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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-Ninth (23rd Ordinary) Session in October 2017, agreed on the mandate for the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) for the 2018/2019 biennium.
2. The IGC's mandate for the 2018/2019 biennium, which was set out in document WO/GA/49/21, provides as follows:

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

“(a) The Committee will, during the next budgetary biennium 2018/2019, continue to expedite its work, 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 2018/2019 biennium will build on the existing work carried out by the Committee, including text-based negotiations, with a primary focus on narrowing existing gaps and reaching a common understanding on core issues, including definitions, beneficiaries, subject matter, objectives, scope of protection, 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 work program based on sound working methods for the 2018/2019 biennium, including an evidence-based approach as set out in paragraph (d). This work program will make provision for 6 sessions of the Committee in 2018/2019, including thematic, cross-cutting and stocktaking sessions. The Committee may establish ad hoc expert group(s) to address a specific legal, policy or technical issue¹. The results of the work of such group(s) will be submitted to the Committee for consideration.

“(d) The Committee will use all WIPO working documents, including WIPO/GRTKF/IC/34/4, WIPO/GRTKF/IC/34/5 and WIPO/GRTKF/IC/34/8, as well as any other contributions of member states, such as conducting/updating studies covering, inter alia, examples of national experiences, including domestic legislation, impact assessments, databases, and examples of protectable subject matter and subject matter that is not intended to be protected; and outputs of any expert group(s) established by the Committee and related activities conducted under Program 4. The Secretariat is requested to update the 2008 gap analyses on the existing protection regimes related to TK and TCEs. The Secretariat is also requested to produce a report(s) compiling and updating studies, proposals and other materials relating to tools and activities on databases and on existing disclosure regimes relating to GR and associated TK, with a view to identify any gaps. However, studies or additional activities are not to delay progress or establish any preconditions for the negotiations.

“(e) In 2018, the Committee is requested to provide to the General Assembly a factual report along with the most recent texts available of its work up to that time with recommendations, and in 2019, submit to the General Assembly the results of its work in accordance with the objective reflected in paragraph (a). The General Assembly in 2019 will take stock of progress made, and based on the maturity of the texts, including levels of agreement on objectives, scope and nature of the instrument(s), decide on whether to convene a diplomatic conference and/or continue negotiations.

“(f) 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.

¹ The expert group(s) will have a balanced regional representation and use an efficient working methodology. The expert group(s) will work during the weeks of the sessions of the IGC.

Work Program – 6 Sessions

Indicative Dates	Activity
February/March 2018	(IGC 35) Undertake negotiations on GRs with a focus on addressing unresolved issues and considering options for a draft legal instrument Duration 5 days.
May/June 2018	(IGC 36) Undertake negotiations on GRs with a focus on addressing unresolved issues and considering options for a draft legal instrument Expert group(s) Duration 5/6 days.
September 2018	(IGC 37) Undertake negotiations on TK/TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Possible recommendations as mentioned in paragraph (e) Duration 5 days.
October 2018	WIPO General Assembly Factual report and consider recommendations.
November/December 2018	(IGC 38) Undertake negotiations on TK/TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Expert group(s) Duration 5/6 days.
March/April 2019	(IGC 39) Undertake negotiations on TK/TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Duration 5 days.
June/July 2019	(IGC 40) Undertake negotiations on TK/TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Expert group(s) Stocktaking on GRs/TK/TCEs and making a recommendation Duration 5/6 days.
October 2019	WIPO General Assembly will take stock of the progress made, consider the text(s) and make the necessary decision(s)."

3. In accordance with the mandate as reproduced above, the IGC provided a factual report with recommendations to the WIPO General Assembly in 2018, in document WO/GA/50/8. This report covered the period January 2018 to September 2018. The 2018 General Assembly considered the factual report, agreed on the recommendations, and called upon the IGC to expedite its work.

4. Paragraph (e) of the mandate for this biennium (quoted above) requests the IGC, in 2019, to "submit to the General Assembly the results of its work in accordance with the objective reflected in paragraph (a). The General Assembly in 2019 will take stock of progress made, and based on the maturity of the texts, including levels of agreement on objectives, scope and

nature of the instrument(s), decide on whether to convene a diplomatic conference and/or continue negotiations.” This document is prepared pursuant to this decision.

II. IGC SESSIONS SINCE THE 2018 GENERAL ASSEMBLY

5. Pursuant to the mandate for the 2018/2019 biennium and the work program for 2018 and 2019, the IGC held three sessions since the WIPO General Assembly in 2018, as follows:
 - (a) IGC 38, from December 10 to 14, 2018, on the subjects of TK and TCEs;
 - (b) IGC 39, from March 18 to 22, 2019, on the subjects of TK and TCEs; and
 - (c) IGC 40, from June 17 to 21, 2019, on the subjects of TK and TCEs, and taking stock of the progress made and making a recommendation to the 2019 WIPO General Assembly.
6. IGCs 38 and 39 addressed certain cross-cutting issues on TK and TCEs, and developed “The Protection of Traditional Knowledge: Draft Articles Rev. 2” and “The Protection of Traditional Cultural Expressions: Draft Articles Rev. 2”.
7. IGC 40 continued to work on these texts, and decided that “The Protection of Traditional Knowledge: Draft Articles – Facilitators’ Rev.” (annex to document WIPO/GRTKF/IC/40/18, enclosed in the present document as “Annex I”), and “The Protection of Traditional Cultural Expressions: Draft Articles – Facilitators’ Rev.” (annex to document WIPO/GRTKF/IC/40/19, enclosed in the present document as “Annex II”), as at the close of June 19, 2019, be transmitted to Agenda Item 7 (“Taking Stock of Progress and Making a Recommendation to the General Assembly”) of IGC 40.
8. In accordance with the Committee’s mandate for the 2018/2019 biennium and the work program for 2019, as contained in document WO/GA/49/21, IGC 40, under Agenda Item 7, took stock of the progress made during the 2018/2019 biennium, and confirmed that the texts contained in the annexes to documents WIPO/GRTKF/IC/40/6 (enclosed in the present document as “Annex III”), WIPO/GRTKF/IC/40/18 and WIPO/GRTKF/IC/40/19 be transmitted to the 2019 WIPO General Assembly. The Committee decided to also transmit the Chair’s Text of a *Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources* (enclosed in the present document as “Annex IV”) to the 2019 WIPO General Assembly, and to include it as a working document of the Committee as a Chair’s Text.
9. IGC 40 also agreed to recommend to the 2019 WIPO General Assembly that the mandate of the Committee be renewed for the 2020-2021 biennium. The Committee further agreed to recommend to the 2019 General Assembly that the terms of the mandate and work program for 2020-2021 be as follows:

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

 - “(a) The Committee will, during the next budgetary biennium 2020/2021, continue to expedite its work, with the objective of finalizing 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 2020/2021 biennium will build on the existing work carried out by the Committee, including text-based negotiations, with a primary focus on narrowing existing gaps and reaching a common understanding on core issues².

“(c) The Committee will follow, as set out in the table below, a work program based on open and inclusive working methods for the 2020/2021 biennium, including an evidence-based approach as set out in paragraph (d). This work program will make provision for 6 sessions of the Committee in 2020/2021, including thematic, cross-cutting and stocktaking sessions. The Committee may establish ad hoc expert group(s) to address a specific legal, policy or technical issue³. The results of the work of such group(s) will be submitted to the Committee for consideration.

“(d) The Committee will use all WIPO working documents, including WIPO/GRTKF/IC/40/6, WIPO/GRTKF/IC/40/18 and WIPO/GRTKF/IC/40/19, and the Chair’s Text on the Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, as well as any other contributions of Member States, such as conducting/updating studies covering, inter alia, examples of national experiences, including domestic legislation, impact assessments, databases, and examples of protectable subject matter and subject matter that is not intended to be protected; and outputs of any expert group(s) established by the Committee and related activities conducted under Program 4. The Secretariat is requested to continue to update studies and other materials relating to tools and activities on databases and on existing disclosure regimes relating to GRs and associated TK, with a view to identify any gaps, and continue to collect, compile and make available online information on national and regional sui generis regimes for the intellectual property protection of TK and TCEs. Studies or additional activities are not to delay progress or establish any preconditions for the negotiations.

“(e) In 2020, the Committee is requested to provide to the General Assembly a factual report along with the most recent texts available of its work up to that time with recommendations, and in 2021, submit to the General Assembly the results of its work in accordance with the objective reflected in paragraph (a). The General Assembly in 2021 will take stock of progress made, and based on the maturity of the texts, including levels of agreement on objectives, scope and nature of the instrument(s), decide on whether to convene a diplomatic conference and/or continue negotiations.

“(f) The General Assembly requests the Secretariat 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.

² Core issues include, as applicable, inter alia, definitions, beneficiaries, subject matter, objectives, scope of protection, and what TK/TCEs are entitled to protection at an international level, including consideration of exceptions and limitations and the relationship with the public domain.

³ The expert group(s) will have a balanced regional representation and use an efficient working methodology. The expert group(s) will work during the weeks of the sessions of the IGC.

Work Program – 6 Sessions

Indicative Dates	Activity
February/March 2020	(IGC 41) Undertake negotiations on GRs with a focus on addressing unresolved issues and considering options for a draft legal instrument Duration 5 days.
May/June 2020	(IGC 42) Undertake negotiations on GRs with a focus on addressing unresolved issues and considering options for a draft legal instrument Duration 5 days, plus, if so decided, a one day meeting of an <i>ad hoc</i> expert group.
September 2020	(IGC 43) Undertake negotiations on TK and/or TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Possible recommendations as mentioned in paragraph (e) Duration 5 days.
October 2020	WIPO General Assembly Factual report and consider recommendations
November/December 2020	(IGC 44) Undertake negotiations on TK and/or TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Duration 5 days, plus, if so decided, a one day meeting of an <i>ad hoc</i> expert group.
March/April 2021	(IGC 45) Undertake negotiations on TK and/or TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Duration 5 days, plus, if so decided, a one day meeting of an <i>ad hoc</i> expert group.
June/July 2021	(IGC 46) Undertake negotiations on TK and/or TCEs with a focus on addressing unresolved and cross-cutting issues and considering options for a draft legal instrument(s) Stocktaking on GRs/TK/TCEs and making a recommendation Duration 5 days.
October 2021	WIPO General Assembly will take stock of the progress made, consider the text(s) and make the necessary decision(s)."

10. Recalling the decisions of the 2018 WIPO General Assembly, IGC 40 recommended that the 2019 WIPO General Assembly recognize the importance of the participation of indigenous peoples and local communities in the work of the Committee, note that the WIPO Voluntary

Fund for Accredited Indigenous and Local Communities is depleted, encourage Member States to consider contributing to the Fund, and invite Member States to consider other alternate funding arrangements.

III. *AD HOC* EXPERT GROUPS ON TRADITIONAL KNOWLEDGE AND TRADITIONAL CULTURAL EXPRESSIONS

11. Paragraph (c) of the mandate provides that the IGC “may establish *ad hoc* expert group(s) to address a specific legal, policy or technical issue”.

12. Pursuant to this decision and the decisions of IGC 37, an *ad hoc* expert group on TK and TCEs met on December 9, 2018, prior to IGC 38. The documents prepared are available [online](#)⁴.

13. IGC 38 decided to establish an *ad hoc* expert group on TK and TCEs prior to IGC 39 instead of prior to IGC 40. Such an *ad hoc* expert group met on March 17, 2019. The documents prepared are available [online](#)⁵.

IV. CONTRIBUTION TO THE IMPLEMENTATION OF THE DEVELOPMENT AGENDA RECOMMENDATIONS

14. 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 40 also discussed the contribution of the IGC to the implementation of the Development Agenda (DA) Recommendations.

15. In this regard, the following statements were made at IGC 40. These will also appear in the initial draft report of IGC 40 (WIPO/GRTKF/IC/40/20 Prov.), which will be made available, as requested by the IGC, by September 9, 2019:

“The Delegation of the Islamic Republic of Iran said that DA Recommendation 18 was dedicated to the IGC’s work. It proved that the work and the negotiations in the IGC to protect TK, TCEs and GRs could contribute very positively to the development of IP. It encouraged all Member States to engage more positively in the discussion and expedite the work to finalize and conclude the main issues on the IGC agenda. Furthermore, the technical assistance to Member States and capacity-building projects by the TK Division was another aspect that had a very positive impact on the DA recommendations. It encouraged and invited the TK Division to continue their support in delivering technical assistance to Member States.

