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

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THE PROTECTION OF TRADITIONAL KNOWLEDGE: REVISED OBJECTIVES AND PRINCIPLES

Document prepared by the Secretariat

INTRODUCTION

- 1. At its seventeenth session, held from December 6 to 10, 2010, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') decided that the Secretariat should "prepare a further draft of document WIPO/GRTKF/IC/17/5, reflecting, with attribution, the comments and proposals made during the seventeenth session, and to make such further draft available for the second Intersessional Working Group taking place from February 21 to 25, 2011 (IWG 2). The Secretariat was also invited to make structural changes to the document so as to align its structure more closely with that of the Committee's document on traditional cultural expressions [...] and to report on such structural changes in the further draft of document WIPO/GRTKF/IC/17/5".¹
- 2. This present document is the revised version of working document WIPO/GRTKF/IC/17/5, reflecting the structural changes, the amendments proposed and the comments made during the seventeenth session of the Committee.

¹ Draft Report of the Seventeenth Session of the Committee (WIPO/GRTKF/IC/17/12 Prov. 2)

Preparation and structure of this document

- 3. In the interest of keeping the present document as concise and current as possible:
- (a) in the Annex, the original substantive commentary on each objective and principle from document WIPO/GRTKF/IC/9/5 has been retained. The commentary also includes comments made and questions posed at the fifteenth, sixteenth and seventeenth sessions of the Committee and during two intersessional written commenting processes (the intersessional commenting process between the fifteenth and sixteenth sessions and the intersessional commenting process between the sixteenth and seventeenth sessions of the Committee). Comments made previously on document WIPO/GRTKF/IC/9/5 remain available to be consulted online;²
- (b) in line with the decisions of the Committee taken at its fifteenth, sixteenth and seventeenth sessions, specific amendments proposed by Member States at these sessions and during the intersessional written commenting processes 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 or has questioned are put between square brackets. Each such drafting proposal is accompanied by a footnote indicating the delegation that made the proposal, and, where applicable, delegations concurring or opposing the proposal, as the case may be. Furthermore, when the delegation provided an explanation for the proposal, such explanation is recorded in the footnote as well. None of the explanatory text featured in the footnotes is from the Secretariat, unless indicated otherwise. The Annex also records and attributes other comments made and questions posed at the fifteenth, sixteenth and seventeenth sessions and during the intersessional written commenting processes, 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. Comments related generally to the entire document are reflected at the very end of the document.
- in line with the decision of the Committee taken at its seventeenth session, structural (C) changes to the document have been made so as to align its structure more closely with that of the Committee's document on traditional cultural expressions (WIPO/GRTKF/IC/17/9). Original Article 3 (General Scope of Subject Matter) and Article 4 (Eligibility for Protection) have been merged into the current Article 1, namely Subject Matter of Protection. Original Article 5 (Beneficiaries of Protection) has become the current Article 2 with the same title. Original Article 1 (Protection Against Misappropriation) and Article 2 (Legal Form of Protection) have been merged into the current Article 3, namely Protection Against Misappropriation. Original Article 7 (Principle of Prior Informed Consent) and Article 6 (Fair and Equitable Benefit-Sharing and Recognition of Knowledge Holders) have been merged into the current Article 4, namely Principle of Prior Informed Consent, Fair and Equitable Benefit-Sharing and Recognition of Knowledge Holders. Original Article 13 (Administration and Enforcement of Protection) has become the current Article 5 with the same title. Original Article 8 (Exceptions and Limitations) has become the current Article 6 with the same title. Original Article 9 (Duration of Protection) has become the current Article 7 with the same title. Original Article 11 (Formalities) has become the current Article 8 with the same title. Original Article 10 (Transitional Measures) has become the current Article 9 with the same title.

² http://www.wipo.int/tk/en/consultations/draft_provisions/comments-1.html

Original Article 12 (Consistency with the General Legal Framework) has become the current Article 10 with the same title. Original Article 14 (International and Regional Protection) has become the current Article 11 with the same title. Cross-reference within the articles – as well as in the commentary and footnotes – have been modified accordingly.

- (d) in order to show the structural changes of the document clearly, the revised objectives and principles contained in document WIPO/GRTKF/IC/9/5 are enclosed in an Appendix to this document.
 - 4. 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]

REVISED PROVISIONS FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

POLICY OBJECTIVES AND CORE PRINCIPLES

CONTENTS

- I. POLICY OBJECTIVES
- (i) [Recognize value] <u>Recognize the holistic nature of traditional knowledge, including its</u> social, spiritual, economic, intellectual, educational and cultural importance¹
- (ii) Promote respect <u>for traditional knowledge systems</u>; for the dignity, cultural integrity and intellectual and spiritual values of the traditional knowledge holders who conserve and <u>maintain those systems</u>²
- (iii) Meet the actual needs of <u>holders of</u> traditional knowledge [holders]³
- (iv) Promote conservation and preservation of traditional knowledge
- (v) [Empower holders of traditional knowledge and acknowledge the distinctive nature of traditional knowledge systems]⁴
- (vi) Support traditional knowledge systems
- (vii) [Contribute to safeguarding traditional knowledge]⁵
- (viii) Repress unfair and inequitable uses of traditional knowledge⁶
- (ix) [Concord] <u>Operate consistently</u>⁷ with relevant international agreements and processes
- (x) [Promote innovation and creativity]⁸
- (xi) [Ensure prior informed consent and exchanges based on mutually agreed terms]⁹
- (xii) [Promote equitable benefit-sharing] <u>Promote the fair and equitable sharing of benefits</u> arising from the use of traditional knowledge¹⁰
- (xiii) [Promote community development and legitimate trading activities]¹¹
- (xiv) [Preclude the grant of improper intellectual property rights to unauthorized parties]¹²
- (xv) Enhance transparency and mutual confidence 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 consent¹³
- (xvi) [Complement protection of traditional cultural expressions]¹⁴

- ⁷ Delegation of the Russian Federation
- ⁸ Delegation of the Russian Federation
- ⁹ Delegation of the Russian Federation
- ¹⁰ Delegation of the Russian Federation
- ¹¹ Delegation of the Russian Federation
- ¹² Delegation of the Russian Federation
- ¹³ Delegation of the Russian Federation
- ¹⁴ Delegation of the Russian Federation

¹ Delegation of the Russian Federation

² Delegation of the Russian Federation

³ Delegation of the Russian Federation

⁴ Delegation of the Russian Federation

⁵ Delegation of the Russian Federation

⁶ Delegation of the Russian Federation

CORE PRINCIPLES

II. GENERAL GUIDING PRINCIPLES

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- (c) Effectiveness and accessibility of protection
- (d) Flexibility and comprehensiveness
- (e) Equity and benefit-sharing
- (f) Consistency with existing legal systems governing access to associated genetic resources
- (g) Respect for and cooperation with other international and regional instruments and processes
- (h) Respect for customary use and transmission of traditional knowledge
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- (j) Providing assistance to address the needs of traditional knowledge holders
- III. SUBSTANTIVE PRINCIPLES
- 1. Subject Matter of Protection
- 2. Beneficiaries of Protection
- 3. Protection against Misappropriation
- 4. Prior Informed Consent and Fair, Equitable Benefit-Sharing and Recognition of Knowledge Holders
- 5. Administration and Enforcement of Protection
- 6. Exceptions and Limitations
- 7. Duration of Protection
- 8. Formalities
- 9. Transitional Measures
- 10. Consistency with the General Legal Framework
- 11. International and Regional Protection

I. POLICY OBJECTIVES

The protection of traditional knowledge should aim to:

[Recognize value

(i) recognize the [holistic]¹⁵ nature of traditional knowledge and its intrinsic value, including its social, spiritual, [economic]¹⁶, intellectual, scientific, ecological, technological, [commercial]¹⁷, 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, <u>develop</u>¹⁸ 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] <u>conservation and sustainable use of biodiversity¹⁹</u>, to food security and sustainable agriculture, and to the progress of science and technology;

Meet the [actual] rights and²⁰ 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] recognize the value of²¹ 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

¹⁵ Delegation of Colombia

¹⁶ Delegation of Colombia

¹⁷ Delegation of Colombia. The Delegation requested clarification of the differences between the concepts of "economic value" and "commercial value" for the purpose of considering these variables

¹⁸ Delegation of Colombia

¹⁹ Delegation of Colombia. The Delegation stated that the reference to the conservation of the environment would have a more appropriate scope if CBD terminology was used, i.e. "the conservation and sustainable use of biodiversity"

²⁰ Delegation of Colombia

²¹ Delegation of Colombia

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 <u>misuse</u> and²² misappropriation, and should effectively empower <u>associated</u>²³ 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 domain²⁴]²⁵, 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 on the basis of prior informed consent and the mutually agreed terms with the holders of that knowledge²⁶;

Repress [unfair and inequitable uses] misappropriation and misuse²⁷

 (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

 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

 encourage, reward and protect tradition-based creativity and innovation and enhance the internal transmission of traditional knowledge within indigenous and [traditional] <u>local</u>²⁸ 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;

²² Delegation of Colombia

²³ Delegation of Colombia

²⁴ Delegation of the United States of America

²⁵ Delegation of Colombia. The Delegation of Colombia stated that the scope of the phrase "value of a vibrant public domain" was unclear

²⁶ Delegation of Colombia

²⁷ Delegation of Colombia

²⁸ Delegation of Colombia

Ensure prior informed consent and exchanges based on mutually agreed terms

 ensure <u>the use of traditional knowledge with</u>²⁹ 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]³⁰;

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;

²⁹ Delegation of Colombia

³⁰ Delegation of Colombia. The Delegation stated that clarification was needed with regard to the expression "individual holder", since there were a number of situations which could arise which did not provide an exemption from application of the principle of prior informed consent. Procedural adaptations were required not only in relation to obtaining consent, but also in relation to the form of compensation and benefit-sharing, depending on whether it concerned knowledge shared at the national level or at the transnational level and whether the holder was identified as a community but representative authority was not clear, etc. The Delegation noted that it was also necessary to review in more detail the treatment of the protection of rights over "disclosed" knowledge or knowledge that had become part of the "public domain" (public knowledge), with or without the consent of its holders, since such disclosure should not cancel ownership of the knowledge or the rights derived from prior informed consent, to the conclusion of agreements on the conditions of use and benefit-sharing. The Delegation wished to know exactly what the Committee understood by the notion of "public domain" in relation to TK. Although the provision was positive, it was important that there was greater clarity and above all that it was not implied that only a right to compensation survived when it should be possible to apply the other rights too. It should be borne in mind that most knowledge had been made public without informed consent processes or, where there was consent, it was sometimes restricted to specific research purposes and not to other possible uses, and in all these cases in which a holder could be identified, mechanisms should be designed for public recognition of ownership, negotiation of terms of use where possible and compensation

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 resources³¹]³², [in particular, as a condition for the granting of patent rights, that patent applicants for inventions involving traditional knowledge and associated genetic resources, as well as evidence of prior informed consent and benefit-sharing conditions have been complied with in the country of origin]³³;

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]³⁴.]
- (i) <u>recognize the holistic nature of traditional knowledge, including its social,</u> <u>spiritual, economic, intellectual, educational and cultural importance;</u>
- (ii) <u>promote respect for traditional knowledge systems; for the dignity, cultural</u> <u>integrity and intellectual and spiritual values of the traditional knowledge holders</u> <u>who conserve and maintain those systems;</u>
- (iii) <u>meet the actual needs of holders of traditional knowledge;</u>
- (iv) promote conservation and preservation of traditional knowledge;
- (v) <u>support traditional knowledge systems;</u>
- (vi) <u>repress unfair and inequitable uses of traditional knowledge;</u>
- (vii) <u>operate consistently with relevant international agreements and processes;</u>

³¹ Delegation of the United States of America

³² Delegation of Colombia. The Delegation did not agree with the use of the expression "requiring the creation of digital libraries of knowledge", not only because the means or mechanisms of that restriction should not be limited, but also because digital libraries posed problems as a protection mechanism as regards undisclosed knowledge. Until international and national *sui generis* positive protection principles were regulated, to prevent the destruction of novelty of such knowledge, that mechanism could not be regulated as mandatory

³³ Delegation of the United States of America

³⁴ Delegation of Colombia. The Delegation stated that the term "holistic identity" was not very clear, nor was it clear why it was needed for the development of the idea

- (viii) promote the fair and equitable sharing of benefits arising from the use of traditional knowledge;
- (ix) <u>enhance transparency and mutual confidence in relations between</u> <u>traditional knowledge holders on the one hand, and academic, commercial,</u> <u>educational, governmental and other users of traditional knowledge on the other,</u> <u>including by promoting adherence to ethical codes of conduct and the principles</u> <u>of free and prior informed consent.</u>³⁵

[Commentary on Objectives follows]

 $^{^{\}rm 35}$ Paragraphs (i) to (ix) proposed by the Delegation of the Russian Federation

COMMENTARY ON POLICY OBJECTIVES

Background

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 preamble 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.

Comments made and questions posed

The Delegation of the United States of America 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?

The Delegation of Australia 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.

The Delegation of Zambia stated that, as for TCEs, the value of TK should include its value in relation to "moral" and "public order". Further, there might be need for clarity on what constitutes "knowledge systems" under "Promote Respect". Similarly, the "interests" under "Promote conservation and preservation of traditional knowledge" should include "commercial interests".

The Delegation of the European Union and its Member States believed that the Policy Objectives, as written in WIPO/GRTKF/IC/17/5, had become overly long, detailed and complicated. The aim of the objectives should be to set out an overarching statement of what the Committee thought this instrument should do and not how it should be done. Therefore it had a preference to base the discussions on the Policy Objectives on the proposal made by the Delegation of the Russian Federation.

Drafting suggestions by observers

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) proposed to replace "support" with "encourage" in Policy Objective (iv).

The representative of the Southeast Indigenous Peoples' Center proposed to add a new Policy Objective at the very beginning, "Protect human rights: Protect the human rights of indigenous peoples who have developed traditional knowledge which has the potential to benefit the whole world." In relation to Policy Objective (ii) she proposed to insert "and for the indigenous legal systems that protect them" after "those systems". She also proposed to replace Policy Objective (iv) with "Promote conservation and preservation of traditional knowledge holders, users, and developers: Protect traditional knowledge holders, creators, cultivators, and developers from coercion or retaliation from those who seek their permission to use their TK." She proposed to insert "and protect" after "empower" and "Protect indigenous Peoples from violence and retaliation when we non-violently assert these rights to protect Traditional Knowledge" at the end of Policy Objective (v). She proposed to replace Policy Objective (vii) with "Contribute to safeguarding traditional knowledge: Contribute to the safeguarding of traditional knowledge and the appropriate balance of customary means for their development and transmission, 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 as determined by the tradition holders". She proposed to replace Policy Objective (viii) with "Stop unfair and inequitable uses: Stop the misappropriation of traditional knowledge and other unfair activities, recognizing the need to adapt approaches for the cessation of misappropriation of traditional knowledge to national and local needs". In relation to Policy Objective (ix), she proposed to insert "indigenous" before "international". She proposed to replace Policy Objective (xi) with "Ensure prior informed consent and exchanges based on mutually agreed terms: Ensure prior informed consent and exchanges

based on mutually agreed terms arrived at through ethical conduct as determined by the traditional knowledge holder, in coordination with existing indigenous national, international and national regimes governing access to genetic resources". Regarding Policy Objective (xii), she proposed to insert "with free prior and informed consent of the knowledge holder" after "traditional knowledge". She also proposed to replace Policy Objective (xiv) with "*Promote the resolution of disputes:* Promote a legal mechanism for settling disputes that puts indigenous Peoples on equal footing with UN member states. Promote the formation of a court that includes indigenous judges from non-UN Member nations (original nations), and allow organizations to explore and create libraries or registries that facilitate the association of indigenous Peoples with their TK", and to replace Policy Objective (xv) with "*Promote transparency and ethical conduct:* Promote transparency and understanding in relations between traditional knowledge holders and the academic, commercial, educational, governmental and others who use traditional knowledge by promoting adherence to ethical codes of conduct and the principles of free and prior informed consent by TK holders and which maintains the certainty that the indigenous People/Nation and its citizens will continue to perform their roles within their eco-spiritual-system".

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] <u>rights and needs identified</u> <u>by</u>³⁶ 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]

³⁶ Delegation of Colombia

COMMENTARY ON GENERAL GUIDING PRINCIPLES

Background

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.

Comments made and questions posed

The Delegation of China 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.

The Delegation of Australia 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".

The Delegation of Zambia stated that principles of disclosure and prior informed consent could equally stand out on their own.

The Delegation of the Russian Federation stated that the general guiding principles put forward in Section II of the Annex were important, including the principle of responsiveness to the needs and expectations of traditional knowledge holders, the principle of effectiveness and accessibility of protection, principle of respect for and cooperation with other international and regional instruments and processes, principle of flexibility and comprehensiveness, and the principle of respect for customary use and transmission of traditional knowledge. It indicated that the provisions related to the objectives and general guiding principles appeared, on the whole, to be acceptable.

The representative of the International Chamber of Commerce 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.

Drafting suggestions by observers

In relation to General Guiding Principle (e), the representative of the International Chamber of Commerce suggested to replace "equity" with "equitable balance". In the line 5 of Paragraph 1 of General Guiding Principle (e), he suggested to replace "and the maintenance of" with "actual experiences and needs, to produce and maintain". In the line 2 of Paragraph 2 of General Guiding Principle (e), he suggested to insert "defined, clarified" before "and safeguarded".

