

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

Thirty-Ninth Session
Geneva, March 18 to 22, 2019

THE PROTECTION OF TRADITIONAL KNOWLEDGE: UPDATED DRAFT GAP ANALYSIS

Document prepared by the Secretariat

1. At its Twelfth Session, held in Geneva from February 25 to 29, 2008, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the IGC) decided that the Secretariat would, taking into account the previous work of the IGC, prepare, as a working document for the Thirteenth Session of the IGC, a document that would:
 - (a) describe what obligations, provisions and possibilities already exist at the international level to provide protection for traditional knowledge (TK);
 - (b) describe what gaps exist at the international level, illustrating those gaps, to the extent possible, with specific examples;
 - (c) set out considerations relevant to determining whether those gaps need to be addressed;
 - (d) describe what options exist or might be developed to address any identified gaps, including legal and other options, whether at the international, regional or national level;
 - (e) contain an annex with a matrix corresponding to the items mentioned in sub paragraphs (a) to (d), above.
2. The Secretariat was required to “make explicit the working definitions or other bases upon which its analysis is conducted”.
3. A first draft of the gap analysis on the protection of TK was prepared by the Secretariat at that time and circulated amongst IGC participants for comments. Taking into account

comments received¹, a further draft of the gap analysis was prepared and made available as document WIPO/GRTKF/IC/13/5(b) Rev. for the Thirteenth Session of the IGC, which took place from October 13 to 17, 2008.

4. The same decision had been taken by the Twelfth Session of the IGC at that time concerning traditional cultural expressions (TCEs), so that for the Thirteenth Session of the IGC, there were two draft gap analyses before the IGC, contained in documents WIPO/GRTKF/IC/13/4(b) Rev. (for TCEs) and WIPO/GRTKF/IC/13/5(b) Rev. (for TK).

5. By that stage, the IGC had extensively reviewed legal and policy options for the protection of TK. This review had covered comprehensive analyses of existing national and regional legal mechanisms, panel presentations on diverse national experiences, common elements of protection of TK, case studies, ongoing surveys of the international policy and legal environment, as well as key principles and objectives of the protection of TK that received support in the Committee's earlier sessions. As had been requested by the Committee, this earlier foundational work was summarized in document WIPO/GRTKF/IC/13/5(a), which accompanied the draft gap analysis in document WIPO/GRTKF/IC/13/5(b) Rev.

6. The Thirteenth Session of the IGC in October 2008 did not discuss document WIPO/GRTKF/IC/13/5 (b) Rev. at length² and the decisions of that session only reflect that it "took note" of the document³. The IGC did not decide to consider the document at future sessions.

7. In 2017, the WIPO General Assembly requested the Secretariat to "update the 2008 gap analyses on the existing protection regimes related to TK and TCEs."

8. Pursuant to this decision, Annex I of document WIPO/GRTKF/IC/37/6 comprised an updated draft of the 2008 gap analysis on the protection of TK. The structure, format and contents of the earlier gap analysis were largely unchanged, save where more recent international instruments or legislative or policy developments were reflected. The version was, therefore, as requested by the IGC, essentially an "updating". In particular, changes were made to paragraphs 3-6, 12-13, 15, 16-17, 21-24, 33, 35, 39, 54, 59-61, 66, 71-73, 75, 81-84, 94, 98, 101, 108, 111-113, 117, 122, 125-126, 131, 134, 136, 138, 140, 142 and 147. Annex II provided an updated matrix corresponding to the items mentioned in subparagraphs (a) to (d), above. The same document was re-issued for IGC 38 and is re-issued for this session as well.

9. The updated draft gap analysis and the updated matrix are annexed to the present document.

10. The Committee is invited to consider the updated draft gap analysis and matrix contained in Annexes I and II.

[Annexes follow]

¹ The comments received at that time are still available on the WIPO website at <https://www.wipo.int/tk/en/igc/gap-analyses.html>.

² WIPO/GRTKF/IC/13/11.

³ WIPO/GRTKF/IC/13/DECISIONS.

UPDATED DRAFT GAP ANALYSIS
ON THE PROTECTION OF TRADITIONAL KNOWLEDGE

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I. INTRODUCTION

1. The following document contains the present brief introduction and four sections, corresponding with the elements required in the decision of the Committee at its twelfth session, namely:

- Section II: the working definitions or other bases upon which the analysis is conducted;
- Section III: obligations, provisions and possibilities already existing at the international level to provide protection for traditional knowledge ('TK') (sub-paragraph (a) in the decision);
- Section IV: gaps existing at the international level, illustrating those gaps, to the extent possible, with specific examples (sub-paragraph (b) in the decision);
- Section V: considerations relevant to determining whether those gaps need to be addressed (sub-paragraph (c) in the decision);
- Section VI: what options exist or might be developed to address any identified gaps, including legal and other options, whether at the international, regional or national level (sub-paragraph (d) in the decision).

2. Annex II provides a matrix corresponding to the items mentioned in these sections (i.e. sub-paragraphs (a) to (d) in the Committee's decision).

II. WORKING DEFINITIONS AND OTHER BASES FOR ANALYSIS

(a) Working definitions

3. There is no internationally accepted definition of 'traditional knowledge' as such. Other international instruments refer to related concepts, such as:

- knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity⁴
- TK associated with genetic resources⁵
- traditional knowledge relevant to plant genetic resources for food and agriculture⁶
- cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts⁷
- traditional knowledge relevant to animal breeding and production⁸

⁴ Art 8(j), Convention on Biological Diversity.

⁵ Article 7, 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).

⁶ Art 9.2(a), International Treaty on Plant Genetic Resources for Food and Agriculture.

⁷ Art 31, United Nations Declaration on the Rights of Indigenous Peoples, document WIPO/GRTKF/IC/12/INF/6

⁸ para. 12, Interlaken Declaration on Animal Genetic Resources.

4. This draft gap analysis is required to be prepared for ‘traditional knowledge’ as such, and not any more specific concept such as biodiversity related TK, knowledge relevant to plant or animal genetic resources, or TK held by indigenous peoples (also known as ‘indigenous knowledge’); these more precise concepts may be seen as fitting within the broader concept of ‘traditional knowledge’ as such. However, as a distinct gap analysis is required for ‘traditional cultural expressions,’ this suggests that the analysis should focus on traditional knowledge in the strict sense (TK *stricto sensu*), rather than the broader concept of traditional knowledge that has sometimes been used as a general more descriptive term. Accordingly, for the purposes of this analysis only, the term “traditional knowledge” is taken to refer in general to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills and innovations. This general description of TK is based on the work of the Committee itself.⁹

5. The gap analysis also proceeds on the assumption that in considering gaps in legal protection, a more precise definition of traditional knowledge may be appropriate, since a very general description may leave insufficient clarity for a workable gap analysis. Different criteria for eligibility have been put forward and have been considered by the Committee throughout the years. The following criteria have been distilled from the work of the Committee as characteristics of TK that may make it eligible for legal protection¹⁰:

- (i) generated, preserved and transmitted in a traditional and intergenerational context;
- (ii) distinctively associated with a traditional or indigenous community or people which preserves and transmits it between generations; and
- (iii) integral to the cultural identity of an indigenous or traditional community or people which is recognized as holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility. This relationship may be expressed formally or informally by customary or traditional practices, protocols or laws. The innovative quality of traditional knowledge may also be taken into account.

6. For the purposes of this analysis, to be eligible for protection, rather than being described in general terms as being ‘traditional knowledge,’ it may be necessary for knowledge to be intergenerational in character, to have an objective link with the community of origin, and to have a subjective association within that community, so that it forms part of the community’s own self-identity. Knowledge forms part of a community’s social development.

7. Some specific examples of TK include:

- Traditional medical knowledge – knowledge about the medicinal uses of certain genetic resources, but also knowledge about medical treatments that do not involve the use of genetic resources (such as traditional massage)
- Biodiversity-related knowledge, or knowledge that is ‘relevant for the conservation and sustainable use of biological diversity’¹¹

⁹ Source: Glossary on key terms related to intellectual property and genetic resources, traditional knowledge and traditional cultural expressions, available at: <https://www.wipo.int/tk/en/resources/glossary.html>.

¹⁰ These criteria were taken from article 4 – Eligibility for protection, document WIPO/GRTKF/IC/8/5, “The protection of traditional knowledge: Revised objectives and principles”. Considering that no agreement has been reached and that these criteria are still part of the ongoing negotiations at the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, this reference has not been updated.

Nonetheless, for the most recent draft provisions for the protection of TK, see: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=368218.

¹¹ CBD, 8(j)

- Traditional knowledge relevant to plant genetic resources for food and agriculture¹²
- Traditional knowledge relevant to animal breeding and production.¹³

(b) Other bases upon which analysis is conducted

(i) The concept of 'protection'

8. The gap analysis is required to address 'protection' of TK. To some extent, analyzing gaps in protection naturally requires a concept of what 'protection' means. Protection has been used in a variety of ways in the work of the Committee, ranging from legal protection against unauthorized uses and appropriation of TK (the kind of protection that is normally considered in intellectual property law and policy), and practical forms of safeguarding against loss and dissipation of TK (such as practical initiatives to document and record traditional knowledge systems, as well as legal requirements to safeguard TK against loss – in effect, an obligation to safeguard and conserve TK, as well as the social, intellectual and cultural contexts that support TK systems).

9. To clarify the concept of 'protection' helps to determine such questions as:

- the scope of relevant protection:
 - what subject matter is currently protected (e.g. a patentable invention),
 - what that subject matter is protected against (e.g. against certain uses by third parties),
 - what it is *not* protected against (e.g. patentable inventions are not protected against non-commercial research in many countries),
 - and *how* it is protected (e.g. if protection is limited in time, if it is subject to formalities, or if it is subject to other conditions, such as a requirement for protection of undisclosed information to be dependent on the information having commercial rather than cultural or spiritual value);
- and on the other hand what subject matter is *not* protected (e.g. in many countries mere discoveries or publicly disclosed know-how are not protected).

10. The nature of indigenous innovation and the innovative quality of traditional knowledge systems may also be considered to shed light on gaps in legal protection, given that existing forms and standards of legal protection can overlook innovation in these contexts.

11. The word 'protection' takes on many different meanings in relation to TK. It could in principle include physical protection of records against their degradation or loss (e.g. restoring ancient texts containing TK) and laws requiring or promoting programs to preserve TK. For the purposes of this draft gap analysis, 'protection' is taken to mean the kind of protection that is most often considered in intellectual property contexts, that is to say legal measures that limit the potential use of the protected material by third parties, either by giving the right to prevent their use altogether (exclusive rights), or by setting conditions for their permitted use (e.g. the conditions set by license for a patent, trade secret or trademark, or broader requirements for equitable compensation or a right of acknowledgement). In addition, it has been pointed out in the Committee that TK can be protected through physical means and in some senses of protection can be protected against disappearance by encouraging widespread use, and that – depending on the form of protection required – this may be the most cost effective and long

¹² FAO, IGPRFA 9.2(a)

¹³ Para. 12, Interlaken Declaration on Animal Genetic Resources

lasting means of protection. By this notion of protection, a traditional innovation such as traditional medicine would be 'protected' by encouraging many to practice it, but this is not the conception of protection that generally arises in intellectual property policymaking.

12. Nonetheless, given the difficulty of assessing the gaps in practical initiatives internationally, and in view of the intellectual property focus of the Committee's work, for the purpose of this document, protection is taken to refer to protection against unauthorized use or inequitable exploitation of the protected subject matter. More generally, 'protection' in this sense implies a measure of continuing control or authority over the traditional knowledge in question, with perhaps the right to exclude, or other forms of continuing entitlement linked to the knowledge. This control is to be exercised by the community or someone acting on its behalf. It can be contrasted with public domain status in which the user has no liability or responsibility tracing back to the provider of the knowledge.

13. This does not suggest that this is the only legitimate or significant form of protection, nor the most urgent, but reflects distinctive aspects of the work of the Committee itself. This gap analysis therefore addresses areas that have normally been the focus of intellectual property law and policy. Other international legal systems, such as the Convention on Biological Diversity (the CBD) and the conventions of UNESCO deal with aspects of conservation, preservation and safeguarding traditional knowledge within their specific policy contexts.

- For instance, Article 8(j) of the CBD, under the aegis of *In Situ Conservation*, provides for Parties to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices." The CBD has further provisions concerning the dissemination and promotion of traditional knowledge, referring to protecting and encouraging "use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements" (Article 10), "exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with ... technologies referred to in Article 16, paragraph 1 [and] where feasible, include repatriation of information." (article 17), and cooperation for the development and use of technologies, including indigenous and traditional technologies (article 18).
- The objective of the Nagoya Protocol is the fair and equitable sharing of the benefits arising from the utilization of GRs, thereby contributing to the conservation of biological diversity and the sustainable use of its components (article 1). The Protocol also applies to TK associated with genetic resources and to the benefits arising from the utilization of such knowledge (article 3).
- The 2003 UNESCO Convention for the Safeguarding of the Intangible Cultural Heritage noted that 'no binding multilateral instrument as yet exists for the safeguarding of the intangible cultural heritage' and was concluded 'to safeguard the intangible cultural heritage', defining as including "practices ... knowledge, skills ... that communities, groups and, in some cases, individuals recognize as part of their cultural heritage." Safeguarding is defined as "measures aimed at ensuring the viability of the intangible cultural heritage, including the identification, documentation, research, preservation, protection, promotion, enhancement, transmission, particularly through formal and non-formal education, as well as the revitalization of

the various aspects of such heritage.” Intangible cultural heritage is described as including “knowledge, know-how, skills, practices and representations developed and perpetuated by communities in interaction with their natural environment. ... this domain encompasses numerous areas such as traditional ecological wisdom, indigenous knowledge, ethnobiology, ethnobotany, ethnozoology, traditional healing systems and pharmacopeia...”¹⁴ Examples given include the Andean Cosmivision of the Kallawayaya (Bolivia), which includes a pharmacopeia and traditional medical system.

