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THE PROTECTION OF TRADITIONAL KNOWLEDGE:

REVISED OBJECTIVES AND PRINCIPLES

Document prepared by the Secretariat

INTRODUCTION

1. At its fifteenth session, held from December 7 to 11, 2009, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') decided that the Secretariat should "prepare and distribute, before the end of January 2010, a revised version of working document WIPO/GRTKF/IC/9/5, reflecting the proposed amendments and comments made on and questions posed in relation to this document at this session of the Committee. Amendments, comments and questions of observers should be recorded for consideration by Member States. The Secretariat would invite Committee participants to provide written comments on that revised version before the end of February 2010. The Committee invited the Secretariat then to prepare and distribute a further revised version of the document, reflecting the written comments made, as a working document for the next session of the Committee."¹

2. Accordingly, a revised version of working document WIPO/GRTKF/IC/9/5 was prepared and published, as WIPO/GRTKF/IC/16/5 Prov., on January 22, 2010, and Committee participants were invited to provide written comments on that revised version before February 28, 2010.

¹ Draft Report of the Fifteenth Session (WIPO/GRTKF/IC/15/7 Prov.)

3. This present working document is the revised version of working document WIPO/GRTKF/IC/16/5 Prov., reflecting the written comments received thereon during this intersessional written commenting process pursuant to the above invitation. Written comments were received from the following Member States: Australia, China, Germany, Mexico, Switzerland and Uruguay; and from the following accredited observers: the International Chamber of Commerce (ICC). The written comments, as received, are available online at http://www.wipo.int/tk/en/consultations/draft_provisions/comments-3.html.

Preparation and structure of this document

4. Document WIPO/GRTKF/IC/9/5 comprised a cover document prepared by the Secretariat, which provided information on the history, structure and content of the document as at the time it was prepared (January 2006), and an Annex, which contained the “substance” of the document, namely the revised draft objectives and principles.

5. The Annex comprised the objectives and principles themselves as well as a “Commentary”. The Commentary consisted of a substantive commentary on each objective and principle and information identifying and discussing comments received on an earlier version of each objective and principle, as contained in the document prepared for the seventh session of the Committee (WIPO/GRTKF/IC/7/5). These comments had already been reflected in document WIPO/GRTKF/IC/9/5.²

6. In the circumstances and in the interest of keeping the present document as concise and current as possible:

- (a) the cover document to WIPO/GRTKF/IC/9/5 has not been carried over to the present revised version. As the cover document notes, however, the draft objectives and principles are based upon extensive fact-finding, discussion analysis and case-studies and draw directly upon comments and proposals made by Committee participants since they were first published in an earlier form in August 2004. The full history of the draft objectives and principles, and in particular the past comments made on them, is available online.³ The draft objectives and principles are also complemented by other resources, such as the collations and factual extraction of comments on the agreed List of Issues⁴ and the draft Gap Analysis⁵. All this information is available online⁶;

² The comments noted in the Commentary to WIPO/GRTKF/IC/9/5 were comments that had been made on document WIPO/GRTKF/IC/7/5, an earlier version of WIPO/GRTKF/IC/9/5, during an inter-sessional commentary process established by the Committee at its seventh session in November 2004. The commentary process ran from November 2004 to February 2005, and the comments made during that period were incorporated in a revised version of WIPO/GRTKF/IC/7/5 which was issued as a working document for the eighth session of the Committee in June 2005 (WIPO/GRTKF/IC/8/5). Document WIPO/GRTKF/IC/8/5 was subsequently reissued, without any amendment to the Annex, as document WIPO/GRTKF/IC/9/5. In other words, the comments noted in document WIPO/GRTKF/IC/9/5 have already been taken into account in the preparation of the present document.

³ http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_9/wipo_grtkf_ic_9_5.pdf

⁴ Working documents WIPO/GRTKF/IC/11/5(A) on the “Collation of Written Comments on the List of Issues” and WIPO/GRTKF/IC/12/5(B) on the “Factual Extraction”.

⁵ Working document WIPO/GRTKF/IC/13/5(B)Rev.

⁶ <http://www.wipo.int/tk/en/igc>

- (b) in the Annex, the substantive commentary on each objective and principle has been retained. The information on the comments made on the earlier version of document WIPO/GRTKF/IC/9/5 has not been included and is in effect replaced by comments made and questions posed at the fifteenth session and during the intersessional written commenting process. To avoid confusion between the earlier comments and those made at the fifteenth session and during the intersessional written commenting process, references to earlier comments in footnotes have also been removed. The comments made previously on the “original” document WIPO/GRTKF/IC/9/5 remain available to be consulted online;⁷
- (c) in line with the decisions of the Committee taken at its fifteenth session, specific amendments proposed by Member States at this session and during the intersessional written commenting process are reflected in the objectives and principles in the Annex. Proposed insertions and additions are underlined, while words or phrases that a Member State has proposed be deleted are “struck through”. Where more than one proposal has been made, the proposals are separated by two forward slash (/). The Annex also records other comments made and questions posed at the fifteenth session and during the intersessional written commenting process, as well as drafting suggestions, comments and questions of observers which are recorded for consideration by Member States. The comments and questions are, as far as possible, grouped by issue. Several comments made during the intersessional written commenting process related generally to the entire document; these general comments are reflected at the very end of the document.

7. The Committee is invited to continue to review and comment on the draft provisions contained in the Annex towards developing a revised and updated version thereof.

[Annex follows]

⁷ http://www.wipo.int/tk/en/consultations/draft_provisions/comments-1.html

ANNEX

REVISED PROVISIONS
FOR THE PROTECTION OF
TRADITIONAL KNOWLEDGE

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I. POLICY OBJECTIVES

The protection of traditional knowledge should aim to:

Recognize value

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

Promote respect

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

Meet the actual needs of holders of traditional knowledge

(iii) be guided by the aspirations and expectations expressed directly by traditional knowledge holders, respect their rights as holders and custodians of traditional knowledge, contribute to their welfare and economic, cultural and social benefit and reward the contribution made by them to their communities and to the progress of science and socially beneficial technology;

Promote conservation and preservation of traditional knowledge

(iv) promote and support the conservation and preservation of traditional knowledge by respecting, preserving, protecting and maintaining traditional knowledge systems and providing incentives to the custodians of those knowledge systems to maintain and safeguard their knowledge systems;

Empower holders of traditional knowledge and acknowledge the distinctive nature of traditional knowledge systems

(v) be undertaken in a manner that empowers traditional knowledge holders to protect their knowledge by fully acknowledging the distinctive nature of traditional knowledge systems and the need to tailor solutions that meet the distinctive nature of such systems, bearing in mind that such solutions should be balanced and equitable, should ensure that conventional intellectual property regimes operate in a manner supportive of the protection of traditional knowledge against misappropriation, and should effectively empower traditional knowledge holders to exercise due rights and authority over their own knowledge;

Support traditional knowledge systems

(vi) respect and facilitate the continuing customary use, development, exchange and transmission of traditional knowledge by and between traditional knowledge holders; and support and augment customary custodianship of knowledge and associated genetic resources, and promote the continued development of traditional knowledge systems;

Contribute to safeguarding traditional knowledge

(vii) while recognizing the value of a vibrant public domain, contribute to the preservation and safeguarding of traditional knowledge and the appropriate balance of customary and other means for their development, preservation and transmission, and promote the conservation, maintenance, application and wider use of traditional knowledge, in accordance with relevant customary practices, norms, laws and understandings of traditional knowledge holders, for the primary and direct benefit of traditional knowledge holders in particular, and for the benefit of humanity in general;

Repress unfair and inequitable uses

(viii) repress the misappropriation of traditional knowledge and other unfair commercial and non-commercial activities, recognizing the need to adapt approaches for the repression of misappropriation of traditional knowledge to national and local needs;

Respect for and cooperation with relevant international agreements and processes

(ix) take account of, and operate consistently with, other international and regional instruments and processes, in particular regimes that regulate access to and benefit-sharing from genetic resources which are associated with that traditional knowledge;

Promote innovation and creativity

(x) encourage, reward and protect tradition-based creativity and innovation and enhance the internal transmission of traditional knowledge within indigenous and traditional communities, including, subject to the consent of the traditional knowledge holders, by integrating such knowledge into educational initiatives among the communities, for the benefit of the holders and custodians of traditional knowledge;

Ensure prior informed consent and exchanges based on mutually agreed terms

(xi) ensure prior informed consent and exchanges based on mutually agreed terms, in coordination with existing international and national regimes governing access to genetic resources;

Promote equitable benefit-sharing

(xii) promote the fair and equitable sharing and distribution of monetary and non-monetary benefits arising from the use of traditional knowledge, in consistency with other applicable international regimes, the principle of prior informed consent and including through fair and equitable compensation in special cases where the individual holder is not identifiable or the knowledge has been disclosed;

Promote community development and legitimate trading activities

(xiii) if so desired by the holders of traditional knowledge, promote the use of traditional knowledge for community-based development, recognizing the rights of traditional and local communities over their knowledge; and promote the development of, and the expansion of marketing opportunities for, authentic products of traditional knowledge and associated community industries, where traditional knowledge holders seek such development and opportunities consistent with their right to freely pursue economic development;

Preclude the grant of improper IP rights to unauthorized parties

(xiv) curtail the grant or exercise of improper intellectual property rights over traditional knowledge and associated genetic resources, by requiring the creation of digital libraries of publicly known traditional knowledge and associated genetic resources, ~~in particular, as a condition for the granting of patent rights, that patent applicants for inventions involving traditional knowledge and associated genetic resources disclose the source and country of origin of those resources, as well as evidence of prior informed consent and benefit sharing conditions have been complied with in the country of origin;~~

Enhance transparency and mutual confidence

(xv) enhance certainty, transparency, mutual respect and understanding in relations between traditional knowledge holders on the one hand, and academic, commercial, educational, governmental and other users of traditional knowledge on the other, including by promoting adherence to ethical codes of conduct and the principles of free and prior informed consent;

Complement protection of traditional cultural expressions

(xvi) operate consistently with protection of traditional cultural expressions and expressions of folklore, respecting that for many traditional communities their knowledge and cultural expressions form an indivisible part of their holistic identity.

[Commentary on Objectives follows]

COMMENTARY ON
POLICY OBJECTIVESBackground

Most existing measures, legal systems and policy debates concerning the protection of traditional knowledge have expressly stated the policy objectives which they seek to achieve by protecting TK, and often they share certain common objectives. These objectives are often articulated in preambular language in laws and legal instruments, clarifying the policy and legal context. The draft policy objectives draw on the common goals expressed within the Committee as the common objectives for international protection.

Part A sets out the policy objectives of traditional knowledge (TK) protection, as they have been articulated by the Committee. These objectives give a common direction to the protection established in the principles of Part B. Such objectives could typically form part of a preamble to a law or other instrument. The listed objectives are not mutually exclusive but rather complementary to each other. The list of objectives is non-exhaustive and, given the evolving nature of the provisions, the Committee members may supplement the current list with additional objectives or decide to combine existing objectives from the current list which are notionally related.

Amendments proposed, comments made and questions posed at the fifteenth session (December 7 to 11, 2009) and during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by the United States of America.

Comments made and questions posed

The comments made and questions posed were proposed by Australia and the United States of America.

