights

(vii) Recognize and protect that everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits and that this right may not be subject to distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. Furthermore, no distinction shall be made on the basis of the political, jurisdictional or international status of the country or territory to which a person belongs, whether it be independent, trust, non-self-governing or under any other limitation of sovereignty.]

Promote innovation

(viii) [the protection of traditional knowledge should] contribute toward the promotion of innovation and to the transfer and dissemination of knowledge to the mutual advantage of holders and users of traditional knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations;

Alt

[Innovation based on traditional knowledge may contribute to the transfer and dissemination of knowledge for the benefit of the holders and legitimate users of traditional knowledge, as long as it contributes to the facilitation of social and economic welfare and a balance of rights and obligations.

The protection of the innovation derived from traditional knowledge empowers communities to manage and control the commercial exploitation of owned intellectual property, as well as collectively benefit from it;]

Provide new rules and disciplines

(ix) [recognize the need for new rules and disciplines concerning the provision of effective and appropriate means for the enforcement of rights relating to traditional knowledge, taking into account differences in national legal systems;]

Relationship with customary use

(x) not restrict the generation, customary use, transmission, exchange and development of traditional knowledge by the beneficiaries, within and among communities in the traditional and customary context, [in accordance with national law].

POLICY OBJECTIVES

[Alt 1

This instrument should aim to:

1. Provide beneficiaries with the means to:
 - (a) prevent the [misappropriation/illegal appropriation, misuse, and unauthorized use], of their traditional knowledge;
 - (b) [control ways in which their traditional knowledge is used beyond the traditional and customary context;]
 - (c) achieve the fair and equitable sharing of benefits arising from the use of their traditional knowledge, with prior informed consent or approval and involvement and taking customary law into consideration as appropriate; and
 - (d) encourage and protect tradition-based creation and innovation, whether or not commercialized.
- [2. Aid in the prevention of the grant of erroneous intellectual property/[patent rights] over [traditional knowledge and [[traditional knowledge] associated [with] genetic resources].]]

[Alt 2

This instrument should aim to prevent the [misuse]/[unlawful appropriation] of protected traditional knowledge and encourage [tradition-based] creation and innovation.]

[Alt 3

The objective of this instrument is to contribute toward the protection of innovation and to the transfer and dissemination of knowledge, to the mutual advantage of holders and users of protected traditional knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations.

Recognize the value of a vibrant public domain, the body of knowledge that is available for all to use and which is essential for creativity and innovation, and the need to protect, preserve and enhance the public domain.]

USE OF TERMS

For the purposes of this instrument:

[Misappropriation means

Alt 1

Any access or use of the [subject matter]/[traditional knowledge] without prior informed consent or approval and involvement and, where applicable, without mutual agreed terms, for whatever purpose (commercial, research, academic and technology transfer).

Alt 2

The use of protected traditional knowledge of another where the [subject matter]/[traditional knowledge] has been acquired by the user from the holder through improper means or a breach of confidence and which results in a violation of national law in the provider country, recognizing that acquisition of traditional knowledge through lawful means such as [independent discovery or creation], reading books, receiving from sources outside of intact traditional communities, reverse engineering, and inadvertent disclosure resulting from the holders' failure to take reasonable protection measures is not [misappropriation/misuse/unauthorized use/unfair and inequitable uses.]

[Alt 3

Any access or use of traditional knowledge of the beneficiaries in violation of customary law and established practices governing the access or use of such traditional knowledge.]

[Alt 4

Any access or use of traditional knowledge of the [beneficiaries] indigenous [peoples] or local communities, without their free prior and informed consent and mutually agreed terms, in violation of customary law and established practices governing the access or use of such traditional knowledge.]

[Misuse may occur where the traditional knowledge which belongs to a beneficiary is used by the user in a manner that results in a violation of national law or measures endorsed by the legislature in the country where the use is carried out; the nature of the protection or safeguarding of traditional knowledge at the national level may take different forms such new forms of intellectual property protection, protection based on principles of unfair competition or a measures-based approach or a combination thereof.]

[Protected traditional knowledge is traditional knowledge that satisfies the criteria for eligibility under Article 1 and the scope and conditions for protection under Article 3.]