The representative of the Southeast Indigenous Peoples' Center proposed to add a new paragraph in the chapeau "The rights provided for here will be governed by the UN Declaration on the Rights of Indigenous Peoples and the Convention on Sustainable Development". A new General Guiding Principle "Principle of rejecting violence and the threat of violence as a means of acquiring TK" was proposed. She proposed to replace General Guiding Principle (c) with "Principle of effectiveness and accessibility by and protection of indigenous Peoples". She stated that General Guiding Principle (f) appeared to rob indigenous Peoples/Nations of their rights. The current document devalued international law in asserting that UN Member nations had rights to TK and GR irrespective of how illegally and violently the Member Nation acquired them. She proposed to replace "existing" with "indigenous" in (f). In relation to General Guiding Principle (g), she proposed to insert "indigenous" before "international". She proposed to replace General

Guiding Principle (h) with "Principle of respect for customary use and private transmission of traditional knowledge apart from colonial monitoring that allows indigenous Peoples to discuss and practice their TK out of the presence of colonial forces". In relation to General Guiding Principle (j), she proposed to insert "requested" before "assistance".

III. SUBSTANTIVE PROVISIONS

ARTICLE 137

SUBJECT MATTER OF PROTECTION

<u>Encourage, reward and protect tradition-based creativity and innovation and enhance the internal</u> <u>transmission of traditional knowledge within indigenous and traditional communities.</u>³⁸

The protection of traditional knowledge should ensure:

(a) the safeguarding and preservation of traditional knowledge;

[(b) the recognition and respect for traditional knowledge, including through the dignity, cultural integrity and intellectual and spiritual values of the traditional knowledge holders who conserve and maintain those systems, the contribution which traditional knowledge has made in sustaining the livelihoods and identities of traditional knowledge holders, the contribution which traditional knowledge holders have made to the conservation of the environment, to food security and sustainable agriculture, and the progress of science and technology³⁹;

(c) a balanced approach between the holders of traditional knowledge and users, which should also consider the need to facilitate access and dissemination of traditional knowledge aiming at innovation and need to ensure the dynamic and vibrant nature of the public domain⁴⁰, and ensure equitable benefit-sharing⁴¹.J⁴²

1. These principles concern protection of <u>protected</u>⁴³ traditional knowledge against misappropriation and misuse [beyond its traditional context]⁴⁴, and should not be

³⁷ Original Articles 3 and 4

³⁸ Delegation of Canada. The Delegation believed that that objective was really important under 1(1) and 1(2)

³⁹ Delegation of Canada. The Delegation proposed to add "including through the dignity ... and the progress of science and technology"

⁴⁰ Delegation of Spain, on behalf of the European Union and its Member States. The Delegation proposed adding "[t]he protection of traditional knowledge should ensure (a) the safeguarding and preservation of traditional knowledge; (b) the recognition and respect for traditional knowledge; and (c) a balanced approach between the holders of traditional knowledge and the users, which should also consider the need to facilitate access and dissemination of traditional knowledge aiming at innovation, and the need to ensure the dynamic and vibrant nature of the public domain". The Delegation of Canada supported the proposal in the paragraph (c) on the need for a balanced approach. It believed that that was a very useful addition and promoting respect for TK would only be possible if the views of all TK creators and users as well as those of the public in general were taken into account in that balanced approach

⁴¹ Delegation of South Africa. The Delegation proposed to add "and ensure equitable benefit-sharing". In order to provide a balanced approach between the TK holders and the users, clear distinction was necessary and a balance should be provided by including the knowledge holders' interests

⁴² Delegation of Nigeria. The Delegation suggested to delete paragraphs (b) and (c). It stated that a number of proposals were totally out of context with the general scope as originally intended. For example, all communities in Africa had TK for many years and TK was passed from generation to generation. Based on those new proposals, lots of TK from Africa which had been patented were currently in the public domain. Thus, it had been disconnected from the originated communities

⁴³ Delegation of the United States of America

⁴⁴ Delegation of the United States of America. The reason was that the use of the internet could be included and uses might not strictly speaking be within the traditional context

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 <u>inter-generational⁴⁵ process⁴⁶</u> nature of traditional knowledge and the nature of traditional knowledge systems as frameworks of ongoing innovation.

- 2. [For the purpose of these principles only]⁴⁷, 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 and continuously developed following any changes in the environment, geographical conditions and other factors⁴⁸. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and any traditional⁴⁹ knowledge associated with <u>cultural expressions and</u>⁵⁰ genetic resources.
- 3. Protection $[should]^{51} \underline{shall}^{52}$ be extended $[at \ least]^{53}$ to that traditional knowledge which $[is] \underline{satisfies any of the following}^{54}$:
 - (*i*) [Generated, <u>constituted</u>⁵⁵, <u>developed</u>⁵⁶, preserved and transmitted in a traditional and intergenerational context; <u>or</u>⁵⁷

[Footnote continued from previous page]

The Delegation of South Africa opposed because that was why the misappropriation and misuse beyond the control of communities happened and that was why they needed protection. The use and misappropriation within the traditional communities was regulated by customary law within those communities. To delete "beyond its traditional context" meant that protection which was beyond its boundaries was actually being eliminated in that context

The Delegation of Iran (Islamic Republic of) concurred with the Delegation of South Africa

The Delegation of Nigeria concurred with the Delegation of South Africa because the abuse of TK was not within the traditional societies that had lost control of that knowledge. Therefore, if the traditional communities and their knowledge were going to be protected, the essence of that work should be achieved

⁴⁵ Delegation of South Africa

⁴⁶ Delegation of Ecuador. The Delegation stated that the evolution of TK was permanent and there was a process behind that

⁴⁷ Delegation of Colombia. The Delegation stated that it was not clear why the definition given was limited to the principles and not to the operative provisions

⁴⁸ Delegation of Indonesia

⁴⁹ Delegation of Mexico

⁵⁰ Delegation of Iran (Islamic Republic of). The reason was that TK might be merged not only in TK associated with GR but also in association with folklore

⁵¹ Delegation of the United States of America. The Delegation assumed that it did not need to reinsert "should" which was replaced by "shall"

⁵² Delegation of Venezuela (Bolivarian Republic of) and Indonesia

⁵³ Delegation of Venezuela (Bolivarian Republic of). The Delegation of India opposed

⁵⁴ Delegation of India

⁵⁵ Delegation of Sudan

⁵⁶ Delegation of Morocco. The Delegation proposed to insert "constituted, developed" so there had to be compatibility between all those factors

⁵⁷ Delegation of India

(ii) [[distinctively]⁵⁸ associated with] <u>customarily recognized as belonging to</u>⁵⁹ a traditional or indigenous community, <u>local community⁶⁰</u>, [or] people <u>or ethnic</u> <u>group⁶¹</u> which preserves and transmits it between generations; [and] <u>or</u>⁶²] <u>generated</u>, preserved and constituted in a traditional context and shared within a community or collectively and usually transmitted from one generation to another; and/or⁶³

(iii) [integral to [the cultural identity of]]⁶⁴ [<u>a nation and</u>⁶⁵ an indigenous] <u>a local</u>⁶⁶ or traditional community. [or] <u>cultural identity of</u>⁶⁷ people <u>or ethnic group</u>⁶⁸ 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 <u>applicable national⁶⁹</u> laws; <u>and</u>

⁵⁸ Delegation of India and Sudan. The Delegation of Norway and the United States of America opposed The Delegation of Norway stated a line had to be drawn between protected TK and knowledge which was a part of the public domain. The word "distinctively" pointed at something essential with respect to the delimitation of the protection of TK. Therefore, the Delegation opposed. TK eligible for protection had to be distinctively associated with a traditional or indigenous community or people. This would ensure that knowledge which was a part of the public domain fell outside the scope of protection and could still be freely used by everyone. Firstly the criterion "distinctively associated" would imply that knowledge which was evolved separately by several traditional or indigenous communities or peoples or/and by people which were not a part of a traditional community or indigenous people, were a part of public domain and could be used freely by anyone. The fact that the same knowledge was generated by several groups of people that had developed the knowledge independently indicated that it was not fair to recognize exclusive rights to the knowledge for a certain group. This was a clear example of knowledge that should be considered as a part of the public domain. That important point was not sufficiently expressed merely by the criterion "distinctively associated with a traditional or indigenous community or people". The Delegation considered that the definition of TK should clearly state that knowledge which was evolved independently or held by several groups of people did not enjoy TK-protection. Secondly, the criterion "distinctively associated with a traditional or indigenous community or people" meant that knowledge that originally fulfilled the characteristics of protected TK would no longer enjoy protection once it had been widely known and used by a broader public for a certain time. However, the Delegation considered that the criterion "distinctively associated with a traditional or indigenous community or people" alone did not safeguard that important distinction sufficiently.

The Delegation of the United States of America stated "distinctively" had a special meaning and showed that that TK was characteristically associated with the indigenous community and not the public as a whole

⁶¹ Delegation of China. The Delegation noted that TK sometimes was owned by ethnic groups in China

62 Delegation of India

⁶⁴ The Delegation of India proposed to delete "integral to the cultural identity of". The Delegation of Mexico opposed. The Delegation of Uruguay proposed to delete "the cultural identity of"

⁵⁹ Delegation of Morocco. The Delegation proposed to replace "distinctively associated with" with "customarily recognized as belonging to"

⁶⁰ Delegation of the United States of America

⁶³ Delegation of Colombia. The Delegation merged Articles 1(3)(i) and 1(3)(ii)

⁶⁵ Delegation of Morocco. The Delegation stated that a nation was a part of the cultural identity of a people or a nation ⁶⁶ Delegation of Zambia. The Delegation stated that this Article equally fairly reflected its draft law and proposed the

following wording: "... integral to the cultural identity of a local or traditional community that is recognized as ..."

⁶⁷ Delegation of Uruguay

⁶⁸ Delegation of China. See note 61

⁶⁹ Delegation of Indonesia

- (iv) [has not been made public;]⁷⁰[has not been made widely and voluntarily known outside that community;]⁷¹
- (v) <u>contained in codified knowledge systems;</u>
- (vi) <u>passed through generations which may not be necessarily confined to a</u> <u>community.</u>⁷²

⁷⁰ Delegation of the United States of America. The Delegation of Venezuela (Bolivarian Republic of) opposed. The Delegation stated that the notions of "public domain" and "private domain" actually referred to public and private property, including the legal right that had been discussed in the courts. There was no clarity about that. The laws on the notion of public or private domain varied from country to country and from society to society. It asserted that the introduction of discussion in this area would lead to conditions which were not favorable and not in line with the aims of the document ⁷¹ Delegation of Norway. The Delegation of Turkey concurred. The Delegation of Venezuela (Bolivarian Republic of)

contested, because if "widely known" or "voluntary known" was used, the question would be to be known by whom, when and where. The Delegation of Norway responded to the comments on "outside that community". No suggestions had been made on how to define a community so it suggested working with language that took care of the problem raised by other delegations and representatives

⁷² Delegation of India. The Delegation reiterated that satisfaction of any one condition should be adequate to qualify for eligibility for protection

COMMENTARY ON ARTICLE 1

Articles 1(1) and 1(2) do two things: they clarify the general nature of traditional knowledge for the purposes of these provisions, and they set appropriate bounds to the scope of protectable subject matter. They therefore give effect to concerns that international provisions on TK should reflect the distinctive qualities of TK, but also respond 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 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.

Article 1(2) 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.

Article 1(3) 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 paragraph 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.

Article 1(4) 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 paragraph 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 organization⁷³". This could be a form of 'distinctive association' as suggested in subparagraph (ii).

Article 1(3) builds on the general description of TK in the first two paragraphs, and provides a conceptual link with the beneficiaries of protection, who are specified in Article 2. 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.

Comments made and questions posed

Meaning of indigenous and local communities

The Delegation of Italy noted the inconsistency between Articles 1(1) and 1(2), 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.

The Delegation of Switzerland suggested that the term "indigenous and local communities" in Article 1(2) should be understood in the same broad and inclusive sense as the term "communities", as described in footnote 64 of the Annex of the Draft Provisions on TCEs.

Definition of TK

The Delegation of the Russian Federation expressed that the provision of Article 1(2) was an adequate definition of what was assumed by protection in accordance with this document.

The Delegation of South Africa suggested that Articles 1(1) and 1(2) should be clearer and sharper.

The Delegation of Switzerland 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 1(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.

The Delegation of Spain, on behalf of the European Union and its Member States, stated that TK had different meanings for different people in different fora. For the purposes of work of the Committee, the current definition of TK and the criteria for eligibility would benefit from an in-depth debate aiming at a better qualification, drawing a line between what would fall under the scope of the international instrument and what will be left outside. It should be clearly defined what would and would not be covered by an international instrument. As a first step towards reaching internationally agreed working definition, the Secretariat was requested to complement

⁷³ Section 309.2(f), 25 CFR Chapter II 309 (Protection of Indian Arts and Crafts Products)

the gap analysis carried out, with an analysis of categories of the different manifestations of TK. Such categorization would respond to the different ways in which such TK was maintained and transmitted, publicly available or publicly accessible, under the direct control of the indigenous and local community or not, already in the public domain but not previously commercialized, among other issues. Those questions could be used as criteria for a matrix in the categorization process. In the spirit of making real progress, the one-size-fits-all model of protection for one type of TK had to be abandoned. Each of those categories might require a different consideration in the kind of protection received as decided by each country.

The Delegation of Japan raised the following questions: (1) What should fall within the scope of "traditional"? For example, the passing of how many generations would be sufficient to be "traditional"? (2) Were there any requirement for a community in which knowledge was shared and passed to be regarded as "traditional"? For example, could the knowledge which was shared and passed within a whole country be regarded as "traditional"? (3) How could the scope of the specific TK be defined to ensure predictability for users of such knowledge and the third parties?

The Delegation of Australia 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 the wording in Article 1(3) related to possible protection for TK produced by a contemporary generation.

The Delegation of India suggested including TK which was no more confined to a community but was generally used. Codified knowledge systems included traditional medicine, agriculture and environment which were codified in ancient scriptures and were passed on from generation to generation on the basis of those scriptures or through recognized courses of study.

The representative of the International Chamber of Commerce 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.

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) stated that this article covered the essential elements for defining TK, but it needed to be more specific. Knowledge resulting from intellectual activity might be intangible knowledge that could not be reproduced and fixed in a material form.

<u>Glossary</u>

The Delegation of Spain, on behalf of the European Union and its Member States, stated that other concepts introduced in the current text might also require definitions. In that context, the international instrument would greatly benefit from the introduction of a glossary of technical terms.

Public Domain

The Delegation of Spain, on behalf of the European Union and its Member States, considered the concept of public domain was another important element in the discussion since it established a balance between the rights of IP owners and the rights of the third parties. What could be considered in the public domain in the area of TK might require more reflection. The Delegation

recognized the need for a study of that issue and requested the Secretariat to prepare such a study for the next meeting of the Committee.

The Delegation of Norway stated, as several delegations had stated at the earlier sessions, that there was a need for further clarification of what actually was the subject matter for protection, namely how protected TK should be defined. As a part of the clarification, it was especially important to find the right balance between TK that was subject to protection and knowledge which was or had become part of the public domain. In that context, there was not a coherent view on what the notion of public domain actually meant. In that regard, Article 1 was crucial. These two articles had to be seen in connection to secure an adequate scope for the protection of TK. Article 1(3) was especially important. The Delegation believed that any international obligation on protection of TK should only apply for TK that was covered by the definition in Articles 1(1) and 1(2) and in addition fulfilled all the criterions in Article 1(3). Consequently, the criterions for eligibility for protection in Article 1(3) should be cumulative. A line had to be drawn between protected TK and knowledge which was a part of the public domain. The former wording of Article 1(3)(ii) pointed at something essential with respect to the delimitation of the protection of TK. Therefore, it opposed the proposed amendment of the deletion of "distinctively". TK eligible for protection had to be distinctively associated with a traditional or indigenous community or people. This would ensure that knowledge which was a part of the public domain fell outside the scope of protection and could still be freely used by everyone. Firstly, the criterion "distinctively associated" would imply that knowledge which was evolved separately by several traditional or indigenous communities or peoples or/and by people which were not a part of a traditional community or indigenous people, were a part of public domain and could be used freely by anyone. The fact that the same knowledge was generated by several groups of people that had developed the knowledge independently indicated that it was not fair to recognize exclusive rights to the knowledge for a certain group. This was a clear example of knowledge that should be considered as a part of the public domain. That important point was not sufficiently expressed merely by the criterion "distinctively associated with a traditional or indigenous community or people". It considered that the definition of TK should clearly state that knowledge which was evolved independently or held by several groups of people did not enjoy TK-protection. Secondly, the criterion "distinctively associated with a traditional or indigenous community or people" meant that knowledge that originally fulfilled the characteristics of protected TK would no longer enjoy protection once it had been widely known and used by a broader public for a certain time. According to Article 7, TK enjoyed protection as long as the criteria in Article 1(3) were fulfilled. That reflected the dynamic aspects of development and dissemination of knowledge. Knowledge that at a certain point in time was protected could at a later stage be disseminated to the public to such an extent that it was no longer reasonable to recognize that the use of the knowledge should depend on someone's consent. It was crucial to also draw such a distinction between protected TK and knowledge that had been free for all to use. However, it considered that the criterion "distinctively associated with a traditional or indigenous community or people" alone did not safeguard that important distinction sufficiently. The definition of protected TK should more explicitly clarify the criteria for when originally protected TK should be considered to have become a part of the public domain. Thus, the essential criterion was the dissemination and use of the knowledge outside the community that had made the knowledge. It believed that the knowledge at least should be considered as a part of public domain when it had become widely known outside the community that had generated it and consequently was easily accessible by the public from other sources than the community that had generated it or representatives for that community. The decisive criterion for when TK had become a part of public domain would then be the level of dissemination and the knowledge outside the group that had developed it. How the knowledge had been disseminated should be irrelevant in that assessment, it should be a mere objective assessment. The idea to draw the line between protected TK and knowledge in the public domain based on the extent the knowledge was disseminated to the public did not imply that TK

would lose its protection merely on the ground that someone outside the community had accessed the knowledge or the knowledge was accessible outside the community (*inter alia* through databases). It said that the intention was just to avoid a situation where someone claimed rights to knowledge that had been so widely disseminated that it was fair to consider it free for all to access and use. If protected TK was accessible also outside the holder's community, as time passed situations would occur where the knowledge had become widely disseminated to an extent that implied that the knowledge no longer would be distinctively associated with a certain group of people, and consequently was no longer protected. That was a consequence of the dynamic characteristics that was inherent in all knowledge. Knowledge which at one stage could represent an important contribution to the greater public would be a part of the common knowledge base after a while. That was reflected in how the protection of other types of knowledge and works were limited in time, for example the case for patents or copyrights.