A delegation raised the following questions: (1) generally, what objective was sought to be achieved through according intellectual property protection (economic rights, moral rights)? Historically, information had been freely shared, except in limited circumstances, and for periods of limited duration. Furthermore, even with the limited circumstances of Intellectual Property rights such as Copyright and Patent, such legal systems had within them a concept of fair use or research use. How should these norms be balanced with any new exclusive rights granted on TK? In addition, in the case of patents, not all countries that provided for patents provided for patents in all areas of technology. Some countries excluded “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” from patentability, because they believed that no one should have exclusive rights on such inventions. Should countries be able to exclude from protection TK related to diagnostic, therapeutic and surgical methods for the treatment of humans or animals? Who should benefit from any protection of TK? Who should hold the rights to protectable TK? Should holders of TK that reside within the traditional origin of the TK and those who no longer reside within the same area be treated in the same way? How would a new system to protect TK change the right of TK holders to continue to use their TK? How would the international concept of non-discrimination apply? If TK was protectable by patent, copyright or other traditional intellectual property rights, should TK also be protectable by other means, i.e., new national laws? (2) For Policy

Objective (iv), how would an international legal instrument support the maintenance and preservation of TK more than actively working to maintain and preserve TK in archives, databases and other recorded means? (3) For Policy Objective (viii), what was misappropriation of TK? Can access to such knowledge through channels that were entirely consistent with national laws be considered misappropriation in particular cases? If so, in what cases? For Policy Objective (viii), what were unfair and inequitable uses of TK? Some examples of fair uses of TK, as well as unfair uses of TK, should be provided. (4) For Policy Objective (x), how would the restriction of the ability to use TK promote innovation and creativity? (5) For Policy Objective (xiv), for Member States that required patent applicants for inventions involving TK to disclose the source and country of origin for the TK and/or proof of prior informed consent and/or mutually agreed terms, what were the provisions outside of the patent regime to ensure that commercial uses of TK were done with prior informed consent and mutually agreed terms? For Member States that required patent applicants for inventions involving TK to disclose the source and country of origin for the TK and/or proof of prior informed consent and/or mutually agreed terms, the circumstances under which the requirement must be met should be explained. Examples of inventions related to TK where the requirement must be met and other situations where it did not need to be met should be provided. For example, if the TK was well known by many, and the invention was an improvement that builds upon the TK, was the disclosure requirement still required to be met? For Member States that had a patent disclosure requirement, why was this requirement more appropriate than a requirement to disclose information that was material to patentability?

A delegation stated that, in general, the “Objectives” should outline what the instrument aimed to achieve, rather than how to achieve it. In this context it did not support the identification of specific mechanisms under Policy Objective (xiv) for the implementation of this objective.

II. GENERAL GUIDING PRINCIPLES

These principles should be respected to ensure that the specific substantive provisions concerning protection are equitable, balanced, effective and consistent, and appropriately promote the objectives of protection:

- (a) Principle of responsiveness to the needs and expectations of traditional knowledge holders*
- (b) Principle of recognition of rights*
- (c) Principle of effectiveness and accessibility of protection*
- (d) Principle of flexibility and comprehensiveness*
- (e) Principle of equity and benefit-sharing*
- (f) Principle of consistency with existing legal systems governing access to associated genetic resources*
- (g) Principle of respect for and cooperation with other international and regional instruments and processes*
- (h) Principle of respect for customary use and transmission of traditional knowledge*
- (i) Principle of recognition of the specific characteristics of traditional knowledge*
- (j) Principle of providing assistance to address the needs of traditional knowledge holders*

[Commentary on General Guiding Principles follows]

COMMENTARY ON
GENERAL GUIDING PRINCIPLESBackground

The substantive provisions set out in the next section are guided by and seek to give legal expression to certain general guiding principles which have underpinned much of the discussion within the Committee since its inception and in international debate and consultations before the Committee's establishment.

Elaboration and discussion of such principles is a key step in establishing a firm foundation for development of consensus on the more detailed aspects of protection. Legal and policy evolution is still fast-moving in this area, at the national and regional level, but also internationally. Equally, strong emphasis has been laid on the need for community consultation and involvement. Broad agreement on core principles could put international cooperation on a clearer, more solid footing, but also clarify what details should remain the province of domestic law and policy, and leave suitable scope for evolution and further development. It could build common ground, and promote consistency and harmony between national laws, without imposing a single, detailed legislative template.

(a) Principle of responsiveness to the needs and expectations of traditional knowledge holders

Protection should reflect the actual aspirations, expectations and needs of traditional knowledge holders; and in particular should: recognize and apply indigenous and customary practices, protocols and laws as far as possible and appropriate; address cultural and economic aspects of development; address insulting, derogatory and offensive acts; enable full and effective participation by all traditional knowledge holders; and recognize the inseparable quality of traditional knowledge and cultural expressions for many communities. Measures for the legal protection of traditional knowledge should also be recognized as voluntary from the viewpoint of indigenous peoples and other traditional communities who would always be entitled to rely exclusively or in addition upon their own customary and traditional forms of protection against unwanted access and use of their traditional knowledge.

(b) Principle of recognition of rights

The rights of traditional knowledge holders to the effective protection of their knowledge against misappropriation should be recognized and respected.

(c) Principle of effectiveness and accessibility of protection

Measures for protecting traditional knowledge should be effective in achieving the objectives of protection, and should be understandable, affordable, accessible and not burdensome for their intended beneficiaries, taking account of the cultural, social and economic context of traditional knowledge holders. Where measures for the protection of traditional knowledge are adopted, appropriate enforcement mechanisms should be developed permitting effective action against misappropriation of traditional knowledge and supporting the broader principle of prior informed consent.

(d) Principle of flexibility and comprehensiveness

Protection should respect the diversity of traditional knowledge held by different peoples and communities in different sectors, should acknowledge differences in national circumstances and the legal context and heritage of national jurisdictions, and should allow sufficient flexibility for national authorities to determine the appropriate means of implementing these principles within existing and specific legislative mechanisms, adapting protection as necessary to take account of specific sectoral policy objectives, subject to international law, and respecting that effective and appropriate protection may be achieved by a wide variety of legal mechanisms and that too narrow or rigid an approach may preempt necessary consultation with traditional knowledge holders.

Protection may combine proprietary and non-proprietary measures, and use existing IP rights (including measures to improve the application and practical accessibility of such rights), *sui generis* extensions or adaptations of IP rights, and specific *sui generis* laws. Protection should include defensive measures to curtail illegitimate acquisition of industrial property rights over traditional knowledge or associated genetic resources, and positive measures establishing legal entitlements for traditional knowledge holders.

(e) Principle of equity and benefit-sharing

Protection should reflect the need for an equitable balance between the rights and interests of those that develop, preserve and maintain traditional knowledge, namely traditional knowledge holders, and of those who use and benefit from traditional knowledge; the need to reconcile diverse policy concerns; and the need for specific protection measures to be proportionate to the objectives of protection and the maintenance of an equitable balance of interests. In reflecting these needs, traditional knowledge protection should respect the right of traditional knowledge holders to consent or not to consent to access to their traditional knowledge and should take into account the principle of prior informed consent.

The rights of traditional knowledge holders over their knowledge should be recognized and safeguarded. Respect for prior informed consent should be ensured, and holders of traditional knowledge should be entitled to fair and equitable sharing of benefits arising from the use of their traditional knowledge. Where traditional knowledge is associated with genetic resources, the distribution of benefits should be consistent with measures, established in accordance with the Convention on Biological Diversity, providing for sharing of benefits arising from the utilization of the genetic resources.

Protection which applies the principle of equity should not be limited to benefit-sharing, but should ensure that the rights of traditional knowledge holders are duly recognized and should, in particular, respect the right of traditional knowledge holders to consent or not to consent to access to their traditional knowledge.

(f) Principle of consistency with existing legal systems governing access to associated genetic resources

The authority to determine access to genetic resources, whether associated with traditional knowledge or not, rests with the national governments and is subject to national legislation. The protection of traditional knowledge associated with genetic resources shall be consistent with the applicable law governing access to those resources and the sharing of

benefits arising from their use. Nothing in these Principles shall be interpreted to limit the sovereign rights of States over their natural resources and the authority of governments to determine access to genetic resources, whether or not those resources are associated with protected traditional knowledge.

(g) Principle of respect for and cooperation with other international and regional instruments and processes

Traditional knowledge shall be protected in a way that is consistent with the objectives of other relevant international and regional instruments and processes, and without prejudice to specific rights and obligations already codified in or established under binding legal instruments and international customary law.

Nothing in these Principles shall be interpreted to affect the interpretation of other instruments or the work of other processes which address the role of traditional knowledge in related policy areas, including the role of traditional knowledge in the conservation of biological diversity, the combating of drought and desertification, or the implementation of farmers' rights as recognized by relevant international instruments and subject to national legislation.

(h) Principle of respect for customary use and transmission of traditional knowledge

Customary use, practices and norms shall be respected and given due account in the protection of traditional knowledge, subject to national law and policy. Protection beyond the traditional context should not conflict with customary access to, and use and transmission of, traditional knowledge, and should respect and bolster this customary framework. If so desired by the traditional knowledge holders, protection should promote the use, development, exchange, transmission and dissemination of traditional knowledge by the communities concerned in accordance with their customary laws and practices, taking into account the diversity of national experiences. No innovative or modified use of traditional knowledge within the community which has developed and maintained that knowledge should be regarded as offensive use if that community identifies itself with that use of the knowledge and any modifications entailed by that use.

(i) Principle of recognition of the specific characteristics of traditional knowledge

Protection of traditional knowledge should respond to the traditional context, the collective or communal context and inter-generational character of its development, preservation and transmission, its relationship to a community's cultural and social identity and integrity, beliefs, spirituality and values, and constantly evolving character within the community.

(j) Principle of providing assistance to address the needs of traditional knowledge holders

Traditional knowledge holders should be assisted in building the legal-technical capacity and establishing the institutional infrastructure which they require in order to effectively utilize and enjoy the protection available under these Principles, including, for example, in the setting up of collective management systems for their rights, the keeping of records of their traditional knowledge and other such needs.

Amendments proposed, comments made and questions posed during the intersessional written commenting process

Comments made and questions posed

The comments made and questions posed were proposed by Australia, China and, as observers, by the International Chamber of Commerce (ICC).

A delegation believed that, as an interim achievement made with concerted efforts by Member States and the Secretariat after years of hard work, the document on policy objectives and core principles for the protection of TK had laid down a sound basis for future work, and should thus be brought into full play.

A delegation considered that, without prejudice to any position on particular elements, the Objectives and Principles in Parts I and II should support and provide guidance to any suggested working text provided in Part III. Any suggested amendments to Part III had to be referenced to the Objectives and Principles that supported it to give sufficient information to Member States regarding the intent or purpose of any suggestions in relation to the document. It noted that the lack of agreement or consensus on elements of the Objectives and Principles made discussion of Part III very difficult. Without agreement on what the objective of protection was to be, and the principles that guided the Committee in achieving those objectives, there was little substance to discussion. With respect to part III, in general, it noted that references to “Articles” resembled draft treaty text and pre-empt discussion about the form and status of any international legal instrument which would ensure the protection of TK. It noted the lack of consensus on the need for a legally binding instrument, and called for further general discussion at an appropriate time on the adoption of prescriptive principles that focused on conferring legally enforceable rights in light of the core General Guiding Principle (g) “respect for and cooperation with other international and regional instruments and processes”.

An observer noted that two of the stated principles of the negotiation required more emphasis: efficiency and balance. In the corresponding document on TCEs, WIPO/GRTKF/IC/16/4 Prov., balance, between users and holders of knowledge, was specifically included as a principle. WIPO/GRTKF/IC/16/5 Prov. did not include this paragraph. Balance was equally important in both contexts.