[Public domain refers, for the purposes of this instrument, to intangible materials that, by their nature, are not or may not be protected by established intellectual property rights or related forms of protection by the legislation in the country where the use of such material is carried out. This could, for example, be the case where the subject matter in question does not fill the prerequisite for intellectual property protection at the national level or, as the case may be, where the term of any previous protection has expired.]

[Publicly available means [subject matter]/[traditional knowledge] that has lost its distinctive association with any indigenous community and that as such has become generic or stock knowledge, notwithstanding that its historic origin may be known to the public.]

[Alt 1

Traditional knowledge for the purposes of this instrument, is knowledge that is created, maintained, and developed by indigenous [peoples], local communities, [and nations/states], and that is linked with, or is an integral part of, the national or social identity and/or cultural heritage of indigenous [peoples], local communities,[and nations/states] ; that is transmitted between or from generation to generation, whether consecutively or not; which subsists in codified, oral, or other forms; and which may be dynamic and evolving, and may take the form of know-how, skills, innovations, practices, teachings or learnings.]

[Alt 2

Traditional knowledge for the purposes of this instrument, is knowledge that is created, maintained, controlled, protected and developed by indigenous [peoples], local communities, [and nations] and that is directly linked with the social identity and/or cultural heritage of indigenous [peoples] and local communities; that is transmitted from generation to generation, whether consecutively or not; which subsists in codified, oral, or other forms; and which may be dynamic and evolving, and may take the form of know-how, skills, innovations, practices, teachings or learnings.]

[Secret traditional knowledge is traditional knowledge that is held by beneficiaries under certain measures of secrecy, in accordance with customary law, and under the common understanding that the traditional knowledge is to be used and known only within the specific group.]

[Sacred traditional knowledge is traditional knowledge that in spite of being secret, narrowly diffused, or widely diffused, constitutes part of the spiritual identity of the beneficiaries.]

[Narrowly diffused traditional knowledge is traditional knowledge that is shared by beneficiaries amongst whom measures to keep it secret are not taken, but is not easily accessible to non-group members.]

[Widely diffused traditional knowledge is traditional knowledge which is easily accessible by the public but is still culturally connected to its beneficiaries' social identity.]

[Unlawful appropriation is the use of protected traditional knowledge that has been acquired by a user from a traditional knowledge holder through improper means or a breach of confidence which results in a violation of national law in the traditional knowledge holder's country. Use of protected traditional knowledge that has been acquired by lawful means such as independent discovery or creation, reading publications, reverse engineering, and inadvertent or deliberate disclosure resulting from the traditional knowledge holders failure to take reasonable protective measures, is not unlawful appropriation.]

[Unauthorized use is use of protected traditional knowledge without the permission of the right holder.]

[[“Use”]/[“utilization”] means

- (a) where the traditional knowledge is included in a product [or] where a product has been developed or obtained on the basis of traditional knowledge:
 - (i) the manufacturing, importing, offering for sale, selling, stocking or using the product beyond the traditional context; or
 - (ii) being in possession of the product for the purposes of offering it for sale, selling it or using it beyond the traditional context.
- (b) where the traditional knowledge is included in a process [or] where a process has been developed or obtained on the basis of traditional knowledge:
 - (i) making use of the process beyond the traditional context; or
 - (ii) carrying out the acts referred to under sub-clause (a) with respect to a product that is a direct result of the use of the process;
- (c) the use of traditional knowledge in non-commercial research and development; or
- (d) the use of traditional knowledge in commercial research and development.]

ARTICLE 1

SUBJECT MATTER OF THE INSTRUMENT

[Alt 1

This instrument applies to traditional knowledge.]

[Alt 2

The subject matter of this instrument is traditional knowledge, which is knowledge that is created and maintained in a collective context, that is directly linked with the social identity and[/or] cultural heritage of indigenous [peoples] and local communities [and nations]; that is transmitted between generations or from generation to generation, whether consecutively or not; which subsists in codified, oral, or other forms.]

[Alt 3

The subject matter of this instrument is traditional knowledge, which is knowledge that is created, maintained, and developed by indigenous [peoples], local communities, and [nations/states], whether it is widely spread or not, and that is linked with, or is an integral part of, the social identity and/or cultural heritage of indigenous [peoples], local communities; that is transmitted from generation to generation, whether consecutively or not; which subsists in codified, oral, or other forms; and may take the form of know-how, skills, innovations, practices, teachings or learnings.