The Delegation of Japan raised the following question: How would the knowledge which belonged to the public domain be treated and how would the public domain in this context be defined?

The representative of the Tulalip Tribes made comments on the issue of the public domain which was one core issue. When knowledge was shared, it was shared with responsibilities and obligations. These responsibilities and obligations would continue to exist into time unknown in the future. And those obligations included the use of the knowledge. That was a common indigenous world view concerned with their knowledge systems and there was substantive customary law related to that. Public domain was a western concept that was designed for commerce and was a bargain that was set for a grant of private property rights for a limited amount of time after which knowledge would go into the public domain. Such a concept did not necessarily exist in indigenous knowledge systems. When making claims of public domain against TK, demands of very large societies superseded those of the small societies *i.e.* indigenous communities. There were over 6 billion people on the planet out of which 20 million were indigenous peoples. Those claims would put indigenous knowledge into the public domain, for example the criterion of dissemination. At first, knowledge might leak out and be limited in its distribution but over time it would become more and more widespread. And if there were not protection mechanisms, that would be a form of flow into the public domain. He stated that a healthy public domain should be supported, but those ideas should be constructed very carefully. He supported the European Union's call for a report, but he believed such a report should involve indigenous peoples and local communities in order to provide significant input.

The representative of the Tupaj Amaru believed that the Delegation of Spain, on behalf of the European Union and its Member States, had confused the different issues between public domain and users and the balanced or equitable terms of the use. He believed the proposed changes were removed from the issues. The very heart of the question behind Articles 1(1) and 1(2) was what should be protected and what should not and the issues on the public domain. TK had been used for many years and it had been misused and misappropriated for at least 500 years. Much of TK was secret even to the indigenous peoples. Some TK had been transmitted from generation to generation but not necessarily among indigenous peoples and it was kept at a very secret place so it could not be disseminated or disclosed into the public domain.

The representative of the Indigenous Peoples Council on Biocolonialism supported the comments made by the representative of the Tulalip Tribes of Washington that the concept of public domain did not fit well with indigenous peoples' rights to control and protect their knowledge. She did not consider indigenous knowledge to be in the public domain, particularly if it had become publicly available without the explicit consent of the indigenous people.

The representative of the Saami Council believed that the exact problem was that the public domain had been wrongfully defined and that concept had allowed misappropriation of TK of the indigenous people. It should be decided what sort of TK deserved to be protected and then that would not be in the public domain rather than the other way around.

Need for balance

The representative of the Indigenous Peoples Council on Biocolonialism stated that Articles 1(1) and 1(2), as originally drafted, was intended to prevent misappropriation and misuse of TK. Articles 1(1) and 1(2), as amended, currently suggested that indigenous peoples would freely contribute their knowledge for use by others. The amended text in paragraph (c) therefore conflicted with the need to protect the rights of the indigenous knowledge holders first, rather than to prioritize or compromise the rights of indigenous peoples with the interest of the general public. Indigenous knowledge existed to benefit the peoples to whom the knowledge belonged and indigenous knowledge systems were inherent, inalienable and intended to last in perpetuity as dynamic and evolving knowledge systems as long as the indigenous peoples existed. She suggested that Member States considered language that recognized rights holders or owners over TK and their right to protect that knowledge and within the context of their human rights.

The representative of the Saami Council stated that it was not helpful in paragraph (c) to discuss balancing of the interests which could be an objective but not a part of an operative paragraph. It was not necessary to discuss how to define the subject matter and there was no need for balance, because it would be done when an agreement on the subject matter had been reached.

Definition of cultural identity

The Delegation of Morocco suggested clarifying the definition of "cultural identity".

Traditional arts and artisanal works

The Delegation of Oman suggested adding traditional arts and artisanal works.

Relationship with policy objectives

Noting the relevance of Policy Objective (vi) "Support TK systems", and the amendment suggested for Article 1(1) to include the term "inter-generational", the Delegation of Australia 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.

The Delegation of Canada stated that Article 1(3) would be inconsistent with the objective to promote innovation and creativity and to enhance transparency and mutual respect as it provided for perpetual protection and did not contemplate entry into the public domain. Thus significant concerns were raised for creators and users and this had implications for the broader public interest. There was need for some balance in that provision.

The representative of the Saami Council did not think it was helpful to add a number of objectives into each article. It would be better to keep the current structure and to have the objectives in a separate section at the front.

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) stated that the compensation measure was very relevant as it allowed injured populations to be compensated. However, a choice had to be made between a persuasive measure and a measure that did not smother TK. Where measures were too persuasive, potential users no longer wanted to touch the knowledge concerned and the knowledge ended up disappearing. This issue was related to the issue of exclusive rights. Being a holder of exclusive rights over knowledge should not lead to the right to completely prohibit the use of that knowledge. Policy Objectives (xiii) and (xii) were referred to.

<u>Sui generis text</u>

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) indicated that in New Caledonia the key problem was to identify the individual author of TK. All their TK was held by clans, tribes and communities. That situation was not covered by French legislation, which required that authors be identified in order to be protected by the French Intellectual Property Code. That was why he was calling for a *sui generis* text which could take all collective rights into account.

Compensation measure

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) said that Article 3(1)(c) did not indicate the body that should enforce the sanctions and its powers. He hoped this body to be known and for it to be independent of the public authorities. For example, an independent administrative authority could be created that would be responsible for enforcing the measures provided for in this text.

<u>Criteria</u>

The Delegation of Cameroon noted that the criteria included in Article 1(3) should not be cumulative. Article 1(3)(iii) was the only necessary criterion of protection.

The Delegation of El Salvador suggested the protection should be broader.

The Delegation of the United States of America 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.

The Delegation of Australia 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 2. 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.

Proposal of "has not been made public"

The representative of the Tulalip Tribes made comments on the proposal "has not been made public" made by the Delegation of the United States of America. That proposal seemed to be

imposing conditions on indigenous peoples for the use of their knowledge. When indigenous peoples used the knowledge, they often made it public among themselves. For example, a family song that was held by a single family might be a song in public, others might know the song and they might know the music. Others from outside the community came in and viewed the ceremony which had been made public. But under customary law that did not confer a right for others to use that family's song. He therefore thought that it was a precondition on imposing external criteria through the indigenous knowledge systems and he hoped to have it withdrawn.

The representative of the Ethio-Africa Diaspora Union Millenium Council supported the statements made by the representative of the Tulalip Tribes. He noted that the relationship between communities, indigenous peoples and their knowledge had been complicated by the issue of the public domain. There was need for balance. However, the public domain could not be prioritized over rights.

Proposal of "has not been made widely and voluntarily known outside that community"

The representative of the Tulalip Tribes believed that there was still a problem and he hoped to have it bracketed because it was not clear. For example, where indigenous peoples had shared some knowledge with an academic researcher, but did not understand the publishing system or what would happen once the knowledge got published. Of course, that had been voluntarily shared and was being disseminated. The question was whether that became eligible for protection. He repeated that if the ideas and the concepts of indigenous peoples needed to be reflected they needed to give PIC in the sharing. Voluntariness was an issue that needed to be looked at more.

The representative of the Indigenous People (Bethechilokono) of Saint Lucia Governing Council stated that that proposal by the Delegation of Norway would definitely strike out the indigenous peoples of St. Lucia who could be found in 17 constituencies around St. Lucia. He had a great difficulty with that proposal because it was going to pose some problems for them. He would be willing to work with the Delegation of Norway to resolve that particular issue, because it was imperative that the developed countries understood exactly where he was coming from. From the Caribbean, they had a unique situation and that must be taken into consideration.

Relationship among paragraphs

The Delegation of Brazil suggested that the wording of Article 1(3)(i) should be included in Article 1(2).

Terms used in Article 1(3)

The Delegation of Italy suggested that the words in the document should be the same. For example, the words "indigenous and local communities" as used in Article 1(2) should also be used in Article 1(3). It also highlighted that the scope of "local communities" was needed.

The Delegation of Uruguay suggested to clarify the words "indigenous or traditional community or people" and "cultural identity".

The Delegation of Australia noted that the suggestions in relation to Article 1(3)(iii) focused that part of Article 1(3) 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.

The Delegation of Canada stated that the definition of traditional or indigenous communities would clarify who was included in those groups and whether it excluded non-indigenous groups.

The representative of Indigenous Peoples (Bethechilokono) of Saint Lucia noted that the term "traditional or indigenous community or people" in Article 1(3)(ii) was confusing. The explanation should be given after consulting outside of the Committee for a study on the terms.

Traditional medicine

The Delegation of India suggested that more legal text should be submitted in writing. It also noted that traditional medical knowledge was not always linked to communities.

The Delegation of Nigeria suggested that Article 1(3)(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

The representative of the African Regional Intellectual Property Organization 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 Article 1(2).

The representative of the InBraPi suggested adding "developed" after "activity" in lines 2 of Article 1(2).

The representative of the International Chamber of Commerce proposed to delete "and misuse" and "and holistic" in Article 1(1) and to insert "as defined in national law" in Article 1(2).

The representative of the Southeast Indigenous Peoples' Center proposed to insert "For example: governance, trade, mathematical, hunting, husbandry, herding, agriculture, aquaculture, fishing, gathering, healing, parenting, nutritional, burial, artistic, leadership, construction, ship-building, peace-making, war-making, and medicine-making methods; traditional recipes, formulas, schematics, diagrams, or directions for blending elements; information contained in maps, mapmaking techniques, conceptual and phonetical written storytelling/language pattern-making methods and the meaning of the symbols, knowledge found in or derived from human remains, burials, and in depictions of indigenous Peoples/Nations..." at the end of Article 1(2). She proposed to insert "by indigenous People/Nations" after "recognized" in Article 1(3)(ii). She proposed to delete "or ethnic group" in Article 1(3)(ii). In relation to Article 1(3)(iii), she proposed to insert "indigenous" before "national laws".

The representative of Arts Law Center of Australia suggested deleting "distinctively" in Article 1(3)(ii). She also suggested using "indigenous" with a capital "I".

The representative of the Saami Council believed that the criteria in Article 1(3)(i), as currently formulated, were restricting the application too much because they suggested that TK, to be protected, had to be actively used in the community. He suggested to include the words "have been" before "generated" in the beginning. Articles 1(3)(ii) and 1(3)(iii) took care of the issue that TK should also be associated with the particular culture and people but it should not be active. So "is" had to be taken out from the chapeau and "is" would be added as stated the first word in Articles 1(3)(ii) and 1(3)(iii). The important one was that the words "have been" would be inserted

before "generated" in Article 1(3)(i).

The representative of the International Chamber of Commerce proposed a new paragraph "Traditional knowledge that has become known outside its traditional context shall not be protected" in Article 1(3).

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) proposed to add the word "acquired" in Article 1(3)(i) and to replace the word "associated" with "recognized" in Article 1(3)(ii). The reason to use the word "acquired" was that some TK was acquired through customary exchange (bartering) between indigenous tribes and local communities. Sometimes those were castes. That knowledge then became part of their heritage which needed to be protected and handed down to future generations. As indicated above, the holder might also be known as a custodian or as an entity invested with responsibility within the community.

ARTICLE 274

BENEFICIARIES OF PROTECTION

Protection of traditional knowledge should benefit the communities who generate, <u>protect</u>,⁷⁵ preserve and transmit the knowledge in a traditional and intergenerational context, who are [associated with it]⁷⁶ and who identify with it in accordance with Article 1(3). Protection should accordingly benefit the indigenous and traditional <u>or local</u>⁷⁷ communities themselves that hold traditional knowledge in this manner, [as well as recognized individuals within these communities and peoples]⁷⁸ <u>as well as individuals within the communities who are recognized under customary laws, practices and protocols to hold the knowledge for the community, or who are designated as trustees of such knowledge by appropriate traditional processes, customs or institutions⁷⁹ /, taking into account in particular those individuals who act as the custodians of that knowledge or who are given special recognition within these communities and peoples⁸⁰. Entitlement to the benefits of protection should, [as far as possible and appropriate]⁸¹, [take account of] be according to⁸² the customary protocols, understandings, laws and practices of these communities and peoples.</u>

<u>For codified traditional knowledge, either in the form of ancient scriptures or digital libraries of</u> <u>public texts, or if the knowledge is not confined to a community but is generally used, the relevant</u> <u>legislation of Member States shall provide for identification of the beneficiary.</u>⁸³

⁷⁴ Original Article 5

⁷⁵ Delegation of the United States of America. If the knowledge was not protected within the indigenous and local communities, the international communities should not have an obligation to protect that information either
⁷⁶ Delegation of Switzerland. The Delegation was not sure about the meaning of "who are associated with it and who identify with it in accordance with Article 1(3)". It was not sure about what was the additional requirement compared to Articles 1(3)(ii) and 1(3)(iii) where it said "associated with" and "cultural identity"

⁷⁷ Delegation of Uruguay. In some parts of the document "traditional communities and other local communities" was used. It seemed there was a problem with definition. Nobody should be excluded. There was a difference between local and traditional communities and it was aware of that. The Delegation suggested inserting the words "or local" until how to define those different groups had been decided

⁷⁸ Delegations of Zambia and Colombia

⁷⁹ Delegation of Zambia. It was not clear who recognized those, according to what law and whether it could also be someone outside the community. The ambiguity was compounded by the last sentence which suggested that customary law was one of the laws that should be taken into account in identifying those individuals. It also indicated that under its draft law, "individuals within the communities who are recognized under customary laws, practices and protocols to hold the knowledge for the community, or who are designated as trustees of such knowledge by appropriate traditional processes, customs or institutions" were recognized as beneficiaries

⁸⁰ Delegation of Colombia

⁸¹ Delegation of Colombia

⁸² Delegation of the United States of America. It should be the customary protocols that supported the benefit of protection not necessarily national laws

⁸³ Delegation of India

COMMENTARY ON ARTICLE 2

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.⁸⁴

⁸⁴ 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 of America ...; 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)

Comments made and questions posed

Relationship with Article 1(3)

In association with the comments made concerning Article 1(3), the Delegation of China 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.

The Delegation of Australia noted that the suggestions in relation to eligibility for protection in Article 1(3) needed to be considered in light of the beneficiaries of protection in this part.

The Delegation of India stated that even if the TK had lost its community identity and was used by many peoples, the benefit must flow to the community. In such cases the agency/authority identified by the national law should be the beneficiary and the benefit should flow from the agency/authority to the identifiable community or the communities that at present preserved, maintained, and transmitted the TK. The manner in which that was to be ensured might be left to national legislation. There should not be any reference to Article 1(3) if it was not broadened to cover all forms of TK. The principles to be followed were: (i) right to the community if identifiable with the TK; (ii) right of a national authority to be the beneficiary in case of TK not directly associated with a community and share the benefit to the community originally developed and currently protected and promoted.

The Delegation of Morocco stated that Article 1(3) was much more detailed than Article 2. Article 2 referred only to indigenous and traditional communities. Whereas in other parts of the document, local communities, even peoples or nations were mentioned. It should therefore be ensured that Articles 1(3) and 2 were fully in line with each other and the wording was standardized.

National law

The Delegation of Australia 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

The Delegation of Australia 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.

"Detienen" vs. "poseen"

The Delegation of Peru stated that in the Spanish version, it said that protection should accordingly benefit the indigenous and traditional communities who held TK in that manner. The Delegation thought that perhaps the word "detienen" in Spanish was not the most appropriate. It suggested using the word "poseen" instead. That was probably a translation issue but it hoped to have on record its preference for the word "poseen" rather than "detienen".

Proposal of "protect"

The representative of the Tulalip Tribes asked for some clarification on what was intended by inserting that phrase. He went back to the issue of those communities where they might share

knowledge innocently or share knowledge under their understandings with somebody that did not have the same understandings. The question was whether it would be considered that they had not taken the steps to protect their knowledge. A protection was kind of a term which assumed that somebody understood what happened when sharing or transmitting knowledge. A lot of indigenous peoples had never had much contact with the western IP system. They did not understand that when knowledge was shared it immediately came under the western IP system. It was fated to eventually fall in the public domain. So he thought the use of that term in an unqualified way was problematic.

Relationship with Article 3(1)

The Delegation of Morocco stated that reference had already been made to beneficiaries of protection. It had to be absolutely clear from the very start of the Article which beneficiaries were going to be focused on. Who those beneficiaries of protection should be in accordance with what had been decided upon in Article 3(1), because in Article 3(1) the term protection was referred to. It should be very clear that those beneficiaries were going to benefit from protection as understood and defined in Article 3(1).

Beneficiaries of the specific TK

The Delegation of Japan posed the following questions: (1) How could the boundary of beneficiaries of the specific TK be defined? (2) What were the objective requirements for beneficiaries of the specific TK? For example, was a kind of biological connection such as kinship needed? (3) How could predictability on beneficiaries of the specific TK be ensured for users?