[Substantive provisions follow]

III. SUBSTANTIVE PROVISIONS

ARTICLE 1

PROTECTION AGAINST MISAPPROPRIATION AND MISUSE

1. *Traditional knowledge shall be protected against the following acts if these acts have a commercial goal or take place outside the context of the customary or traditional uses of this traditional knowledge ~~misappropriation~~ //misappropriation and misuse.*

2. *Any acquisition, appropriation, revelation or utilization of traditional knowledge by unfair or illicit means ~~constitutes shall constitute~~ an act of misappropriation and misuse. Misappropriation and misuse ~~may also include~~ also include // shall include deriving // Any acquisition, appropriation or utilization of traditional knowledge by unfair or illicit means ~~constitute that constitutes~~ an act ~~of misappropriation~~. ~~Misappropriation may also include~~ deriving to derive // commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows, or ~~fails is negligent in failing~~ to know, that it was acquired or appropriated by unfair means; and other commercial activities contrary to honest practices that gain inequitable benefit from traditional knowledge.*

3. *In particular, legal means ~~should~~ shall be provided to prevent:*

(i) *acquisition of traditional knowledge by theft, bribery, coercion, fraud, trespass, breach or inducement of breach of contract, breach or inducement of breach of confidence or confidentiality, breach of fiduciary obligations or other relations of trust, deception, misrepresentation, the provision of misleading information when obtaining prior informed consent for access to traditional knowledge, or other unfair or dishonest means;*

(ii) *acquisition of traditional knowledge or exercising control over it in violation of legal measures that require prior informed consent as a condition of access to the knowledge, and use of traditional knowledge that violates terms that were mutually agreed as a condition of prior informed consent concerning access to that knowledge;*

(iii) *false claims or assertions of ownership or control over traditional knowledge, including acquiring, claiming or asserting intellectual property rights over traditional knowledge-related subject matter when those intellectual property rights are not validly held in the light of that traditional knowledge and any conditions relating to its access;*

(iv) *~~if traditional knowledge has been accessed,~~ commercial or industrial use of traditional knowledge ~~without just and appropriate compensation~~ // ~~benefit sharing~~ // to the recognized holders of the knowledge in violation of the recognized rights of the holders of the knowledge, when such use has gainful intent and confers a technological or commercial advantage on its user, ~~and when compensation would be consistent with fairness and equity in relation to the holders of the knowledge in view of the circumstances in which the user acquired the knowledge~~ // in view of the circumstances in which the user acquired the knowledge and according to the national and international regimes // regimes-legislation where applicable; and*

(v) ~~willful~~ *offensive use of traditional knowledge of particular moral or spiritual value to its holders by third parties outside the customary context, when such use clearly constitutes a mutilation, distortion or derogatory modification of that knowledge and is contrary to ordre public or morality;*

(vi) *the granting of patent rights for inventions involving traditional knowledge and associated genetic resources without the disclosure of the country of origin of the knowledge and/or resources, as well as evidence that prior informed consent and benefit-sharing conditions have been complied with in the country of origin.*

4. *Traditional knowledge holders should also be effectively protected against other acts of unfair competition, including acts specified in Article 10bis of the Paris Convention. This includes false or misleading representations that a product or service is produced or provided with the involvement or endorsement of traditional knowledge holders, or that the commercial exploitation of products or services benefits holders of traditional knowledge. It also includes acts of such a nature as to create confusion with a product or service of traditional knowledge holders; and false allegations in the course of trade which discredit the products or services of traditional knowledge holders.*

5. *The application, interpretation and enforcement of protection against misappropriation and misuse of traditional knowledge and other recognized rights, including determination of equitable sharing and distribution of benefits, should be guided, as far as possible and appropriate, by respect for the customary practices, norms, laws and understandings of the holder of the knowledge, including the spiritual, sacred or ceremonial characteristics of the traditional origin of the knowledge.*

COMMENTARY ON
ARTICLE 1

This provision builds on an international consensus that traditional knowledge should not be misappropriated, and that some form of protection is required to achieve this. Existing international and national laws already contain norms against misappropriation of related intangibles such as goodwill, reputation, know-how and trade secrets. These norms can be viewed as part of the broader law of unfair competition and civil liability rather than as necessarily requiring distinct exclusive rights as provided for in the chief branches of modern intellectual property law. This provision establishes a general principle against the misappropriation of TK as a common frame of reference for protection, drawing together existing approaches and building on existing legal frameworks.

The general norm against misappropriation is elaborated in three, cumulative steps. The provision first articulates a basic norm against misappropriation as such; second, it develops the nature of “misappropriation” by providing a general, non-exclusive description of misappropriation; and finally it catalogues specific acts of misappropriation which should be suppressed. This drafting structure (but not its legal content) mirrors the structure of a provision in the Paris Convention which has proven to be widely adaptable (Article 10*bis*) and which has engendered several new forms of protection, such as the protection of geographical indications and the protection of undisclosed information. Importantly for traditional knowledge protection, this article does not create exclusive property rights over intangible objects. Rather, it represses unfair acts in certain spheres of human intellectual activity without creating distinct private property titles over the knowledge which is being protected against those illegitimate acts. Similarly, the first paragraph in this provision defines misappropriation as an unfair act which should be repressed, without creating monopolistic property rights over TK.

The second paragraph describes the nature of misappropriation in a general and non-exclusive manner. A link with unfair competition law is suggested by the focus on acquisition *by unfair means*. Akin to Article 10*bis*, the term “unfair means” may be defined differently, depending on the specific legal settings in national law. This allows countries to take into account various domestic and local factors when determining what constitutes misappropriation, in particular the views and concerns of indigenous and local communities. The non-exclusive nature of this description of “misappropriation” allows the term “misappropriation” to become the umbrella term and structure under which the various unfair, illicit and inequitable acts, which should be repressed, may be subsumed.

Paragraph 3 provides an inclusive list of those specific acts which, when undertaken in relation to TK covered by these Principles, would, at a minimum, be considered acts of misappropriation. By allowing a wide range of measures as appropriate “legal means” within national law to suppress the listed acts, the chapeau of this paragraph applies the Guiding Principle of flexibility and comprehensiveness. The different subparagraphs of Article 1.3 distil specific acts of misappropriation, which include: (i) the illicit acquisition of TK, including by theft, bribery, deception, breach of contract, etc; (ii) breach of the principle of prior informed consent for access to TK, when required under national or regional measures; (iii) breach of defensive protection measures of TK; (iv) commercial or industrial uses which misappropriate the value of TK where it is reasonable to expect the holders of TK to share the benefits from this use; and (v) willful morally offensive uses of TK which is of particular moral or spiritual value to the TK holder. The provision gives wide flexibility for countries to use different legal means to suppress these listed acts. In countries which admit this

possibility, judicial and administrative authorities may even draw upon these principles directly, without requiring specific legislation to be enacted. The words “in particular” leave the choice open to national policy makers to consider additional acts as forms of misappropriation and include these in the list nationally. This could include, for example, passing-off, misrepresentation of the source of TK, or failure to recognize the origin of TK.

Paragraph 4 supplements the basic misappropriation norm by clarifying that the specific acts of unfair competition already listed in Article 10*bis* do have direct application to TK subject matter. As requested by commentators, the paragraph now been extended to clarify the relation between protection against misappropriation and protection under Article 10*bis* of the Paris Convention. It expressly states that TK holders are additionally protected against misleading representations, creating confusion and false allegations in relation to products or services produced or provided by them.

Since the notion of misappropriation would need to be more closely interpreted under national law, paragraph 5 suggests that concepts such as “unfair means”, “equitable benefits” and “misappropriation” should in particular cases be guided by the traditional context and the customary understanding of TK holders themselves. The traditional context and customary understandings may be apparent in a community’s traditional protocols or practices, or may be codified in customary legal systems.

Amendments proposed, comments made and questions posed at the fifteenth session (December 7 to 11, 2009) and during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by Brazil, Cameroon, India, Indonesia, Mexico, Morocco, Peru and Venezuela (Bolivarian Republic of).

Comments made and questions posed

The comments made and questions posed were proposed by Australia, Burundi, Cameroon, China, Germany, Italy, Japan, Kenya, Morocco, Nepal, New Zealand, Nigeria, Norway, the Russian Federation, Spain, South Africa, Sweden, on behalf of the European Union, Switzerland, the United States of America and, as observers, by the African Regional Intellectual Property Organization (ARIPO), the Indigenous Peoples Council on Biocolonialism (IPCB), the Instituto Indígena Brasileiro da Propriedade Intelectual (InBraPi), the International Chamber of Commerce (ICC), the Maya To’Onik Association, the Saami Council, the Tulalip Tribes of Washington, and the Tupaj Amaru.

Relationship with elements of policy objectives and principles

A delegation noted this article specifically related to elements of a number of policy objectives and principles in the operative document, particularly Policy Objectives (v) and (viii) and Principles (b) and (c). There were elements of these policy objectives and principles that were worthy of further discussion that would assist in a thorough analysis of the operation of any text of this nature. For example, what would the relationship or interface be with the existing IP system, to what extent did it accord with flexibility for national and local implementation, what impact would it have with respect to public domain knowledge, and what elements of such protection related to the IP system specifically, and which elements did not. Also the text was very dense and it might be useful to distill the operative

elements and consider each separately. Furthermore, it noted the current text of this provision was too detailed and prescriptive and was not consistent with Article 2 and the principle of flexibility and comprehensiveness. This provision also contained broad subjective terms and phrases such as “unfair means” and “contrary to honest practices”, which required further consideration and definition. The general norm articulated in this provision in the original working document reflected Policy Objective (viii) “repress unfair and inequitable uses”. This objective also noted the need to adapt approaches for the repression of misappropriation of TK to national and local needs. The Commentary on this provision established a number of key points. Paragraph two of the commentary noted that the original drafting structure of this part mirrored the structure of Article 10bis of the Paris Convention. It questioned the applicability of Article 10bis of the Paris Convention to the protection of TK and called for further discussion of this element. Additionally, if Policy Objective (viii) was to provide a basis for part of a legal instrument, arguably, the nature of misappropriation should be described “in a general and non-exclusive manner” allowing it to become an umbrella term under which various unfair acts might be subsumed. Akin to Article 10bis, the term “unfair means” might be defined differently according to national law. However, it noted that many of the suggestions in relation to this working document at the fifteenth session of the Committee would appear to limit the capacity of Member States to adapt approaches that they might take according to national and local needs. Consequently, the Committee would benefit from further discussion of Policy Objective (viii) to provide guidance as to any appropriate textual embodiment of this objective. In relation to suggested amendments to paragraph 2 to delete the phrase “negligent in failing to know”, this expanded the scope of “repress unfair and inequitable uses” to acts without fault. To what extent did this meet Policy Objective (viii), or the Paris Convention concept of “honest business practices”? In relation to Paragraph 3 (vi), it noted the connection with Policy Objective (xi) “ensure prior informed consent and exchanges based on mutually agreed terms”. The issue of prior informed consent in the protection of TK did not, as far as it was aware, have consensus between Member States. It called for further discussion of the applicability of a binding obligation in this respect.

Three delegations suggested that in-depth examination of policy objectives and principles was the prerequisite for the discussion on the substantive provisions.

A delegation noted that the objective of protection in this document was too limited. Protection against misappropriation should not be the only objective. The protection of TK should expand to other areas, such as sustainable development, promotion of innovation and research, as well as the protection of moral rights.

A delegation highlighted that the protection against misappropriation of TK should not be the only direction of protection of TK. Therefore, other additional policy objectives were important to the protection of TK and should be reflected in any provision of protection of TK.

A delegation asked for greater clarification on what actually should be the objective and subject of protecting TK through Article 1. It reserved its right to make additional comments on the other substantive provisions once this upstream issue had been clarified sufficiently. This did not imply that it accepted the substantive provisions contained in the Annexes of this document as the only basis for future discussions.

An observer noted objectives needed to be discussed.

An observer noted indigenous peoples and local communities were the object of protection.

Glossary

A delegation called for a glossary.

A delegation highlighted there was the need for clear definitions in all the articles in order to maintain clear perspective on all the issues and subject matter, since it was observed that certain delegations were ascribing meanings to certain terms based on their perception, interpretation and interest.

An observer called for a glossary. This glossary should be prepared according to the perspective or world vision of indigenous peoples, taking into account that concepts such as acquisition, misappropriation, ownership and so on had other connotations in the cultural world vision of indigenous peoples, particularly in the Maya culture.

An observer noted that clarity was important because business needed to know what they can do and what they cannot do.

Definition of misappropriation

Four delegations suggested that misappropriation should be defined.

A delegation noted that the list of possible cases of misappropriation included in Article 1 paragraph 3 was not necessary.

A delegation noted that Article 1 was restrictive as protection of TK should not be solely based on acts of misappropriation. The entire Article should be reviewed to include all rights that should be protected thoroughly under TK, including economic and moral rights.

An observer noted that the concept of misappropriation appeared to vary widely. As a fundamental matter, the concept of misappropriation should be linked to notions of appropriate access and benefit-sharing through compliance with national ABS laws. In other words, if there was no violation of the national ABS law, there was no “misappropriation.” When considering how to define specific instances of “misappropriation” under national laws, the following circumstances might be taken into account: (1) whether the relevant TK was communicated directly to the user by traditional holders; (2) whether the relevant TK was not known, disclosed or used anywhere else; (3) whether permission to use the relevant TK was obtained from at least some genuine holders; and (4) whether mutually agreed terms for benefit-sharing existed and were respected. Other circumstances might be considered, but clear rules were needed to determine which conditions were essential. There were many outstanding questions that governments had to consider. Should there be special conditions regarding research or non-commercial use or publication of TK? If the information claimed to be TK had become publicly known or was in use by other – perhaps unrelated – indigenous peoples, would ABS laws still apply? How could a system be designed to put users on notice that published information was not freely available for use (as the patent system does)? If the relevant TK was unpublished, should it be treated in the same way as other proprietary unpublished information – so that, for example, if it was developed independently, it could not be subject to restrictions on use?