[Traditional knowledge may be associated, in particular, with fields such as agriculture, the environment, healthcare and indigenous and traditional medical knowledge, biodiversity, traditional lifestyles and natural resources and genetic resources, and know-how of traditional architecture and construction technologies.]]

[Alt 4

This instrument applies to traditional knowledge.

Criteria for Eligibility

In order to be eligible for protection under this instrument, traditional knowledge must be distinctively associated with the cultural heritage of beneficiaries as defined in Article 2, and be created, generated, developed, maintained, and shared collectively, as well as transmitted from generation to generation for a term as has been determined by each Member State, but not less than for 50 years.]

ARTICLE 2

BENEFICIARIES OF PROTECTION

[Alt 1

2.1 Beneficiaries of this instrument are indigenous [peoples] and local communities who hold protected traditional knowledge.

[2.2 Member States may also designate competent bodies to act as custodians on behalf of beneficiaries, with the [consent]/[direct involvement, and approval] of the beneficiaries, in accordance with national law. The identity of any competent agency [should/shall] be communicated to the International Bureau of the World Intellectual Property Organization.]]

[Alt 2

2.1 The beneficiaries of this instrument include, where applicable, indigenous [peoples], local communities, states, [nations], and other beneficiaries as may be determined under national law.

2.2 States may establish competent national authorities, as appropriate, to determine beneficiaries of traditional knowledge in consultation with indigenous [peoples], local communities, and stakeholders that create, maintain, develop, and exercise rights of traditional knowledge in accordance with customary law and practices.]

[Alt 3

2.1 The beneficiaries of this instrument include, where applicable, indigenous [peoples], local communities, and other beneficiaries as may be determined under national law.

2.2 Member States may also designate, as deemed appropriate, competent bodies to act as custodians on behalf of the beneficiaries in accordance with national law.]

ARTICLE 3

SCOPE OF [AND CONDITIONS OF] PROTECTION

[Alt 1

Member States [should/shall] safeguard the economic and moral interests of the beneficiaries concerning [protected] traditional knowledge as defined in this instrument, as appropriate and in accordance with national law, in a reasonable and balanced manner.]

[Alt 2

3.1 Where the traditional knowledge is secret, whether or not it is sacred, Member States [should/shall] ensure that:

- (a) Beneficiaries have the exclusive and collective right to maintain, control, use, develop, authorize or prevent access to and use/utilization of their traditional knowledge; and receive a fair and equitable share of benefits arising from its use.
- (b) Users attribute said traditional knowledge to the beneficiaries, and use the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the traditional knowledge.

3.2 Where the traditional knowledge is narrowly diffused, whether or not it is sacred, Member States [should/shall] ensure that:

- (a) Beneficiaries receive a fair and equitable share of benefits arising from its use; and
- (b) Users attribute said traditional knowledge to the beneficiaries, and use the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the traditional knowledge.

3.3 Member States should use best endeavors [,in consultation with indigenous and local communities,] to protect the integrity of traditional knowledge that is widely diffused.]

[Alt 3

3.1 Where the traditional knowledge is secret, whether or not it is sacred, Member States [should/shall] ensure that:

- (a) Beneficiaries have the exclusive and collective right to maintain, control, use, develop, authorize or prevent access to and use/utilization of their traditional knowledge; and receive a fair and equitable share of benefits arising from its use.
- (b) Users attribute said traditional knowledge to the beneficiaries, and use the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the traditional knowledge.

3.2 Where the traditional knowledge is narrowly diffused, whether or not it is sacred, Member States [should/shall] ensure that:

- (a) Beneficiaries receive a fair and equitable share of benefits arising from its use; and
- (b) Users attribute said traditional knowledge to the beneficiaries, and use the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the traditional knowledge.

3.3 Where the traditional knowledge is not protected under Paragraphs 3.1 or 3.2, Member States [should/shall] ensure that users of said traditional knowledge:

- (a) Attribute said traditional knowledge to the beneficiaries;
- (b) Use the knowledge in a manner that respects the cultural norms and practices of the beneficiary as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the traditional knowledge; and
- (c) Where applicable, deposit any user fee into the fund constituted by such Member state, except in cases where the use is for research or development leading to new and useful products or processes, and in such cases, provide the beneficiaries with a fair and equitable share of benefits realized from the use of said traditional knowledge, based on prior and informed consent and on mutually agreed terms.]