- Also in the domain of cultural policy instruments, the UNESCO Convention on the Protection and Promotion of the Diversity of Cultural Expressions 2005 defines “protection” as “the adoption of measures aimed at the preservation, safeguarding and enhancement of the diversity of cultural expressions.” It illustrates the linkage of the diffusion of TK with TCE protection in that it recognizes “that the diversity of cultural expressions, including traditional cultural expressions, is an important factor that allows individuals and peoples to express and to share with others their ideas and values.”

14. Recognizing the importance and standing of such existing international instruments, and their important objectives regarding conservation and safeguarding, this gap analysis does not attempt to assess possible gaps in such instruments, which are administered under separate mandates, but, as has been mentioned above, focuses instead on that aspect of legal protection which has been considered most often in IP policymaking and IP law.

15. Commentators on the first draft of this gap analysis have pointed out that this focusing of the gap analysis should not be taken to create the prejudgment that traditional knowledge can be protected under an IP system, noting that there are diverse opinions and concerns regarding the concept of protection that is appropriate. Accordingly, the analysis of gaps is undertaken in a descriptive manner – identifying the existence of a gap in ‘protection’ in this IP sense is not intended to imply that such a gap can or should be filled. Nor does it suggest that what is technically one ‘gap’ should be filled as a priority as against other gaps (including gaps in other forms of protection beyond the sphere of intellectual property law and policy). Accordingly, Section IV seeks to identify gaps as a factual observation, and Section V below sets out considerations that may apply when Member States separately consider whether or not, and if so how, to fill any gaps that are identified.

(ii) Linkage with the TCE gap analysis

16. For the sake of clarity in this gap analysis, and in line with the general operational approach taken in the Committee, TK is distinguished from traditional cultural expressions (TCEs). Some forms of protecting TCEs will have the indirect effect of also protecting TK – for instance, in the protection of recordings of traditional songs and narratives that are used to maintain and pass on TK within a community, or handicrafts that embody distinctive TK methods or know-how. The Andean Cosmivision of the Kallawayaya noted above is a system of medical knowledge that is also incorporated into textiles in the form of motifs by Kallawayaya women. Both aspects of traditional cultures and knowledge systems clearly need attention – both the substance or content of know-how that communities hold, and also the forms of expression used by communities. The kinds of protection of the forms of expression of traditional cultures and cultural heritage are properly dealt with in the updated draft TCE gap analysis (WIPO/GRTKF/IC/37/7), and are only briefly noted in this gap analysis on TK, recognizing the complementarity of these two facets of protection.

¹⁴ <http://www.unesco.org/culture/ich/index.php?pg=56>

(iii) *Diverse characteristics of TK*

17. The following assumptions are made about the general characteristics of TK¹⁵:

- TK may include specific elements of knowledge, including innovations made by a member of a traditional community, or it may include a broader systematic body of knowledge. No assumption is made as to whether ‘traditional knowledge’ should be limited to specific elements of knowledge or a knowledge system.
- No assumption is made as to whether certain TK is necessarily patentable or necessarily not patentable; elements of TK may be either. Simply because an innovation occurs in a traditional context, this does not in itself make it unpatentable (provided the patent is granted to the true inventor, the traditional innovator(s), or to their true successors in title). In other words, the mere fact that certain knowledge is ‘traditional’ does not exclude it from patentability. Even so, there may be legal uncertainty over how to apply the standards of novelty, inventive step and utility for claimed inventions that are TK as such, or derived from TK, or developed within a traditional knowledge system. Further, there may be uncertainty as to how the appropriate applicant should be determined, for instance when patentable TK is developed within a traditional community or other collective.
- TK is not necessarily considered to be publicly disclosed, or undisclosed; it may be either. There may also be legal uncertainty over whether TK disclosed within a local or indigenous community can be considered ‘undisclosed’, or not to be in the public domain.
- TK may be subject to diverse forms of ownership, custodianship, entitlement and equitable interests. These interests may vest with an individual within a community, with a community collectively (whether or not legally recognized as such), or with a state (either in its own right or in trust for individuals or communities). Certain aspects of TK may be identified with a particular individual within a community, even where the body of TK overall is held and maintained by the community as such. Some TK may also be part of the common heritage of mankind and not vested exclusively in a specific community or state.
- *Indigenous knowledge* is identified as a more precise body of knowledge than TK, being developed, maintained and disseminated by indigenous peoples recognized as such. TK may be held by other local and cultural communities who are not recognized as being indigenous. Some approaches to gap analysis may need to address possible differences in treatment between indigenous knowledge and the broader concept of traditional knowledge – noting, for instance, that rights of indigenous peoples relating to traditional knowledge have been identified in an international declaration (discussed below).

(iv) *The nature of ‘gaps’ to be identified*

18. Views are likely to differ as to what is a true ‘gap’ in protection, in part because the term ‘protection’ may have very broad connotations or very precise legal applications. This draft gap analysis deals with these different perspectives by covering a wide range of possibilities for considering what a ‘gap’ should be; these different possible assumptions are made clear in

¹⁵ Also see WIPO/GRTKF/IC/17/INF/9, List and brief technical explanation of various forms in which traditional knowledge may be found, available at:
https://www.wipo.int/edocs/mdocs/sct/en/wipo_grtkf_ic_17/wipo_grtkf_ic_17_inf_9.pdf.

Part IV. In Part IV(c) of the analysis, possible gaps are listed with examples, but it should be recognized that what is a significant 'gap' in the view of some users of the gap analysis will not be considered a gap at all, or not a significant gap, in the view of other users. Accordingly, this gap analysis seeks to identify potential 'gaps' to facilitate policy discussion rather than to make a definitive pronouncement on matters which are the subject of continuing discussions.

19. In particular, a gap in legal protection may be seen as a valuable state of affairs, rather than as necessarily something that must be filled – broadly speaking, a healthy public domain relies on or can be structured by specific 'gaps' in legal protection.

20. At the broadest level, one 'gap' is the lack of any legal mechanism for protecting knowledge as such. Existing legal protection mechanisms address specific forms or aspects of knowledge and in limited ways, such as undisclosed information which has to meet certain conditions to be eligible for protection as a trade secret or through confidentiality, and is then protected in a limited way – for instance, protection doesn't extend to third parties who independently derive the knowledge. Identifying a 'gap' in protection may therefore mean clarifying the scope of subject matter that should be protected, and defining the scope of third party acts that are excluded by the protection, so that third parties know what they may not do.

Gaps in the context of a tiered approach to scope of protection

21. At its Twenty Seventh Session, the IGC introduced for discussion a tiered approach to scope of protection whereby different kinds or levels of rights or measures would be available to rights holders depending on the nature and characteristics of the subject matter, the level of control retained by the beneficiaries and its degree of diffusion. The tiered approach proposes differentiated protection along a spectrum from TK that is available to the general public to TK that is secret or not known outside the community and controlled by the beneficiaries. For example, it posits that exclusive economic rights might be appropriate for some forms of TK (for instance, secret TK), whereas a moral rights-based model might, for example, be appropriate for TK that is publicly available or widely known but still attributable to specific indigenous peoples and local communities.

22. It should be noted that in the context of a tiered approach to scope of protection, the gaps that could be identified at the international level are likely to be different, depending on the determination of the tiers, taking into account elements such as the nature and characteristics of the TK, the level of control retained by the beneficiaries, and their degree of diffusion¹⁶.

III. EXISTING OBLIGATIONS, PROVISIONS AND POSSIBILITIES FOR PROTECTION

23. This section deals with 'obligations, provisions and possibilities that already exist at the international level to provide protection'. The analysis considers in detail the form of protection available in accordance with the main international instruments in the general field of intellectual property protection, and in less detail the international instruments in other fields of public international law that refer directly to traditional knowledge and its protection. For the sake of brevity and clarity, it does not analyse or discuss the specific legal instruments directly (these have been extensively discussed in the Committee's previous documentation). In addition, reference is made to various international legal instruments and recent developments such as the UN Declaration on the Right of Indigenous Peoples, the Interlaken Declaration on Animal Genetic Resources and the Nagoya Protocol. These are cited purely to illustrate areas of current international policy interest. No attempt is made to analyse legal texts, nor to attribute legal status to any text.

¹⁶ See: Information Note for IGC 31 and Information Note for IGC 32, prepared by Mr. Ian Goss, the IGC Chair.

(a) Protection under existing international instruments in the field of intellectual property

General observations

24. On the general applicability of conventional IP to TK subject matter, any general approach to the IP protection of this subject matter, including its international dimension, could necessarily entail consideration of what legal tools and mechanisms are required at the national level, how they should operate, and what legal and operational contributions the international dimension can make to protection at the national level, noting that IP rights systems are not sufficient to cater to the holistic and unique character of TK subject-matter. Several measures, as well as conventional IP law, have recognized elements of such customary law within a broader framework of protection. Economic aspects of development need to be addressed and the effective participation by TK holders is also important, in line with the principle of prior informed consent holders. Even so, existing IP laws have been successfully used to protect against some forms of misuse and misappropriation of TK, including through the laws of patents, trademarks, geographical indications, industrial designs, and trade secrets¹⁷.

(i) *Positive patent protection of TK*

International instruments referred to: World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Patent Cooperation Treaty (PCT).
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25. While considerable flexibility and differences exist in their interpretation and application at the national level, in general international patent law standards would allow for patent protection to be extended to specific innovations developed within a traditional context, provided that they are:

- novel or new;
- inventive or non-obvious;
- useful or industrially applicable; and
- generally meet the definition of 'invention'.

26. None of these criteria is formally defined in a binding legal manner in international instruments. Accordingly, their application to traditional knowledge is a matter of potential flexibility within national law.

27. Flexibility exists concerning the definition of 'invention' as against a discovery, which may, for example, be relevant for TK that is considered to be a discovery of a principle of nature rather than an invention as such.

28. Flexibility exists as to whether TK should be considered inherently patentable subject matter in the event that the traditional knowledge constitutes:

- an invention, the prevention of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that this exclusion is not made merely because the exploitation of the invention is prohibited by their law; or
- a diagnostic, therapeutic and surgical method for the treatment of humans or animals;

¹⁷ See: WIPO (2017) Protect and promote your culture: A practical guide to intellectual property for indigenous peoples and local communities, available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1048.pdf. Also see WIPO/GRTKF/IC/17/INF/9, List and brief technical explanation of various forms in which traditional knowledge may be found, available at: https://www.wipo.int/edocs/mdocs/sct/en/wipo_grtkf_ic_17/wipo_grtkf_ic_17_inf_9.pdf.

- a plant or animal other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

29. Flexibility also exists as to how conventional patentability criteria are construed in relation to traditional knowledge – in particular, novelty (e.g. whether oral traditions passed on relatively privately within an indigenous or local community are considered to be disclosed prior art relevant to the determination of patentable novelty) and non-obviousness (for example, whether a practitioner of a traditional knowledge system would be considered a person skilled in the art for the assessment of obviousness).

30. Also, the observation that a practitioner of traditional knowledge has developed an innovation that would be considered patentable clearly does not imply that the practitioner would necessarily wish it to be patented, or would have the necessary resources to proceed with the patenting process; in other words, being patentable in principle does not mean TK is actually *patented*. The lack of practical use of the patent system, or a choice not to use it because the form of protection is out of line with TK holders' requirements, may also be viewed as a 'gap' in protection, even where some elements of TK are technically patentable. However, in making a gap analysis, a distinction may be needed between a formal gap in the legal scope of possible protection in principle, and a practical gap in the sense of the omission to seek possible protection for specific elements of TK – in other words, the extent to which TK that is already *eligible* for protection in some way is *actually* protected in practice. Since the latter form of gap analysis entails extensive empirical field work, it is not undertaken here. Nonetheless the Committee has conducted extensive surveys in this regard.¹⁸¹⁹

(ii) *Defensive protection of TK within the patent system*

International instruments referred to: PCT, International Patent Classification

31. Defensive protection concerns measures to forestall or to reverse the illegitimate grant of patents over elements of TK. The protection of TK within the patent system has more frequently been considered from a defensive point of view, rather than in terms of positively seeking patents over TK. Existing obligations, provisions and possibilities at the international level are directly relevant to defensive protection. These include legal and practical defensive measures within conventional patent law, as well as proposals to revise international patent law standards to create specific disclosure measures regarding TK (in conjunction with genetic resources).

32. Defensive protection of TK within existing international patent law standards includes the following measures:

- The right of the inventor to be mentioned as such in a patent, as established under the Paris Convention.
- The expansion of PCT minimum documentation to include a range of traditional knowledge publications. This has the effect of ensuring that significant amounts of already published traditional knowledge will systematically be taken into account at an

¹⁸ See, for example, documents WIPO/GRTKF/IC/5/7 and WIPO/GRTKF/IC/5/8, and the surveys and questionnaires that they draw upon.

¹⁹ WIPO's publication "Protect and promote your culture: A practical guide to intellectual property for indigenous peoples and local communities", includes two examples of patents granted to indigenous peoples and local communities for innovations developed using TK. TK as such was not patented, new and inventive innovations developed using TK were patented.

early stage in the life of many patents, and will be included in published international search reports before a patent application even enters the national phase.

- The revision of the International Patent Classification in 2006 to extend and focus its coverage of a specific type of traditional knowledge related material, namely “medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants, or derivatives thereof, e.g. traditional herbal medicines” (A61K 36/00). This revision recognizes the intellectual and technological importance of traditional knowledge systems. It increases the likelihood that relevant TK related documents will be located during patent search procedures, thus increasing the practical basis for defensive protection of TK.

33. The Committee has developed the following standards and guidelines that are not formally contained within existing international patent law standards, but however are relevant for defensive protection:

- Adoption by the Committee of standards for documentation of traditional knowledge, standards that recognize the need to record and respect the conditions of access to and use of documented traditional knowledge²⁰.
- Preparation within the Committee of guidelines for examination of TK-related patents, the application of which would significantly enhance the likelihood that illegitimate patents would not be granted over traditional knowledge.

