WIPO-SAARC/GRTK/DEL/03/xx

**ORIGINAL:** English

DATE:





# WIPO/SOUTH ASIAN ASSOCIATION FOR REGIONAL COOPERATION (SAARC) EXPERT WORKSHOP ON INTELLECTUAL PROPERTY, TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES

organized by the World Intellectual Property Organization (WIPO)

in cooperation with the Ministry of Human Resource Development, Government of India

New Delhi, November 17 and 18, 2003

#### SUMMARY OF DISCUSSIONS AND CONSULTATIONS

Prepared by the Secretariat

1. Participants in the WIPO/South Asian Association for Regional Cooperation (SAARC) Expert Workshop on Intellectual Property, Traditional Knowledge and Genetic Resources prepared a 'Summary of Discussions and Consultations,' which is annexed to the present document for reference.

#### WIPO-SAARC/GRTK/DEL/03/xx ANNEX

## SAARC EXPERT WORKSHOP ON INTELLECTUAL PROPERTY, TRADITIOINAL KNOWLEDGE AND GENETIC RESOURCES SUMMARY OF DISCUSSIONS AND CONSULTATIONS

#### I. BACKGROUND:

The SAARC Forum for Intellectual Property Cooperation (Thimpu, October 2002) inter alia:

- emphasized the need to develop a consensus on legal and policy mechanisms for the protection, conservation, promotion and use of traditional knowledge (TK);
- agreed to commence work and coordinate positions on:
  - model legislation, mechanisms, contractual terms and practices could contribute to internationally accepted standards;
  - identify, catalogue, record, document genetic resources (GR)/TK;
  - prepare inventory of TK, with focus on known medicinal plants and associated TK calling for an expert meeting to discuss blueprint.

The session considered possible elements of a SAARC process towards coordinated protection of traditional knowledge could include:

- clarifying and specifying the general principles that should apply to the protection and documentation of TK in SAARC countries (this could help 'develop a consensus on legal and policy mechanisms' as the Thimpu declaration calls for);
- developing a coordinated program for regional action, addressing the practical work items set out in the Thimpu declaration, which would:
  - identify steps to clarify and enhance the legal and policy framework, including a model law for the region;
  - create practical mechanisms, such as protocols for academic researchers, guidelines for TK documentation, and a toolkit for protection of intellectual property (IP) interests when documenting TK; and
  - common awareness and capacity-building programs focused on TK holders and local and indigenous communities.
- On this basis, drawing up the blueprint for inventories or databases proposed in the Thimpu declaration.

#### 1. Coordinated Program for SAARC Regional Action

The SAARC Forum for IP Cooperation (Thimpu, October 2002) inter alia:

- emphasized the need to develop a consensus on legal and policy mechanisms for the protection, conservation, promotion and use of TK;
- agreed to commence work and coordinate positions on:
  - model legislation, mechanisms, contractual terms and practices could contribute to internationally accepted standards;
  - identify, catalogue, record, document GR/TK;
  - prepare an inventory of TK, with focus on known medicinal plants and associated TK calling for an expert meeting to discuss a blueprint;

The above discussion of policy framework, principles and elements of TK protection could be a contribution to the need to 'develop a consensus on legal and policy mechanisms' as that Thimpu declaration calls for.

This Section concerns the development of a coordinated program for regional action, addressing the practical work items set out in the Thimpu declaration, which would:

- identify steps to clarify and enhance the legal and policy framework, including a model law for the region;
- create practical mechanisms, such as protocols for academic researchers, guidelines for TK documentation, and a toolkit for protection of IP interests when documenting TK; and
- common awareness and capacity-building programs focused on TK holders and local and indigenous communities;
- the SAARC Expert Workshop also recommended to cooperate in the area of folklore and traditional cultural expressions (TCE);

In addition, it is necessary to draw up draft materials to help develop a blueprint for inventories or databases proposed in the Thimpu declaration.

Practical elements that could be developed on a regional basis include:

- Guidelines for the documentation of TK
- Protocols for academic researchers and others concerned with the collection of TK
- A toolkit for the use of TK holders, to safeguard their interests when their TK is being collected.