Definition of TK

Two delegations noted that the definition of TK was absolutely necessary. The kind of definition included in Article 3 paragraph 2 was insufficient.

Four delegations noted that there was no clear understanding among members on the fundamental term “TK” and it was no clear what TK encompassed. The definition should be dealt with before entering substantive discussion on respective articles.

A delegation highlighted a need for greater clarification of what actually was the subject matter for protection, namely how TK should be defined for this purpose.

A delegation commented on the specific drafting amendment of deleting “if traditional knowledge has been accessed”. The purpose of that phrase was to make clear that if someone created that same knowledge independently he would have the right to use his own independent creation. Furthermore, it questioned how to deal with the concept of evolving TK.

A delegation noted that Paragraph (iv), in particular, was very prescriptive and required further consideration in the context of TK as well as more broadly in the context of the relationship between GR and TK.

Definition of holders and recognized holders

A delegation suggested that the terms “holders” and “recognized holders” needed to be defined: (a) were these concepts synonymous?; (b) if not, what was the basis for including holders among “recognized holders”?

An observer stated that throughout the document reference was made to the holders of TK, but only in Article 4 was it clearly expressed that indigenous peoples and local communities were the holders of that TK. She proposed that, in accordance with Article 4 (iii), “indigenous peoples and local communities” be placed before the word “holders”.

Rights of the holders

A delegation suggested that the first thing to do would be to define the rights which were to be recognized to the holders, since misappropriation meant a breach of rights.

A delegation believed that Article 1 did not say what right was offered to the TK holder in which the holders would be able to seek legal redress in case they were misused.

Enforcement

A delegation questioned what body should be responsible for penalization. It also noted it was not clear, in Article 1 paragraph 3, who should make the legal means available and to whom.

Concept of compensation

A delegation commented on the specific drafting amendment that the concept of “compensation” should remain in Article 1 paragraph 3 (iv).

Commercial and non-commercial issues

A delegation suggested that Article 1 should cover wider issues on exploitation of TK, not only on commercial exploitation of TK.

A delegation raised the issue of potentially differentiating commercial and non-commercial misappropriation. It noted that Article 1 set a higher threshold for non-commercial misappropriation than for commercial misappropriation. However, the Policy Objective (viii) aimed to “repress the misappropriation of traditional knowledge and other unfair commercial and non-commercial activities”. It should be sufficient that the effect of the use was offensive.

An observer noted that it was important that the legal form of protection should extend to commercial and non-commercial use of TK because misuse often resulted from non-commercial use of TK, and TK acquired under non-commercial auspices could easily move into commercial use.

Ordre public or morality

A delegation noted that the *ordre public* or morality was different from country to country and the definition of “the *ordre public* or morality” was not clear.

A delegation wondered, if an international regime was created, how to enforce laws of another country when morals were involved, since the perspectives on the concept of *ordre public* or morality could be quite different.

Public domain

A delegation highlighted that it was especially important to find the right balance between protectable TK and knowledge which had become part of the public domain. There was not a coherent approach to what the notion of public domain actually meant.

A delegation asked (1) What was the relationship between the foreseen protection of TK and knowledge already in the public domain? Where was the relevant point of access to TK, which was not fixed locally in nature, to be determined? (2) How Member States foresaw protection of TK contained in databases?

An observer noted that the concept of public domain could not be applied to TK. Publicly available TK should be distinguished from TK in the public domain.

Disclosure requirement

A delegation believed that development and use of TK that has been obtained by third parties beyond the traditional context should comply with the principles of prior informed consent and benefit sharing, and should duly and truthfully indicate its source without, in particular, concealment, misrepresentation or distortion, in such a way as to manifest respect for the source of TK.

An observer opposed the specific drafting amendment on requiring the origin of biological materials to be disclosed in patents. However, a full discussion of this proposal between experts was welcomed.

Concept of misuse

In relation to the suggested change to include the concept of “misuse” as well as “misappropriation”, a delegation noted that misuse was a term that was used in the CBD context within the draft negotiating text for an international regime on access and benefit sharing of GR and associated TK. It was used to refer to acts that were contrary to mutually agreed terms, while misappropriation referred specifically to acquisition without prior informed consent. It called for further discussion as to the meaning of these terms in the context of this Committee and in relation to IP rather than access to TK associated with GR.

Relationship with Gap Analysis

A delegation stated that the Gap Analysis (WIPO/GRTKF/IC/13/5(B)) had shown that the legal means in Paragraph 3 were already available, though not all (note 3(iv)). It wondered to what extent was this international instrument filling the gaps identified in that analysis.

Drafting suggestions by observers

An observer suggested to add “or non-commercial” in line 5 of Article 1 paragraph 2 after the word “commercial”.

An observer suggested to add “of the indigenous peoples and local communities, holders of traditional knowledge” after “prior informed consent” in line 2 of Article 1 paragraph 3 (ii).

An observer suggested, in relation to Article 1 paragraph 2, to delete “by unfair or illicit means” and to replace by “without the free, prior informed consent of the indigenous peoples or communities that have developed traditional knowledge”. He also suggested to replace “the acquisition, appropriation or utilization of traditional knowledge” with “the utilization of traditional knowledge that has entered the public domain without the consent of the indigenous peoples or communities that have developed the traditional knowledge”.

An observer suggested, in Article 1 paragraph 3 (v), to add “of the indigenous peoples and local communities” after “*ordre public* or morality”.

An observer proposed that “shall” in Article 1 paragraph 1 should be replaced with “should”. In relation to Article 1 paragraph 2, he suggested to replace “may include” with “also includes”, to replace in its line 3 “from” by “through” and to replace “the person using that knowledge knows” in line 4 of this paragraph with “the person or persons using that knowledge know or should have known”. In relation to Article 1 paragraph 3, he suggested to add “and sanction” after the word “prevent”. In relation to Article 1 paragraph 3 (i), he also suggested to add “and illicit appropriation” after “acquisition” in line 1, as well as “including recourse to violence” after the word “theft”. In number (ii) he suggested to add “possession” after “acquisition” and also “the legislation currently in place” after “in violation of”. In number (iii) he suggested to change wording to “claims that have no legal foundation”. He noted that number (v) had to be redrafted as the Spanish text was not clear. He proposed “violation of customary rights of indigenous peoples” should replace the concept “morality”.

He suggested to add in Article 1 paragraph 4 “indigenous peoples and local communities” and to add “customary laws of indigenous peoples and local communities” in paragraph 5.

Other submissions by observers

An observer submitted the relevant provision of the ARIPO Protocol on Traditional Knowledge as follows:

“Rights conferred to holders of traditional knowledge

7.1 This Protocol shall confer on the owners of rights referred to in Section 6 the exclusive right to authorize the exploitation of their traditional knowledge.

7.2. In addition, owners shall have the right to prevent anyone from exploiting their protected traditional knowledge without their prior informed consent.

7.3. For the purposes of this Protocol, the term “exploitation” with reference to protected traditional knowledge shall refer to any of the following acts:

(a) Where the traditional knowledge is a product:

(i) manufacturing, importing, offering for sale, selling or using beyond the traditional context the product;

(ii) being in possession of the product for the purposes of offering it for sale, selling it or using it beyond the traditional context;

(b) Where the traditional knowledge is a process:

(i) making use of the process beyond the traditional context;

(ii) carrying out the acts referred to under paragraph (a) of this subsection with respect to a product that is a direct result of the use of the process.”

ARTICLE 2

LEGAL FORM OF PROTECTION

1. *The protection of traditional knowledge against misappropriation and misuse shall ~~may~~ be implemented through a range of legal measures, including, inter alia: a special law on traditional knowledge; laws on intellectual property, including laws governing unfair competition and unjust enrichment; the law of contracts; the law of civil liability, including torts and liability for compensation; criminal law; laws concerning the interests of indigenous peoples; fisheries laws and environmental laws; regimes governing access and benefit-sharing; or any other law or any combination of those laws. This paragraph is subject to Article 11(1).*

2. *The form of protection need not be through exclusive property rights, although such rights may be made available to, ~~as appropriate, for the individual and collective~~ holders of traditional knowledge, including through existing or adapted intellectual property rights systems, in accordance with the needs and the choices of the holders of the knowledge, national laws and policies, and international obligations.*

COMMENTARY ON
ARTICLE 2

Existing *sui generis* measures for TK protection at the level of domestic law already display a high diversity of legal forms and mechanisms. If the current provisions are not to pre-empt or supersede existing national and regional choices for TK protection, this diversity of legal mechanism would need to be accommodated in these international standards. Again, this approach is not new in the articulation of international standards. Provisions similar to this Article can be found in existing international instruments covering diverse fields of protection. Examples that have earlier been cited include the Washington Treaty¹, the Paris Convention, and the Rome Convention.² This provision applies the guiding principle of flexibility, to ensure that sufficient space is available for national consultations with the full and effective participation of TK holders, and legal evolution as protection mechanisms are developed and applied in practice.

Accordingly, in order to accommodate existing approaches and ensure appropriate room for domestic policy development, paragraph 1 gives effect to the Guiding Principle of flexibility and comprehensiveness and reflects the actual practice of countries which have already implemented *sui generis* forms of TK protection. It allows the wide range of legal approaches which are currently being used to protect TK in various jurisdictions, particularly in the African Union, Brazil, China, India, Peru, Portugal and the United States of America. It leaves national authorities a maximum amount of flexibility in order to determine the appropriate legal mechanisms which best reflect the specific needs of local and indigenous communities in the domestic context and which match the national legal systems in which protection will operate. The paragraph is modeled on a provision from a binding international instrument, namely Article 4 of the Washington Treaty.

Paragraph 2 clarifies that these principles do not require the creation of exclusive property titles on TK, which are perceived by many TK holders as inappropriate (see commentary on Article 1). Many TK holders have expressed the concern that new forms of protection of TK against misappropriation should not impose private rights on their TK. On the contrary, these principles give effect to an underlying norm against misappropriation by third parties, and thus against the illegitimate ~~privatisation~~ privatization or ~~commodification~~ commoditization of TK, including through the improper assertion of illegitimate private property rights. Instead they leave open the scope for using alternative legal doctrines in formulating policy on these issues as suggested by several Committee participants. However, since several countries have already established *sui generis* exclusive rights over TK, the paragraph gives scope for such exclusive rights, provided that they are in accordance with the needs and choices of TK holders, national laws and policies, and international obligations.

Amendments proposed, comments made and questions posed at the fifteenth session (December 7 to 11, 2009) and during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by Indonesia and Mexico.

¹ *Treaty on Intellectual Property in Respect of Integrated Circuits* (1989) (hereinafter, “the Washington Treaty”)

² *International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations* (1961) (hereinafter, “the Rome Convention”)

Comments made and questions posed

The comments made and questions posed were proposed by Australia, China, Ecuador, the Russian Federation, Venezuela (Bolivarian Republic of) and, as observers, by ARIPO.

Meaning of “individual”

Two delegations suggested that, in relation to Article 2 paragraph 2 on the scope of the rights of holders of knowledge, the word “individual” should be reviewed due to the collective nature of TK.

Meaning of “this paragraph is subject to Article 11(1)”

A delegation noted Article 2(1) states that “this paragraph is subject to Article 11(1)”. However, not all the legal measures listed in the aforementioned Article 2(1) may be applied in accordance with the provisions of Article 11(1), i.e. without formalities. For example, the intellectual property legislation referred to in Article 2(1), in relation to individual intellectual property subject matter, required particular formalities to be performed for the provision of legal protection of such subject matter, in particular its registration.

Legal forms or measures

A delegation suggested that any sanction or punishment in respect of unacceptable or illegal acts should include various punitive measures covering IP related legal actions, such as refusal and invalidation of patent applications, as well as civil and penal actions. The establishment of sanction or punishment should, on the one hand, allow for sufficient compensation to the injured party and add no unreasonable burden to legal actors, and, on the other hand, constitute a sufficient deterrent to illegal actors.

