

WIPO



WIPO/GRTKF/IC/7/6
ORIGINAL: English
DATE: August 27, 2004

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WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

**INTERGOVERNMENTAL COMMITTEE ON
INTELLECTUAL PROPERTY AND GENETIC RESOURCES,
TRADITIONAL KNOWLEDGE AND FOLKLORE**

Seventh Session
Geneva, November 1 to 5, 2004

THE PROTECTION OF TRADITIONAL KNOWLEDGE:
OUTLINE OF POLICY OPTIONS AND LEGAL ELEMENTS

Document prepared by the Secretariat

SUMMARY

1. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee') decided at its sixth session to develop two complementary sets of materials: (i) "an overview of policy objectives and core principles for the protection of traditional knowledge (TK)"; and (ii) "an outline of the policy options and legal elements for the protection of TK subject matter, together with a brief analysis of the policy and practical implications of each option and element."

2. The separate document WIPO/GRTKF/IC/7/5 provides draft material for the first proposed outcome, the overview of policy objectives and core principles. Such general requirements may in practice be implemented by a wide range of distinct national and regional legal mechanisms, ranging over diverse forms of IP right, adapted IP rights, the general law of unfair competition and various general legal mechanisms beyond the scope of IP law proper (such as criminal law, the law of delict/torts, the general law of civil liability, cultural heritage preservation laws, blasphemy laws, customary laws, contract law, employment law and marketing and labeling laws and schemes). National policymakers have a wide choice of policy options and legal mechanisms to give effect to objectives and principles such as those suggested in WIPO/GRTKF/IC/7/5. The present document illustrates the choice by providing draft materials for the Committee's review that could form the second agreed outcome, the outline of policy options and legal mechanisms. It illustrates that it is possible to draw from varied existing practical experiences and select specific mechanisms, causes of action, doctrines and other means to achieve such objectives and to implement such principles.

3. Similarly to WIPO/GRTKF/IC/7/5, the material in this companion document is not, in substance, new to the Committee: it simply distils and structures the existing legal mechanisms and the extensive practical experience with protection of TK that have already been widely discussed by the Committee, and draws on the Committee's own deliberations and on the diverse materials put to the Committee by many Member States and observers. The contents of this document find their origins in the extensive community-based consultations in 1998 and 1999 which allowed WIPO to listen directly to TK holders about their needs for legal protection; in the many interventions and submissions made by Member States, TK holders and other stakeholders during the past six sessions of the Committee; in community-level, national and regional consultations and projects; in responses to questionnaires, reports and studies reporting on actual experience in many countries; and in stakeholder comments on earlier working documents made at previous sessions of the Committee. This companion document and document WIPO/GRTKF/IC/7/5 therefore distill the substantive results from the full sweep of WIPO's work on TK since the current program was initiated in 1998.

4. To serve as a useful reference and to maintain consistency, this document follows closely the structure proposed in WIPO/GRTKF/IC/7/5. Both documents draw on the same background of legal measures used and practical experience developed by countries and communities in many geographical regions, at every level of economic development. They both draw extensively on policy discussions and conclusions from related international policy processes which touch upon TK protection. Yet this document has a different focus, and a complementary role in relation to WIPO/GRTKF/IC/7/5. It is structured as follows:

(a) *policy options for the protection of TK*, comprising:

(i) *options for the objectives of protection*, recording various ways in which the policy objectives suggested in WIPO/GRTKF/IC/7/5 have been expressed in international, regional and national laws and instruments;

(ii) *options relating to the general form of protection*, recording the range of legal doctrines and general principles that have been applied to the protection of TK, corresponding broadly to the general guiding principles suggested in WIPO/GRTKF/IC/7/5;

(b) *legal elements of protection of TK*, showing how legal provisions that have been developed and used in international, national and regional laws and instruments could implement the specific substantive principles suggested in WIPO/GRTKF/IC/7/5.

5. For ease of reference, the draft outline of policy options and legal elements is set out in Annex I to this document.

I. INTRODUCTION

6. At its sixth session in March 2004, the Committee decided that the WIPO Secretariat should prepare drafts of “an overview of policy objectives and core principles for TK protection; and an outline of the policy options and legal elements for the protection of TK subject matter, together with a brief analysis of the policy and practical implications of each option.”¹ This was on the basis of the proposal that the Committee “could consider the development of an agreed platform for comprehensive TK protection, based on the identification of common policy objectives and core principles, and supplemented by an array of the detailed legal mechanisms, annotated and clarified, that could be used as flexible and adaptable means to achieve shared objectives within national law and in consultation with TK holders and the intended beneficiaries of protection.”²

7. Document WIPO/GRTKF/IC/7/5 suggests for the Committee’s consideration draft policy objectives and core principles for the protection of TK, which may evolve into an agreed international platform for protection. The present document is a supplementary resource that sets out for the Committee’s review a draft outline of the policy options and legal mechanisms that would operate at the national level to protect TK in line with the objectives and principles articulated at the international level.

8. TK is necessarily diverse in its nature; it is developed and maintained by a wide range of communities, people and individuals in diverse cultural and legal contexts and in many different countries; and the needs and aspirations of relevant communities are similarly diverse. It follows that the possible means of protecting TK against misuse or misappropriation, and the choices actually taken, also vary widely. Many communities cherish this diversity as integral to their cultural identity. Yet the Committee has also worked towards a common approach or shared international perspective on the protection of TK, and the current mandate of the Committee excludes no outcome, including an international instrument or instruments.

¹ Report of Sixth Session, WIPO/GRTKF/IC/6/14, para. 109, approving the approach set out in subparagraph 104 (ii) of WIPO/GRTKF/IC/6/4.

² WIPO/GRTKF/IC/6/4, paragraph 103

9. Respecting these complementary goals, WIPO/GRTKF/IC/7/5 and this document together seek firstly to set out a common approach, built on actual experience with TK protection; and secondly to leave open the policy space for this necessary diversity to find practical expression and to support policymakers and communities in considering all possible options, so that protection can be tailored and appropriate to the actual needs and context of communities. WIPO/GRTKF/IC/7/5 therefore articulates suggested policy objectives and core principles, with a view to establishing common ground internationally. By contrast, this companion document seeks to document the diverse measures that have been used at the international, regional and national levels to protect TK, to give practical effect to the policy objectives of protection, and to apply in practice the principles of protection. WIPO/GRTKF/IC/7/5 is an attempt to distil a wide range of policy and legal approaches into a shared international platform for protection; this document aims to serve as a menu of options to assist policymakers and communities in making practical choices about protection.

10. This document gives only an outline of options and legal mechanisms, giving several examples of diverse ways of implementing broader objectives and principles, so that it remains brief and provisional. It could evolve and be further developed in line with the further evolution of the objectives and principles set out in WIPO/GRTKF/IC/7/5. No specific decisions in respect of this document are suggested at this stage, and the Committee is invited merely to note and comment on it.

11. The options and mechanisms set out in this document are examples only. They do not seek to place limits on the parameters of the debate concerning TK protection, to prescribe any particular outcomes or solutions, nor to define the form that they may take. Clearly it is open for the Committee to base its work on alternative approaches and proposals, and this document is provided as only one input to its deliberations.

Flexibility for national policy and legislative development

12. A wide range of distinct national and regional legal mechanisms are available to give effect to the kind of policy objectives and core principles set out in WIPO/GRTKF/IC/7/5. These range over diverse forms of IP right, adapted IP rights, the general law of unfair competition and various general legal mechanisms beyond the scope of IP law proper (such as criminal law, the law of delict/torts, cultural heritage preservation laws, blasphemy laws, customary laws, contract law, employment law and marketing and labeling laws, environmental law and indigenous rights law); laws governing genetic resources have also been used to protect TK. This document documents some of the policy options taken, and the legal mechanisms deployed, to achieve the objectives of protection and to give effect to the principles established for protection.

13. This approach is consistent with and expresses most directly the ‘principle of flexibility and comprehensiveness’ suggested in WIPO/GRTKF/IC/7/5. This principle concerns the need to respect that effective and appropriate protection may be achieved by a wide variety of legal mechanisms, and that too narrow or rigid an approach at the level of principle may constrain effective protection, conflict with existing laws to protect TCEs/EoF, and pre-empt necessary consultation with stakeholders and holders of TCEs in particular. It also concerns the need to draw on a wide range of legal mechanisms to achieve the intended objectives of protection.

14. This approach – broader than a regime strictly of exclusive proprietary rights – is relatively common in the IP field. Previous documents gave examples of IP conventions which establish certain general principles and which give scope for wide variation within the laws of the signatories.³ Even where international obligations create minimum substantive standards for national laws, it is accepted that the choice of legal mechanisms is a matter of national discretion. This is evident in the protection of unfair competition law and *sui generis* IP protection for layout designs of integrated circuits: for example, the Washington Treaty provides that each Contracting Party ‘shall be free to implement its obligations under this Treaty through a special law on layout-designs or its law on copyright, patents, utility models, industrial designs, unfair competition *or any other law or a combination of any of those laws*.’⁴ A standard commentary on the Rome Convention, 1961 similarly notes that a provision on rights of performers is worded ‘to leave complete freedom of choice as to the means used to implement the Convention, and to choose those which [is thought] most appropriate and best. They may be based on any one or more of a number of legal theories: law of employment, of personality, of unfair competition or unjust enrichment, etc. [including criminal law] – and of course, if they wish, an exclusive right. The important thing is that those means achieve the purpose [of the defined protection].’ The protection of TK is undoubtedly an area of considerable legal evolution and active domestic consultation and lawmaking at present. The present document therefore illustrates how this necessary consultation and evolution can continue, on the basis of a stronger shared international perspective.

15. Actual experience with TK protection has shown that it is unlikely that any single ‘one-size-fits-all’ or ‘universal’ international template will be found to protect TK comprehensively in a manner that suits the national priorities, legal and cultural environment, and needs of traditional communities in all countries. Forms of traditional knowledge systems and customary means of regulating the use, transmission, protection and preservation of TK are diverse. Concerns have been expressed that attempts to codify and institutionalize protection of TK are undesirable and that a flexible and inclusive approach is preferable. An indigenous organization has put it best: “Any attempt to devise uniform guidelines for the recognition and protection of indigenous peoples’ knowledge runs the risk of collapsing this rich jurisprudential diversity into a single ‘model’ that will not fit the values, conceptions or laws of any indigenous society.”⁵ Provisions for the protection of TK adopted at the international level would also have to accommodate legislative and jurisprudential diversity within current national and regional approaches. In particular, experience has shown that a mix of measures, between proprietary and non-proprietary approaches, and between distinct new measures and adaptations of existing IP rights, is more likely to achieve the objectives of protection.

³ WIPO/GRTKF/IC/6/6, referring for example to the TRIPS Agreement, Article 1.1; Rome Convention, Article 7; the Satellites Convention, Article 2; the Lisbon Convention, Article 8; the Washington Treaty, Article 4; and the Phonograms Convention, Article 3.

⁴ Art. 4, *Treaty on Intellectual Property in Respect of Integrated Circuits* (1989), highlighted as a model for TK protection by the Delegation of Syria (WIPO/GRTKF/IC/6/14, para 80).

⁵ Four Directions Council, ‘Forests, Indigenous Peoples and Biodiversity,’ Submission to the Secretariat for the CBD, 1996.

II. THE USE OF CERTAIN TERMS

Traditional knowledge and traditional cultural expressions (TCEs)/folklore

16. This document and WIPO/GRTKF/IC/7/5 deal specifically with the protection of traditional knowledge as such, not the complementary question of protection of traditional cultural expressions (TCEs) or expressions of folklore (EoF), which is dealt with in WIPO/GRTKF/IC/7/3 and WIPO/GRTKF/IC/7/4. This follows the Committee's established approach of considering the protection of TCEs/EoF and the protection of TK in parallel but separately, as explained and discussed in previous documents⁶ and as suggested by many Member States.⁷ The need for these forms of protection to be complementary is, however, also recognized in the objectives and principles.