34. A further measure, present in some national laws but not in international standards, entails requiring the applicant for the patent to disclose information, including its source, that is material to patentability of the invention.

35. Further initiatives, aim to ensure that patent search and examination procedures have full access to existing TK, to ensure a richer base from which to assess patentability, but without precipitating unwanted disclosure and dissemination of TK contrary to the wishes of the original providers of TK.

(iii) TK-specific disclosure requirements

36. With the aim of strengthening the defensive protection of TK, in the sense of avoiding patents on inventions making use of TK that are either not novel or lack prior informed consent or equitable benefit sharing from the use of TK, a number of countries have introduced measures in their national laws requiring specific forms of disclosure relating to traditional knowledge and genetic or biological resources used in the claimed invention²¹. A number of proposals have been submitted within the WTO and within WIPO for strengthened international patent law standards to incorporate such disclosure requirements. Such mechanisms represent a significant form of defensive protection of TK, and are thus relevant to the present analysis. For the present, none have been adopted internationally in the form of binding law²². However, the Bonn Guidelines, which are not binding but may be considered ‘provisions’ or ‘possibilities’ in the terms of reference for this analysis, encourage CBD Contracting Parties to consider:

²⁰ See document WIPO/GRTKF/IC/4/14, available at: https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_4/wipo_grtkf_ic_4_14.pdf.

²¹ See WIPO’s publication “Key questions on patent disclosure requirements for genetic resources and traditional knowledge”, 2017, available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047.pdf.

²² The Nagoya Protocol does not include any reference to disclosure requirements.

- Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights.

37. The range of 'provisions' or 'possibilities' have been explored in some detail in two studies prepared by WIPO at the invitation of the CBD.²³

38. In addition, it has been pointed out that the Bonn Guidelines, in identifying this measure, sets it in the context of a range of other legal, administrative or policy measures concerning users of genetic resources, in particular mechanisms to provide information to potential users on their obligations regarding access to genetic resources; measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources; cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements; voluntary certification schemes for institutions abiding by rules on access and benefit-sharing; and measures discouraging unfair trade practices.²⁴ For the most part, these do not directly concern the law and practice of intellectual property, although unfair trade practices are to some extent suppressed through the law of unfair competition (discussed separately in this gap analysis).

39. Considerable divergence of opinion has been expressed, including in comments made on an earlier draft of this gap analysis, about the necessity and value of such disclosure requirements that are specific to TK, and whether citing this kind of provision is a judgment as to its value. No attempt is made in the gap analysis to evaluate such requirements from a policy perspective, but the discussion below does identify the objective, factual absence of an international standard as a 'gap' in a formal sense, since it is a form of protection introduced in some countries which is absent from international standards.

(iv) *Undisclosed TK*

International instruments referred to: Paris Convention for the Protection of Industrial Property (Paris Convention), TRIPS

40. Where TK has not been publicly disclosed, it may be covered by the existing international standards governing the protection of undisclosed or confidential information. The general international minimum standards, set by the WTO TRIPS Agreement, require that to be protected, information should:

- be secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- have commercial value because it is secret; and
- have been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

41. Protection extends to information "being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices," which is defined as meaning "at least practices such as breach of contract, breach of confidence and inducement to

²³ These studies are available at: https://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_32/wo_ga_32_8.pdf and https://www.wipo.int/edocs/pubdocs/en/tk/786/wipo_pub_786.pdf.

²⁴ Bonn Guidelines, 16(d)

breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.” This is potentially relevant to much traditional knowledge, where it is not necessarily the original person who accessed the information, but a downstream commercial or industrial interest, who actually commercializes the TK.

42. This international standard is described as a means of ‘ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967).’ The duration of protection is effectively unlimited, provided the conditions remain (for instance, protection would not be available after the holder of the knowledge publicly disclosed it).

43. This international standard would clearly apply to considerable amounts of traditional knowledge, but equally clearly considerable amounts would not be covered. Some of the considerations that could arise in applying this standard include:

- when would TK disclosed within a defined traditional community still be considered to be ‘secret’?
- what is the possible role of the customary law or customary practices of a community in determining whether the conditions for protection apply? (For example, in the case, often cited before the Committee, of *Foster v Mountford*,²⁵ the customary law of an indigenous community was considered sufficient to establish an obligation of confidentiality)
- would knowledge that has spiritual and cultural value to the community, but not commercial value for the community, still be protected when a third party realizes commercial benefit in their terms? In other words, if a community keeps TK secret for spiritual and non-commercial reasons, and indeed actively rejects the idea that the TK should be valued commercially, would it still be protected as undisclosed information?

44. As this is a minimum standard, possibilities exist for broader forms of protection under national law that would ensure, for instance, that TK only disseminated within a specific community could still be recognized as undisclosed and thus subject to protection. The spiritual and cultural value of knowledge could also be considered a relevant factor (so that commercial value alone may not be necessary for protection), and the role of customary law could be recognized (for instance, in establishing the ‘reasonable steps to protect’).

(v) *Unfair competition*

International instruments referred to: Paris Convention, TRIPS
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45. The Paris Convention requires “effective protection against unfair competition,” stipulating that “[a]ny act of competition contrary to honest practices in industrial or commercial matters constitutes an act of unfair competition.” This conception of unfair competition is therefore expressed in general terms, but there is a specific focus on:

- acts that create confusion with the establishment, goods or industrial or commercial activities of a competitor;
- false allegations in the course of trade to discredit a competitor’s establishment, goods, or industrial or commercial activities;

²⁵ E.g. *IP Needs And Expectations Of Traditional Knowledge Holders: WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999)*, WIPO, 2001. p 75

- indications or allegations liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of goods.

46. These more precise characterizations of unfair competition would apply, for instance, to acts of commercializing TK-related products that falsely or confusingly suggest that they are genuine products of an indigenous or local community when they are not, or falsely or confusingly suggest they are endorsed or authorized by such a community²⁶.

47. One possible reading of these international standards (which are also given effect through the TRIPS Agreement) is that they could cover broader forms of protection, beyond the specific acts of confusing, false or misleading representations cited in particular. According to one commentary on this provision:

What is to be understood by 'competition' will be determined in each country according to its own concepts: countries may extend the notion of acts of unfair competition to acts which are not competitive in a narrow sense ... Any act of competition will have to be considered unfair if it is contrary to honest practices in industrial or commercial matters. This criterion is not limited to honest practices existing in the country where protection against unfair competition is sought. The judicial or administrative authorities of such country will therefore also have to take into account honest practices established in international trade. If a judicial or administrative authority of the country where protection is sought finds that an act complained of is contrary to honest practices in industrial or commercial matters, it will be obliged to hold such act to be an act of unfair competition and to apply the sanctions and remedies provided by its national law. A wide variety of acts may correspond to the above criteria.²⁷

48. Accordingly, it may be possible to read into this provision protection against other forms of use of traditional knowledge that are considered to be contrary to honest practices. It remains a possibility to determine at national level that acts of unfair competition can include unjust enrichment from the use of traditional knowledge and deriving commercial benefit from illicitly acquired TK.

49. Many national laws on unfair competition suppress other forms of commercial behaviour, apart from acts that create confusion or false or misleading allegations. They also deal with unfair business practices such as forming monopolies and other forms of use of traditional knowledge that may be considered honest, but not fair competition, such as predatory pricing.

(vi) *Distinctive signs*

International instruments referred to: TRIPS, Madrid Agreement and Protocol, Lisbon Agreement on Protection of Appellations of Origin, Paris Convention

50. The protection of distinctive signs under international instruments includes:

- conventional trademarks (including service marks)
- certification and collective marks
- geographical indications.

²⁶ See examples in WIPO's *Protect and promote your culture: A practical guide to intellectual property for indigenous peoples and local communities*, page 57.

²⁷ G.H.C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property* (1968), at 144 (footnote omitted).

51. Such protection cannot protect knowledge as such. However, it can indirectly provide protection, by providing a means of protecting distinctive signs, symbols, motifs and geographical indications, as well as providing certification of community endorsement or authenticity, when these are applied to products and services based on or using traditional knowledge.

52. Such distinctive signs can also be defensively protected through these legal mechanisms, in particular through the opposition or legal challenge of registrations that amount to a misleading or deceptive use of TK-related signs, symbols, or words, or TK-related geographical references²⁸. International standards apply for refusal or invalidation of marks that are contrary to morality or public order. In some cases, these prohibitions have been applied to refuse or revoke trademarks that would create cultural or spiritual offence to indigenous communities. (See the updated draft TCE gap analysis for discussion of defensive protection of TCEs in the trademark system²⁹).

(vii) Industrial design law

International instruments referred to: TRIPS, Berne Convention, The Hague Agreement Concerning the International Deposit of Industrial Designs, Paris Convention

53. Protection of designs does not address the content of knowledge as such, and is more relevant to the protection of traditional cultural expressions than for TK (see the complementary updated draft gap analysis on TCEs). Nonetheless, international standards on design protection may provide some indirect protection for some TK, particularly when designs are closely associated with a particular TK system, such as a way of producing tools, musical instruments or handicrafts. Protection is available for industrial designs that are new or original, but it is possible to exclude protection for designs dictated essentially by technical or functional considerations.

54. A proposal concerning the possibility to require, as an element of an application, a disclosure of the origin or source of TCEs, TK or biological/genetic resources utilized or incorporated in an industrial design has been put forward by some Member States in the context of the draft Design Law Treaty.³⁰

(viii) Copyright and related law

International instruments referred to: TRIPS, Berne, WIPO Performances and Phonograms Treaty (WPPT)

²⁸ New Zealand and the Andean Community have adopted specific provisions that do not allow the registration of trademarks that include the names or expressions of the culture of indigenous peoples, unless the trademark applications are filed by the indigenous people or with their consent. See further information in examples in WIPO's Protect and Promote your Culture: A practical guide to intellectual property for indigenous peoples and local communities, page 44.

²⁹ Document WIPO/GRTKF/IC/37/7, Annex: Part II "The meaning of gaps" para 34; Part III A "Indigenous and traditional names, words and symbols" paras 58 and 59; Part III B "Indigenous and traditional names, words and symbols" paras 71 to 75; and Part III D "Use of distinctive signs and unfair competition principles to combat misappropriation of reputation associated with TCEs ("style")" para 101; and Part III D "Indigenous and traditional names, words and symbols" para 113.

³⁰ SCT/35/2.

55. Protection of copyright deals with the form of expression and does not address the content of knowledge as such, and it is therefore more relevant to the protection of traditional cultural expressions than for TK (see the complementary updated draft gap analysis on TCEs, document WIPO/GRTKF/IC/37/7). Nonetheless, international standards on copyright and related rights may be seen as one way of providing indirect protection of TK. In particular, copyright may apply to descriptions of TK included in a database, as well as compilations of TK which are protected as compilations when they “by reason of the selection or arrangement of their contents constitute intellectual creations.” However, such indirect protection of TK through copyright would not extend to the content of the TK as such; hence the know-how and substantive content of TK could be taken and used by third parties even if included in a copyright protected database.

56. In general, when TK is communicated through TCEs, the protection of TCEs may be seen as an indirect protection of the TK (for instance, a sound recording of a traditional performance used to transmit TK within a community can be protected as a recording of a TCE; this would limit the distribution of and access to the recording, which indirectly would limit access to and dissemination of the TK communicated through the TCE); for details, see the complementary updated draft gap analysis on TCEs.

(b) Within other areas of public international law

57. The present gap analysis concentrates on international standards specifically concerning intellectual property law and its relationship with TK. However, broader standards of public international law, such as environmental protection, plant genetic resources and indigenous peoples’ rights may be considered relevant to the general international legal and policy framework. These standards are briefly reviewed here.

International instruments referred to: Convention on Biological Diversity (CBD), Nagoya Protocol, FAO International Treaty, United Nations Convention to Combat Desertification (UNCCD)

(i) Convention on Biological Diversity

58. A specific domain of traditional knowledge, namely knowledge relevant for the conservation and sustainable use of biological diversity, is governed by the Convention on Biological Diversity, which requires that a Contracting Party shall:

Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

(ii) Nagoya Protocol

59. Article 7 of the Nagoya Protocol provides the following:

“In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent

or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.”

60. Article 5.5 is also relevant in this context:

“Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.”

61. Moreover, article 16 provides the following:

“1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.

2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.”

(iii) FAO International Treaty

62. Similarly dealing with another domain of traditional knowledge, namely knowledge relevant to plant genetic resources for food and agriculture, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) provides that “each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers’ Rights, including: (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture; (...)”³¹

(iv) UN Desertification Convention

63. The United Nations Convention to Combat Desertification (UNCCD) provides that Parties shall protect, promote and use relevant traditional and local technology, know-how, and practices and, to that end, undertake to “make inventories of such technology, knowledge, know-how and practices and their potential uses with the participation of local populations, and disseminate such information, where appropriate, in cooperation with relevant intergovernmental and non-governmental organizations” (Article 18.2(a)). It provides further that regional activities may include “preparing inventories of technologies, knowledge, know-how and practices, as well as traditional and local technologies and know-how, and promoting their dissemination and use” (Article 6(b) of Annex II).

(c) Other international texts

International texts referred to: CBD Bonn Guidelines, Declaration on the Rights of Indigenous Peoples, Interlaken Declaration on Animal Genetic Resources

³¹ Article 9 – Farmers’ rights, ITPGRFA.

(i) *Bonn Guidelines*

64. *The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization* are described in the Executive Secretary's Introduction to the Guidelines as 'not legally binding ... [but were adopted unanimously by some 180 countries and as having] a clear and indisputable authority' provide for some protection of traditional knowledge in recommending that '[p]roviders should: ... Only supply genetic resources and/or traditional knowledge when they are entitled to do so' and that 'Contracting Parties with users of genetic resources under their jurisdiction ... could consider, inter alia... [m]easures to encourage the disclosure of the country ... of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights'

65. The objective of the Guidelines is to "contribute toward the development of access and benefit regimes that recognize the protection of traditional knowledge" (Paragraph 11(j)) and the Guidelines encourage "cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements" which may be relevant to TK.

