PACIFIC ISLANDS FORUM SECRETARIAT

Guidelines for developing legislation for the protection of traditional biological knowledge, innovations and practices based on the Traditional Biological Knowledge, Innovations and Practices Model Law

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We also acknowledge organisations such as the Secretariat of the Convention on Biological Diversity and the World Intellectual Property Organization whose work on the protection of traditional knowledge, innovations and practices has greatly assisted the development of these guidelines. The Guidelines draw from documents, publications and other materials prepared by the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) particularly WIPO documents WIPO/GRTKF/IC/7/3, WIPO/GRTKF/IC/7/4, WIPO/GRTKF/IC/8/4, WIPO/GRTKF/IC/9/4 and WIPO/GRTKF/IC/9/5. These documents, which summarise the key legal and policy issues and suggest draft objectives, guiding principles and substantive provisions for the protection of traditional cultural expressions and traditional knowledge, draw from national and regional experiences and are based directly on extensive deliberations within the WIPO IGC among the diverse range of stakeholders who participate in sessions of the Committee, as well as on comments submitted by them through open commenting processes. At the same time, these materials are informing national and regional developments in many parts of the world and are a useful resource for policy-makers, legislators, communities and others. For further information, see http://www.wipo.int/tk/en/index.html.

Lastly, we acknowledge the author of the Guidelines, Anne Haira, for her support for this project.

ACRONYMS AND ABBREVIATIONS

ABS	access and benefit sharing
CBD	Convention on Biological Diversity
IP	intellectual property
IPRs	intellectual property rights
PIC	prior informed consent
PICTs	Pacific Island countries and territories
SPC	Secretariat of the Pacific Community
SPREP	Pacific Regional Environment Programme
TBKIPs	traditional biological knowledge, innovations and practices
TK	traditional knowledge
TKECs	traditional knowledge and expressions of culture
WIPO	World Intellectual Property Organization
WIPO IGC	WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

EXECUTIVE SUMMARY

The Guidelines have been developed to assist policy-makers to develop national legislation for the protection of traditional biological knowledge, innovations and practices based on the Traditional Biological Knowledge, Innovations and Practices Act, a high-level framework referred to as the 'TBKIP Model Law'.

The Guidelines cover the policy development portion of developing legislation. Countries will need to progress through this to develop matters of detail and also to determine which aspects of the TBKIP Model Law are appropriate to their national circumstances. The Guidelines include a suggested policy development process that could be followed in this regard. It is separated into five broad phases:

Part 1: Assessing the approach of the TBKIP Model Law
Part 2: Developing the policy framework of the legislation
Part 3: Developing the content and/or scope of the legal elements of protection
Translating the legal elements of protection into legislative language
Part 4: Developing the additional legislative features
Part 5: Developing secondary legislation (regulations).

The Guidelines cover Parts 1-4 of this process.[1]

Part 1: Assessing the approach

As a first step, the Guidelines suggest that countries assess the approach of the TBKIP Model Law. It is assumed that those using the Guidelines have reached the stage in the policy development process where the lack of legal protection for TBKIPs has been identified as a problem, and *sui generis* approaches, specifically, *sui generis* legislation, is needed to meet a country's objectives of protection. The TBKIP Model Law is one approach that can be used but there are others. Countries need to assess the approach of the TBKIP Model Law as to whether it is a suitable means for doing so. Part 1 of the Guidelines assists countries in this regard by explaining the various dimensions of the model's approach: the nature, the subject matter, the legal form of protection, and the application of the system.

If a country is to use the TBKIP Model Law as the basis for national legislation, it will need to firstly adopt its approach as this sets the framework for the legislation.

Part 2: Developing the policy framework

If the general approach is acceptable to a country, Part 2 of the Guidelines cover the next stage in developing the legislation which is to develop the policy framework, that is, the policy objective and the guiding principles. In a similar way to Part 1, countries will need to adopt the policy framework of the TBKIP Model Law but can articulate the matters differently if they wish.

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[1] The translating of the legal elements of protection into legislative language is included within Part 3 as it is at that stage of the policy process when drafting would typically occur. However, as it is not strictly policy development work, it is not covered within the Guidelines.

While the TBKIP Model Law does not specify its policy objective, the Guidelines suggest that it can be described as follows:

> To protect the rights of traditional owners in their TBKIPs and provide them with the means to control the commercialisation of their TBKIPs, and ensure that such commercialisation is subject to their prior informed consent and the fair and equitable sharing of benefits arising from that utilisation with the traditional owners.

There is also not a provision within the TBKIP Model Law specifying the guiding principles of the legislation but to assist policy-makers, these are extracted and included within the Guidelines.

Part 3: Developing the legal elements of protection

In developing legislation for the protection of TBKIPs, various legal elements need to be addressed as follows:

- What is the subject matter of protection?
- What are the criteria for protection?
- Who are the beneficiaries?
- What is the scope of protection?
- What are the exceptions and limitations?
- How will rights be managed?
- What is the term of protection?
- What are the formalities for protection?
- How will rights be enforced?
- What are the legal proceedings for taking actions (including remedies and penalties)?
- What processes can be used for dispute resolution?
- What is the relationship with IP protection?
- What is the relationship with the regulation of access to genetic resources and the fair and equitable sharing of benefits arising out of their utilisation (commonly referred to as ‘ABS’)?
- How will international and regional protection be addressed?

Part 3 of the Guidelines explains the nature of each element along with why the element needs to be addressed as part of the policy development process.

Guidance is provided on the policy questions that should be considered with respect to each element and the associated implementation options. Where relevant, the Guidelines identify important policy considerations for policy-makers.

Part 4: Developing additional legislative features

Following the development of the legal elements of protection of the legislation, policy-maker will need to address a number of additional legislative features. The majority of these features will be shaped by national legislative practices. Part 4 of the Guidelines focus only on complex matters in which policy-makers are likely to require assistance: the development of transitional measures and regulatory making powers.

ABOUT THE GUIDELINES

Objective

The Guidelines have been developed to provide technical assistance to policy-makers in PICTs in the development of national legislation for the protection of traditional biological knowledge, innovations and practices (TBKIPs) based on the Traditional Biological Knowledge, Innovations and Practices Act (the 'TBKIP Model Law').

The Guidelines have been designed to align with the areas in which PICTs have indicated they require assistance as follows:

- guidance on an effective policy process that could be followed when using the TBKIP Model Law as the basis for developing national legislation;

- guidance on the policy questions that need to be considered when developing the legal elements of protection in the legislation; and

- guidance on implementation options, and their associated policy considerations, when using the TBKIP Model Law as the basis for developing national legislation.

Scope

The Guidelines cover the policy development portion only of developing legislation for the protection of TBKIPs. The Guidelines do not extend to the parliamentary process, as this will differ between countries and this has not been a matter on which PICTs have indicated that they require technical assistance.

Additionally, the Guidelines cover only the legal protection of TBKIPs. 'Protection' in these Guidelines refers to protection of the creativity, innovation and distinctiveness embodied in TBKIPs against misappropriation and misuse. This is distinct from, but complementary to, 'preservation' and 'conservation' (see next paragraph). Achieving comprehensive protection will require extending beyond legislation to a range of proprietary and non-proprietary tools such as customary and Indigenous laws and protocols, trade practices and marketing laws, contracts and licenses, and registers and databases. These measures are not mutually-exclusive options, and each may have a role to play in a comprehensive approach to protection. A *sui generis* system should not be considered to replace the need for such measures and programmes.

The Guidelines also do not cover important and closely related themes of safeguarding and preserving traditional knowledge, innovations and practices. These would need to be addressed through complementary policy measures such as preservation laws and programmes.

Approach

The Guidelines:

- are voluntary and should not be interpreted as affecting the sovereign rights of countries;

- presuppose that PICTs have reached the stage in the policy development process where the lack of legal protection for TBKIPs has been identified as a problem, and *sui generis* approaches, specifically, *sui generis* legislation, is needed to meet a country's objectives of protection;

- do not seek to promote any particular outcome nor to express any preference, but simply aim to catalogue and describe the available options to address issues;

- highlight, where relevant, commonalities with the substance and approach of the Pacific Model Law 2002 in keeping with the holistic view of traditional knowledge and also in recognition of the need for harmonisation especially given the size of many PICTs and the limited resources available to progress this work;

- acknowledge that the forms of TBKIPs and the customary means of regulating their use, transmission, protection and preservation are diverse;

- reflect the understanding that different countries have varied interests and concerns in respect of TBKIPs and also that their positions may be based on different assumptions and ideological standpoints;

- recognise that a 'one-size-fits-all' or universal template to protecting TBKIPs is not likely to be workable in terms of accommodating national priorities, the legal and cultural environment and the needs of traditional communities;

- acknowledge that complementary measures, such as intellectual property (IP) laws, contracts and customary laws, will also be needed to provide comprehensive legal protection.

Structure

The Guidelines are structured according to the broad stages of policy development when developing legislation of this nature. In respect of the legal elements of protection, the Guidelines group this process into thematic areas rather than follow the structure of the TBKIP Model Law itself.

Use of terms

For the purposes of the Guidelines, the use of the following terms should be interpreted as follows:

- the legislation: refers to the legislation that is being developed with reference to the Guidelines for the protection of TBKIPs based on the TBKIP Model Law;

- protection: means the legal ability to restrain third parties from undertaking certain unauthorised acts that involve the use of protected material. It is distinguishable from the concepts of 'conservation' or 'preservation' but should not be construed as suggesting these are less important;

- social group: means a family, clan, tribe, village or similar social organisation;

- traditional communities: encompasses both Indigenous and local communities and cultural communities and is used interchangeably within the Guidelines with 'social group';

- traditional owners: encompasses those that from traditional communities that hold TBKIPs in accordance with traditional or customary law and practices, a relationship that is akin to custodianship and stewardship;

- traditional biological innovation: means a product, belonging to a social group, which has resulted from biological material whose usefulness has been enhanced by the application of traditional biological knowledge;

- traditional biological knowledge: means knowledge whether embodied in tangible form or not, belonging to a social group and gained from having lived in close contact with nature, regarding: (a) living things, their spiritual significance, their constituent parts, their life cycles, behaviour and functions, and their effects on and interactions with other living things, including humans, and with their physical environment; (b) the physical environment; (c) the obtaining and utilising of living or non-living things for the purpose of maintaining, facilitating or improving human life;

- traditional biological practice: means a process, method or way of doing things, belonging to a social group and gained from having lived in close contact with nature.

THE POLICY DEVELOPMENT PROCESS

The TBKIP Model Law is a high-level framework. Countries will need to progress through the standard policy development process to develop matters of detail, and also determine which aspects of the TBKIP Model Law are appropriate to their national circumstances.

A suggested process for developing the policy component of the legislation as well as the drafting phases is outlined below. It is recognised that countries may redefine these steps in order to meet their needs and requirements.

A suggested policy development process

Part 1: Review the approach of the TBKIP Model Law and determine whether or not it is an appropriate means to address some or all of the problems identified and/or the objectives of protection. Seek appropriate ministerial approval for this approach to form the basis of the new legislation.

Part 2: Develop the overarching policy framework of the legislation, that is, the policy objectives and the guiding principles. Seek appropriate ministerial approval.

Part 3: Determine the content or scope of the legal elements of protection and seek appropriate ministerial approval:

- What is the subject matter of protection?
- What are the criteria for protection?
- Who are the beneficiaries of protection?
- What is the scope of protection?
- What are the exceptions and limitations regarding rights?
- How will rights be managed?
- What is the term of protection?
- What are the formalities for protection?
- How will rights be enforced?
- What are the legal proceedings for taking action, including remedies and penalties?
- What processes can be used for dispute resolution?
- What is the relationship with intellectual property protection?
- What is the relationship with ABS policy?
- How will international and regional protection be addressed?

Translate the legal elements of protection into legislative language.

Part 4: Develop the additional legislative features such as transitional measures and regulatory making powers.

Part 5: Develop secondary legislation (regulations).

Ideally, this process would form part of a broader process of developing a legal and policy framework for traditional knowledge generally. This could include initiatives targeting the preservation and maintenance of traditional knowledge, as well as the development of core IP legislation.

Further, prior to commencing policy development, policy-makers may wish to consider whether it would be useful to develop process principles to guide the process. These are sometimes referred to as 'behavioural principles' and can be a useful means of ensuring policy-makers exhibit a specified level of behaviour. They can also serve as a benchmark for all decisions taken by policy-makers, where appropriate, during the policy development process.

It is important to note that in the context of developing legislation for the protection of traditional knowledge, the relationship between policy-makers and traditional communities is critical. It is, therefore, essential that policy-makers operate to a high standard in their engagement with traditional communities.

If countries wish to establish behavioural principles, policy-makers may wish to draw on the following points that are commonly emphasised:

- Recognise that the broad and active participation of traditional communities throughout the process is critical in order to ensure that their rights as traditional knowledge holders are fully and effectively protected.

- Acknowledge that policy development should be guided by the aspirations and expectations expressed directly by traditional communities as well as the nature, specific characteristics and forms of traditional cultures, expression and creativity.

- Respect the rights of traditional communities, including Indigenous peoples, under national and international law.

PART 1. ASSESSING THE APPROACH

The TBKIP Model Law is a tool for PICTs that have determined that new, *sui generis* legislation is necessary and require assistance with developing such legislation. From the outset, it should be noted that the TBKIP Model Law is only one approach that can be used. There are, of course, others.

It is not the intention of the Guidelines to advocate that the TBKIP Model Law will meet some or all of a country's objectives of protection. Countries will need to individually assess the approach of the TBKIP Model Law as to whether it is a suitable means for doing so. To assist countries in this regard, this section explains the various dimensions of the TBKIP Model Law approach. These dimensions can be broadly characterised by nature, subject matter, and the legal form of protection. An additional dimension is the application of the *sui generis* system: countries can elect to develop a national system shaped according to their particular circumstances or opt to implement a regional approach (such as the TBKIP Model Law) or an international approach.

If a country is to use the TBKIP Model Law as the basis for national legislation, it will need to firstly adopt the approach of the TBKIP Model Law as this sets the framework for the legal elements of protection (discussed in Part 3). A country may elect to take a differing approach to that of the TBKIP Model Law, in which case, the Guidelines may be of limited assistance although policymakers may gain guidance on generic matters.

1.1 Nature of the *sui generis* system

Existing *sui generis* systems for the protection of traditional knowledge against misappropriation and misuse can be loosely grouped by nature into two areas:

i. *Sui generis* systems with new IP, or IP-like, rights, often referred to as *sui generis* IP protection. The WIPO-UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore against Illicit Exploitation and other Prejudicial Actions 1982 (the 'Model Provisions 1982') provide *sui generis* IP protection for expressions of folklore/traditional cultural expressions. Other examples are the Tunis Model Law on Copyright for Developing Countries 1976 (the 'Tunis Model Law 1976') and the Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defence of their Cultural Identity and their Traditional Knowledge of Panama 2000 (the 'Panama Law 2000').

ii. *Sui generis* systems that have been developed within a different policy area or context but nonetheless provide IP-like protection. This can often refer to systems of protection based on the customary laws/traditional protocols of traditional knowledge holders and bearers of cultural traditions.

The TBKIP Model Law falls into the second group. It creates new IP-like protection in terms of the nature and scope of protection it offers, but it is not based directly on a particular area of conventional IP law. It also incorporates customary laws and traditional protocols.

1.2 Subject matter of the *sui generis* system

Existing national *sui generis* systems of protection have taken different approaches to what subject matter will be covered. While traditional knowledge holders have frequently stressed that they view traditional knowledge holistically, many countries have opted not to incorporate all traditional knowledge into a single system.