General comment

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) stated that there was a risk of the entire Article being undermined by certain customary uses which were unwritten and therefore adaptable according to the goodwill of notables. This provision therefore should certainly be studied in greater depth.

ARTICLE 385

PROTECTION AGAINST MISAPPROPRIATION AND MISUSE⁸⁶

1. (a) Traditional knowledge shall be protected against [misappropriation <u>and misuse</u>⁸⁷] <u>the following acts if these acts have a commercial goal or take place outside the context</u> <u>of the customary or traditional uses of this traditional knowledge</u>⁸⁸.

(b) Any acquisition, appropriation<u>, revelation</u>⁸⁹ or utilization of traditional knowledge by unfair or illicit means <u>that [shall⁹⁰]</u> constitute[s] an act [of misappropriation <u>and misuse⁹¹</u>. Misappropriation <u>and misuse⁹²</u> [may] <u>shall⁹³</u> also include deriving] <u>to derive⁹⁴</u> commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows, or [is negligent in failing] <u>fails⁹⁵</u> 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.

- (c) In particular, legal means [should] <u>shall⁹⁶</u> 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, <u>failure to provide or supply important information</u>⁹⁷ when obtaining prior informed consent for access to traditional knowledge, or other unfair or dishonest means;
 - (ii) acquisition <u>or use⁹⁸</u> of traditional knowledge [or exercising control over it]⁹⁹ 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

⁸⁵ Original Articles 1 and 2

⁸⁶ Delegation of Indonesia. The Delegation of Australia 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. The Delegation of Zambia noted that what amounted to "misuse" may require elaboration

⁸⁷ Delegation of Indonesia. The Delegation of Australia and Zambia called for further discussion. See note 86

⁸⁸ Delegation of Morocco

⁸⁹ Delegation of Peru

⁹⁰ Delegation of India

⁹¹ Delegation of Indonesia. The Delegation of Australia and Zambia called for further discussion. See note 86

⁹² Delegation of Indonesia. The Delegation of Australia and Zambia called for further discussion. See note 86

⁹³ Delegation of Cameroon proposed to delete "may". Delegation of India proposed to replace "may" with "shall"

⁹⁴ Delegation of Venezuela (Bolivarian Republic of) proposed to replace "shall constitutes an act of misappropriation.

Misappropriation may also include deriving" with "that constitutes an act to derive"

⁹⁵ Delegation of Venezuela (Bolivarian Republic of)

⁹⁶ Delegation of India

⁹⁷ Delegation of Colombia

⁹⁸ Delegation of Colombia

⁹⁹ Delegation of Colombia

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] <u>use of</u>¹⁰⁰ 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,]¹⁰¹ commercial or industrial use of traditional knowledge [without just and appropriate [compensation] <u>benefit-sharing¹⁰²</u> to the recognized holders of the knowledge] in violation of <u>the recognized rights of the holders of the knowledge</u>¹⁰³, 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]¹⁰⁴ in view of the circumstances in which the user acquired the knowledge]¹⁰⁵ and according to the national and international [regimes]¹⁰⁶ legislation where applicable¹⁰⁷; and
- (v) [willful]¹⁰⁸ 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] <u>and/or</u>¹⁰⁹ [is contrary to ordre public or morality.]¹¹⁰;
- (vi) the granting of patent rights for inventions involving traditional knowledge [and] and/or¹¹¹ 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.¹¹²

¹⁰⁰ Delegation of Colombia

¹⁰¹ Delegation of Brazil. The Delegation of the United States of America commented that 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

¹⁰² Delegation of Brazil. The Delegation of Burundi opposed

¹⁰³ Delegation of India

¹⁰⁴ Delegation of Brazil

¹⁰⁵ Delegation of India

¹⁰⁶ Delegation of Brazil

¹⁰⁷ Delegation of Mexico. The Delegation proposed to replace "regimes" with "legislation where applicable"

¹⁰⁸ Delegation of Brazil

¹⁰⁹ Delegation of Colombia

¹¹⁰ Delegation of Mexico. The reason was that as the text of the article appeared, the sanction for voluntary offensive use, outside the customary context, by third parties, of TK with special moral or spiritual value, could only be applied when said offense was considered contrary to *ordre public* or morality. The Delegation considered that the offensive use referred to had to be sanctioned owing to the violation which it represented for the moral or spiritual sphere of an indigenous people or community, and the effect that had on community life or identity

¹¹¹ Delegation of Colombia

¹¹² Delegation of Brazil

(d) 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.

(e) The application, interpretation and enforcement of protection against misappropriation <u>and misuse</u>¹¹³ of traditional knowledge <u>and other recognized rights</u>¹¹⁴, including determination of equitable sharing and distribution of benefits, should be guided, as far as possible [and appropriate]¹¹⁵, 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.

2. (a) The protection of traditional knowledge against misappropriation <u>and misuse shall</u> [may]¹¹⁶ be implemented through a range of legal measures, including, inter alia¹¹⁷: 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 8(1).]¹¹⁸

(b) The form of protection [need not be through exclusive property rights] <u>may be</u> <u>through the recognition of property rights</u>¹¹⁹, although such rights may be made available [, as appropriate, for the [individual]¹²⁰ [and] <u>and/or</u>¹²¹ collective] <u>to</u>¹²² 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.

¹¹³ Delegation of Indonesia. The Delegation of Australia and Zambia called for further discussion. See note 86

¹¹⁴ Delegation of India

¹¹⁵ Delegation of Colombia

¹¹⁶ Delegation of Indonesia

¹¹⁷ Delegation of Mexico

¹¹⁸ Delegation of the Russian Federation. The Delegation noted that Article 3(2)(a) states that "this paragraph is subject to Article 8(1)". However, not all the legal measures listed in the aforementioned Article 3(2)(a) may be applied in accordance with the provisions of Article 8(1), i.e. without formalities. For example, the intellectual property legislation referred to in Article 3(2)(a), 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

¹¹⁹ Delegation of Colombia

¹²⁰ Delegations of Ecuador and Venezuela (Bolivarian Republic of). They suggested that, in relation to Article 3(2)(b) on the scope of the rights of holders of knowledge, the word "individual" should be reviewed due to the collective nature of TK

¹²¹ Delegation of Colombia

¹²² Delegation of Mexico

COMMENTARY ON ARTICLE 3

Article 3(1) 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. Article 3(1) 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. Article 3(1) 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.

Article 3(1)(b) 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.

Article 3(1)(c) 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 3(1)(c) 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.

Article 3(1)(d) 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, Article 3(1)(e) 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.

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 Article 3(2) can be found in existing international instruments covering diverse fields of protection. Examples that have earlier been cited include the Washington Treaty¹²³, the Paris Convention, and the Rome Convention.¹²⁴ Article 3(2) 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, Article 3(2)(a) 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.

Article 3(2)(b) clarifies that these principles do not require the creation of exclusive property titles on TK, which are perceived by many TK holders as inappropriate. 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 privatization or 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

¹²³ Treaty on Intellectual Property in Respect of Integrated Circuits (1989) (hereinafter, "the Washington Treaty")

¹²⁴ International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (1961) (hereinafter, "the Rome Convention")

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.

Comments made and questions posed

Relationship with elements of policy objectives and principles

The Delegation of Australia noted Article 3(1) 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 Article 3(1) was too detailed and prescriptive and was not consistent with Article 3(2) and the principle of flexibility and comprehensiveness. Article 3(1) 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 Article 3(1) 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 Article 3(1)(b) 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 Article 3(1)(c)(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.

The Delegation of Japan, New Zealand and Switzerland suggested that in-depth examination of policy objectives and principles was the prerequisite for the discussion on the substantive provisions.

The Delegation of South Africa 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.

The Delegation of Switzerland 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.

The Delegation of Germany asked for greater clarification on what actually should be the objective and subject of protecting TK through Article 3(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.

The representative of the International Chamber of Commerce noted objectives needed to be discussed.

The representative of the Tupaj Amaru noted indigenous peoples and local communities were the object of protection.

<u>Glossary</u>

The Delegation of Spain called for a glossary.

The Delegation of Nigeria 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.

The representative of the Maya To'Onik Association 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.

The representative of the International Chamber of Commerce noted that clarity was important because business needed to know what they can do and what they cannot do.

Definition of misappropriation

The Delegation of Cameroon, Morocco, Nepal and Nigeria suggested that misappropriation should be defined.

The Delegation of Italy noted that the list of possible cases of misappropriation included in Article 3(1)(c) was not necessary.

The Delegation of Nigeria noted that Article 3(1) was restrictive as protection of TK should not be solely based on acts of misappropriation. The entire Article 3(1) should be reviewed to include all rights that should be protected thoroughly under TK, including economic and moral rights.

The Delegation of Zambia noted that, as for TCEs, Article 3(1) seemed to merely provide for negative rights and positive rights could thus be included. Further, unless Article 3(1)(c) was intended to be the definition of what amounted to misappropriation, there might be need for a definition.

The representative of the International Chamber of Commerce 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

The Delegation of Italy and Nepal noted that the definition of TK was absolutely necessary. The kind of definition included in Article 1(2) was insufficient.

The Delegation of Japan, Kenya, Morocco and Nigeria 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.

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

The Delegation of Australia noted that Article 3(1)(c)(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.

The Delegation of Japan raised the following questions: (1) What should fall within the scope of "traditional"? For example, the passing of how many generations would be sufficient to be "traditional"? (2) Were there any requirement for a community in which knowledge was shared and passed to be regarded as "traditional"? For example, could the knowledge which was shared and passed within a whole country be regarded as "traditional"? (3) How could the scope of the specific TK be defined to ensure predictability for users of such knowledge and the third parties?

The Delegation of Zambia stated that the definition of TK as provided under Article 1 was a replica of the definition provided in its draft law.

Definition of holders and recognized holders

The Delegation of the Russian Federation 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"?

The representative of the InBraPi stated that throughout the document reference was made to the holders of TK, but only in Article 1(3) was it clearly expressed that indigenous peoples and local communities were the holders of that TK. She proposed that, in accordance with Article 1(3)(iii), "indigenous peoples and local communities" be placed before the word "holders".

Rights of the holders

The Delegation of Italy 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.

The Delegation of Kenya believed that Article 3(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.

The Delegation of India believed that Article 3(1) should at the very outset define the rights of the TK holders. The impression given by Article 3(1) was that the instrument only covered protection against misappropriation and misuse. The approach was therefore very narrow especially in the context of the Policy Objectives and the General Guiding Principles. It asserted that the scope must be expanded in that Article or through a new article. The Article should first assert collective ownership of TK with the communities. That would clarify the positive protection of TK. As it stood currently, there were no positive rights to the owners of TK similar to that of TCEs. There was no justification for the different approach in case of TK. Besides, the legal basis for taking action to prevent misappropriation was not expressly stated though it was implied. Minimum rights that the communities had in their TK should also be identified. These rights should include rights to collective ownership over TK, rights of collective management of TK, rights against misappropriation, rights to insist for prior informed consent, rights to benefit sharing, rights to deny access and rights to recognize the identity of TK.

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) stated that it was true that the obligations of holders were different to those of recognized holders who were at the origin of a creation and to whom knowledge had been handed down by the previous generation in accordance with the customary rules of the region or clan. Holders were those who may use knowledge but might not customarily transmit that knowledge. In addition, he referred to "custodians of knowledge" who, regardless of their status, were invested with the authority of custodian together with a duty to hand that knowledge down to the next generation. The list of types of appropriation should be maintained and should not be regarded as restrictive. When referring to acquisition, the commercial aspect inevitably arose. It was therefore right to retain the concept of financial compensation. In the region of the Pacific (New Caledonia, Fiji, Vanuatu, Samoa, Tonga, Papua New Guinea, the Solomon Islands and the Cook Islands), TK had become a currency. The old system of bartering was in decline in favor of money.

Enforcement

The Delegation of Cameroon questioned what body should be responsible for penalization. It also noted it was not clear, in Article 3(1)(c), who should make the legal means available and to whom.

Commercial and non-commercial issues

The Delegation of Kenya suggested that Article 3(1) should cover wider issues on exploitation of TK, not only on commercial exploitation of TK.

The Delegation of New Zealand raised the issue of potentially differentiating commercial and non-commercial misappropriation. It noted that Article 3(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.

The Delegation of India stated that misappropriation should not be confined to commercial or industrial use but all use identified in the treaty and national laws.

The representative of the Indigenous Peoples Council on Biocolonialism 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

The Delegation of Morocco 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.

The Delegation of the United States of America 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

The Delegation of Norway 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.

The Delegation of Sweden 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?

The Delegation of Japan raised the following question: How would the knowledge which belonged to the public domain be treated and how would the public domain in this context be defined?

The representative of the InBraPi 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.

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) stated that it was difficult to define the boundary between the public domain and the private domain of TK. Nowadays, TK was used by everyone to such an extent that people talk about "knowledge that has become part of the public domain" because it was known by everyone. He believed that the difficulty arose because it was sometimes impossible to determine which individual person was the author of that knowledge. Knowledge was often attributed to a clan or community without being able to identify the author of the creation. Even the definition of the term "author" differed from the Western definition in that it was not the creator who was referred to as the author (and therefore the copyright holder) but rather another person (uncle, tribe, mother, etc.).

Disclosure requirement

The Delegation of China 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.

The Delegation of India stated that the disclosure requirement should be for all forms of TK and should not be confined to TK associated with GR.

The representative of the International Chamber of Commerce 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.

Relationship with Gap Analysis

The Delegation of Australia stated that the Gap Analysis (WIPO/GRTKF/IC/13/5(B)) had shown that the legal means in Article 3(1)(c) were already available, though not all (note Article 3(1)(c)(iv)). It wondered to what extent was this international instrument filling the gaps identified in that analysis.

Legal forms or measures

The Delegation of China 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.

The Delegation of Zambia stated that while States might choose the appropriate means of protection, statutory law was preferable to "common law" for instance.

The representative of the African Regional Intellectual Property Organization noted that Article 3(2) provided a range of legal forms or measures that can be used to protect TK. However, those measures indicated in Article 3(2)(a), 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

The Delegation of Australia 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.

The representative of the African Regional Intellectual Property Organization stated that the commentary on Article 3(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 3(2)(b). 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)

The Delegation of Australia 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.

Drafting suggestions by observers

The representative of the Indigenous Peoples Council on Biocolonialism suggested to add "or non-commercial" in line 5 of Article 3(1)(b) after the word "commercial".

The representative of the InBraPi suggested to add "of the indigenous peoples and local communities, holders of traditional knowledge" after "prior informed consent" in line 2 of Article 3(1)(c)(ii).

The representative of the Saami Council suggested, in relation to Article 3(1)(b), 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".

The representative of the Tulalip Tribes of Washington suggested, in Article 3(1)(c)(v), to add "of the indigenous peoples and local communities" after "*ordre public* or morality".

The representative of the Tupaj Amaru proposed that "shall" in Article 3(1)(a) should be replaced with "should". In relation to Article 3(1)(b), 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 3(1)(c), he suggested to add "and sanction" after the word "prevent". In relation to Article 3(1)(c)(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 Article 3(1)(c)(ii) he suggested to add "possession" after "acquisition" and also "the legislation currently in place" after "in violation of". In Article 3(1)(c)(ii) he suggested 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 3(1)(d) "indigenous peoples and local communities" and to add "customary laws of indigenous peoples and local communities" and to add "customary laws of indigenous peoples and local communities" and to add "customary laws of indigenous peoples and local communities" and to add "customary laws of indigenous peoples" and local communities" and to add "customary laws of indigenous peoples and local communities" and to add "customary laws of indigenous peoples" and local communities" and to add "customary laws of indigenous peoples" and local communities" and to add "customary laws of indigenous peoples" and local communities" and to add "customary laws of indigenous peoples and local communities" and to add "customary laws of indigenous peoples and local communities" and to add "customary laws of indigenous peoples and local communities" and to add "customary laws of indigenous peoples and local communities" and to add "customary laws of indigenous peoples and local communit

The representative of the International Chamber of Commerce suggested to delete "or utilization" in Article 3(1)(b). He suggested to insert "in violation of national access and benefit-sharing law" before "by unfair or illicit means". He also suggested to insert "without obtaining prior informed consent and without entering into mutually agreed terms on access and benefit-sharing arising from the utilization of the traditional knowledge" after "by unfair or illicit means". He proposed to delete Article 3(1)(c) *in toto*. In relation to Article 3(1)(e), he proposed to insert "as defined in paragraph 1" after "misappropriation". He also proposed to insert "as defined in Article 3(1)" after

"misappropriation" in Article 3(2)(a).

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) proposed to replace "appropriated by unfair means" with "obtained by unfair means" in Article 3(1)(b). He stated that this paragraph should be strengthened in the sense that it should also apply to anyone who knew of someone who was exploiting a traditional knowledge without asking whether it was acquired legally or who continued to exploit it despite having doubts as to the legality of its acquisition. Another paragraph to Article 3(1)(c) was proposed, reading as follows: "(vii) fraudulent attempts at misappropriation, unlawful acquisition or acquisition by means of violence or an act of aggression of traditional knowledge for the purpose of commercial use giving rise to financial gain and certain benefits for the perpetrator or with the aim of making degrading use of that knowledge". He agreed with the Delegations of Ecuador and Venezuela (Bolivarian Republic of) on the meaning of the word "individual" in Article 3(2).