The specific sense of 'traditional knowledge'

17. This document and WIPO/GRTKF/IC/7/5 deal with traditional knowledge in the specific or strict sense of the term: the content or substance of traditional know-how, innovations, information, practices, skills and learning, rather than the form of its expression.⁸ In the past, notably in WIPO fact-finding missions, the term 'traditional knowledge' has been used with a broad, inclusive sense, covering TCEs/folklore as well as traditional knowledge in the strict sense of the term. This reflected the informality and exploratory nature of earlier consultations, but as the Committee's work has taken on a more focussed and concrete quality, the need for distinct use of these terms clearly emerged and has been reflected in working documents. This led to the Committee's established approach of considering the legal protection of TCEs/EoF and of TK *stricto sensu* in parallel but separately, as explained and discussed in previous documents and as suggested by many Member States. As these principles clarify, this concerns specific means of legal protection against misuse of this material by third parties beyond the traditional context, and does not seek to impose definitions or categories on the customary laws, protocols and practices of indigenous peoples and traditional and other communities. This approach is accordingly compatible with and respectful and supportive of the traditional context in which TCEs/EoF and TK are often perceived as integral parts of an holistic cultural identity, subject to the same body of customary law and practices.

The term 'protection'

18. Continuing past practice,⁹ the term 'protection' refers to protection such as that typically provided by IP laws, essentially to provide legal means to restrain third parties from undertaking certain unauthorized acts that involve the use of the protected material. As for other forms of IP, this extends to forms of protection through means other than distinct,

⁶ See the distinctions drawn in WIPO/GRTKF/IC/5/12 and further discussion in WIPO/GRTKF/IC/6/3.

⁷ See African Group (WIPO/GRTKF/IC/5/15, par. 123); Ecuador (WIPO/GRTKF/IC/5/15, para. 157), Switzerland (WIPO/GRTKF/IC/5/15, para. 143), European Union and its Member States (WIPO/GRTKF/IC/3/17, para. 218 and WIPO/GRTKF/IC/6/14, paras. 27 and 192), Canada (WIPO/GRTKF/IC/3/17 para. 235), China (WIPO/GRTKF/IC/3/17, para. 242) and the USA (WIPO/GRTKF/IC/3/17, para. 254), African Group (WIPO/GRTKF/IC/6/14, para. 188), GRULAC (WIPO/GRTKF/IC/6/14, para. 189), Venezuela (WIPO/GRTKF/IC/6/14, para. 34), Egypt (WIPO/GRTKF/IC/6/14, para. 196).

⁸ See discussion of these key distinctions in WIPO/GRTKF/IC/5/12, and further in WIPO/GRTKF/IC/5/3 and WIPO/GRTKF/IC/6/4

⁹ See WIPO/GRTKF/IC/5/8 and WIPO/GRTKF/IC/6/4; more generally WIPO/GRTKF/IC/5/12.

exclusive property rights (such as through the suppression of unfair competition and other legal means), noting that this approach is recognized in a number of IP treaties. ‘Protection’ in this sense should be distinguished from the concept of ‘conservation’ or ‘preservation.’ Hence, in this document, the term ‘TK protection’ refers to all matters affecting the availability, acquisition, scope, maintenance, and enforcement of rights and interests related to TK, as well as those matters affecting the use, exercise and administration of rights and interests in TK. It thus defines TK protection comprehensively and continues the Committee’s past use of the term “protection” to refer to a wide range of measures.¹⁰

Beneficiaries of TK protection: holders of TK

19. Any agreed international perspective on TK protection should take account of the diverse custodianship structures of TK in the different regions, in the manner in which it designates the beneficiaries of protection. For example, it was stated at the Committee’s sixth session that, while indigenous peoples are important stakeholders in this discussion, not all TK belonged to indigenous peoples, and that it was necessary also to consider non-indigenous holders of TK, such as farming communities. In addition, the narrow sense of ‘ownership’ may be inapplicable in some circumstances, the relationship between a community and its TK often being seen in terms of custodianship or responsibility. Concerns about misappropriation may be expressed in terms of failure to respect the distinctive linkage between the TK and the community, rather than a strict sense of ownership.

20. In WIPO’s work programme since 1998, the broad and inclusive term ‘TK holders’ or ‘holders of TK’ has been used in a comprehensive manner which includes, but is not limited to, indigenous peoples. The present document follows the practice, established at the beginning of WIPO’s work programme, of using the term “TK holders” to designate the beneficiaries of TK protection. This practice dates back to the *WIPO Fact-finding Missions on the IP Needs and Expectations of TK Holders*, prior to the creation of the Committee, and has since proven to be a widely followed approach.

III. BASIS IN PAST DISCUSSION AND ACTUAL EXPERIENCE

21. The document draws directly upon the full range of materials that have served as the basis of the Committee’s work so far, such as previous working documents prepared for the Committee; interventions and submissions made by Member States, communities and other stakeholders, during Committee sessions but also at national and regional consultations; reports; studies; responses to questionnaires; and comments on the earlier working documents made at previous sessions of the Committee. More recent documents and submissions have also been taken into account, such as the proposal put to the Committee by the African Group at the Committee’s sixth session (document WIPO/GRTKF/IC/6/12, entitled “Objectives, Principles and Elements of an International Instrument, or Instruments, on Intellectual Property in relation to Genetic Resources and on the Protection of Traditional Knowledge and Folklore”), which many delegations welcomed and found helpful as a framework for further discussion and elaboration.¹¹

¹⁰ See document WIPO/GRTKF/IC/6/4, para. 12 and WIPO/GRTKF/IC/4/8, para. 1. See also generally GRULAC document (WIPO/GRKTF/IC/1/5, Annex I, page 6, item V.1).

¹¹ Such as Group B (WIPO/GRTKF/IC/6/14, para. 191), European Community (WIPO/GRTKF/IC/6/14, para. 192), Group of Central and Baltic States (WIPO/GRTKF/IC/6/14, para. 193), China (WIPO/GRTKF/IC/6/14, para. 194), Syrian Arab Republic (WIPO/GRTKF/IC/6/14, para. 203), Canada (WIPO/GRTKF/IC/6/14, para. 205),

[Footnote continued on next page]

22. A wide variety of international, regional and national instruments and laws (many of which are summarized and analyzed in WIPO/GRTKF/IC/5/INF/2, WIPO/GRTKF/IC/5/INF/3, WIPO/GRTKF/IC/5/INF/4, WIPO/GRTKF/IC/5/7, WIPO/GRTKF/IC/5/8, and WIPO/GRTKF/IC/6/4) have been studied and taken into account.

23. A table analysing and comparing many of these laws is attached as Annex II (previously circulated to the Committee as document WIPO/GRTKF/IC/5/INF/4).

IV. THE INTERNATIONAL DIMENSION

24. Many Member States have stated that the ‘international dimension’ of the protection of TK is of paramount importance. The renewed mandate for the Committee’s work in 2004-2005 requested the Committee to focus in particular on the international dimension of the issues under its mandate. Accordingly, at its sixth session, the Committee discussed the international dimension of its work, drawing on a survey of the ‘international dimension’ of TK and TCEs/EoF in general (WIPO/GRTKF/IC/6/6). The Committee concluded that the international dimension was not a distinct issue but an integral part of the substantive consideration of the protection of TK and TCEs/EoF.¹² Accordingly, this document integrally discusses policy options and legal mechanisms relevant to the international dimension.

V. CAPACITY-BUILDING AND OTHER PRACTICAL ACTIVITIES

25. It has been widely stressed that any protection for the benefit of the holders of TK should be both effective in practice, and should be tailored to the specific context and resource constraints of these communities. Hence the suggested principles in WIPO/GRTKF/IC/7/5 refer to the need for effective, appropriate and accessible measures for protection. This also underscores the need for coordinated capacity-building and awareness-raising to ensure the practical effectiveness of any protection. A series of practical capacity-building tools is under development. These are not described in detail in the current document, but are set out in the Annex both to WO/GA/31/5 and to WIPO/GRTKF/IC/7/INF/3, with the following notation:

These materials already produced or in development: background capacity-building and information resources to support community-level planning and decision-making and to provide background for legal and policy advisors for indigenous and local communities, other stakeholders, policymakers and legislators. Practical resources for action at the community level, for assessing and exploring in detail the options that are chosen at the policy level, and to support the elaboration or implementation of national and regional protection mechanisms. Draw extensively on the actual experiences documented in the

[Footnote continued from previous page]

Norway (WIPO/GRTKF/IC/6/14, para. 216), Pakistan (WIPO/GRTKF/IC/6/14, para. 217), ARIPO (WIPO/GRTKF/IC/6/14, para. 225), URTNA (WIPO/GRTKF/IC/6/14, para. 227) and the Kaska Dena Council speaking on behalf of several indigenous peoples’ organizations (WIPO/GRTKF/IC/6/14, para. 228).

¹² The African Group (WIPO/GRTKF/IC/6/14, para. 188), Brazil (WIPO/GRTKF/IC/6/14, para. 195), Thailand (WIPO/GRTKF/IC/6/14, para. 201), Canada (WIPO/GRTKF/IC/6/14, para. 205). See also para. 231 of WIPO/GRTKF/IC/6/14.

IGC at the community, national and regional levels, as well as relevant international processes. Consistent with overall policy settings and outcomes established by IGC, but prepared as sources of technical information only and not to pre-empt or determine policy choices.

V. CONCLUSIONS

26. This document has been prepared as a supplementary resource, following the basic structure suggested in WIPO/GRTKF/IC/7/5. If this approach is generally acceptable, it would suggest that the further evolution of this material should also track the further development of that document. For this reason, the current draft avoids detail, and instead provides an outline of a more detailed set of material that could be developed in accordance with the development of the framework proposed in WIPO/GRTKF/IC/7/5. This material is essentially proposed as a guide to the development of TK protection at the national or regional level, in contrast to WIPO/GRTKF/IC/7/5 which suggests material for a shared international perspective. Given the requirement in the Committee's mandate that it focus on the international dimension, it is suggested that this document be given less immediate priority (while still underscoring the continuing need for coordinated capacity-building and policy development at the national and regional levels). It could then be further developed and enhanced based on the overall guidance provided by the Committee in the context of the development of WIPO/GRTKF/IC/7/5.

27. The Committee is invited: (i) to note and comment on the suggested outline of policy options and legal elements for protection set out in Annex I to this document; and (ii) to note the possible further development of this material in the light of any decisions concerning the proposals in WIPO/GRTKF/IC/7/5

[Annexes follow]

ANNEX I

DRAFT OUTLINE OF POLICY OPTIONS AND LEGAL ELEMENTS
FOR THE PROTECTION OF TRADITIONAL KNOWLEDGE

A. POLICY OPTIONS FOR THE PROTECTION OF TK

A.1: options for the objectives of protection

1. This section records the range of objectives that have been identified for the protection of TK in a range of regional and national laws¹ and international instruments.² They are grouped according to several broad themes, corresponding generally to the policy objectives suggested in WIPO/GRTKF/IC/7/5. This material illustrates how specific policy objectives may be developed at the national level, to promote specific interests reflecting the context of individual countries and societies, while operating consistently with the broad objectives articulated at the international level.

2. The *sui generis* laws that were analyzed in the context of the panel discussion at the Committee's fifth session have stated policy objectives which fall in the following five categories:

- (i) Objectives related directly to TK and TK holders:
 - to create an appropriate system for access to TK;³
 - to ensure fair and equitable benefit-sharing for TK;⁴

¹ The national laws chiefly referred to in this Annex are: *African Union*: African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources of 2000 (hereafter 'African Model Law'); *Brazil*: Provisional Measure No. 2186-16 of 2001 Regulating Access to the Genetic Heritage, Protection of and Access to Associated Traditional Knowledge ('Brazilian Measure'); *China*: Patent Law of 2000, and Regulations on the Protection of Varieties of Chinese Traditional Medicine; *Costa Rica*: Law No. 7788 of 1998 on Biodiversity ('Costa Rican Biodiversity Law'); *India*: Biological Diversity Act of 2002 ('Indian Biodiversity Act'); *Japan*: Unfair Competition Prevention Law No. 47 ('Japanese Unfair Competition Law'); *Peru*: Law No. 27,811 of 2002 Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources ('Peruvian Law'); *Philippines*: Indigenous Peoples Rights Act of 1997 ('Philippines Act'); *Portugal*: Decree Law No.118 of 2002 Establishing a Legal Regime of Registration, Conservation, Legal Custody and Transfer of Plant Endogenous Material ('Portuguese Law'); *Republic of Korea*: Unfair Competition Prevention and Trade Secret Protection Law No. 911 ('ROK Unfair Competition Law'); *Thailand*: Act on Protection and Promotion of Traditional Thai Medicinal Intelligence, B.E 2542 ('Thai Act'); *United States of America*: Indian Arts and Crafts Act of 1990 ('US Arts and Crafts Act'), Uniform Trade Secrets Act of 1979 with 1985 Amendments ('US Trade Secrets Act'). Document WIPO/GRTKF/IC/5/INF/2 and INF/4 contain further details of many of these laws.