“The Delegation of Brazil said the DA was a major landmark in the history of WIPO. It recalled Recommendation 18, which explicitly concerned the IGC. Regarding the renewal of the IGC mandate, Recommendation 18 assisted the IGC in its reflection on how to accelerate the process and deliver concrete outcomes. Concerning Cluster A, the Secretariat had a very important role to play in providing assistance to Member States, including legislative assistance and capacity-building, enabling indigenous peoples and local communities (IPLCs) to enjoy the fruits of the IP system. It urged all to show a constructive spirit in contributing to the discussions in light of Recommendation 18.

“The Delegation of Uganda, speaking on behalf of the African Group, underscored the principle underpinning the DA recommendations, i.e. to change the character of WIPO

⁴ http://www.wipo.int/meetings/en/details.jsp?meeting_id=48546

⁵ http://www.wipo.int/meetings/en/details.jsp?meeting_id=48546

from its primary focus on protection of IP to introduce development dimensions of the programs and activities in line with the wider aspirations of the UN system. That principle reflected the strong ambition of WIPO to ensure that developing countries effectively used IP as a tool for encouraging and promoting creativity and innovation for sustainable development. As a mechanism for measuring progress made in the implementation of the DA recommendations, the WIPO GA in 2010 had directed all of the WIPO bodies, including the IGC, to include in their annual report to the GA, a description of their contribution to the implementation of the DA recommendations. The African Group commended the Secretariat for inviting Member States to provide their own assessment of the IGC's contribution. There were tangible traces of progress made thus far by the IGC in the implementation of the DA recommendations through the mainstreaming of development in its program and activities. The IGC negotiations were the subject of DA Recommendation 18. The IGC's mandate in the 2018-2019 biennium reflected the strong ambition of the IGC to continue to expedite its work with the objective of reaching an agreement on an international legal instrument(s) relating to IP, which would ensure the balanced and effective protection of GRs, TK and TCEs. However, after almost two decades of negotiations and 12 years since the DA recommendation had come into play, the IGC was yet to finalize its work. One wondered if the phrase 'expedite its work', which was always put in the mandate, had real meaning, if year after year there was no conclusion of the IGC's work. The IGC continued to be guided in its work by DA Recommendations 15, 40, and 42 respectively. With regard to the preservation of the public domain within WIPO normative processes and its implications (DA Recommendation 16), there was a significant conceptual misunderstanding of the public domain and its relationship and limits when linked with TK/TCEs. The concept of the public domain was inherent to the IP system and often reflected in the careful balancing of the interests of rights holders and users. In the IGC, there was the contention by a few Member States that large facets of TK/TCEs were in the public domain. That was a conceptual misunderstanding of the public domain. Furthermore, the DA enjoined WIPO and its bodies to take into account flexibilities in international IP agreements in line with Recommendations 12, 14 and 17, as well as the UN Sustainable Development Goals, in line with Recommendation 22. One of the relevant goals of the IGC related to the conservation of biological diversity and the work of the IGC on the international protection of GRs and TK contributed to that goal.

"The Delegation of India said that the DA ensured that development considerations formed an integral part of WIPO's work. India, along with hundreds of other countries, was affected by misappropriation and biopiracy. Accordingly, an early finalization of an international legal instrument(s) on all three issues was highly solicited. The absence of any such legally-binding instrument would continuously allow the misappropriation and biopiracy of GRs and TK, thereby resulting in an imbalance of the global IP system. It looked forward to an early finalization of a balanced legal framework(s) on GRs, TK and TCEs through the IGC.

"The Delegation of Nigeria aligned itself with the statement made by the Delegation of Uganda, on behalf of the African Group. It took notice of the statement made by the Delegation of Brazil, with reference to DA Recommendation 18. The IGC had to accelerate its process. It was holding down the advancement of the DA at the IGC. That was contrary to what it was expected to be doing. Negotiating ad infinitum was undermining the DA and therefore running contrary to the mandate. It called attention to the bias of impact studies and assessments in the context of the litany of one-sided industry biased and sponsored studies that had bombarded the IGC for quite a while. If Member States wanted to be very serious and sensitive to the dictates of the DA, they should be inclined toward impact studies that created balance as to the impact of lack of protection of TK, TCEs and GRs that hurt IPLCs. In order to be faithful to the DA, Member States needed to be serious with the kind of studies the IGC accepted in its

deliberations and whether those studies actually created the balance required to advance the DA.

“The Delegation of Egypt agreed with all the statements that had been made with regard to the DA, particularly Recommendation 18. It wondered why, after 20 years of work and negotiation, the IGC had not fulfilled its mandate under Recommendation 18. In the upcoming two years, the IGC should significantly accelerate its work and put aside all attempts to waste time on secondary issues that were not directly linked to the essential ones. It hoped to really commit to the DA on the ability for countries to control GRs, TK and TCEs to allow for sustainable development in those countries. That ownership had to be managed by those countries in order to accelerate the IGC’s work and arrive at a binding instrument(s).”

16. The WIPO General Assembly is invited to:

(i) take note of the information contained in this document;

(ii) renew the mandate of the IGC for the biennium 2020/2021 on the terms and according to the program set out in paragraph 9 above; and

(iii) recognize the importance of the participation of indigenous peoples and local communities in the work of the Committee, note that the WIPO Voluntary Fund for Accredited Indigenous and Local Communities is depleted, encourage Member States to consider contributing to the Fund, and invite Member States to consider other alternate funding arrangements.

[Annexes, referred in paragraphs 7 and 8, follow]

The Protection of Traditional Knowledge: Draft Articles

Facilitators' Rev. (June 19, 2019)

PREAMBLE/INTRODUCTION

1. ACKNOWLEDGING the **UN Declaration on the Rights of Indigenous Peoples**, and the aspirations of indigenous [peoples] and local communities [therein];
2. [[Recognizing that indigenous [peoples] and local communities have the right] Recognizing the rights of indigenous [peoples] and the interests of local communities] to maintain, control, protect and develop their intellectual property over their cultural heritage, including their traditional knowledge;]
3. Recognizing that the situation of the indigenous [peoples] and local communities varies from region to region and from country to country and that the significance of national and regional particularities and various historical and cultural backgrounds should be taken into consideration;
4. Recognizing that the traditional knowledge of indigenous [peoples] and local communities have [intrinsic] value, including social, cultural, spiritual, economic, scientific, intellectual, commercial and educational values;
5. Acknowledging that traditional knowledge systems are frameworks of ongoing innovation and distinctive intellectual and creative life that are [intrinsically] important for indigenous [peoples] and local communities;
6. Respecting the continuing customary use, development, exchange and transmission of traditional knowledge by, within and between communities;
7. Promoting respect for traditional knowledge systems, for the dignity, cultural integrity and spiritual values of the traditional knowledge holders who conserve and maintain those systems.
8. Acknowledging that the protection of traditional knowledge should contribute toward the promotion of creativity and innovation, and to the transfer and dissemination of knowledge to the mutual advantage of holders and users in a manner conducive to social and economic welfare and to a balance of rights and obligations.
9. [Promoting intellectual and artistic freedom, research or other fair practices and cultural exchange [based on mutually agreed terms including fair and equitable sharing of benefits and subject to the free, prior and informed consent and approval and involvement of indigenous [peoples],[local communities and nations/beneficiaries];]
10. [Ensuring mutual supportiveness with international agreements relating to the protection and safeguarding of traditional knowledge, and those relating to IP;]
11. Recognizing and reaffirming the role the IP system plays in promoting innovation and creativity, transfer and dissemination of knowledge and economic development, to the mutual advantage of stakeholders, providers and users of traditional knowledge;
12. Recognizing 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 and preserve the public domain];
13. [Recognizing 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;]

14. [Nothing in this instrument may be construed as diminishing or extinguishing the rights that indigenous [peoples] or local communities have now or may acquire in the future.]

[ARTICLE 1
USE OF TERMS

For the purposes of this instrument:

[Misappropriation] means

[Alt 1

Any access or use of the [subject matter]/[traditional knowledge] without free, prior and 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 to 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 as 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 substantive traditional knowledge that satisfies the criteria for eligibility under [Article] 3 and the scope and conditions for protection under [Article] 5.]

Alt

[Protected traditional knowledge] is substantive traditional knowledge that is distinctively associated with the cultural heritage of [beneficiaries as defined in Article 4] indigenous [peoples] and local communities, and is 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 for not less than 50 years or a period of five generations, and satisfies the scope and conditions for protection under Article 5.]

[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.]

Traditional Knowledge refers to knowledge originating from indigenous [peoples], local communities and/or [other beneficiaries] that may be dynamic and evolving and is the result of intellectual activity, experiences, spiritual means, or insights in or from a traditional context, which may be connected to land and environment, including know-how, skills, innovations, practices, teaching, or learning.

[Alt 1

Secret traditional knowledge is traditional knowledge that is held and regarded as secret by applicable indigenous [peoples] and local communities [beneficiaries] in accordance with their customary laws, protocols, practices under the understanding that the use or application of the traditional knowledge is constrained within a framework of secrecy.]

[Alt 2

Secret traditional knowledge is traditional knowledge that is not generally known or readily accessible to the public; has commercial value because it is secret; and has been subject to measures to maintain secrecy of the knowledge.]

[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 [non-secret] 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 [non-secret] 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 [protected] traditional knowledge holder through improper means or a breach of confidence which results in a violation of national law in the [protected] 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 [protected] 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 [protected] traditional knowledge is included in a product [or] where a product has been developed or obtained on the basis of [protected] 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 [protected] traditional knowledge is included in a process [or] where a process has been developed or obtained on the basis of [protected] 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 [protected] traditional knowledge in non-commercial research and development; or
- (d) the use of [protected] traditional knowledge in commercial research and development.]]

[ARTICLE 2
OBJECTIVES

[Alt 1

The objective of this instrument is to provide effective, balanced and adequate protection relating to intellectual property against:

- (a) unauthorized⁶ and/or uncompensated⁷ uses of traditional knowledge; and
- (b) the erroneous grant of intellectual property rights over traditional knowledge,

[while supporting the appropriate use of traditional knowledge].]

[Alt 2

The objective of this instrument is to support the appropriate use and effective, balanced and adequate protection of traditional knowledge within the intellectual property system, in accordance with national law, recognizing the rights of [indigenous [peoples] and local communities] [beneficiaries].]

[Alt 3

The objective of this instrument is to support the appropriate use of traditional knowledge within the patent system, in accordance with national law, respecting the values of traditional knowledge holders, by:

- (a) contributing 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;
- (b) recognizing 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; and
- (c) preventing the erroneous grant of patent rights over non-secret traditional knowledge.]]

⁶ Unauthorized uses comprise inter alia misappropriation, misuse and unlawful uses of traditional knowledge.

⁷ Uncompensated uses include the failure to provide monetary or non-monetary benefits.

[ARTICLE 3

[PROTECTION CRITERIA/ELIGIBILITY CRITERIA]

[Alt 1

3.1. Subject to Article 3.2, protection shall be extended under this instrument to traditional knowledge, which is:

- (a) created, generated, received, or revealed, by indigenous [peoples], local communities and/or [other beneficiaries] and developed, held, used, and maintained collectively by them [in accordance with their customary laws and protocols];
- (b) linked with, and is an integral part of, the cultural and social identity and traditional heritage of indigenous peoples, local communities and/or [other beneficiaries]; and
- (c) transmitted between or from generation to generation, whether consecutively or not.

3.2 A Member State/Contracting Party may under its national law, condition protection on the prior existence of the traditional knowledge for a reasonable term as determined by the Member State/Contracting Party.]

[Alt 2

Protection should be extended under this instrument to traditional knowledge which is:

- (a) created, generated, received, or revealed, by indigenous [peoples], local communities and/or [other beneficiaries] and developed, held, used, and maintained collectively by them [in accordance with their customary laws and protocols];
- (b) linked with, is an integral part of, and is distinctively associated with, the cultural identity and traditional heritage of indigenous peoples, local communities and/or [other beneficiaries]; and
- (c) transmitted between or from generation to generation, whether consecutively or not for a term not less than fifty years or five generations.]]