The representative of the Southeast Indigenous Peoples' Center suggested to delete "if these acts have a commercial goal or take place outside the context of the customary or traditional uses of this traditional knowledge" in Article 3(1)(a). In relation to Article 3(1)(c)(i), she suggested to insert "espionage" before "or other unfair or dishonest means", and to insert "or by violence, kidnapping, incarceration, enslavement, hostage-taking, drugging, raping, sexual abuse, physical/psychological abuse, starving, arson, torture, destruction of ecosystem or threats of these" at the end. She explained that TK had to be protected from espionage so that they were free to pass down and develop TK without fear of theft and misuse. Indigenous Peoples/Nations needed to discuss and practice their TK out of the presence of colonial forces. For this reason, indigenous Peoples/Nations needed special protection from those claiming to take TK without their knowledge or consent for conservation, preservation, educational, or scientific uses. In relation to Article 3(1)(c)(ii), she proposed to insert "indigenous and international" before "legal measures". In relation to Article 3(1)(c)(iv), she proposed to insert "indigenous" before "national and international regimes". In relation to Article 3(1)(c)(vi), she proposed to replace "country" with "People" in the second line, and to replace "in the country" with "the People" in the last line. In relation to Article 3(2)(a), she proposed to insert "indigenous laws" before "a special law" and to insert "including the UNDRIP and the Conventions on Biological Diversity and Sustainable Development" after "those laws". In relation to Article 3(2)(b), she proposed to insert "indigenous" before "national laws and policies".

Other submissions by observers

The representative of the African Regional Intellectual Property Organization (ARIPO) 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 4¹²⁵

PRINCIPLE OF PRIOR INFORMED CONSENT, [FAIR] <u>DIRECT¹²⁶</u> AND EQUITABLE BENEFIT-SHARING AND RECOGNITION OF KNOWLEDGE HOLDERS

[1. (a) The principle of prior informed consent <u>or approval and involvement</u>¹²⁷ [should] <u>shall</u>¹²⁸ govern any access <u>and use</u>¹²⁹ of <u>protected</u>¹³⁰ traditional knowledge from [its traditional holders] <u>beneficiaries as defined in Article 2</u>¹³¹, subject to these principles and [relevant] <u>applicable</u>¹³² national laws.

(b) The [holder of traditional knowledge] <u>beneficiaries as defined in Article 2¹³³</u> [[shall] <u>should¹³⁴ be]</u> <u>is¹³⁵</u> entitled to grant prior informed consent <u>or approval and involvement</u>¹³⁶ for access to traditional knowledge, or to approve <u>or deny¹³⁷</u> the grant of such consent by an appropriate <u>designated¹³⁸</u> national authority, as provided by applicable national legislation <u>and that is not attributable to nor is confined to a community, a national authority, as determined by the national law¹³⁹.</u>

(c) Measures and mechanisms for implementing the principle of prior informed consent <u>or approval and involvement¹⁴⁰ [should] shall¹⁴¹ be understandable, appropriate [,</u>

¹²⁸ Delegation of India

¹³¹ Delegation of the United States of America. The Delegation suggested defining the beneficiary group and then use the same terminology throughout. "Beneficiaries as defined in Article 2" might not be the best wording but a terminology that was consistent and could refer back to the definition of a beneficiary should be sought. It also pointed out that "traditional holder" was used in Article 4(1)(a) while "the holder of traditional knowledge" was used in Article 4(1)(b). A consistent phrase would be used throughout the document

The Delegation of Canada concurred

¹³³ Delegation of the United States of America. See note 131

The Delegation of Canada concurred

¹³⁵ Delegation of Colombia

¹⁴⁰ Delegation of Canada. See note 127

¹⁴¹ Delegation of India

¹²⁵ Original Articles 7 and 6

¹²⁶ Delegation of Panama. The word "fair" somewhat contradicted the right to direct participation or direct sharing because the indigenous community did not have the direct access to those benefits. Thus, the Delegation proposed to replace the word "fair" with "direct"

¹²⁷ Delegation of Canada. The Delegation stated that those were terms that were generally more understood in an IP setting. It suggested that any provision on PIC would need to be flexible to allow for countries to implement it as appropriate in accordance with national law, policy and measures

¹²⁹ Delegation of Colombia

¹³⁰ Delegation of the United States of America. The Delegation highlighted that one of the important points it had been discussing repeatedly both in relation to TCE and TK was the recognition that there was some that was protected and some that was not protected. And it wished to differentiate the two

¹³² Delegation of Mexico. The Delegation of Angola, on behalf of the African Group opposed

The Delegation of Angola, on behalf of the African Group opposed

¹³⁴ Delegation of Belgium. The Delegation of Angola, on behalf of the African Group opposed

¹³⁶ Delegation of Canada. See note 127

¹³⁷ Delegation of Colombia. The Delegation stated that that was the prerogative which communities had when access was requested to the resources. They could grant it or deny it

¹³⁸ Delegation of Colombia

¹³⁹ Delegation of India

[and not burdensome for [all relevant stakeholders, in particular for]¹⁴² traditional knowledge holders]¹⁴³; 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]¹⁴⁴.]¹⁴⁵

Where a dispute arises between beneficiaries or between beneficiaries and users of traditional knowledge, each party shall be entitled to refer the issue to an independent and recognized alternative dispute resolution mechanism, recognized by international and/or national law.¹⁴⁶¹⁴⁷

PRIOR INFORMED CONSENT AND BENEFIT-SHARING

Access to traditional knowledge held by indigenous peoples or local communities requires their prior informed consent. The use of such knowledge shall be in accordance with the conditions set out when the consent was given. Such conditions can inter alia imply that benefit arising from the use of the knowledge shall be shared with the holder.¹⁴⁸

2. [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 those who use and benefit from traditional knowledge.]¹⁴⁹

¹⁴⁵ Delegation of New Zealand. The Delegation recommended that article on Principle of Prior Informed Consent be deleted and that the concept of prior informed consent be dealt with in an amended article on Protection Against Misappropriation, which would deal with the Scope of Protection

¹⁴⁷ Delegation of the European Union and its Member States. The Delegation stated that the text came from the CBD and that there were different possibilities to address the issue

¹⁴⁸ Delegation of Norway. The Delegation proposed an alternative new article. It explained that its intention was that the proposed article should deal with both prior informed consent and benefit-sharing when knowledge was accessed from the holder. There was also a need for provisions dealing with these principles when protected TK was accessed from other sources than the holder

¹⁴⁹ Delegation of Canada. The Delegation repeatedly emphasized the importance of balance between the holders of TK and the interests of the broader society. The proposed text would reflect its concern about the interest of general society and protecting the public domain

Delegation of Australia and the United States of America concurred

The Delegation of Australia also considered Principle (i) regarding recognition of the specific characteristics of TK to be important

The Delegation of the United States of America stated that the concept of balance was critical in all forms of property, whether the real property or the traditional intellectual

The Delegation of Zambia, India and Bolivia (Plurinational State of) opposed

The Delegation of Zambia stated that the instrument that the Committee was trying to generate was sui generis. It was not necessarily within the IP regime where the balance between users and the owners of that property had to be struck. Therefore it suggested that the whole motion of balance was perhaps displaced. That was owned by those communities who should deal with it as they wished

The Delegation of India stated that there should be a clear definition of what the right of a TK holder is and that would take care of the balance. That particular inserted paragraph should not be part of the substantive provisions in a legal text. It

[Footnote continued on next page]

¹⁴² Delegation of India

¹⁴³ Delegation of Colombia and Belgium

¹⁴⁴ Delegation of Colombia. The Delegation was concerned that the measures and mechanisms for implementing the principles of PIC should be done on mutually agreed terms. There were two different steps: (1) the prior informed consent and (2) mutually agreed terms, which was basically a negotiation process, during which there was a possibility of not reaching an agreement.

The Delegation of Angola, on behalf of the African Group opposed

¹⁴⁶ Such as the WIPO Arbitration and Mediation Center

(a) [[The benefits of protection of traditional knowledge <u>of indigenous and local</u> <u>peoples</u>¹⁵⁰, <u>as described under Article 1(3)</u>, to which] [When traditional knowledge is <u>protected</u>, <u>pursuant to Article 1(3)</u>,]¹⁵¹ its holders [or custodians]¹⁵² are entitled to may

[Footnote continued from previous page]

should be in the guiding principles. That whole issue in fact needed further examination because the balance could only be created when the rights were created. The rights had not been defined in the text at all

The Delegation of Bolivia (Plurinational State of) considered to put it in a preambular way might work

¹⁵⁰ Delegation of Panama

¹⁵¹ Delegation of the United States of America. The Delegation suggested the deletion of "The benefits of protection of traditional knowledge to which" and replacing that text with "When traditional knowledge is protected," and then after "are entitled" the Delegation would insert the word "to". So it should say "When traditional knowledge is protected its holders are entitled to include…"

Delegation of Zambia, India, Bolivia (Plurinational State of), South Africa, Yemen and Peru opposed

The Delegation of Zambia stated that TK was something that was owned by those communities. Therefore they did have proprietary rights. If enjoyment of benefits was made subject to protection, it was difficult to understand and to accept. If someone had property, there were instances of property rights he or she enjoyed by virtue of being the owner of that property. It cannot be conditional to enjoy benefits from someone's own property by keeping it protected The Delegation of India stated that definitely did not take into account different types of existing TK The Delegation of Yemen supported the deletion of the term "protected" because the deletion might enable indigenous

people to continue to benefit from a certain degree of protection

The Delegation of the United States of America responded that its intention in proposing the word "protected" was not to impose additional obligations on indigenous local or traditional communities but to clearly establish the reference to Articles 1(3) and 2. Article 1(3) established eligibility for protection. Article 2 was called "beneficiaries of protection". Article 1(3) clearly was to define those things which were the subject of the legal protection. As the Committee was trying to establish an instrument which expressed new legal norms, it was very important to have cohesiveness and an understand ability. If the main disagreement was that Article 4(2) had no attachment to Articles 1(3) and 2, the Delegation respectfully disagreed and it recommended to the Committee that that was not the appropriate way to craft an expression of international legal norms

The Delegation of Zambia clarified the response by the Delegation of the United States of America. It did consider that there were no rights that were absolute, even the right to life. If the rights of balance had to be respected, the question was what balance was being talked about. For example, if someone had a car, obviously he or she could drive it. The other person who just came, took away that car and used it in any manner could not impose on him or her a duty to protect that car and to enjoy the benefit. One of the fundamentals of the IP system was to strike a balance between society and those resources. But it thought that that approach was not the right approach. What the Committee was trying to solve was a novel idea but to borrow from the IP system was something different. It believed that those resources belonged to the peoples that owned them. They were their property. It was important to clarify what balance was struck

The Delegation of Peru did not understand the reference to Article 1(3) because the phrase could be misinterpreted. Its understanding was that the TK holders had to comply to protect their TK

The Delegation of Brazil believed that the word "protected" did not need to be included and requested that reference be made to Article 1(3). So the Delegation wondered whether it was possible to keep the existing sentence and to make a reference to Article 1(3)

The Delegation of the United States of America stated that without proposing to add the language, the paragraph could be either "The benefits of protection of traditional knowledge as described under Article 1(3)" or "When traditional knowledge is protected pursuant to Article 1(3)". That would provide the proper consistent linkage between those articles ¹⁵² Delegation of Mexico. The Delegation of the Russian Federation concurred because the holders or custodians of TK would be entitled to sharing of benefits of TK. The Delegation of Switzerland opposed. The reason was that, in Article 1(3)(iii), communities were "holding the knowledge through a form of custodianship, guardianship, collective ownership or cultural responsibility". So "custodianship" was just one form of holding TK and not something different to it

[shall¹⁵³] include the [fair] <u>direct</u>¹⁵⁴ and equitable sharing of benefits arising out of the [commercial or industrial use] <u>industrial marketing</u>¹⁵⁵ of that traditional knowledge, [according to national laws]¹⁵⁶.] <u>The protection of traditional knowledge includes the fair</u> and equitable sharing of benefits arising out of the use of that traditional knowledge, with the aim of respecting traditional knowledge systems and providing incentives to indigenous peoples and local communities to preserve, protect and maintain their traditional knowledge systems.¹⁵⁷

(b) Use of [<u>protected</u>]¹⁵⁸ traditional knowledge for [non-commercial] <u>non-profit</u> <u>making</u>¹⁵⁹ purposes [need only] <u>may</u>¹⁶⁰ give rise to [<u>reasonable</u>¹⁶¹ non-monetary]¹⁶² benefits, such as access to <u>non-profit making</u>¹⁶³ research outcomes and involvement [of the source community] <u>of the holders [or custodians]¹⁶⁴ of [protected]¹⁶⁵ traditional¹⁶⁶ knowledge¹⁶⁷ in research and educational activities.</u>

(c) Those, <u>other than the holders of traditional knowledge</u>,¹⁶⁸ using traditional knowledge beyond its traditional context should mention its source, acknowledge its holders, and use it in a<u>n appropriate</u>¹⁶⁹ manner that respects the [cultural]¹⁷⁰ values of its holders.

(d) Legal means <u>according to their nature¹⁷¹ [should] shall¹⁷² be available to provide</u>

¹⁵⁶ The Delegations of Australia. Delegation of Bolivia (Plurinational State of) and South Africa opposed. The Delegation of Bolivia (Plurinational State of) stated that a global context of benefit-sharing was wanted and it could be seen how that global framework could actually be expressed by national law. The Delegation of South Africa stated that as an international norm the relevance of national laws did not arise

¹⁵⁷ Delegation of Switzerland. The Delegation of Switzerland highlighted that Policy Objective (iv) was not adequately reflected in the substantive provisions and, therefore, it proposed to redraft paragraph 1 of Article 4(2)

¹⁵⁸ Delegation of the United States of America. Delegation of Zambia, India, Bolivia (Plurinational State of), South Africa, Yemen and Peru opposed. See note 151

¹⁶³ Delegation of South Africa. The Delegation stated that with regard to "non-profit making purposes" it appeared that access to research left it open that research needed to be marketed as well as non-profit making research. So it was consistent if it was left open as research that would also give opportunity for profit making research to not be specified ¹⁶⁴ Delegation of Switzerland. See note 152

¹⁶⁶ Delegation of the United States of America. Addition was "protected traditional"

¹⁶⁷ Delegation of Mexico. The Delegation proposed to replace "of the source community" with "of the holders or custodians of knowledge"

¹⁶⁸ Delegation of the United States of America

¹⁶⁹ Delegation of Australia

¹⁷⁰ Delegation of Switzerland. Policy Objective (i) listed a number of values that TK holders had. Policy Objective (ii) enumerated important values of TK itself – not only cultural values, but also for example social, spiritual and ecological values. It therefore thought that those values should be added as well or, alternatively, the word "cultural" should be deleted

¹⁷¹ Delegation of Panama

¹⁷² Delegation of India

¹⁵³ Delegation of India

¹⁵⁴ Delegation of Panama. See note 126

¹⁵⁵ Delegation of Panama

¹⁵⁹ Delegation of Panama

¹⁶⁰ Delegation of Colombia

¹⁶¹ Delegation of Australia

¹⁶² Delegation of South Africa. The reason was that it was introducing a condition and limiting

¹⁶⁵ Delegations of Zambia, India, Bolivia (Plurinational State of), South Africa, Yemen and Peru. See note 151

remedies for [traditional knowledge]¹⁷³ holders <u>of [protected]¹⁷⁴ traditional knowledge</u>¹⁷⁵ in cases where the [fair] <u>direct</u>¹⁷⁶ and equitable sharing of benefits as provided for in Article 4(2)(a) and 4(2)(b) has not occurred, or where knowledge holders were not recognized as provided for by Article 4(2)(c).

(e) Customary laws [within local communities] <u>and normative systems of holders [or</u> <u>custodians</u>¹⁷⁷]¹⁷⁸ may play an important role in sharing benefits that may arise from the use of [protected]¹⁷⁹ traditional knowledge.

¹⁷³ Delegation of the United States of America

¹⁷⁴ Delegation of Zambia, India, Bolivia (Plurinational State of), South Africa, Yemen and Peru. See note 151

¹⁷⁵ Delegation of the United States of America

¹⁷⁶ Delegation of Panama. See note 126

¹⁷⁷ Delegation of Mexico. The Delegation proposed to replace "within local communities" with "and normative systems of holders or custodians"

¹⁷⁸ Delegation of Switzerland. See note 152

¹⁷⁹ Delegation of the United States of America. The Delegations of Zambia, India, Bolivia (Plurinational State of), South Africa and Peru opposed. See note 151

COMMENTARY ON ARTICLE 4

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 3(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 Article 4(1)(a), 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. Article 4(1)(b) 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. Article 4(1)(c) sets out basic features of mechanisms to implement 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.

Article 4(1) 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,¹⁸⁰ 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.

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).

Article 4(2) therefore supplements the broad reference to equitable benefit-sharing in the general description of misappropriation (Article 3(1) above), and covers commercial or non-commercial uses. Internationally agreed guidelines on biodiversity-related TK suggest that basic principles

¹⁸⁰ 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)

for benefit-sharing can include (i) covering both monetary and non-monetary benefits and (ii) developing different contractual arrangements for different uses.¹⁸¹ Accordingly, Article 4(2) differentiates between commercial and non-commercial uses of TK and specifies different benefit-sharing principles for these uses.

Article 4(2)(a) 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 Article 4(2)(a), Article 4(2)(b) 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.

Article 4(2)(c) 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.

Article 4(2)(d) specifies that civil judicial procedures should be available to TK holders to receive equitable compensation when the provisions in Articles 4(2)(a) and 4(2)(b) 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.

Comments made and questions posed

Relationship with policy objectives

As with the principles outlined in Article 4(2), the Delegation of Australia noted that Article 4(1) 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. The Delegation noted that there were a number of significant issues that arose from Article 4(2). 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"

¹⁸¹ 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)

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.