² The treaties referred to in this document include: the UN Convention to Combat Desertification in Those Countries Experiencing Serious Drought and/or Desertification, Particularly in Africa (1996) (hereinafter 'the UNCCD'); the International Treaty on Plant Genetic Resources for Food and Agriculture (2001) ('ITPGR'); the Convention on Biological Diversity (1992) ('CBD');

³ See the laws of the African Union, Brazil, Costa Rica, Peru.

- to promote respect, preservation, wider application and development of TK;⁵
 - to provide mechanisms for the enforcement of rights of TK holders;⁶
 - to improve the quality of TK-based products and remove low quality traditional medicine from the market;⁷
- (ii) Objectives related to biodiversity and genetic resource policy:
- to promote the conservation and sustainable use of biological resources and associated TK;⁸
 - to promote the legal safeguarding and transfer of genetic resources associated with TK;⁹
- (iii) Objectives related to indigenous peoples rights:
- to promote development of indigenous peoples and local communities;¹⁰
 - to recognize, respect and promote the rights of indigenous peoples and local communities;¹¹
- (iv) Objectives related to sustainable development and capacity building:
- to enhance scientific capacity at the national and local levels;¹²
 - to promote the transfer of technologies which make use of TK and associated genetic resources;¹³
- (v) Objectives related to innovation promotion:
- to promote and recognize innovation based on TK;¹⁴
 - to promote the development of Native arts and crafts.¹⁵

[Footnote continued from previous page]

⁴ See the laws of the African Union, Brazil, Costa Rica, Indian Biological Diversity Act of 2002, Peru. See also Objective (2) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

⁵ See the laws of Peru and Portugal. See also Objective (1) of the six objectives of TK protection proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

⁶ See the African Model Law.

⁷ See multiple *sui generis* administrative regulations of China.

⁸ See the African Model Law and the Biological Diversity Act of India. See also Objective (6) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

⁹ See the law of Portugal.

¹⁰ See the law of Peru. See also Objective (5) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

¹¹ See the laws of the African Union, Peru and the Philippines Indigenous Peoples Rights Act (1997).

¹² See the African Model Law and the law of Peru.

¹³ See the provisional measure of Brazil.

¹⁴ See the laws of China and Costa Rica. See also Objective (3) of the six objectives proposed by GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 3).

¹⁵ See the *sui generis* measures of the United States of America, in particular the Indian Arts and Crafts Act of 1990.

Examples of objectives in national and regional laws

3. The preamble of the Andean Community Decision 391 provides that: “the biological diversity, the genetic resources, their endemism and rarity, as well as the know-how, innovations and practices of the native, Afro-American and local communities associated with them, have a strategic value in the international context” and “it is necessary to strengthen integration and scientific, technical and cultural cooperation, while moving ahead with the harmonious and comprehensive development of the Member Countries.”

4. The Panamanian law provides that “the purpose of the law is to protect the collective rights of intellectual property and traditional knowledge of the indigenous communities upon their creations such as inventions, models, drawings and designs, innovations contained in the pictures, figures, symbols, illustrations, old carved stones and others; likewise, the cultural elements of their history, music, art and traditional artistic expressions, capable of commercial use, through a special registration system, promotion, commercialization of their rights in order to stand out the value of the indigenous cultures and to apply social justice.” (Article 1) It further specifies that “the customs, traditions, believing, spirituality, religiosity, folkloric expressions, artistic manifestations, traditional knowledge and any other type of traditional expressions of the indigenous communities, constitute part of their cultural assets: consequently, cannot be object of any form of exclusive right by unauthorized third parties under the intellectual property system such as copyrights, industrial models, trademarks, geographical indications and others, unless the application is filed by the indigenous community. However, rights previously recognized under the legislation on the matter will be respected and will not be affected.” (Article 2)

A.2: options for the general form of protection

Introduction

5. This section records the range of legal doctrines and general principles that have been applied to the protection of TK in a variety of international instruments, and regional and national laws. These include use of existing IP systems, adapted IP rights and new, stand-alone *sui generis* systems, as well as non-IP options. The options selected by various countries have depended to a large degree on the policy objectives and national goals being served. Countries which have already elected to provide specific protection for folklore have elected to do so through specific laws on TK, within other IP laws, within broader laws on such issues as genetic resources or indigenous rights, or in conjunction with TK protection.

6. The debate about the protection of TK often centers on whether adequate and appropriate protection is best provided through either the conventional IP system or through an alternative *sui generis* system. Yet the documented practical experiences of many Member States reflects that existing IP rights and *sui generis* measures are not mutually exclusive but are complementary options. A comprehensive approach is likely to consider each of these options, and apply them judiciously to achieve the objectives of protection, accepting the practical reality that the boundaries between these options are not rigid. Effective protection may therefore be found in a combined and comprehensive approach, with a menu of differentiated and multiple levels and forms of protection. The options selected by various countries have depended to a large degree on the policy objectives and national goals being served.

7. This flexibility – encapsulating a comprehensive and combined approach – is a practical articulation of several of the general guiding principles proposed in WIPO/GRTKF/IC/7/5. The suggested ‘principle of flexibility and comprehensiveness’ underscores that protection should respect the diversity of TK and the wide range of needs of the beneficiaries of protection, should acknowledge diversity in national circumstances and legal systems, and should allow sufficient flexibility for national authorities to determine the appropriate means of achieving the objectives of protection. Protection has accordingly drawn on a comprehensive range of options, combining proprietary, non-proprietary and non-IP measures, and using existing IP rights, *sui generis* extensions or adaptations of IP rights, and specially-created *sui generis* IP measures and systems, including both defensive and positive measures. Private property rights should complement and be carefully balanced with non-proprietary and non-IP measures.

8. The other suggested principles are also directly advanced by such an approach. For example, the ‘principle of responsiveness to aspirations and expectations of relevant communities’ concerns the need to recognize and apply indigenous and customary laws and protocols as far as possible, promote complementary use of positive and defensive protection, address cultural and economic aspects of development, address insulting, derogatory and offensive acts, enable full and effective participation by these communities, and recognize the inseparable quality of TK and TCEs/EoF for many communities. Measures for the legal protection of TK should also be recognized as voluntary from the viewpoint of indigenous peoples and other 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 TK.

9. A ‘principle of balance and proportionality’ calls for an equitable balance between the rights and interests of those that develop, preserve and sustain TK, and of those who use and benefit from them; the need to reconcile diverse policy concerns; and the need for specific protection measures to be proportionate to the objectives of protection, actual experiences and needs, and the maintenance of an equitable balance of interests. A ‘principle of respect for and cooperation with other international and regional instruments and processes’ means that TK should 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 established under binding legal instruments. The principle of recognition of the specific nature of TK calls for protection to respond to the traditional character of TK; its collective or communal context and the inter-generational character of their development, preservation and transmission; their relationship to a community’s cultural and social identity and integrity, beliefs, spirituality and values; their often being vehicles for religious and cultural expression; and, their constantly evolving character within a community. It also means that special measures for legal protection should also recognize that in practice TK elements are not always created within firmly bounded identifiable ‘communities’ that can be treated as legal persons or unified actors. TK elements are not necessarily always the expression of distinct local identities; nor are they often truly unique, but rather the products of cross-cultural exchange and influence.

10. A key principle of ‘respect for customary use and transmission of TK’ expresses that protection should promote the use, development, exchange, transmission and dissemination of TK by the communities concerned in accordance with their customary laws and practices. Customary use, practices and norms should guide the legal protection of TK as far as possible, on such questions as ownership of rights, management of rights and communal

decision-making, equitable sharing of benefits, exceptions and limitations to rights and remedies. A ‘principle of effectiveness and accessibility of protection’ indicates that measures for the acquisition, management and enforcement of rights and for the implementation of other forms of protection should be effective, appropriate and accessible, taking account of the cultural, social, political and economic context of indigenous peoples and traditional and other cultural communities.

IP and non-IP options

11. IP-type property rights are not the only way to provide protection for TK. Comprehensive protection may require a range of IP and non-IP legal tools. Approaches for TK protection, both within and beyond the IP system, could include:

- (a) Disinct intellectual property rights, including:
 - (i) existing IP rights,
 - (ii) modified or adapted IP rights, and
 - (iii) stand-alone *sui generis* IP systems;
- (b) Unfair competition law;
- (c) Laws governing access to genetic resources and sharing of benefits;
- (d) Trade practices and marketing laws;
- (e) Use of contracts and licenses;
- (f) Registers, inventories and databases;
- (g) Customary and indigenous laws and protocols;
- (h) Cultural heritage preservation laws and programs;
- (i) General law of civil liability and other remedies, such as rights of publicity, unjust enrichment, confidential information and blasphemy;
- (j) Criminal law.

12. These are not mutually-exclusive options, and each may, working together, have a role to play. Which modalities and approaches are adopted will also depend upon the nature of the TK to be protected, and the policy objectives that protection aims to advance.

Legl basis for protection

13. The main doctrines that have been used in their existing protection systems are:

(a) *the grant of exclusive property rights for TK*: the creation of property rights, giving the right to prevent others from certain use of the protected TK. Such rights may be communally or collectively held. Typically, including in existing *sui generis* systems, this entails the protection of certain aspects of TK which are susceptible to misappropriation, rather than a direct equivalence with all aspects of TK in its customary setting. This approach may include:

- (i) use of existing IP rights;
- (ii) modified, adapted or extended forms of conventional IP rights;
- (iii) *sui generis* measures granting newly defined exclusive property rights;

(b) *the application of the principle of prior informed consent*: this approach provides TK holders with the entitlement for prior informed consent (PIC) for the use, reproduction or commercial exploitation of their TK, and provides for benefit-sharing arrangements to be

established as a condition of access. Measures applying the PIC principle to TK are often part of a regime regulating access to genetic or biological resources;

(c) *a compensatory liability approach*: systems providing for some form of equitable remuneration or compensation to TK holders for the use of their TK, without creating an exclusive IP right over the TK. This is found in some national copyright and related rights systems, such as compulsory licensing arrangements for certain public uses of musical works. A compensatory liability approach for the protection of TK is found in the *sui generis* law of Peru, ‘in cases where the collective knowledge has passed into the public domain within the previous 20 years,’ in which case a payment is made into a common fund based on “a percentage of the value, before tax, of the gross sales resulting from the marketing of the goods developed on the basis of that knowledge.”¹⁶

(d) *an unfair competition approach*: the suppression of unfair competition and misleading or deceptive trade practices through the application of a cluster of principles such as truth-in-advertising, the protection of confidentiality, unjust enrichment, and passing off.

(e) *the recognition of customary law*: for Indigenous and local communities, the recognition and protection of TK is often rooted in customary laws and protocols, that govern how knowledge is generated, maintained and transmitted within the community, and the call has been made for TK protection to be based on enhanced respect for these customary laws. Several *sui generis* measures, as well as conventional IP law, have recognized elements of such customary law within a broader framework of protection.

14. There is considerable overlap between these different approaches, and the boundaries between them are not precise. Nonetheless, they are useful characterizations of the main general possibilities that have been used. Most existing *sui generis* systems combine at least two of these legal concepts. For example, some *sui generis* protection laws for TK regulate access and benefit-sharing for a broad range of TK and also provide for the grant of exclusive rights over a more confined span of TK.¹⁷ A compulsory liability regime or PIC regime (setting a rate of compensation for use of protected TK) could be combined with a right to exclude culturally offensive or degrading uses altogether. Customary law could be used in conjunction with any of the other doctrines to determine questions of ownership, sharing of benefits within the community, nature and degree of damages and other remedies, and means of dispute settlement.

Grant of exclusive rights over TK

15. A core characteristic of numerous intellectual property systems is the grant and exercise of exclusive property rights in the protected subject matter, and this is one option for TK that is sufficiently distinct and has a clear owner or custodian, even if this entails recognizing rights and entitlements that are communally or collectively held. Exclusive property rights in protectable elements of TK can be undertaken through (i) conventional forms of IP rights;

¹⁶ See WIPO/GRTKF/IC/5/INF/2, Annex II, page 14.