Possible reasons for this include the subject matter being too diverse which raises issues of practicality. In addition, the design of regimes with a broad scope or that are applicable to a wide range of beneficiary communities requires the drafting of rules that, due to their generality, may not be adequate when applied to specific types of subject matter or particular types of communities.[2] Cultural expressions, medicinal methods, etc. may require different legal treatments in view of their different nature, as is the case under IP law.[3]

The subject matter of *sui generis* systems can be grouped into three areas:

i. traditional cultural expressions or expressions of culture - examples include the Tunis Model Law 1976 and the Panama Law 2000;

ii. biodiversity-related traditional knowledge - examples include the Peru Law of 2002 Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources (the 'Peru Law 2002') and Brazil's Provisional Measure No. 2186-16 of 2001 Regulating Access to the Genetic Heritage, Protection of and Access to Associated Traditional Knowledge ('Brazil's Provisional Measure 2001'); and

iii. all traditional knowledge - an example is the Philippines Indigenous Peoples Rights Act 1997 (the 'Philippines Law 1997').

The TBKIP Model Law covers traditional biological knowledge, innovations and practice and therefore falls within the second grouping. It does not cover the protection of traditional cultural expressions which is addressed in the Pacific Model Law 2002. However, given the holistic nature of traditional knowledge and the desire of traditional communities to not artificially separate and isolate it into different elements, the Guidelines identify areas where the implementation of the two model laws can be aligned together.

1.3 Legal form of protection

Existing laws for the protection of traditional knowledge utilise a wide range of legal doctrines and mechanisms. Some extend a true exclusive right but others do not, focusing rather on regulating use of the protected traditional knowledge.

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[2] Correa, C, (2003) *Protection of Traditional Knowledge: Lessons from National Experiences* 34-36 http://r0.unctad.org/trade_env/test1/meetings/tk2/correa.draft.doc

[3] Ibid

The range of existing approaches to the legal form of protection includes:

i. exclusive property rights: giving the right to authorise or prevent others from undertaking certain acts in relation to traditional knowledge. An exclusive rights approach is one way of giving effect to the principle of prior informed consent. Exclusive rights are provided for in the Tunis Model Law 1976, the Model Provisions 1982, the Panama Law 2000, the Pacific Model Law 2002, and the Philippines Law 1997;

ii. entitlements under a scheme for equitable remuneration: providing for some form of equitable return to the rights holders for use of their traditional knowledge, without creating an exclusive right in the traditional knowledge. This approach has been used in some systems for the protection of traditional knowledge, often through a domaine public payant system;

iii. a moral rights approach: normally providing the rights of: attribution of ownership; not to have ownership falsely attributed; not to have the protected materials subjected to derogatory treatment; and, at least in some jurisdictions, the right to publish or disclose (the right to decide if, when and how the protected materials ought to be made accessible to the public).[4] The integrity right that protects the reputation of creators may address the anxiety over the inappropriate use of expressions of culture by preventing distortion, alteration or misrepresentation of creators' works. This may provide redress against culturally inappropriate treatment of expressions of culture. The publication right is the creator's right to decide when, where and in what form a work will be published. It may be effective in providing communities with a degree of control over the publication or disclosure of sacred works and thus reduce the possibility of inappropriate use. Furthermore, it could potentially be coupled with a breach of confidence action if the sacred information was communicated in confidence.[5] A number of *sui generis* systems for the protection of traditional knowledge and/or traditional cultural expressions provide for moral rights including the Model Provisions 1982, the Pacific Model Law 2002 and the Copyright Act of Nigeria 1992;

iv. an unfair competition approach: providing a right to prevent various acts that constitute 'unfair competition' broadly speaking, such as misleading and deceptive trade practices, unjust enrichment, passing off and taking of undue commercial advantage. This approach underlies the US Indian Arts and Crafts Act 1990 which prevents the marketing of products as 'Indian made' when the products are not made by lndians as they are defined by that legislation;

v. a penal sanctions approach: where certain acts and omissions are treated as criminal offences. The Model Provisions 1982 and the Pacific Model Law 2002 provide for criminal offences.

These options are not necessarily mutually exclusive, and can be combined. Most *sui generis* systems include at least one of these options.

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[4] Lucas-Schloetter (2004) 'Folklore' in von Lewinski, S. (Ed.), *Indigenous Heritage and Intellectual Property* Kluwer 298.

[5] Palethorpe and Verhulst (2000) *Report on the International Protection of Expressions of Folklore Under Intellectual Property Law* 31.

The TBKIP Model Law combines some of the approaches above and provides:

- for exclusive property rights by providing that particular uses of TBKIPs require the prior and informed consent of the traditional owners;

- that the traditional owners of TBKIPs are the holders of moral rights in their TBKIPs which comprise the right of attribution of ownership in relation to their TBKIPs; and the right not to have ownership of TBKIPs falsely attributed to them; and the right not to have their TBKIPs subject to derogatory treatment.

The TBKIP Model Law requires fair and equitable benefit sharing arrangements (monetary or non-monetary compensation) with the traditional owners where TBKIPs are used for a commercial purpose. However, this differs from the 'entitlements under a scheme for equitable remuneration/compensatory liability' approach where the entitlement is not based on the creation of an exclusive property right.

In addition, while there are no specific provisions in the TBKIP Model Law regarding unfair competition, it is still possible to utilise common law remedies for passing off, unjust enrichment and the like, as well as trade practices.

1.4 Application of the *sui generis* system

Countries can elect to develop their own national system or opt to implement a regional approach (such as the TBKIP Model Law or the Pacific Model Law 2002) or an international approach. Each has its own advantages and disadvantages.

i. National approach: The benefit of developing a national system 'from scratch' is that it enables a country to develop measures that reflect and respond to its particular circumstances. However, the disadvantage is that in the absence of bilateral or multilateral agreements providing protection in foreign jurisdictions, protection is limited to within the particular country. This may, for example, lead to situations where a protection system in a country is circumvented by the use of the same or similar traditional knowledge in another country that does not have the necessary system of protection in place;

ii. Regional approach: A regional approach has the potential to provide more effective protection than a national system depending on the form followed. For example, a regional instrument, which may impose obligations on signatory parties to implement its provisions, is likely to include an integrated system that could enable mutual recognition of rights between joining territories, reciprocal enforcement of rights in territories of the region, and a regional mechanism for the resolution of disputes. This is especially useful where particular traditional knowledge is not confined to one country alone, as is the case in the Pacific and other regions. A regional model or framework on the other hand does not typically impose obligations; it simply provides a model that countries may wish to follow to create their own national regime of protection. It can achieve harmonisation across national systems through the use of minimum substantive standards while providing flexibility for countries to modify matters of details to suit their particular circumstances. While it guides national laws and ensures a certain level of similarity between them, the national laws remain, however, national, and in the absence of

agreements between countries regarding mutual recognition and reciprocal enforcement of rights etc, their application is limited to their respective territories.

iii. International approach: It is often suggested that comprehensive protection can only be achieved by way of an international system. Such a system is likely to consist of norms and principles with matters of detail left to national and regional levels. This is important given the world's cultural diversity as well as jurisprudential diversity. It is also realistic given the varied interests and concerns of countries, with positions based on quite different assumptions and ideological standpoints concerning traditional knowledge and traditional knowledge-holding groups. Nonetheless, any international regime that provides effective international legal protection will require a degree of harmonisation, and this can be achieved via norms and principles adopted at the international level. An international system has as its main and most attractive feature the facility to enforce rights regarding traditional knowledge of one ratifying country in another ratifying country.

The TBKIP Model Law is a hybrid of the national and regional approach. It sets out a high-level framework for national legislation and leaves matters of detail or implementation to be determined in accordance with national systems and practices. It has also been designed with the circumstances of PICTs in mind, with the expectation that it will form the basis of a harmonised legal framework for the regional protection of TBKIPs.

PART 2. DEVELOPING THE POLICY FRAMEWORK

If the general approach of the TBKIP Model Law is acceptable to a country, the next step in developing the legislation is to develop the policy framework, that is, the policy objective and the guiding principles. In a similar way to Part 1, countries will need to agree to these but can articulate the matters differently if they wish. This section explains the policy objective and guiding policy principles of the TBKIP Model Law and provides guidance on possible implementation options.

Depending on countries' policy processes, it may be beneficial to obtain the appropriate ministerial approvals regarding the policy framework before proceeding to the development of the legal elements of protection in Part 3. This will ensure policy-makers have clear guidance on ministers' preferences and expectations as they progress through this stage of the process. The approvals could be obtained at the same time as seeking approval for the approach of the legislation in Part 1.

2.1 Policy objective

The way in which a protection system is shaped and defined will depend to a large extent on the objectives it is intended to serve. In developing the legislation, it is critical that careful consideration is given to the objectives sought and that these are stated clearly.

This is not necessarily akin to the overarching objectives of protection of a legal and policy framework for traditional knowledge. These overarching objectives are likely to extend beyond the protection that can be achieved via this legislation to include matters such as the prevention of the granting of erroneous intellectual property rights over traditional knowledge as well as preservation initiatives. The policy objective, in this case, concerns the aim of the legislation and what it is seeking to achieve. It would form part of, and contribute to, the overarching objectives of protection of a legal and policy framework for traditional knowledge.

The TBKIP Model Law does not specify its objective, however, it could be described as follows: to protect the rights of traditional owners in their TBKIPs and provide them with the means to control the commercialisation of their TBKIPs, and ensure that such commercialisation is subject to their prior informed consent and the fair and equitable sharing of benefits arising from that utilisation with the traditional owners.

Countries can utilise this articulation of the policy objective of the TBKIP Model Law or state it different recalling that the core substance of the policy objective would need to be retained. There is also the option to develop more detailed objectives and sub-objectives specific to a country's needs.

2.2 Guiding policy principles

Generally, the guiding policy principles of a law are designed to both promote the policy objective of the law and, at a practical level, to provide guidance for policy-makers as they develop its substance (in this case, the legal elements of protection addressed in Part 3). Where there is uncertainty as to the intent of a particular provision, the courts, government agencies, traditional knowledge holders and others can refer to the guiding policy principles for assistance. Whether a country includes provisions articulating the principles that have guided a law's development often depends on national legislative practices.

The TBKIP Model Law does not contain a provision stating the guiding policy principles of the legislation. However, to assist policy-makers, the guiding policy principles have been extracted as follows. There is flexibility to adapt the articulation of the guiding principles and to add additional principles if desired. However, as with the policy objective, if countries have elected to develop legislation based on the TBKIP Model Law, the thrust of the guiding principles needs to be retained.

i. *Value*: Recognise that traditional knowledge systems are frameworks of ongoing innovation and play a central and beneficial role in the cultures of traditional communities and the conservation and sustainable use of biological diversity, and are of equal scientific value as other knowledge systems.

ii. *Respect*: Recognise the importance of those interacting with traditional communities respecting the integrity, morality and spirituality of the cultures, traditions and relationships of traditional communities and avoiding the imposition of external standards and value judgements.

iii. *Ownership*: Recognise that traditional communities are the owners, rights holders, and custodians of TBKIPs and the primary decision-makers regarding their use.

iv. *Beneficiaries*: Recognise that the benefits of protection should accrue to the communities who generate, preserve and transmit the knowledge in a traditional and intergenerational context, who are associated with it and who identify with it, rather than individuals (individual rights, including conventional IP rights, will be able to be recognised in other systems).

v. *Access, disclosure and use*: Recognise, respect and give effect to the rights of traditional communities to control access to, disclosure and use of TBKIPs.

vi. *Prior informed consent*: Recognise that traditional communities should be fully informed about the nature, scope, and purpose of any proposed activity that may involve the use of their TBKIPs.

vii. *Benefit sharing*: Ensure that traditional communities derive fair and equitable benefits from the utilisation of their TBKIPs.

viii. *Documentation*: Recognise that the documentation and recording of TBKIPs should primarily benefit traditional communities and that their participation in such schemes should be subject to their prior informed consent.

ix. *Customary laws and systems:* Encourage the use of customary laws and systems as far as possible, and recognise that communities are entitled to rely exclusively or in addition upon their own customary and traditional forms of protection against unwanted access.

x. *Enforcement and dispute resolution:* Ensure enforcement and dispute-resolution mechanisms are accessible, appropriate and adequate in cases of breach of the protection for TBKIPs.

xi. *Non-interference*: Recognise that the continued uses, exchange, transmission and development of TBKIPs within the customary context by the relevant traditional community, as determined by customary laws and practices, should not be restricted or interfered with.

xii. *Non-burdensome:* Ensure measures and procedures for the protection of TBKIPs are fair and equitable, accessible, transparent and not burdensome for traditional communities, including through the provision of support by the state in the management and enforcement of rights in TBKIPs.

xiii. *Balance:* Strike an appropriate balance between the rights and interests of traditional communities, users and the broader public, including taking international human rights standards into account.

xiv. *Relationship with IP:* Recognise that special protection for TBKIPs should be complementary to any applicable conventional IP protection;

xv. *Regional and international protection:* Take account of, and operate consistently with, other regional and international instruments and processes, in particular regimes that regulate access to and benefit sharing from genetic resources.

PART 3. THE LEGAL ELEMENTS OF PROTECTION

In developing legislation for the protection of TBKIPs, various legal elements of protection need to be addressed:

- What is the subject matter of protection?
- What are the criteria for protection?
- Who are the beneficiaries?
- What is the scope of protection?
- What are the exceptions and limitations?
- How will rights be managed?
- What is the term of protection?
- What are the formalities for protection?
- How will rights be enforced?
- What are the legal proceedings for taking actions (including remedies and penalties)?
- What processes can be used for dispute resolution?
- What is the relationship with IP protection?
- What is the relationship with ABS policy?
- How will international and regional protection be addressed?

This section of the Guidelines provides technical information on each of these elements. The nature of each element is detailed along with why the element needs to be addressed as part of the policy development process. Guidance is provided on the policy questions that should be considered with respect to each element and the associated implementation options. Where relevant, the Guidelines identify important policy considerations for policy-makers.

3.1 Subject matter of protection

The subject matter of protection is that which will be protected under the legislation. There is an important distinction between the subject matter in general and the protectable subject matter. It is only the latter that will receive protection under the legislation.

In order to establish the protected subject matter, policy-makers may wish to utilise a two-step process. The first step is to develop a description of the subject matter that should be protectable. Policy-makers may find it useful to consider this exercise as that of defining the scope of the protectable subject matter. It is commonplace for the scope of the protectable subject matter to be determined at the national level rather than at the regional or international level. Therefore, the TBKIP Model Law should be viewed as indicative only. The second step is to develop a more precise delimitation of those TBKIPs that are eligible for protection (addressed under the next element, 'Criteria for Protection').

3.1.1 Policy questions

The following questions are intended to assist policy-makers to identify the protectable subject matter of the legislation that is appropriate to their national circumstances. This is not an exhaustive list and policy-makers should note that there may be additional questions to be considered.

a) Which TBKIPs should receive protection?

The legislation should identify as clearly as possible which TBKIPs will be protectable or the scope of the subject matter may appear too wide and imprecise.

In developing a description of the TBKIPs for which protection is sought, policy-makers may find it useful to work through the following list taken from section 4 of the TBKIP Model Law and the definition of 'traditional biological knowledge':

- living things, their spiritual significance, their constituent parts, their life cycles, behaviour and functions, and their effects on and interactions with other living things, including humans, and with their physical environment;

- the physical environment;

- the obtaining and utilising of living or non-living things for the purpose of maintaining, facilitating or improving human life.