The Delegation of Canada echoed what the Delegation of Switzerland had said on the importance of Policy Objective (ii) about promoting respect in relation to Article 4(2). It believed that it was important to read Article 4(2) in conjunction with that objective and it also added the importance of Policy Objective (i) about recognizing the value.

As to the balancing issue suggested by the Delegation of Canada, the representative of the Saami Council believed that if that was some objective to achieve the instrument it should be discussed in a preambular paragraph in the objectives. But if that was a principle in an operative paragraph, that balance should be defined, if there was to be one, and what rights apply to TK should be explicitly told. It was unnecessary to restate as a principle in the actual operative text.

The Delegation of Japan stated that even if the purpose of the protection of TK was to correct the inequities in economic development and to ensure sustainable development of certain communities by providing new financial resources, it had not been yet justified that granting a right to TK was an appropriate method for achieving such purpose. The Delegation wondered how benefits, which were shared by users of TK, could be distributed to all appropriate beneficiaries in a equitable manner. The Delegation noted that if the protection of TK gave incentive for future invention that would lead to efficient development by a third party through using protected subject matter, indefinite protection of TK was inappropriate in consideration of the balance between interests of the right holders and the public.

Relationship with Article 6

The Delegation of Australia noted that the exclusion in Article 6 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.

Capable representative

The Delegation of Japan posed the following questions: Was it feasible to identify the right person capable of granting prior informed consent without clear decision-making mechanism or representation of a community? Could a State act legitimately to represent the welfare and benefit of all appropriate beneficiaries considering the same fact without clear decision-making mechanism or representation of a community? The delegation provided a supplemental explanation with regard to those questions. First of all, it believed that lack of transparency of the process to acquire prior informed consent caused uncertainty for potential users and discouraged the use of the TK. Therefore, transparent procedure was a prerequisite for prior informed consent. The Delegation posed questions on the mechanics of granting PIC for TK and stated that the answers to those questions were critical for further elaboration.

Source of the TK

The Delegation of the United States of America questioned, in relation with Article 4(2)(c), 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.

Definition of TK

The Delegation of Japan drew attention to its questions about the definition of TK, quoted at pages 35 and 37 in document WIPO/GRTKF/IC/17/5. Without clear and common understanding of the scope of the subject matter for protection, prior informed consent imposed undue burden on potential users of the knowledge and caused adverse effects on innovation. It expected technical contribution to those questions from experts at the coming IWG.

Community's use

The Delegation of India stated that the uses for which the prior informed consent was required also had to be clearly stated, i.e, all uses, except those made in association with the community.

General comment on Article 4(1)

The Delegation of Zambia stated that Article 4(1) was equally acceptable save perhaps that there appeared to be no provision for disclosure of origin of GR and/or related TK used in inventions.

The Delegation of Norway supported the principle that TK held by indigenous people or local communities only could be accessed and used in accordance with their prior informed consent. The principle of prior informed consent and the principle of benefit-sharing were strongly linked. Therefore, these two principles should be dealt with together in the same provision. Article 4(1) should be simplified so that the principle of prior informed consent was clearly established. As the article stood now, it also contained provisions on objectives that should not be part of this substantive provision.

The Delegation of India believed that the principle that had to be followed with reference to prior informed consent was that there had to be a binding obligation on the part of the people using TK to take prior informed consent. Second, the uses for which the prior informed consent was required had also to be clearly stated. This was in all cases except the uses in association with the community's use. The third principle which the Delegation reiterated was that the community had the complete authority to give prior informed consent whenever it was identifiable with the community, wherever the TK was identified by the community. But there were situations where it might not be possible to identify the community. Clearly in the context of text, the prior informed consent had to be from a national authority as recommended by the national law.

The representative of the FILAIE supported the statement made by the Delegation of Norway. In relation to Article 4(1)(a), he had difficulties with the fact that access to TK might be subject to national laws, where it could be to the detriment of the holders of the TK. In relation to Article 4(1)(b), he believed it was actually making a statement of a right, which should not be the role of a WIPO document. In relation to Article 4(1)(c), he believed that that would require some explanation and that there should be clarity and legal certainty in relation to how that principle operated. It should not take the focus away from the rights of the holders of TK to the interests of other stakeholders.

The representative of the Tulalip Tribes made reference to a recent report on the mechanism on the Human Rights Council which perhaps could be forwarded to the IWG. It was a progress report on the study of indigenous peoples and their rights to participate in decision-making, and

there was a substantive section on prior informed consent that provided examples of good practices at different levels of decision-making and would be useful to the deliberations of the Committee.

Proposal of "approval or involvement"

The representative of the ICC supported the amendment proposed by the Delegation of Canada by adding "approval or involvement" after "prior informed consent", wherever that occurred. As he did in connection with TCEs, he thought the same arguments applied and there were various difficulties with prior informed consent. One was that it was not yet clear whether there would be protection for TK which was already publicly available. If TK was already publicly available, people might have access to it already without any idea that it was protected. In that situation, prior informed consent was no longer possible for those people who had accessed to that information. That was one particular situation which supported the need for the amendment proposed by the Delegation of Canada.

The representative of the Tulalip Tribes commented on the issue of "approval and involvement". The language came from the CBD and his understanding of that language was that it was no different than prior informed consent. Canada used that as a term of art within their legislation. He expected that the Delegation of Canada could enlighten him on that issue. The representative of the ICC brought up the issue of publicly available knowledge, which he believed was a different issue. The representative of the ICC brought up the issue of the ICC also stated that it was difficult for the public to know whether there were rights attached to it or not, when encountering TK. The representative of the Tulalip Tribes pointed out that, when the public encountered songs on the radio, they actually had the burden of searching and due diligence to discover who the owner was if they wished to use it. He believed that it was the purpose of this regime to build awareness and that the publicly available knowledge should fall under this regime.

Proposal of "and that is not attributable to nor is confined to a community..."

The representative of the Tulalip Tribes commented on the statement made by the Delegation of India. He believed that it was a little narrow. In the United States of America, there was knowledge shared among the communities and there were indigenous mechanisms and protocols to deal with such shared knowledge. So he understood that if there was orphan knowledge or knowledge that could not be identified with any community, there was a problem. Confining it only to the one community was very narrow.

Definition of holders, custodians and beneficiaries

The Delegation of the Russian Federation stated the following: In accordance with Article 4(2)(a), the holders or custodians of TK were entitled to the benefits arising from the protection of TK. In addition, pursuant to Article 4(1)(b) only holders should be entitled to grant prior informed consent for access to TK, or to approve such consent, if it is given by an appropriate national authority. The Delegation of the Russian Federation asked what the difference between those two subjects of protection was. It considered it appropriate to examine the question of producing a glossary and including an article on "Definitions".

The Delegation of Switzerland stated that in Article 4(2) and throughout the text, there seemed to be a distinction between "holders" and "beneficiaries". It was not clear why and how the difference between "holders" and "beneficiaries" was made.

The representative of the Indian Council of South America stated that to put all custodians in brackets needed to be thought carefully. In the end, there should be a balance of the whole environment.

Customary law

The Delegation of the Russian Federation stated that Article 4(2)(e) referred to the role of customary laws (laws based on customs of local and indigenous peoples) and the role "of normative systems of holders or custodians". It was unclear what these systems were and whether they went beyond customary law.

Time limit

The Delegation of the Russian Federation stated that in traditional terms, the protection granted to IP subject matter was always limited according to the term, and from the provisions laid down in Section III of the annex to document WIPO/GRTKF/IC/16/5 it was clear that the protection granted, which was close in terms of its essential features to protection for IP subject matter, might in reality be without a time limit. It considered it appropriate to study in more detail the possible consequences of granting such protection, taking into account the fact that the rights of TK holders must not prevail over already existing IP rights. The Delegation suggested analyzing the following situation: A patent was granted for an invention using TK. The conditions of PIC had been observed and an agreement on equitable benefit-sharing had been signed. In a maximum of 20 years, the patent in question, in which TK was used, in accordance with the existing patent system entered the "public domain", i.e. it might be used without restrictions in the full scope of protection defined by the claims. At the same time, in accordance with the given draft, TK forming part of the invention had to be protected without specifying a term of protection. Taking into account the above, it wondered which of those contradictory requirements would be observed.

Use and benefit

The Delegation of Switzerland did not see a reason or a need to limit consequences of noncommercial use to non-monetary benefits. It rather thought that that issue should be left to the mutually agreed terms between holders and users.

The Delegation of Colombia stated that benefits from the use of TK would be established by the parties when they knew how use was made and who should use. With regard to non-monetary uses and non-monetary benefits, it believed communities had possibility to establish what the benefits arising from that use were. There was a lot of TK associated with genetic and biologic sources that were of great use for research. The Delegation suggested looking at research not for profit or commercial profit. The research not for commercial profit could be found very often in various case laws. There were some researches that initially were not considered as commercial ones but which later did become benefits from monetary use. So there was a shift and very often patents were given to the research that initially started as non commercial research. The Delegation thought it was a bit restrictive.

The representative of the CAPAJ thought that the creations of indigenous peoples were from the physical and spiritual contact with the earth. The earth should be able to be compensated for what it gave them. Therefore he thought should non-monetary benefits should be had as mentioned in Article 4(2)(b). What was to be protected was a matter that went beyond the individual human being and was a spiritual secret knowledge. For example, if the Aymara were recruited and their idea was used for building a house, they were only paid a regular wage without the payment for their knowledge which was not assessed. The problem would be how the Aymara could be compensated for loss of jobs because of depravation of a knowledge which was a part of their heritage. He thought non-monetary compensations arose.

The representative of the Tupaj Amaru stated that indigenous peoples were calling for benefits of the use or misuse of their TK and they were not calling for protection. He thought it was necessary to redraft the text entirely. There were terms and subjects that were being confused and mixed up in the text. Secondly, the deletion of benefits made the text meaningless. What they were talking about was how to distribute those enormous benefits that had been misappropriated by the very large corporations. With regard to proposal made by the Delegation of Canada, he thought what should be protected was the intrinsic rights of indigenous peoples. The rights to participation and distribution of benefits should perhaps be in accordance with other instruments, such as the United Nations Declaration on the Rights of Indigenous Peoples. He quoted Article 12 thereof. He suggested that all the provisions should fit with already existing texts because the words and terms that had no customary value had no source in UN legal texts.

The representative of the Indigenous Peoples Council on Biocolonialism was concerned about the wording in of Article 4(2)(b) regarding non-commercial use. Research that began as non-commercial or academic research could often result in privatization or commercial use. In fact in the United States of America there was a national law that mandated academic researchers to seek IP protection when they discovered information or data that could be put in use commercially. That paragraph, as written, limited the nature of the kinds of benefits that the holders and owners of TK might receive as result of their participation to non-monetary benefit, access to the research outcomes, and/or involvement in research and educational activities. That was very restrictive. If TK holders were partners in research and they were participating with their FPIC, they brought valuable expertise and other resources to that partnership. Therefore, the nature of the benefits they might receive should not be limited by that instrument. She recommended bracketing the words non-monetary in Article 4(2)(b).

Placement

The Delegation of Switzerland suggested placing Article 4(2) after Article 1(1). Based on the current wording of Article 4(2)(a), it was assumed that benefit-sharing was part of the protection of TK.

Uniform terms

The Delegation of Switzerland made comments on the use of terms. Article 4(2)(d) stated with the expression "legal means" which was also used in some other articles, while Article 3(2)(a) spoke of "legal measures" and Article 4(1)(c) spoke of "measures and mechanisms". Thus, the Delegation suggested using uniform terminology throughout the text. The expression "customary laws and normative systems of holders" was used in Article 4(2)(e). In Article 1(3) it said "customary or traditional practices, protocols or applicable national laws". Article 2 used other terms and Article 4(2) spoke of "customary laws and normative systems". So again the Delegation suggested using identical wording in all articles.

The Delegation of Belgium reminded that there should be some consistency in the use of words "measures and mechanisms" in Article 4(1)(c). In Article 3(2)(a), the words "legal measures" were used, while "legal means" were used in Article 4(2)(d). It preferred to use "measures and mechanisms" in those two articles too.

The Delegation of Barbados referenced to indigenous peoples and communities in Article 4(1) as well as Article 2 and other articles. As the issue of beneficiaries was being addressed in the informal working group on TCEs, it would not comment at this stage of what it considered to be the appropriate definition of beneficiaries. But it would revert to this issue either at this or at a future meeting, once agreement had been reached on the definition of "beneficiaries" for TCEs.

Definition of the community

The Delegation of India suggested first defining the community where TK had been known and used generally and then kept in secret use.

Commercial and non-commercial use

The Delegation of India stated that benefit-sharing must reflect the assessment of value of the TK and the potential value of TK when it was commercialized and industrially used. There had to be a clear text on it. It should also cover non-commercial activities. The article might be redrafted with mandatory obligation reflecting the following principles: identify the users where there was no obligation to give fair and equitable benefit sharing; uses that did not require benefit-sharing; and uses that required an acknowledgement.

Proposal of "protected" in Article 4(2)

The representative of the Tulalip Tribes asked for some clarification on what was meant by that phrase. It seemed that the burden was being put on those who owned the property to protect their property and then the question arose to protect under whose system. There were several ways that knowledge could get disclosed. It could be disclosed under naivety and it could be disclosed by those who swindled peoples out of their heritage. So the question was what it meant when it was protected. If it was de facto disclosed and that meant the rights to the knowledge were lost, it could not be accepted. This was similar to a situation where for example, someone came into your house and stole your cultural heritage that you had failed to take steps to protect, an a result it was no longer yours. Indigenous peoples were faced by new circumstances, the internet, the ability to copy things digitally, and the rapid transmission of their TK. They might not have those mechanisms of protection and might not understand the system against which they needed to create mechanisms for protection. He said the concept seemed to be placing on the holders and owners of that knowledge a burden of protection. For the balancing criteria, it seemed that the user had rights to access TK. The holders of the knowledge who wished to deny access should therefore have that right. One example not in the intellectual property realm but in the physical realm was given. There was a decision in the Supreme Court on the case of fisheries. The Tribes of Washington State claimed a right to fish based on a treaty. The Supreme Court was interpreting treaty language "to fish in common" and the analysis was that 50% of the fish should go to the tribes, 50% of the fish should go to the United States. It was very clear that the property of the tribes belonged to the tribes and could not be balanced against citizens of the United States. The citizens had no claim on that 50% share. He thought the same principle applied to TK.

The representative of the Saami Council did not agree to the proposal because the proposal took away that dual dimensional benefit-sharing. The proposal was saying there should only be benefit sharing in the instances where there were consent procedures applicable to that TK so only in its definition protected TK that the holder still controlled. It meant that only in those instances there should be benefit-sharing. He would therefore object to it.

The representative of the Indian Council of South America supported what the other indigenous representatives stated on the proposal made by the United States of America.

The representative of the Indigenous People (Bethechilokono) of Saint Lucia Governing Council, on behalf of the indigenous peoples in St. Lucia, indicated the opposition to the proposal "protected" by the Delegation of the United States of America. He requested to make United Nations Declaration on the Rights of Indigenous Peoples available to the Committee. It had already been established and accepted by States. He quoted Article 31 which stated

indigenous peoples had the right to maintain heritage culture. However, the proposal by the Delegation of the United States of America made it conditional that the TK had to be protected in order that benefit-sharing could occur. Article 38 of United Nations Declaration on the Rights of Indigenous Peoples stated: "States in consultation and cooperation with indigenous peoples, shall take the appropriate measures, including legislative measures ...". Therefore, on behalf of the indigenous peoples in St. Lucia, he could not accept that proposal. Article 43 of the United Nations Declaration of Rights of Indigenous Peoples stated: "The rights recognized herein constitute the minimum standard for the survival, dignity and well-being of the indigenous peoples of the world". The indigenous peoples of St. Lucia could not accept the proposal by the Delegation of the United States of America because it humiliated them.

Two kinds of benefit-sharing

The representative of the Saami Council stated that two kinds of benefit-sharing were dealt with and he believed that was the way it probably had to be. One was benefit-sharing that occurred on mutual agreed terms when there had been an ethnic process and there was then an agreement of benefit-sharing by the TK being used by a non-holder. But the instrument also dealt with another sort of benefit-sharing. When it had defined TK as not being subject to ethnic procedures but it could be used because it was already publicly available, there should be benefit-sharing. He believed that the instrument and the definition of what was protected TK was too limited but probably there would be instances even though they should be fewer. If the ethnic procedures were difficult to get in all instances, it should be benefit-sharing. He agreed with that approach. But he thought that when dealing with those two kinds of different benefit-sharing, those probably should be clearer in Article 6 and spelt out more explicitly. For that purpose it would be beneficial to do as the delegation of Switzerland had proposed and connected the Article on benefit-sharing directly to the Article on ethnic to highlight the connection between consent procedures and benefit sharing arrangements.

Proposal on national law

The representative of the Indian Council of South America agreed with the Delegation of Bolivia (Plurinational State of) to bracket "national laws" in Article 4(2)(a). The reason to promote self determination is that development and exploitation could denigrate whole ecosystems where medicine was used for the health and clothing was used and it was traditional. So if not, the whole ecosystems were destroyed because other people desired to develop. Therefore, the reference to national law proposed by the Delegation of Australia could not be accepted.

Free and prior informed consent

The representative of the Indian Council of South America stated that with regard to the free and prior informed consent (FPIC) process, more of those needed to be discussed and developed because when and where benefit-sharing applied and to what degree that would be made available to states needed to be decided. He knew that there were international legislation rights based on human rights that should allow the protection while national law did not allow the protection.