¹⁷ See African Model Legislation of 2000; Provisional Measure No. 2186-16 of 2001 of Brazil; Law No. 7788 of 1998 on Biodiversity of Costa Rica; Biological Diversity Act of 2002 of India; Law No. 27,811 of 2002 of Peru; Indigenous Peoples’ Rights Act of 1997 of the Philippines; and Decree Law No.118 of 2002 of Portugal.

(ii) amended forms of existing IP rights; or (iii) new *sui generis* rights which are tailored to suit the characteristics of TK subject matter and the interests of TK holders. This is the distinctive mechanism most associated with IP policy and legislation, and is common to most forms of IP protection, although other associated mechanisms (moral rights, rights to equitable remuneration or other compensation, standing as an aggrieved party to take action against unfair competition and similar wrongs) are also part of the broader architecture of the IP system.

Use of Conventional IP Rights

16. Although the limitations of existing IP laws have been widely underlined in the TK debate, conventional IP mechanisms have been effectively used to protect TK and related genetic resources. There are many examples of the successful use of existing IP rights to protect TK against misuse, misappropriation and commercial free-riding, including through the laws of patents, trademarks, geographical indications, industrial designs, and trade secrets.¹⁸ Certain modifications to IP law may improve its functionality in TK protection. For example, concerns have been expressed that TK holders have difficulty in availing themselves of the benefits of the IP system, because of the costs associated with the acquisition, maintenance and enforcement of IPRs. A number of improvements have been considered by the Committee to improve the access for TK holders to existing IP systems. These include legal evolution (including identifying the legal personality of traditional communities, altering evidentiary rules, altering the base of prior art used in assessing TK-related patents, revisiting the application of the concept of ‘person skilled in the art’ in assessing inventive step,¹⁹ and recognizing customary law), capacity building and appropriate dispute settlement mechanisms.

17. Existing IP rights have been used to protect TK or TK-related subject matter in the following ways:²⁰

- Geographical indications or collective/certification marks: these forms of IP have been used to protect products made with traditional technologies, including products that are particularly associated with a particular region or community (for example, Vietnam is establishing geographical indications to protect traditional Vietnamese pickled food products, which are associated with a particular region);
- Unfair competition and trade practices laws: such laws have been used to take action against false claims of indigenous authenticity or other claims that a product is produced by or associated with a particular traditional community;
- Patent rights: the patent system has been used by practitioners of traditional medicine to protect their innovations (for example, in 2002 China granted 4479 patents for Traditional Chinese Medicine (TCM) in China), and systems have

¹⁸ See WIPO/GRTKF/IC/3/7, WIPO/GRTKF/IC/4/7 and WIPO/GRTKF/IC/5/7 for a survey of existing uses of these IPR tools for TK protection in WIPO Member States.

¹⁹ See Asian Group submission, WIPO/GRTKF/IC/4/14.

²⁰ See ARIPO (WIPO/GRTKF/IC/4/15, para. 114), European Community (WIPO/GRTKF/IC/3/16, page 3, and WIPO/GRTKF/IC/1/8, Annex IV, page 6), Argentina (WIPO/GRTKF/IC/4/15, para. 158), the Republic of Korea (WIPO/GRTKF/IC/4/15, para. 155) and the United States of America (WIPO/GRTKF/IC/4/15, para.128).

been developed to ensure that illegitimate patent rights are not granted over non-novel TK subject matter;

- Trade mark rights: distinctive signs, symbols and terms associated with TK have been protected as trade marks, and have been safeguarded against third parties' claims of trade mark rights (for example, the logo for the Kyana Aboriginal Cultural Festival has been registered by the indigenous artist who created it²¹);
- Copyright and related rights: while extending only to the form of expression of TK, and not its ideas or content, copyright and related rights have been useful in protecting TK when it is recorded in a fixed form, or protecting against the illicit recording of TK, for instance when it may be passed on by the performance of a traditional chant, song or story (document WIPO/GRTKF/IC/6/3 deals with legal and policy options for the protection of traditional cultural expressions);
- The law of confidentiality and trade secrets: non-disclosed TK, including secret and sacred TK, has been protected as confidential or undisclosed information, and remedies have been awarded for breach of confidence in contravention of customary laws.

18. In its past work, the Committee has developed possible means for improving access of TK holders to existing IP rights systems. Ways of enhancing existing IP systems to take account of TK holder interests may include:²²

- Clarifying the legal identity and status as IP right holders of TK holders as individuals or as communities;
- Applying established principles such as protection of *ordre public* and morality in a manner that deals with concerns about offence to Indigenous and local communities;
- Clarifying the status of pre-existing TK as prior art and as unpatentable subject matter to ensure that third parties cannot obtain valid patents over such TK;
- Recognition of community interests and customary law considerations in determining sanctions, such as additional damages for cultural offence, in the enforcement of IP rights;
- Recognition of community interests and customary law considerations in giving standing to traditional communities on the basis of an equitable interest in a protected work;
- Tailoring alternative dispute resolution mechanisms to create appropriate and accessible avenues for TK holders to seek remedies.

For further details on these options see documents WIPO/GRTKF/IC/5/7 and WIPO/GRTKF/IC/5/8.²³

²¹ See Case Study 2, page 13 ('Use of Trade Marks to protect Traditional Cultural Expressions') in *Minding Culture: Case-Studies on Intellectual Property and Traditional Cultural Expressions*. See WIPO/GRTKF/STUDY/2.

²² See Asian Group (WIPO/GRTKF/IC/4/14, Annex, page 4, and WIPO/GRTKF/IC/4/15, para. 14), ARIPO (WIPO/GRTKF/IC/4/15, para. 114), the European Community and its Member States (WIPO/GRTKF/IC/3/16, page 3), France (WIPO/GRTKF/IC/5/15, para. 14), Japan (WIPO/GRTKF/IC/4/15, para. 129) and Switzerland (WIPO/GRTKF/IC/4/15, para. 135).

²³ See WIPO/GRTKF/IC/5/8.

Use of sui generis exclusive rights

19. In the judgement of some communities and countries, however, the above-mentioned adaptations of existing IP rights systems may not be fully sufficient to cater to the holistic and unique character of TK subject matter.²⁴ The call for *sui generis* measures generally arises from such perceived shortcomings of conventional IP rights. Surveys of national experiences with the IP protection of TK²⁵ have mentioned the following issues, which may be relevant to the development of *sui generis* measures:

(i) difficulty meeting requirements such as novelty or originality, and inventive step or non-obviousness (this may be due at least in part to the fact that TK often dates back prior to the time periods associated with conventional IP systems, or are developed in a more diffuse, cumulative and collective manner, making invention or authorship difficult to establish at a fixed time);

(ii) requirements in many IP laws for protected subject matter to be fixed in material form (given that TK is often preserved and transmitted by oral narrative and other non-material forms);

(iii) the frequently informal nature of TK and the customary laws and protocols that define ownership (or other relationships such as custody and guardianship) which form the basis of claims of affinity and community responsibility;

(iv) the concern that protection systems should correspond to a positive duty to preserve and maintain TK, and not merely provide the means to prevent or exclude others from making unauthorized use (the characteristic function of IP rights);

(v) the perceived tension between individualistic notions of IP rights (the single author or inventor), as against the tendency for TK to be originated, held and managed in a collective environment (often making it difficult to identify the specific author, inventor or analogous creator that IP law is viewed as requiring); and

(vi) limitations on the term of protection in IP systems (calls for better recognition of TK often highlight the inappropriate nature of relatively brief terms of protection in conventional IP systems, as need for protection are seen as enduring beyond individual life spans for TK subject matter).

20. In practice, some of these shortcomings have in fact been overcome within the conventional IP system (for example, providing for communally held rights in TK). Even so, for policymakers in a number of countries these factors have led to the judgement that *sui generis* measures should be considered.²⁶ Section IV below discusses the key elements of

²⁴ Regional organizations which have expressed such views include of African Group (WIPO/GRTKF/IC/4/15, para. 95, and WIPO/GRTKF/IC/3/15, Annex, page 3), ARIPO (WIPO/GRTKF/IC/4/15, para. 114), the European Community and its Member States (WIPO/GRTKF/IC/3/16, Annex, page 5, and WIPO/GRTKF/IC/5/15, para. 18), and the GRULAC (WIPO/GRTKF/IC/4/15, para. 12). For statements to this effect by individual countries, see China (WIPO/GRTKF/IC/4/15, para. 134), France (WIPO/GRTKF/IC/5/15, para. 14), India (WIPO/GRTKF/IC/5/15, para. 100), New Zealand (WIPO/GRTKF/IC/3/17, para. 230), Norway (WIPO/GRTKF/IC/4/15, para. 133), Turkey (WIPO/GRTKF/IC/4/15, para. 109), Venezuela (WIPO/GRTKF/IC/5/15, para. 98), Zambia (WIPO/GRTKF/IC/5/15, para. 19 and WIPO/GRTKF/IC/4/15, para. 100). See also United Nations University (WIPO/GRTKF/IC/5/15, para. 103).

²⁵ See WIPO/GRTKF/IC/5/7.

²⁶ See African Group (WIPO/GRTKF/IC/3/15, Annex, page 3), the European Community and its Member States (WIPO/GRTKF/IC/5/15, para. 18), Canada (WIPO/GRTKF/IC/4/15, para. 142),

sui generis measures, which would have to be considered in the development of any national system or any agreed model for protection. In cases where the grant of exclusive property rights – be they conventional IP rights or *sui generis* exclusive rights – may not be appropriate, the three other policy tools for TK protection may be considered, namely the prior informed consent principle, liability rules and unfair competition law. If the choice were taken to establish a stand-alone exclusive right in TK *per se*, this right would need to be communally held and exercised, associated with certain well-defined subject matter, and create the entitlement to take legal action to exclude third parties from certain prescribed uses of the protected TK.

TK and prior informed consent

21. Regulation of TK is often linked with the regulation of access to tangible biological material and benefit-sharing. Under such regimes, access or other acts in relation to TK may be dependent on the prior informed consent (PIC) of the TK holders, and contracts, licenses or agreements may determine how benefits arising from the use of the TK are shared. At its sixth session, the Committee supported PIC as a general principle of a combined approach of TK protection.²⁷ The application of the PIC principle to TK enables a regulatory option to control the use of TK by third parties and ensure a flow of benefits to the knowledge holders, in a way that may be consistent with the collective nature of TK. Numerous Committee members have therefore integrated PIC into their TK protection measures or their policy statements.²⁸ PIC may be granted by a competent State authority;²⁹ or it may be dependent on the direct consent of the indigenous/local community or TK holder.³⁰ Conditions for the grant of PIC may differ according to the proposed use of the TK.³¹ Continuing access for

[Footnote continued from previous page]

Egypt (WIPO/GRTKF/IC/4/15, para. 153), Ghana (WIPO/GRTKF/IC/4/15, para. 149), Guyana (WIPO/GRTKF/IC/4/15, para. 143), Haiti (WIPO/GRTKF/IC/4/15, para. 154), Morocco (WIPO/GRTKF/IC/4/15, para. 152), Myanmar (WIPO/GRTKF/IC/5/15, para. 16), New Zealand (WIPO/GRTKF/IC/4/15, para. 138), Panama (WIPO/GRTKF/IC/4/15, para. 157), Venezuela (WIPO/GRTKF/IC/4/15, para. 147), Inuit Circumpolar Conference (WIPO/GRTKF/IC/4/15, para. 159), Mejlis of the Crimean Tartar Peoples (WIPO/GRTKF/IC/4/15, para. 162).

²⁷ See, WIPO/GRTKF/IC/6/4, para. 21.

²⁸ See, African Group (WIPO/GRTKF/IC/1/10, Annex, page 6, proposal 3.3(b)), Brazil (WIPO/GRTKF/IC/2/14, Annex, para. 15), Colombia (WIPO/GRTKF/IC/3/17, para. 223), Peru (WIPO/GRTKF/IC/3/17, para. 221) South Africa (WIPO/GRTKF/IC/3/17, para. 225), Venezuela (WIPO/GRTKF/IC/3/17, paragraph 213).

²⁹ See Art.4 (1)(xi) and 4(1)(x), African Model Law; Art.11 (IV)(b), Brazilian Provisional Measure; Art.62, Costa Rican Biodiversity Law; Art.3(1), Indian Biodiversity Act; Art.7(1), Portuguese Decree Law 118.