[Alternative ARTICLE 3

[SUBJECT MATTER OF THE INSTRUMENT]

This instrument applies to patents and traditional knowledge, that is:

- (a) distinctively associated with the cultural heritage of beneficiaries as defined in Article 4; and
- (b) 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 50 years or a period of five generations.]

[ARTICLE 4
BENEFICIARIES

[Alt 1

The beneficiaries of this instrument are indigenous peoples, local communities, and other beneficiaries,⁸ as may be determined under national law.]

[Alt 2

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

[Alt 3

The beneficiaries of this instrument are indigenous [peoples], local communities, and other beneficiaries, [such as states [and/or nations]], as may be determined under national law.]]

⁸ The term other beneficiaries may include states or nations.

[ARTICLE 5

SCOPE [AND CONDITIONS] OF PROTECTION

[Alt 1

5.1 Member States [should/shall] [safeguard] [protect] the economic and moral [interests] [rights] of the beneficiaries concerning [protected] traditional knowledge as defined in this instrument, as appropriate and in accordance with national law, [taking into consideration exceptions and limitations, as defined in Article 9, and in a manner consistent with Article 14] [in a reasonable and balanced manner].

5.2 Protection under this instrument does not extend to traditional knowledge that is widely known or used outside the community of the beneficiaries as defined in this [instrument], [for a reasonable period of time], in the public domain, or protected by an intellectual property right.]

[Alt 2

5.1 Member States [should/shall] take legislative, administrative and/or policy measures, as appropriate, in accordance with national law, in a reasonable and balanced manner, and in a manner consistent with Article 14, with the aim of ensuring that:

(a) Where with reference to the customary laws and practices of indigenous [peoples] and local communities/beneficiaries, access to traditional knowledge is restricted, including where the traditional knowledge is secret or sacred:

i. 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.

ii. Beneficiaries have the moral right of attribution and the moral right to the use of their traditional knowledge in a manner that respects the integrity of such traditional knowledge.

(b) Where with reference to the customary laws and practices of indigenous [peoples] and local communities/beneficiaries, the traditional knowledge is no longer under the exclusive control of beneficiaries, but is still distinctively associated with the beneficiaries' cultural identity:

i. Beneficiaries receive a fair and equitable share of benefits arising from its use; and

ii. Beneficiaries have the moral right of attribution and the right to the use of their traditional knowledge in a manner that respects the integrity of such traditional knowledge.

5.2 [For traditional knowledge that is being utilized without the prior informed consent and/or not in accord with customary laws and practices of indigenous [peoples] and local communities, indigenous [peoples] and local communities or other beneficiaries, as applicable, shall have the possibility to request from the relevant national authorities protection provided for in paragraph 5.1(a), taking into account all relevant circumstances, such as: historical facts, indigenous and customary laws, national and international laws, and evidence of cultural harms that could result from such unauthorized utilization.]]

[Alt 3

Where traditional knowledge is distinctively associated with the cultural heritage of beneficiaries as defined in Article 4, and 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 or a period of five generations, traditional knowledge should be protected according to the scope and conditions defined below:

5.1 Where the protected traditional knowledge is secret, whether or not it is sacred, Member States should encourage that:

(a) Beneficiaries that directly communicate traditional knowledge to users, have the possibility under national law 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 by said users.

(b) Users identify clearly discernible holders of said protected traditional knowledge and use the knowledge in a manner that respects the cultural norms and practices of the beneficiaries.

5.2 Where the protected traditional knowledge is narrowly diffused, whether or not it is sacred, Member States should encourage as a best practice that:

(a) Beneficiaries that directly communicate protected traditional knowledge to users receive a fair and equitable share of benefits arising from its use by said users; and

(b) Users identify clearly-discernable holders of the protected traditional knowledge when using said traditional knowledge, and use the knowledge in a manner that respects the cultural norms and practices of the beneficiaries.

5.3 Member States should use best endeavors to archive and preserve traditional knowledge that is widely diffused.]]

[ARTICLE 5BIS

[DATABASE], [COMPLEMENTARY] [AND] [DEFENSIVE] PROTECTION

Database Protection

Recognizing the importance of cooperation and consultation with indigenous and local communities in determining access to traditional knowledge, Member States should endeavor to, subject to and consistent with national and customary law, facilitate and encourage the development of the following national traditional knowledge databases to which beneficiaries may voluntarily contribute their traditional knowledge:

5BIS.1 Publicly accessible national traditional knowledge databases for the purpose of transparency, certainty, conservation, and transboundary cooperation, and to facilitate and encourage, as appropriate, the creation, exchange and dissemination of, and access to traditional knowledge.

5BIS.2 National traditional knowledge databases accessible only by intellectual property offices for the purpose of prevention of the erroneous grant of intellectual property rights. Intellectual property offices should seek to ensure that such information is maintained in confidence, except where the information is cited during the examination of an application for intellectual property protection.

5BIS.3 Non-public national traditional knowledge databases for the purpose of codifying and conserving traditional knowledge within indigenous and local communities. Non-public national traditional knowledge databases should only be accessible by beneficiaries in accordance with their respective customary laws and established practices that govern the access or use of such traditional knowledge.

[Complementary][Defensive] Protection

5BIS.4 [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;]

5BIS.5 [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.]

5BIS.6 [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 2 is included in a database, the [protected] traditional knowledge should only be made available to others with the free, prior and informed consent or approval and involvement of the traditional knowledge holder.]

5BIS.7 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.

5BIS.8 Efforts [should]/[shall] be made by national authorities to codify the publicly accessible 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.

5BIS.9 Efforts [should]/[shall] also be made to facilitate access to publicly accessible information including information made available in [publicly accessible] databases relating to traditional knowledge by intellectual property offices.

5BIS.10 [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 6

SANCTIONS, REMEDIES AND EXERCISE OF RIGHTS/APPLICATION

[Alt 1

Member States shall put in place appropriate, effective, dissuasive, and proportionate legal and/or administrative measures to address violations of the rights contained in this instrument.]

[Alt 2

6.1 [Member States [should]/[shall] ensure that [accessible, appropriate and adequate] [criminal, civil [and] or administrative] enforcement procedures[, dispute resolution mechanisms][, 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.]

6.2 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.]

6.3 [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.]

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

6.5 [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].]

6.6 [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.]

6.7 If an infringement of the rights protected by this instrument is determined in the procedure established in Paragraph 6.1, the sanctions may consider the inclusion of restorative justice measures, according to the nature and effect of the infringement.]]

[ARTICLE 7
DISCLOSURE REQUIREMENT

[Alt 1

Where required by national law, the users of traditional knowledge shall comply with requirements concerning the disclosure of source and/or origin of traditional knowledge.]

[Alt 2

7.1 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] 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 free, prior and informed consent or approval and involvement to access and use has been obtained.]

7.2 [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] applicant collected or received the traditional knowledge.]

7.3 [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 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 intellectual property office may reject the application.]

7.4 [Rights arising from a grant shall be revoked and rendered unenforceable when the applicant has failed to comply with mandatory requirements or provided false or fraudulent information.]]

[Alt 3

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

7.2 [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] applicant collected or received the [protected] traditional knowledge.]

7.3 [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] 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] intellectual property office may reject the application.]

7.4 [Rights arising from a granted patent 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, provided for in national law, including criminal sanctions such as fines, may however be imposed.]

7.5 [Rights arising from a grant shall be revoked and rendered unenforceable when the applicant has knowingly provided false or fraudulent information.]]

[Alt 4

[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.]]]

[ARTICLE 8

ADMINISTRATION [OF RIGHTS]/[OF INTERESTS]

[Alt 1

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

[Alt 2

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

[Alt 3

Member States may establish competent authorities, in accordance with national and customary law, that are responsible for the national traditional knowledge databases provided for by this [instrument]. Responsibilities may include the receipt, documentation, storage and online publication of information relating to traditional knowledge.]]

[ARTICLE 9

EXCEPTIONS AND LIMITATIONS

[Alt 1

In complying with the obligations set forth in this instrument, Member States [may in special cases,] [should] adopt justifiable exceptions and limitations necessary to protect the public interest, in consultation with the beneficiaries, where applicable, provided such exceptions and limitations shall not unreasonably conflict with the rights of beneficiaries nor unduly prejudice the implementation of this instrument.]

[Alt 2

General Exceptions

9.1 [Member States]/[Contracting Parties] [may] [should] adopt appropriate limitations and exceptions under national law [with the free, prior and 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;] or
- (d) [does not unreasonably prejudice the legitimate interests of the beneficiaries taking account of the legitimate interests of third parties.]]

9.2 [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

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

- (a) teaching, learning, but not research resulting in profit-making 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, to protect public health or the environment [or in cases of public non-commercial use];
- (d) [the creation of an original work of authorship inspired by traditional knowledge];
- (e) to exclude from protection diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

This provision, with the exception of Subparagraph (c), [should]/[shall] not apply to traditional knowledge described in Article 5(a)/5.1.]

9.4 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.]

9.5 [[There shall be no right to [exclude others] from using knowledge that:]/[The provisions of Article 5 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.]

9.6 [[Protected] traditional knowledge shall not be deemed to have been misappropriated or misused if:

(a) the [protected] traditional knowledge was obtained from a printed publication;

(b) the [protected] traditional knowledge was obtained from one or more holders of the [protected] traditional knowledge with their free, prior and 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.]]

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

ARTICLE 10

TERM OF PROTECTION/RIGHTS

[Member States]/[Contracting Parties] may determine the appropriate term of protection/rights of traditional knowledge in accordance with [Article 5/[which may] [should]/[shall] last as long as the traditional knowledge fulfills/satisfies the [criteria of eligibility for protection] according to Article [3]/[5].]

ARTICLE 11
FORMALITIES

[Alt 1

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

[Alt 2

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

[Alt 3

[The protection of traditional knowledge under Article 5 [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 Article 5.]]

ARTICLE 12

TRANSITIONAL MEASURES

12.1 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 [3]/[5].

[Optional addition

12.2 [[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

12.2 [[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

12.2 [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 13

RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

13.1 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.]

[13.2 Nothing in this instrument shall be interpreted as prejudicing or detrimental to the rights of indigenous [peoples] enshrined in the United Nations Declaration on the Rights of Indigenous Peoples.]

[13.3 In case of legal conflict, the rights of the indigenous [peoples] included in the aforementioned Declaration shall prevail and all interpretation shall be guided by the provisions of the said Declaration.]

ARTICLE 14

NON-DEROGATION

Nothing in this [instrument] may be construed as diminishing or extinguishing the rights that indigenous [[peoples]] or local communities have now or may acquire in the future.

[ARTICLE 15

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 3, accord within its territory to beneficiaries of protection as defined in Article 4, 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 16

TRANSBOUNDARY COOPERATION

Where the same [protected] traditional knowledge [under Article 5] is found within the territory of more than one [Member State]/[Contracting Party], or 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].]

[Annex II follows]

The Protection of Traditional Cultural Expressions: Draft Articles

Facilitators' Rev. (June 19, 2019)

PREAMBLE/INTRODUCTION

1. ACKNOWLEDGING the **UN Declaration on the Rights of Indigenous Peoples**, and the aspirations of indigenous [peoples] and local communities [therein];
2. [[Recognizing that indigenous [peoples] and local communities have the right] Recognizing the rights of indigenous [peoples] and the interests of local communities] to maintain, control, protect and develop their intellectual property over their cultural heritage, including their traditional cultural expressions;]
3. Recognizing that the situation of the indigenous [peoples] and local communities varies from region to region and from country to country and that the significance of national and regional particularities and various historical and cultural backgrounds should be taken into consideration;
4. Recognizing that the traditional cultural expressions of indigenous [peoples] and local communities have [intrinsic] value, including social, cultural, spiritual, economic, scientific, intellectual, commercial and educational values;
5. Acknowledging that traditional cultural expressions are frameworks of ongoing creation and distinctive intellectual and creative life that are [intrinsically] important for indigenous [peoples] and local communities;
6. Respecting the continuing customary use, development, exchange and transmission of traditional cultural expressions by, within and between communities;
7. Promoting respect for traditional cultural expressions, and for the dignity, cultural integrity and spiritual values of the traditional cultural expression holders who maintain those expressions.
8. Acknowledging that the protection of traditional cultural expressions should contribute toward the promotion of creativity and innovation, and to the transfer and dissemination of traditional cultural expressions for the mutual advantage of holders and users in a manner conducive to social and economic welfare and to a balance of rights and obligations.
9. [Promoting intellectual and artistic freedom, research or other fair practices and cultural exchange [based on mutually agreed terms including fair and equitable sharing of benefits and subject to the free, prior and informed consent, and approval and involvement of indigenous [peoples],[local communities and nations/beneficiaries];]
10. [Ensuring mutual supportiveness with international agreements relating to the protection and safeguarding of traditional cultural expressions, and those relating to IP;]
11. Recognizing and reaffirming the role that the IP system plays in promoting innovation and creativity, transfer and dissemination of traditional cultural expressions and economic development, to the mutual advantage of stakeholders, providers and users of traditional cultural expressions.
12. Recognizing the value of a vibrant public domain and the body of traditional cultural expressions that are available for all to use, [and] which are essential for creativity and innovation [and the need to protect and preserve the public domain].
13. [Recognizing the need for new rules and disciplines concerning the provision of effective and appropriate means for the enforcement of rights relating to traditional cultural expressions, taking into account differences in national legal systems;]

14. [Nothing in this instrument may be construed as diminishing or extinguishing the rights that indigenous [peoples] or local communities have now or may acquire in the future.]