This definition is a non-exhaustive list intended to be used as a starting point only. Other approaches in this area include the following:

- Decision 391 of the Andean Community - Common Regime on Access to Genetic Resources defines the 'intangible component' as "all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes";

- Lao's Decree on Biological Resources and Related Traditional Knowledge defines 'traditional knowledge' as "all individual and collective knowledge, innovations or practices of local communities based on biological resources";

- the Peru Law 2002 defines 'collective knowledge' as "the accumulated, transgenerational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity";[6]

- the African Model Legislation for the Protection of the Rights of Local Communities, Farmers, Breeders and for the Regulation of Access to Biological Resources (the 'African Model Legislation') defines 'community knowledge' or 'indigenous knowledge' as "the accumulated knowledge that is vital for conservation and sustainable use of biological resources and/or which is of socio-economic value, and which has been developed over the years in indigenous/local communities";

- the WIPO IGC Revised Draft Provisions for the Protection of Traditional Knowledge: Policy Objectives and Core Principles state that "the term "traditional knowledge" refers to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources."[7]

It is also important to recall the multi-dimensional nature of traditional knowledge. The Secretariat of the CBD has written that traditional knowledge encompasses three dimensions: a cultural aspect (it reflects the culture and values of a community), a temporal aspect (it is passed on through the generations, and slowly adapts to respond to changing realities) and a spatial aspect (it relates to the territory or the relationship which a community has with its lands and waters traditionally occupied or used).[8]

In countries with a number of distinct traditional communities, policy-makers should also consider whether the description adequately accommodates that diversity. It is not necessary to have separate definitions for each traditional community provided the scope of the subject matter sufficiently captures the perspectives of the communities.

b) What terminology should be used to describe the subject matter?

Flexibility regarding terminology is important and many international IP standards defer to the national level for determining such matters. Accordingly, the TBKIP Model Law has generally left detailed decisions on terminology to be determined at the national level. For example, there is an option to use the term, 'biodiversity-related knowledge' rather than 'biological knowledge' or another term that may be considered appropriate. The

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[6] Article 2(a).
[7] Article 3 of document WIPO/GRTKF/IC//9/5
[8] Convention on Biological Diversity. 2007. *Development of Elements of Sui Generis Systems for the Protection of Traditional Knowledge, Innovations and Practices to Identify Priority Elements*. UNEP/CBD/WG8J/5/6, Montreal. p.4

TBKIP Model Law uses the term 'biological' in preference to 'ecological' as the latter has a narrower meaning. Existing laws show diversity in the terms used to refer to this subject matter. For example, the Peru Law 2002 refers to knowledge derived from biological resources whereas Brazil's Provisional Measure 2001 refers to genetic resources and the associated traditional knowledge.

Further, a country may wish to use vernacular terms to describe particular aspects of TBKIPs, such as rongoa, the Maori word for medicine in New Zealand.

c) Should all protectable subject matter be treated equally under the legislation?

It is important for policy-makers to consider whether all TBKIPs should be treated uniformly or whether their treatment should reflect differences, where they exist. In many traditional communities, some knowledge is considered to hold greater cultural or spiritual significance than others. There is also some knowledge that is sacred-secret where access and use is highly restricted. Therefore, in developing a description, countries may wish to make reference to different layers or levels of TBKIPs.

Recognising these distinctions can be critically important from a protection perspective, particularly in respect of the term of protection, the scope of protection and formalities (all of which are legal elements of protection discussed later in the Guidelines). Varying and multiple levels and forms of treatment may be appropriate for different areas of traditional knowledge. For example, there may be traditional knowledge that is of such significance that under no circumstances should it be commercialised.

In terms of existing approaches and commentary in this area, some guidance can be drawn from regimes for the protection of traditional cultural expressions. Under the Pacific Model Law, traditional knowledge and expressions of culture are treated in two 'layers': there is a stronger degree of protection for sacred-secret material while the remaining others are treated equally. The WIPO IGC has identified three 'layers' or groupings of expressions of culture: secret, confidential or undisclosed expressions; expressions of particular cultural or spiritual value to a community; and other expressions. This approach takes an additional step to the Pacific Model Law and identifies two layers within non-sacred-secret expressions: those of particular cultural or spiritual value, and others. While these two examples deal with cultural expressions, the principles are equally relevant to TBKIPs as some knowledge is considered to hold greater spiritual significance than others and some is also highly restricted with respect to access and use.

3.1.2 Further information

Another source of information regarding the subject matter of protection includes:

- WIPO. 2002. *Traditional Knowledge - Operational Terms and Definitions* WIPO/GRTKF/IC/3/9. Geneva: WIPO

3.2 Criteria for protection

Having developed a description of the subject matter generally, the next step is to consider whether all TBKIPs should receive protection.

The TBKIP Model Law does not include explicit criteria for protection. Therefore, all TBKIPs are protected by the legislation. However, it is acknowledged that some countries may wish to take a different approach and modify this provision. This section of the Guidelines has been prepared to assist policy-makers in this regard. Laws typically establish what part of a subject matter is eligible for protection by stipulating the substantive criteria that the subject matter should display in order to be protectable.

3.2.1 Policy considerations

In identifying the characteristics that TBKIPs should possess in order to be protectable, an important policy consideration is the balance between protection imperatives and the promotion of innovation. If a criterion is too rigorous, the level of protection will be reduced. However, if a criterion is relatively loose, it could have a negative impact on the public domain, which is likely to impact on innovation and creativity.

Another consideration is that of extra-territorial protection. While generous and flexible criteria may provide protection for more TBKIPs nationally, lesser protection may be available in other jurisdictions that do not take such a broad approach. A difficulty for countries is that there is currently no international standard regarding criteria for protection of TBKIPs or traditional knowledge generally. That being the case, countries could take guidance from provisions developed within international fora such as the WIPO IGC which have the potential, in their existing or modified form, to evolve into a form of international norm or standard.

3.2.2 Policy questions

The following questions are intended to assist policy-makers to develop criteria for protection that are appropriate to their national circumstances. This is not an exhaustive list and policy-makers should note that there may be additional questions to be considered.

a) What characteristics should TBKIPs have in order to be protected?

In an IP context, in order to be protected, subject matter must be the result of creative human intellectual activity.[9] Examples of this principle include the 'originality' requirement of copyright works and the 'novel' requirement in patent laws. However, existing *sui generis* systems for the protection of traditional knowledge do not generally require the protected traditional knowledge to be 'original' or 'new' because such a requirement would generally protect only contemporary knowledge. WIPO has also

[9] The Convention Establishing the World Intellectual Property Organisation 1967 defines IP by reference to rights relating to: literary, artistic and scientific works; performances of performing artists, sound recordings and broadcasts, inventions in all fields of human endeavour, scientific discoveries, industrial designs, trademarks, service marks and commercial names and designations, protection against unfair competition, and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

suggested that an 'originality' requirement would be out of step with evolving practice and would exclude significant amounts of the subject matter.[10]

This raises the question of what an appropriate principle might be for the protection of TBKIPs. . If a country wishes to include a substantive criterion for protectable TBKIPs, the use of a 'value' criterion is one option. In Decision 391 of the Andean Community - Common Regime on Access to Genetic Resources, the definition of 'intangible component' includes a specific reference to know-how, innovations and practices of 'real or potential value'. The African Model Legislation restricts within the definition of community knowledge or indigenous knowledge protection to that which is 'vital for conservation and sustainable use of biological resources and/or which is of socio-economic value'.

Another option is restricting the protectable TBKIPs to those which relate to the properties, uses and characteristics of biological diversity, the approach taken in the Peru Law 2002. This would have a broader scope than the 'value' criterion as it would, for example, include knowledge regarding properties and uses that might not have economic value.

In the related domain of traditional cultural expressions, policy-makers may find it useful to note that WIPO has suggested that a focus on 'intellectual creativity' may be appropriate as a substantive criterion for protectable traditional cultural expressions.[11] Traditional cultural expressions are the products of creative and intellectual processes and this criterion would acknowledge the creative and intellectual value of the material.

b) To be protected, should TBKIPs be required to have an association with a traditional community?

Most, if not all, existing systems for the protection of traditional knowledge establish a criterion requiring some form of linkage between the traditional knowledge and the community, often to distinguish between 'authentic' and 'non-authentic' traditional knowledge.

Such a linkage is contained within the TBKIP Model Law which makes specific reference in section 4 to belonging to a social group and being gained from having lived in close contact with nature. The TBKIP Model Law goes on to define a social group as a family, clan, tribe, village or similar social organisation.

c) To be protected, should there be a requirement that the TBKIPs be maintained or used by a community?

An unfortunate reality is that some TBKIPs are no longer maintained or used by traditional communities. This raises a policy question of whether protection should be extended to TBKIPs that, although once characteristic of a traditional community, are no longer maintained or used by the community or by individuals having the responsibility to

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[10] WIPO 2004, The Protection of Traditional Cultural Expressions/Expressions of Folklore: Revised Objectives and Principles WIPO/GRTKF/IC/7/3, Geneva: WIPO, Annex II 15

[11] Ibid

do so. Recalling the policy consideration of balancing protection with the promotion of creativity and innovation, countries may wish to consider whether it would be beneficial to include a criterion that TBKIPs be maintained, used or developed by a community, or by individuals having the right or responsibility to do so in accordance with the customary law and practices of that community. If this criterion is not met, then the TBKIPs would not be protectable even if it is the result of 'creativity' and 'innovation'.

While this may appear to promote fairness, it is important to bear in mind that many PICTs are in the process of developing cultural preservation and revitalisation programmes to address the loss of traditional practices. Moreover, in some countries, traditional communities cannot access lands, waters and resources traditionally occupied and this has a direct effect on their ability to maintain and transfer traditional knowledge. If a 'maintenance or use' criterion were instituted, it may result in the exclusion of traditional knowledge that has not been utilised in recent times.

3.3 Beneficiaries

A guiding principle of the TBKIP Model Law is that the protection of TBKIPs should benefit the communities who generate, preserve and transmit the knowledge in a traditional and intergenerational context, who are associated with it and who identify with it. Further, any rights and interests in TBKIPs are commonly considered to be those of communities rather than individuals (even though individual innovators or traditional knowledge holders may have distinct personal rights or entitlements within the community structure). This is reflected in a further guiding principle of the TBKIP Model Law which states that the benefits of protection should accrue to traditional communities rather than individuals while recalling that individual rights (including conventional IP rights) for innovators or creators of original works would be able to be recognised in other systems.

The development of this element involves elaborating these principles in more detail and clarifying who will benefit from the legal protection provided by the legislation.

3.3.1 Policy considerations

Clarity with regard to ownership of TBKIPs and the associated rights and interests is critical in developing a protection system. In addition, a country should also ensure there is clarity with regard to ownership of the genetic resources associated with a community's traditional knowledge. This can affect how PIC and benefit sharing requirements are met.

3.3.2 Policy questions

The following questions are intended to assist policy-makers to develop a substantive policy regarding beneficiaries of protection that is appropriate to their national circumstances. This is not an exhaustive list and policy-makers should note that there may be additional questions to be considered.

a) What groups or communities should benefit from the protection of TBKIPs?

Traditional biological knowledge is held by a range of communities, including Indigenous peoples, tribal peoples, local communities and other cultural communities. In the Pacific region, there is likely to be a range of traditional knowledge-holding communities within one particular country. An initial question for policy-makers is which groups or communities should benefit from protection and whether this should extend to all traditional knowledge holding communities or only specific groups.

In regard to identifying which groups or communities should benefit from conferred communal rights and interests in their TBKIPs, including considering whether or not to delimit the possible beneficiary groups, a country's objectives of protection should be instructive. There may also be moral or historical reasons that justify particular groups benefiting from protection ahead of other groups.

Existing laws for the protection of traditional knowledge utilise a range of approaches. In some cases protection is limited to knowledge held by Indigenous communities,[12] while in others the concept of beneficiaries is much broader and involves knowledge held by Indigenous as well as local communities or populations.[13] Therefore, more than one type of community may qualify for protection.

Under the TBKIP Model Law, section 6 provides that ownership by a *social group* over an item of knowledge or an innovation or a practice is established according to the history and traditions and customs and usages of that social group (therefore, the legislation itself does not establish the existence of ownership, it merely recognises that it has already been determined by customary law). Section 4 of the TBKIP Model Law defines the types of social group as being a family, clan, tribe, village or similar social organisation. These are the beneficiaries of protection. In developing the legislation, policy-makers will need to develop a particularised definition that is appropriate to their national circumstances. The definition of 'social group' in section 4 is intended to provide guidance on the types of groups rather than act as a definition in and of itself.

If a country considers it appropriate to delimit the possible beneficiary groups, it could include specific criteria in the legislation that beneficiary groups have to meet, such as being an Indigenous or local community of the country in question.

b) How should beneficiary groups be described?

The TBKIP Model Law uses several different terms to describe the beneficiaries of protection - an owner, the owners and social group. Each of these terms is broad in nature and is intended to cover the variety of traditional knowledge-holding communities. There is flexibility for countries to use an alternative term to describe the beneficiary group(s) in the legislation.

As well, some countries may prefer an alternative term to 'owners'. To 'own' in relation to TBKIPs is defined in section 4 of the TBKIP Model Law as including owning as a trustee, as a custodian and as a steward, and its meaning in any particular context is determined by the history, traditions, customs and usages of the social group which claims ownership. The term 'holders', however, is often considered to be more appropriate than 'owners'. It is used to convey the relationship between a community and its traditional knowledge, often seen as being more akin to custodianship.

In addition, existing laws for the protection of traditional knowledge do not necessarily identify beneficiaries as holders of distinct intangible property rights as such, although some have elected to establish distinct rights. Some laws identify the right holders through the term 'local communities' or 'Indigenous peoples', or a combination thereof. Others do not identify rights holders, but define 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 medical intelligence'. The Costa Rican law provides that the titleholder of *sui generis* community intellectual rights shall be determined by a participatory process.

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[12] For example, the Panama Law 2000.

[13] Examples include laws in Bangladesh, Brazil and Portugal.

c) Should particular linkages be required between the beneficiaries of protection and the protected TBKIPs?

The establishment of required linkages between the beneficiaries of protection and the protectable subject matter can be used for several purposes. If a form of 'relationship linkage' is required between the beneficiary group and the TBKIPs, this can be useful in ensuring that the appropriate groups benefit from the protection provided under the legislation. It can also promote greater certainty and transparency within the regime. The linkage could be demonstrated by reference to customary law or community practices. For example, under the TBKIP Model Law, section 4 provides ownership is determined according to history, traditions, customs and usages. In the absence of such a linkage, a traditional community could potentially claim rights and interests in particular TBKIPs that are, in actual fact, held by another traditional community.

Relationship linkages can also be useful in scenarios where a small group within a broader community holds TBKIPs that other parts of that particular community do not. In this situation, it may be considered appropriate for the group to benefit from protection rather than the community as a whole. The group could use the relationship linkage to demonstrate that it has the relationship required in order to benefit from the protection of the TBKIPs in question.

In terms of linkages that could be used, two possibilities are:

- those to whom the custody, care and safeguarding of the TBKIPs are entrusted in accordance with customary law and practices; and

- those who maintain, use or develop the TBKIPs as characteristic of their cultural and social identity and cultural heritage (or simply 'as being characteristic of their traditional cultural heritage').

d) How should the beneficiary group be represented?