(ii) *Declaration on the Rights of Indigenous Peoples*

66. Traditional knowledge held by indigenous peoples as such is covered by the United Nations Declaration on the Rights of Indigenous Peoples,³² which as a declaration may be considered a 'provision' or 'possibility' existing at the international level, although some commentators point out that the Declaration is legally non-binding, was not adopted by consensus and characterize it 'as a source that reflects the aspirations of indigenous peoples.' Article 31 of the Declaration stipulates that:

Indigenous peoples have the right to maintain, control, protect and develop their ... traditional knowledge (...), as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such (...) traditional knowledge (...).

67. It further provides that '[i]n conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.'

(iii) *Interlaken Declaration on Animal Genetic Resources*

68. The Interlaken Declaration on Animal Genetic Resources, adopted by the International Technical Conference on Animal Genetic Resources for Food and Agriculture on September 7, 2007 "affirm[s] the desirability, as appropriate, subject to national legislation, of respecting, preserving and maintaining traditional knowledge relevant to animal breeding and production as a contribution to sustainable livelihoods[.]" Linked to the Declaration is the Global Plan of Action for Animal Genetic Resources which aims, among other things, "to promote a fair and equitable sharing of the benefits arising from the use of animal genetic resources for food and agriculture, and recognize the role of traditional knowledge, innovations and practices relevant to the conservation of animal genetic resources and their sustainable use, and, where appropriate, put in place effective policies and legislative measures."

³² WIPO/GRTKF/IC/12/INF/6 (February 15, 2008), adopted by the United Nations General Assembly in 2007.

IV. GAPS EXISTING AT THE INTERNATIONAL LEVEL

illustrating those gaps, to the extent possible, with specific examples;

69. In considering the protection of TK at the international level, possible ‘gaps’ are considered at two levels:

- gaps in the *objectives* of protection expressed at the international level
- gaps in the international *legal mechanisms* that have been established to address such objectives

70. However, a preliminary consideration is the scope of the concept of ‘traditional knowledge’ that is the subject of gap analysis, and this is considered first.

(a) Gaps in the definition or identification of TK to be protected

71. The working assumptions upon which this gap analysis is based, drawing in turn on the Committee’s own extensive review of these questions, include the following distinctions:

(i) The distinction between:

- ‘traditional knowledge’ as a broad description of subject matter, generally the intellectual and intangible cultural heritage, practices and knowledge systems of traditional communities, including indigenous and local communities (TK in a general sense or *lato sensu*), and
- ‘traditional knowledge’ as the specific subject of rights and entitlements, with a more precise focus as the content and substance of knowledge as such (TK in a precise sense or *stricto sensu*), to be distinguished for example from traditional cultural expressions (TCEs)/expressions of folklore.

(ii) *The distinction between:*

- what can be generally characterized as TK, and
- those elements of TK that are or should be especially subject to legal protection.

72. In line with the working assumptions above, the work of the Committee has applied these distinctions. Concerning the first distinction ((i) immediately above), the term “traditional knowledge” is used in the more precise sense as referring to:

Knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, skills and innovations.³³

73. TK in this sense is broader than the more specific areas of knowledge (medicinal, biodiversity-related, associated with genetic resources or relating to plant genetic resources) identified in other areas of public international law and policy.

74. Concerning the second distinction ((ii) immediately above), the Committee has considered at length the principle that in order to be *protected* through specific legal mechanisms, TK may need to be:

³³ Source: Glossary on key terms.

- (i) generated, preserved and transmitted in a traditional and intergenerational context;
- (ii) distinctively associated with a traditional or indigenous community or people which preserves and transmits it between generations; and
- (iii) integral to the cultural identity of an indigenous or traditional community or people which is recognized as holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility. This relationship may be expressed formally or informally by customary or traditional practices, protocols or laws.³⁴

75. For the purposes of this analysis, this would mean that, to be eligible for protection, more than simply being described in general terms as being 'traditional knowledge,' knowledge should be intergenerational in character, should have an objective link with the community of origin, and should have a subjective association within that community, so that it forms part of the community's own self-identity.

(b) Gaps in the objectives or policy rationales of protection:

76. Part of the analysis of any legal system is the consideration of the objectives or rationale of the system. Accordingly, a gap analysis may need to consider those common objectives that could be expressed at the international level, but have not so far been expressed in a formal sense. Policy objectives that have not been formally expressed or affirmed at the international level in relation to intellectual property and TK include the following:

- Recognizing the intrinsic value of traditional knowledge systems, and their contribution to conservation of the environment, food security and sustainable agriculture, and the progress of science and technology;
- Recognizing that traditional knowledge systems are valuable forms of innovation
- Promoting respect for traditional knowledge systems and the cultural and spiritual values of the holders of traditional knowledge
- Respecting the rights of holders and custodians of traditional knowledge
- Promoting conservation and preservation of traditional knowledge
- Strengthening traditional knowledge systems, including supporting continuing the customary use, development, exchange and transmission of traditional knowledge;
- Supporting continuing innovation within traditional knowledge systems and encouraging innovation derived from the traditional knowledge base;
- Supporting the safeguarding and preservation of traditional knowledge;
- Repress misappropriation and unfair and inequitable uses of traditional knowledge, and promoting equitable benefit-sharing from traditional knowledge;

³⁴ Note: Document WIPO/GRTKF/IC/13/5(b) Rev. was prepared using as reference document WIPO/GRTKF/IC/8/5, The protection of traditional knowledge: Revised objectives and principles. Considering the ongoing negotiations at the IGC, this reference has not been updated.

- Ensuring that access and use of traditional knowledge is subject to prior informed consent;³⁵
- Promoting sustainable community development and legitimate trading activities based on traditional knowledge systems;
- Curtailing the grant or exercise of improper intellectual property rights over traditional knowledge

77. This is a distillation of objectives that have been put forward in international debate, including in the Committee. These objectives have not been adopted in any formal sense and may not attract consensus. Nonetheless, several of these general objectives are addressed to some extent through existing international instruments, even though these instruments only address a subset of the full range of traditional knowledge – for example, the CBD promotes respect for and preservation of TK relevant for the conservation and sustainable use of biodiversity, but doesn't expressly address other forms of TK such as codified medical knowledge systems. The FAO ITPGRFA recognizes "the enormous contribution that the local and indigenous communities and farmers ... have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world."

78. Policy guidance regarding international objectives may be given by the legally non-binding Declaration on the Rights of Indigenous Peoples. The Declaration articulates the rights of indigenous peoples in particular (in contrast with other holders of traditional knowledge) to "maintain, control, protect and develop their ... traditional knowledge" and "to maintain, control, protect and develop their intellectual property over such ... traditional knowledge", with the range of TK referred to being broader in scope than in other existing instruments.

(c) Gaps in the existing legal mechanisms

79. Intellectual property protection, in its precise legal sense, consists of defining the entitlement of the right holder to object to others' use of the protected material, or at least to derive an equitable benefit from its use, as well as rights to object to lack of acknowledgement or distortion (loss of integrity). In other words, protection consists in giving the right holder the authority to prevent unwanted forms of use or distribution of knowledge, or illicit access to it, or else an entitlement to receive equitable remuneration (including a compensatory liability regime). Intellectual property protection therefore concentrates on the rights to object to or to prevent a third party's way of using the protected material.

80. Therefore, gaps in protection of TK in specific legal mechanisms can be characterized in terms of:

- (i) subject matter not covered under existing IP law;
- (ii) right holders not recognized as such, and other beneficiaries excluded from the benefits of protection;
- (iii) forms of use and other actions that cannot be prevented;
- (iv) absence of entitlement to obtain remuneration or other benefits.

³⁵ Or "prior, free and informed consent" as set out in the *United Nations Declaration on the Rights of Indigenous Peoples*

81. However, analysis of such potential gaps is necessarily dependent on a full survey of the possibilities for protection of TK through existing IP law. The Committee has extensively reviewed these possibilities, including on the basis of detailed Member State surveys, and has reviewed these options as set out in a number of substantive documents (listed in document WIPO/GRTKF/IC/13/5(a)); these are not reproduced in the current document but may be considered as relevant to this gap analysis; see for example:

- policy options and legal mechanisms, set out in WIPO/GRTKF/IC/7/6 and WIPO/GRTKF/IC/9/INF/5
- surveys, reports and comparative analysis of protection of TK at national, regional and international levels contained in WIPO/GRTKF/IC/3/7, WIPO/GRTKF/IC/3/8, WIPO/GRTKF/IC/3/9, WIPO/GRTKF/IC/4/7, WIPO/GRTKF/IC/4/8, WIPO/GRTKF/IC/5/7, WIPO/GRTKF/IC/5/8, and WIPO/GRTKF/IC/6/4.

(i) Subject matter not covered under existing IP law

TK that is not covered by existing forms of IP protection.

82. Introduction: A gap can clearly be identified for that traditional knowledge which is excluded from the conventional forms of IP that are identified in III(a) above. In some cases, such TK may be protected under existing national IP laws within the flexibilities provided under international IP law. But an indicative list of such unprotected knowledge would logically include:

- TK which is considered not novel, by virtue of having being disclosed to the public in a relevant manner;
- TK which is considered obvious, including obvious to persons skilled in the relevant art, which may include practitioners or holders of traditional knowledge, as persons skilled in the relevant art, with reference to other knowledge already available to the relevant public;
- TK which has been publicly disclosed and otherwise doesn't meet the criteria for protection of confidential information, trade secrets, or undisclosed information

Innovation that is cumulative and collective over generations within the one community

83. Introduction: One characteristic of traditional knowledge as defined for the purposes of this analysis is that it is developed and evolves over generations within the one community. Some elements of TK are developed by individuals within the community, and they may have specific entitlements within the community as well as responsibilities to that same community. But, on the whole, protection of TK relates to the protection of cumulative knowledge that is collectively held, unless it is considered undisclosed or confidential information.

84. Such knowledge may be considered to be covered by the CBD (TK related to the conservation and sustainable use of biodiversity), the Nagoya Protocol (TK associated with genetic resources) and the FAO (TK related to plant genetic resources), with an obligation to protect expressed in broad terms. These provisions don't cover TK in the broader sense, but define it in relation to specific policy goals of these instruments.

85. Protection in the form of trademarks or geographical indications may be collectively held and may protect intergenerational traditional knowledge in effective ways, without the TK meeting criteria for undisclosed or confidential information. Similarly, such mechanisms may be viewed as being applicable to protecting systems of knowledge, and a number of mechanisms to preserve, promote and protect TK exist in the current IP system and extend widely to many different forms or expressions of this knowledge.

86. Gap: Protection does not extend to cumulative, collectively held and intergenerational traditional knowledge, unless it meets criteria for undisclosed or confidential information. Direct means do not exist to protect such traditional knowledge as an object of protection in itself, although forms of IP protection relevant to TK are available, such as protection of geographical indications and distinctive marks and signs traditionally associated with the knowledge.

87. Gap: Intellectual property protection does not extend to an integrated traditional knowledge system as such, in the sense of preventing the appropriation of a distinct system of knowledge. IP protection may extend to certain, isolated elements of knowledge within a TK system, and may protect distinctive reputations, signs and marks associated with knowledge systems, and can protect misleading references to knowledge systems including through the certification of authenticity.

88. Gap: The term of protection applicable in most forms of IP protection is relatively limited compared to the intergenerational timeframe in which TK is developed and might not be adequate to ensure the due preservation of TK. Thus the limited duration of protection may be considered a gap.

89. Example: A community has developed a range of useful applications for a medicinal plant, and has developed a systematic understanding of how that plant should be cultivated, harvested and then used (including in synergistic combination with other plant extracts) to treat a range of diseases. This system of knowledge is distinctively associated with that community and is maintained within the community through customary practices. International standards do not allow for this community to prevent others from taking and using elements of this knowledge for industrial and commercial use without any acknowledgement and without providing equitable benefits in return (apart from elements of that knowledge which are patented or comply with the criteria for undisclosed information). Available forms of protection, where they apply at all, generally do not endure for a period of time relevant to the intergenerational context and the need to preserve traditional knowledge systems. Aspects of the community's use of the medicinal plant may be protected through related means, such as through protection of the community's name in association with the plant and its medical uses, or through systems for certification of the community's approval or participation in the commercialization of their knowledge.

(ii) Beneficiaries or right holders not recognized

Recognition of collective rights, interests and entitlements within a TK system

90. Introduction: Current legal mechanisms typically base the entitlement of IP rights on an individual or small group of individuals (such as a recognized inventor or inventors). To some extent, some forms of IP can recognize a collective entity as being entitled to exercise and benefit from rights over protected subject matter – for instance, geographical indications, collective trademarks and protection of undisclosed information, when a collective entity, including a legally recognized indigenous or local community, may be owner or beneficiary. But in general, there are no systems of recognizing collective or community ownership, custodianship or other forms of authority or entitlement over their knowledge, or distinct elements of the knowledge. Such systems may need to take account of the experience that more than one community can be the rights owner of a TK.

91. This gap is addressed in part through the UNDRIP, which provides that “Indigenous peoples have the right to maintain, control, protect and develop their (...) traditional knowledge (...) [and] (...) the right to maintain, control, protect and develop their intellectual property over such (...) traditional knowledge.” However, in view of its status as an international non-binding

instrument, this is a general statement, rather than a specific legal mechanism directly applicable to address this gap in practice.

92. Gap: Recognition that an indigenous or local community as such may have rights, authority, custodianship or other entitlements over knowledge within a traditional knowledge system that is distinctively associated with them.

93. Example: In the example above, the community concerned would not currently have, as a community, any collective right to take action against forms of misuse or misappropriation of their knowledge.