[ARTICLE 1
USE OF TERMS

For the purposes of this instrument:

Traditional Cultural Expressions are any forms in which traditional culture practices and knowledge are expressed, [appear or are manifested] [the result of intellectual activity, experiences, or insights] by indigenous [peoples], local communities and/or [other beneficiaries] in or from a traditional context, and may be dynamic and evolving and comprise verbal forms⁹, musical forms¹⁰, expressions by movement¹¹, tangible¹² or intangible forms of expression, or combinations thereof.

[Public domain refers, for the purposes of this instrument, to tangible and 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.]

[Alternative

Public domain means the public domain as defined by national law.]

[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.]

[["Use"]/["Utilization"] means

- (a) where the traditional cultural expression is included in a product:
 - (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 cultural expression is included in a process:
 - (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; or
- (c) the use of traditional cultural expression in research and development leading to profit-making or commercial purposes.]]

⁹ [Such as stories, epics, legends, popular stories, poetry, riddles and other narratives; words, signs, names and symbols.]

¹⁰ [Such as songs, rhythms, and instrumental music, the songs which are the expression of rituals.]

¹¹ [Such as dance, works of mas, plays, ceremonies, rituals, rituals in sacred places and peregrinations, games and traditional sports/sports and traditional games, puppet performances, and other performances, whether fixed or unfixed.]

¹² [Such as material expressions of art, handicrafts, ceremonial masks or dress, handmade carpets, architecture, and tangible spiritual forms, and sacred places.]

[ARTICLE 2
OBJECTIVES

[Alt 1

The objective of this instrument is to provide effective, balanced and adequate protection relating to intellectual property against:

- (d) unauthorized¹³ and/or uncompensated¹⁴ uses of traditional cultural expressions; and
- (e) the erroneous grant of intellectual property rights over traditional cultural expressions,

[while supporting the appropriate use of traditional cultural expressions].]

[Alt 2

The objective of this instrument is to support the appropriate use and effective, balanced and adequate protection of traditional cultural expressions within the intellectual property system, in accordance with national law, recognizing the rights of [indigenous [peoples] and local communities] [beneficiaries].]

[Alt 3

The objective of this instrument is to support the appropriate use and protection of traditional cultural expressions within the intellectual property system, in accordance with national law, respecting the interests of indigenous peoples and local communities to:

- (a) prevent the misappropriation, misuse, and unauthorized use of their traditional cultural expressions[, while making the most of the existing intellectual property system];
- (b) encourage and protect creation and innovation, whether or not commercialized, recognizing the value of public domain and the need to protect, preserve and enhance the public domain; and
- (c) prevent the erroneous grant or assertion of intellectual property rights over traditional cultural expressions.
- (d) promote the appropriate use of traditional cultural expression for sustainable, community-based development where so desired by indigenous peoples and local communities.]]

¹³ Unauthorized uses comprise inter alia misappropriation, misuse and unlawful uses of traditional cultural expressions.

¹⁴ Uncompensated uses include the failure to provide monetary or non-monetary benefits.

[ARTICLE 3

PROTECTION CRITERIA/ELIGIBILITY CRITERIA

[Alt 1

3.1 Subject to Article 3.2, protection shall be extended under this instrument to traditional cultural expressions which are:

- (a) created, generated, received, or revealed, by indigenous [peoples], local communities and/or [other beneficiaries] and developed, held, used, and maintained collectively by them [in accordance with their customary laws and protocols];
- (b) linked with, and are an integral part of, the cultural and social identity and traditional heritage of indigenous [peoples], local communities and/or [other beneficiaries]; and
- (c) transmitted between or from generation to generation, whether consecutively or not.

3.2. A Member State/Contracting Party may under its national law, condition protection on the prior existence of the traditional cultural expressions for a reasonable term as determined by the Member State/Contracting Party.]

[Alt 2

3.1 Protection should be extended under this instrument to traditional cultural expressions which are:

- (a) created, generated, received, or revealed, by indigenous [peoples], local communities and/or [other beneficiaries] and developed, held, used, and maintained collectively by them [in accordance with their customary laws and protocols];
- (b) linked with, are an integral part of, and are distinctively associated with the cultural and social identity and traditional heritage of indigenous [peoples], local communities and/or [other beneficiaries]; and
- (c) transmitted between or from generation to generation, whether consecutively or not for a term not less than fifty years or five generations.]]

[ARTICLE 4
BENEFICIARIES

[Alt 1

The beneficiaries of this instrument are indigenous peoples, local communities, and other beneficiaries,¹⁵ as may be determined under national law.]

[Alt 2

Beneficiaries of protection under this instrument are indigenous [peoples] and local communities who hold, express, create, maintain, use, and develop [protected] traditional cultural expressions.]

[Alt 3

The beneficiaries of this instrument are indigenous [peoples], local communities, and other beneficiaries, [such as states [and/or nations]], as may be determined under national law.]]

¹⁵ The term other beneficiaries may include states or nations.

[ARTICLE 5

SCOPE OF [PROTECTION]/[SAFEGUARDING]

[Alt 1

5.1 [Member States]/[Contracting Parties] [should]/[shall] safeguard the economic and moral interests of the beneficiaries concerning their [protected] traditional cultural expressions, as defined in this [instrument], as appropriate and in accordance with national law, [taking into consideration exceptions and limitations, as defined in Article 7,] in a reasonable and balanced manner.

5.2 Protection under this instrument does not extend to traditional cultural expressions that are widely known or used outside the community of the beneficiaries as defined in this [instrument], [for a reasonable period of time], in the public domain, or protected by an intellectual property right.]

[Alt 2

5.1 Member States [should/shall] take legislative, administrative and/or policy measures, as appropriate, in accordance with national law, in a reasonable and balanced manner, and in a manner consistent with Article 14, with the aim of ensuring that:

(c) Where with reference to the customary laws and practices of indigenous [peoples] and local communities/beneficiaries, access to traditional cultural expressions is restricted, including where the traditional cultural expressions are secret or sacred:

iii. Beneficiaries have the exclusive and collective right to maintain, control, use, develop, authorize or prevent access to and use/utilization of their traditional cultural expressions; and receive a fair and equitable share of benefits arising from their use.

iv. Beneficiaries have the moral right of attribution and the moral right to the use of their traditional cultural expressions in a manner that respects the integrity of such traditional cultural expressions.

(d) Where with reference to the customary laws and practices of indigenous [peoples] and local communities/beneficiaries, the traditional cultural expressions are no longer under the exclusive control of beneficiaries, but are still distinctively associated with the beneficiaries' cultural identity:

iii. Beneficiaries receive a fair and equitable share of benefits arising from their use; and

iv. Beneficiaries have the moral right of attribution and the right to the use of their traditional cultural expressions in a manner that respects the integrity of such traditional cultural expressions.

5.2 [For traditional cultural expressions that are being utilized without the prior informed consent and/or not in accord with customary laws and practices of indigenous [peoples] and local communities, indigenous [peoples] and local communities or other beneficiaries, as applicable, shall have the possibility to request from the relevant national authorities protection provided for in paragraph 5.1(a), taking into account all relevant circumstances, such as: historical facts, indigenous and customary laws, national and international laws, and evidence of cultural harms that could result from such unauthorized utilization.]]

[Alt 3

5.1 Where the [protected] traditional cultural expression is [sacred], [secret] or [otherwise known only] [closely held] within indigenous [peoples] or local communities, Member States should/shall:

- (a) provide legal, policy and/or administrative measures, as appropriate and in accordance with national law that allow beneficiaries to:
 - i. [create,] maintain, control and develop said [protected] traditional cultural expressions;
 - ii. [discourage] prevent the unauthorized disclosure and fixation and prevent the unlawful use of secret [protected] traditional cultural expressions;
 - iii. [authorize or deny the access to and use/[utilization] of said [protected] traditional cultural expressions based on free, prior and informed consent or approval and involvement and mutually agreed terms;]
 - iv. protect against any [false or misleading] uses of [protected] traditional cultural expressions, in relation to goods and services, that suggest endorsement by or linkage with the beneficiaries; and
 - v. [prevent] prohibit use or modification which distorts or mutilates a [protected] traditional cultural expression or that otherwise diminishes its cultural significance to the beneficiary.
- (b) encourage users [to]:
 - i. attribute said [protected] traditional cultural expressions to the beneficiaries;
 - ii. use best efforts to enter into an agreement with the beneficiaries to establish terms of use of the [protected] traditional cultural expressions]; and
 - iii. use/utilize 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 [protected] traditional cultural expressions.

5.2 [Where the [protected] traditional cultural expression is still [held], [maintained], used [and]/[or] developed by indigenous [peoples] or local communities, and is/are publicly available [but neither widely known, [sacred], nor [secret]], Member States should/shall encourage that users]/[provide legal, policy and/or administrative measures, as appropriate and in accordance with national law to encourage users [to]]:

- (a) attribute and acknowledge the beneficiaries as the source of the [protected] traditional cultural expressions, unless the beneficiaries decide otherwise, or the [protected] traditional cultural expressions is not attributable to a specific indigenous people or local community[; and][.]
- (b) use best efforts to enter into an agreement with the beneficiaries to establish terms of use of the [protected] traditional cultural expressions;
- (c) [use/utilize 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 [protected] traditional cultural expressions[; and][.]]

(d) [refrain from any [false or misleading uses] of [protected] traditional cultural expressions, in relation to goods and services, that suggest endorsement by or linkage with the beneficiaries.]

5.3 [Where the [protected] traditional cultural expressions is/are [publicly available, widely known [and in the public domain]] [not covered under Paragraphs 1 or 2], [and]/or protected under national law, Member States should/shall encourage users of said [protected] traditional cultural expressions [to], in accordance with national law:

(a) attribute said [protected] traditional cultural expressions to the beneficiaries;

(b) use/utilize 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 [protected] traditional cultural expressions;

(c) [protect against any [false or misleading] uses of traditional cultural expressions, in relation to goods and services, that suggest endorsement by or linkage with the beneficiaries[;]] [and]

(d) where applicable, deposit any user fee into the fund constituted by such Member State.]]

[ARTICLE 6

ADMINISTRATION OF [RIGHTS]/[INTERESTS]

[Alt 1

6.1 [Member States]/[Contracting Parties] may establish or designate a competent authority, in accordance with national law, to administer, in close consultation with the beneficiaries, where applicable, the rights/interests provided for by this instrument.

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

[Alt 2

6.1 [Member States]/[Contracting Parties] may establish or designate a competent authority, in accordance with national law, with the explicit consent of/in conjunction with the beneficiaries, to administer the rights/interests provided for by this [instrument].

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

[ARTICLE 7

EXCEPTIONS AND LIMITATIONS

[Alt 1

In complying with the obligations set forth in this instrument, Member States [may in special cases,] [should] adopt justifiable exceptions and limitations necessary to protect the public interest, in consultation with the beneficiaries, where applicable, provided such exceptions and limitations shall not unreasonably conflict with the rights of beneficiaries, [and the customary law of indigenous [peoples] and local communities,] nor unduly prejudice the implementation of this instrument.]