[Alt 4

3.1 Where the protected traditional knowledge is secret, whether or not it is sacred, Member States [should/shall] ensure that:

- (a) Beneficiaries have the exclusive and collective right to maintain, control, use, develop, authorize or prevent access to and use/utilization of their protected traditional knowledge; and receive a fair and equitable share of benefits arising from its use.
- (b) Users attribute said protected traditional knowledge to the beneficiaries, and use the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the traditional knowledge.

3.2 Where the protected traditional knowledge is narrowly diffused, whether or not it is sacred, Member States [should/shall] ensure that:

- (a) Beneficiaries receive a fair and equitable share of benefits arising from its use; and
- (b) Users attribute said protected traditional knowledge to the beneficiaries, and use the knowledge in a manner that respects the cultural norms and practices of the beneficiaries as well as the inalienable, indivisible and imprescriptible nature of the moral rights associated with the traditional knowledge.

3.3 Member States should use best endeavors [,in consultation with indigenous and local communities,] to protect the integrity of protected traditional knowledge that is widely diffused [and sacred].]

[ARTICLE 3 BIS

COMPLEMENTARY MEASURES

- 3BIS.1 [Member States]/[Contracting Parties] should [endeavour to], subject to and consistent with national and customary law:
- (a) facilitate/encourage the development of [publicly accessible] national traditional knowledge databases for the defensive protection of traditional knowledge, [including through the prevention of the erroneous grant of patents], and/or for transparency, certainty, conservation purposes and/or transboundary cooperation;
 - (b) [facilitate/encourage, as appropriate, the creation, exchange and dissemination of, and access to, [publicly accessible] databases of genetic resources and traditional knowledge associated with genetic resources;]
 - (c) [provide opposition measures that will allow third parties to dispute the validity of a patent [by submitting prior art];]
 - (d) encourage the development and use of voluntary codes of conduct;
 - (e) [discourage information lawfully within the beneficiaries' control from being disclosed, acquired by or used by others without the beneficiaries' [consent], in a manner contrary to fair commercial practices, so long as it is [secret], that reasonable steps have been taken to prevent unauthorized disclosure, and has value;]
 - (f) [consider the establishment of [publicly accessible] databases of traditional knowledge that are accessible to patent offices to avoid the erroneous grant of patents compile and maintain such databases in accordance with national law;
 - (ii) there should be minimum standards to harmonize the structure and content of such databases;
 - (iii) the content of the databases should be:
 - a. languages that can be understood by patent examiners;
 - b. written and oral information regarding traditional knowledge;
 - c. relevant written and oral prior art related to traditional knowledge.]
 - (g) [develop appropriate and adequate guidelines for the purpose of conducting search and examination of patent applications relating to traditional knowledge by patent offices;]
- 3BIS.2 [In order to document how and where traditional knowledge is practiced, and to preserve and maintain such knowledge, efforts [should]/[shall] be made by national authorities to codify the oral information related to traditional knowledge and to develop [publicly accessible] databases of traditional knowledge.]]
- 3BIS.3 [Member States]/[Contracting Parties] [should]/[shall] consider cooperating in the creation of such databases, especially where traditional knowledge is not uniquely held within the boundaries of a [Member States]/[Contracting Parties]. If protected traditional knowledge pursuant to article 1.2 is included in a database, the protected traditional knowledge should only be made available to others with the prior informed consent or approval and involvement of the traditional knowledge holder.

- 3BIS.4 Efforts [should]/[shall] also be made to facilitate access to such databases by intellectual property offices, so that the appropriate decision can be made. To facilitate such access, [Member States]/[Contracting Parties] [should]/[shall] consider efficiencies that can be gained from international cooperation. The information made available to intellectual property offices [should]/[shall] only include information that can be used to refuse a grant of cooperation, and thus [should]/[shall] not include protected traditional knowledge.
- 3BIS.5 Efforts [should]/[shall] be made by national authorities to codify the information related to traditional knowledge for the purpose of enhancing the development of [publicly accessible] databases of traditional knowledge, so as to preserve and maintain such knowledge.
- 3BIS.6 Efforts [should]/[shall] also be made to facilitate access to information including information made available in [publicly accessible] databases relating to traditional knowledge by intellectual property offices.
- 3BIS.7 Intellectual property offices [should]/[shall] ensure that such information is maintained in confidence, except where the information is cited as prior art during the examination of a patent application.]