An observer noted that Article 2 provided a range of legal forms or measures that can be used to protect TK. However, those measures indicated in Article 2.1, which related principally to forms of existing intellectual property legal tools and were also based on the notion what the instrument seeks to, were to prevent misappropriation, an objective which has been referred to as inadequate or limiting.

Exclusive rights

A delegation noted the following comment from an observer regarding exclusive rights, and would seek further discussion of the particular issues relating to collective versus individual rights as a key issue that needed further discussion in relation to the protection of TK.

An observer stated that the commentary on Article 2 suggested that holders of TK did not require the creation of exclusive rights over their TK. This understanding was not what had been gathered in their experiences with TK holders in Africa. Most holders had rather called for collective rights over their TK and not private or individual rights as had been referred to in Article 2.2. Without conferring rights, there could not be consequential action taken. Therefore, he suggested that the Article should be substantially amended to reflect the aspirations of TK holders who had called for a new form of *sui generis* system to protect their TK and not a conglomerate of legal options.

Relationship with Principle (d)

A delegation stated that this provision was premised on Principle (d) of “flexibility and comprehensiveness”. It had been argued that a flexible approach to the protection of TK helped ensure that appropriate mechanisms were available to suit the range of needs of indigenous peoples, and to ensure that an appropriate balance was achieved between those needs and the maintenance of a stable framework for investment. This flexibility should also extend to respect for the diversity of legal systems amongst Member States.

ARTICLE 3

GENERAL SCOPE OF SUBJECT MATTER

1. *These principles concern protection of traditional knowledge against misappropriation and misuse beyond its traditional context, and should not be interpreted as limiting or seeking externally to define the diverse and holistic conceptions of knowledge within the traditional context. These principles should be interpreted and applied in the light of the dynamic and evolving inter-generational nature of traditional knowledge and the nature of traditional knowledge systems as frameworks of ongoing innovation.*

2. *For the purpose of these principles only, the term “traditional knowledge” refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and any traditional knowledge associated with genetic resources.*

COMMENTARY ON
ARTICLE 3

This provision does two things: it clarifies the general nature of traditional knowledge for the purposes of these provisions, and it sets appropriate bounds to the scope of protectable subject matter. It therefore gives effect to concerns that international provisions on TK should reflect the distinctive qualities of TK, but also responds to concerns that provisions against misappropriation of TK should not intrude on the traditional context and should not place external constraints or impose external interpretations on how TK holders view, manage or define their knowledge in the customary or traditional context.

International IP standards typically defer to the national level for determining the precise scope of protected subject matter. The international level can range between a description in general terms of eligible subject matter, a set of criteria for eligible subject matter, or no definition at all. For example, the Paris Convention and the TRIPS Agreement do not define “invention”. The Paris Convention defines ‘industrial property’ in broad and expansive terms. This provision takes a comparable approach which recognizes the diverse definitions and scope of TK that already apply in existing national laws on TK, and does not seek to apply one singular and exhaustive definition. Guided by existing national laws, however, this provision clarifies the scope of TK in a descriptive way. Its wording draws on a standard description that has been developed and consistently used by the Committee, which was based in turn on the Committee’s analysis of existing national laws on the protection of TK. In essence, if intangible subject matter is to constitute traditional knowledge for the purposes of these provisions, it should be “traditional”, in the sense of being related to traditions passed on from generation to generation, as well as being “knowledge” or a product of intellectual activity.

The second paragraph clarifies that these provisions cover traditional knowledge as such. This means that they would not apply to TCEs/EoF, which are treated in complementary and parallel provisions (document WIPO/GRTKF/IC/8/4). In its general structure, but not its content, the paragraph is modeled on Article 2(1) of the Berne Convention which delineates the scope of subject matter covered by that Convention by first providing a general description and then an illustrative list of elements that would fall within its scope. In following a similar approach, this paragraph does not seek to define the term absolutely. A single, exhaustive definition might not be appropriate in light of the diverse and dynamic nature of TK, and the differences in existing national laws on TK.

Amendments proposed, comments made and questions posed at the fifteenth session (December 7 to 11, 2009) and during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by Mexico and South Africa.

Comments made and questions posed

The comments made and questions posed were proposed by Australia, El Salvador, Italy, Morocco, Oman, the Russian Federation, South Africa, Switzerland, Venezuela (Bolivarian Republic of) and, as observers, by ARIPO, ICC and InBraPi.

Relationship with Article 1

Three delegations suggested that Article 3 should be merged with Article 1 or moved before Article 1.

Meaning of indigenous and local communities

A delegation noted the inconsistency between Article 4, in which “local communities” were not considered, and other provisions. Furthermore, it suggested that the language and definitions used should be the same throughout the document.

A delegation suggested that the term "indigenous and local communities" in Article 3 paragraph 2 should be understood in the same broad and inclusive sense as the term “communities”, as described in footnote 23 of the Annex of the Draft Provisions on TCEs.

Definition of TK

A delegation expressed that the provision of Article 3(2) was an adequate definition of what was assumed by protection in accordance with this document.

A delegation suggested that Article 3 should be clearer and sharper.

A delegation noted that the establishment of a working definition of TK was considered to be one of the prerequisites of a substantial discussion. The definition of TK as contained in Article 3 paragraph 2 constituted a good working definition. The Committee could and should revisit this definition during the course of its negotiations to amend or modify the definition if necessary. It was highlighted that the definition of TK should encompass all TK, that was, TK from developing countries and developed countries.

An observer noted that the concept of “TK” was difficult to define precisely because of its holistic, context-dependent, dynamic and intergenerational characteristics. However, a definition with clear criteria was required if TK was to be respected. The current definitions were vague in the extreme and, for that reason, would be very difficult to apply. Clear criteria were essential to assist Member States to distinguish between TK that was to be protected in accordance with national law and general knowledge that was available to all.

Definition of cultural identity

A delegation suggested to clarify the definition of “cultural identity”.

Traditional arts and artisanal works

A delegation suggested adding traditional arts and artisanal works in Article 3.

Relationship with policy objectives

Noting the relevance of Policy Objective (vi) “Support TK systems”, and the amendment suggested for paragraph 1 to include the term “inter-generational”, a delegation called for further discussion of the intent of this amendment, and the extent to which the current working definition met the needs of all Member States. This was a complex issue which required further consideration. It noted in particular Policy Objective (ii) regarding the

“promotion of respect” and Policy Objective (iii) to “meet the actual needs of holders of Traditional Knowledge”. It was not clear to what extent a tight definition promoted respect for TK systems and the cultural integrity of TK holders. Arguably, an “open” definition would be more able to meet the actual needs of the diverse range of holders of TK.

Drafting suggestions by observers

An observer suggested to add the sentence “The specific choice of terms to denote the protected subject matter under Traditional Knowledge may be determined at the national level” after paragraph 2 of Article 3.

An observer suggested adding “developed” after “activity” in lines 2 of Article 3 paragraph 2.

ARTICLE 4

ELIGIBILITY FOR PROTECTION

Protection ~~should~~ shall be extended ~~at least~~ to that traditional knowledge which is:

- (i) generated, preserved, constituted and transmitted in a traditional and intergenerational context; or*
- (ii) ~~distinctively associated with~~ // ~~distinctively associated with~~ customarily recognized as belonging to // a traditional or indigenous community, ~~or~~ people or ethnic group which preserves and transmits it between generations; or ~~and~~*
- (iii) integral to the cultural identity of // ~~integral to the cultural identity of~~ // integral to an indigenous or traditional community, ~~or~~ cultural identity of people or ethnic group 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 applicable national laws.*

COMMENTARY ON
ARTICLE 4

This provision clarifies what qualities TK should have at least to be eligible for protection against misappropriation in line with these provisions. Again without intruding on the traditional domain, this provision would help set out the criteria that TK should meet in order to be assured protection against misappropriation by third parties in the external environment, beyond the traditional context. It leaves open the possibility of wider eligibility for protection, where this is in line with particular national choices and needs.

This provision is guided by the criteria that are applied in existing national *sui generis* TK laws and by the extensive Committee discussions on the criteria that should apply for TK protection. These national laws and Committee discussions cover diverse criteria, but certain common elements have emerged. This provision articulates those common elements: in essence, providing that TK should have (i) a traditional, intergenerational character, (ii) a distinctive association with its traditional holders, and (iii) a sense of linkage with the identity of the TK holding community (which is broader than conventionally recognized forms of ‘ownership’ and embraces concepts such as custodianship). For example, TK might be integral to the identity of an indigenous or traditional community if there is a sense of obligation to preserve, use and transmit the knowledge appropriately among the members of the community or people, or a sense that to allow misappropriation or offensive uses of the TK would be harmful. Some guidance on these concepts may be found in existing national laws. For example, the Indian Arts and Crafts Act in the United States of America specifies that a product is a product of a particular tribe when “the origin of a product is identified as a named Indian tribe or named Indian arts and crafts organization³”. This could be a form of ‘distinctive association’ as suggested in subparagraph (ii).

This provision builds on the general description of TK in Article 3, and provides a conceptual link with the beneficiaries of protection, who are specified in Article 5. Together, these three articles clarify the minimal traditional linkage that would apply between TK and its holders, in order for protection against misappropriation to be assured under these provisions. They do not rule out broader scope of protection, since they define a minimum only (this is the intent of the term ‘at least’ in the chapeau). Yet the reference to “at least” in the chapeau of this provision clarifies that policymakers can choose more inclusive criteria to meet with national needs and circumstances.

*Amendments proposed, comments made and questions posed at the fifteenth session
(December 7 to 11, 2009) and during the intersessional written commenting process*

The specific drafting amendments reflected in the draft provision were proposed by China, India, Indonesia, Morocco, Sudan, Uruguay and Venezuela (Bolivarian Republic of).

Comments made and questions posed

The comments made and questions posed were proposed by Australia, Brazil, Cameroon, China, El Salvador, Italy, Morocco, Nigeria, the United States of America, Uruguay and, as observers, by the Arts Law Center of Australia and the Indigenous Peoples (Bethchechilokono) of Saint Lucia Governing Council.

³ Section 309.2(f), 25 CFR Chapter II 309 (Protection of Indian Arts and Crafts Products).

Criteria

A delegation noted that the criteria included in Article 4 should not be cumulative. Article 4 (iii) was the only necessary criterion of protection.

A delegation suggested the protection should be broader.

A delegation wondered whether TK that was created by a single individual would be eligible for protection and what was the basis for such an inclusion. It also questioned why to provide for protection for some innovations under a system of protection of TK, and other innovations under the patent system.

A delegation noted the insertion of the word “or”, however there was some question as to what extent non-cumulative criteria for eligibility for protection provided for the needs or interests of holders of TK. A consistent theme in international TK debated that TK was, in general, (i) held by, (ii) associated with and (iii) related to the cultural identity of a community as reflected in Article 5. A non-cumulative understanding of eligibility for protection provided broader scope, and this raised the principle of recognition of the specific characteristics of TK outlined in Principle (i). This non-cumulative understanding also raised the question of whether a tight “definition” suited the diverse nature of TK holders. It called for further discussion of this principle in relation to issues of eligibility of protection.

Definition of TK

A delegation suggested that further consideration needed to be given to the definitions, and to the flexibilities required for local circumstances. In particular, for example, it wondered how did the wording in Article 4 relate to possible protection for TK produced by a contemporary generation.

Relationship with Article 3

A delegation suggested that the wording of Article 4 (i) should be included in Article 3 paragraph 2.

Terms used in Article 4

A delegation suggested that the words in the document should be the same. For example, the words “indigenous and local communities” as used in Article 3.2 should also be used in Article 4. It also highlighted that the scope of “local communities” was needed.

A delegation noted that TK sometimes was owned by ethnic groups in China. Thus, it suggested that a reference to different ethnic groups should be added in Article 4 (ii).

A delegation suggested to clarify the words “indigenous or traditional community or people” and “cultural identity”.

A delegation noted that the suggestions in relation to Paragraph (iii) focused that part of Article 4 on the holders rather than the knowledge itself. It called for further discussion on whether the eligibility for protection was focused on the nature of the knowledge itself, or the nature of the knowledge holders. Another issue with respect to eligibility related to

competing claims between TK holders who might meet the criteria and yet have separate cultural identities. This was a key issue that required further discussion.