[Alt 2

In implementing this instrument, Member States [may] [should] adopt exceptions and limitations as may be determined under national legislation including incorporated customary law.

1. To the extent that any act would be permitted under national law for works protected by copyright, signs and symbols protected by trademark law, or subject matter otherwise protected by intellectual property law, such acts [shall/should] not be prohibited by the protection of TCEs.

2. Regardless of whether such acts are already permitted under paragraph (1), Member States [shall/should] [may] have exceptions[, such as] for:

- (a) learning teaching and research;
- (b) preservation, display, research, and presentation in archives, libraries, museums or other cultural institutions;
- (c) the creation of literary, artistic, or creative works inspired by, based on, or borrowed from traditional cultural expressions.

3. A Member State may provide for exceptions and limitations [other than] [in addition to] those permitted under paragraph (2).

4. A Member State shall/should provide for exceptions and limitations in cases of incidental use/utilization/inclusion of a [protected] traditional cultural expression in another work or another subject matter, or in cases where the user had no knowledge or reasonable grounds to know that the traditional cultural expression is protected.]

[Alt 3

General Exceptions

7.1 [[Member States]/[Contracting Parties] [may]/[should]/[shall] adopt appropriate limitations and exceptions under national law [in consultation with the beneficiaries] [with the involvement of beneficiaries][, provided that the use of [protected] traditional cultural expressions:

- (a) [acknowledges the beneficiaries, where possible;]
- (b) [is not offensive or derogatory to the beneficiaries;]
- (c) [is compatible with fair use/dealing/practice;] or

(d) [does not unreasonably prejudice the legitimate interests of the beneficiaries taking account of the legitimate interests of third parties.]]

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

Specific Exceptions

7.3 [[Subject to the limitations in Paragraph 1,]/[In addition,] [Member States]/[Contracting Parties] [may]/[should]/[shall] adopt appropriate limitations or exceptions, in accordance with national law or, as appropriate, of the [holders]/[owners] of the original work:

- (a) [for learning, teaching and research, in accordance with nationally established protocols, except when it results in profit-making or commercial purposes;]
- (b) [for preservation, [display], research and presentation in archives, libraries, museums or other cultural institutions recognized by national law, for non-commercial cultural heritage or other purposes in the public interest;]
- (c) [for the creation of an original work [of authorship] inspired by, based on or borrowed from traditional cultural expressions;]

[This provision [should]/[shall] not apply to [protected] traditional cultural expressions described in Article 5.1.]]

7.4 [Regardless of whether such acts are already permitted under Paragraph 1, the following [should]/[shall] be permitted:

- (a) [the use of traditional cultural expressions in cultural institutions recognized under the appropriate national law, archives, libraries and museums, for non-commercial cultural heritage or other purposes in the public interest, including for preservation, [display], research and presentation;]
- (b) the creation of an original work [of authorship] inspired by, based on or borrowed from traditional cultural expressions;]
- (c) [the use/utilization of a traditional cultural expression [legally] derived from sources other than the beneficiaries; and]
- (d) [the use/utilization of a traditional cultural expression known [through lawful means] outside of the beneficiaries' community.]]

7.5 [[Except for the protection of secret traditional cultural expressions against disclosure], to the extent that any act would be permitted under the national law, for works protected by [intellectual property rights [including]]/[copyright, or signs and symbols protected by trademark, or inventions protected by patents or utility models and designs protected by industrial design rights, such act [should]/[shall] not be prohibited by the protection of traditional cultural expressions].]]

[ARTICLE 8]

[TERM OF [PROTECTION]/[SAFEGUARDING]

[Option 1

8.1 [Member States]/[Contracting Parties] may determine the appropriate term of protection/rights of traditional cultural expressions in accordance with [this [instrument]/[[which may] [should]/[shall] last as long as the traditional cultural expressions fulfill/satisfy the [criteria of eligibility for protection] according to this [instrument], and in consultation with beneficiaries.]]

8.2 [Member States]/[Contracting Parties] may determine that the protection granted to traditional cultural expressions against any distortion, mutilation or other modification or infringement thereof, done with the aim of causing harm thereto or to the reputation or image of the beneficiaries or region to which they belong, [should]/[shall] last indefinitely.]

[Option 2

8.1 [Member States]/[Contracting Parties] shall protect the subject matter identified in this [instrument] as long as the beneficiaries of protection continue to enjoy the scope of protection in Article 3.]

[Option 3

8.1 [[Member States]/[Contracting Parties] may determine that the term of protection of traditional cultural expressions, at least as regards their economic aspects, [should]/[shall] be limited.]]]

[ARTICLE 9]
FORMALITIES

[Option 1

9.1 [As a general principle,] [Member States]/[Contracting Parties] [should]/[shall] not subject the protection of traditional cultural expressions to any formality.]

[Option 2

9.1 [[Member States]/[Contracting Parties] [may] require formalities for the protection of traditional cultural expressions.]

9.2 Notwithstanding Paragraph 1, a [Member State]/[Contracting Party] may not subject the protection of secret traditional cultural expressions to any formality.]

[ARTICLE 10

[SANCTIONS, REMEDIES AND EXERCISE OF [RIGHTS]/[INTERESTS]]

[Alt 1

Member States shall put in place appropriate, effective, dissuasive, and proportionate legal and/or administrative measures, to address violations of the rights contained in this instrument.]

[Alt 2

10.1 Member States shall, [in conjunction with indigenous [peoples],] put in place accessible, appropriate, effective, [dissuasive,] and proportionate legal and/or administrative measures to address violations of the rights contained in this instrument. Indigenous [peoples] should have the right to initiate enforcement on their own behalf and shall not be required to demonstrate proof of economic harm.

10.2 If a violation of the rights protected by this instrument is determined pursuant to paragraph 10.1, the sanctions shall include civil and criminal enforcement measures as appropriate. Remedies may include restorative justice measures, [such as repatriation,] according to the nature and effect of the infringement.]

[Alt 3

Member States should undertake to adopt appropriate, effective and proportionate legal and/or administrative measures, in accordance with their legal systems, to ensure the application of this instrument.]

[Alt 4

Member States/Contracting Parties should/shall provide, in accordance with national law, the necessary legal, policy or administrative measures to prevent willful or negligent harm to the interests of the beneficiaries.]]

[ARTICLE 11]

[TRANSITIONAL MEASURES

11.1 This [instrument] [should]/[shall] apply to all traditional cultural expressions which, at the time of the [instrument] coming into effect/force, fulfill the criteria set out in this [instrument].

[11.2 *Option 1* [[Member States]/[Contracting Parties] [should]/[shall] secure the rights acquired by third parties under national law prior to the entry into effect/force of this [instrument]].]

[11.2 *Option 2* Continuing acts in respect of traditional cultural expressions that had commenced prior to the coming into effect/force of this [instrument] and which would not be permitted or which would be otherwise regulated by the [instrument], [[should]/[shall] be brought into conformity with the [instrument] within a reasonable period of time after its entry into effect/force, subject to Paragraph 3]/[[should]/[shall] be allowed to continue].]

11.3 With respect to traditional cultural expressions that have special significance for the beneficiaries and which have been taken outside of the control of such beneficiaries, these beneficiaries [should]/[shall] have the right to recover such traditional cultural expressions.]

[ARTICLE 12]

[RELATIONSHIP WITH [OTHER] INTERNATIONAL AGREEMENTS]

12.1 [Member States]/[Contracting Parties] [should]/[shall] implement this [instrument] in a manner [mutually supportive] of [other] [existing] international agreements.]

[12.2 Nothing in this instrument may/shall be construed as diminishing or extinguishing the rights that indigenous [peoples] or local communities have now or may acquire in the future, as well as the rights of indigenous [peoples] enshrined in the United Nations Declaration on the Rights of Indigenous Peoples.

12.3 In case of legal conflict, the rights of the indigenous [peoples] included in the aforementioned Declaration shall prevail and all interpretations shall be guided by the provisions of said Declaration.]

[ARTICLE 13]

[NATIONAL TREATMENT]

Each [Member State]/[Contracting Party] [should]/[shall] accord to beneficiaries that are nationals of other [Member States]/[Contracting Parties] treatment no less favourable than that it accords to beneficiaries that are its own nationals with regard to the protection provided for under this [instrument].]

[ALTERNATIVES TO ARTICLES 8, 9, 10, 11 and 13
NO SUCH PROVISIONS]

[ARTICLE 14]

[TRANSBOUNDARY COOPERATION]

In instances where [protected] traditional cultural expressions are located in territories of different [Member States]/[Contracting Parties], those [Member States]/[Contracting Parties] [should]/[shall] co-operate in addressing instances of transboundary [protected] traditional cultural expressions., with the involvement of indigenous [peoples] and local communities concerned, where applicable, with a view to implementing this [instrument].]

ARTICLE 15

[CAPACITY BUILDING AND AWARENESS RAISING

15.1 [Member States]/[Contracting Parties] [should]/[shall] cooperate in the capacity building and strengthening of human resources, in particular, those of the beneficiaries, and the development of institutional capacities, to effectively implement the [instrument].

15.2 [Member States]/[Contracting Parties] [should]/[shall] provide the necessary resources for indigenous [peoples] and local communities and join forces with them to develop capacity-building projects within indigenous [peoples] and local communities, focused on the development of appropriate mechanisms and methodologies, such as new electronic and didactical material which are culturally adequate, and have been developed with the full participation and effective participation of indigenous [peoples] and local communities and their organizations.

15.3 [In this context, [Member States]/[Contracting Parties] [should]/[shall] provide for the full participation of the beneficiaries and other relevant stakeholders, including non-government organizations and the private sector.]

15.4 [Member States]/[Contracting Parties] [should]/[shall] take measures to raise awareness of the [instrument,] and in particular educate users and holders of traditional cultural expressions of their obligations under this instrument.]

[Annex III follows]

**The Consolidated Document Relating to Intellectual Property and
Genetic Resources Rev. 2**

(Dated March 23, 2018)

[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, 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 and [traditional knowledge associated with genetic resources.]]

ALT

[Contribute to the prevention of unauthorized use of genetic resources and [traditional knowledge associated with genetic resources.]]

[Minimize the erroneous granting of [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 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 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 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 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 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 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] [consistent] 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], and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.]]

[Recognizing that the [IP][patent] system, which protects inventions and fosters innovation, intersects with the CBD and has a role to play in protecting genetic resources and traditional knowledge associated with genetic resources.]

Ensure that patent offices have appropriate information available to them on genetic resources and traditional knowledge associated with genetic resources, which they need in order to make informed decisions, in terms of granting patents

Reaffirm the stability and predictability of correctly granted patent rights.

Recognize that the erroneous granting of patents can be effectively addressed by improving databases for storing information related to genetic resources and non-secret traditional knowledge associated with genetic resources, which can thus be used to search prior rights and reference materials not only in the procedures of examination, but also in the proceedings of a procedure of invalidation against granted patents.

[ALTERNATIVE PREAMBLE

Acknowledging the UN Declaration on the Rights of Indigenous Peoples.

Recognizing the principles of free and prior informed consent and mutually agreed terms in relation to accessing and utilization of genetic resources and traditional knowledge associated with genetic resources.

Recognizing the role of the IP system in contributing to the protection of genetic resources, and traditional knowledge associated with genetic resources, including preventing misappropriation.

Ensuring mutual supportiveness with international agreements relating to the protection of genetic resources and traditional knowledge associated with genetic resources, and those relating to IP.

Promoting transparency in the IP/Patent system in relation to genetic resources and traditional knowledge associated with genetic resources.

Emphasizing the the importance of IP/Patent Offices having access to the the appropriate information on genetic resources and traditional knowledge associated with genetic resources to prevent the erroneous granting of IP/patent rights.

Recognizing the role of databases for storing information related to genetic resources and non secret traditional knowledge associated with genetic resources, in preventing the erroneous granting of patents, pre and post grant.

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

Reaffirming the stability and predictability of granted patents.

Recognizing and reaffirming the role the IP system plays in promoting innovation, transfer and dissemination of knowledge and economic development, to the mutual advantage of stakeholders, providers, holders and users of genetic resources, and traditional knowledge associated with genetic resources.

Emphasizing that no [patents] [intellectual property] on life forms, including human beings, are to be granted.]

Reaffirming, (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.]