(iii) Clarifying or confirming the application to TK of existing principles

A norm expressly applying patent principles in TK contexts

94. Introduction: It is already not possible in principle to obtain a legitimate patent on traditional knowledge that is not novel or is obvious to a relevant group of those skilled in the relevant art (which may include traditional knowledge practitioners). Further, a legitimate patent cannot be obtained on a claimed invention when the applicant is not the actual inventor or has not obtained the right to apply directly from the actual inventor, for instance if the patent claims extend to traditional knowledge obtained from a TK holder, or if the TK holder made an inventive contribution to the claimed invention. In addition, the true inventor or inventors are entitled to be mentioned as such on the patent document. These broad principles are accepted in international patent law, although they have never been explicitly applied to traditional knowledge at the level of international norm setting.

95. It may be debated whether this lack of an express principle is a 'gap' at all: is it 'filling a gap' to apply general principles specifically to TK, and to bring out explicitly what is already implicit in patent law and principle? On the other hand, it may be considered a useful clarification of existing principles to spell out internationally an understanding of how general patent principles apply specifically to traditional knowledge to preclude certain invalid patents, such as any attempt to claim that traditional knowledge obtained from a TK holder is another party's invention. This expectation is implicit in existing principles, and a question arises as to whether to articulate such expectations more explicitly is a true gap to be filled.

96. Gap: There is no formal international statement applying general patent norms and principles directly to the context of traditional knowledge: for instance, specifically and expressly precluding patents directly claiming TK (i) that is not novel because it is publicly known or available, (ii) that is obvious to a relevant traditional knowledge practitioner as a person skilled in the art, or (iii) that has been obtained from a TK holder who is not acknowledged as inventor and proper title has not been obtained from him or her.

97. Example: A person obtains valuable traditional knowledge when visiting an indigenous community. He files two patent applications on this knowledge as it was obtained, citing himself as inventor, without making any further significant improvements to it, and without informing or mentioning the TK holder from whom he obtained the knowledge. One patent application is a genuinely patentable invention: in this case the applicant has no right to apply for a patent, as the true inventor is the original TK practitioner, and the applicant has not based the application on a legal title obtained from the true inventor. The other patent application claims TK which has been publicly disclosed, and represents a method already known to the TK holder's community: in that case, the patent would be also invalid for lack of novelty or lack of inventive step.

(iv) Forms of protection not provided under existing international standards

A specific disclosure requirement relating to TK

98. Introduction: A number of countries have established specific mechanisms relating to TK (as well as genetic resources, not covered in this gap analysis), in the form of additional disclosure requirements in their national patent laws. These require the patent applicant to disclose the source or origin of TK used in the claimed invention, and in some cases also to provide evidence of prior informed consent and conclusion of arrangements for equitable sharing of benefits. Such a requirement has not been established under international law, although proposals³⁶ has been made and supported by a number of countries to revise the TRIPS Agreement to introduce such a requirement, and several proposals for such a requirement have also been made in WIPO. Other parties have opposed such a requirement and have called its value into question. No assessment is made here of these divergent views, beyond the objective fact that there is technically a gap or absence in international standards concerning any such requirement. The need to fill such a gap, and how to fill it, are of course matters for policy debate between states.

99. Gap: There is no specific international requirement that patent applicants should disclose the source or origin of TK used in the claimed invention, nor to disclose information on prior informed consent and equitable benefit sharing.

100. Gap: There is no specific international requirement that patent applicants should disclose information relevant to patentability, such as all relevant known prior art.

Protection against unjust enrichment, misappropriation or misuse of TK

101. Introduction: There are different analyses of the full scope of the existing international standard in the Paris Convention requiring the suppression of unfair competition. The required scope of unfair actions to be suppressed under this standard is likely to cover at least some forms of misappropriation or misuse of TK, but equally is likely not to cover all such acts, including all commercial and industrial uses of TK that would be considered either contrary to honest commercial practices or contrary to equity. Internationally, there are widely divergent views as to what specific uses of TK could be considered misappropriation, unjust enrichment or other illegitimate uses, and what usage of TK by people beyond the original community (including commercial uses) could be considered fair and legitimate. Not all uses by third parties of TK could be considered either wholly legitimate or wholly illegitimate, and views differ as to how to draw the line between the two. These divergent views reflect a gap in the form of an absence of international guidance on these points.

102. Gap: There is no express international requirement to suppress unjust enrichment from TK or misappropriation or misuse of TK, and no international guidance as to what is legitimate and fair use of TK, and how unjust enrichment or misappropriation should be defined.

103. Example: In the example above, this gap concerns the entitlement to object or to obtain remedies when a community's TK is used by a third party, for example to produce 'natural product' remedies, or medicines that are directly derived from that knowledge and directly use the known properties of the biological materials employed in that knowledge.

³⁶ See submissions to the Trade Negotiations Committee of the WTO: documents TN/C/W/52 of 19 July 2008 and TN/CW/59 of 19 April 2011.

104. Other examples include:

- a remedy or a medicine is produced directly relying on the TK of an indigenous community
- a remedy or a medicine is produced relying on a piece of publicly-known knowledge;
- a remedy or a medicine is produced utilizing a piece of knowledge in addition to TK.

105. Further consideration should also be given to cases where the TK has contributed to the subject matter of a given IPR, even when the latter was not directly derived from the TK. It may be considered a gap in protection of TK if this kind of contribution to a new product is not taken into account.

106. In each case, identifying a gap in protection against misappropriation or unjust enrichment would entail answering such questions as:

- when would such a use of TK create an obligation to acknowledge, to share benefits with or otherwise to compensate or recognize the community, and when would each form of usage be considered unjust enrichment or an act of misappropriation?
- what linkage should exist between the form of access to the knowledge, and its subsequent downstream use?
- do the circumstances in which the knowledge was originally acquired from the community influence whether or not such use is considered misappropriation or unjust enrichment, or is it the manner of use only that is considered?
- Is misappropriation limited to extensive commercial exploitation of such knowledge, or does it extend to non-commercial usages or usage on a limited commercial scale?

107. One comment voiced concern that international standards do not allow for communities to prevent others from taking and using elements of TK for industrial and commercial use without any acknowledgement and without providing equitable benefits in return. Another comment pointed to the impact that the lack of adequate sanctions would have on redressing the damages caused by the acts of misappropriation.

Prior informed consent

108. Introduction: The CBD recognizes a right of prior informed consent over genetic resources, and the Bonn Guidelines suggests that this may apply also to TK associated with biodiversity. Article 7 of the Nagoya Protocol provides the following: "In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established." However, there is no explicit international norm expressly recognizing a right of prior informed consent over all traditional knowledge.

109. Gap: An express principle of free prior informed consent over TK held by a recognized indigenous or local community.

110. Gap: A further gap identified in the comments concerns the scenario when prior informed consent obligations and the application of access and benefit sharing (ABS) legislation in one country may not apply in a third country, raising the question of what obstacles exist to the

extraterritorial application of such legislation by courts in third countries, including in the absence or the presence of an international norm on the protection of TK.

111. Example: An ethnobotanical researcher is undertaking a field research program concerning the traditional knowledge of a certain community. The researcher may be under no obligation to seek the consent of the community before collecting the knowledge, which would then be freely available for her to share with others, and others to use it commercially or industrially.

112. There may also be a gap in a practical sense, since practical support is needed to establish an effective certification and database system as well as institutional support and legislation for certifying the prior informed consent, especially the consent of local and indigenous communities, and this assistance, in the short term, would help address problems of misuse and misappropriation.

A right of acknowledgement and integrity

113. Introduction: A user of traditional knowledge is normally under no obligation to acknowledge the provider or source of the knowledge. Moreover, the user is under no obligation to treat the knowledge with respect, such as when certain uses cause cultural offence, or when the traditional knowledge is used in a way that impairs its authenticity or integrity. In many cases, it may be difficult or impossible to identify all sources of knowledge, and it may be inappropriate or socially counterproductive to give a right to object to certain uses of TK. Nonetheless, the value of having such a mechanism has been pointed to, for instance at least in the case of TK which has particular sacred significance or is especially linked to the collective identity of a community. Formally, there is an absence of such a requirement in international standards, and in that technical sense a gap can be said to exist: this does not imply that the gap needs to be filled at all, nor how and to what extent it should be filled; these are deep policy issues that need careful reflection. Nonetheless, in a formal sense a gap can be identified.

114. Gap: Right to object to the use of TK without explicit acknowledgement of the community which is the actual source of the knowledge.

115. Gap: Right to object to the use of TK when the use creates cultural or spiritual offence, or otherwise impairs its integrity.

116. Example: Traditional knowledge that is distinctive of a certain community is used in a commercial product by a third party; there is no acknowledgement of the community as the source, developer or traditional custodian of the knowledge. Alternatively, such a product is presented and distributed in a way that disparages or offends the original community (the latter concern is partially covered by the Paris Convention, article 10bis).

(v) Absence of entitlement to obtain remuneration or other benefits

117. Introduction: By analogy with the right of equitable remuneration in some IP systems, and according to theories of 'compensatory liability' and the principle of equitable sharing of benefits, it has been proposed that holders of TK should be entitled to an equitable share of the benefits that others derive from the use of their knowledge, particularly when this use entails financial or commercial gain. (Yet the benefits need not be financial or monetary in themselves, especially when this runs contrary to the values or express wishes of the community concerned). There may be many different holders of traditional knowledge: an individual may be entitled to compensation or receipt of benefits, or TK may be so diffuse in origin that only a national, global or regional fund could be an equitable means of distributing benefits. Therefore, along with

consideration of a possible entitlement to equitable remuneration, the gap analysis may also extend to the absence of appropriate institutional frameworks for managing and sharing benefits, financial or otherwise.

118. Gap: A collective entitlement to equitable remuneration or other equitable benefit-sharing from the commercial use of TK in general or other derivation of benefits from TK, apart from the entitlements established for specific forms of TK, such as biodiversity-related TK under the CBD.

119. Gap: Appropriate institutional framework for the collection and equitable distribution of benefits (especially when these are financial in character).

120. Example: The traditional medical knowledge of a certain community is used to develop a successful line of consumer medical products. Apart from other considerations (such as the right to be acknowledged), the community may be entitled to a share of the benefits from this commercial activity: this need not be in strictly financial terms (and community members may not welcome such monetization of their knowledge), but may be in terms of non-financial benefits such as involvement in research activities, culturally appropriate community level development, and sustainable harvesting of the materials used.

V. CONSIDERATIONS RELEVANT TO DETERMINING WHETHER THOSE GAPS NEED TO BE ADDRESSED

121. The considerations relevant to determining whether the gaps identified need to be addressed may be classed as:

- institutional/process-oriented considerations, and
- substantive considerations.

122. Institutional/process considerations include whether an existing international process is already addressing a particular gap, and what this means for further work addressing the same gap. Apart from the discussion about the substantive issue, there is also a process-related debate about which should be the appropriate forum or forums for dealing with such a gap.

123. By contrast, substantive considerations include considering whether there are compelling policy reasons for a particular gap to be addressed. For example, there may be a legal 'gap' in principle over the protection of TK against non-commercial private use, but this may not be seen as a policy priority, in contrast at least to profitable commercial uses of knowledge.

124. Further considerations may relate to determining not whether but how a gap may be filled – for instance, whether binding international law, political encouragement or a model law may best fill an identified gap. These are discussed largely in the final section of this gap analysis.

(a) Substantive considerations

(i) International law and policy

125. The emerging framework of international law and policy touching on TK may create an expectation that standards of intellectual property protection may need to be adjusted to address perceived gaps. In other words, shifts and outcomes in international public law may be seen as a 'consideration' relevant to determining whether gaps should be filled – a legal or political outcome in a related area may potentially be viewed as highlighting a gap at the level of

detail in the system of IP law. Relevant developments – which cover both binding international law and other policy guidance, such as declarations - include:

- The conclusion and entry into legal force of the CBD article 8(j), which provides for respect, preservation and maintenance of biodiversity-related traditional knowledge;
- The adoption of the United Nations Declaration on the Rights of Indigenous Peoples, which articulates a wide range of rights with direct bearing both on traditional knowledge as such, and IP related to TK (which as an international declaration is understood to articulate existing norms rather than serving to create distinct legal obligations in itself);
- The conclusion and entry into legal force of the FAO ITPGRFA which requires protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
- The increasing recognition of traditional knowledge as a vital policy consideration for public health policy (notably in the report of the World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health and the global strategy on public health, innovation and intellectual property adopted by the World Health Assembly in May 2008).
- The UNCCD provides obligations to protect, promote and use relevant traditional and local technology, know-how, and practices.
- Given the linkages between TK and TCEs, the development of stronger legal and policy outcomes concerning the safeguarding of intangible cultural heritage and the promotion of cultural diversity may have bearing on TK protection (although these areas of policy are more directly relevant to TCE protection as such – accordingly, the updated draft gap analysis on TCE protection should be referred to concerning this policy domain).
- The adoption of the Interlaken Declaration on Animal Genetic Resources, which provides for respecting, preserving and maintaining traditional knowledge relevant to animal breeding and production.
- The adoption of the Nagoya Protocol, which expands the TK-related provisions of the CBD.

126. Within WIPO, two particular considerations may be viewed as relevant to the filling of some of the gaps identified in this process:

- In the context of the WIPO Development Agenda, under consideration by the Committee on Development and Intellectual Property (CDIP) (see, e.g., document CDIP/1/3), proposal 18 is as follows:

To urge the IGC to accelerate the process on the protection of genetic resources, traditional knowledge and folklore, without prejudice to any outcome, including the possible development of an international instrument or instruments.

- The WIPO General Assembly, meeting in October 2017, also decided, in renewing the mandate of the Committee, that it “will (...) 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 (...) traditional knowledge (...)”.