ARTICLE 4

SANCTIONS, REMEDIES AND EXERCISE OF RIGHTS/APPLICATION

4.1 [Member States [should]/[shall] ensure that [accessible, appropriate and adequate] [criminal, civil [and] or administrative] enforcement procedures[, dispute resolution mechanisms][, border measures][, sanctions] [and remedies] are available under their laws against the [willful or negligent [harm to the economic and/or moral interest]] [infringement of the protection provided to traditional knowledge under this instrument] [[misappropriation/ misuse/unauthorized use/unfair and inequitable uses] or misuse of traditional knowledge] sufficient to constitute a deterrent to further infringements.]

4.2 The procedures referred to in Paragraph 1 should be accessible, effective, fair, equitable, adequate [appropriate] and not burdensome for [holders]/[owners] of protected traditional knowledge. [These procedures should also provide safeguards for legitimate third party interests and the public interest.]

4.3 [The beneficiaries [should]/[shall] have the right to initiate legal proceedings where their rights under Paragraphs 1 and 2 are violated or not complied with.]

4.4 [Where appropriate, sanctions and remedies should reflect the sanctions and remedies that indigenous people and local communities would use.]

4.5 [Where a dispute arises between beneficiaries or between beneficiaries and users of traditional knowledge, each party [may]/[shall be entitled to] refer the issue to an [independent] alternative dispute resolution mechanism recognized by international, regional or [, if both parties are from the same country, by] national law [, and that is most suited to the holders of traditional knowledge].]

4.6 [Where, under applicable domestic law, the [intentional] wide diffusion of [protected subject matter]/[traditional knowledge] beyond a recognizable community of practice has been determined to be the result of an act of [misappropriation/misuse/unauthorized use/unfair and inequitable uses] or other violation of national law, the beneficiaries shall be entitled to fair and equitable compensation/royalties.]

[ARTICLE 4 BIS

DISCLOSURE REQUIREMENT

4 BIS.1 [[Patent and plant variety] Intellectual property applications that concern [an invention] any process or product that relates to or uses traditional knowledge shall include information on the country from which the [inventor or the breeder] applicant collected or received the knowledge (the providing country), and the country of origin if the providing country is not the same as the country of origin of the traditional knowledge. The application shall also state whether prior informed consent or approval and involvement to access and use has been obtained.]

4 BIS.2 [If the information set out in Paragraph 1 is not known to the applicant, the applicant shall state the immediate source from which the [inventor or the breeder] applicant collected or received the traditional knowledge.]

4 BIS.3 [If the applicant does not comply with the provisions in Paragraphs 1 and 2, the application shall not be processed until the requirements are met. The [patent or plant variety] intellectual property office may set a time limit for the applicant to comply with the provisions in paragraphs 1 and 2. If the applicant does not submit such information within the set time limit, the [patent or plant variety] intellectual property office may reject the application.]

4 BIS.4 [Rights arising from a granted patent or a granted plant variety right shall not be affected by [any later discovery of] a failure by the applicant to comply with the provisions in Paragraphs 1 and 2. Other sanctions, outside of the patent system and the plant variety system, provided for in national law, including criminal sanctions such as fines, may however be imposed.]

Alternative

4 BIS.4 [Rights arising from a grant shall be revoked and rendered unenforceable when the applicant has failed to comply with the obligations of mandatory requirements as provided for in this article or provided false or fraudulent information.]

[End of alternative]

Alternative

[NO DISCLOSURE REQUIREMENT

Patent disclosure requirements shall not include a mandatory disclosure requirement relating to traditional knowledge unless such disclosure is material to the patentability criteria of novelty, inventive step or enablement.]