[ARTICLE 1] DEFINITIONS

TERMS USED IN THE OPERATIVE ARTICLES

[Traditional Knowledge Associated with Genetic Resources

ALT 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.]

ALT 2

“Traditional knowledge associated with genetic resources” means substantive knowledge of the properties and uses of genetic resources 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].]

ALT 3

[“Traditional knowledge associated with genetic resources” means substantive knowledge of the properties and uses of genetic resources generated in a traditional context, collectively preserved and transmitted from generation to generation, 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].]

[Country of Origin

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

ALT

“Country of origin” is the country which first possessed genetic resources in in-situ conditions and still possesses those genetic resources.]

[[Country Providing]][Providing Country]

“Country providing/Providing country” means, [[in accordance] [consistent] 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] [consistent] with the [Convention on Biological Diversity].]

[Erroneous Grant/Granting of Patents

Erroneous grant/granting of patents means the granting of patent rights on inventions that are not novel, that are obvious, or that are not industrially applicable.]

[[Invention] Directly Based On

“[[Invention] Directly based on” means that the [subject matter][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.]

ALT

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

Genetic Material

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

ALT

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

Genetic Resources

“Genetic resources” are genetic material of actual or potential value.

ALT

“Genetic resources” means any material of plant, animal, or microbial origin containing functional units of heredity of actual or potential value, and includes derivatives and genetic information thereof.

[Source

ALT 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.]

ALT 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].]

ALT 3

“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] or any other depository of genetic resources.]

[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, 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 [outside of the traditional uses by the knowledge holders] [including commercialization] on the genetic and/or biochemical composition of genetic resources 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.]]]

OTHER TERMS

[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 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 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].]

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].

Ex-Situ Conservation

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

[Misappropriation

“Misappropriation” is the [acquisition] [utilization] of genetic resources [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].]

ALT

[“Misappropriation” is the use of genetic resources 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 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 and [traditional knowledge associated with genetic resources] failure to take reasonable protective measures, is not misappropriation.]

[[Physical] Access

“[Physical]/[Direct] access” to the genetic resource is its physical 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.]

[Source of Traditional Knowledge Associated with 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. ^{16]}

[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.]

¹⁶ 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.

[I. [MANDATORY] DISCLOSURE]

[ARTICLE 2] [OBJECTIVE]

[The objective of this instrument is to contribute to the protection of genetic resources and traditional knowledge associated with genetic resources within the [IP] [patent] system by:

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

[ARTICLE 3] [SUBJECT MATTER OF INSTRUMENT]

This instrument applies to genetic resources, 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.]

[ARTICLE 4] [DISCLOSURE REQUIREMENT]

4.1 Where the [subject matter] [claimed invention] within a [IP] [patent] application [includes utilization of] [is directly based on] genetic resources and/or [traditional knowledge associated with genetic resources] each [Member State]/[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, and/or [traditional knowledge associated with genetic resources.]
- (b) [If the source and/or [providing country that is the country of origin] [country of origin] is not known, a declaration to that effect.]

4.2 In accordance with national law, a [Member State]/[Party] may require applicants to provide relevant information regarding compliance with ABS requirements, including PIC, [in particular from indigenous [people[s]] and local communities], where appropriate.]

ALT

4.2 The disclosure requirement of Paragraph 1 shall not include a requirement to provide relevant information regarding compliance with ABS requirements, including PIC.

4.3 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 the disclosure requirement.

4.4 Each [Member State]/[Party] [shall]/[should] make the information disclosed publicly available[, except for information considered confidential.¹⁷]

[ARTICLE 5] [EXCEPTIONS AND LIMITATIONS]

[In complying with the obligation set forth in Article 4, 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, or mutual supportiveness with other instruments.]

[ALT

5.1 A [IP] [patent] disclosure requirement related to genetic resources 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];]
- (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]];
- (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]; and
- (g) [Genetic resources and traditional knowledge associated with genetic resources necessary to protect human, animal or plant life or health [including public health] or to avoid serious prejudice to the environment].

5.2 [[Member States]/[Parties] [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].]]

¹⁷ An alternative formulation from the Nagoya Protocol Art. 14(2) is "without prejudice to the protection of confidential information".

**[ARTICLE 6]
[SANCTIONS AND REMEDIES]**

6.1 [Each [Member State]/[Party] [shall]/[should] put in place appropriate, effective and proportionate legal and administrative measures to address non-compliance with the disclosure requirement of Article 4.

6.2 Such measures [should/shall/may] include pre and/or post grant measures.

ALT

6.2 Subject to national legislation, such measures [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].
 - (iv) Providing an opportunity for [IP] [patent] applicants to supplement the [IP] [patent] application with additional information to disclose the source or origin of any genetic resource or traditional knowledge used. Since such information is irrelevant to how to make and use the invention, there would be no impact upon the filing date of the application and no fee required for its submission after the filing date of the application.

- (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, and [traditional knowledge associated with genetic resources] including indigenous peoples and/or local communities] may be considered, in accordance with national law.]]

6.3 Revocation of [an IP right] [a patent] as a sanction for non-compliance with Article 4 may be provided under national law for willful or deliberate instances of refusal to comply, but only after the [IP right] [patent] holder has been offered the opportunity to reach a mutually satisfactory resolution with relevant parties, as defined under national law, and such negotiations have failed.

ALT

6.3 Failure to fulfill the disclosure requirement [shall]/[should] not affect the validity or enforceability of granted [IP] [patent] rights.

6.4 [Member States]/[Parties] [shall]/[should] put in place adequate dispute resolution mechanisms.]

**[II. ALTERNATIVES TO ARTICLES 2-6
NO NEW DISCLOSURE REQUIREMENT]**

**ALT
[ARTICLE 2]
[OBJECTIVE]**

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

The objectives of this instrument are to:

- (a) prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to genetic resources and traditional knowledge associated with genetic resources, which could protect Indigenous peoples and local communities from the limitations of the traditional use of genetic resources and their traditional knowledge associated with genetic resources that might result from the erroneous patenting thereof;
- (b) ensure that patent offices have the appropriate available information on genetic resources and traditional knowledge associated resources needed to make informed decisions on granting patents; and
- (c) preserve a rich and accessible public domain in order to foster creativity and innovation.]

**ALT
[ARTICLE 3]
[SUBJECT MATTER OF INSTRUMENT]**

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

**ALT
[ARTICLE 4]
[DISCLOSURE]**

4.1 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 and [traditional knowledge associated with genetic resources], for reasons other than those related to novelty, inventive step, industrial applicability or enablement.]

4.2 [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 a specification of any 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.]]

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

4.4 [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 and without payment of a fee.]

4.5 The disclosure of the [geographic location] where the genetic material was obtained [shall]/[should]/[may][does] not place an obligation on the patent office to verify the contents of the disclosure. But patent offices [shall]/[should] provide guidance to patent applicants on how to meet the disclosure requirement as well as an opportunity for applicants or patentees to correct any disclosures that are erroneous or incorrect.

4.6 Failure to examine a patent application in a timely manner shall result in an adjustment of the term of the granted patent to compensate the patentee for administrative delays.]

[III. [DEFENSIVE]/[COMPLEMENTARY] MEASURES]

[ARTICLE 7] [DUE DILIGENCE]

[Member States]/[Parties] [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]/[parties] [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 8] [[PREVENTION OF THE [ERRONEOUS]¹⁸ GRANT OF PATENTS AND VOLUNTARY CODES OF CONDUCT]

8.1 [Member States]/[Parties] [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 and [traditional knowledge associated with genetic resources] where, under national law, those genetic resources 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 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 and [traditional knowledge associated with genetic resources].]
- (d) Facilitate, as appropriate, the creation, exchange, dissemination of, and access to, databases containing [information associated with] genetic resources and [traditional knowledge associated with genetic resources] for use by patent offices] [with appropriate safeguards].

[8.2 As a complement to the disclosure obligation provided for in Article 4, and in the implementation of this instrument, the [Member State]/[Party] 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

¹⁸ 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.

8.3 Members are encouraged to facilitate the establishment of databases [information associated with] of genetic resources 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

8.4 [Member States]/[Parties] [shall]/[should] establish a database search system (the WIPO Portal) that links databases of WIPO members that contain information on genetic resources 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].]

8.5 [Member States]/[Parties] should provide effective, legal, policy or administrative measures, as appropriate and in accordance with national law, to implement and administer the WIPO portal.]

[IV. FINAL PROVISIONS]

[ARTICLE 9] [PREVENTIVE MEASURES FOR PROTECTION]

[Genetic resources 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 10] RELATIONSHIP WITH INTERNATIONAL AGREEMENTS

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

ALT

10.1 [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.]

10.2 [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.]

10.3 [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.]]

[10.4 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 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 11] INTERNATIONAL COOPERATION

[[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 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

[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 12]
TRANSBOUNDARY COOPERATION

[In instances where the same genetic resources 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 13]
TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING

[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 IV follows]

Draft
**International Legal Instrument Relating to Intellectual Property, Genetic Resources and
Traditional Knowledge Associated with Genetic Resources**

Prepared by Mr. Ian Goss
**Chair, WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources,
Traditional Knowledge and Folklore**

April 30, 2019

Introductory remarks¹⁹

1. To date, the negotiations being conducted by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) relating to intellectual property and the effective and balanced protection of genetic resources (GRs) and traditional knowledge associated with genetic resources (Associated TK)²⁰ have been unable to reach a conclusion.
2. The IGC's inability so far to find a consensus position is reflected in the different policy interests contained in the alternate objectives within the IGC's current draft text on GRs and Associated TK²¹. There is, in my view, scope for bridging these different perspectives and room for balancing the rights and interests of users and the rights and interests of providers and knowledge holders. In addition, **a clearer understanding of the modalities of an international disclosure requirement would enable policymakers to make informed decisions regarding the costs, risks and benefits of a disclosure requirement.**
3. From this perspective, I have prepared this draft text of an international legal instrument on intellectual property and GRs and Associated TK for consideration by the IGC.
4. I have prepared this draft text solely under my own authority as a contribution to the negotiations being conducted by the IGC.
5. This draft is without prejudice to any Member States' positions and reflects my views alone. My draft text attempts to take account of the policy interests of all Member States and other stakeholders expressed over the past nine years of text-based negotiations in the IGC. In particular, it attempts to balance the interests and rights of the providers and users of GRs and Associated TK, without which, in my view, a mutually beneficial agreement will not be achieved.

¹⁹ Note from the Chair: These introductory remarks do not form part of the draft instrument.

²⁰ These negotiations are currently being conducted pursuant to the IGC's mandate for 2018/19.

²¹ WIPO/GRTKF/IC/40/6 Consolidated Document Relating to Intellectual Property and Genetic Resources.

6. In developing this text, I have given careful consideration to the existing documentation of the IGC²² and the WIPO Secretariat's publication *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge*. I have also conducted a detailed review of existing national and regional disclosure regimes. There has been a significant cross regional growth in GRs and Associated TK disclosure regimes at regional and national levels. Currently around 30 regimes are in place and a number of Member States are currently considering the introduction of such regimes. These regimes vary significantly in terms of scope, content, relationship with access and benefit-sharing regimes, and sanctions. In my view, these differences create inherent risks to users in terms of legal certainty, accessibility to GRs and Associated TK, and transactional costs/burdens with potential negative impacts on innovation. In addition, a global and mandatory disclosure regime would enhance transparency in relation to the use of GRs and Associated TK within the patent system, improving the efficacy and quality of the patent system. This would, in my view, also facilitate benefit-sharing and the prevention of the granting of erroneous patents and the misappropriation of GRs and Associated TK.

7. I invite Member States to consider this draft text in the context of the IGC's work on GRs and Associated TK. I look forward to receiving feedback on the draft from Member States and stakeholders.

8. The text of the draft legal instrument follows below. Several but not all of the articles are accompanied by explanatory notes. These notes do not form part of the text, and are simply meant to provide further background and explanation. In the event of any inconsistency between the text of an article and the note accompanying it, the text of the article takes precedence.