Factors and considerations that should apply in the development of each of these materials are set out briefly below:

#### 1.1. Prior to documentation:

#### Policy directions

It is necessary to set clear directions for the purpose of the documentation process, and to clarify how the practice of collection and storage of data should be consistent with particular objectives.

Networking of existing database centers

#### (a) Consultation

The need for extensive consultations with the community concerned, including:

- Consultation on administrative, financial and organizational matters
- Consultation on customary law and community cultural concerns
- Consultation on the intended use and implications of the documented TK
- Compliance with any applicable requirements for prior informed consent, including relevant government authorities and community representatives
- Consultation on the possible role of the SAARC Documentation Center.

#### (b) Choice of mechanism for documentation

Depending on the nature of the objectives and community interests concerned, the means of documentation may differ – this could include preservation of secret or sacred TK solely for the use of the community, confidential collection of commercially valuable TK for potential use in commercial partnerships, or the preparation of some TK that is intended for publication or other forms of public access.

#### 1.2 During documentation

- Confidentiality measures
- Application of the Standards for Registries and Databases of Traditional Knowledge and Genetic Resources (reference WIPO/GRTKF/IC/4/14);
- Define the rights and obligations attached to the documentation process and the database that may be created;
- Recording of and compliance with customary law and cultural concerns;
- Clarifying ownership of copyright in any fixations or documents of recorded TK;
- Complying with national laws of the Member States

#### 1.3. After documentation

- To explore publication of the documentation.
- Policy formulation for usage of databases and ownership of its elements.
- Identify further areas of cooperation.

### II. INTERNATIONAL COOPERATION AND POLICY ENVIRONMENT FOR TK PROTECTION

The challenge for policymakers can be characterized as a search for ways to:

- preserve TK and the traditional ways of life, value and legal structures it embodies;
- while promoting its use for public benefit and for further innovation; and
- protecting it against misappropriation and illegitimate uses.

The legal and policy options include:

- better use of the existing IP system;
- adapting, expanding or refocusing the existing IP system;
- creating new legal instruments (new national and regional TK laws, and new international instruments)

#### III. NEEDS

Policy planning has to address a set of overlapping needs:

- The legal and policy need: to define and articulate existing IP principles, rules and practices, and establish new IP norms or standards where these are needed;
- The practical need: to make effective use of existing IP rights and create operational systems so that IP rights relating to TK can be recognized, administered and enforced for the benefit of TK holders; and to document, record and codify TK and customary laws and protocols as the basis for protection;
- The capacity-building need: to build awareness, skills and necessary resources among the TK holders, their representatives, and policymakers.

#### IV FORMS OF PROTECTION:

Traditional knowledge is generally conceived in an holistic way, integral to a traditional community, and its way of life and value systems. But specific forms of IP protection may be defined for:

- Protection of content, substance or concept of knowledge and culture e.g. traditional know-how about the medicinal use of a plant, or traditional ecological management practices;
- Protection of form, expression or representation of traditional cultures e.g. song, performance, oral narrative, designs;
- Protection of reputation and distinctive character of names, signs, words, symbols, indications, patterns and styles associated with traditional culture and to prevent misleading, deceptive and offensive use.

#### V. SUI GENERIS PROTECTION:

The session discussed the various forms of *sui generis* protection that can be developed for traditional knowledge, and participants highlighted the approaches currently being taken in SAARC member countries.

A system of *sui generis* protection of TK or TCEs may rest on various legal foundations, for example:

- The creation of distinct IP rights in TK or TCE subject matter, rights to exclude others from doing certain specified unauthorized acts (the central quality of IP rights);
- A more general remedy against unfair commercial practices, extending such established concepts as misappropriation, unjust enrichment, slavish imitation or misleading or confusing the consumer;
- A right to be compensated for commercial use of protected material, without absolute rights over it (termed a 'compensatory liability regime'), using the concepts of equitable remumeration or equitable benefit-sharing;
- A right to set binding contractual or licensing conditions, based for example on the principle of prior informed consent relating to the use of protected material;

A recognition of the customary laws and protocols that govern how TK and TCEs are to be owned, maintained, used or reproduced.