Having clarified the beneficiary group or groups in name or description, the next step is to consider whether or not the legislation will prescribe how these groups may or should be represented to receive benefits under the legislation (and to assert their rights). Existing laws for the protection of traditional knowledge use a range of approaches to address this issue, including the following:

- Requiring the beneficiary group to have legal personality: For the purpose of legal procedures such as enforcing rights, a country may require the beneficiary group to have some form of legal personality. The legislation could prescribe a particular form or provide that the beneficiary group must designate a distinct legal person (such as an association, a legal representative or a trustee) as rights holder in trust. Countries may wish to draw on existing legal models in their domestic law and the experience with any community-held IP, such as collective marks, and on applicable customary law. For example, in the Panama Law 2000, existing models are utilised so that the relevant Indigenous communities may be represented by their general congresses or traditional authorities.

- Determining representation through processes such as registration or certification: A registration or certification process can be used to ensure there is a distinct entity to represent the beneficiary group. While it would require state involvement, it would be without the formalities of obtaining and maintaining a legal personality. This approach could also be used to support communities' own rules and customary practices by providing that beneficiary groups determine their representative(s) according to customary practices and notify the appropriate state body for registration or certification purposes. Alternatively, the legislation can specify the criteria to be met in order for a community to register as a beneficiary group. Such criteria could reflect any required linkages between a community and TBKIPs. In Portugal, the representation claimed by any private or public entity for registration of a local plant variety must be certified by the competent municipal chamber.

- Not prescribing a representation requirement: It is not imperative that the beneficiary group be identified as distinct 'owners'. The legislation could be silent in respect of representation requirements, thereby leaving the matter open to all forms of representation. IP need not be separately owned by distinct right holders. 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. Collective marks and certification marks may be protected on behalf of a group of beneficiaries. Where the 'right' 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. There would be implications for international protection if the beneficiary group is to be granted rights in foreign jurisdictions and there are no distinct right holders.

The TBKIP Model Law does not prescribe how 'traditional owners' may or should be represented for the purposes of the legislation. This is not a policy of the TBKIP Model Law but rather reflects its approach that it is a high-level framework and a matter such a representation should be determined at the national level. There is flexibility to institute a representation requirement if desired. However, if the primary driver for taking this approach is to provide certainty for third parties, policy-makers should note that under the TBKIP Model Law, a prospective user wishing to use TBKIPs must apply to the Competent National Authority established under the legislation which then follows a process to identify the relevant owners. This will significantly reduce, if not eliminate, uncertainty for users.

e) Should the state have a beneficiary role?

While it is well established that the beneficiaries of protection should be the communities that hold the TBKIPs, in some cases, it may be considered appropriate for the state to have a beneficiary role as well. For example, where there are difficulties in identifying which groups have rights over TBKIPs, particularly those that are shared across communities, the state could receive the benefits of protection on behalf of these communities and then apply the proceeds towards initiatives that are for the betterment of all of the communities concerned. In existing laws that take this approach, proceeds from the granting of such rights are applied towards national heritage, social welfare and culture-related programs for the general benefit of traditional communities but without transferring the proceeds directly to these communities. In addition, if there are issues with transferring the benefits

of protection to the beneficiary group, the state could act as a conduit and receive the benefits, then transfer the benefits to the beneficiary group.

If the state assumes a beneficiary role, policy-makers may wish to consider whether the state should also have a role in the management and enforcement of rights, which are often a heavy burden for traditional communities to bear (see the elements, 'Management of Rights' and 'Enforcement').

The TBKIP Model Law provides in section 6 for the state to assert ownership over an item of knowledge or an innovation or a practice in the following situations.

- Where the Competent National Authority is satisfied there is no immediately verifiable owner of the TBKIPs, it will be considered to be the owner for the purposes of the legislation as trustee on behalf of the eventual owner.

- Where the Competent National Authority is satisfied, after having made extensive efforts to locate an owner of TBKIPs, that an owner will not be found, it will be considered to be the owner for the purposes of the legislation as trustee on behalf of the particular country.

As a safeguarding measure, countries could also make provision for a neutral, third-party to hear complaints from communities if they consider that the Competent National Authority has asserted ownership under section 6 without sufficient grounds.

f) How can the relationship between the beneficiary group and the individual creator be addressed?

It is widely recognised that traditional knowledge is the collective property and cultural patrimony of traditional communities, and that ownership rights in traditional knowledge should be vested in communities, rather than in individuals. However, within those communities, individuals or specific families may be 'custodians' of the knowledge on behalf of the community. Where an individual has developed a tradition-based innovation within his or her customary context, it is regarded from a community perspective as the product of communal processes. The innovation is not 'owned' by the individual but 'controlled' by the community according to customary legal systems and practices. There are often customs and traditions involving permission for individuals to use elements of traditional knowledge, within or outside the community concerned, as well as issues concerning ownership, entitlement to benefits, etc. This is what marks such an innovation as 'traditional' and provides a policy rationale for providing benefits under the legislation at the collective rather than the individual level.

In terms of how the interests of individual creators within their communities can be reflected in the legislation, the TBKIP Model Law takes the approach that this is a matter for customary law and practices to address. Customary law often establishes the attribution of rights and benefits within a community, including individual interests in traditional knowledge. This will also be relevant for individual rights that may accrue under existing IP laws. There is, of course, flexibility for countries to incorporate measures that regulate the relationship between individual innovators and their community. However, the use of such measures is not often considered desirable.

g) Can there be two or more beneficiary groups in particular TBKIPs?

In some cases, two or more traditional communities in a country may hold the same or similar TBKIPs. As well, communities in different countries and even regions may lay claim to the same or similar TBKIPs. This can result in potentially overlapping rights in the same or similar TBKIPs, and therefore it will be necessary to clarify the allocation of rights or distribution of benefits among those communities. As this is not a question of whether these groups should benefit, but rather how benefits should be distributed, this issue is addressed under the element, 'Management of Rights'. For the purposes of the present element, it is useful to note that there may be two or more beneficiary groups in some traditional knowledge and that policy measures will be needed to address these multiple interests.

h) How should ownership of TBKIPs be determined?

Once policy-makers have developed policies regarding the beneficiary group(s) generally, the next step is to determine how to address ownership of TBKIPs within that.

A key component of the TBKIP Model Law is the policies and procedures for identifying the owners of TBKIPs. Under section 10, a prospective user of TBKIPS must apply to the Competent National Authority who must then give a copy of the application to the social group they believe to be the owner, as well as publicise the application. Any social group claiming ownership must identify itself to the Competent National Authority and satisfy the Competent National Authority of its claim to ownership. Once the Competent National Authority is satisfied as to the identity of the owner, it must inform the prospective user and publicise the identity nationally.

Policy-makers may wish to consider whether a state body should be tasked with determining the identity of the owner or whether this would be more appropriately addressed through other means, such as customary laws and practices. This may or may not be an issue within a country depending on the particular dynamics between traditional communities and the state.

If a country considers that ownership should be determined according to customary laws and practices, one option is to retain the policy that the Competent National Authority receive all applications but modify the approach so that it is charged with facilitating consideration of the ownership question in accordance with customary laws and practices.

i) How should disputes regarding ownership be resolved?

Section 12 provides that any person may lodge an enquiry with the Competent National Authority regarding ownership of an item of knowledge, an innovation or practice and sets out the process that is to be followed in this regard.

Ownership enquiry

(1) Any person may lodge an enquiry at any time with the [Competent National Authority] regarding ownership of an item of knowledge, an innovation or a practice. He must specify the owner of as well as the knowledge, innovation or practice being enquired about and the basis for the enquiry. He may present such other submissions as he considers relevant.

(2) The owner being challenged is to be given a copy of the enquiry by the [Competent National Authority] and must within thirty days provide a written reply along with any other submissions it considers relevant to the [Competent National Authority] and to the enquiring party.

(3) The [Competent National Authority] will publicise the enquiry in summary form and invite submissions from the public.

(4) The [Competent National Authority], acting as mediator, after it has considered all submissions and when it is satisfied that the issues in dispute have been clarified, must call a conference between the parties at which the following matters are to be discussed:

  (a) whether there is any merit in the enquiry and if not, then the enquiring party is to be requested to withdraw its enquiry and where this is done then the enquiry will terminate upon the entry of that information in the database.

  (b) whether the parties are owners of different items of knowledge, innovations or practices and if the parties agree that this is the case then the enquiry will terminate upon the entry of that information in the database.

  (c) whether the parties are co-owners of the knowledge, innovation or practice in dispute and if the parties agree that this is the case then the enquiry will terminate upon the entry of that information in the database.

  (d) whether only one of the parties is the owner of the knowledge, innovation or practice in dispute because the other party agrees that this is the case or does not answer the enquiry then the enquiry will terminate and the appropriate information entered in the database.

  (e) such other matters as the [Competent National Authority] or parties consider relevant.

Section 12, TBKIP Model Law

In the event, that a consensual decision is not reached regarding ownership, the TBKIP Model Law provides for a body referred to as the ‘Traditional Ownership Tribunal’ to adjudicate on the dispute.

The Traditional Ownership Tribunal

(1) In the event that a consensual decision pursuant to section 12, or any other additional means, is not reached either of the parties may then request the [Competent National Authority] to convene a body, to be known as the Traditional Ownership Tribunal, to adjudicate on the dispute.

(2) Where, pursuant to subsection (1), a party requests the [Competent National Authority] to convene the Tribunal, the [Competent National Authority] shall do so within 30 days.

(3) The Tribunal shall consist of three people with expertise in the area under dispute.

(4) The Tribunal shall:

(a) select a chairperson;

(b) model its rules of procedure as closely as practicable to those of the [principal] Court;

(c) hear all such evidence as it considers necessary to hear;

(d) consider the evidence and dispose of the dispute by deciding:

(i) that there is no merit in the enquiry, or

(ii) that the parties are owners of different items of knowledge, innovations or practices, or

(iii) that the parties are co-owners of the knowledge, innovation or practice, or

(iv) that only one of the parties is the owner of the knowledge, innovation or practice, or

(v) that none of the foregoing decisions can be made and that the matter will be referred back to the [Competent National Authority],

and shall have all such powers as are required to carry out these functions.

(5) The [Competent National Authority] shall make available all documents in its possession or control pertaining to the dispute to the Tribunal and shall act as the secretariat to the Tribunal.

Section 13, TBKIP Model Law

The TBKIP Model Law provides for a right of appeal regarding a decision of the Traditional Ownership Tribunal. This may be modified if desired. If a country elects to adopt this policy, it will need to identify the court to which appeals may be made (referred to as the 'principal court' in section 14).

Appeal

A party may, within twenty one days of having received the decision of the Tribunal, appeal against the decision to the principal [Court] whose decision shall be final.

Section 14, TBKIP Model Law

The policies and processes set out in the TBKIP Model Law are detailed and extensive and will have considerable resourcing implications that need to be taken into account. If a country does not wish to adopt this aspect of the TBKIP Model Law, there is flexibility to do so. In a similar manner to identifying ownership, a country could make provision in the legislation for the matter to be determined according to customary laws and practices.

3.3.3 Further information

Another source of information regarding beneficiaries of protection is:

- WIPO. 2006. *Revised Draft Provisions for the Protection of Traditional Knowledge: Policy Objectives and Core Principles.* WIPO/GRTKF/IC/9/5 Pages 24-26 of the Annex discuss beneficiaries of protection.

3.4 Scope of protection

The protection of TBKIPs is a central component of the legislation. The form of legal protection in the TBKIP Model Law consists of:

- exclusive property rights where particular uses of TBKIPs require the prior informed consent of the traditional owners; and
- the moral rights of traditional owners in their TBKIPs.

The development of this element entails clarifying the scope of these rights, that is, the uses, appropriations and omissions that should be prohibited, require authorisation or be regulated in other ways.

3.4.1 Policy questions

The following questions are intended to guide policy-makers through the issues relevant to developing a substantive policy on the scope of protection that is appropriate to their national circumstances. This is not an exhaustive list and policymakers should note that there may be additional questions to be considered.

a) What acts regarding TBKIPs should be regulated?

A central element of protection is the scope of acts that will be regulated, in other words, what conduct or acts will now be controlled by the legislation. The TBKIP Model Law introduces new requirements that must be met for any use of TBKIPs for a commercial purpose, or for an activity that is likely to assist in achieving a commercial purpose. It applies to all uses and is therefore a blanket provision rather than specifying particular uses.

Economic rights

(1) In addition to any rights available under applicable intellectual property laws an owner of an item of knowledge, an innovation or a practice has the exclusive right to use or to authorise the use of its knowledge, innovation or practice:
  (a) for a commercial purpose, or
  (b) for an activity that is likely to assist in achieving a commercial purpose.

(2) Any person wanting to use an item of knowledge, an innovation or a practice for a commercial purpose, or an activity that is likely to assist in achieving a commercial purpose, must comply with sections 10 and 11 of this Act.

(3) Subsection (2) shall not apply to plant genetic resources for food and agriculture whose collection, holding, transfer and use are covered by a policy approved by the Secretariat of the Pacific Community.

(4) Any person who contravenes subsection (2) commits an offence and is liable upon conviction to a fine not exceeding [$].

Section 8, TBKIP Model Law

b) What acts should be excepted from regulation?

Policy-makers will also need to consider what will not be affected by the legislation. It is common for some acts to be exempted from regulation, referred to as 'exceptions' or 'limitations'. A guiding principle of the TBKIP Model Law is that traditional and customary uses, exchanges and transmissions of TBKIPs, as determined by customary laws and practices, and whether or not of a commercial nature, should not be restricted or interfered with by the legislation. This means that if TBKIPs are used for a commercial purpose but within a customary context, this will fall outside the scope of the legislation and the legislative requirements do not apply. This is discussed further under the element, 'Exceptions and limitations'.

c) What moral rights regarding TBKIPs should be established?

Moral rights appear in national laws for the protection of traditional knowledge as well as copyright law. Moral rights relate to the protection of the personality of the creator or author and the integrity of the work and similar matters.[14] While the scope of moral rights differs across jurisdictions, certain features are fairly common: moral rights are almost invariably treated in national legislation separately from those sections dealing with economic rights; moral rights are not assignable although they may descend to heirs or successors; and moral rights have the same term of protection as economic rights or a longer term. Also, in civil law jurisdictions, where moral rights and economic rights clash, the moral right is likely to prevail.[15]

Policymakers will need to identify which moral rights owners of TBKIPs will have. Section 9 of the TBKIP Model Law provides for the following types of moral rights:

- the right of attribution of ownership;
- the right not to have ownership of traditional knowledge falsely attributed to them;
- the right not to have their traditional knowledge subject to derogatory treatment.

Moral rights

(1) Owners of knowledge, innovations and practices have the following moral rights:

  (a) the right of attribution of ownership in relation to their knowledge, innovations or practices;

  (b) the right not to have ownership over an item of knowledge, an innovation or practice falsely attributed to them; and

  (c) the right not to have their knowledge, innovations and practices subject to derogatory treatment.

(2) Any person who, upon the commencement of this Act, contravenes subsection (1) commits an offence and is liable upon conviction to a fine not exceeding [$].

Section 9, TBKIP Model Law

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[14] J.A.L Sterling. 1998. *World Copyright Law* London: Sweet & Maxwell 279
[15] Ibid at 281

These three types of moral rights are common and appear in many national laws for the protection of traditional knowledge and also copyright law although in the latter, it is generally the right of attribution of authorship rather than ownership. The Pacific Model Law 2002 provides for the moral right of attribution of source rather than ownership which may be an alternative option for countries to consider. There are also other types of moral rights such as the divulgation right (the right to decide when, where and in what form the work will be divulged to any other person or persons) and the retraction right (the right of an author to withdraw a work from publication) but these do not commonly appear in national laws for the protection of traditional knowledge.

d) How should acts regarding TBKIPs be regulated?