²² Such as WIPO/GRTKF/IC/40/6 Consolidated Document Relating to Intellectual Property and Genetic Resources; WIPO/GRTKF/IC/38/10 Joint Recommendation on Genetic Resources and Associated Traditional Knowledge; WIPO/GRTKF/IC/38/11 Joint Recommendation on the Use of Databases for the Defensive Protection of Genetic Resources and Traditional Knowledge Associated with Genetic Resources; WIPO/GRTKF/IC/11/10 Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals by Switzerland; WIPO/GRTKF/IC/8/11 EU Proposal: Disclosure of Origin or Source of Genetic Resources and Associated Traditional Knowledge in Patent Applications; WIPO/GRTKF/IC/17/10 Proposal of the African Group on Genetic Resources and Future Work; and, WIPO/GRTKF/IC/38/15 The Economic Impact of Patent Delays and Uncertainty: U.S. Concerns about Proposals for New Patent Disclosure Requirements.

IGC CHAIR'S DRAFT

**INTERNATIONAL LEGAL INSTRUMENT RELATING TO INTELLECTUAL PROPERTY,
GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC
RESOURCES**

April 30, 2019

The Parties to this instrument,

Desiring the promotion of the efficacy, transparency and quality of the patent system in relation to genetic resources (GRs) and traditional knowledge associated with genetic resources (Associated TK),

Emphasizing the importance of patent offices having access to appropriate information on GRs and Associated TK to prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to GRs and Associated TK,

Recognizing the potential role of the patent system in contributing to the protection of GRs and Associated TK,

Recognizing that an international disclosure requirement related to GRs and Associated TK in patent applications contributes to legal certainty and consistency and, therefore, has benefits for the patent system and for providers and users of such resources and knowledge,

Recognizing that this instrument and other international instruments related to GRs and Associated TK should be mutually supportive,

Recognizing and reaffirming the role that the intellectual property (IP) system plays in promoting innovation, transfer and dissemination of knowledge and economic development, to the mutual advantage of providers and users of GRs and Associated TK,

Acknowledging the UN Declaration on the Rights of Indigenous Peoples (UNDRIP),

Have agreed as follows:

ARTICLE 1 OBJECTIVES

The objectives of this instrument are to:

- (a) enhance the efficacy, transparency and quality of the patent system with regard to GRs and Associated TK, and
- (b) prevent patents from being granted erroneously for inventions that are not novel or inventive with regard to GRs and Associated TK.

Notes on Article 1

The objectives have been drafted in a short and concise manner. Specific measures to implement the objectives of the instrument are contained in the subsequent provisions of the instrument. Moreover, the instrument does not contain any provisions that are already addressed by other international instruments, or that are not relevant to the patent system. For instance, there is no reference to issues related to access and benefit-sharing or to misappropriation, as these issues are already dealt with in other international instruments, such as the Convention on Biological Diversity (CBD), 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 (Nagoya Protocol), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of the Food and Agriculture Organization of the United Nations and the World Health Organization's Pandemic Influenza Preparedness Framework, 2011. Yet, it is important to note that, in my view, enhanced efficacy, transparency and quality of the patent system will ultimately result in facilitating benefit-sharing and avoiding misappropriation. The term "efficacy" also makes it clear that a disclosure requirement implemented at the national level should be effective, practical, easily implementable and not result in overly burdensome transaction costs.

ARTICLE 2 LIST OF TERMS

The terms defined below shall apply to this instrument, unless expressly stated otherwise:

“Applicant” means the person whom the records of the Office show, pursuant to the applicable law, as the person who is applying for the granting of a patent, or as another person who is filing or prosecuting the application.

“Application” means an application for granting of a patent.

“Contracting Party” means any State or intergovernmental organization party to this instrument.

“Country of origin of genetic resources” means the country which possesses those genetic resources in *in situ* conditions.

“[Materially/Directly] based on” means that the GRs and/or Associated TK must *have been necessary or material to the development of the claimed invention, and that the claimed invention must depend on the specific properties of the GRs and/or Associated TK.*

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

“Genetic resources²³” (GRs) are genetic material of actual or potential value.

“In situ conditions” means conditions where GRs 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.

“Office” means the authority of a Contracting Party entrusted with the granting of patents.

“PCT” refers to the Patent Cooperation Treaty, 1970.

“Source of Genetic Resources” refers to any source from which the applicant has obtained the GRs, such as a research centre, gene bank, the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), or any other *ex situ* collection or depository of GRs.

“Source of Traditional Knowledge Associated with Genetic Resources” means any source from which the applicant has obtained the traditional knowledge associated with genetic resources, such as scientific literature, publicly accessible databases, patent applications and patent publications.

²³ The definition of “genetic resources” is, in line with the manner in which the term is understood in the context of the CBD, not intended to include “human genetic resources”.

Notes on Article 2

1. The definitions of *genetic resources*, *genetic material*, *country of origin* and *in situ conditions* detailed in the list of terms have been taken directly from existing multilateral agreements relating to the GRs, notably the CBD.
2. The following definitions have not previously been defined at the multilateral level: *materially/directly based on*, *source of genetic resources*, and *source of traditional knowledge associated with genetic resources*.
3. The term “*materially/directly based on*” specifies the relationship between the claimed invention and the GRs and Associated TK which activates the obligation to disclose (referred to in the IGC discussions as the “trigger”).
4. Currently there is a significant divergence in triggers at the national and regional levels e.g. *directly based on*, *based on*, *based on or derived from*, *is the basis of*, *used in an invention*, *invention concerns*, *relates to or makes use of*, *an invention-creation accomplished by relying on genetic resources*. There is also significant ambiguity regarding the meaning of these terms. In order to maximise legal certainty, two amplifying adverbs (*materially/directly*) have been proposed, in addition to the trigger concept “*based on*”, for consideration by Member States, reflecting discussions held during IGC 36 in June 2018. The alternate term “*materially*” has been included as the term “*directly*” has been contentious within the IGC’s deliberations. However, by defining the term in the list of terms it is hoped that this concern has been addressed. An alternative to the inclusion of amplifying adverbs (“*materially/directly*”) in the trigger language is to simply retain the trigger concept “*based on*” and use a definition of “*based on*” to clarify the scope of the trigger.
5. A contentious issue related to the concept of “*directly based on*”, which is included in the proposal of the EU first tabled in 2005²⁴, is the requirement for the inventor to have physically accessed the GRs. This touches on different views within the IGC as to whether or not physical access to a GR is still required by an inventor noting technological advances in this area. To address this difference of view, the definition is now silent on this issue. In addition, it was also proposed by the EU that the definition includes the phrase “*must make immediate use*”. In my view, respectfully, there is a lack of clarity in relation to the meaning of this term. To address this issue, the terms “*necessary*” and “*material to*” have been included to reduce ambiguity. In addition, the phrase “*the claimed invention must depend on the specific properties of the GRs and Associated TK*” is included in the definition.
6. “*Source*” should be understood from its common meaning “*from which something originates or can be obtained*”²⁵. The two definitions relating to GRs and Associated TK simply provide a non-exhaustive list of from where GRs or Associated TK may have been sourced.
7. The definition for *traditional knowledge* is still under discussion within the IGC, as part of the traditional knowledge track of the negotiations and is yet to be agreed, though, in my view, there has been some convergence of views reflected in recent discussions. Nor have any definitions been agreed at the international level in other processes, leaving it to national interpretation. Pending agreement on this matter in the IGC, it is proposed not to define the term at this time and leave it to national interpretation.

²⁴ Document WIPO/GRTKF/IC/8/11.

²⁵ Oxford Dictionary of English (3rd Edition), (2010), OUP Oxford.

ARTICLE 3 DISCLOSURE REQUIREMENT

3.1 Where the claimed invention in a patent application is [*materially/directly*] based on GRs, each Contracting Party shall require applicants to disclose:

- (a) the country of origin of the GRs, or,
- (b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the GRs.

3.2 Where the claimed invention in a patent application is [*materially/directly*] based on Associated TK, each Contracting Party shall require applicants to disclose:

- (a) the indigenous peoples or local community that provided the Associated TK, or,
- (b) in cases where the information in sub paragraph (a) is not known to the applicant, or where sub paragraph (a) does not apply, the source of the Associated TK.

3.3 In cases where none of the information in paragraphs 3.1 and/or 3.2 is known to the applicant, each Contracting Party shall require the applicant to make a declaration to that effect.

3.4 Offices shall provide guidance to patent applicants on how to meet the disclosure requirement as well as an opportunity for patent applicants to rectify a failure to include the minimum information referred to in paragraphs 3.1 and 3.2 or correct any disclosures that are erroneous or incorrect.

3.5 Contracting Parties shall not place an obligation on Offices to verify the authenticity of the disclosure.

3.6 Each Contracting Party shall make the information disclosed available in accordance with patent procedures, without prejudice to the protection of confidential information.

Notes on Article 3

1. Article 3 establishes a mandatory disclosure requirement. To support legal certainty, it is crucial, in my view, that the provisions on a disclosure requirement clarify the following:

- (a) the relationship between the claimed invention and the GRs and Associated TK which activates the obligation to disclose, referred to in the IGC discussions as the “*trigger*”; and,
- (b) the information which needs to be disclosed, referred to in the IGC discussions as the “*content*”.

2. The trigger and the content should be workable in practice and reflect the various circumstances where GRs and Associated TK can be sourced. This means that any disclosure requirement should not lead to obligations for patent applicants which cannot be fulfilled or which can only be fulfilled with unreasonable time and effort and which would, therefore, hinder innovation based on GRs and Associated TK.

Trigger

3. Articles 3.1 and 3.2 clarify the relationship between the claimed invention and the GRs and Associated TK, which activates the obligation to disclose. Accordingly, Articles 3.1 and 3.2 require the invention to be “*materially/directly based on*” one or more GRs and Associated TK.

4. In the context of GRs, the term “*materially/directly based on*” clarifies that the subject matter which is triggering a disclosure are GRs which were necessary or material to the development of the claimed invention. “Based on” includes any GRs that were involved in the development of the invention. The term “*materially/directly*” indicates that there must be a causal link between the invention and the GRs. In practical terms, this means that only those GRs without which the invention could not be made, should be disclosed. Those GRs, which may be involved in the development of the invention but which are not material to the claimed invention, shall not trigger the disclosure requirement. This includes in particular research tools such as experimental animals and plants, yeasts, bacteria, plasmids, and viral vectors, which, while technically GRs, are often standard consumables that may be acquired from commercial suppliers and that do not form part of the claimed invention, and thus need not be disclosed.

5. In the context of Associated TK, “*materially/directly based on*” means that the inventor must have used the TK in developing the claimed invention and the claimed invention must have depended on the TK.

Content of Disclosure

6. Depending on the specific circumstances, Article 3 requires different information to be disclosed in patent applications:

- (a) Paragraphs 3.1 and 3.2 detail the information which should be disclosed, if applicable and if known to the patent applicant.

*In the context of GRs (paragraph 3.1), a Contracting Party shall require the patent applicant to disclose the country of origin of the GRs. In order to ensure mutual supportiveness with other international instruments, in accord with the principles of this instrument, the country of origin should be understood as defined in the CBD, i.e., the country which possesses the GRs in *in situ* conditions. However, many GRs are found *in situ* in more than one country. Therefore, there often exists more than one country of origin for a specific GR. However, according to Article 3.1 (a), what should be disclosed is the specific “country of origin of the GR” (underlining added), i.e. the same GR on which the claimed invention is [*materially/directly*] based, which is the country from which that GR was*

actually obtained (of which there can only be one in respect of each GR).

In the context of Associated TK, a Contracting Party shall require the patent applicant to disclose the indigenous people or local community that provided this knowledge, i.e., the holder of that knowledge from which it was accessed or learned.

- (b) Sub paragraphs 3.1(b) and/or 3.2(b) apply in those cases where the information in sub paragraph 3.1(a) and/or 3.2(a) is not available or these sub-paragraphs do not apply, and thus it is not possible for the patent applicant to disclose this information. For example, GRs in areas beyond national jurisdiction such as the high seas.

In the context of GRs, this may be the case, for instance, if the invention is based on a GR taken from the Multilateral System of the ITPGRFA. It may also provide national flexibility to those Parties that, in accordance with Article 6 paragraph 3 (f) of the Nagoya Protocol, require applicants to disclose the specific indigenous people or local community from which a GR has been sourced. In these cases, which are just examples, the applicable sources will therefore be the Multilateral System of the ITPGRFA or the specific community, respectively.