(ii) Social, cultural, political and economic considerations

127. Social, cultural, political and economic considerations that may be viewed as potentially relevant include:

- The emphasis laid by many community representatives and many governments on claims of the inequities arising from misappropriation and misuse of TK
- The role of TK in sustainable, grass roots development
- The linkages between protection of TK and the continuing cultural and social identity of indigenous and local communities
- The increasing uptake of TK in a host of industrial and commercial applications
- The value and practical application of TK relevant for the conservation and sustainable use of biological diversity in dealing with environmental change and climate change
- The increasing use of TK in a range of regulatory contexts, such as in making environmental impacts and assessing the safety and efficacy of medicines
- Conceptions of social responsibility and morality, including ethical obligations.

(iii) Significance of TK protection for broader policymaking and regulatory contexts.

128. As evidenced by the range of legal and policy outcomes listed above in section (i), TK is referred to and actively used in many policymaking contexts; these include:

- Protection of biodiversity, and equitable use of its benefits;
- Recognition of the rights of indigenous peoples;
- Promoting food security and promoting diversity of food crops;
- Ensuring culturally appropriate access to health;
- Sustainable grass roots development;
- Climate change abatement and mitigation;
- The overlap in research and development programs between traditional knowledge as such and formal scientific disciplines such as biotechnology and pharmacology;
- The contribution of traditional knowledge systems to innovation and cultural diversity.

(b) Process or formal considerations

(i) Specific process or formal considerations

129. Apart from these broader policy questions, there are more specific considerations that may be viewed as relevant to addressing identified gaps; these include:

- The fact that many national or regional processes are already developing stronger protection of TK: the development of an international dimension and a common platform may reduce practical complexities and legal uncertainties that may otherwise result from diverse national or regional TK protection systems;

- The need, nonetheless, for appropriate continuing regulatory diversity, recognizing that traditional knowledge systems and specific means of protecting them should respond to local needs and cultural norms;
- The possible systemic implications from lack of clarity in the international law of IP in areas where it is relevant to TK and traditional knowledge and innovation systems;
- The possible gains from a reduction in legal uncertainty associated with concerns about possible ownership or custodial responsibilities relating to TK;
- The costs and benefits arising from a common international approach towards TK protection issues or the creation of a new form of intellectual property protection, including the implications for national and regional administration and accessibility of protection for foreign TK holders;
- The contrast and interplay between a legislative and norm setting approach which sets general expectations and standards, and a bilateral contractual approach in which TK holders and users define specific terms of use.

(ii) Considerations specifically weighing against addressing gaps

130. The Committee's work has also seen suggestions of particular considerations that might weigh against addressing the gaps identified; these include:

- The possibility that it is premature to fill certain gaps at international level, even when gaps are clearly identified, in view of the need for more national experience to be developed and shared as a precondition for clearer international outcomes;
- The diversity of TK and the communities holding TK, which may set limits to the international dimension of norm-setting
- Uncertainty over rights and entitlements of foreign right holders, such as TK holding communities in dramatically different cultural and social contexts;
- The possible need for stronger, more diverse consultative processes before moving towards high profile political and legal outcomes that would be difficult and costly to revisit once concluded.

VI. OPTIONS THAT EXIST OR MIGHT BE DEVELOPED TO ADDRESS ANY IDENTIFIED GAPS

Legal and other options, whether at the international, regional or national level;

131. At the international level, document WIPO/GRTKF/IC/14/6 and the preceding documents in that series identified the options as including:

- (i) a binding international instrument or instruments;
- (ii) authoritative or persuasive interpretations or elaborations of existing legal instruments;
- (iii) a non-binding normative international instrument or instruments;
- (iv) a high level political resolution, declaration or decision, such as an international political declaration espousing core principles, stating a norm against misappropriation and misuse, and establishing the needs and expectations of TCE/TK holders as a political priority.
- (v) strengthened international coordination through guidelines or model laws
- (vi) coordination of national legislative developments.
- (vii) Coordination and cooperation on capacity building and practical initiatives.

These are discussed in turn below.

(a) Legal and other options at the international level:

(i) *A binding international instrument or instruments*

132. A binding instrument addressing any specific gaps in protection would oblige Contracting Parties to apply the prescribed standards in their national law, as an obligation under international law. Possible vehicles include stand-alone legal instruments, protocols to existing instruments or special agreements under existing agreements. Past WIPO treaties have become binding under international law through the choice of the parties concerned to adhere to the treaties; other states are not bound by the treaty as such (in some cases, they have chosen to apply the standards created by a treaty without formally adhering to it as a matter of law, for instance in the field of industrial property classifications). A distinct treaty-making process would be required (typically, a diplomatic conference) to negotiate such an instrument. The treaty would become binding only on those countries which elect to adhere to them through a distinct act of ratification or accession.

133. Binding instruments may have the character of framework or policymaking conventions, providing a basis or policy platform for further normative development and for greater convergence and transparency of national policy initiatives, while also leaving appropriate scope for necessary diversity of approaches at the national and regional levels. Specific international legal mechanisms with more precise obligations may then be negotiated as protocols under the original framework agreement.

IGC context: Many delegations have called for the development of international binding instrument or instruments as the ultimate outcome of the Committee's work. The Committee and the WIPO General Assembly do not themselves have the capacity to create binding international law, and a distinct process would be necessary both to conclude such a text and for such a text to enter into force with legal effect on those countries which adhere to it.

Examples in related fields: Convention on Biological Diversity, Convention on the Safeguarding of Intangible Cultural Heritage, FAO International Treaty on Plant Genetic Resources for Food and Agriculture, Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, ILO Convention 169, International Covenant on Economic, Social and Cultural Rights.

Examples in intellectual property: Singapore Trademark Law Treaty, Patent Law Treaty, WIPO Copyright Treaty (WCT), WIPO Performances and Phonograms Treaty (WPPT).

(ii) *Interpretations or elaborations of existing legal instruments*

134. Authoritative or persuasive interpretations of existing legal instruments may require, guide or encourage the interpretation of existing obligations to fulfil in part any identified gaps in protection of TK. Options range from a legal protocol to an existing treaty to a non-binding persuasive statement. They may nonetheless be influential in interpreting treaty standards and in giving practical guidance to domestic policymakers on the basis of agreed international standards. It may give more precise guidance on how to implement international standards, without creating distinct obligations. Without reflecting on the precise legal status of this text, it

may be noted that, among other things, the Doha Declaration on TRIPS and Public Health includes guidance on how the TRIPS Agreement should be interpreted.³⁷

IGC context: The Committee considered the possibility of interpreting or adapting existing international general rules against unfair competition explicitly to include acts of misappropriation, which may be done through a form of interpretation or extension of the Paris Convention Article 10*bis* by analogy.

Examples in related fields: General Comment No. 17 (2005) The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15, paragraph 1 (c), of the International Covenant on Economic, Social and Cultural Rights).

Examples in intellectual property: Joint Recommendation Concerning Provisions on the Protection of Well-Known Marks; Agreed statements of the Diplomatic Conference that adopted the WCT and WPPT, 1996 (WIPO Diplomatic Conference on Certain Copyright and Neighboring Rights Questions).

(iii) A non-binding normative international instrument

135. A non-binding (“soft-law”) instrument could recommend or encourage States to give effect to certain standards in their national laws and in other administrative and non-legal processes and policies, or could simply provide a framework for coordination among those States which chose to follow the agreed approach. Options could include an authoritative recommendation or a soft-law instrument, with persuasive influence or potentially moral force. Other international organizations have developed such instruments in areas of relevance to the work of the Committee, listed below. Several of such instruments were subsequently developed into binding instruments. The Universal Declaration of Human Rights itself (which includes some provisions relevant to the IP policy) was drafted as a non-binding instrument. The concept of a non-binding or soft-law instrument may overlap with political declarations and other forms of political commitment: in other words, a political declaration could be seen as having similar exhortative effect and policy guidance as a document prepared as a soft-law instrument. There is considerable overlap between a non-binding instrument and related outcomes such as model laws and provisions. However, the shortcomings of the existing soft law in effectively addressing problems of misappropriation should also be taken into account; the non-binding character of such norms may be considered a gap in itself.

IGC context: As noted, no instrument emerging from the Committee or adopted by the General Assembly could have binding legal effect in itself. The Committee has done extensive work on objectives and principles of protection of TK, on options and mechanisms for protection of TK, on guidelines for examination of TK-related patents, and on guidelines for IP aspects of access and benefit sharing, material which may in some form be forwarded to the WIPO General Assembly and other WIPO bodies for adoption or recognition as non-binding guidance and as the basis for further normative development.

Examples cited in the Committee’s work: Universal Declaration of Human Rights, UNESCO Declaration on Bioethics and Human Rights, FAO International Code of Conduct for Plant

³⁷ Paragraph 5(a): In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Germplasm Collecting and Transfer, Declaration on the Rights of Indigenous Peoples, UNESCO declarations on bioethics and cultural diversity; FAO International Undertaking on Plant Genetic Resources and resolutions on issues such as farmers' rights; Decisions of the Conference of Parties of the CBD, including the Bonn Guidelines.

Examples in intellectual property: Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, WIPO-UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and other Prejudicial Actions³⁸.

(iv) High level political resolution, declaration or decision

136. One option, discussed in earlier documents, would be a high-level resolution, declaration or joint declaration by relevant WIPO assemblies. The themes of such a declaration might reflect current negotiations at the Committee and it may in part address the gaps identified in this analysis or in other work by the Committee. For instance, it could recognize the value and significance of TK as "intellectual property"; stress the need to empower their traditional holders or custodians to defend their interests regarding TK and to use them as the basis for sustainable cultural and economic development; establish core objectives and principles for protection; call on Member States actively to apply these objectives and principles as they work towards enhanced national and international protection; and establish goals for future work including a more specific instrument or instruments. Such an approach need not preclude nor retard subsequent development of binding international law, and in some cases such outcomes have been used as the basis for negotiations on binding instruments (one example is the development of the FAO International Treaty from the past non-binding International Undertaking). Past WIPO joint recommendations have been widely applied and followed, for instance in the field of trademarks, and have been recognized and given effect in other legal instruments.

IGC context: The possibility of such an outcome has been raised in general discussion in the Committee. Options include a recommendation for a decision to be taken by the WIPO General Assembly (possibly jointly with other WIPO bodies) that would make a high level political statement, acknowledging the progress made to date, and would set the agenda for WIPO's future work in these fields.

Examples in related fields: Declaration of Alma-Ata International Conference on Primary Health Care; FAO International Undertaking on Plant Genetic Resources for Food and Agriculture, UNESCO Declaration on Cultural Diversity, 2001.

Examples in intellectual property: United Nations General Assembly Resolution 60/184 on International Trade and Development; Resolution 2000/7 of the Sub-Commission on the Promotion and Protection of Human Rights on Intellectual Property Rights and Human Rights; Joint Recommendation Concerning Trademark Licenses; Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples.

(v) Strengthened coordination through guidelines or model laws

137. Model laws or guidelines have in the past been used to express a shared international approach, to assist in the coordination of national laws and policy development, and in particular to address gaps such as those identified in this analysis, without the adoption of a specific

³⁸ These Model Provisions relate exclusively to TCEs.

international instrument. This can provide the basis for cooperation, convergence and mutual compatibility of national legislative initiatives for the protection of TK, and can also lay the groundwork for more formal international instruments, as well as define the scope for appropriate diversity of approach. In practice, it may be difficult to distinguish between model laws or guidelines and the kind of soft-law norms discussed above. Several guidelines, frameworks and model laws already exist in areas of direct relevance to the work of the Committee.

138. A number of other influential international instruments on the protection of TK have been prepared as non-binding instruments with potential capacity to determine the legal obligations established under national laws (these include the African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, established in 2000, and the Pacific Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture of 2002). These models have in turn contributed to the discussion and review of protection within the Committee. In the past, it has been noted that “while this is very plainly a matter for Committee members to consider and determine, experience in other domains suggests the possibility of a phased approach, in which one mechanism for framing international standards and for promoting the desired approach to protection in national standards leads in turn to further elaborated or revised mechanisms, with increasing expectation of compliance and increasing legal effect.”

IGC context: The objectives and principles for protection of TK, developed on the basis of the Committee’s work and with its direction in 2005, have been used widely as benchmarks for protection at the level of regional instruments, international processes and national legislation and policy processes. More recently, the different versions, alternatives and options included in the draft articles on protection of TK have inspired regional instruments and national legislation and policy processes. While not adopted or agreed in their current form, they may provide content for any guidelines, model laws or other “instruments”. The Committee earlier declined a proposal to prepare model provisions for patent disclosure mechanisms relating to genetic resources and TK.

Examples in related fields: *Akwe: Kon* voluntary guidelines for the conduct of cultural, environmental and social impact assessment, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization; FAO International Code of Conduct on the Distribution and Use of Pesticides; UNIDO Code of Conduct for Environmental Release of GMOs; the African Union Practical Guidelines for the Coordinated Implementation of the Nagoya Protocol in Africa.

Examples in intellectual property: Tunis Model Law, WIPO-UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and other Prejudicial Actions, Pacific Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture; OECD Guidelines for the Licensing of Genetic Inventions.

(vi) *Coordination of national legislative developments*

139. Many countries are currently engaged in the development of new laws and policies in the protection of TK (in some cases also addressing TCEs/folklore)³⁹. Those doing so have expressed strong interest in learning from other governments and regional bodies concerning

³⁹ WIPO Lex, available at <https://www.wipo.int/wipolex/en/>, is a global database that can be used to identify national laws and regional instruments adopted for the protection of TK (and TCEs).

their choices, and experiences in implementing such measures. This is to ensure the application of “best practice” but also to promote consistency and comity between national laws, given the need for different national legal systems to interact appropriately. One effect of even draft international materials on the nature and policy context of protection may be to encourage and support such coordination of national and regional initiatives, where this is desired by the governments concerned. Informal feedback and an increased level of requests for capacity-building support and input has suggested that many governments have chosen to move forward as a priority on developing national protection for TK, but that they are concerned to ensure a consistent approach in which governments can share experiences in a structured way, ensure reasonable consistency, and avoid conflicting approaches. Some form of non-binding instrument may be a means to assist in this process. While drawing essentially on domestic laws, even distillations of national legislation and related texts can have a “soft-law” influence at the international dimension, by promoting coherence and compatibility between national laws, and strengthening the common basis for collective protection at the international level.