#### VI. ELEMENTS OF A FRAMEWORK FOR PROTECTION OF TK

The formulation of a national law, regional framework or international instrument for the protection of TK may need to clarify each of the following elements:

- 1. Policy objectives
- 2. Scope of protected subject matter
- 3. Criteria for eligibility for protection
- 4. Nature of rights in TK
- 5. Conditions of protection
- 6. Scope of rights and exceptions
- 7. Right holders
- 8. Acquisition of rights
- 9. Expiration and loss of rights
- 10. Exercise and enforcement of rights
- 11. Registration mechanisms and other procedures
- 12. Defenses to protection/defensive protection
- 13. Recognition of customary laws and protocols
- 1. Setting New Standards for TK Protection

The SAARC Expert Workshop has the following recommendations regarding the setting of legal standards for TK protection:

(a) Policy tools that may be used for TK protection

A comprehensive approach to TK protection would need to draw on a range of existing and new legal tools and doctrines, including sui generis elements. Relevant policy and legal tools, that could be used in this context, would include the following:

- (i) IP rights approach: grant of exclusive property rights in the protected TK;
- (ii) Repressions of unfair competition;

TK which may not be protectable through exclusive IP rights, may be protected through the repression of unfair competition by extension of IP principles;

#### (iii) Access regulation and benefit-sharing;

An access and benefit-sharing approach, as set out in the Bonn Guidelines, could be applied to TK, including capacity building, revenue sharing (lumpsum and royalty based), and technology transfer;

#### (iv)Compensatory liability regimes;

TK holders should be entitled to compensatory contributions from TK users who use tradition-based know-how for industrial and commercial applications during a specified period of time. These liability rules should reward TK holders for the conservation and

development efforts invested by the communities in the TK elements, without endowing exclusive property rights to control such uses;

#### (v)Customary laws and protocols.

As far as possible, the protection may utilize references to customary laws and protocols as a supplement to the above tools.

#### (b) Basic Principles of TK Protection

- A principle of prior informed consent: Traditional knowledge should not be collected, used or commercialized without the prior informed consent of traditional knowledge holders;
- A principle of exceptions for educational and customary uses;
- A principle of indication of source: Use and publication of traditional knowledge should indicate the source of the knowledge;
- A principle thatany false, misleading or culturally offensive references to traditional knowledge, and any false or misleading indications of linkage with or endorsement by TK holders, should be legally suppressed;
- A principle of *ordre public* and morality should be respected;
- A principle of fair and equitable benefit-sharing for the commercial use of TK;
- A principle of holistic recognition: A system of traditional knowledge protection should respect and be in harmony with rights relating to associated genetic resources, expressions of folklore, and other valid intellectual property rights;
- A principle of social equity: the protection of traditional knowledge should be undertaken in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
- A principle that IP issues arising in the fields of TK and GR should be dealt with in conjunction;
- A principle of safeguard and promoting customary uses of TK and associated biological resources: customary uses shall not be restrained through legal protection of TK from non-customary uses by outsiders.

#### (c) Elements of Sui Generis Systems

#### (i) Policy Objectives

To devise a legal system of sui generis protection for TK, which may in particular include the following: Objectives related directly to TK and TK holders, objectives on biodiversity and genetic resource policy, objectives on indigenous and local communities, objectives related to sustainable development, and objectives related to innovation promotion.

- The policy objectives should be inclusive but focused on TK;
- GR policy is closely linked to TK protection and should be integrated from the viewpoint of protection objectives;
- TK and traditional cultural expressions (TCE) are also closely related and are two
  aspects of the traditional cultural heritage and should be protected in a holistic,
  coordinated manner.

*The following priority objectives should guide the development of TK protection:* 

- to evolve mechanisms for scientifically re-validating the TK, whereverpossible;
- to create an appropriate system for access to TK;
- to ensure fair and equitable sharing with TK holders (tribes, communities included)
   of benefits arising from the use of TK and associated genetic resources;
- to promote respect, preservation, wider application and development of TK and associated genetic resources;
- to provide mechanisms for the enforcement of rights of TK holders;
- to prevent misappropriation and misuse of TK and associated genetic resources;
- to enhance scientific capacity at the national and community levels;
- to promote the transfer of technologies which make use of TK and associated genetic resources;
- to promote and recognize innovation based on TK.

#### (ii) Scope of Protected Subject Matter

#### Use of terms:

- The term "traditional knowledge" (TK) should be used to refer to the subject matter;
- The term "TK" should be defined through an non-exhaustive list of subject matter, which illustrates the concept.