In the context of Associated TK, sub paragraph 3.2(b) provides flexibility, for instance, if the TK cannot be attributed to a single indigenous people or local community, or if the indigenous people or local community does not wish to be mentioned in the patent application. It would also cover those situations where the TK has been taken from a specific publication, which does not indicate the indigenous people that held the knowledge.

- (c) Paragraph 3.3 applies where none of the information referred to in paragraph 3.1 and/or 3.2 is known to the patent applicant. In these cases, the applicant shall make a declaration that the relevant information is not known. This paragraph is not an alternative to paragraph 3.1 or 3.2, but only applies if the information according to paragraphs 3.1 and/or 3.2 is not known to the patent applicant. That allows patent applicants to still apply for a patent if for justified and very exceptional reasons the relevant information is not known to them e.g., because the provenance of a GR cannot be identified anymore due to the relevant documents having been destroyed by *force majeure*.

7. Paragraph 3.5 specifically states that the Contracting Parties shall place no obligations on patent offices to verify the authenticity of the disclosure. This article is directed at minimising the disclosure regime's transactional cost/burden on patent offices and ensuring it does not create unreasonable processing delays for patent applicants. It also recognises that patent offices do not have the inherent expertise to carry out such actions.

8. A specific scope issue in relation to the disclosure regime is the requirement for an applicant to declare the source of Associated TK if they are aware that the invention was materially/directly based on such TK. I am aware that some members believe that a further in-depth discussion of the concept of TK is needed before including references to TK in a disclosure regime. However, taking into account that other international instruments refer to but do not necessarily define TK, and noting the objectives of this instrument and ongoing developments in this area, this subject matter has been retained.

ARTICLE 4
EXCEPTIONS AND LIMITATIONS

In complying with the obligation set forth in Article 3, Contracting Parties 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 or mutual supportiveness with other instruments.

ARTICLE 5
NON-RETROACTIVITY

Contracting Parties shall not impose the obligations of this instrument in relation to patent applications which have been filed prior to that Contracting Party's ratification of or accession to this instrument, subject to national laws that existed prior to such ratification or accession.

Notes on Article 5

This article recognises that in order to maintain legal certainty within the patent system a non-retroactivity clause is required. However, it also recognises that a number of mandatory disclosure regimes already exist at the national and regional level.

ARTICLE 6 SANCTIONS AND REMEDIES

6.1 Each Contracting Party shall put in place appropriate, effective and proportionate legal, administrative, and/or policy measures to address an applicant's failure to provide the information required in Article 3 of this instrument.

6.2 Each Contracting Party shall provide an applicant an opportunity to rectify a failure to include the minimum information detailed in Article 3 before implementing sanctions or directing remedies.

6.3 Subject to Article 6.4, no Contracting Party shall revoke or render unenforceable a patent solely on the basis of an applicant's failure to disclose the information specified in Article 3 of this instrument.

6.4 Each Contracting Party may provide for post grant sanctions or remedies where there has been fraudulent intent in regard to the disclosure requirement in Article 3 of this instrument, in accordance with its national law.

6.5 Without prejudice to non-compliance as a result of a fraudulent intention as addressed under Article 6.4, Contracting Parties shall put in place adequate dispute mechanisms that allow all parties concerned to reach timely and mutually satisfactory solutions, in accordance with national law.

Notes on Article 6

1. Paragraph 6.1 requires each Party to put in place appropriate and effective legal, administrative and/or policy measures to address non-compliance with the disclosure requirement of Article 3. This provision leaves it up to the Parties to decide which measures are appropriate, effective and proportionate. The measures could include pre-grant sanctions, such as suspending the further processing of a patent application until the disclosure requirement is met, or withdrawing/lapsing the application if the applicant fails or refuses to provide the minimum information required in Article 3 within a time period as determined at the national level. These measures could also include post-grant sanctions, such as fines for wilfully failing to disclose the required information or intentionally providing incorrect information as well as the publication of judicial rulings.
2. Paragraph 6.2 provides for an initial opportunity for an applicant who unintentionally failed to provide the minimum information detailed in Article 3 to address the disclosure requirement. The time period to correct the failure would be determined based on national patent laws. See also Article 3, Paragraph 4.
3. Paragraph 6.3 proposes a ceiling for non-compliance with the disclosure obligations detailed in Article 3. This provision aims to ensure that no patents will be revoked or rendered unenforceable based **solely** on an applicant's failure to provide the information required by Article 3 of this instrument. This is important for ensuring legal certainty for patent applicants. It also facilitates the sharing of benefits, as revoking a patent based on non-compliance with the disclosure requirement would destroy the very basis for benefit-sharing – namely, the patent. This is because the invention protected by the revoked patent would fall into the public domain, and no monetary benefits would be generated through the patent system. Therefore, revoking patents or rendering patents unenforceable would run counter to the stated objective of the instrument for the effective and balanced protection of GRs and Associated TK.
4. Paragraph 6.4 recognises the policy space already inherent in international, regional and national patent regimes for a patent to be revoked or the scope narrowed post grant in extreme cases such as provision of false or fraudulent information, either by the patent office or through legal challenge by a third party. Paragraph 6.5 recognises the serious consequences of revocation of a patent to a provider and user and incorporates a requirement for a dispute resolution mechanism at the national level to allow all parties to reach a mutually agreed solution, such as a negotiated royalty agreement.

ARTICLE 7 INFORMATION SYSTEMS

7.1 Contracting Parties may establish information systems (such as databases) of GRs and Associated TK, in consultation with relevant stakeholders, taking into account their national circumstances.

7.2 The information systems, with appropriate safeguards, should be accessible to Offices for the purposes of search and examination of patent applications.

7.3. In regard to such information systems, the Assembly of the Contracting Parties may establish one or more technical working groups to:

- (a) Develop minimum interoperability standards and structures of information systems content;
- (b) Develop guidelines relating to safeguards;
- (c) Develop principles and modalities related to the sharing of relevant information related to GRs and Associated TK, especially periodicals, digital libraries and databases of information related to GRs and Associated TK, and how WIPO Members should cooperate in the sharing of such information;
- (d) Make recommendations as to the possible establishment of an online portal to be hosted by the International Bureau of WIPO through which Offices would be able to directly access and retrieve data from such national and regional information systems, subject to appropriate safeguards; and,
- (e) Address any other related issue.

ARTICLE 8
RELATIONSHIP WITH OTHER INTERNATIONAL AGREEMENTS

This instrument shall be implemented in a mutually supportive manner with other international agreements relevant to this instrument²⁶.

²⁶ Agreed Statement to Article 8: The Contracting Parties request the Assembly of the International Patent Cooperation Union to consider the need for amendments to the Regulations under the PCT and/or the Administrative Instructions thereunder with a view towards providing an opportunity for applicants who file an international application under the PCT designating a PCT Contracting State which, under its applicable national law, requires the disclosure of GRs and Associated TK, to comply with any formality requirements related to such disclosure requirement either upon filing of the international application, with effect for all such Contracting States, or subsequently, upon entry into the national phase before an Office of any such Contracting State.

ARTICLE 9 REVIEW

The Contracting Parties commit to a review of the scope and contents of this instrument, addressing issues such as the possible extension of the disclosure requirement in Article 3 to other areas of IP and to derivatives and addressing other issues arising from new and emerging technologies that are relevant for the application of this instrument, no later than four years after the entry into force of this instrument.

Notes on Article 9

1. This article is a compromise text developed to address the view of some members that the scope of the instrument should include other IP rights and issues. Notwithstanding this view, members also recognised that the primary commercial use of GRs within the IP system is within the patent system and that further work is required to determine the applicability to other IP rights. In addition, this article attempts to reconcile differences of view regarding the inclusion of derivatives within the scope of the instrument. This would appear to be prudent noting ongoing discussions in other international forums.

2. This approach enables the instrument to be progressed as a foundation instrument with an in-built mechanism to address additional issues within a predetermined time-frame.

[ARTICLE 10²⁷
GENERAL PRINCIPLES ON IMPLEMENTATION

10.1 Contracting Parties undertake to adopt the measures necessary to ensure the application of this instrument.

10.2 Nothing shall prevent Contracting Parties from determining the appropriate method of implementing the provisions of this instrument within their own legal systems and practices.]

²⁷ Note from the Chair: I have adapted the final and administrative clauses (Articles 10 to 20) from other existing WIPO treaties. I recognize that they have not yet been discussed before by the IGC and that they would still need to be formally considered and reviewed by Member States and the WIPO Secretariat. Therefore, each of these articles is bracketed.

**[ARTICLE 11
ASSEMBLY**

11.1 The Contracting Parties shall have an Assembly:

- (a) Each Contracting Party shall be represented in the Assembly by one delegate who may be assisted by alternate delegates, advisors and experts.
- (b) The expenses of each delegation shall be borne by the Contracting Party that has appointed the delegation. The Assembly may ask WIPO to grant financial assistance to facilitate the participation of delegations of Contracting Parties that are regarded as developing countries in conformity with the established practice of the General Assembly of the United Nations or that are countries in transition to a market economy.
- (c) The Assembly shall deal with matters concerning the maintenance and development of this instrument and the application and operation of this instrument. The Assembly shall conduct the review referred to in Article 9 above, and may agree on amendments, protocols and/or annexes to this instrument pursuant to the review. The Assembly may establish one or more technical working groups to advise it on the matters referred to in Articles 7 and 9 above, and on any other matter.
- (d) The Assembly shall perform the function allocated to it under Article 13 in respect of the admission of certain intergovernmental organizations to become party to this instrument.
- (e) Each Contracting Party that is a State shall have one vote and shall vote only in its own name. Any Contracting Party that is an intergovernmental organization may participate in the vote, in place of its Member States, with a number of votes equal to the number of its Member States which are party to this instrument. No such intergovernmental organization shall participate in the vote if any one of its Member States exercises its right to vote and *vice versa*.

11.2 The Assembly shall meet upon convocation by the Director General of WIPO and, in the absence of exceptional circumstances, during the same period and at the same place as the General Assembly of WIPO.

11.3 The Assembly shall endeavour to take its decisions by consensus and shall establish its own rules of procedure, including the convocation of extraordinary sessions, the requirements of a quorum and, subject to the provisions of this instrument, the required majority for various kinds of decisions.]

**A. [ARTICLE 12
INTERNATIONAL BUREAU**

The Secretariat of WIPO shall perform the administrative tasks concerning this instrument.]

**[ARTICLE 13
ELIGIBILITY TO BECOME A PARTY**

13.1 Any Member State of WIPO may become party to this instrument.

13.2 The Assembly may decide to admit any intergovernmental organization to become party to this instrument which declares that it is competent in respect of, and has its own legislation binding on all its Member States on, matters covered by this instrument and that it has been duly authorized, in accordance with its internal procedures, to become party to this instrument.]

**[ARTICLE 14
REVISIONS**

This instrument may only be revised by a diplomatic conference. The convocation of any diplomatic conference shall be decided by the Assembly of Contracting Parties to this instrument.]

**[ARTICLE 15
SIGNATURE**

This instrument shall be open for signature at the Diplomatic Conference in, and thereafter at the headquarters of WIPO by any eligible party for one year after its adoption.]

**[ARTICLE 16
ENTRY INTO FORCE**

This instrument shall enter into force three months after 20 eligible parties referred to in Article 13 have deposited their instruments of ratification or accession.]

**[ARTICLE 17
DENUNCIATION**

This instrument may be denounced by any Contracting Party by notification addressed to the Director General of WIPO. Any denunciation shall take effect one year from the date on which the Director General of WIPO received the notification.]

**[ARTICLE 18
RESERVATIONS**

No reservations to this instrument shall be permitted.]

**[ARTICLE 19
AUTHORITATIVE TEXT**

19.1 This instrument shall be signed in a single original in the English, Arabic, Chinese, French, Russian and Spanish languages, all texts being equally authentic.

19.2 An official text in any language other than those referred to in paragraph 19.1 shall be established by the Director General of WIPO on the request of an interested party, after consultation with all the interested parties. For the purposes of this paragraph, "interested party" means any Member State of WIPO whose official language, or one of whose official languages, is involved and the European Union, and any other intergovernmental organization that may become party to this instrument, if one of its official languages is involved.]

**[ARTICLE 20
DEPOSITARY**

The Director General of WIPO is the depositary of this instrument.]

Done at

[End of Annex IV and of document]