The representative of the Indigenous Peoples Council on Biocolonialism stated that with regard to of Article 4(2)(c), that paragraph suggested that someone other than the holder of the TK could use that TK, as long as they acknowledged its holders and used it appropriately. That paragraph was very subjective, and there should be specific requirement of FPIC mentioned there. In fact, FPIC should be indicated as one of the operative principles that applied to the entire instrument.

Drafting suggestions by observers

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) suggested to insert "or withhold" before "prior informed consent" in Article 4(1)(b). He also wondered what the situation would be in those countries which did not have national legislation in force on TK. He suggested to add a new paragraph "f. This shall be supplemented by the other national texts on traditional knowledge that are in force" in Article 4(2). Article 3(2)(a) was referred to.

The representative of the Southeast Indigenous Peoples' Center proposed to insert "indigenous" before "national laws". She also proposed to replace Article 4(1)(b) with "Where disputes arise about the use of force or threats thereof, or about whether consent was actually given an international culture-keeping court including indigenous judges will decide the matter based on the laws of the People/Nation who hold the knowledge and internationally agreed accords and instruments". She proposed to delete "commercial or industrial" in Article 4(2)(a). She proposed to replace Article 4(2)(b) with "Use of traditional knowledge for non-commercial purposes must be consented to by the knowledge holders and must give the knowledge holders opportunities to direct the operations that make use of their knowledge". In relation to Article 4(2)(c), she proposed to insert "if that is agreeable by the knowledge holders" at the end. In relation to Article 4(2)(d), she proposed to insert "free prior and informed consent was not obtained and/or" before "fair and equitable sharing". In relation to Article 4(2)(e), she proposed to insert "returning TK to the knowledge holders and" before "sharing benefits".

The representative of the Call of the Earth supported the statement made by the Delegation of Colombia. TK was generated and preserved and had been for thousands of years on the basis of the customary rules and practices of indigenous peoples and of local communities and that was recognized by, for example, Article 8(j) of the CBD. The UN Declaration on the Rights of Indigenous Peoples recognized the same thing in Article 21 and it had been ratified by many countries, including recently by Canada. The Andean court in a decision recognized the same right. National legal systems of some countries, like particularly in Latin America, conferred the same recognition. This meant that the TK was recognized as belonging to indigenous peoples and local communities who had the real legitimacy to grant prior informed consent and to participate in any benefit-sharing. Therefore, he proposed to add "the representative authorities of indigenous peoples and local communities legally constituted with the consent and agreement of the national authority empowered to grant them legal status" after "as provided by" in Article 4(1)(b).

The representative of the GRTKF International welcomed the contribution of the Delegation of Colombia in regard to PIC and supported the inclusion of the word "deny". He also supported the position of the Delegation of Angola, on behalf of the African Group, and associated with the African Group for the removal of the expressed brackets.

ARTICLE 5¹⁸²

ADMINISTRATION AND ENFORCEMENT OF PROTECTION

- [1. [(a) An appropriate national or regional authority, or authorities, should be competent for:
 - (i) [distributing] <u>disseminating</u>¹⁸³ 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 <u>[or misuse</u>¹⁸⁴]¹⁸⁵ 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] <u>supervising effective</u>,¹⁸⁶ 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]¹⁸⁷ authority or authorities should be communicated to [an international body] <u>the World Intellectual Property</u> <u>Organization</u>¹⁸⁸ 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.] <u>There shall be an appropriate competent national or regional authority or</u> <u>authorities delegated with the responsibility for the administration and enforcement.</u>¹⁸⁹

- 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]¹⁹⁰.]
- <u>1.</u> Parties undertake to adopt, in accordance with their legal systems, the measures necessary to ensure the application of this instrument.

¹⁸² Original Article 13

¹⁸³ Delegation of Mexico

¹⁸⁴ Delegation of Mexico

¹⁸⁵ Delegation of the European Union and its Member States

¹⁸⁶ Delegation of Mexico

¹⁸⁷ Delegation of Mexico

¹⁸⁸ Delegation of Mexico

¹⁸⁹ Delegation of Angola, on behalf of the African Group

¹⁹⁰ Delegation of Colombia. The Delegation stated that the text was not clear

- 2. Where so requested by and in consultation with traditional knowledge holders, a competent authority may:
 - (i) [distributing] disseminating¹⁹¹ 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 misuse¹⁹² of, or an other act of unfair competition in relation to, that knowledge;
 - (iv) determining whether prior informed consent for access to and use of traditional knowledge has been granted;
 - (v) [determining] supervising effective,¹⁹³ fair and equitable benefit-sharing:
 - (vi) determining whether a right in traditional knowledge has been infringed, and for determining remedies and damages:
 - (vii) assisting, where possible and appropriate, holders of traditional knowledge to use, exercise and enforce their rights over their traditional knowledge.¹⁹⁴

¹⁹¹ Delegation of Mexico

¹⁹² Delegation of Mexico

¹⁹³ Delegation of Mexico

¹⁹⁴ Delegation of New Zealand. The Delegation of New Zealand noted that the TK document dealt with the issue of remedies and enforcement in several places. In addition to Article 5, the following articles were relevant to this matter: Article 3(2) set out the legal form of protection; Article 4(2)(d) provided that legal means would be available to provide remedies where benefit sharing did not occur; and Article 4(1)(c) referred to measures and mechanisms for implementing prior informed consent. The Delegation suggested removing this duplication and replacing the various references to sanctions, remedy, and enforcement in one simplified Article 5

COMMENTARY ON ARTICLE 5

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*.

Comments made and questions posed

Role of the national or regional authorities

The Delegation of Australia 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.

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) stated Article 5 in some way met the expectation that an independent authority would administer the protection. As indicated above, the limits and powers of such administrative authority should be established. Article 5 listed the functions of such authority but he hoped the text to be more explicit as regards its powers and organization. The national authorities would create such authority based on a model proposed by the Committee. Organizations such as the African Regional Intellectual Property Organization (ARIPO), the Indigenous Peoples Council on Biocolonialism (IPCB), the Instituto Indígena Brasilero da Propriedade Intelectual (InBraPi), the Maya To'Onik Association, the Saami Council, the Tulalip Tribes, and the Tupaj Amaru could share their experiences. The Pacific Community had already embarked on work to find the administrative entity. He called for further discussion on this subject.

Relationship with principles

The Delegation of Australia 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.

Dispute settlement mechanism

The Delegation of the European Union and its Member States suggested adding a dispute settlement mechanism to Article 5, such as inter alia, as an example, the WIPO Arbitration and Mediation Center.

Proposal made by the Delegation of New Zealand

The Delegation of Canada strongly believed that this provision would need to allow maximum flexibility for states to implement it, as appropriate and in accordance with domestic law, policy, and administrative measures. In this connection, it supported the proposal made by the Delegation of New Zealand as a good basis for discussions in the IWG.

With regard to the proposals made by the Delegations of Canada and New Zealand, the Delegation of the European Union and its Member States retained for the time being their position on this article.

Drafting suggestions by observers

The representative of the International Chamber of Commerce proposed to insert, "proportionate" after "accessible, appropriate" in Article 5(2).

In relation to the chapeau of Article 5(1)(a), the representative of the Southeast Indigenous Peoples' Center proposed to insert "indigenous" before "national or regional", and to replace "authority" with "court". In relation to Article 5(1)(a)(vi), she proposed to delete "where possible and appropriate". She proposed to replace Article 5(1)(b) with "[t]he opportunity to: register TK with an international organization, to bring TK disputes to an international court, to include their judges on the international courts, or to publish their TK laws shall be communicated to indigenous Peoples/Nations, and/or traditional communities by an indigenous international body, which may notify 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".

ARTICLE 6¹⁹⁵

EXCEPTIONS AND LIMITATIONS

- [1. The application and implementation of protection of traditional knowledge should not [adversely affect] <u>be prejudicial to continued availability</u>¹⁹⁶:
 - (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] [use for public health purposes as recognized by the national legislation¹⁹⁷]¹⁹⁸ [; or use for other public health purposes]¹⁹⁹] parties may adopt appropriate limitations or exceptions, provided that the use of traditional knowledge is compatible with fair practice, acknowledges the indigenous and local community where possible, and is not offensive to the indigenous or local community²⁰⁰.
- 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]²⁰¹]²⁰².

The Delegation of India believed that this proposal was very broad and needed to be reconsidered, so it had a reservation ¹⁹⁸ Delegation of Angola, on behalf of the African Group

¹⁹⁵ Original Article 8

¹⁹⁶ Delegation of Zambia. The Delegation stated that this Article was acceptable and that the only departure from the draft Zambian law was reflected. Needless to say that had much to do with semantics as opposed to substance.

The Delegation of Angola, on behalf of the African Group, opposed.

¹⁹⁷ Delegation of the European Union and its Member States.

¹⁹⁹ Delegation of Colombia

²⁰⁰ Delegation of New Zealand. The Delegation stated that Article 6(1)(ii) provided some specific exceptions to TK protection. While it might be argued that there were strong public policy reasons to enable the use of traditional medicines for public health purpose, there might be equally strong reasons that TK might be important for educational or environmental reasons. Rather than trying to agree on a list of appropriate exceptions that would include the different national circumstances and the different views of indigenous people and the local communities on what was appropriate use, the Delegation recommended that Article 6 be amended to take a similar approach used in the TCE text, as amended by the IWG. However, instead of using the three-step test which was recommended by the IWG, it recommended reference to policy considerations more directly connected with TK

²⁰¹ Delegation of the European Union and its Member States. The Delegation stated that these words led to legal uncertainty and led to active application of requested protection of TK

²⁰² Delegation of India. The Delegation of India had serious concerns on the existing draft of Article 6.2, because it really took away the freedom which was the right that had just been given to the community. What was important to recognize was that, when talking about public domain in the case of TK, the Committee should use a different set of parameters and convert that to the public domain, which was used for normal IP rights. There seemed to be an attempt when coming to exceptions and other benefits to import the same concept of public domain into TK or even protection of TCEs. It diluted the whole exercise which the Committee was undertaking to protect the communities on their knowledge. It was fairly known that the knowledge was not confined but was spread. The knowledge was available to the public. So the whole exercise needed to take note of this reality and then the limitations and exceptions to be looked accordingly. The Delegation of China concurred

[3. Except for secret traditional knowledge to the extent that any act would be permitted under national law in relation to technology or technical knowledge protected by patent law or trade secrecy law, such act shall not be prohibited by the protection of traditional knowledge, provided such exceptions are limited and do not conflict with the normal use of the traditional knowledge by the beneficiaries and do not unreasonably prejudice the legitimate interests of the beneficiaries, taking into account the legitimate interests of third parties.²⁰³]²⁰⁴]

[The protection of traditional knowledge does not affect the use of such knowledge:

(i) for private use, teaching and other non-commercial purposes;

(ii) for experiments and research with regard to the subject matter of traditional knowledge;

(iii) when the subject matter is a method of treatment of humans or animals.²⁰⁵²⁰⁶

²⁰³ Delegation of the United States of America. The Delegation stated that the proposal would provide a parallelism with the counterpart technological knowledge in the TRIPS Agreement and parallelism to the TCEs instrument that the Committee was working on.

The Delegation of India did appreciate the concern and the spirit behind the proposal, but it would consider it carefully and find out the positive and negative implications of such a provision and it would come back to it with details

²⁰⁴ Delegation of Angola, on behalf of the African Group

²⁰⁵ Delegation of Norway

²⁰⁶ Delegation of Angola, on behalf of the African Group

COMMENTARY ON ARTICLE 6

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.

Comments made and questions posed

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

The Delegation of China 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. It expressed concern on the issue of the public domain. It noticed that Paragraph 24 of the preamble of the CBD Nagoya protocol which recognized the diversity of TK stated "further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity". The Delegation emphasized this point, because some traditional medicines had already been documented and had been spread more widely, but they continued to be TK and continued to fall within the scope of this protection. For this type of TK, different ways of protection could be explored, but it should not be distorted.

The Delegation of Australia 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.

The Delegation of Canada stated that Article 6 needed to provide sufficient flexibility for Member States to provide for exceptions and limitations as appropriate and according to domestic IP regimes. Limitations and exceptions needed to embody the principle of balancing the interests of holders and users. The inclusion of language on compensation was problematic particularly in this article. It expected that the IWG's experts would provide more clarity on this article.

The Delegation of New Zealand stated that Article 6(1)(i) established the important principle that any new protections for TK should not interfere with customary use. It suggested that the language used to convey this principle should be consistent with that used in the TCE document drafted by the IWG. It also noted that the TK text referred to the continued availability of TK, while the TCE text referred to not restricting the normal use. On this basis, the Delegation suggested that the IWG consider replacing this paragraph with the same or similar text to that in the TCE document.

The Delegation of the European Union and its Member States agreed with the previous speakers that there was a need for finding a proper balance between the holders of TK and users in society at large. It also noted a need for further revising the substance of Article 6. It was concerned about a need to align Article 6 with similar language contained or to be foreseen in the instrument on TCEs. If it could not be aligned, at least it should be similar.

The Delegation of Norway considered it was important to secure that any possible TK protection did not hinder fair use, in particular private use and other non-commercial use. For IP protection, exceptions and limitations were essential in striking and keeping the right balance between the holders of rights and the public at large. The Delegation suggested endeavoring to achieve the same balance when drafting the exceptions and limitation for TK. It supported the exceptions and limitations set out in Article 6(1)(ii). The issue dealt with in Article 6(1)(i) was for assessment, not an exception or limitation. Consequently, it proposed that this provision should be deleted. In addition to the exceptions and limitations set out in Article 6, the Delegation believed that there was a need for additional exceptions and limitations to secure a fair balance between the holder of TK and the public. Thus, it considered that there was a need to draft exceptions from the protection for TK for private use and non-commercial use in general inter alia for use in teaching and for experimental use and scientific research. There should also be an exception for TK where the subject matter was a method of treatment for humans and animals. However, its idea was not that these exceptions and limitations should hinder the holders from allowing access to or claiming payment or other benefits when someone sought to obtain access directly from the holders, even though the intention was to use the knowledge for such purposes. Rather, it was the intention to secure that knowledge could be used freely for research purpose, without consent from the holders, when it was obtained from other sources or for other purposes. This important distinction should be reflected in the draft. The exceptions for experimental use and research should cover these activities as such. This would, for example, comprise experiments with the aim to clarify all technical matter function. If the results of such experiments or research led to public or were commercialized, that would not be covered by the exception, and might be covered by the protective rights of the holders of TK if it was substantive that TK was used in the product. Regarding Article 6(2), the Delegation again recalled the need for drawing a line between protected knowledge and knowledge that was a part of the public domain. Not all knowledge that was available to the general public should be considered as a part of the public domain.

The Delegation of the United States of America expressed that it was sensitive to the issue of which TK was in the public domain and which was not. It never wanted to create the impression that all TK was in the public domain, certainly it was not. It was for that reason that the Delegation had emphasized the difference between TK and protected TK. These were difficult issues. The Delegation reminded everyone of the importance of the public domain, particularly as recognized in the Development Agenda Recommendations which all delegations worked so hard on to agree to and to put forward for WIPO in 2007. It recommended that all delegations took a look at Recommendation 16 and Recommendation 20 of the Development Agenda Recommendations, which were very important for the governance of this Committee.

The Delegation of Senegal had a problem with Article 6(2). It considered that the holders of traditional medicine had an important social role to play and that they were being restricted in their action which deprived them of their dignity. Based on the experience, the holders of traditional medicine were not always practicing their medicine in hospitals. They had separate centers. There had been an attempt to collaborate between the two forms of medicine in the

treatment of mental diseases with Professor Collomb in the 1950s, which was at the time of independence. But this experiment was not continued, so the Delegation expected Article 6(2) to be reworded.

The representative of the International Chamber of Commerce 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.

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) stated that TK used by the general public should not be subject to the principle of prior informed consent. However, it would be necessary to pay equitable compensation to the holders or to the persons known to be at the origin of the knowledge used.

The representative of the Tulalip Tribes supported the idea that it should be in confirmation with the principles under TCEs. He also supported the proposal by the Delegation of India that Article 6(2) should be bracketed. IWG would probably need to revisit in-depth this article because the Committee kept coming back to that debate over whether the TK or TCEs were in the public domain or not. With regard to the issue of excluding from prior informed consent, indigenous peoples and local Communities did not always have an interest, but they had rights in that knowledge. As he said many times before, the touchstone was the customary law and the community protocols. The normal kind of exceptions, such as copyright law, could be very problematic. Was there any situation where somebody from outside a community could use a family song that belongs to that family and where they could use the song without their consent? Was there any case where they could take somebody's individual story?

Drafting suggestions by observers

The representative of the International Chamber of Commerce proposed to replace Article 6(2) with "Traditional knowledge that has become known outside its traditional context shall not be protected."

The representative of the Southeast Indigenous Peoples' Center proposed to delete Articles 6(1)(ii) and 6(2). She stated that the use of TK, TCE/EoF, and GR for household purposes should be governed by the laws of the People/Nation that created, cultivated, and carried the TK, TCE/EoF, and GR. The People/Nation had good reasons for proscribing the terms under which their TK, TCE/EoF, and GR should be used. If TK, TCE/EoF and GR were used for cosmetic purposes without the People/Nation's consent, their eco-spiritual-system could be put into dangerous imbalance which could endanger the survival of the People/Nation and their neighbors, including those using their TK, TCE/EoF, and GR.