#### Delimitation of the Scope of Protectable Subject Matter

The scope of subject matter to be covered should be circumscribed through a combination of the following criteria:

#### (a) Sectoral criteria:

The delimitation of the scope of protected subject matter should allow for sectoral distinctions, such as the distinction between traditional medicine and traditional agriculture. For example, the needs for legal protection in the field of traditional medicine are quite different from the IP needs of traditional farmers;

#### (b) Association of TK with Tangible Subject Matter

The protection should focus on TK related to any properties of biodiversity, including genetic resources, biological resources and other components of biodiversity;

- (c) Association with specific Knowledge Holders, such as local and tribal communities, including farming communities.
- A "differentiated scope" of protected subject matter should be provided: the protection system should distinguish between different types of TK, depending on the nature of the TK and ownership or custodianship of the TK.

#### (iii) Mechanisms of Access to TK

#### Access to TK

Prior informed consent shall be required for collection, recording, use or commercialization of TK and shall provide for benefit-sharing on mutually agreed terms. Benefit-sharing should be such that benefits arising from usage of TK should flow to the TK holders. Certain limitations and exceptions can be provided for educational and bona fide and non-commercial research purposes.

The roles and responsibilities in the granting of access with PIC which should be specified, incuding the following:

- Role of the state and its national competent authority;
- Role of the local and tribal community(ies) holding the TK;
- Role of possible owners of the TK under established systems, such as customary laws or modern IPRs.

Access regulation for TK might follow certain basic principles of PIC systems which have been internationally agreed:

- Legal certainty and clarity;
- Transaction costs for the access procedures should be minimized;
- Restrictions on access should be transparent, based on legal grounds, and not lead to the non-transmission of TK and the stifling of traditions;
- Consent of the relevant competent national authority(ies)/TK holders should be obtained.

The *sui generis* law, and its implementing rules and regulations, could establish certain basic elements of an access system as specified in the Bonn Guidelines:

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

#### Access conditions to TK documentation data and databases:

Access shall be consistent with national laws, rules and regulations.

#### (iv) Requirements for Protection of TK

#### Substantive requirements

Factors regarding substantive requirements that could be considered include:

- demonstrated linkage of the TK to the cultural identity of the community;
- trans-generational character.

#### Formal requirements

There should be no mandatory formal requirements for the protection of TK. Notification or registration systems may be used to facilitate recognition and enforcement of rights by giving prima facie evidence of ownership.

Future work could address Scope of Rights, right holders, procedures for Acquisition & Maintenance of Rights.

#### 2. The International Dimension of TK Protection

By analogy with the general development of international IP law, the following elements of the international dimension of TK protection were identified:

- coordination with overall international law environment;
- current international IP law and standards;
- development of new international standards;
- international means for enabling nationals of one country to enjoy TK rights in a foreign jurisdiction;
- coordination and articulation of common policy positions and objectives;
- international notification or registration;
- administrative coordination, including international classification and documentation standards;
- international coordination of collective administration and management of TK rights;
- settlement of international disputes;
- settlement of private disputes with an international character.

The core principles and the elements of protection identified in this document could form the basis for the development of appropriate international instruments to promote the creation of TK rights in a consistent and balanced manner. The transmission of this document to the Intergovernmental Committee would be a suitable means of introducing these principles and elements into the international discussions.

#### 3. Recommended Next Steps for SAARC: Process and Procedure

#### The SAARC Secretariat

These recommendations should be transmitted to the SAARC Secretary General with a request to put these recommendations before the appropriate decision making bodies of SAARC for further consideration and direction.

These recommendations should be submitted to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, for issuance as a document at its sixth session, to be held in March 2004.

#### SAARC Documentation Center

The SAARC TK Task Force which has been mandated by the SAARC Secretariat to the SAARC Documentation Center shall continue to work on creating classification on TK matters and the associated documentation in accordance with programme and budget approved by the SAARC Secretariat.

The Workshop noted the proposals for increased cooperation between WIPO and the SAARC Documentation Center and encouraged the two organizations to develop a concrete workplan for further consideration.

The SAARC Member countries should continue to work together and develop substantive elements identified in this document.

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