An observer noted that the term “traditional or indigenous community or people” in Article 4(ii) was confusing. The explanation should be given after consulting outside of the Committee for a study on the terms.

Traditional medicine

A delegation suggested that more legal text should be submitted in writing. It also noted that Traditional Medical Knowledge was not always linked to communities.

A delegation suggested that Article 4(iii) should include a reference to the nature of ownership of traditional medicine and in particular within the dynamics of its intergenerational use, generation, preservation and transaction.

Drafting suggestions by observers

An observer suggested deleting “distinctively” in Article 4(ii). She also suggested to use “indigenous” with a capital “I”.

ARTICLE 5

BENEFICIARIES OF PROTECTION

Protection of traditional knowledge should benefit the communities who generate, preserve and transmit the knowledge in a traditional and intergenerational context, who are associated with it and who identify with it in accordance with Article 4. Protection should accordingly benefit the indigenous and traditional communities themselves that hold traditional knowledge in this manner, as well as recognized individuals within these communities and peoples. Entitlement to the benefits of protection should, as far as possible and appropriate, take account of the customary protocols, understandings, laws and practices of these communities and peoples.

COMMENTARY ON
ARTICLE 5

Preceding principles have focused on the subject matter of protection. This provision seeks to clarify who should principally benefit from protection of TK. It articulates the principle that the beneficiaries should be the traditional holders of TK. This draws on established practice in existing national systems and the consistent theme in international TK debates. The same approach is found in existing proposals for international protection frameworks.

Because TK is in general held by, associated with and related to the cultural identity of a community, the basic principle provides for that community collectively to benefit from its protection. Studies and actual cases have, nonetheless, shown that in some instances a particular individual member of a community may have a specific entitlement to benefits arising from the use of TK, such as certain traditional healers or individual farmers, working within the community. This provision therefore clarifies that beneficiaries may also include recognized individuals within the communities. Typically, the recognition will arise or be acknowledged through customary understandings, protocols or laws.

Entitlement to and distribution of benefits within a community (including the recognition of entitlements of individuals) may be governed by the customary law and practices that the community itself observes. This is a key area where external legal mechanisms for protection of TK may need to recognize and respect customary laws, protocols or practices. Case law suggests that financial penalties imposed for IP infringement can be distributed according to customary law. The mutually agreed terms for access and benefit-sharing agreements can also give effect to customary laws and protocols by allowing the communities to identify internal beneficiaries of protection according to their own laws, practices and understandings. This option is recognized in the third sentence.

This provision reflects a balance between the diverse forms of custodianship of TK at national and community levels, and the need for guidance on the determination of the beneficiaries of protection, entailing a trade-off between flexibility and inclusiveness on the one hand, and precision and clarity on the other hand. Existing national and community laws may already define the communities who would be eligible for protection. (See further detailed discussion of this question in document WIPO/GRTKF/IC/8/6). In contrast to seeking to create a new body of law *ab initio* concerning the identity of indigenous and other local communities, this text currently allows scope for reference to the national laws of the country of origin to determine these matters. Relevant law at the national or local levels can define relevant communities and/or individuals.⁴

⁴ For example, the Indian Arts and Crafts Act in the United States of America, at WIPO/GRTKF/IC/5/INF/6, specifies that an “Indian tribe” means “any Indian tribe, band, nation, Alaska Native village, or any organized group or community which is recognized as eligible ... by the United States ...; or (2) Any Indian group that has been formally recognized as an Indian tribe by a State legislature or by a State commission or similar organization legislatively vested with State tribal recognition authority”. (Section 309.2(e), 25 CFR Chapter II 309).

Amendments proposed, comments made and questions posed during the intersessional written commenting process

Comments made and questions posed

The comments made and questions posed were proposed by Australia and China.

Relationship with Article 4

In association with the comments made concerning Article 4, a delegation believed that, in establishing beneficiaries of protection, the existence of ethnic groups as bearers of TK should also be taken into consideration. Moreover, the transmission of TK should not affect the uniqueness of its original source, in order to ensure respect and protection of its original creators and sources.

A delegation noted that the suggestions in relation to eligibility for protection in Article 4 needed to be considered in light of the beneficiaries of protection in this part.

National law

A delegation noted that the commentary suggested there was scope for reference to national law to determine matters. It called for further discussion as to the extent that this was reflected in this part.

Traditional context

A delegation noted that a key issue to discuss was linking the traditional context to the entitlement. It also noted that the language in the last sentence highlighted a connection between traditional custodianship and the identification of beneficiaries that would be worthy of further discussion.

ARTICLE 6

FAIR AND EQUITABLE BENEFIT-SHARING
AND RECOGNITION OF KNOWLEDGE HOLDERS

1. *The benefits of protection of traditional knowledge to which its holders or custodians are entitled include the fair and equitable sharing of benefits arising out of the commercial or industrial use of that traditional knowledge.*
2. *Use of traditional knowledge for non-commercial purposes need only give rise to non-monetary benefits, such as access to research outcomes and involvement ~~of the source community~~ of the holders or custodians of knowledge in research and educational activities.*
3. *Those using traditional knowledge beyond its traditional context should mention its source, acknowledge its holders, and use it in a manner that respects the cultural values of its holders.*
4. *Legal means should be available to provide remedies for traditional knowledge holders in cases where the fair and equitable sharing of benefits as provided for in paragraphs 1 and 2 has not occurred, or where knowledge holders were not recognized as provided for by paragraph 3.*
5. *Customary laws ~~within local communities~~ and normative systems of holders or custodians may play an important role in sharing benefits that may arise from the use of traditional knowledge.*

COMMENTARY ON
ARTICLE 6

The misappropriation of traditional knowledge may include gaining benefits, especially commercial benefits, from the use of the knowledge without equitable treatment of the holders of the knowledge. This is generally congruent with the concerns expressed that TK should not be the subject of unjust enrichment or should not give rise to inequitable benefits for third parties. Accordingly, the elaboration of a system of protection of TK against misappropriation may entail providing for positive standards for equitable sharing of benefits from the use of TK. Such equitable benefit-sharing is also a means of implementing such policy objectives as “recognition of the value of TK”; “ensuring respect for TK and TK holders”; and “promoting equitable benefit-sharing” (Objectives (i), (ii) and (xi), above).

This provision therefore supplements the broad reference to equitable benefit-sharing in the general description of misappropriation (Article 1 above), and covers commercial or non-commercial uses. Internationally agreed guidelines on biodiversity-related TK suggest that basic principles for benefit-sharing can include (i) covering both monetary and non-monetary benefits and (ii) developing different contractual arrangements for different uses.⁵ Accordingly, this provision differentiates between commercial and non-commercial uses of TK and specifies different benefit-sharing principles for these uses.

Paragraph 1 establishes the general principle that TK holders are entitled to the sharing of benefits arising from commercial or industrial uses of their TK. The paragraph is worded in such a way that benefits would be shared directly with the TK holder, i.e. the traditional and local communities.

In contrast to the first paragraph, paragraph 2 concerns non-commercial uses of TK and concedes that such uses may give rise only to non-monetary benefit-sharing. The paragraph gives an illustration of non-monetary benefits that could be shared, namely access to research outcomes and involvement of the source community in research and educational activities. Other examples might include institutional capacity building; access to scientific information; and institutional and professional relationships that can arise from access and benefit-sharing agreements and subsequent collaborative activities.

The third paragraph concerns the recognition of TK holders and specifies that users should identify the source of the knowledge and acknowledge its holders. It also provides that TK should be used in a manner that respects the cultural values of its holders.

The final paragraph specifies that civil judicial procedures should be available to TK holders to receive equitable compensation when the provisions in paragraph 1 and 2 have not been complied with. It also specifies the possible role of customary laws and protocols in benefit-sharing since, as has been observed, “customary laws within local communities may play an important role ... in sharing any benefits that may arise” from access to TK.

⁵ See Section IV.D.3 (“Benefit-sharing”), *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (Decision VI/24A, Annex)

Amendments proposed, comments made and questions posed at the fifteenth session (December 7 to 11, 2009) and during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by Mexico.

Comments made and questions posed

The comments made and questions posed were proposed by Australia and the United States of America.

Source of the TK

A delegation questioned, in relation with Paragraph 3, when TK was used beyond its original context, and then further used in other ways, if the first use acknowledged the source of the TK, whether it would be sufficient for the second and subsequent uses to reference the immediate prior source. It also questioned when identifying the source, what research the subsequent would be required to undergo to avoid misidentifying the actual source.

Relationship with policy objectives

A delegation noted that there were a number of significant issues that arose from this provision. Policy Objective (xii) suggested that protection of TK should promote equitable benefit-sharing. While there had been no consensus reached on the applicability of this policy objective, a number of questions were raised. Particular issues included the relationship between Policy Objective (xii) and General Guiding Principle (g) “respect for and cooperation with other international and regional instruments and processes” and Principle (e) regarding the “equitable balance between the rights and interests of those that develop, preserve and maintain TK, and those who use and benefit from TK”. In particular, this provision raised a key issue with respect to the protection of TK in light of the key balance in the IP system as it related to the public domain. This balance was a key issue that required further consideration.

Relationship with Article 8

A delegation noted that the exclusion in Article 8 allowed national authorities to exclude from the principle of prior informed consent the fair use of TK which was already readily available to the general public, provided that users of that TK provided equitable compensation for industrial and commercial uses of that TK. Further discussion was warranted on how this could practically be achieved in a domestic setting. The sharing of experiences with those countries that had *sui generis* protection systems already in place that addressed this issue would be welcome.

ARTICLE 7

PRINCIPLE OF PRIOR INFORMED CONSENT

1. *The principle of prior informed consent should govern any access of traditional knowledge from its traditional holders, subject to these principles and ~~relevant~~ applicable national laws.*
2. *The holder of traditional knowledge shall be entitled to grant prior informed consent for access to traditional knowledge, or to approve the grant of such consent by an appropriate national authority, as provided by applicable national legislation.*
3. *Measures and mechanisms for implementing the principle of prior informed consent should be understandable, appropriate, and not burdensome for all relevant stakeholders, in particular for traditional knowledge holders; should ensure clarity and legal certainty; and should provide for mutually agreed terms for the equitable sharing of benefits arising from any agreed use of that knowledge.*

COMMENTARY ON
ARTICLE 7

The application of the principle of prior informed consent is central to the policy debates and existing measures concerning TK protection. The expanded conception of misappropriation of TK in Article 1 includes violation of legal measures that require the obtaining of prior informed consent. Prior informed consent has been recognized by some Committee members as a key legal principle and by others as “a valuable practice”. The principle essentially requires that at the point of access, when an external party first gains access to traditional knowledge held within a community, formal consent is required on the part of the community that holds the knowledge. National laws stipulate a contract or permit, containing mutually agreed terms, is agreed between TK users and providers, based on which consent is granted for access to the TK. The principle has been widely implemented through permits, contract systems or specific statutes.

The general principle, as expressed in the first paragraph, provides that TK holders should be both informed about the potential use of TK and should consent to the proposed use, as a condition of fresh access to their TK. The second paragraph expresses the roles and responsibilities concerning the prior informed consent principle, but leaves flexibility to adapt the application of the principle to national legal systems, stakeholder needs and custodianship structures. The third paragraph sets out basic features of mechanisms to implement prior informed consent, applying the guiding principle ‘effectiveness and accessibility of protection’ to prior informed consent mechanisms, so as to ensure that such mechanisms provide for legal certainty and are appropriate. An explicit link with equitable benefit-sharing is made through the requirement that prior informed consent should also entail concluding mutually agreed terms on the use and sharing of benefits arising from the use.

The provision recognizes and accommodates the diversity of existing approaches to prior informed consent and merely provides *that* the principle should be applied. In practice, prior informed consent systems might follow certain basic principles that have been developed and agreed internationally,⁶ such as providing for legal certainty and clarity; minimizing transaction costs for access procedures; ensuring that restrictions on access are transparent and legally based. However, from the point of view of these principles, as long as the basic principle is applied, the provision leaves the precise modalities of application to the national law of the country where the TK is located, given the numerous and diverse existing TK laws and the diverse needs of TK holders and custodianship structures.

Amendments proposed, comments made and questions posed during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by Mexico.

Comments made and questions posed

The comments made and questions posed were proposed by Australia.