³⁰ See, African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders (2000); Brazilian Provisional Measure Regulating Access to the Genetic Heritage, Protection of and Access to Associated Traditional Knowledge; Costa Rican Biodiversity Law No. 7788; Peruvian Law No. 27,811 Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources; and Portuguese Decree Law No. 118 of 2002.

³¹ Laws of Peru and Portugal (as above-mentioned in foot note No. 71).

customary uses of TK may be expressly exempted from the requirement for prior informed consent.³²

3. Compensatory Liability Regimes

22. Suggestions have also been made for TK-specific innovation laws, built on modified liability principles. Such laws would entitle TK holders to compensatory contributions from TK users who borrowed traditional know-how for industrial applications of their own during a specified period of time. Some *sui generis* regimes utilize similar rules to reward TK holders for the conservation and development costs invested by the communities in certain elements of TK, without endowing exclusive property rights to control such uses.³³ They would combine the equitable reallocation of benefits without constraining open access to know-how, and avoid the division or atomization of the community's shared TK base into ever-smaller parcels that are withdrawn from the TK holding community's own intellectual commons through the vehicle of private property rights. In some cases, there is concern that a web of exclusive rights over pre-existing TK, overlaying communal customary laws, could stand in tension with collective transmission and custodianship. The compensatory liability approach has also been used in cases where TK has already been published and publicly available for some time, so as to balance equitable benefit-sharing with prior use of TK undertaken in good faith.³⁴ Compensatory liability concepts for TK had been suggested by the think tanks and governmental research services of numerous member states³⁵ and have been proposed by several Committee members and regional groups during the Committee's discussions.³⁶ Concepts of this kind are generally considered to be closely related to the law of unfair competition, as has been described in the literature on liability principles.³⁷

Repression of unfair competition

23. While the repression of unfair competition has been recognized since 1900 as an object of industrial property protection under the Paris Convention³⁸, it does not grant exclusive rights over intangible property to the right holder. The law of unfair competition, construed in the broadest sense, covers a wide range of remedies, including repression of misleading and deceptive trade practices, unjust enrichment, passing off, and taking of unfair commercial advantage. Unfair competition law is potentially broad in scope, and it has been used in

³² Art.2(2)(ii), African Model Law, and Art.7, Indian Biodiversity Act.

³³ See Peruvian Law No. 27811 of August 10, 2002.

³⁴ See, GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 2), Panama (WIPO/GRTKF/IC/4/15, para. 157) and Peru (WIPO/GRTKF/IC/6/INF/6 and Peru WIPO/GRTKF/IC/3/17, para. 221).

³⁵ See, for example, American Law Division (Ackerman et al.), *Biotechnology, Indigenous Peoples and Intellectual Property Rights*, Congressional Research Service. United States of America, (April 16, 1993) at 65 and footnote 280. See document WIPO/GRTKF/IC/7/5, para. 79, for a more detailed description of the findings of the Congressional Research Service and the suggestions of the Director of the American Folklife Center on compensatory liability principles.

³⁶ See, GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 2), Panama (WIPO/GRTKF/IC/4/15, para. 157).

³⁷ See, for example, Reichman, J. Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation. 53:6 *Vanderbilt Law Review* at 1743.

³⁸ See Art.1(2) and Art.10*bis*, Paris Convention.

international instruments as a potential basis for protection of integrated circuit layout designs, geographical indications, undisclosed information and test data, and phonograms; in practice, it is also associated with the protection of trade marks, especially unregistered marks. As in other industrial property systems, it has therefore been discussed and used as a tool for *sui generis* systems of TK protection,³⁹ which supplements the grant of exclusive rights and the application of PIC for TK subject matter. This is the case, for example, in several *sui generis* measures, which apply a truth-in-advertising approach to the marketing of indigenous craft products⁴⁰. The courts have also applied general unfair competition laws.

Customary laws and protocols

24. With each of these possible policy tools special attention must be given to the recognition of customary laws and protocols, which functions as a cross-cutting interface with local legal systems in all the above-mentioned tools.⁴¹ A number of existing *sui generis* systems utilize references to customary laws and protocols as an alternative or as a supplement to the creation of modern IP rights over TK. For example, the African Model Law and the *sui generis* laws of Peru and the Philippines incorporate by reference certain elements of customary laws into the *sui generis* protection of TK. The relation between modern *sui generis* laws and customary laws ranges from the principle of independence of the rights granted by the modern and traditional systems (Peru) to the principle that the State protects rights specified in the modern *sui generis* legislation “as they are enshrined and protected under the ... customary law found in ... the concerned local and indigenous communities, whether such law is written or not” (African Model Legislation). The substantive use of customary laws ranges from obtaining Prior Informed Consent for access to TK “in accordance with customary laws” (Philippines), over the settlement of disputes arising among indigenous peoples in the implementation of TK protection (Peru), to the identification, interpretation and ascertaining of “community, knowledge or technology ... under their customary ... law” (African Model Law).

25. Even though the policy discussions surrounding customary laws and TK protection have been extensive, actual references to customary laws in existing *sui generis* laws have, to date, been fairly limited. Most existing *sui generis* laws do not contain direct references to customary laws, although recognition of customary law may be important in their practical implementation.

³⁹ See GRULAC (WIPO/GRTKF/IC/1/5, Annex I, page 2), South Africa (WIPO/GRTKF/IC/5/15, paragraphs 116 and 129), and the United States of America (WIPO/GRTKF/IC/3/17, para. 213).

⁴⁰ See, for example, the Indian Arts and Crafts Act of 1990 of the United States of America.

⁴¹ See document submission of the African Group (WIPO/GRTKF/IC/1/10, Annex, page 6, proposal 3.3(b)). See the statements of the African Group (WIPO/GRTKF/IC/4/15, para. 95 and WIPO/GRTKF/IC/3/5, Annex, page 5), European Community (WIPO/GRTKF/IC/1/8, Annex IV, page 6), Iran (WIPO/GRTKF/IC/4/15, para. 150), Switzerland (WIPO/GRTKF/IC/1/9, Annex, pages 4 and 9), Peru (WIPO/GRTKF/IC/3/17, para. 221), South Africa (WIPO/GRTKF/IC/3/17, para 225), Venezuela (WIPO/GRTKF/IC/3/17, paragraph 213), Saami Council (WIPO/GRTKF/IC/5/15, para. 76), Indigenous Peoples’ Biodiversity Network (WIPO/GRTKF/IC/4/15, para. 160)

Expression of general guiding principles in national laws

26. The general guiding principles suggested in document WIPO/GRTKF/IC/7/5 have been applied in various forms in national laws. Several specific examples are given here:

(i) *The principle of recognition of rights.* The Peruvian Law provides under Article 1 (Recognition of rights): “The Peruvian State recognizes the rights and power of indigenous peoples and communities to dispose of their collective knowledge as they see fit.” The Brazilian Measure (Article 8) provides that “Traditional knowledge of indigenous and local communities relating to the genetic heritage is protected by this Provisional Measure against illegal use and exploitation and other actions that are harmful or have not been authorized by the Management Council referred to in Article 10 or by an accredited institution. The State recognizes the right of indigenous and local communities to decide on the use of their traditional knowledge associated with the genetic heritage, as provided in this Provisional Measure and the regulations under it.”

(ii) *The principle of equity and benefit-sharing.* The Brazilian Measure provides for “the benefits, rights and obligations concerning ... the fair and equitable sharing of the benefits deriving from exploitation of components of the genetic heritage and the associated traditional knowledge.”

B. LEGAL ELEMENTS OF PROTECTION OF TK

27. This section sets out the specific legal provisions that have been developed and used in national and regional laws and legal systems, corresponding in general to the substantive principles, describing the legal essence of protection, that are suggested in WIPO/GRTKF/IC/7/5.

28. The scope of the rights will determine the degree of control which the right holder will be able to exercise over the protected TK.⁴² It defines what activities the right holder is entitled to prevent, and what exceptions may limit the exercise of such rights. Potential rights over TK may include the entitlement to prevent:

- unauthorized access to, recording of or disclosure of the protected TK;
- unauthorized commercial use of the protected TK;
- third party IP claims over protect TK subject matter;
- culturally offensive, degrading or inappropriate use of TK material;
- a form of moral right, such as rights to integrity and attribution of source of TK; or
- misleading or deceptive practices relating to the use of TK, and other forms of unfair competition associated with TK such as unjust enrichment, taking inequitable commercial advantage or slavish imitation.

29. Such rights or entitlements need not require stand-alone *sui generis* property rights, and have typically been implemented in a range of national laws by various combinations of the above-mentioned foundational legal doctrines. TK holders need not be identified as distinct right holders in order to have the entitlement to exercise rights, which may be open to any

⁴² For technical comments on the appropriate scope of rights and exceptions see Norway (WIPO/GRTKF/IC/4/15, para. 133) and Thailand (WIPO/GRTKF/IC/3/17, para.135).

aggrieved or interested party, including community representatives and government authorities.

The rights available to TK holders may also vary according to the nature of the knowledge held. The laws of Costa Rica and India provide that the scope of rights shall be determined in due course by the National Competent Authority, in the case of Costa Rica through a consultative process. Three laws grant two different sets of rights with differing scope: the African Model Law grants ‘community intellectual rights’ and farmers’ rights which have different scopes, and the laws of Peru and Portugal grant a wider scope of rights if TK has remained undisclosed, has not entered into the public domain, or has commercial novelty. Ideally, the scope of protection should also recognize communities’ customs and traditions involving the permission for individuals to use elements of TK, within or outside the community concerned, as well as issues concerning ownership, entitlement to benefits, damages and dispute settlement.⁴³

30. Like all other IP rights (as well as all other private property rights), rights in TK may be limited or qualified so as to avoid unreasonable prejudice to the interests of society as a whole, and other legitimate interests. Rights over TK subject matter may, therefore, be subject to exceptions, such as the use by third parties for academic or purely private purposes, or compulsory licenses on grounds of public interest. Exceptions or limitations may also deal with the interests of third parties who develop follow-on innovations based on TK, similar to arrangements for dependent patents. In general, potential exceptions and limitations to the granted rights include:

- the exemption of traditional exchange systems of TK among communities;
- research, personal and other non-commercial use;
- measures necessary for the preservation and development of TK, and the promotion of traditional innovation;
- production of traditional medicines for household use or use in public health facilities;
- continuing prior use in good faith by third parties;
- no limitations or prejudice to other IP rights; and
- an exemption of customary use from the scope of rights granted.

31. The options for setting the scope of rights to be provided by TK protection measures include:

- defining the scope of rights by specifying what third party activities in relation to the protected TK which the right holder or aggrieved party is entitled to restrain;
- clarifying how different tiers of rights may need to be recognized for different categories of TK that fulfill different criteria;
- providing for some aspects of the scope of rights to be determined through a consultative process with TK holders in the course of the implementation of possible measures, including references to customary law requirements; and

⁴³ Those customs and traditions could be described and recorded together with the elements of TK, so that legal security could be created not only as regards the appropriated elements of TK themselves, but also in connection with their sharing within the communities. For instance, see Panama’s *sui generis* law.

- defining appropriate exceptions and limitations to the scope of rights, such as the exemption of customary use of TK, conservation activities, and research activities.

General scope of subject matter: approaches to definition

(a) *Approaches to defining core IP concepts*

32. Discussion of IP-related definitions of TK may be assisted by consideration of how core concepts are defined and applied in other IP systems. International harmonization, standard-setting and cooperation across the field of IP have not, overall, been dependent on the determination of definitive, exhaustive definitions of the subject matter of protection. There has been a tendency to leave specific determinations of the boundaries of protectable subject matter up to domestic authorities, and for terminology at the international level to be used more to express a common policy direction. This applies equally whether the legal instrument under consideration is binding or non-binding, an expression of principles, a set of guidelines, or firm rules that aim at coordinating or harmonizing national systems of protection.

33. Accordingly, a general definition of the subject matter of IP protection, especially at the international level, can be distinguished from the more precise tests that are developed and applied case-by case at the national (or regional) level, using interpretative principles based in domestic law. In some instances, individual objects of IP-related protection can be defined in direct and explicit terms at the international level (for example, State emblems and official signs notified under the Paris Convention⁴⁴), but for most categories of IP protection, the approach taken to defining subject matter is more general and remains open to distinct interpretation and application at the national level.