IGC context: The different versions, alternatives and options included in the draft articles on protection of TK to a large extent represent a distillation of actual practice of Member States legislating to protect aspects of TK through IP and IP-related mechanisms – the documents provide extensive references explaining the sources in Member States’ laws. Extensive analyses of how Member States have implemented these principles and objectives are provided in WIPO/GRTKF/IC/9/INF/5 (protection of traditional knowledge). Other resources developed for the Committee include a Comparative Summary of *Sui Generis* Legislation for the Protection of Traditional Cultural Expressions (WIPO/GRTKF/IC/5/INF/3); a Comparative Summary of Existing National *Sui Generis* Measures and Laws for the Protection of Traditional Knowledge (WIPO/GRTKF/IC/5/INF/4); and questionnaires on protection of folklore/TCEs and TK.

Examples in related fields: National Reports under the CBD (<http://www.biodiv.org/reports/list.aspx>); Ethics Related Legislation and Guidelines, Global Ethics Observatory, UNESCO.

Examples in intellectual property: Survey of practices regarding biotechnological inventions (WIPO/GRTKF/IC/1/6).

(vii) Coordination and cooperation on capacity building and practical initiatives.

140. The gap analysis is required to cover ‘legal and other options’. Since the effective protection of TK would require a range of capacity building and practical measures to implement or supplement legal measures, a full gap analysis may need to address the need, if any exists, for international steps to coordinate, cooperate and practically deliver such capacity building and practical measures. Possible capacity and practical measures could be considered within the following categories:

Capacity building and substantive materials for legal and policy processes

141. Work has proceeded on developing materials to support policymakers, negotiators and legislators seeking to deal with the identified gaps, including:

- Resources for legislation and policy development, including model provisions, databases of laws and policy instruments, and analysis of policy options and legal mechanisms, to support and assist policymaking and legislative processes;

- Analysis of legal questions such as IP law and practice with bearing on TK protection, and the recognition of customary law, to provide background information for legislators and policymakers; and
- Review of possible approaches to appropriate community consultation when developing options, and policies and legislation

Strengthening practical capacity of TK holders

142. In line with the general observation that no legal instrument and no set of legal norms, whether existing or envisaged, will be effective in meeting the needs of TK holders unless the necessary capacity and resources are made available to those TK holders in order to ensure the principles are carried out in practice, work has proceeded on developing materials to support TK holders, including:

- Models and databases of community protocols, licenses and agreements for access to TK, to strengthen the capacity of TK holders to develop protocols, licenses or other agreements governing access to their TK;
- Support for communities in identifying and promoting their interests during the documentation of TK⁴⁰;
- Models, databases and guidelines on equitable benefit sharing for access to TK and associated genetic resources⁴¹; and
- Awareness raising materials, case studies and legal analysis on issues such as recognition of customary law tailored to the needs of communities holding TK.

Building and guiding institutions

143. National, scientific and educational institutions and other authorities such as patent offices are frequently called upon to play an active role in ensuring that practical gaps in the protection of TK are addressed in the interests of TK holders. Work has therefore proceeded in developing practical materials for such institutions and authorities, such as:

- Model protocols, recommended policies and best practice guidelines for institutions with responsibility for collecting or maintaining collections of TK, such as museums, ethnographic institutions, national authorities and research and educational institutions;
- Guidelines and recommendations for the examination of TK-related patents;
- Guidance on measures to ensure that communities can identify and promote their interests during the documentation of TK, including in the form of the TK documentation toolkit project;
- Standards for documenting TK, including measures to ensure the identity and requirements of the TK holder are documented together with the TK itself; and
- Studies on policy and legal questions such as patent disclosure mechanisms and bioethics standards with bearing on TK

Interagency cooperation and coordination within UN system

144. Coordination and cooperation on capacity building and practical initiatives at the international level would include the kind of interagency cooperation, coordination and exchange of technical information and other materials that has been undertaken by WIPO in cooperation with other international agencies, such as the CBD, the FAO, South Centre, UNCTAD, UNEP,

⁴⁰ For instance, see: WIPO (2017) Documenting Traditional Knowledge – A Toolkit, available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1049.pdf.

⁴¹ Another example: WIPO (2018) A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements, available at: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1048.pdf.

UNESCO and the WHO, as well as with NGOs and other international actors dealing with TK and related issues.

Awareness and capacity-building for the general public

145. One clear gap is the substantial lack of awareness and understanding of TK, TK systems, and their cultural and intellectual context on the part of the general public and international policymakers, business representatives, and civil society organizations. Filling this gap would entail initiatives such as:

- Case studies, analyses and briefings;
- Fact-finding missions and consultations;
- Educational and training activities;
- Surveys of national experiences; and
- Overviews of legal and policy options

(b) Legal and other options at the regional level

146. Some measures to fill identified gaps may be especially appropriate to the regional or subregional context, reflecting the benefits of building common norms, institutions and practical measures that reflect shared or overlapping legal cultures and traditional knowledge systems. In addition, a number of regional organizations already play active roles both in developing new legal instruments and in undertaking practical capacity building work to strengthen the protection of TK. Many of the international measures identified above would apply equally well to the regional level. Several examples are cited in the above review of international measures. The general categories of possible measures include:

- Legal instruments concluded at the regional, subregional or bilateral level, including *sui generis* instruments and conventional IP law
- Political or policy-level declarations proclaimed at the regional, subregional or bilateral level
- Model laws and other forms of legislative guidance adopted at the regional level
- Model protocols, guidelines and best practice recommendations adopted at the regional or subregional levels
- Regional, subregional and bilateral initiatives and programs to support community capacity building relating to TK

(c) Legal and other options at the national level

147. Many States, and communities within those States, have undertaken specific initiatives to develop and implement legal and other options in order to address gaps in the legal protection of TK. A full survey is not attempted in the present gap analysis. However, briefly, these include:

- Legislation to protect TK, including *sui generis* instruments and adaptations or revisions of conventional IP law
- Policy frameworks and administrative mechanisms to promote and protect TK, including within specific domains such as medicine and public health, the environment, and agriculture

- Model protocols, guidelines and best practice recommendations adopted either by national authorities or other institutions
- National initiatives and programs to support community capacity building relating to TK

[Annex II follows]

GAP ANALYSIS MATRIX

This matrix corresponds to the items mentioned in sub-paragraphs (a) to (d) of the decision of the Twelfth Session of the WIPO Intergovernmental Committee, as required by that decision, and as updated if and as needed. Following a summary table, the full matrix includes the material covered in the gap analysis above.

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SUMMARY OF MATRIX

- A. EXISTING MEASURES
- B. GAPS EXISTING AT THE INTERNATIONAL LEVEL
- C. CONSIDERATIONS RELEVANT TO DETERMINING WHETHER THOSE GAPS NEED TO BE ADDRESSED
- D. OPTIONS THAT EXIST OR MIGHT BE DEVELOPED TO ADDRESS ANY IDENTIFIED GAPS:

I. SUMMARY OF MATRIX

Aspects of protecting TK	(a) existing measures	(b) gaps identified	(c) and (d) considerations and options
Objectives and principles of IP protection applied to TK	Existing public international law (non-IP) instruments on indigenous peoples' rights, the environment (including biodiversity and genetic resources), agriculture	<p>Authoritative statement on the role of IP law and policy in addressing public policy issues relating to TK. Objectives may include:</p> <ul style="list-style-type: none"> Recognizing value and promoting respect for TK systems; Responding to the actual needs of TK holders; Protecting against misappropriation of TK and other unfair and inequitable uses; Protecting tradition-based creativity and innovation; Support of TK systems and empowerment of TK holders; Promoting fair equitable benefit-sharing from use of TK; Promoting use of TK for appropriate development; supporting the safeguarding and preservation of TK. 	<p>International treaty or declaration establishing framework for TK protection in IP system that:</p> <ul style="list-style-type: none"> - expresses objectives of protection - articulates general principles of protection <p>Considerations:</p> <ul style="list-style-type: none"> - role of hard law and soft law instruments - political as against legal aspects of issues - coordinated international approach as against autonomous national initiatives - benefit of firmer policy basis and general settled principles for further work on legal protection - need to address positive and defensive protection; - address prior informed consent and benefit sharing
Definition of protectable TK	<p>TK covered in existing non-IP legal instruments without precise legal definition</p> <p>Working definition in IGC</p>	<p>Working definition of TK:</p> <ul style="list-style-type: none"> - in general - as precise object of legal protection <p>Clarifying communal basis of rights and entitlements</p>	<p>Binding legal definition of TK:</p> <ul style="list-style-type: none"> - legal certainty and clarity, but may not capture full diversity of TK and knowledge systems, and TK holding communities - linked to question of scope of protection and scope of beneficiaries

Aspects of protecting TK	(a) existing measures	(b) gaps identified	(c) and (d) considerations and options
			<p>Agreed international characterization of TK, without binding legal force:</p> <ul style="list-style-type: none"> - higher level of clarity, firmer basis for work - not prejudging deeper legal and policy questions
Positive patent protection	<p>Established patent system, including standards and procedures in TRIPS and PCT</p> <p>Protection of marks, symbols and names associated with TK and TK systems</p>	<p>No direct protection for:</p> <ul style="list-style-type: none"> (i) Collective, cumulative and intergenerational innovation <i>as such</i> (ii) Systems of TK <i>as such</i> (in contrast to specific innovations within TK systems, and means of certifying authenticity and protecting distinctive signs and reputations) 	<p>Review or adapt patentability criteria and standards to recognize TK systems and collective interests:</p> <ul style="list-style-type: none"> - internationally for a coordinated approach, and/or - nationally/regionally to maintain necessary flexibility <p>Establish <i>sui generis</i> protection (see below)</p> <p>Recognize that as much of TK falls outside the boundaries of the patent system it may be preferable to deal with TK innovation systems on their own terms</p>
Inventions based on TK	Specific PCT, IPC, IGC measures to recognize TK	<p>No agreed international norm for specific disclosure mechanism for TK and associated genetic resources</p> <ul style="list-style-type: none"> - several proposals (CBD, WTO, WIPO) 	<p>Introduce disclosure mechanisms for TK</p> <ul style="list-style-type: none"> - internationally for a coordinated approach, and/or - nationally/regionally to maintain necessary flexibility <p>Strengthen framework of contractual obligations governing access to TK under national law to require disclosure and other conditions of access to TK</p>
Undisclosed TK	TRIPS standards on the protection of undisclosed information in general	<p>No explicit standards on:</p> <ul style="list-style-type: none"> (i) TK disclosed within a defined community (ii) TK that community values culturally/ 	<p>Clarify or adapt existing standards to ensure:</p> <ul style="list-style-type: none"> (i) Restricted dissemination within a defined community does not amount to full public disclosure

Aspects of protecting TK	(a) existing measures	(b) gaps identified	(c) and (d) considerations and options
		spiritually not commercially (iii) Disclosure of TK constrained by customary law	(ii) That TK is protected even if source community values for non-commercial reasons (iii) Constraints of customary law and practices deemed to be sufficient to preserve confidentiality/ 'secret' quality
TK-related signs and symbols	Law of trademarks (including collective and certification marks) and geographical indications	Defensive protection of TK-related signs and symbols against third party appropriation	Special registers of TK-related material Strengthened measures against TM registration contrary to morality (see also updated draft TCE gap analysis) Only applicable to protect against illegitimate commercial uses of signs and symbols related to TK, not TK itself.
TK subject matter covered by conventional IP system	Some TK or elements of TK are potentially covered: - <i>directly</i> by patents, undisclosed information, unfair competition law and - <i>indirectly</i> by copyright and related rights, TCE protection, TM and GI protection, design protection and unfair competition law.	TK not covered by existing IP protection, e.g.: - non-novel TK; - not patentably inventive TK; - publicly disclosed TK or TK otherwise ineligible for trade secret/confidentiality Duration of available protection ill suited to the intergenerational aspect of development and preservation of TK systems. Recognition of direct or less immediate contributions of TK to patentable inventions.	<i>Sui generis</i> protection of subject matter not already covered: - internationally for coordinated approach - nationally/regionally for maximum flexibility Adaptation of existing IP measures, e.g. - interpretation or adaptation of existing international standards to address TK subject matter more appropriately - national legislative and administrative initiatives (and judicial evolution of law) to recognize distinct TK systems within the framework of IP law Possible substantive considerations: The holistic nature of TK and collective rights over TK TK holders right to control their natural resources and manage their knowledge;

Aspects of protecting TK	(a) existing measures	(b) gaps identified	(c) and (d) considerations and options
			TK holders human right to self-determination; TK holders right to prior informed consent Recognition of the role of customary laws and customary knowledge systems in the protection and preservation of TK
Rights and interests of communities in their cumulative, collectively held and intergenerational TK, and their integrated traditional knowledge systems as such	Limited protection, mostly as confidential information	Direct recognition of collective rights and interests in cumulative, collectively held and intergenerational TK Protection of the integrity of traditional knowledge systems as such. Potential ownership by several communities	Specific protection of collective rights and interests in traditional knowledge as such (rather than separately IP-protectable elements): - internationally for coordinated approach - nationally/regionally for maximum flexibility Specific protection of rights and interests of communities in traditional knowledge systems as such: - internationally for coordinated approach - nationally/regionally for maximum flexibility
Specific mechanisms of TK protection against certain prejudicial acts and acts of misappropriation	None in conventional IP law. May be protected in part through contract and broader doctrine of unfair competition and unjust enrichment.	See detailed elements below	