[End of alternative]

ARTICLE 5

ADMINISTRATION [OF RIGHTS]/[OF INTERESTS]

5.1 [Member States]/[Contracting Parties] [may]/[shall] [establish]/[appoint] a competent authority or authorities, [with the free, prior and informed consent of] [in consultation with] [traditional knowledge [holders]/[owners]], in accordance with their national law [and without prejudice to the right of traditional knowledge [holders]/[owners] to administer their rights/interests according to their customary protocols, understandings, laws and practices].

Optional addition

[Where so requested by the beneficiaries, a competent authority may, to the extent authorized by the beneficiaries and for their direct benefit, assist with the management of the beneficiaries' rights/interests under this [instrument].]

[End of optional addition]

Alternative

5.1 [Member States]/[Contracting Parties] may establish a competent authority, in accordance with national law, to administer the rights/interests provided for by this [instrument].

[End of alternative]

5.2 [The [identity] of any authority established under Paragraph 1 [should]/[shall] be communicated to the International Bureau of the World Intellectual Property Organization.]

[ARTICLE 6
EXCEPTIONS AND LIMITATIONS

General Exceptions

6.1 [Member States]/[Contracting Parties] may adopt appropriate limitations and exceptions under national law [with the prior informed consent or approval and involvement of the beneficiaries] [in consultation with the beneficiaries] [with the involvement of beneficiaries][, provided that the use of [protected] traditional knowledge:

- (a) [acknowledges the beneficiaries, where possible;]
- (b) [is not offensive or derogatory to the beneficiaries;]
- (c) [is compatible with fair practice;]
- (d) [does not conflict with the normal utilization of the traditional knowledge by the beneficiaries; and]
- (e) [does not unreasonably prejudice the legitimate interests of the beneficiaries taking account of the legitimate interests of third parties.]]

6.2 [When there is reasonable apprehension of irreparable harm related to [sacred] and [secret] traditional knowledge, [Member States]/[Contracting Parties] [may]/[shall]/[should] not establish exceptions and limitations.]

Specific Exceptions

6.3 [[In addition to the limitations and exceptions provided for under Paragraph 1,] [Member States]/[Contracting Parties] may adopt appropriate limitations or exceptions, in accordance with national law, for the following purposes:

- (a) teaching, learning, but not research resulting in profit-marking or commercial purposes;
- (b) for preservation, display, research and presentation in archives, libraries, museums or cultural institutions, for non-commercial cultural heritage or other purposes in the public interest; and
- (c) in the case of a national emergency or other circumstances of extreme urgency [or in cases of public non-commercial use];
- (d) [the creation of an original work of authorship inspired by traditional knowledge.]

This provision, with the exception of Subparagraph (c), [should]/[shall] not apply to traditional knowledge described in Article 3.1.]

6.3 Regardless of whether such acts are already permitted under Paragraph 1, the following shall be permitted:

- (a) the use of traditional knowledge in cultural institutions recognized under the appropriate national law, archives, libraries, museums for non-commercial cultural heritage or other purposes in the public interest, including for preservation, display, research and presentation should be permitted; and

(b) the creation of an original work of authorship inspired by traditional knowledge.]

6.4 [[There shall be no right to [exclude others] from using knowledge that:]/[The provisions of Article 3 shall not apply to any use of knowledge that:]

- (a) has been independently created [outside the beneficiaries' community];
- (b) [legally] derived from sources other than the beneficiary; or
- (c) is known [through lawful means] outside of the beneficiaries' community.]

6.5 [Protected traditional knowledge shall not be deemed to have been misappropriated or misused if the protected traditional knowledge was:

- (a) obtained from a printed publication;
- (b) obtained from one or more holders of the protected traditional knowledge with their prior informed consent or approval and involvement; or
- (c) mutually agreed terms for [access and benefit sharing]/[fair and equitable compensation] apply to the protected traditional knowledge that was obtained, and were agreed upon by the national contact point.]]

6.6 [[Member States]/[Contracting Parties] may exclude from protection diagnostic, therapeutic and surgical methods for the treatment of humans or animals.]]

6.7 [National authorities shall exclude from protection traditional knowledge that is already available without restriction to the general public.]

ARTICLE 7

TERM OF PROTECTION/RIGHTS

[Member States]/[Contracting Parties] may determine the appropriate term of protection/rights of traditional knowledge in accordance with [Article 3/[which may] [should]/[shall] last as long as the traditional knowledge fulfills/satisfies the [criteria of eligibility for protection] according to Article [1]/[3].]