34. The way relevant IP subject matter is identified may also be influenced by the policy objectives of the legal instrument. International instruments on IP protection have addressed various objectives, such as:

- creation of reciprocal rights, involving mutual recognition of foreign nationals' rights to protection under national systems, effectively a guarantee of access for foreign nationals to the national IP system in line with the applicable national standards;
- establishment of agreed minimum standards for protection, so that there is a guarantee of a certain level of protection for eligible subject matter; and
- coordination of specific protection, so that there is convergence in the scope of specific IP rights.

35. The degree of precision in the definition of protected subject matter can vary according to which of these objectives applies. For instance, the Paris Convention defines 'industrial property' in explicitly broad terms⁴⁵ and does not define specific terms such as 'patents' and

⁴⁴ Following notification of such material under Article 6*ter* of the Paris Convention for the Protection of Industrial Property.

⁴⁵ Article 1(3) provides that: 'Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive

[Footnote continued on next page]

‘trademarks.’ Yet this is not a barrier to the effective operation of the international instrument, precisely because the protection which it coordinates or harmonizes still has its operational effect in domestic law, and the specific rights granted in different jurisdictions are intended to be independent of one another.⁴⁶ Hence the need for the use of an exhaustive definition may only arise at the domestic level. Even though it may be considered desirable to promote convergence and predictability in the operation of national IP systems, an international instrument need not aim to ensure that different national systems grant individual IP rights that are identical in scope, as an end in itself.

36. The definition of IP-related subject matter may also be expressed very generally when the definition does not determine or delimit the actual scope of protection to be granted under law. It is possible to define relevant subject matter in broad terms, and then separately to specify what distinct subset or portion of that material is actually eligible for legal protection. In other words, defining subject matter that is generally relevant and defining the exact scope of protected subject matter can be separate conceptual steps. The second step, of determining exactly which portion of the general subject matter is to be protected, can be taken by applying specific eligibility criteria, by making explicit exclusions to the scope of protectable subject matter, or by referring to specific categories of subject matter. Commonly, some or all of these approaches are adopted in the same legal instrument.

37. Hence ‘invention,’ the object of patent protection in most countries,⁴⁷ tends to be defined broadly in legal instruments (and is not defined at all in key international instruments such as the Paris Convention and the WTO TRIPS Agreement).⁴⁸ Whether protection is actually to be afforded under patent law depends on whether the claims are directed to an invention broadly defined, and on whether the claims also specifically comply with the criteria of novelty, non-obviousness and utility.⁴⁹ Some inventions can also be excluded for policy reasons, such as inventions which would otherwise be eligible for patent protection but are deemed to be contrary to *ordre public*. Specific provisions can be made to clarify that certain technologies are included within or are excluded from the definition of patentable subject matter, setting aside any interpretative uncertainty.

[Footnote continued from previous page]

industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.’

⁴⁶ See, for instance, Articles *4bis* and 6(3) of the Paris Convention.

⁴⁷ In the United States, discoveries, under some strict circumstances, are also patent subject matter. See 35 U.S.C. §§ 100(a) and 101.

⁴⁸ See document WIPO/GRTKF/IC/1/3, paragraph 65.

⁴⁹ To some extent, it could be argued that these criteria are overlapping with the inherent notion of ‘invention.’ However, it is possible for an invention, so defined, to fail to meet the criteria, for instance for want of novelty or utility. The reverse engineering of a technique that the emulator ignored had been previously disclosed is an invention, in spite of not being new. The only criterion that is actually overlapping with the notion of ‘invention’ is non-obviousness. There are no obvious inventions. But there are inventions that are more inventive than others. In other words, in contrast with the two other criteria, non-obviousness is a relative one. Patentability depends on the amount of level of inventiveness. If correctly worded, a statutory provision on patentability should actually read: “patents shall be available for any invention provided that it is new, *involves a sufficient inventive step* and is useful.”

38. Similarly, the general object of copyright protection ('literary and artistic works') is defined in broad terms in Article 2(1) of the Berne Convention (it 'shall include every production in the literary, scientific and artistic domain...'), but the actual scope of protected subject matter is defined by specific conditions, such as the need for originality and for material fixation; and it is possible to specify that certain subject matter is deemed to be protectable (such as the requirement that computer programs be protected as literary works⁵⁰), thus confirming how the general definition is applied in that specific case.

39. In IP systems, there is often a dynamic linkage between the definition of subject matter and the actual scope of protection, so that the way the definition is applied is guided by the policy rationale for the particular IP protection. Indeed, in some jurisdictions it can be more instructive to look at decided case law than at the formal statutory definition to get a sense of the actual scope of the definition in practice. The definition of relevant subject matter is often informed and molded by consideration of the policy objectives of the IP law in question, and so an operational definition needs to take account of the policy context in which the subject matter is defined and protected. For instance, trademark rights are typically defined with reference to the way a sign is used by commercial undertakings and is perceived in the marketplace, rather than its use or perception in non-commercial contexts, because trademark law generally aims to promote fair competition between traders and to prevent confusion or deception of consumers. The sign generally needs to be used in a commercial context to function as a trademark. If the same sign were used in a different, non-commercial context it may not be subject to trademark law, since the policy focus is on the commercial sphere.

40. What does this mean for definitions of 'traditional knowledge' and related terms? A relatively general approach to definition may be called for in relation to traditional knowledge as the subject matter of protection, in contrast to the areas of intellectual property already surveyed here. TK subject matter is particularly dynamic and variable, and more likely to be shaped by local, cultural factors than other forms of IP. Moreover, there have been calls in the work of the Committee for there to be some recognition of customary law⁵¹ as an element in the definition and protection of TK. If there is to be reflection of customary law in the characterization of traditional knowledge, this would necessarily involve a more general form of definition at the international level, given the diverse and distinct quality of customary laws; equally, if weight is to be given to local cultural factors, this could also entail a general umbrella definition at an international level. This general approach was foreshadowed in document WIPO/GRTKF/IC/1/3 (itself echoing comments in the 'WIPO Report on Intellectual Property Needs and Expectations of Traditional Knowledge Holders'⁵²):

"Given this highly diverse and dynamic nature of traditional knowledge it may not be possible to develop a singular and exclusive definition of the term. However, such a singular definition may not be necessary in order to delimit the scope of subject matter

⁵⁰ WIPO Copyright Treaty, Article 4 and TRIPS Agreement, Article 10.1.

⁵¹ See document WIPO/GRTKF/IC/2/16, at paragraphs 90, 94, 100, 108, 152

⁵² WIPO, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999)* (WIPO, 2001)

for which protection is sought. This approach has been taken in a number of international instruments in the field of intellectual property.”⁵³

(b) *National approaches to defining TK*

Since the present document merely describes the policy options and legal mechanisms that would operate at the national level in line with the objectives and principles set out in document WIPO/GRTKF/IC/7/5, this section illustrates various approaches taken in national legal systems to the definition of traditional knowledge. The section illustrates such approaches by referring to four different *sui generis* statutes (see Annex II for summaries of each law). This discussion is not intended to interpret or analyse the legal provisions in themselves, nor to assess the value or validity of any particular approach, but to illustrate the policy options concerning the definition of ‘traditional knowledge.’ The full text of the four laws is provided in document WIPO/GRTKF/IC/5/INF/2.

41. Article 7(II) of the Brazilian statute (Provisional Measure No. 2.186-16, of August 23, 2001) defines associated TK as follows:

“Associated traditional knowledge: information or individual or collective practices of an indigenous or local community having real or potential value and associated with the genetic heritage.”

42. The first impression is that the scope of protection of TK — and, consequently, the very concept of TK as well — is limited to knowledge that is associated to the Brazilian genetic heritage, which corresponds, more or less, to the genetic information contained in biological diversity. As noted above, a general notion of TK might include not only knowledge itself, but also the expressions of the traditional knowledge, such as verbal or musical expressions, expressions by action (such as dances), whether or not reduced to a material form, and tangible expressions (such as drawings, paintings, carvings), musical instruments and architectural forms.⁵⁴ Those traditional expressions may be (and are frequently) associated with the physical environment of Indigenous peoples and traditional communities, and therefore are not easily separable from the knowledge they express. However, this particular definition provides that “associated traditional knowledge” consists of “information or individual or collective practices.” Besides, the Brazilian statute deals basically with access to genetic resources. This suggests that the protected “associated traditional knowledge” is mainly technical knowledge about the uses of genetic resources. It may be, however, that the definition could extend to cover the situation when that knowledge is conveyed through TCEs/expressions of folklore. The definition above contains two additional elements: the requirement that the knowledge be either created or in control of indigenous and local communities; and the stipulation that the knowledge should have real or potential value, which is relevant to the entitlement of TK holders to sharing of benefits, even if the value of the associated TK is to be developed or realized at a later stage.

⁵³ See document WIPO/GRTKF/IC/1/3, paragraph 65

⁵⁴ See WIPO/UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions.

43. The *sui generis* statute of Panama does not attempt an exhaustive definition of TK.⁵⁵ Instead, it lists some examples of TK subject matter and identifies a few elements that make such subject matter eligible for legal protection. TK, therefore, may consist of “inventions, models, drawings and designs, innovations contained in pictures, figures, symbols, illustrations, old carved stones, and others; likewise, the cultural elements of [...] history, music, art and traditional expressions.” The scope of this concept is, therefore, very broad, and appears to comprise “technical” TK as well as expressions of TK.⁵⁶ This law has two additional elements: first, only TK that is owned by indigenous communities shall be protected; second, TK must be “capable of commercial use.” TK that is not susceptible of commercial use may eventually be protected under other provisions of Panama’s legislation, but not under the *sui generis* system of registration and protection of Law No. 20.

44. Article 2(b) of Law No. 27811 of Peru defines “collective knowledge” as
“the accumulated, transgenerational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity.”

45. The scope of Peru’s statute is thus limited to TK that is (a) collective; (b) accumulated and transgenerational; (c) created by indigenous peoples and communities; (d) concerning properties, uses and characteristics of biodiversity components. This definition restricts the scope of protected material according to its subject matter (relating to biological diversity), its source or origin (evolved by indigenous peoples and communities), and its relationship with tradition (TK must be accumulated and transgenerational). This link with a knowledge tradition need not imply that the definition is limited only to TK that has been created several generations ago and has already been transmitted from generation to generation. If so, the law would deny protection to TK that will be created by indigenous communities in the future. Rather, it suggests that TK is knowledge that is (or has been, or will be) created according to the traditions of a community. Thus, the words “accumulated and transgenerational” may essentially refer to subject matter created in the past,⁵⁷ but they may also link new (or future) knowledge to the transgenerational culture of the community, construing new insights as further accumulation of that tradition. Traditions are the thread of Ariadne that links today’s TK to the past and future of Indigenous peoples and traditional communities.

46. Article 3(1) of Portugal’s Decree-Law No. 118/2002 contains a more detailed definition of TK:

“Traditional knowledge is all the intangible elements associated to the commercial or industrial use of local varieties and other endogenous material developed by local communities, collectively or individually, in a non-systematic manner and that are inserted in the cultural and spiritual traditions of those communities, including, but not limited to, knowledge relating to methods, processes, products and denominations that

⁵⁵ See Law No. 20, of June 26, 2000, Article 1.1.

⁵⁶ However, Article 3 of Law No. 20, which deals with “Objects Susceptible of Protection” leans very clearly to a much narrower approach, and focuses essentially on handicrafts and associated expressions of folklore. Undoubtedly, handicrafts have a technical substract, and the associated techniques must indeed be described as a condition for their registration with the authority in charge.

⁵⁷ The law of Peru establishes some criteria for assessing the “novelty requirement.” See *infra* paragraphs 87 *et seq.*

are applicable in agriculture, food and industrial activities in general, including handicrafts, trade and services, informally associated to the use and preservation of local varieties and other endogenous and spontaneous material that is covered by the present law.”

This definition is limited to TK that is associated to local plant varieties (both wild varieties and landraces). Within that relatively narrow technical area, TK may consist of a wide range of knowledge. The provision above is not exhaustive as the expression “including, but not limited to” indicates. The other elements designated for identifying protectable TK are: TK may be either of a collective or an individual nature; but its creation must be “traditional” in the sense that it must be (i) non-systematic, and (ii) inserted in the cultural and spiritual tradition of the traditional communities. In other words, in spite of protecting TK owned by individuals, TK must have had a collective (or community-related) origin. Whether the individual TK may have kept its links (the “thread of Ariadne”) with the cultural traditions of the community from which it originated is a matter to be decided under customary law.