[ARTICLE 7²⁰⁷

DURATION OF PROTECTION

- [1. Protection of traditional knowledge against misappropriation [and misuse²⁰⁸]²⁰⁹ should last as long as the traditional knowledge fulfills the criteria of eligibility for protection according to Article 1(3).
- 2. If competent authorities make available through national or regional <u>laws or²¹⁰</u> measures additional or more extensive protection for traditional knowledge than is set out in these Principles, those laws or measures [shall] <u>should</u>²¹¹ specify the duration of protection.]²¹²J²¹³

- ²⁰⁹ Delegation of Belgium
- ²¹⁰ Delegation of Mexico
- ²¹¹ Delegation of Belgium

²⁰⁷ Original Article 9

²⁰⁸ Delegation of Mexico

²¹² Delegation of Colombia. The Delegation believed that the approach to regulating this area was inappropriate. The duration of protection should be regulated in a similar way to the moral rights of authors, i.e. the rights and duties relating to protection should last throughout the author's lifetime and should be transmitted to his or her heirs, which in this case was the community itself. This was not a right that might be limited in time

²¹³ Delegation of Canada. The Delegation did not support the renegotiation of possible invalidation of IP rights that were legitimately required before the coming into force of any new international instrument for the protection of TK. Canada believed that all efforts should be made to maintain a robust public domain and expected Article 1(3) to be clear on that aspect. Article 1(3) was the key to the interpretation of Article 7. With those comments just made, the Delegation could not support protection for TK in the public domain or already protected by what was currently contemplated in draft Article 7. It believed that would be detrimental to all creators. The Delegation supported the call made by the Delegation of the United States of America in favor of a robust public domain

COMMENTARY ON ARTICLE 7

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 1(3) and 2). 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.

Comments made and questions posed

Relationship with policy objectives

The Delegation of Australia 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 (vi) recognizing the value of a vibrant public domain.

The Delegation of Japan stated that, as described by Policy Objective (x), it was important to promote innovation and creativity. Without prejudice to whether economic right was an appropriate form to protect TK, the Delegation believed that indefinite time of protection of TK

was inappropriate in consideration of the balance between the interests of right holders and the public.

Relationship between two paragraphs

The Delegation of Australia 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.

Relationship with Article 1(3)

The Delegation of Norway suggested leaving Article 7 for now. It already followed from Article 1(3) that the protection only lasted as long as the conditions in this article were fulfilled. Any possible qualifier should be addressed in Article 1(3).

Balance between interests of the right holders and the public

The Delegation of Japan noted that if the protection of TK gave incentive for future invention that would lead to efficient development by a third party through using protected subject matter, indefinite protection of TK was inappropriate in consideration of the balance between interests of the right holders and the public.

Public domain

The representative of the Tulalip Tribes supported the intent of the language that was in the current draft on duration of protection. He called on evidence from those who said that such kind of protection would pose any kind of threat to the existing public domain. His understanding was that information, knowledge and other kinds of intangibles on which people could innovate and create were not based on TK. Thus, he believed that the argument that this constituted any kind of threat to the existing public domain was specious and he would like to see some evidence.

General comments

The Delegation of Zambia stated that the Article was fairly acceptable.

The Delegation of the European Union and its Member States reserved their statement on this article.

The Delegation of India agreed that the duration must be as long as it maintained the eligibility condition. But one problem was the use of the word "misappropriation" and "misuse". It gave the impression that the duration was applicable only with reference to misappropriation and misuse. It did understand that the list of misappropriation and misuse that had just been reflected in Article 3(1) was not exhaustive. But it still would like to revisit and find out whether all types of protection was covered and the duration extended to all forms of TK that had been covered under this instrument, as well as all types of activities. To that extent, it reserved its right to come back and comment on this article.

Drafting suggestions by observers

The representative of the International Chamber of Commerce proposed to replace "Article 1(3)" in Article 7(1) with "Articles 1(3) and 6".

The representative of the Southeast Indigenous Peoples' Center proposed to delete Article 7.

ARTICLE 8²¹⁴

FORMALITIES

- 1. [Eligibility for protection of traditional knowledge against acts of misappropriation [or \underline{misuse}^{215}]²¹⁶ should not require any formalities.]²¹⁷
- 2. In the interests of transparency, certainty and the conservation of traditional knowledge, relevant national authorities may maintain registers or other records of [protected²¹⁸]²¹⁹ 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.

²¹⁴ Original Article 11

²¹⁵ Delegation of Mexico

²¹⁶ Delegation of the European Union and its Member States

²¹⁷ Delegation of Colombia. The Delegation stated that Article 8(1) was unclear. It wondered why no formalities were required

²¹⁸ Delegation of the United States of America

²¹⁹ Delegation of Angola, on behalf of the African Group

COMMENTARY ON ARTICLE 8

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.

Comments made and questions posed

Relationship with policy objectives and principles

The Delegation of Australia 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 7

The Delegation of Australia noted that this part also related to the issue of defensive protection or positive rights as discussed in relation to Article 7.

Definitions

The Delegation of Japan stated that from the viewpoint of predictability for users, clearer definitions of TK and beneficiaries would be needed especially if any protection would be given to TK irrespective of formality. The Delegation believed that more clarity would be needed on the scope of the TK protection and beneficiaries, if such knowledge would be protected even without requiring formality. Lack of a clear definition of TK for protection and beneficiaries would cause uncertainty and unpredictability and hence, without a deterrent, affect further innovation based on TK.

Drafting suggestions by observers

The representative of the International Chamber of Commerce proposed to insert "undisclosed" before "traditional knowledge" in Article 8(1).

The representative of the Southeast Indigenous Peoples' Center proposed to replace Article 8(2) with "Where disputes arise between indigenous Peoples, nations, and communities and traditional and other cultural communities and UN member nations or corporations they license over who is the right holder it should be referred to an intellectual property world court, established with indigenous nations and UN member nations, which includes judges with "tribal" or indigenous court experience who are citizens of original nations that are not UN members. Support shall be given to the courts of indigenous Peoples/Nations in recording and distributing their laws in the interest of transparency".

ARTICLE 9²²⁰

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.

<u>These provisions should apply to all traditional knowledge which, at the moment of the provisions</u> coming into force fulfill the criteria set out in Article 1(3).²²¹

²²⁰ Original Article 10

²²¹ Delegation of the European Union and its Member States

COMMENTARY ON ARTICLE 9

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.

Comments made and questions posed

General comments

The Delegation of Australia 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.

The Delegation of Colombia stated that it was important not to confuse or distort the principle of non-retroactivity of the law in the regulations based on this Article, since it should be recalled that the issue here was not rights created from conventional or sui generis intellectual property titles, but previous rights which already existed before this instrument. The phrases "prior to the entry into force of the protection" and "within a reasonable period of that protection coming into force" were unclear. The Delegation wondered what was understood by "protection" for the purposes of this Article. It considered it was unclear what types of conduct could be understood to constitute appropriation of knowledge "in good faith". The Committee needed to be especially careful since rights acquired in violation of public order standards could not be protected. In addition, in the context of public law, rights acquired tended to become diluted (the treatment of those rights was very different to rights acquired in accordance with civil law), as pointed out by the Constitutional Court.

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) stated the entry into force of protection of TK was not retroactive. That non-retroactivity should be linked to the compensation as indicated in his comments concerning Article 6. If such compensation did not exist, many holders would feel wronged and excluded by the protection. That would not be the case based on the principle outlined above with regard to Article 4(1) concerning the principle of prior informed consent.

Public domain

The Delegation of Australia 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.

Drafting suggestions by observers

The representative of the Southeast Indigenous Peoples' Center proposed to insert "as adjudicated by the knowledge holders" at the end.

ARTICLE 10²²²

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] <u>should</u>²²³ be consistent with national laws regulating access to those components of biological diversity. [Permission to] <u>Granting to</u>²²⁴ access and/or use traditional knowledge does not imply [permission to]²²⁵ access and/or [use] <u>utilization of</u>²²⁶ associated genetic resources and vice versa.

[Article 10bis

Where a dispute arises between beneficiaries or between beneficiaries and users of traditional knowledge, each party shall be entitled to refer the issue to an independent alternative dispute resolution mechanism recognized by national or international law.²²⁷²²⁸J²²⁹

²²² Original Article 12

²²³ Delegation of the European Union and its Member States. The Delegation of Indonesia and the Delegation of Angola, on behalf of the African Group, opposed. The Delegation of Indonesia suggested retaining the word "shall" instead of "should". It stated that that was very important for it, because in the context of consistency with the national law, it was the point of opinion that the national treatment should come first

²²⁴ Delegation of Mexico. Delegation of Angola, on behalf of the African Group, concurred

²²⁵ Delegation of Mexico. Delegation of Angola, on behalf of the African Group, concurred

²²⁶ Delegation of Mexico. Delegation of Angola, on behalf of the African Group, concurred

²²⁷ Such as the WIPO Arbitration and Mediation Center

²²⁸ Delegation of the European Union and its Member States

The Delegation of Indonesia would like to reserve its comment

²²⁹ Delegation of Angola, on behalf of the African Group

COMMENTARY ON ARTICLE 10

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.

Comments made and questions posed

Relationship with policy objectives and principles

The Delegation of Australia 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.

General comments

The Delegation of New Zealand noted that the commentary in the document WIPO/GRTKF/IC/17/5 referred to the general legal framework, but the content of the article actually only dealt with one element of the framework, namely biological diversity. So it suggested that the IWG on TK consider whether the article should deal with other elements of the general legal framework. Another option might be for matters concerning general legal framework to be dealt with as a matter of general principle in preambular language rather than in a substantive provision.

The Delegation of Canada found that Article 10 as currently drafted was somewhat narrow in scope. It believed that this article should be broadened from a focus on biodiversity and GR to a more general focus on relationship of this potential instrument with other domestic laws and international instruments and agreements in general. In this regard, the IWG should seek inspiration from Article 10 or the analogous article in the TCE text.

Drafting suggestions by observers

The representative of the Southeast Indigenous Peoples' Center proposed to insert "Access to TK and GR shall be in accordance with the laws of the indigenous People/Nation that created, cultivated, or carries it" at the end of this Article.

ARTICLE 11²³⁰

INTERNATIONAL AND REGIONAL PROTECTION

The protection, benefits and advantages available to holders of [TK] <u>traditional knowledge</u>²³¹ under the national measures or laws that give effect to these international standards should be available to all eligible traditional knowledge holders, who <u>are</u> nationals or [habitual]²³² residents of a prescribed country as defined by international obligations or undertakings. Eligible foreign holders of [TK] <u>traditional knowledge</u>²³³ 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.

²³⁰ Original Article 14

²³¹ Delegation of Mexico

²³² Delegation of Mexico

²³³ Delegation of Mexico

COMMENTARY ON ARTICLE 11

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 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.

Comments made and questions posed

International dimension

Noting the commentary regarding limited guidance from the Committee on how the international dimension should be addressed on a technical level, the Delegation of Australia 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.

National law

The representative of the Association des étudiants et chercheurs sur la gouvernance des États insulaires (AECG) stated that it was desirable for national law to provide for equality of treatment in respect of assets held by foreigners. In order to do that, it would be necessary to consider reciprocal legal instruments and that was clearly easier for neighboring countries.

General comments

The Delegation of Zambia stated that the Article was acceptable.

Drafting suggestions by observers

The representative of the Southeast Indigenous Peoples' Center proposed to replace this Article with "Signatories to the provisions will work to protect Indigenous Peoples/Nations and communities from all entities, including UN member nations, who seek to forcibly acquire indigenous acquiescence to the unauthorized use of TK or who attempt to retaliate against indigenous Peoples/Nations, or communities who refuse permission to use TK".

GENERAL COMMENTS

Comments made and questions posed

The Delegation of Mexico 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.

The Delegation of China 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.

The Delegation of Germany 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.

The Delegation of Switzerland 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.

The Delegation of Japan stated that, with respect to Objectives and General Guiding Principles in WIPO/GRTKF/IC/16/4 and WIPO/GRTKF/IC/16/5, the comments submitted by the Delegation of Japan included in WIPO/GRTKF/IC/10/INF/2 Add. were still valid and could be useful materials for further discussion. The Delegation reserved its right for further comments and questions. In discussing substantive provisions, General Guiding Principles on flexibility and comprehensiveness should be respected and duly reflected in the wording of each article.

The Delegation of Zambia stated that documents WIPO GRTKF/IC/16/4 (TCEs), WIPO/GRTKF/IC/16/5 (TK) and WIPO/GRTKF/IC/16/6 (GR) remained the basis for the negotiations but while being open to any additional documents that added value as long as confusion and delay were not introduced in the process. The instruments arising from the negotiations set minimum standards and obligate Member States to adopt such standards. Essentially, they should be "binding". The exact means through which protection was to be provided might nonetheless be determined at the national level as was the case under the TRIPs Agreement. Minimum standards should include disclosure of the source and country of origin of the biological or GR used in the inventions as well as the related TK; evidence of prior informed consent by holders or competent authorities; and evidence of fair and equitable sharing. Further, the instrument (s) should be forward looking and crafted in a manner that was clear, concise, unambiguous, self interpreting and to the extent possible, "self contained". It should equally reflect the cultural and legal diversity of the Member States. The three substantive matters should be afforded equal priority. However, given that more progress had been made on TK and TCEs in comparison with GR, the former could be given preference. Over all, the process itself had to be transparent and treat all Member States equally.

The Delegation of the European Union and its Member States emphasized that every objective, principle and article of WIPO/GRTKF/IC/17/5 needed to respect the existing international regimes and in particular the IP regime. The Delegation was of the opinion that the eventual protection of TK could not prevail in any way over the existing conventional IP regimes. It reserved the right to make further comments on the text.

The representative of the International Chamber of Commerce 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.

[Appendix follows]

APPENDIX

REVISED PROVISIONS FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

POLICY OBJECTIVES AND CORE PRINCIPLES

CONTENTS

N.B. This Appendix is an extract from WIPO document WIPO/GRTKFIC/9/5. It is appended to this document simply to enable a comparison between the original structure of the text and the restructured WIPO/GRTKF/IC/18/5.

- I. POLICY OBJECTIVES
- (i) Recognize value
- (ii) Promote respect
- (iii) Meet the actual needs of traditional knowledge holders
- (iv) Promote conservation and preservation of traditional knowledge
- (v) Empower holders of traditional knowledge and acknowledge the distinctive nature of traditional knowledge systems
- (vi) Support traditional knowledge systems
- (vii) Contribute to safeguarding traditional knowledge
- (viii) Repress unfair and inequitable uses
- (ix) Concord with relevant international agreements and processes
- (x) Promote innovation and creativity
- (xi) Ensure prior informed consent and exchanges based on mutually agreed terms
- (xii) Promote equitable benefit-sharing
- (xiii) Promote community development and legitimate trading activities
- (xiv) Preclude the grant of improper intellectual property rights to unauthorized parties
- (xv) Enhance transparency and mutual confidence
- (xvi) Complement protection of traditional cultural expressions

CORE PRINCIPLES

II. GENERAL GUIDING PRINCIPLES

- (a) Responsiveness to the needs and expectations of traditional knowledge holders
- (b) Recognition of rights
- (c) Effectiveness and accessibility of protection
- (d) Flexibility and comprehensiveness
- (e) Equity and benefit-sharing
- (f) Consistency with existing legal systems governing access to associated genetic resources
- (g) Respect for and cooperation with other international and regional instruments and processes
- (h) Respect for customary use and transmission of traditional knowledge
- (i) Recognition of the specific characteristics of traditional knowledge
- (j) Providing assistance to address the needs of traditional knowledge holders
- III. SUBSTANTIVE PRINCIPLES
- 1. Protection Against Misappropriation
- 2. Legal Form of Protection
- 3. General Scope of Subject Matter
- 4. Eligibility for Protection
- 5. Beneficiaries of Protection
- 6. Fair and Equitable Benefit-sharing and Recognition of Knowledge Holders
- 7. Principle of Prior Informed Consent
- 8. Exceptions and Limitations
- 9. Duration of Protection
- 10. Transitional Measures
- 11. Formalities
- 12. Consistency with the General Legal Framework
- 13. Administration and Enforcement of Protection
- 14. International and Regional Protection

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) 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

 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

 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

 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, 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.

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

III. SUBSTANTIVE PROVISIONS

ARTICLE 1

PROTECTION AGAINST MISAPPROPRIATION

- 1. Traditional knowledge shall be protected against misappropriation.
- 2. Any acquisition, appropriation or utilization of traditional knowledge by unfair or illicit means constitutes an act of misappropriation. Misappropriation may also include deriving commercial benefit from the acquisition, appropriation or utilization of traditional knowledge when the person using that knowledge knows, or 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 be provided to prevent:
 - 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 to the recognized 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; 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.
- 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 of traditional knowledge, 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.

LEGAL FORM OF PROTECTION

- 1. The protection of traditional knowledge against misappropriation may be implemented through a range of legal measures, including: 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, 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.

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 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 knowledge associated with genetic resources.

ELIGIBILITY FOR PROTECTION

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

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

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.

FAIR AND EQUITABLE BENEFIT-SHARING AND RECOGNITION OF KNOWLEDGE HOLDERS

- 1. The benefits of protection of traditional knowledge to which its holders 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 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 may play an important role in sharing benefits that may arise from the use of traditional knowledge.

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 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.

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.

DURATION OF PROTECTION

- 1. Protection of traditional knowledge against misappropriation 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 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.

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.

FORMALITIES

- 1. Eligibility for protection of traditional knowledge against acts of misappropriation 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.

CONSISTENCY WITH THE GENERAL LEGAL FRAMEWORK

1. 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.

ADMINISTRATION AND ENFORCEMENT OF PROTECTION

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

INTERNATIONAL AND REGIONAL PROTECTION

The protection, benefits and advantages available to holders of TK under the national measures or laws that give effect to these international standards should be available to all eligible traditional knowledge holders, who nationals or habitual residents of a prescribed country as defined by international obligations or undertakings. Eligible foreign holders of TK 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.

[End of Annex and of document]