Having determined *what* should be regulated, the next step is to consider *how* these acts should be regulated. This has largely been predetermined by:

- the legal form of protection in the TBKIP Model Law of exclusive property rights, which enable rights holders to authorise or prevent others from undertaking certain acts; and

- the guiding principle of the TBKIP Model Law that traditional communities are the owners, holders and custodians of TBKIPs and the primary decision-makers regarding their use.

Based on these factors, the TBKIP Model Law regulates acts regarding TBKIPs by providing that particular uses require the prior informed consent (PIC) of the traditional owners. This is referred to as an 'economic right'. Failure to obtain the PIC of traditional owners to use TBKIPs where required, constitutes an offence under the TBKIP Model Law.

The TBKIP Model Law establishes an elaborate process regarding how the PIC of the relevant traditional community should be obtained. Given that it is an operational matter and therefore appropriately addressed through regulations, it is covered in Part 4 - Developing Secondary Legislation.

Of note is that under the TBKIP Model Law, the PIC requirement applies to all TBKIPs. However, there is flexibility for countries to take a different approach if desired. For example, a country may not wish to impose a PIC requirement for all TBKIPs and may wish to only introduce the PIC requirement in relation to particular TBKIPs while others may be more 'lightly' regulated, if at all.

3.4.2 Further information

Another source of information regarding the scope of protection is:

- J.A.L Sterling. 1998. *World Copyright Law.* London: Sweet & Maxwell. Chapters 8 and 9 provide information on the types of moral rights and economic rights respectively used in copyright law.

3.5 Exceptions and limitations

It is generally recognised that restrictions should be placed on the exercise or scope of established rights, referred to as 'exceptions' or 'limitations'. Such provisions can stipulate that a right is not infringed by the doing of certain acts, the right does not subsist in relation to a particular class of subject matter, the right does not apply to things done by the right holder, and/or the right does not apply to certain categories of work.

Restrictions on the exercise or scope of established rights can also occur through the application of legal or other principles which are separate from the law of intellectual property such as freedom of speech or international human rights standards. The rationale for such restrictions can include consideration of the public interest and prevention of monopoly control.

Further, many traditional knowledge holders have stressed that protection should be subject to certain limitations so as not to interfere with the use of TBKIPs by traditional communities. This is reflected in a guiding principle of the TBKIP Model Law which recognises that the continued uses, exchange, transmission and development of TBKIPs within the customary context by the relevant traditional community, as determined by customary laws and practices, should not be restricted or interfered with.

The development of this element involves identifying the exceptions that will be provided for in the legislation regarding uses of TBKIPs (i.e. uses that are exempt) as well as defining the limitations on the scope of protection - in other words, what will not be affected by the legislation.

For simplicity, the Guidelines use 'exceptions' to describe those uses that are exempted from the need to seek authorisation, and 'limitations' to describe the limits on the scope of protection. There is no definition in international instruments of the difference between an exception and a limitation. Sometimes what it called a limitation in one law is referred to as an exception in another. 'Exceptions and limitations' is often used to cover all types of restrictions on the exercise or scope of established rights.

3.5.1 Policy considerations

At the national level, a number of factors may influence the determination of the exceptions and limitations to be introduced. It is apparent from existing national laws that different countries have different concepts as to what restrictions should be admitted, and as to the extent of such restrictions. For example, in the United States, while copyright law is considered to secure a fair return for an author's creative labour, its ultimate aim is provide an incentive to stimulate the creation of useful works for the general public good.[16] In contrast, the French system is based on the concept of the pre-eminent position of the individual author and the recognition of the principle that the author's right is a right of personality which must be accorded the highest respect.

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[16] See *Twentieth Century Music Corp.* v. *Aiken* 422 U.S at 156, 186 U.S.P.Q at 67, quoted in *Harper and Row*, supra, 471, U.S at 558.

In the context of protecting TBKIPs, a core policy consideration is striking an appropriate balance between protection against misappropriation of TBKIPs, and the freedom and encouragement of further development and dissemination of innovations. As well, TBKIPs form a living body of human culture and therefore, a key policy consideration is ensuring that they are not protected too rigidly. For example, Article 4 of the Peru Law 2002 provides that the regime shall not affect the traditional exchange between indigenous peoples of the collective knowledge protected under the regime.

3.5.2 Policy questions

a) What uses should be exempted from the PIC requirement under the legislation?

The requirement established under the TBKIP Model Law that uses of TBKIPS require the PIC of the traditional owners only relate to uses for a commercial purpose or for an activity that is likely to assist in achieving a commercial purpose. Therefore, non-commercial uses or uses that are not likely to assist in achieving a commercial purpose are exempted from the PIC requirement. Depending on county's drafting practices, it may be sufficient for this exemption to be implied, or explicit provision can be made.

The TBKIP Model Law also specifies in section 8(3) that the PIC requirement does not apply to "plant genetic resources for food and agriculture whose collection, holding, transfer and use are covered by a policy approved by the Secretariat of the Pacific Community."

There may be some uses that have a commercial dimension but may not be the intended target of the legislation. If so, specific provision should be made for these uses to be exempted from the PIC requirement.

Furthermore, a country may wish to include exceptions and limitations such as criticism or review, education, and administrative and judicial procedures which often appear in particular types of intellectual property law.

b) Should conditions be established for the application of the exception?

Some national laws provide that an exception is only applicable when certain conditions or procedures are observed. For example, there could be a condition that in order to rely on a specific exception, a use must: be compatible with fair practice; the relevant community is acknowledged as the source where practicable and possible; and such uses would not be offensive to the relevant community. This approach is followed in the Pacific Model Law which provides that the user must make sufficient acknowledgement of the traditional owners by mentioning them and/or the geographical place from which the traditional knowledge or expressions of culture originated (clause 7(5)).

c) What limitations should be applied on the scope of protection of the legislation?

As noted previously, many traditional knowledge holders have stressed that any intellectual property-type protection of TBKIPs should be subject to certain limitations so

as not to protect them too rigidly. Overly strict protection may stifle creativity and cultural exchanges, as well as be impracticable in its implementation, monitoring and enforcement.

In terms of defining the limitations of the scope of protection, it is widely acknowledged that protection should not prevent communities themselves from using, exchanging and transmitting amongst themselves expressions of their heritage in customary ways and in developing them by continuous recreation and imitation. This is reflected in a guiding principle of the TBKIP Model Law which states that the continued use, exchange, transmission and development of TBKIPs within the traditional and customary context by members of the relevant traditional community, as determined by customary laws and practices, should not be interfered with or restricted by the legislation.

Stated differently, this means that protection will extend only to utilisations of TBKIPs taking place outside the traditional or customary context (*ex situ* uses), that is for a commercial purpose. As it is frequently utilisations outside the traditional or customary context that have caused most concern to traditional communities, this type of limitation is a useful way of achieving a balance between protection and ongoing use and development of TBKIPs by traditional communities.

The legislation could provide that all members of a community, or even all nationals of a country, would be allowed in accordance with traditional or customary practice, unrestricted use of the TBKIPs, or certain of them so specified.

3.6 Management of rights

Having progressed through the development of rights regarding TBKIPs, the next step is to consider how those rights will be managed. Under conventional IP laws, this would generally involve consideration of whether the rights holder will exercise the rights, or assign or license their use, or confide their administration to another. In the context of the protection of TBKIPs, the scope needs to be much broader.

There is, of course, the standard exercising of rights and consideration of how and to whom prospective users apply to use TBKIPs. However, there are also a number of additional measures that can be used to support this process, such as the provision of technical assistance and training to traditional communities as well as awareness-raising and cultural sensitisation programmes with industry and the general public. Consequently, the phrase 'management of rights' is purposely used in the Guidelines to convey that this element requires a broader consideration than the standard 'exercise of rights'.

This broad approach is particularly critical from a prevention perspective. Prevention is an important component of protection. Traditional communities frequently emphasise that when their traditional knowledge is misappropriated, the damage is often of a spiritual nature that cannot be remedied through monetary compensation or, in some cases, at all. It is therefore important that a proactive approach is taken to try and minimise the incidence of infringement as much as possible.

Given this broad conception of the management of rights, it is likely that the state will need to play a role in this area. This is reflected in a guiding principle of the TBKIP Model Law that recognises the role of the state in providing assistance to traditional communities in the management and enforcement of their rights in TBKIPs. The use of a state body also provides an identifiable point for prospective users of TBKIPs to engage with, and that can promote certainty. Under the TBKIP Model Law, a state body, referred to as the Competent National Authority, is established to fill this role.

The development of this element involves clarifying what the management of rights will consist of and who will carry out the various aspects, including consideration of the respective roles of the state and traditional communities. It is also useful to note at this point that matters of policy relating to the management of rights should be included in the legislation, while matters of detail should be included in delegated or secondary legislation (addressed in Part 4.2 of the Guidelines).

3.6.1 Policy considerations

Key policy considerations in this area include striking a balance between recognising the rights of traditional communities to control access and use of their TBKIPs on the one hand, and on the other hand, recognising the capacity and resourcing constraints that many communities face and the need to provide assistance in this regard.

3.6.2 Policy questions

The following questions are intended to assist policy-makers to develop a framework for the management of rights under the legislation. This is not an exhaustive list and policy-makers should note that there may be additional questions to be considered.

a) What should the 'management of rights' consist of?

Given that the management of rights has a broader scope than the typical 'exercise of rights', policy-makers will need to consider what should be encompassed within that scope, based on their national circumstances and other relevant factors.

At a minimum, the management of rights involves the administration of rights including consideration of how and to whom prospective users apply to use TBKIPs. Additional measures and initiatives that could form part of the management of rights include:

i. the provision of technical assistance to traditional communities (such as capacity building, training and education programmes etc);

ii. maintaining relationships with regional or government bodies in other countries within the region with responsibilities for the protection of TBKIPs; and

iii. undertaking prevention work with industry and the general public (such as developing a code of ethics for industry groups, conducting public awareness campaigns and cultural sensitisation activities).

Policy-makers may also find it useful to proceed on the basis of identifying what needs to be done and then identifying who will carry out those tasks as appropriate.

b) Who will carry out the various measures and initiatives under 'management of rights'?

Once a country has determined what will be encompassed within the scope of the management of rights, the next step is to consider who will carry out the various measures and initiatives. Much of this will already be determined by the approach taken in the TBKIP Model Law which provides for a significant state role, consistent with the guiding principle recognising the role of the state in providing assistance to traditional communities in the management of their rights. This role is carried out by the Competent National Authority established in section 5 and it is a key component of the TBKIP Model Law. Countries will therefore need to either establish a new body or assign an existing body with the functions provided for in the legislation.

Competent National Authority

The Competent National Authority for the purposes of this Act is the [insert body] which shall carry out the functions described in this Act.

Section 5, TBKIP Model Law

While there is this requirement, there is flexibility to determine what roles and functions the state body will have and what roles traditional communities will have. In some countries, there may be additional bodies, such as pan-tribal organisations, that should have a role as well.

Some management measures, such as technical assistance and capacity-building work with traditional communities would most likely be carried out or supported by the state, as would bilateral and regional relationship management. Prevention work through awareness campaigns and the development of codes of ethics may be more suitably progressed as joint initiatives between traditional communities and the state, depending on resourcing constraints.

Once policy-makers have clarified the various functions, it is advisable that these be specified in the legislation. Guidance can be taken from clause 37 of the Pacific Model Law which includes the following:

- to receive and process applications
- to monitor compliance with authorised user agreements and to advise traditional owners of any breaches of such agreements
- to develop standard terms and conditions for authorised user agreements
- to provide training and education programmes for traditional owners and users
- to develop a Code of Ethics in relation to use of traditional knowledge
- to liaise with regional bodies in relation to matters under the legislation
- to maintain a record of traditional owners and/or traditional knowledge

c) To whom should prospective users have to apply to use TBKIPs?

Two guiding principles of the TBKIP Model Law are instructive in this regard:

- recognise that traditional communities are the owners, right holders and custodians of TBKIPs and the primary decision-makers regarding their use;
- respect and give effect to the right of traditional communities to control access to their TBKIPs, especially those of particular cultural or spiritual value or significance, such as sacred-secret TBKIPs.

Under the TBKIP Model Law, a prospective user must in all cases apply to the Competent National Authority.[17] This approach differs from that of the Pacific Model Law 2002 which provides that while authorisation can be obtained only from the relevant traditional community, prospective users have the option of applying to a state body (referred to as the Cultural Authority) that then performs an intermediary function between the prospective user and the community, or applying directly to the traditional community.

[17] Section 10, TBKIP Model Law

However, in some circumstances traditional communities may not wish to or cannot exercise the rights directly. In this case, the Pacific Model Law provides that a state body may be designated to act at all times at the request of and on behalf of relevant communities.

If a country is strongly opposed to the policy of prospective users not being able to deal directly with a traditional community, this can be modified. Policy-makers may wish to refer to the following approaches which are utilised in existing laws for the protection of traditional knowledge:

i. the relevant traditional community;

ii. a state body (whether existing or specially created);

iii. both a state body and the relevant traditional community;

An explanation of each approach follows.

Option i): The relevant traditional community

Under this option, a prospective user would apply directly to the relevant traditional community for authorisation. This approach could be considered to be the ideal arrangement as traditional communities themselves will decide whether or not to grant authorisation. It therefore gives recognition to the principle that traditional communities are the primary decision-makers regarding their TBKIPs.

However, at a practical level, a number of limitations have been identified with this approach. For example, there are often capacity issues within communities that can negatively impact on the negotiation of a fair and equitable agreement. Moreover, communities may face resourcing constraints that hamper their ability to obtain external advice on the proposed use and the terms and conditions of the agreement.

Option ii): A state body

Where the relevant communities are not able or do not wish to exercise rights directly, a state body may be designated to act at all times at the request of and on behalf of relevant communities. In this case, the rights holder would confide the administration of their rights to this state body so that the body could grant authorisation, where appropriate, on behalf of the traditional community concerned. Many Indigenous peoples, however, have expressed serious reservations about any state body acting on their behalf. This underscores the need for any state body to derive its entitlement to act from the explicit wishes and authority of the community concerned.

This approach may be useful where there are shared TBKIPs across a number of traditional communities in the same country and it difficult to agree upon an equitable way to distribute benefits received across the communities involved. The agency could collect the benefits and transfer them to an initiative that benefits all the communities.

If this approach is taken, policy-makers will need to address a number of questions including:

- What form of consultation should the state body have with the relevant traditional community? While this approach is based on the rights holder confiding the administration of their rights to a state body, it may not be preferable to grant the body an absolute power in this regard. For example, a country may wish to include a provision establishing that where authorisations are granted by an agency, such authorisations should be granted only in appropriate consultation with the relevant community, in accordance with their traditional decision-making and governance processes.

- What authorisations can be granted by the state body? It may not be desirable for the body to have an absolute power to grant authorisations and some parameters may be necessary. A provision could also be included specifying that in order to act on behalf of a community, a state body would need to negotiate the scope of its authority with the community. This may, for example, include specified restricted uses that require consultation with the community concerned.

- What should the state body do with the benefits received? The state body may receive benefits for the use of particular TBKIPs. A country may wish to include a provision specifying that monetary or non-monetary benefits collected by the authority for the use of TBKIPs should be provided directly by the authority to the community concerned.

This body could also carry out various tasks associated with the management of rights such as prevention work.

Option iii): Both a state body and the relevant traditional community

Under this option, the state body plays a primarily administrative role in the authorisation process although in some instances it can grant authorisation. Both the state body and the relevant traditional community have specified roles in the authorisation process. The state body, whether existing or specially created, acts as a contact point for prospective users and receives applications for authorisations to use TBKIPs if communities are not able to, and then forwards the application to the relevant communities. The state body acts in the interests of the relevant communities and mediates between the communities and users.