47. The reference to the non-systematic manner of creating TK, as mentioned in the Portuguese law, has been the subject of the following analysis in document WIPO/GRTKF/IC/4/8:

“The fact that TK is created in a distinctively cultural context also gives rise to another important characteristic: in essence, to understand the full nature of TK or simply even to record or define it, it may be necessary to understand the cultural influences that shape it. Whether or not TK is produced within a formal or systematic tradition, or in a more informal or ad hoc context, it tends to be developed in a way that is closely related to the immediate environment in which traditional communities dwell, and to respond to the changing situation of that community. In that regard, it can have an empirical or trial-and-error basis. Yet TK may be developed in accordance with systems of knowledge, and be incorporated into systematic concepts and beliefs. Culturally-based rules may apply to the way innovation proceeds. Yet the way TK is created may appear from an external or universal perspective to be non-systematic or unmethodical, partly because the rules or system governing its creation can be passed on in an informal or cultural manner, partly because the systematic element is not explicitly articulated, and partly because the process leading to the creation of TK may not be formally documented in the way that much scientific and technological information is recorded. The apparent non-systematic manner of creation of TK does not diminish its cultural value or its value from the point of view of technical benefit, and raises the question of how to record or define its relationship with the culturally-specific knowledge system, set of rules or guidelines, or set of background beliefs which help shape it. As with the “tradition-based” characteristic, the apparent “non-formal” characteristic leads to particular emphasis on the context in which is created, and the potential need for elements of this cultural context to be considered along with the knowledge *per se*.”⁵⁸

(c) *Evolution and use of an existing possible working definition of TK*

48. The WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) contains a definition of TK that uses the two approaches taken by the

⁵⁸ At paragraph 30.

statutes above referred to: on the one hand, a list of possible subject matters if provided; and, on the other hand, some elements necessary for TK' characterization are indicated. The definition is the following:

“WIPO currently uses the term “traditional knowledge” to refer to tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields. “Tradition-based” refers to knowledge systems, creations, innovations and cultural expressions which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment. Categories of traditional knowledge could include: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; biodiversity-related knowledge; “expressions of folklore” in the form of music, dance, song, handicrafts, designs, stories and artwork; elements of languages, such as names, geographical indications and symbols; and, movable cultural properties.”⁵⁹

49. This working definition was cast deliberately very broadly, fittingly for a fact-finding and consultative process. Notably, it includes both the knowledge itself, and expressions of traditional culture or folklore. The stipulation that knowledge be ‘tradition-based’ is explained with reference in particular to transgenerational transmission (similar to the definition in the Peruvian law cited above) and a link to a particular community or territory. It recognises, too, that knowledge will evolve in response to the environment, and that this can be part of its traditional characteristic.

50. This working definition of traditional knowledge may need to be focussed or refined for specific forms of international cooperation. In particular, the Committee has maintained a distinction between TK *stricto sensu*, and traditional cultural expressions, reflecting the different modes of protection and different policy objectives that may apply to such subject matter. As has been noted, how a working definition of TK is to be framed will be influenced by its practical purpose. For instance, when the definition forms part of a TK protection system that gives effect to the Convention on Biological Diversity, the concept of TK will be naturally adapted to that purpose. Thus the laws of Brazil, Peru and Portugal variously limit the definition of TK with reference to genetic heritage, biological diversity or local plant varieties, and focus on technical TK in the strict sense of actual knowledge rather than the form of its expression. In contrast, the law of Panama is much broader, and comprises both technical TK and expressions of TK.

51. These examples illustrate that TK is an encompassing notion which covers several, if not many, areas of human creativity. Thus, to attempt to establish a concept based on a list of covered subject matters may be not very effective, either because areas that have no relation one to another may be included (which may be confusing) or because the list will necessarily be incomplete. On the other hand, the identification of characteristics of TK as subject matter

⁵⁹ *Intellectual Property Needs and Expectations of Traditional Knowledge Holders*, WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) (WIPO Publication 768E), at 25.

of protection, although more accurate, may be limited to the extent it will reflect national approaches rather than an international one. In a document that seeks a composite view of TK, it may make sense to attempt to provide for a more general and comprehensive definition of TK.

(d) *Proposal for a comprehensive working definition of TK*

52. The Committee has generally made use of the term ‘traditional knowledge’ at two levels: as a general, umbrella term (*lato sensu*) and as a specific term denoting the subject of specific IP protection focussed on the use of knowledge (*stricto sensu*). There is also an established working distinction between TK *stricto sensu*, which refers to knowledge as such as the object of protection, and traditional cultural expressions (and the synonymous term expressions of folklore).

53. As a broad characterization, TK *lato sensu* can be understood as ‘the *ideas and expressions thereof* developed by traditional communities and Indigenous peoples, in a traditional and informal way, as a response to the needs imposed by their physical and cultural environments and that serve as means for their cultural identification.’ TK *lato sensu* becomes a convenient umbrella term covering both aspects of protection of TK *stricto sensu* and TCEs⁶⁰ (in this broader sense, it goes beyond ‘knowledge’ as such). Some objects of protection touch simultaneously upon those two distinct fields of IP, such as technical creations that have an aesthetic character. For instance, many handicrafts have a utilitarian function, having been developed with a utilitarian purpose and giving effect to a technical idea, but may acquire an additional aesthetic quality. Either because of their use in religious services and other spiritual events, or because of their general association with a culture and a community, handicrafts may become more important as a cultural expression than simply as the product of a technical idea. In this vein, handicrafts may embody TK *stricto sensu* or may be viewed as expressions of TK or TCEs. This lack of a clear distinction about the application of different legal regimes to the same underlying subject matter is not new in IP law. Indeed, industrial designs may be protected under the law of industrial property,⁶¹ the law of copyright,⁶² or both,⁶³ and each of these options has been applied to TCEs (i.e. for TK protection *lato sensu*).

54. Assuming that a definition “is not aimed at prescribing exactly what portion of knowledge is to be given legal protection ... and does not itself define the nature of protection,” then a definition of ‘traditional knowledge’ in the narrower sense (*stricto sensu*) and in the context of IP protection might concern “knowledge which is:

- generated, preserved and transmitted in a traditional context;

⁶⁰ For a discussion on the meaning, scope and nature of “traditional culture expressions,” see documents WIPO/GRTKF/IC/3/10, paragraphs 88 to 109, and WIPO/GRTKF/IC/4/3, paragraphs 23 to 35. It should be noted that this definition is offered with full understanding that the term “traditional knowledge” constitutes a misnomer, in the sense that it covers more than knowledge in a strict sense.

⁶¹ Paris Convention, Articles 1(2) and 5^{quinquies}.

⁶² Berne Convention, Article 2(1).

⁶³ TRIPS Agreement, Article 25.2.

- distinctively associated with the traditional or Indigenous culture or community which preserves and transmits it between generations;
- linked to a local or Indigenous community or other group of persons identifying with a traditional culture through a sense of custodianship, guardianship or cultural responsibility, such as a sense of obligation to preserve the knowledge, or a sense that to permit misappropriation or demeaning usage would be harmful or offensive, a relationship that may be expressed formally or informally by customary law;
- knowledge in the sense that it originates from intellectual activity in a wide range of social, cultural, environmental and technological contexts; and
- identified by the community or other group as being traditional knowledge.”⁶⁴

55. This definition draws on a number of the themes in the analysis of existing laws noted above, although it does not tie the definition to one particular policy goal or subject area of knowledge (such as biodiversity or medicinal health). This is proposed as a general and more neutral definition of TK that concentrates on knowledge as such (i.e. the content, substance or idea of knowledge, technical know-how and culture), rather than its form of expression (which may be the subject of distinct protection, including copyright and *sui generis* TCE protection): although the scope of protection may effectively extend to the form of expression of the TK, this maintains the essential distinction between protection of content and protection of the form of expression, a distinction that has deep roots in the structure of intellectual property law.

56. These approaches to definition highlight certain key qualities of TK that distinguish it from general forms of knowledge and from TCEs as objects of protection in their own right.

(a) the context of creation: traditional knowledge must clearly be traditional: this refers to the context of its creation, preservation and transmission, so that TK originates in a way that makes it inseparable from the culture and the identity of the community; this can be defined as creation ‘in a traditional and informal context,’ but may also relate to how the knowledge has been preserved and passed down between generations. This aspect overlaps with the sense of a link to the community.

(b) association with the community: TK must be ‘distinctively associated with the traditional or Indigenous culture or community which preserves and transmits it between generations:’ this indicates that there is a distinctive link to the community which originates the knowledge, and serves as means for their cultural identification. This highlights that TK is often part of the social fabric and everyday life of a community, and is generally not seen as a distinct body of ‘knowledge’ separate from the community’s culture, but rather as integral with the community’s culture and its identity as a community. Because its generation, preservation and transmission is based on cultural traditions, TK is essentially culturally-oriented or culturally-rooted, and it is integral to the cultural identity of the social

⁶⁴ WIPO/GRTKF/IC/5/12, paragraph 45, drawn from document WIPO/GRTKF/IC/3/9, at paragraph 35. At the fourth session of the IGC, the delegation of Switzerland noted that the elements as set out in that paragraph would be a good basis for further work in this area. See *Report, supra* note ..., at paragraph 135.

group in which it operates and is preserved.⁶⁵ From the point of view of the culture of the community in which it has originated, every component of TK can help define that community's own identity. This characteristic may sound obvious as far as expressions of folklore and handicrafts are concerned, but it also applies to other areas of TK, such as medicinal and agricultural knowledge. A piece of medicinal knowledge developed from a given combination of plants by a South American community, for example, necessarily differs from knowledge developed by an African community, based on similar plants. The reason is that the origination of medicinal knowledge by traditional communities, in spite of its predominantly technical nature, does not only attend to a certain practical need, but also responds to cultural approaches and beliefs. This contrasts sharply with two scientific inventions made separately by two different teams of employed inventors, with the objective of solving the same technical problem: it is not uncommon that the two inventions turn out to be very similar, which, in patent law, may give rise to interference proceedings or similar legal procedures which attribute ownership to one claimant or the other.⁶⁶ Competing patent claims to overlapping subject matter are resolved without reference to the cultural environment which gave rise to the inventions; by contrast, the inherent link to the community of TK has important implications for its protection. This raises the importance of a linkage based on a sense of custodianship or responsibility.

(c) link to the community through a sense of ownership or responsibility: This aspect of the definition concerns the sense of violation and cultural damage that may arise from the misappropriation and misuse of traditional knowledge, in that misappropriation or demeaning usage would be harmful or offensive, and would run counter to customary obligations to preserve and respect the knowledge in a suitably respectful manner. This can include a responsibility to restrict the distribution of or access to the knowledge in line with customary law. Broadly, misuse or unauthorized access may run counter to a sense of custodianship, guardianship, or cultural or spiritual responsibility. The cultural identity dimension and customary law obligations of TK may have a dramatic impact on any future legal framework for its protection, because, being a means of cultural identification, the protection of TK, including TK of a technical nature, ceases to be simply a matter of economics or of exclusive rights over technology as such. It may acquire a human rights dimension, and TK protection may intertwine with the cultural identification and integrity, and the dignity of traditional communities. Analogues could also be drawn with the concept of 'moral rights' in copyright law, specifically the rights of integrity and of attribution, in that it may be considered necessary to protect against culturally offensive use of TK or other non-economic aspects of perceived misuse of TK. Specific remedies, such as additional damages, may also be stipulated in case of culturally offensive misuse of protected material.

(d) the requirement that it be knowledge: this is a relatively open requirement, but does limit the definition by excluding form or expression as such, and cultural objects with no knowledge content, and therefore distinguishes TK *stricto sensu* from protection of TCEs and distinctive signs and insignia. The knowledge may also be limited to a conscious "response to the needs imposed by [TK holders'] physical and cultural environments." The definition, nonetheless, encompasses all areas, without any limit or discrimination as to the field of technology or culture.

⁶⁵ See document WIPO/GRTKF/IC/4/8, paragraph 28.

⁶⁶ The "Act on the Protection and Promotion of Traditional Thai Medicinal Knowledge" admits interference procedures in the context of TK registration. See *infra* Part VIII.