⁶ See Section IV.C.1 (‘Basic Principles of a Prior Informed Consent System’), *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (Decision VI/24A, Annex)

Relationship with Principle (e)

As with the principles outlined in Article 6, a delegation noted that this provision related specifically to the General Guiding Principle (e) on “equity and benefit sharing”, noting that this principle outlined that protection should, in particular, respect the right of TK holders to consent or not to consent to access to their TK. It also noted that this was a CBD obligation in relation specifically to TK associated with GR. It did not support an unqualified principle of free and prior informed consent in all circumstances but did acknowledge that indigenous peoples should be consulted in relation to decisions that affected them, where possible. It supported further discussions on the contexts in which free, prior and informed consent would be practical, possible and desirable, and the sharing of experiences from those Member States who had such a regime as to its practical effect and implementation.

ARTICLE 8

EXCEPTIONS AND LIMITATIONS

1. *The application and implementation of protection of traditional knowledge should not adversely affect:*

(i) *the continued availability of traditional knowledge for the customary practice, exchange, use and transmission of traditional knowledge by traditional knowledge holders;*

(ii) *the use of traditional medicine for household purposes; use in government hospitals, especially by traditional knowledge holders attached to such hospitals; or use for other public health purposes.*

2. *In particular national authorities may exclude from the principle of prior informed consent the fair use of traditional knowledge which is already readily available to the general public, provided that users of that traditional knowledge provide equitable compensation for industrial and commercial uses of that traditional knowledge.*

COMMENTARY ON
ARTICLE 8

Like the rights and entitlements granted in other fields of legal protection, rights in traditional knowledge may be limited or qualified so as to avoid unreasonable prejudice to the interests of society as a whole, to the customary transmission of TK systems themselves, and other legitimate interests. This provision sets out such exceptions and limitations in relation to the entitlements and rights provided in the preceding provisions. It ensures that *sui generis* protection does not adversely affect the customary availability of TK to the TK holders themselves by interfering with their customary practices of using, exchanging, transmitting and practicing their TK. It also foresees that TK protection should not interfere with household uses and public health uses of traditional medicine. Besides the general exclusions in paragraph 1 which apply to misappropriation in general, a specific optional exclusion is foreseen for the prior informed consent requirement. It concerns knowledge that is already readily available to the general public and the exclusion is subject to the requirement that users provide equitable compensation for industrial and commercial uses.

Amendments proposed, comments made and questions posed at the fifteenth session (December 7 to 11, 2009) and during the intersessional written commenting process

Comments made and questions posed

The comments made and questions posed were proposed by Australia, China, Norway and, as observers, by ICC.

A delegation noted, with regard to the question of limitations and exceptions, it was important that TK not hinders fair use, and in particular private use.

A delegation considered appropriate to provide for exceptions and limitations to the protection of TK, as it was considered necessary to ensure that the routine use and reasonable development of TK under its traditional context were not affected.

A delegation stated that this list of exceptions related specifically to the scope of protection. A key issue was the extent to which there was a gap in current IP protection that stopped traditional uses. A key question that arose in relation to the principle expressed in Paragraph 2 was how this could be achieved. For TK that was already readily available to the public, it questioned to what extent it would be possible to identify to whom the equitable compensation be paid.

An observer highlighted that balance between the interests of users and holders of TK was essential. There needed to be a remedy for clear cases of misappropriation – i.e., in cases where it was shown that an entity had violated the national ABS laws. However, likewise, there could be no liability for cases of legitimate use. These included, among others: (1) use of information in the public domain; (2) use of protected TK with permission from an authority entitled to give it; (3) use of information for purely private purposes; and (4) use of information that could be shown to have been developed independently. Any legislation in the area had to recognize that public knowledge had a special status. There were both ideological and practical difficulties in controlling its use. Exceptions to this should be very carefully crafted. An international instrument that did not take this into account could not succeed.

ARTICLE 9

DURATION OF PROTECTION

1. *Protection of traditional knowledge against misappropriation and misuse should last as long as the traditional knowledge fulfills the criteria of eligibility for protection according to Article 4.*
2. *If competent authorities make available through national or regional laws or measures additional or more extensive protection for traditional knowledge than is set out in these Principles, those laws or measures shall specify the duration of protection.*

COMMENTARY ON
ARTICLE 9

An important element of any protection measure is the duration of the rights or entitlements which are made available by that measure. In the field of TK protection this has been a particularly difficult element and most conventional IP rights have been considered inappropriate for this field because they foresee a limited term of protection. Existing *sui generis* systems for TK protection have utilized a range of options to define the duration of protection: a single, limited term of protection; successively renewable limited terms; or an unlimited term of protection. Given the inter-generational transmission and creation of traditional knowledge, TK holders have called for a long or unlimited term of protection.

This provision foresees a duration of protection which is not limited to a specific term. This is because TK protection under these Principles is not comparable to those IP titles which grant a time-limited exclusive property right (e.g., a patent or a trademark), but rather resembles those forms of protection which deal with a distinctive association between the beneficiaries of protection and the protected subject matter, and which last as long as that association exists (e.g., the protection of goodwill, personality, reputation, confidentiality, and unfair competition in general). Therefore, the entitlement of TK holders to be protected against misappropriation has been described by one delegation as “an inalienable, unrenouncable and imprescriptable right”. In analogy with other forms of unfair competition law based on this distinctive association and based on “support [for] the protection of TK through the suppression of unfair competition”, this provision stipulates that the duration of protection against misappropriation should last as long as the distinctive association remains intact and the knowledge therefore constitutes “traditional knowledge”. The distinctive association exists as long as the knowledge is maintained by traditional knowledge holders, remains distinctively associated with them, and remains integral to their collective identity (see Articles 4 and 5). So long as these criteria of eligibility are fulfilled, the protection of TK under these Principles may be unlimited.

Since numerous countries already make available through their national or regional laws more extensive TK protection than is required in these Principles, the second paragraph specifies that the duration of this more extensive or additional protection should be specified in the relevant laws or measures. The provision is silent on the whether the duration of such additional rights should be for a limited term or not. It merely requires that the duration should be specified and thus leaves to national policy making the decision what the specified duration should be. This accommodates all existing national *sui generis* laws, whether or not they provide for a limited term of protection.

Amendments proposed, comments made and questions posed during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by Mexico.

Comments made and questions posed

The comments made and questions posed were proposed by Australia.

Relationship with policy objectives

A delegation noted that a key issue with respect to IP in general was the quid pro quo attached to any monopoly right. This related specifically to the grant of a time limited monopoly right in exchange for an ultimate public benefit through the expansion of the public domain. This was a key issue, relating to Policy Objective (i), particularly in relation to frameworks of ongoing innovation and scientific knowledge systems, Policy Objective (v) relating to empowerment to protect knowledge bearing in mind balance and equity in possible solutions, and Policy Objective (vii) recognizing the value of a vibrant public domain.

Relationship between two paragraphs

A delegation noted that the differentiation between Paragraphs 1 and 2 raised issues of balance with other provisions outlined in this part. There were ultimately two basic protection models encompassed by this provision. One was defensive protection against misappropriation, and the other was positive protection for TK in and of itself. The implication in Paragraph 2 was that the provisions as a whole related specifically to the first protection model. Given this, further consideration as to appropriate scope of discussions as a whole would be valuable.

ARTICLE 10

TRANSITIONAL MEASURES

Protection of traditional knowledge newly introduced in accordance with these principles should be applied to new acts of acquisition, appropriation and use of traditional knowledge. Acquisition, appropriation or use prior to the entry into force of the protection should be regularized within a reasonable period of that protection coming into force. There should however be equitable treatment of rights acquired by third parties in good faith.

COMMENTARY ON
ARTICLE 10

The application of a new requirement for legal protection may have retrospective effect, may exclude retroactivity, or may adopt a range of intermediate approaches which apply varying degrees of retroactivity. Applying protection with retrospective effect can create difficulties because third parties may have already used the protected material in good faith, believing it not to be subject to legal protection. In some legal and policy contexts, the rights and interests of such good faith third parties are recognized and respected through measures such as a continuing entitlement to use the protected material, possibly subject to an equitable compensation, or a prescribed period within which to conclude any continuing good faith use (such as sales of existing goods that would otherwise infringe the new right). On the other hand, the traditional context of TK means that proponents of protection have sought some degree of retrospectivity.

Between the extreme positions of absolute retroactivity and non-retroactivity, this provision seeks to provide an intermediate solution, in terms of which recent utilizations, which become subject to authorization under the law or under any other protection measure, but were commenced without authorization before the entry into force, should be regularized as far as possible within a reasonable period. This requirement of regularization, however, is subject to equitable treatment of rights acquired by third parties in good faith. With this arrangement, the provision conforms broadly with the approach taken in other protection systems, and is consistent with the exceptions and limitations set out in Article 8 above.

Amendments proposed, comments made and questions posed during the intersessional written commenting process

Comments made and questions posed

The comments made and questions posed were proposed by Australia.

General

A delegation noted that the commentary suggested that this provision conformed broadly to the approach taken in other protection systems. Nonetheless, the need for appropriate details of this provision could not be determined until the scope and legal effect of any instrument was agreed. In general, however, a key policy objective for any IP rights was certainty in those rights. Any protection system that might eventuate should be consistent with this fundamental principle.

Public domain

A delegation noted that this part also touched on the issue of TK already in the public domain. Views on this issue had been raised by both observers and Member States at various times, and would appear to be a key discussion given the balance in the IP system between invention, creation, discovery, knowledge and the value of a rich and accessible public domain.

ARTICLE 11

FORMALITIES

1. *Eligibility for protection of traditional knowledge against acts of misappropriation or misuse should not require any formalities.*

2. *In the interests of transparency, certainty and the conservation of traditional knowledge, relevant national authorities may maintain registers or other records of traditional knowledge, where appropriate and subject to relevant policies, laws and procedures, and the needs and aspirations of traditional knowledge holders. Such registers may be associated with specific forms of protection, and should not compromise the status of hitherto undisclosed traditional knowledge or the interests of traditional knowledge holders in relation to undisclosed elements of their knowledge.*

COMMENTARY ON
ARTICLE 11

Existing TK protection systems take a variety of approaches towards formalities as a requirement of protection: they may expressly require registration of the knowledge as a condition of protection; they may establish registries or databases, but not link them as a requirement to the acquisition of rights; or they may provide that protection does not require formalities. In the legal protection of know-how and innovation, there are trade-offs between legal predictability and clarity on the one hand, and flexibility and simplicity on the other hand. A registration-based system provides greater predictability and makes it easier in practice to enforce the rights. But it can mean that the TK holders need to take specific legal steps, potentially within a defined time-frame, or risk losing the benefits of protection; this may impose burdens on communities who lack the resources or capacity to undertake the necessary legal procedures. A system without formalities has the benefit of automatic protection, and requires no additional resources or capacity for the right to be available.

This provision clarifies that the general safeguard against misappropriation would not be conditional on registration of TK in databases, registries or any other formalities. This reflects concerns and skepticism which certain countries and communities have expressed about the use of registry and database systems.

However, a number of countries have already established *sui generis* systems which provide for registration as a condition of acquiring exclusive rights over registered knowledge. Therefore, paragraph 2 clarifies that such additional protection, established subject to national law and policies, may require such formalities. It thereby recognizes the diversity of existing protection systems which include registration-based systems, but does not prescribe any approach which requires formalities. In addition, it clarifies that appropriate registration or recordal should not jeopardize or compromise the rights and interests of TK holders in relation to undisclosed elements of their knowledge.

Amendments proposed, comments made and questions posed during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by Mexico.

Comments made and questions posed

The comments made and questions posed were proposed by Australia.

Relationship with policy objectives and principles

A delegation called for further discussion of the appropriateness of registers or other records of TK, while this would appear to pre-empt discussion about the eligibility requirements for protection of TK. This was particularly in relation to Policy Objectives (ii) to “promote respect”, (iii) “meet the actual needs of holders of TK”, (vi) “support TK systems”, and (x) “promote innovation and creativity”. Also relevant to this provision were General Guiding Principles (a) “responsiveness to the needs and expectations of TK holders”, (c) “effectiveness and accessibility of protection”, (h) “principle of respect for customary use and transmission”, and (i) “principle of recognition of the specific characteristics of TK”. Of

greatest concern would be clarity around the flexibility that national authorities had regarding the option to maintain registers or other records of TK.