This is the approach taken in the Peru Law 2002. It provides for a 'Competent National Authority' and an 'Indigenous Knowledge Protection Board', each having various specific duties. Prospective users are also able to apply directly to the relevant traditional community if desired although the state body will carry out a 'watchdog' role to ensure the interests of the community are appropriately promoted.

The Pacific Model Law 2002 also takes a similar approach and provides for the establishment of a 'Cultural Authority' to which application can be made by a prospective user of particular TKECs to obtain the PIC of the 'traditional owners'. The prospective user can also apply directly to the community concerned. Where an application is made to the Cultural Authority, it has to identify the traditional owners and act as a liaison between the prospective user and traditional owners, including resolving uncertainties or disputes as to ownership. If no 'traditional owners' can be found or there is no agreement as to ownership, the Cultural Authority can be determined to be the traditional owner. In cases where the prospective user deals directly with the traditional owners, the Cultural Authority still has a role in providing advice on the terms and conditions of the agreement.

If this approach is taken, policy-makers will need to address a number of questions including:

- What authorisations can be granted by the state body? The Pacific Model Law 2002 provides that where no 'traditional owners' can be found or there is no agreement as to ownership, the Cultural Authority can be determined to be the traditional owner. It can then grant authorisations if appropriate. For countries using this approach, it is important that any authority of a state body to act is obtained from the traditional communities. In some countries, it may not be appropriate that a state body grant authorisations in any situation. A provision could be included in the legislation specifying that in order to act on behalf of a community, a state body would need to negotiate the scope of its authority with the community concerned;

- Should the state body have a role in determining whether PIC has been obtained?

- Should the state body have a role in determining equitable compensation and as appropriate, facilitating and administering the payment and use of equitable compensation?

d) How should prospective users make application to use TBKIPs?

Having determined whom prospective users make application to, the next question is how this is done. However, matters of operational detail in this regard would typically form part of secondary legislation rather than primary legislation. Therefore, further information on this issue is provided in Part 4 of the Guidelines.

e) What should the requirements be for access to TBKIPs?

The requirements for access to TBKIPs under the TBKIP Model Law can be generally described as follows:

i. Application to the Competent National Authority in the prescribed form.

ii. The PIC of the traditional owners of the particular TBKIPs.

iii. The endorsement of the Access and Benefit Sharing Agreement by the Competent National Authority.

In terms of drafting, policy-makers may wish to consider whether a specific provision should be included in the legislation stating these requirements, and whether additional requirements are warranted. For example, article 63 of Costa Rica's Biodiversity Law No.7788 1998 provides as follows.

Basic requirements for access

The basic requirements for access will be:

(1) The prior informed consent of the representatives of the place where the access occurs, the regional council of Areas of Conservation, the indigenous owners of property or authorities, when access is in their territories.

(2) The endorsement of this prior informed consent by the Technical Office of the Commission.

(3) The terms of technology transfer and equitable distribution of benefits, when they exist, agreed to in the permissions, agreements and concessions, as well as the type of protection of the associated knowledge that demands the representatives of the place where access occurs

(4) The definition of the ways in which these activities will contribute to the conservation of the species and the ecosystems.

(5) The designation of a resident legal representative in the country, when one is domiciled physically or legally abroad.

Article 63, Biodiversity Law No.7788 1998

It is advisable that there is clarity in the legislation regarding each of the requirements for access and what procedures or standards must be met. This will require the addition of new provisions to the legislation.

Regarding the requirement to obtain the PIC of the traditional owners, it is important that the legislation establish a clear standard in this regard. In terms of indicators of what constitutes PIC, some of the characteristics of PIC that are often identified include all members of the communities affected consent to the decision, consent is determined in accordance with customary processes, there is full disclosure of the intent and scope of the proposed activities, and decisions are made in a language and process understandable to the communities.

3.7 Term of protection

It is commonplace for IP laws to establish a term of protection following which the protected subject matter enters the public domain for the common good, thereby facilitating and encouraging disclosure of innovation.

However, many traditional communities seek indefinite protection for some, if not all, of their traditional knowledge and in this instance, most branches of the IP system do not meet their needs.[18] On the other hand, it is generally seen as integral to the balance within the IP system that the term of protection not be indefinite so that works ultimately enter the 'public domain'.

The development of this element involves determining the term of protection for TBKIPs, particularly where different layers of TBKIPs have been identified. It also involves consideration of whether particular conditions should be invoked in order to maintain the term of the protection.

3.7.1 Policy considerations

A fundamental policy consideration is striking an appropriate balance between traditional knowledge holders desire for indefinite protection and that of the promotion of the public domain for the general public good.

3.7.2 Policy questions

The following questions are intended to assist countries to develop a policy regarding the term of protection that is appropriate to their national circumstances. This is not an exhaustive list and policy-makers should note that there may be additional questions to be consider-ed.

a) Should all TBKIPs receive the same term of protection?

Depending on decisions taken under the element, 'Subject matter of protection', a country may have determined that there are different layers of TBKIPs, and for the purposes of protection, these layers should be treated differently. It may be considered inappropriate that a single term of protection be used to cover all TBKIPs. Therefore, in determining the term of protection, countries may need to consider whether different terms of protection are necessary to accommodate the different layers of TBKIPs.

b) What should be the term of protection?

The TBKIP Model Law does not establish a time limit. There is a presumption that the rights established under the legislation will continue in perpetuity. This is a matter that countries have the flexibility to change if desired. Regardless of the decision taken, it is advisable for policy-makers to insert a provision specifying the term of protection.

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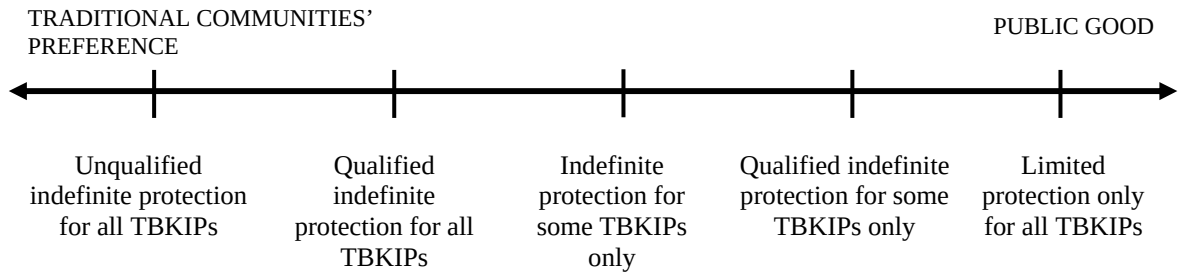
[18] Trademarks are renewable, and unfair competition protection is indefinite, however. Extended protection in the copyright domain is also not entirely without precedent. While the Berne Convention and the TRIPS Agreement stipulate 50 years as a minimum period, countries are free to protect copyright for longer periods.

The range of options regarding the possible terms of protection for TBKIPs can be loosely illustrated using a spectrum as follows:



Each of these options cater for the interests of traditional communities and the public good in differing ways:

- unqualified, indefinite protection for all TBKIPs: All TBKIPs would receive indefinite protection and protection would not be linked to any conditions. This is the approach taken in the Pacific Model Law 2002 as well as the Model Provisions 1982;

- qualified, indefinite protection for all TBKIPs: This option would provide the same coverage of protection for TBKIPs but qualifies that protection with conditions that must be met in order for protection to be maintained;

- indefinite protection for some TBKIPs only: Indefinite protection would be available for some TBKIPs only. The policy rationale is that it may be inappropriate that a single term of protection be used to cover all TBKIPs;

- qualified indefinite protection for some TBKIPs only: Indefinite protection would be available for some TBKIPs provided particular conditions are met. Such conditions could be the criteria for protection established under the legislation;

- limited protection only for all TBKIPs: Only limited protection would be available for all TBKIPs. No distinction would be drawn between different layers of TBKIPs.

c) Should the term of protection be linked to particular conditions?

If TBKIPs receive indefinite protection, one way to ensure that protection remains valid is to impose conditions that must be met for protection to continue. For example, such conditions could be that the TBKIPs continue to be maintained and used by, and is characteristic of, the relevant community. This would entail a trademark-like emphasis on current use, so that once a community no longer uses the particular TBKIPs, protection would lapse.[19]

Such an approach has the merit of giving effect to customary laws and practices and drawing upon the very essence of the subject matter of protection. When particular TBKIPs cease to be characteristic of and identify a community, it ceases by definition to be TBKIPs for the purposes of protection under the legislation and it follows that protection should lapse. This general line of thinking is reflected in the US Indian Arts and Crafts Act 1990, which excludes from protection products which are no longer

[19] Scafidi, S., 'Intellectual Property and Cultural Products,' 81 *B.U.L. Rev.* 793.

'Indian' because, for example, they have become 'industrial products'. This Act sets out in some detail what constitutes an 'Indian product'. The Panama Law 2000 seems to link the term of protection to the protected subject matter continuing to display the characteristics that qualify it for protection in the first place (as protection is indefinite rather than unlimited).

If any notification or registration requirements (discussed in the element, 'Formalities') were to be considered useful, and depending also on their legal effects, the period of protection might also be linked to the maintenance of any registrations.

3.7.3 Further information

Another source of information regarding the term of protection is:

- WIPO. 2006. *The Protection of Traditional Knowledge: Revised Objectives and Principles.* WIPO/GRTKF/IC/9/5. Geneva: WIPO. Pages 35-36 of the Annex discuss the duration of protection.

3.8 Formalities

This element concerns how protection will be acquired and maintained under the legislation, referred to as 'formalities'. The TBKIP Model Law does not contain a formalities provision. Automatic protection for all TBKIPs is granted without formalities. The policy rationale for this is that the imposition of formalities has been identified by traditional knowledge holders as having a significant bearing on the accessibility of protection. There is flexibility to modify this policy if countries wish to incorporate greater certainty and precision.

3.8.1 Policy considerations

Important considerations for policy-makers include the need for practically feasible formalities and avoiding excessive administrative burdens for rights holders or administrators alike. At the same time, it is important to be cognisant of the need for transparency and certainty, particularly for external researchers and other users of TBKIPs in their relations with traditional communities.

3.8.2 Policy questions

The following questions are intended to assist policy-makers to develop a substantive policy regarding beneficiaries of protection that is appropriate to their national circumstances. This is not an exhaustive list and policy-makers should note that there may be additional questions to be considered.

a) How should protection be acquired?

There are three broad approaches that are used across existing laws for the protection of traditional knowledge regarding how protection is acquired:

i. automatic protection without formalities: Protection is provided automatically without formalities. Examples of this approach include the Pacific Model Law 2002 as well as the Model Provisions 1982;

ii. a registration or notification system: An alternative to automatic protection is to provide for some kind of registration, possibly subject to formal or substantive examination. It may merely have declaratory effect, in which case proof of registration would be used to substantiate a claim of ownership, or it may constitute rights. It is often used to provide greater transparency and certainty which can be important for external users of traditional knowledge. Existing laws that utilise this approach include the Panama Law 2000 and the Peru Law 2002. The TBKIP Model Law also includes the establishment of a database, however, this is not linked to the acquisition of rights, its focus is on preservation;

iii. a hybrid of automatic protection and registration: This approach reflects the general principle that TBKIPs should be protected without formality and in an endeavour to make protection as easily available as possible, whilst using registration or notification to provide clarity on which community's assert rights and interests in particular TBKIPs.

Option 1: Automatic protection without formalities

If the automatic protection approach is considered appropriate, policy-makers may wish to consider whether or not it would be beneficial to add a specific provision to the legislation clarifying this.

Option 2: Registration or notification system

If a country wishes to include formalities and considers registration or notification to be appropriate, a simple option would be to utilise the database established in section 7 of the TBKIP Model Law and expand the provision to specify the legal effect of registration in relation to rights. For example, if a traditional owner enters TBKIPs in the database, this might only have a declaratory effect or, it may constitute rights. The implications of each option include the following:

- If registration or notification has only a declaratory effect, it can be used to substantiate and support an ownership claim but would not on its own, constitute rights. Therefore, in a dispute, traditional owners would need to provide additional information to support their claim. It would also put third parties on notice that a particular community is asserting an ownership interest in respect of particular TBKIPs. The benefit of this approach is that registration would not be obligatory: protection could remain available for unregistered TBKIPs.

- If registration or notification constitutes rights in relation to TBKIPs, by definition, only those that are registered or notified would be protected. The primary benefit of this approach is the greater certainty, especially for third parties, on what is protected under the legislation. A key disadvantage is that if a community does not register or notify their TBKIPs, those TBKIPs will not be protected. Further, a robust and stringent registration or notification process would need to be implemented otherwise disputes may arise regarding competing claims from communities in relation to TBKIPs. Some of the matters that secondary legislation or administrative measures would need to provide guidance on include:

    - the manner in which applications for registration should be made;

    - to what extent and for what purposes applications are examined by the registration office;

    - measures to ensure that the registration or notification of TBKIPs is accessible and affordable;

    - public access to information concerning which TBKIPs have been registered or notified;

    - appeals against the registration or notification of TBKIPs;

    - the resolution by the registration office of disputes relating to which community or communities should be entitled to benefit from the protection of TBKIPs, including competing claims from communities from more than one country; and

    - the legal effect of notification or registration.

Option 3: a hybrid of automatic protection, and registration or notification

This approach involves a combination of automatic protection and registration or notification. All TBKIPs would be automatically protected, and registration or notification could be used to provide clarity on which communities asserted rights and interests in particular TBKIPs.

Policy-makers may wish to note the following regarding how this approach could be implemented:

- So as not to confuse the automatic protection provided by the legislation, the effect of registration or notification should be declaratory only.

- Registration or notification need not be an obligation – it is a tool that communities can utilise to declare their interest in particular TBKIPs.

- While the effect of registration or notification would only be declaratory, in order to ensure the system maintains a strong degree of integrity and accuracy, it is advisable for countries to implement a robust and stringent registration or notification process (as discussed under Option 2).

- Only a community which asserts rights and interests of particular TBKIPs should be able to register or notify, or, in cases where the community is not able to do so, the competent national authority with rights management responsibilities could do so, acting at the request and in the interests of the community.

- The competent national authority receiving such registrations or notifications could resolve any uncertainties or disputes as to which communities should be entitled to registration or notification or should be the beneficiaries of protection, using customary laws and processes, alternative dispute resolution and existing cultural resources, as far as possible.

b) Should a database be established and for what purpose?

The terms ‘database’ and ‘register’ often appear in discussions regarding the protection and documentation of traditional knowledge. The terms are often used interchangeably, especially as there is no agreed international definition of either term. The WIPO IGC, for example, generally uses ‘traditional knowledge registers’ to refer to legal registers enabled by statute, and ‘databases’ to refer to non-statutory databases developed to address a legal issue such as to assert positive rights of ownership or to assist in the pre-emption or revocation of patents based on misappropriated traditional knowledge and genetic resources.[20] Others use ‘databases’ to refer to any compilation of traditional knowledge, regardless of function, and use ‘register’ to mean a database into which people put information in order to gain legal rights relating to that information.[21]

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[20] Hardison, Preston. 2005 *Report on Traditional Knowledge Registers and Related Traditional Knowledge Databases.* UNEP/CBD/WG8J/4/INF/9. pg 4.

[21] Downes, D., Laird S et al 1999. *Community Registers of Biodiversity Related Knowledge: Role of Intellectual Property in Managing Access and Benefit Sharing*. UNCTAD Biotrade Initiative.

The TBKIP Model Law utilises the term 'database'. Section 7 provides for the establishment and maintenance of a database of TBKIPs and it functions as a compilation of information only. It is not linked to the acquisition of rights and interests in TBKIPs although the Competent National Authority is able to access the database in determining the identity of an owner of TBKIPs. As noted above, its focus is on preservation.