(e) community to identify traditional knowledge: This aspect of the definition deals with the sensitive question of who is to identify knowledge as being traditional, given especially that the need for distinct IP protection of traditional knowledge generally only arises when it is removed from its traditional or customary context. While this is dealt with to some extent by the other aspects of this definition, a final test should be that the community itself recognizes or identifies the knowledge as forming part of their living heritage of traditional knowledge. This identification may be informal and implicit, in that it is part of the community's social fabric, or may be explicit, such as knowledge which is the subject of particular obligations, rituals or practices established by customary law. Ultimately, the very notion of TK is based on traditions, and the communities themselves are in the best position to identify them as such. This should be distinguished, however, from the determination of the scope of protection afforded to traditional knowledge, and the question of compliance with distinct IP laws giving protection to TK. This would typically be the role of the judicial or administrative systems of law enforcement specified in the applicable national legislation.

57. The definition of 'traditional knowledge' can be summarized simply: it must be 'traditional' in that there is an appropriate association with a relevant cultural tradition, and it must be 'knowledge' in that it refers to the content of what is known, rather than its form or expression as such.

Beneficiaries of protection

58. Different concepts of ownership and of right holders may apply in relation to TK. TK is generally understood as a collective product of a TK holding community, even though individual innovators or TK holders may have distinct personal rights or entitlements within the community structure. The general rule would therefore be for TK rights to be vested in communities, rather than in individuals, but to recognize individual rights (including conventional IP rights) for innovators or creators of original works.⁶⁷ The collective right holder should have legal personality for the purpose of legal procedures, including enforcing their rights. This issue has international dimensions, if the TK holder is to be granted rights in foreign jurisdictions. The Paris Convention (Article 7*bis*) already provides for the protection of 'collective marks belonging to associations the existence of which is not contrary to the law of the country of origin, even if such associations do not possess an industrial or commercial establishment.'

59. But IP need not be separately owned by distinct right holders. Collective marks and certification marks may be protected on behalf of a group of beneficiaries. Some forms of IP protection, such as geographical indications, need not have distinct 'owners' and may be administered by the state, on behalf of groups of eligible producers. Where the 'right' over TK is essentially an entitlement to seek certain legal remedies and injunctions, there may not be a need to identify a specific right holder, and it may be possible to define aggrieved or interested parties who may have standing to take action. International standards reflect this

⁶⁷ For technical comments on the identification of right holders see the statements of the African Group (WIPO/GRTKF/IC/3/5, Annex, page 5, para. 1(c)), Andean Community (WIPO/GRTKF/IC/3/17, para. 240), Brazil (WIPO/GRTKF/IC/3/17, para 210), the Russian Federation (WIPO/GRTKF/IC/4/15, para. 144), South Africa (WIPO/GRTKF/IC/3/17, para. 225), Thailand (WIPO/GRTKF/IC/3/17, para. 135) and Venezuela (WIPO/GRTKF/IC/3/17, para. 216), Zambia (WIPO/GRTKF/IC/3/17, para. 232).

approach in referring to obligations to ensure that ‘persons shall have the possibility of preventing’ certain actions,⁶⁸ to ‘provide the legal means for interested parties to prevent’ certain actions,⁶⁹ and ‘to provide measures to permit federations and associations ... to take action in the courts or before the administrative authorities’.⁷⁰

60. Similarly, national TK laws do not necessarily identify beneficiaries of TK protection as holders of distinct intangible property rights as such, although some have elected to establish distinct rights, either through registration or automatic entitlement. Four laws identify the right holders through the terms “local communities,” “indigenous peoples”, or a combination thereof. The Chinese Regulation on the Protection of Varieties of Traditional Chinese Medicine refers only to “manufacturing enterprises,” reflecting the policy context of this regulation in relation to the manufacturing sector. The Indian law does not identify right holders, but defines that “benefit claimers” shall include “creators and holders of knowledge and information relating to biological resources.” Other laws contain open definitions such as “those who have registered their IPRs on traditional Thai medical intelligence” and “any entity, whether public or private, Portuguese [or not], individual or corporate.” Finally, the Costa Rican law provides that the titleholder of *sui generis* community intellectual rights shall be determined by a participatory process. An alternative to the attribution of rights to communities is the designation of the State as the custodian of the interests and rights of TK holders, to be exercised on their behalf and in their interests;⁷¹ some forms of unfair competition and geographical indication law entail direct enforcement by the State in the community’s interests.

61. Although TK protection is generally perceived as a matter of collective rights, it may nonetheless be vested in individuals within a traditional knowledge system. Customary law can therefore help establish the attribution of rights and benefits within the community. An example of how customary law can be integrated into a *sui generis* system of TK protection is found in the Panamanian Law.⁷²

62. In sum, identifying the right holder or beneficiary for TK rights may require three elements:

- the right holder or the entity seeking legal remedies should be recognized under the law as having legal personality – this may entail recognizing a collective, a traditional community as having distinct legal existence; or the TK holding community may designate a distinct legal person (such as an association, a legal representative, a trustee, a corporation, or a government agency) as right holder in trust;
- the right holder may have to meet specific criteria (such as being an indigenous or local community); and

⁶⁸ TRIPS Agreement, Article 39.

⁶⁹ TRIPS Agreement, Article 22.

⁷⁰ Paris Convention, Article 10*ter*.

⁷¹ An approximate precedent in international law for this approach can be found in Article 15(4)(a) of the Berne Convention.

⁷² See Article 15, Law No. 20 of Panama.

- a sufficient connection must be established between the right holder and the protected TK; this linkage would normally be defined by or at least consistent with customary law or community practices.

63. A comparative approach shows that while countries have taken diverse approaches to this aspect, there are certain common denominators. Several laws, including the African Model Law, the Brazilian, Peruvian, Philippines and Portuguese laws identify the right holders through the terms “local communities”, “indigenous peoples,” or a combination thereof. The Chinese Regulation on the Protection of Varieties of Traditional Chinese Medicine allows only “manufacturing enterprises” which hold the know-how to manufacture Traditional Chinese Medicine products. The Indian law does not identify right holders, but defines that “benefit claimers” shall include “creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application” (Art.2(a)). The Costa Rican law provides that the titleholder of *sui generis* community intellectual rights shall be determined by a participatory process. The Portuguese Law provides a general definition of owners of rights:

“The owner of the rights can be any entity, whether public or private, Portuguese or from another country, individual or corporate that represents the interests of the geographical area in which the local variety is most widely found or where the spontaneously occurring autochthonous material displays the greatest interest for genetic variability. In the case of TK the owner must represent the interests of the region from where such knowledge is originated.” (Art.9)

Duration of protection

64. The duration of the right is normally a key issue in establishing the appropriate policy balance in IP protection.⁷³ The discussion concerning TK stresses the need for a longer, inter-generational time-frame to be taken into account – and this is one of the arguments put forward for its protection through *sui generis* means, rather than conventional IP laws. Therefore, some *sui generis* laws do not contain express provisions on the expiration and loss of rights. For example, the African Model Law states that community intellectual rights “shall at all times remain inalienable” (Art.23(1)). The Chinese, Portuguese and Thai Acts establish specific terms of protection, varying between terms ranging from 7 to 30 years; 50 years from the time of application for the right; and 50 years after the death of the right holder. Furthermore, under the Chinese and Portuguese laws the term may be renewed. If the protection of TK is to be established upon an initial act of commercial exploitation (for example, a fixed term counted from the first commercial act involving the protected element of TK, which could be renewable for a certain number of successive periods), then it might make sense to establish a predefined expiration, provided it would apply exclusively to those isolated elements of TK which have a commercial or industrial application, rather than the holistic background of TK. Other laws provide for the lapse of rights in TK once the original community has ceased to identify with it.

⁷³ For technical comments on expiration and loss of rights see Andean Community (WIPO/GRTKF/IC/3/17, para. 240), Brazil (WIPO/GRTKF/IC/2/14, Annex, para. 15), Fiji (WIPO/GRTKF/IC/3/17, para. 236), Thailand (WIPO/GRTKF/IC/3/17, para. 216), Zambia (WIPO/GRTKF/IC/3/17, para. 232).

65. The term or other conditions of expiration of rights and entitlements in TK may be determined with reference to the following possibilities, which may co-exist within the one comprehensive framework for protection:

- the possibility of inalienable and perennial rights, for instance in relation to an entitlement to take action against derogatory or damaging activities, and to prevent illegitimate third-party IP rights;
- the possibility of a limited term for some forms of protection, for instance in relation to protection of those aspects or elements of TK that are considered important to cultural exchange and development, or have been commercially or industrially applied by the TK holders;
- the possibility of rights or entitlements lapsing when the original community has ceased to identify with the TK, or the TK has ceased to be protected in its country of origin;
- the possibility of a two-tier system to balance various legitimate interests by allowing for expiration of rights over material that has been commercially exploited.

Consistency with the general legal framework

Access and benefit sharing regimes for genetic resources

66. Some TK is closely associated with biological and genetic resources, particularly when these resources are linked with traditional ways of life and practices. A number of existing laws use the regulation of access to biological resources as the basis for *sui generis* protection of TK. Under some laws, access to TK is granted by the competent State authority.⁷⁴ Even if access is ultimately granted by the State, in some laws the indigenous/local community or the TK owner may refuse access to the TK.⁷⁵ In two cases the access conditions differ, depending on the purpose of utilization for which access is requested⁷⁶ and in two laws many customary uses of TK are expressly exempted from access regulation.⁷⁷ Specific conditions of access to TK may apply to specified national institutions.⁷⁸

67. Some access regimes therefore control the use of TK and ensure benefit-sharing without creating exclusive rights in TK. This option may apply to some types of biodiversity-related TK, when a private property right is considered inappropriate, where the TK holder cannot be identified, or where property rights could not be exercised and enforced. In these cases, access regulation provides an alternative tool to control the use of TK by third parties and to ensure equitable benefit sharing for TK, which is not contingent upon or limited to the innovative elements of TK systems. Furthermore, access regulation should be coordinated

⁷⁴ See Art.4 (1)(xi) and 4(1)(x), African Model Law; Art.11 (IV)(b), Brazilian Provisional Measure; Art.62, Costa Rican Biodiversity Law; Art.3 (1), Indian Biodiversity Act; Art.7 (1), Portuguese Decree Law 118.

⁷⁵ See, African Model Legislation; Brazilian Provisional Measure; Costa Rican Biodiversity Law; Peruvian Law; and Portuguese Decree Law.

⁷⁶ Laws of Peru and Portugal.

⁷⁷ Art.2 (2)(ii), African Model Law and Art.7, Indian Biodiversity Act.

⁷⁸ Brazilian Provisional Measure and Indian Biodiversity Act.

with the regulation of access to genetic resources by the State, whether or not those resources are related to the TK.

68. Biodiversity access regulation which covers TK might follow the tenets of prior informed consent that have been developed internationally (in particular, the Bonn Guidelines), with a view to:

- providing for legal certainty and clarity;
- minimizing transaction costs for access procedures;
- ensuring that restrictions on access are transparent, legally based, and do not lead to the non-transmission of TK and the stifling of traditions;
- securing consent of the relevant competent national authority(ies) in the provider country, as well as the consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law.

69. Finally, the *sui generis* measure, and its implementing rules and regulations, could establish certain basic elements of an access system:

- Specifying the competent authority(ies) granting access;
- Timing and deadlines;
- Specification of use;
- Procedures for obtaining prior informed consent (PIC);
- Mechanism for stakeholder consultations on access.

70. A comprehensive approach to TK protection measures may need to be coordinated with legal frameworks regulating access to genetic resources. This is particularly the case if protection of TK is linked to the application of the principle of prior informed consent (PIC) to access and use of certain TK elements associated with genetic resources. Practical implementation of the PIC principle to TK subject matter may entail:

- Coordination with the work of the CBD on access and benefit-sharing issues;
- Consideration of the respective roles and responsibilities of the State, indigenous and local communities, and possible owners or custodians of elements of TK in granting PIC on certain acts regarding TK, such as disclosure, reproduction and use of certain TK elements;
- Coordination with the access regime applicable to genetic resources;
- Implementation of basic principles of access regulation, such as prior informed consent, legal certainty, minimized transaction costs, and transparent access restrictions;
- Review of the choices required in establishing the basic elements of an access system, including procedures for prior informed consent, specified competent national authorities, mechanisms for stakeholder consultations, timing and deadlines, and specification of use; and
- An exemption of customary uses of TK from access restrictions and from the application of the PIC principle.

[Annex II follows]