Aspects of protecting TK	(a) existing measures	(b) gaps identified	(c) and (d) considerations and options
		Norm against unjust enrichment, misappropriation, or acts contrary to honest commercial behaviour regarding TK	<p>Specific norm articulated at international level to promote coordinated approach:</p> <ul style="list-style-type: none"> - binding law if timely for precise international norm - political declaration if legal essence of norm is still being formulated <p>Specific norm articulated nationally/regionally for maximum flexibility and legal evolution and diversity.</p>
		<p>Explicit statement of the principle of prior informed consent over TK held by a community</p> <p>Extraterritorial recognition of prior informed consent and access and benefit sharing arrangements in third countries' courts.</p>	<p>Specific norm articulated at international level to promote coordinated approach:</p> <ul style="list-style-type: none"> - binding law if timely for a precise international norm - political declaration if legal essence of norm is still being formulated <p>Specific norm articulated nationally/regionally for maximum flexibility and legal evolution and diversity.</p>
		Norm requiring explicit acknowledgement of source community when using TK distinctively associated with a community.	<p>Specific norm articulated at international level to promote coordinated approach:</p> <ul style="list-style-type: none"> - binding law if timely for precise international norm - political declaration if legal essence of norm is still being formulated <p>Specific norm articulated nationally/regionally for maximum flexibility and legal evolution and diversity.</p>

Aspects of protecting TK	(a) existing measures	(b) gaps identified	(c) and (d) considerations and options
		Norm against use that creates cultural or spiritual offence, or impairs integrity of TK	<p>Specific norm articulated at international level to promote coordinated approach:</p> <ul style="list-style-type: none"> - binding law if timely for precise international norm - political declaration if legal essence of norm is still being formulated <p>Specific norm articulated nationally/regionally for maximum flexibility and legal evolution and diversity.</p>
Patenting of TK contrary to patent law principles	<p>Existing patent law requires application based on true inventor(s) and genuine invention</p> <p>Paris Convention requires express mention of true inventor</p>	<p>Possible ambiguity in patent system for determining the inventive contribution of a TK holder.</p> <p>Explicit norm against:</p> <ul style="list-style-type: none"> - patenting of traditional knowledge as such without consent and involvement of TK holder - patenting of invention made possible by the misappropriation of traditional knowledge 	<p>At international level:</p> <ul style="list-style-type: none"> - internationally binding norm - authoritative interpretation of existing norms - political declaration <p>At national level: Specific amendments to national patent law</p>
	<p>Specific disclosure requirements for TK:</p> <ul style="list-style-type: none"> - national/regional laws - proposals in CBD, WTO, WIPO 	Prior informed consent over TK	<p>At international level:</p> <ul style="list-style-type: none"> - internationally binding norm - authoritative interpretation or extension of existing norms - political declaration <p>At national level: Specific amendments to national patent law</p>

A. EXISTING MEASURES

Obligations, provisions and possibilities that already exist at the international level to provide protection for TK

Form of protection	Extent of coverage	Factors considered
Positive patent protection of TK	<p>Some elements of TK potentially protected under existing patent principles, but not TK systems as such.</p> <p>Title needs to be obtained from true inventor(s), including TK holder(s)</p> <p>Valid protection requires active steps on part of true holders of patentable TK.</p>	<p>Considerable flexibility exists in international standards relevant to patentability of TK, including:</p> <ul style="list-style-type: none"> - defining 'invention' - interpretation of criteria for protection (novelty, inventiveness, utility) when applied to TK - public policy exclusions of patentable subject matter
Defensive protection of TK within the patent system	<p>Much TK is protected in principle from illegitimate assertion of patents, e.g. when patent applicant seeks rights over TK developed by others</p> <p>Specific measures include:</p> <ul style="list-style-type: none"> - improving access to TK as prior art during patent procedures without facilitating misappropriation of TK (e.g. including TK in PCT minimum documentation, TK documentation standards, IPC coverage of TK) - guidelines for examination of TK-related patents - portals, gateways and appropriate databases of TK and related genetic resources for use in patent procedures 	<p>Concerns over making available TK for patent procedures may trigger unwanted misappropriation by third parties.</p>
	<p>Specific patent disclosure mechanisms for TK and related GR, in national laws including:</p> <ul style="list-style-type: none"> - disclosure of source or origin of TK - disclosure of prior informed consent - disclosure of equitable sharing of benefits 	<p>Considerable international discussion and analysis of specific disclosure requirements for TK including over their effectiveness in preventing misappropriation of TK</p> <ul style="list-style-type: none"> - CBD Bonn Guidelines

Form of protection	Extent of coverage	Factors considered
	National access and benefit sharing systems	<ul style="list-style-type: none"> - proposals for new requirements in WTO, WIPO
Undisclosed TK	Protection is available for TK which is secret, has commercial value because it is secret; and has been subject to reasonable steps to keep it secret.	<p>Specific issues concern:</p> <ul style="list-style-type: none"> - when disclosure within a community is considered 'secret' - the role of the customary law or practices - protection of knowledge that has spiritual and cultural value to the community, but not commercial value for the community.
Protection against unfair competition	<p>Protection against</p> <ul style="list-style-type: none"> - acts creating confusion - false allegations in the course of trade - indications or allegations liable to mislead the public. 	Flexibility over interpreting measures against unfair competition to include broader rule against unjust enrichment and misappropriation
Protection of distinctive signs	<p>Applicable not to TK as such but to distinctive signs and symbols associated with TK-related products, in particular:</p> <ul style="list-style-type: none"> - trademarks for goods and services with a TK component - collective or certification marks - geographical indications 	
Industrial design law	Industrial designs that are new or original	Possibility of excluding protection for designs dictated essentially by technical or functional considerations.
Copyright and related law (including protection of databases and performances of expressions of folklore).	No protection for knowledge as such but for means of recording and transmission of TK, especially protectable TCEs.	See updated draft gap analysis on TCEs (WIPO/GRTKF/IC/37/7)

Form of protection	Extent of coverage	Factors considered
Public international law	<p>CBD: Biodiversity-related TK relevant for the conservation and sustainable use of biological diversity</p> <p>FAO ITPGRFA: TK related to plant genetic resources for food and agriculture</p>	
Other international texts	<p>UNDRIP: non-binding declaration articulating indigenous peoples' rights relating to TK</p> <p>Bonn Guidelines: Biodiversity-related TK relevant for the conservation and sustainable use of biological diversity</p>	

B. GAPS EXISTING AT THE INTERNATIONAL LEVEL

Aspect of protection	Identification of gap in protection	Specific considerations
Identification or definition of TK eligible for protection	<p>No formal definition of TK that should be protected, although TK is referred to in several international instruments (within particular domains of TK)</p> <p>Elements of a definition developed in IGC work</p>	
Gaps in the express objectives of protection	<p>Intrinsic value of TK systems</p> <p>TK systems as valuable forms of innovation</p> <p>Respect for TK systems and cultural and spiritual values of TK holders</p> <p>Respect rights of TK holders and custodians</p> <p>Conserving TK and strengthening TK systems</p> <p>Sustaining traditional lifestyles</p> <p>Support innovation within TK systems</p> <p>Support safeguarding and preservation of TK;</p> <p>Repress misappropriation and unfair and inequitable uses of TK,</p>	

Aspect of protection	Identification of gap in protection	Specific considerations
	<p>and promoting equitable benefit-sharing from TK;</p> <p>Ensure access and use of TK is subject to prior informed consent</p> <p>Promote sustainable community development and legitimate trading activities based on TK systems;</p> <p>Curtail the grant or exercise of improper IP rights over TK</p>	

<i>Gaps in existing legal mechanisms</i>		
Subject matter not covered	<p>TK not covered by existing forms of IP protection, such as:</p> <ul style="list-style-type: none"> - TK that is not novel; - TK that is non-inventive; - TK that is publicly disclosed or otherwise not eligible for protection as undisclosed information. 	See Item A above
	Cumulative, collectively held and intergenerational TK that does not meet criteria for undisclosed or confidential information.	
	Integrated traditional knowledge system as such	
Beneficiaries or right holders not recognized	Collective rights, interests and entitlements within a TK system	
Forms of use and other actions that cannot be prevented under existing law	Express norm against illegitimate patenting of TK	
	Specific patent disclosure requirement relating to TK	
	Protection against unjust enrichment or misappropriation of TK	

A right of acknowledgement and integrity	Prevention against the use of TK without explicit acknowledgement of the source community.	
	Prevention against the use that creates cultural or spiritual offence, or impairs integrity of TK	
Prior informed consent over TK	<p>No express recognition that TK holders have prior informed consent over access to certain forms of TK.</p> <p>Clarification of protection of undisclosed information as a means of implementing right of prior informed consent</p>	Need to clarify principle of prior informed consent for knowledge that is shared with other TK holders, and that has been already disclosed beyond the community with the (tacit or express) consent of the community, or without consent.
Prior informed consent over TK and the patent system	<p>No express legal linkage between prior informed consent systems concerning TK, and patenting of</p> <ul style="list-style-type: none"> - TK as such; and - inventions based on TK 	Existing obligation to identify true inventor and to base a patent on title from the inventor
Right of equitable benefit sharing	Absence of entitlement to obtain equitable remuneration or other benefits (including culturally appropriate and other non-financial benefits).	Potential role of customary law in determining what benefits are equitable and appropriate

C. CONSIDERATIONS RELEVANT TO DETERMINING WHETHER THOSE GAPS NEED TO BE ADDRESSED

	Nature of consideration	Details
<i>Substantive considerations</i>	International law and policy	Including legal obligations and policy settings relating to: <ul style="list-style-type: none"> - conservation of biodiversity and the combat against desertification - rights of indigenous peoples - sustainable health policy and access to medicines
	Social, cultural, political and economic considerations	<ul style="list-style-type: none"> - emphasis on claims of inequity arising from misappropriation and misuse of TK - role of TK in sustainable, grass roots development - link between protecting TK and cultural and social identity of communities - industrial and commercial uptake of TK - value of TK in dealing with environmental and climate change - reference to TK in a range of regulatory contexts
	Role of TK protection in broader policymaking contexts	<ul style="list-style-type: none"> - protection of biodiversity, and equitable use of its benefits; - recognition of the rights of indigenous peoples; - promoting food security and promoting diversity of food crops; - ensuring culturally appropriate access to health; - sustainable grass roots development; - climate change abatement and mitigation; - the increasing overlap between traditional knowledge as such and formal disciplines of biotechnology; - the contribution of traditional knowledge systems to innovation and cultural diversity.
	Specific legal and policy considerations	<ul style="list-style-type: none"> - The fact that many national or regional processes are already developing stronger protection of TK, suggesting that there may be difficulties,

	Nature of consideration	Details
		<p>impediments or other obstacles if there is no development on an international dimension to provide a common platform for otherwise diverse national or regional TK protection systems;</p> <ul style="list-style-type: none"> - The possible systemic implications from lack of clarity in the international law of IP in areas where it is relevant to TK and traditional knowledge and innovation systems; - The possible gains from a reduction in legal uncertainty associated with concerns about possible ownership or custodial responsibilities relating to TK; - The costs and benefits arising from a common international approach towards TK protection issues.
	<p>Considerations specifically weighing against addressing gaps</p>	<ul style="list-style-type: none"> - The possibility that it is premature to fill certain gaps at international level, even when gaps are clearly identified, in view of the need for more national experience to be developed and shared as a precondition for clearer international outcomes; - The diversity of TK and the communities holding, which may set limits to the international dimension of norm-setting - Uncertainty over rights and entitlements of foreign right holders, such as TK holding communities in dramatically different cultural and social contexts; - The possible need for stronger, more diverse consultative processes before moving towards high profile political and legal outcomes that would be difficult and costly to revisit once concluded.

D. OPTIONS THAT EXIST OR MIGHT BE DEVELOPED TO ADDRESS ANY IDENTIFIED GAPS:

Options at different levels	Specific considerations that apply
International level	
(i) a binding international instrument or instruments;	<p>What specific norms are sufficiently established in substance and timely to express as binding international law?</p> <ul style="list-style-type: none"> - regarding the protection of TK directly; - regarding recognition of TK in the patent system and other areas of IP law
(ii) authoritative or persuasive interpretations or elaborations of existing legal instruments;	<p>What existing provisions and legal principles may be suitable for authoritative interpretations vis-à-vis TK? For example:</p> <ul style="list-style-type: none"> - unfair competition; - patent law standards and other areas of IP law; - undisclosed information or law of confidentiality.
(iii) a non-binding normative international instrument or instruments;	<p>What norms, standards and political priorities may be agreed in the form of a non-binding instrument at the international level?</p>
(iv) a high level political resolution, declaration or decision,	<p>What norms, standards and political priorities may be agreed in the form of a political resolution at the international level?</p>
(v) strengthened international coordination through guidelines or model laws	
(vi) coordination of national legislative developments.	
(vii) international cooperation on practical measures	<p>Existence of programs, materials and initiatives already aimed at:</p> <ul style="list-style-type: none"> - capacity building and substantive materials for legal and policy processes - strengthening practical capacity of TK holders - building and guiding institutions - interagency cooperation and coordination within UN system - awareness and capacity-building for the general public

Regional level

- Legal instruments concluded at the regional, subregional or bilateral level, including *sui generis* instruments and conventional IP law
- Political or policy-level declarations proclaimed at the regional, subregional or bilateral level
- Model laws and other forms of legislative guidance adopted at the regional level
- Model protocols, guidelines and best practice recommendations adopted at the regional or subregional levels
- Regional, subregional and bilateral initiatives and programs to support community capacity building relating to TK

National level

- Legislation to protect TK, including *sui generis* instruments and conventional IP law
- Policy frameworks and administrative mechanisms to promote and protect TK, including within specific domains such as medicine and public health, the environment, and agriculture
- Model protocols, guidelines and best practice recommendations adopted either by national authorities or other institutions
- National initiatives and programs to support community capacity building relating to TK

[End of Annex II and of document]