If a country does not wish to establish a database, there is flexibility to remove this aspect of the TBKIP Model Law; this will not affect the protection framework. Alternatively, if a country would like to incorporate the database into the protection framework, this can also be done. Examples of implementation options include the following.

i. discard the database from the legislation;

ii. maintain the existing TBKIP Model Law approach;

iii. link to the acquisition of rights;

iv. expand to include multiple registers.

An explanation of each option is provided below. With the exception of Option 1, these options are not mutually exclusive and can be combined.

Option i): Remove the database from the legislation

Some traditional communities have a strong preference that their traditional knowledge (including TBKIPs) is not recorded or documented due to concerns about possible negative implications (such as unauthorised access and use by third parties, or unintentional passing of traditional knowledge into the public domain).

As noted above, if a country does not wish to implement this aspect of the TBKIP Model Law, there is flexibility to remove the database without affecting the general operation and functionality of the legislation.

Option ii): Maintain the existing TBKIP Model Law approach

Under this option, the database would be used principally used as a repository for information regarding TBKIPs. The entering of information is not linked to the acquisition of rights and interests in TBKIPs. In terms of who can enter information, section 7 provides that both an owner may enter information as well as the Competent National Authority (as it receives or collects information). Regarding access, there is a default position in section 7 that where the owner does not specify who can access information, it will be limited to the owner. The Competent National Authority can also access the information but only for the purpose of seeking the identity of an owner as part of the process set out in section 10. Any other person wanting access must apply in writing to the Competent National Authority who can then refuse access, grant access unconditionally or grant access with conditions.

In developing this provision, policy-makers may wish to consider the following matters:

i. What will an application to enter information into the database need to contain? Examples include the identity of the traditional owners, identity of the

representative, the use or uses that are made of the biological resource concerned, and a description of the TBKIPs to be registered.

ii. Should a dedicated body within the Competent National Authority be established to govern the database? Existing laws have representatives of governmental entities, non-governmental organisations and Indigenous associations.

iii. Should there be a requirement that information that is to be entered into the database be validated, and if yes, by whom?

iv. Who will own information contained in the database and should explicit provision be made in the legislation clarifying this matter?

v. In order to protect the confidentiality of the database, are exceptions needed from laws providing freedom of access to public information?

vi. What should be the terms and conditions of access? The TBKIP Model Law does not contain conditions as this is a matter of detail and has been left for individual countries to determine. Examples of terms and conditions include the following:

- Those interested in having access to traditional knowledge for the purposes of scientific, commercial and industrial application shall seek the PIC of the particular traditional owners;

- The information supplied shall be confined to the biological resource to which the traditional knowledge under negotiation relates in order to safeguard the other party's interest in keeping the details of the negotiation secret.

- Where the purpose is a commercial or industrial application, a license agreement shall be signed providing for due reward for the said access and in which the equitable distribution of the benefits deriving there from is guaranteed.

Option iii): Link to the acquisition of rights

Some laws for the protection of traditional knowledge provide that registration has a legal effect in relation to rights. For example, if a traditional owner enters TBKIPs in the register or database, it can constitute in itself a condition for the exercise of rights. Policy-makers may wish to note that if registration is linked to the acquisition of rights, the term 'register' is more applicable. Alternatively, registration can be optional and only have a declaratory effect in terms of rights. This is discussed further under formalities.

Option iv): Expand to include multiple registers

The TBKIP Model Law approach can be built upon to include additional databases or registers. For example, the Peru Law 2002 provides for the establishment of three types of registers: 1) the Public National Register of Collective Knowledge of Indigenous Peoples: which contains knowledge that is in the public domain; 2) Confidential National Register of Collective Knowledge of Indigenous Peoples: This is confidential and may not be consulted by third parties. Only those with authorization from the relevant communities

can access it; and 3) Local Registers of Collective Knowledge of Indigenous Peoples. These are referred to as the 'registers of collective knowledge' and have the dual purpose of preserving and safeguarding the collective knowledge of Indigenous Peoples and their rights therein, and providing INDECOPI (the competent national authority) with information to enable it to defend the interests of Indigenous Peoples where their collective knowledge is concerned.

In addition, the public national register can be used to prevent the inappropriate acquisition of IP rights over TBKIPs. Article 23 of the Peru Law 2002 provides that INDECOPI shall send the information entered in the Public National Register to the main patent offices of the world in order that it may be treated as prior art in the examination of the novelty and inventiveness of patent applications. However, the use of registers as a defensive protection mechanism to pre-empt or invalidate patents has provided some promising but also problematic experiences for traditional communities. Detailed discussion on this matter is beyond the scope of the Guidelines however policy-makers should familiarise themselves with these issues (see sources of information listed below).

3.8.3 Further information

Other sources of information regarding formalities, databases and registers, include:

- Hardison, Preston. 2005 *Report on Traditional Knowledge Registers and Related Traditional Knowledge Databases*. UNEP/CBD/WG8J/4/INF/9.

- The Peruvian Law Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources 2002. A copy of this legislation can be found on the WIPO website- http://www.wipo.int/tk/en/laws/tk.html

- UNU-IAS. 2004. *The Role of Registers and Databases in the Protection of Traditional Knowledge: A Comparative Analysis*. Tokyo: UNU-IAS

- WIPO IGC. 2005. *Update on Technical Standards and Issues Concerning Recorded on Registered Traditional Knowledge* WIPO/GRTKF/IC/8/7. Geneva: WIPO.

3.9 Enforcement

Enforcement is an important and often overlooked aspect of the protection of traditional knowledge. As with other IP laws, whether effective protection is achieved will depend to a significant extent on enforcement. However, due to cultural or economic reasons for example, traditional communities may be unable to enforce their rights established in the legislation.

Many laws for the protection of traditional knowledge provide for the state to have a role in the enforcement of the rights of traditional communities. This approach is also reflected in a guiding principle of the TBKIP Model Law that 'recognises that the state should have a role in the protection of TBKIPs, including providing assistance to traditional communities in the management and enforcement of their rights in TBKIPs'.

The development of this element involves consideration of what role the state should have in enforcing the rights of traditional communities.

3.9.1 Policy considerations

In terms of supporting the enforcement process, there may be national policies or laws that provide a context for the state to have a role in this regard, particularly in the context of Indigenous communities.

At a practical level, it is also important to be cognisant of the costs and resources associated with enforcement. These can be significant depending on factors such as the size of a country and the extent of the use of TBKIPs as well as others areas of traditional knowledge where the state may have a role in the enforcement of rights. The availability of resources is therefore a key consideration.

3.9.2 Policy questions

The following questions are intended to assist countries to develop a policy regarding enforcement that is appropriate to their national circumstances. This is not an exhaustive list and policy-makers should note that there may be additional questions to be considered.

a) What role should the state have in enforcing the rights of traditional communities?

The role of the state depends primarily on the traditional communities concerned. It is therefore useful for policy-makers to firstly consider the capacity of traditional communities to enforce their rights under the legislation. If it is determined that enforcement by traditional communities could be hampered by particular factors, such as capacity and resources, it may be appropriate and/or necessary for the state to have a role in the enforcement of rights under the legislation.

In existing national laws, the role of the state takes a range of forms regarding enforcing IP rights as well as rights in traditional knowledge including the following:

i. Monitoring: In the context of enforcing IP rights, some countries have established specialised IP enforcement units, such as an interagency anti-piracy taskforce. They work closely with industry groups as well as crime and investigation authorities to monitor and enforce against illegal activities. Some countries have established channels or official routes to assist right owners in informing them where suspected infringements or evidence of suspected infringing activity takes place. The US Indian Arts and Crafts Act 1990 vests various rights and responsibilities in an 'Indian Arts and Crafts Board', which has a specific role in monitoring violations of the Indian Arts and Crafts Act in the US.

ii. Legal proceedings: The state can have a role in both civil and criminal matters, if desired. This role can vary from assisting traditional communities, where appropriate, to enforce their rights regarding their TBKIPs through the provision of technical advice or providing financial assistance through dedicated legal funds, to having full responsibility for enforcement. The precise role is likely to be influenced by traditional communities' needs and aspirations.

Policy-makers may wish to consider whether any specialist institution or agency needs to be created to oversee or assist in enforcement of the legislation, such as investigating and prosecuting infringements. Some existing laws use national authorities to ensure effective protection. A specific role may be envisaged for a state body in enforcing protection for traditional knowledge. In respect of criminal proceedings, a country may consider it appropriate for a state body to have a role in enforcement, or as an alternative, to the police. This may be necessary if the police in a country do not see themselves as taking a lead role in investigating and prosecuting what they view as 'regulatory offences'. Within the WIPO IGC, it has been acknowledged that a state body could be tasked with, among other things, advising and assisting communities with regard to the enforcement of rights and with instituting civil, criminal and administrative proceedings on their behalf when appropriate and requested by them.[22]

The US Indian Arts and Crafts Act 1990 contains extensive enforcement provisions. While Indian tribes, Indian arts and crafts organisations and individual Indians have the right to bring civil suits under this Act, the Indian Arts and Crafts Board can also receive complaints and act upon them, including by way of referring criminal matters to the Federal Bureau of Investigation and the US Attorney General. For example, a person who sells a product falsely suggesting it is Indian produced can be subject to very heavy fines and imprisonment, with penalties escalating for repeat infringement.

iii. Enforcement training: Effective enforcement may require enhanced awareness of infringement by police and customs officials, which can be improved through training and cooperative relationships between the officials and traditional communities. Ongoing training is important for enforcement officials.

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[22] WIPO (2005), *The Protection of Traditional Cultural Expressions/Expressions of Folklore: Revised Objectives and Principles WIPO/GRTKF/IC/8/4.* Geneva: WIPO.

iv. Border control: The strengthening of border measures in the region can assist with the importation of infringing products. The above-mentioned training for customs officials can be useful. Also, in some countries, customs and enforcement authorities have procedures to notify right holders in order to carry out verification procedures for IP rights-infringing products.

v. Public education and outreach. Many countries recognise the contribution of IP rights to their economy and have enacted national policies and public education measures, and in some cases established agencies, to promote respect for these rights. This is closely related to but distinct from the education programmes and awareness campaigns discussed under the element 'Management of rights'. These measures are more prevention focused, to try to minimise the incidence of infringements. Enforcement-related campaigns are often directed towards promoting awareness of respect for the rights of others and encouraging consumers to refuse to buy pirated and counterfeit goods. There are also reward schemes for the provision of information by the public on illegal activity or border infringements.

It may not be necessary or appropriate for the state to carry out all of these roles. Policy-makers should draw guidance from their domestic circumstances and the needs of traditional communities. Moreover, some of these enforcement measures would not necessarily require legislative backing and could therefore operate alongside the legislation (such as the public education and training measures as well as the enforcement training).

3.9.3 Further information

Another source of information regarding enforcement is:

- WIPO. 2006. *The Protection of Traditional Knowledge: Revised Objectives and Principles.* WIPO/GRTKF/IC/9/5. Geneva: WIPO. Pages 43-44 of the Annex discuss the administration and enforcement of protection.

3.10 Legal proceedings

It has been broadly acknowledged that both civil and criminal actions should be available where the rights of traditional communities regarding their traditional knowledge have been infringed. In some areas of IP law, it is common for countries to have civil remedies as well as criminal sanctions. The development of this element involves prescribing the civil and criminal legal proceedings.

3.10.1 Policy questions: civil proceedings

Punishment is not the principal focus of civil law; this is the domain of criminal law. The remedies provided by civil law have other purposes, such as compensation, the remedying of wrongs and stopping unlawful conduct. There are exceptions to this general principle, in particular the civil remedy of exemplary damages (designed to inflict punishment rather than compensate).

The following questions are intended to assist countries to clarify the civil proceedings for infringement.

a) What constitutes an infringement?

During the development of the element, 'Scope of protection', countries will have determined what acts will be regulated. It is important to include a provision linking these regulated acts to what constitutes an infringement or offence under the legislation. Sections 8(4) and 9(2) of the TBKIP Model Law contain this linkage.

b) When may proceedings be brought?

The legislation will need to state when proceedings can be brought. The TBKIP Model Law does not contain a provision in this regard and policy-makers will need to incorporate this. Typically, legislation will state that an infringement under the legislation is actionable. Countries may wish to also clarify when infringements proceedings may not be brought. For example, the legislation may include a provision stating that no person may bring proceedings for the infringement of unregistered rights (if a registration or notification system is adopted) where relevant.

In addition, policy-makers may wish to consider whether an action may be brought when there is a strong likelihood that rights may be infringed. For example, under the Peru Law 2002, an action may be brought if imminent danger exists that rights may be violated. Also, under the Panama Law 2000, Indigenous communities or the country or regional governor may take preventative action (Article 22). This 'precautionary' type approach is important given the spiritual and cultural damage that frequently occurs when traditional knowledge is misappropriated. In some cases, the damage to particular individuals and/or traditional communities is irreversible. It is therefore preferable to prevent infringements before they occur rather than have to wait until after the fact to take an action.

c) Who may institute infringement proceedings?

It is important for the legislation to specify who may institute infringement proceedings. This will be influenced by the decisions taken under the element, 'Enforcement', regarding the role of the state in enforcement.

The TBKIP Model Law does not include a provision specifying that traditional owners may institute civil proceedings. However, given that traditional communities are the primary decision-makers regarding the use of TBKIPs it follows that the legislation should provide for traditional communities to be able to take an action to enforce their rights. This is also the case in many laws for the protection of traditional knowledge. Policy-makers are encouraged therefore to incorporate a provision in this regard.

Policy-makers may wish to consider whether it is necessary for the legislation to make provision for other individuals or bodies to also be able to take an action. For example, under the Panama Law 2000, apart from the affected Indigenous communities, the regional or country governor may take preventative action. In the Peru Law 2002, infringement actions may also be brought *ex officio* by decision of INDECOPI (the competent national authority). If a country wished to incorporate this approach, one option could be to provide for the Competent National Authority established under the TBKIP Model Law to be able to institute proceedings. This may be instead of, or in addition to, traditional owners. Some communities may consent to a state body enforcing rights on their behalf while other communities in the same country may not wish to do so. The legislation would need to be able to accommodate the various scenarios.

Policy-makers may also wish to address whether the legislation should include limitations on who can take an action, to prevent erroneous or non-mandated actions. For example, the legislation may provide that only a mandated representative of a traditional community can bring an action rather than individual members of a community.

d) Where may infringement proceedings be brought?

The legislation should specify which court infringement proceedings would need to be brought to. The TBKIP Model Law purposely leaves the court blank as this should be determined at the national level. It simply refers to the 'principal Court'.

However, in considering which court should hear infringement proceedings, a secondary question arises: are the ordinary courts an appropriate body for legal proceedings relating to TBKIPs? Given that the majority of PICTs are small countries with limited resources, the TBKIP Model Law does not establish a specialised body for the purpose of legal proceedings, it uses ordinary courts. However, countries can of course establish such a body if they so wish, especially if the procedural character of the ordinary courts process is not considered appropriate in this context. New or existing institutions other than the ordinary courts may be better able to manage matters requiring resolution under the legislation because of the need for specialist knowledge, the desirability of less formality in proceedings than is the practice of the ordinary courts and the desirability of different fact-finding procedures or other procedures such as mediation which may not be available through the ordinary courts. Indeed, traditional communities have widely criticised the use of the western judicial system and called for more appropriate processes, including greater recognition of customary law processes.