ARTICLE 8
FORMALITIES

Option 1

8.1 [Member States]/[Contracting Parties] [should]/[shall] not subject the protection of traditional knowledge to any formality.

Option 2

8.1 [[Member States]/[Contracting Parties] [may] require formalities for the protection of traditional knowledge.]

Alternative

[The protection of traditional knowledge under Article 3.1 [should]/[shall] not be subject to any formality. However, in the interest of transparency, certainty and the conservation of traditional knowledge, the relevant national authority (or authorities) or intergovernmental regional authority (or authorities) may maintain registers or other records of traditional knowledge to facilitate protection under Articles 3.2 and 3.3.]

[End of alternative]

ARTICLE 9

TRANSITIONAL MEASURES

9.1 These provisions [should]/[shall] apply to all traditional knowledge which, at the moment of the provisions coming into force, fulfills the criteria set out in Article [1]/[3].

Optional addition

9.2 [[Member States]/[Contracting Parties] [should]/[shall] ensure [the necessary measures to secure] the rights [acknowledged by national law] already acquired by third parties are not affected, in accordance with its national law and its international legal obligations.]

Alternative

9.2 [[Member States]/[Contracting Parties] [should]/[shall] provide that continuing acts in respect of traditional knowledge that had commenced prior to the coming into force of this [instrument] and which would not be permitted or which would be otherwise regulated by this [instrument], [should be brought into conformity with these provisions within a reasonable period of time after its entry into force], subject to respect for rights previously acquired by third parties in good faith/should be allowed to continue].

Alternative

9.2 [Notwithstanding Paragraph 1, [Member States]/[Contracting Parties] [should]/[shall] provide that:

- (a) anyone who, before the date of entry into force of this instrument, has commenced utilization of traditional knowledge which was legally accessed, may continue such utilization of the traditional knowledge[, subject to a right of compensation];
- (b) such right of utilization shall also, on similar conditions, be enjoyed by anyone who has made substantial preparations to utilize the traditional knowledge.
- (c) the foregoing gives no right to utilize traditional knowledge in a way that contravenes the terms the beneficiary may have set out as a condition for access.]

[ARTICLE 10

RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

This instrument [should]/[shall] establish a mutually supportive relationship [between [intellectual property [patent] rights [directly based on] [involving] [the utilization of] traditional knowledge and with relevant [existing] international agreements and treaties.]

[ARTICLE 11
NATIONAL TREATMENT

[The rights and benefits arising from the protection of traditional knowledge under national/domestic measures or laws that give effect to these international provisions [should]/[shall] be available to all eligible beneficiaries who are nationals or residents of a [Member State]/[Contracting Party] [prescribed country] as defined by international obligations or undertakings. Eligible foreign beneficiaries [should]/[shall] enjoy the same rights and benefits as enjoyed by beneficiaries who are nationals of the country of protection, as well as the rights and benefits specifically granted by these international provisions.]

Alternative

[Nationals of a [Member State]/[Contracting Party] may only expect protection equivalent to that contemplated in this instrument in the territory of another [Member State]/[Contracting Party] even where that other [Member State]/[Contracting Party] provides for more extensive protection for their nationals.]

[End of alternative]

Alternative

[Each [Member State]/[Contracting Party] [should]/[shall] in respect of traditional knowledge that fulfills the criteria set out in Article 1, accord within its territory to beneficiaries of protection as defined in Article 2, whose members primarily are nationals of or are domiciled in the territory of, any of the other [Member States]/[Contracting Parties], the same treatment that it accords to its national beneficiaries.]

[End of alternative]

ARTICLE 12

TRANSBOUNDARY COOPERATION

12.1 In instances where the same [protected] traditional knowledge [under Article 3] is found within the territory of more than one [Member State]/[Contracting Party], those [Member States]/[Contracting Parties] [should]/[shall] endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this [instrument].

12.2 Where the same [protected] traditional knowledge [under Article 3] is shared by one or more indigenous and local communities in several [Member States]/[Contracting Parties], those [Member States]/ [Contracting Parties] [should]/[shall] endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objectives of this [instrument].

[End of Annex II and of document]