Relationship with Article 9

A delegation noted that this part also related to the issue of defensive protection or positive rights as discussed in relation to Article 9.

ARTICLE 12

CONSISTENCY WITH THE GENERAL LEGAL FRAMEWORK

In case of traditional knowledge which relates to components of biological diversity, access to, and use of, that traditional knowledge shall be consistent with national laws regulating access to those components of biological diversity. Permission to access and/or use traditional knowledge does not imply permission to access and/or use associated genetic resources and vice versa.

COMMENTARY ON
ARTICLE 12

Traditional knowledge protection would inevitably interface with other legal systems, especially legal systems regulating access to genetic resources which are associated with the protected TK. This provision ensures consistency with those frameworks, while allowing for appropriate independence of the two regulatory systems. The first sentence of the provision is a direct counterpart to paragraph 37 of the Bonn Guidelines which establishes the independence of prior informed consent procedures for access to genetic resources from access to TK related to those resources. The sentence in this provision mirrors the same approach by establishing that independence from the direction of prior informed consent for TK related to biodiversity components.

Amendments proposed, comments made and questions posed during the intersessional written commenting process

Comments made and questions posed

The comments made and questions posed were proposed by Australia.

Relationship with policy objectives and principles

A delegation noted that this provision related specifically to Policy Objective (ix) “respect for and cooperation with relevant international agreements and processes”, and General Guiding Principle (g). It called for further discussion regarding the extent to which this provision embodied these elements of the objectives and principles.

ARTICLE 13

ADMINISTRATION AND ENFORCEMENT OF PROTECTION

1.(a). An appropriate national or regional authority, or authorities, should be competent for:

(i) ~~distributing~~ disseminating information about traditional knowledge protection and conducting public awareness and advertising campaigns to inform traditional knowledge holders and other stakeholders about the availability, scope, use and enforcement of traditional knowledge protection;

(ii) determining whether an act pertaining to traditional knowledge constitutes an act of misappropriation or misuse of, or an other act of unfair competition in relation to, that knowledge;

(iii) determining whether prior informed consent for access to and use of traditional knowledge has been granted;

(iv) ~~determining~~ supervising effective, fair and equitable benefit-sharing;

(v) determining whether a right in traditional knowledge has been infringed, and for determining remedies and damages;

(vi) assisting, where possible and appropriate, holders of traditional knowledge to use, exercise and enforce their rights over their traditional knowledge.

(b) The identity of the competent national ~~or regional~~ authority or authorities should be communicated to ~~an international body~~ the World Intellectual Property Organization and published widely so as to facilitate cooperation and exchange of information in relation to protection of traditional knowledge and the equitable sharing of benefits.

2. Measures and procedures developed by national and regional authorities to give effect to protection in accordance with these Principles should be fair and equitable, should be accessible, appropriate and not burdensome for holders of traditional knowledge, and should provide safeguards for legitimate third party interests and the public interest.

COMMENTARY ON
ARTICLE 13

Traditional knowledge protection can be administered and enforced in diverse ways. Typically, TK protection measures identify certain procedures as well as national authorities which ensure effectiveness and clarity in the protection of TK. This provision sets out the key tasks and functions of such a “competent authority”, without seeking to specify any particular form of institutional structure, since institutional and administrative arrangements may vary widely from country to country.

A general role of the competent authority may be to assist in awareness raising about and general administration of the protection of TK. This could entail, for example, providing information about TK protection to raise awareness of TK holders and the general public about TK protection; playing a role in determining misappropriation, prior informed consent and equitable benefit-sharing; and providing a national or regional focal point for TK protection matters.

A specific role may be envisaged for competent authorities in enforcing protection of TK. Most existing *sui generis* laws provide that acts that contravene the laws shall be punished with sanctions such as warnings, fines, confiscation of products derived from TK, cancellation/revocation of access to TK, etc. There may be practical difficulties for holders of TK to enforce their rights, which raises the possibility of a collective system of administration, or a specific role for government agencies in monitoring and pursuing infringements of rights.

The wording in the chapeau specifies that the “appropriate competent authority” could be national or regional. Indeed, several regional institutions and authorities have already decided to examine this possibility, such as ARIPO, OAPI, the South Asian Association for Regional Cooperation (SAARC) and the Pacific Community. This reflects the possibility of addressing the issue of regional TK through appropriate regional and sub-regional institutional arrangements and competent authorities *inter alia*.

Amendments proposed, comments made and questions posed during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by Mexico.

Comments made and questions posed

The comments made and questions posed were proposed by Australia.

Role of the national or regional authorities

A delegation stated that, in general and without prejudice to any position, this provision was fundamentally prescriptive about the role of the national or regional authorities in administering and enforcing any possible protection. There had been insufficient discussion of the possible responsibilities of these authorities.

Relationship with principles

A delegation noted that further discussion would be warranted as to the applicability of this provision in relation to General Guiding Principle (c) relating to “effectiveness and accessibility of protection”, namely that protection should be understandable, affordable, accessible and not burdensome for their intended beneficiaries (or states). It called for information from Member States who had such an authority as to the operation with respect to these principles.

ARTICLE 14

INTERNATIONAL AND REGIONAL PROTECTION

The protection, benefits and advantages available to holders of ~~TK~~ traditional knowledge under the national measures or laws that give effect to these international standards should be available to all eligible traditional knowledge holders, who are nationals or ~~habitual~~ residents of a prescribed country as defined by international obligations or undertakings. Eligible foreign holders of ~~TK~~ traditional knowledge should enjoy benefits of protection to at least the same level as traditional knowledge holders who are nationals of the country of protection. Exceptions to this principle should only be allowed for essentially administrative matters such as appointment of a legal representative or address for service, or to maintain reasonable compatibility with domestic programs which concern issues not directly related to the prevention of misappropriation of traditional knowledge.

COMMENTARY ON
ARTICLE 14

The General Assembly has instructed the Committee “to focus its work on the international dimension”. An essential element of addressing this dimension is to establish standards of treatment which apply to foreign nationals in respect of the protection of TK. Existing systems have utilized several standards which enable nationals of one country to enjoy legal protection in a foreign jurisdiction. These include national treatment, assimilation, fair and equitable treatment, the most-favored nation principle, reciprocity, and mutual recognition. A concise summary of each of these standards and their possible implications for international TK protection are contained in document WIPO/GRTKF/IC/8/6.

To date Committee members have provided limited guidance on how the international dimension should be addressed on a technical level. This provision therefore sets out a flexible form of national treatment, which would ensure that eligible foreign TK holders should be entitled to protection against misappropriation and misuse of their TK, provided that they are located in a country which is prescribed as eligible. “National treatment” is a principle whereby a host country would extend to foreign TK holders treatment that is at least as favorable as the treatment it accords to national TK holders in similar circumstances. In this way national treatment standards seek to ensure a degree of legal equality between foreign and national TK holders. It is important to note that national treatment is a relative standard whose content depends on the underlying state of treatment for domestic TK holders.

The function of the illustrative language contained in this draft provision is not to prescribe any particular approach, but rather to help identify and highlight the important policy choices that must be made in the formulation of an international instrument or instruments in this area, and to invite further guidance from the Committee members.

While a national treatment approach would, in the light of precedent and past experience in the IP field, appear to be an appropriate starting point, the very nature of TK and the *sui generis* forms of protection being called for by many Committee participants, suggests that national treatment be supplemented by certain exceptions and limitations or other principles such as mutual recognition, reciprocity and assimilation, especially when this concerns the legal status and customary laws of beneficiaries of protection. Under one strict conception of national treatment, a foreign court in the country of protection would have recourse to its own laws, including its own customary laws, to determine whether a foreign community qualifies as a beneficiary. This may not satisfactorily address the situation from the community’s viewpoint which would, reasonably, wish for its own customary laws to be referred to. Under mutual recognition and assimilation principles, a foreign court in the country of protection could accept that a community from the country of origin of the TK has legal standing to take action in country A as the beneficiary of protection because it has such legal standing in the country of origin. Thus, while national treatment might be appropriate as a general rule, it may be that mutual recognition, for example, would be the appropriate principle to address certain issues such as legal standing.

The protection of foreign holders of rights in TK is, however, a complex question. In view of this complexity, Committee discussions have thus far provided little specific guidance on this technical question and existing TK *sui generis* national laws either do not protect foreign rights holders at all or show a mix of approaches.

Amendments proposed, comments made and questions posed during the intersessional written commenting process

The specific drafting amendments reflected in the draft provision were proposed by Mexico.

Comments made and questions posed

The comments made and questions posed were proposed by Australia.

International dimension

Noting the commentary regarding limited guidance from the Committee on how the international dimension should be addressed on a technical level, a delegation called for the sharing of experiences from those countries who had IP protection regimes for TK as to national treatment and how it was dealt with in their jurisdictions.

GENERAL COMMENTS

Amendments proposed, comments made and questions posed during the intersessional written commenting process

The comments made and questions posed were proposed by China, Germany, Mexico, Switzerland and, as observers, by the International Chamber of Commerce (ICC).

A delegation suggested that throughout the text the phrase “holders and custodians of traditional knowledge” should be incorporated, due to the fact that either both terms were used indifferently throughout or, in some cases, reference was made to only one of them; both the terms “holders” and “custodians” had different connotations and might be distinguished as regards the subject of benefit, a right, or also of protection.

A delegation proposed that articles in the present document be re-organized in a similar way as document WIPO/GRTKF/IC/9/4. For example, the scope and eligibility of the subject matter of protection were defined first.

A delegation stated that the future discussion based on documents WIPO/GRTKF/IC/9/4 and WIPO/GRTKF/IC/9/5 should not be the only basis for future work. As stated by the European Union at the fourteenth session of the Committee, the discussions should be based on the entire work carried out by the Committee, not excluding any particular document or documents. It also suggested that the Gap Analyses contained in documents WIPO/GRTKF/IC/13/4(B) and WIPO/GRTKF/IC/13/5(B) Rev. should also be referred to, since they contained valuable information on the general characteristics of TCEs and of TK respectively.

A delegation stated that all three substantive issues which were GR, TK and TCEs should be treated on an equal footing. Accordingly, all three issues should be dealt with at each session of the Committee and be allotted comparable attention and time. It recalled its statements at previous sessions of the Committee on document WIPO/GRTKF/IC/9/5, in particular the statements made at the fifteenth session. The renewed mandate stated that “[t]he Committee will [...] continue its work and undertake text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of GRs, TK and TCEs.” It wished to clarify that the absence of square brackets in the revised document WIPO/GRTKF/IC/16/5 Prov. did not mean that there was consensus on any parts of the text, including text not in brackets. Accordingly, the document remained open for discussion in its entirety.

An observer recognized the concerns expressed by some Member States that the Committee had not yet generated sufficient results, including, e.g., an international instrument on TK. However, there had been real progress in reducing the risk of patents inappropriately issuing over TK. For example, the inclusion by WIPO of TK sources in the minimum PCT documentation and the development of TK databases were particularly valuable. The Traditional Knowledge Digital Library compiled by India and made available to the European and US Patent Offices was another example of useful progress. The observer welcomed the renewal of the mandate. However, the goal of agreeing how “to ensure the effective protection of GR, TK and traditional cultural expressions” in the next two years was challenging, given that there was still only limited agreement about principles. An international instrument that effectively protected TK had to be one that was justiciable - that was to say, one in which disputes could be resolved by an impartial judge applying and

interpreting a clear set of principles. An instrument that did not offer such a system would not command respect or gain adherents. At present, there was not enough clarity about the essence of TK, i.e., what would be protected and how misappropriation would be defined, to provide a justiciable system. Until such clarity was provided, there was little chance for an effective international instrument. To succeed in achieving the goals of the mandate, the Committee should not try to do too much. Trying to cater for every possible situation might result in a system that did not work at all. It could be easier to start with a limited scope, and expand it in the light of experience, when it had been seen what worked and what did not. It was suggested that the Committee should seek: (1) to limit and clarify the definition of TK; (2) to limit the definition of misappropriation; (3) to clarify the scope of permitted acts and exceptions; (4) to avoid new requirements, such as “disclosure of origin”, that were burdensome but of little benefit.

[End of Annex and of document]