There are numerous examples that countries can draw on for guidance if they wish to establish a dedicated body under the legislation for civil proceedings rather than use the formal and adversarial processes of the ordinary courts. In terms of specialised bodies on Indigenous issues, examples include the Maori Land Court and the Waitangi Tribunal in New Zealand. In respect of less formality and different fact-finding procedures, many countries have family courts. Regarding IP models, some countries provide that proceedings can be taken to commissioners (such as the Commissioner of Trade Marks) in addition to the ordinary courts.

An additional consideration is whether a country is also implementing legislation for the protection of other areas of traditional knowledge, such as the Pacific Model Law 2002. In that respect, a new or existing institution could have jurisdiction to hear proceedings under both pieces of legislation thereby increasing its utility.

e) Should there be a penalty for bringing unjustified proceedings?

In order to provide a deterrent for vexatious claims, policy-makers may wish to consider whether it is appropriate to incorporate a penalty in the legislation for bringing unjustified proceedings. While not a typical feature of laws for the protection of traditional knowledge, it does appear in some countries IP laws such as New Zealand's copyright and trade mark legislation as well as Fiji's copyright law.

An example of an unjustified proceedings provision from New Zealand's copyright legislation is provided below.

1) Where a person brings proceedings alleging an infringement of copyright, a court may, on the application of any person against whom the proceedings are brought:
   a. make a declaration that the bringing of proceedings was unjustified:
   b. make an order for the payment of damages for any loss suffered by the person against whom the proceedings are brought.
2) A court shall not grant relief under this section if the person who brought the proceedings proves that the acts in respect of which proceedings were brought constituted, or would have constituted if they had been done, an infringement of the copyright concerned.
3) Nothing in this section makes a barrister or solicitor of the High Court of New Zealand liable to any proceedings under this section in respect of any act done in his or her professional capacity on behalf of a client

Section 130, Copyright Act 1994 (New Zealand)

f) What types of remedies should be available for infringement?

Civil remedies that are commonly available under legislation for the protection of traditional knowledge include injunctions, damages and account of profits. Often, a general provision is also included that enables the court to grant additional relief as it considers appropriate. Of particular importance in the prevention of infringement is the availability of judicial procedures which enable speedy recourse to the courts for relief pending trial of the action (such as the issuing of injunctions).

In the context of infringements regarding TBKIPs, traditional communities often argue that the remedies available under current law may not provide for damages equivalent to the degree of cultural and non-economic damage caused by the infringement. While in some cases, damages awarded by the courts have taken cultural issues into account,[23] when traditional knowledge is misappropriated and/or used offensively the primary damage is often not monetary in nature, but cultural. Consequently, monetary remedies will have very limited effect in addressing the cultural harm caused to traditional communities. Forms of cultural redress are therefore critical. Existing customary law practices will be instructive in this regard.

Policy-makers can refer to section 15 of the TBKIP Model Law to assist them in identifying what remedies may be appropriate.

> The [principal] Court shall have full jurisdiction to hear and determine any proceedings for infringement or otherwise relating to knowledge, innovations and practices in [the enacting country], and may grant in addition to any other relief any one or more of the following remedies:
>
> a) an injunction;
>
> b) damages;
>
> c) a declaration that a right has been contravened
>
> d) an order for a public apology;
>
> e) an order that any false attribution or derogatory treatment cease or be reversed;
>
> f) an order for an account of profits;
>
> g) an order for the seizure of any object made contrary to this Act;
>
> h) an order for the impounding and destruction of any object used in the commission of an offence under this Act.
>
> **Section 15(1), TBKIP Model Law**

It may also be useful to note the following regarding section 15.

- It includes civil remedies that are commonly available, such as injunctions, damages and account of profits.

- It includes additional remedies, such as an order for a public apology, a declaration that a right has been contravened and an order for the impounding and destruction of any object used in the commission of an offence under the legislation.

- It provides that the court can make an order that infringements of moral rights cease or be reversed.

- It provides that the court may grant an order for the seizure of any object made contrary to the Act. This can be clarified in more detail by addressing the ability of the court to be able to order removal, obliteration, delivery up and to whom (owner or other person the court thinks fit) and also disposal. It could also clarify whether those

[23] See the Australian case of *George M*, Payunka, Marika and Others v Indofurn Pty. Ltd* 30 IPR 209.

with an interest will be served with notice, and whether those with an interest have any rights and what those rights are. Lastly, it could clarify whether the courts power extends to objects imported or exported that are contrary to the legislation.

- It provides that the court may grant any such orders as it considers appropriate in the circumstances. This could be used to provide cultural redress in respect of cultural and non-economic damage caused by the infringement. However, countries may wish to provide greater clarity through the inclusion of a specific remedy. If there is some uncertainty as to application of a remedy, specific legislative provision is desirable.

Once it has been determined which remedies should be available, policy-makers will need to consider these against the various civil remedies that are available under the common law and the general statute law in their country, and assess their adequacy. The outcomes of this assessment may result in one or more of the following.

- Existing civil remedies are sufficient.

- Some remedies require modification for the purposes of the legislation: it may be necessary to vary some aspect of a remedy to make it effective in the particular context of protecting TBKIPs thereby enlarging the range of circumstances in which the existing remedy would be available under the common law.

- New remedies are needed: this may arise in circumstances such as if existing civil remedies are inadequate in achieving the desired policy objective or there are difficulties in modifying existing remedies to improve their utility. If policy-makers are considering a new remedy, it is wise to consider whether the proposed remedy will create anomalies or inconsistencies in the operation of the law generally.

g) What matters should be considered by the court?

It is common for legislation to specify the criteria for the court to consider when making a decision regarding relief. This can vary from precise rules of law to very broad standards (such as the public interest or the welfare of the child). In developing criteria, policy-makers may wish to refer to section 15(2) of the TBKIP Model Law which specifies what the court may take into account when considering what relief is to be granted. This is indicative only and countries can adapt as desired.

The [principal] Court in deciding what relief is to be granted may take into account all or any of the following:

a) whether the defendant was aware or ought reasonably to have been aware of the rights of the owner;

b) the effect on the reputation of the owner resulting from the unauthorised use;

c) any thing done by the defendant to mitigate the effects of the unauthorised use;

d) any cost or difficulty that may have been associated with identifying the traditional owners;

e) any cost or difficulty in ceasing or reversing any false attribution of ownership, or derogatory treatment of the knowledge, innovation or practice;

f) whether the parties have undertaken any other action to resolve the dispute.

Section 15(2), TBKIP Model Law

The matters set out in section 15(2) closely mirror the matters set out in clause 31(2) of the Pacific Model Law which is the analogous provision regarding which matters the court may take into account with considering relief.

3.10.2 Policy questions: criminal proceedings

a) Is it necessary to create a criminal offence?

Most legal systems draw a distinction between conduct that is treated as a criminal offence and conduct that, while regarded as wrongful, is regulated only by the civil law. A primary question, therefore, for policy-makers to address is whether or not particular conduct requires the intervention of the criminal law or whether civil remedies are adequate and appropriate for the purposes of enforcement. Understandably, rights holders are in a stronger position where both civil and criminal penalties are available. In some countries, the same act of infringement can bring about liabilities for damages, etc. under a civil action, and for fines and/or imprisonment under criminal provisions.

In determining whether there should be criminal offences under the legislation, it is important to note that the criminal law is concerned with the punishment of offenders and the deterrence of others from wrongdoing. Generally, it is not concerned with compensation, which is the province of the civil law (and damages under civil law can be much higher than criminal sanctions, which are normally limited to a fixed amount). The criminal law is intended to punish only that conduct which is in some way blameworthy. The notion of blameworthiness is an integral feature of the criminal process.[24]

Policy-makers may wish to consider the following questions when determining whether to create a criminal offence.[25]

- Will the conduct in question, if permitted or allowed to continue unchecked, cause substantial harm to individual or public interests?

- Would public opinion support the use of the criminal law, or is the conduct in question likely to be regarded as trivial by the general public?

- Is the conduct in question best regulated by the civil law because the appropriate remedies are those characteristic of the civil law (e.g. compensation, restitution)?

- Is the use of the criminal law being considered solely or primarily for reasons of convenience rather than as a consequence of a decision that the conduct itself warrants criminal sanctions?

- If the conduct in question is made a criminal offence, how will enforcement be undertaken, who will be responsible for the investigation and prosecution of the offence, and what powers will be required for enforcement to be undertaken?

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[24] Legislation Advisory Committee (2001) *Guidelines on Process and Content of Legislation* Wellington: Ministry of Justice 141.
[25] Ibid at 143.

- If the new offences in question are unlikely to be enforced, or enforced only rarely, the question of whether a criminal sanction is warranted should be examined carefully, because creating offences that are not going to be enforced brings the law into disrepute. If enforcement of the law is going to be left to the police as part of their general duty to enforce the law, it may be useful to make prior enquiries of the police as to the likely priority to be given to the new offence or offences being created.

- Would it be more economic or practicable to regulate the conduct in question through the use of existing or new civil law remedies?

- Is the conduct that is to be categorised as a criminal offence able to be defined with precision?

- Is the conduct in question likely to be committed by a legal entity or a natural person or both (bearing in mind that the criminal law generally does not apply to legal entities and the natural person acting for a legal entity could be difficult to identify)?

The following policy questions are relevant only if a country decides that the intervention of the criminal law is required.

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b) What should constitute an offence?

Where a country has determined that the intervention of the criminal law is required, it will need to identify what constitutes an offence. Some existing laws for the protection of traditional knowledge provide that particular acts are offences. For instance, under the United States Code, Title 18, Part I, Chapter 53, it is unlawful, and subject to fines or imprisonment, to imitate any government trade mark used or devised by the Indian Arts and Crafts Board (Section 1158. Counterfeiting Indian Arts and Crafts Board trade mark), and to offer or display for sale or sell any good in a manner that falsely suggests it is Indian produced, an Indian product, or the product of a particular Indian or Indian tribe or Indian arts and crafts organization, resident within the United States (Section 1159. Misrepresentation of Indian produced goods and products).

Policy-makers may wish to refer to the TBKIP Model Law for guidance in identifying what constitutes an offence. Under the TBKIP Model Law, any person who does not comply with the requirements set out in sections 10 and 11 (regarding application to the Competent National Authority and obtaining the prior informed consent of the owner), commits an offence.[26] Further, any person who contravenes the moral rights of owners of TBKIPs commits an offence.[27].

Therefore the same act in relation to economic rights (i.e. commercial use without the PIC of traditional owners) constitutes a criminal offence as well as an infringement under civil law. As well, the same act or omission in relation to moral rights constitutes a criminal offence as well as an infringement under civil law. Therefore, a traditional community could potentially take a civil action for damages etc and also for fines under criminal

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[26] Section 8(4) of the TBKIP Model Law
[27] Section 9(2) of the TBKIP Model Law

provisions. As noted previously, some countries copyright laws provide that the same act of infringement can bring about liabilities for damages under a civil action, and for fines and/or imprisonment under criminal provisions.
Policy-makers may wish to note that if a prospective user approached a community directly and the owners gave their consent to the proposed use, under the TBKIP Model Law, the user would still have committed an offence as he or she did not apply to the Competent National Authority in the first instance as required under section 10. It is a question of balance for policy-makers: the Competent National Authority is intended to help safeguard and protect the interests of traditional communities yet communities will also expect their rights to determine their own affairs to be respected and supported rather than frustrated by the legislation.

c) When may criminal proceedings be commenced?

It is commonplace for legislation to establish when criminal proceedings may be commenced and countries may wish to include a provision clarifying this matter.

Under the TBKIP Model Law, proceedings may be brought in three situations:

i. where economic rights are infringed - that is, if a person uses an item of traditional biological knowledge, an innovation or a practice for a commercial purpose, or an activity that is likely to assist in achieving a commercial purpose, and does not apply to the Competent National Authority and does not obtain the prior informed consent of the owners to that use;[28]

ii. where moral rights are infringed - that is, if any person does an act or makes an omission in relation to an item of traditional biological knowledge, an innovation or a practice that is inconsistent with the moral rights of the owners of that knowledge, innovation or practice; and the owners have not given their prior informed consent to the act or omission.[29]

iii. where a person knowingly provides false information for entry into the database established under section 7.[30]

In the case of IP laws, criminal proceedings can generally only be commenced after the matter arose. For example, trade mark legislation may provide that no proceeding may be commenced for any offence that was committed before the actual date of registration of the trade mark concerned.

Similarly to civil proceedings, policy-makers may also wish to consider whether an action may also be brought when there is a strong likelihood that rights are may be infringed. As previously discussed, 'precautionary' type approaches are used in Peru and Panama which allow right holders to bring a preventative action as sometimes, the damage to particular individuals and/or traditional communities from infringing acts is irreversible.

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[28] Section 8 of the TBKIP Model Law
[29] Section 9 of the TBKIP Model Law
[30] Section 7(5) of the TBKIP Model Law

d) Who should be responsible for bringing criminal proceedings?

As it can take considerable resources to bring criminal proceedings, policy-makers may wish to consider this in light of the traditional communities in their country and whether assistance is needed in this regard. This is considered in further detail under the element, 'Enforcement'. It may be necessary to explicitly provide for a particular agency to be responsible for bringing criminal proceedings (such as the police or a state body such as the Competent National Authority). If it is not the police, and instead a state body is to be used, policy-makers will need to give consideration to including provisions in the legislation that grant the agency appropriate powers to gather information (such as search warrants) as well as establishing offences for not cooperating with such investigation.

e) What should be the penalties for offences?

When considering penalties, it is important to recall that the criminal law is concerned with the punishment of offenders and the deterrence of others from wrongdoing, rather than compensation.

There are no rules in international or regional instruments on copyright and related rights specifying the penalties that are to be applied, nor are there rules at these levels in respect of traditional knowledge. Criminal penalties vary widely from country to country, both in respect of the amount of fines that may be imposed and possible terms of imprisonment.

The TBKIP Model Law provides that those persons found guilty of an offence are punishable on conviction by a fine. Imprisonment is not included but countries are free to modify this aspect if they wish. As individual countries are likely to have conventions relating to appropriate penalties, further discussion on this matter is not included.

Policy-makers may also wish to consider is how the proceeds of fines should be used. The proceeds could be treated in the same way as general funds received by the government and form part of the consolidated fund for general purposes. An important policy consideration is that penalties are imposed for the purposes of punishment, not compensation - although there are some exceptions to this principle. If it is considered appropriate, the proceeds could be channelled into a fund for the conservation of biological diversity, for example.

f) Should the court be able to grant orders for delivery up?

Policy-makers may wish to consider whether the legislation should include provisions regarding orders for delivery up in relation to criminal offences. The TBKIP Model Law does not contain a provision in this regard. If it is considered desirable, policy-makers will need to consider:

- when the orders may be made;
- matters to be considered by the court;
- the rights of persons with interest in the goods or other object; and
- whether goods will be returned where no order is made.

g) What types of defences should be provided for?

The TBKIP Model Law does not establish any defences to a criminal offence. Policy-makers may wish to consider whether this is sufficient or whether the legislation should make provision for defences to an offence.

3.10.3 Further information

Another source of information regarding civil and criminal proceedings is:

- Legislation Advisory Committee. 2001. *Guidelines on Process and Content of Legislation.* Wellington: Ministry of Justice. Chapters 11 and 12 provide information on remedies and criminal offences respectively.

3.11 Dispute Resolution

The desirability of alternative dispute resolution mechanisms in cases relating to traditional knowledge is frequently emphasised. Alternative dispute resolution or ADR[31] is a 'catch-all' term that describes a number of methods used to resolve disputes out of court such as negotiation, conciliation, mediation and the many types of arbitration. In matters involving Indigenous and traditional communities, ADR can be considered to either encompass the use of customary laws, or customary laws can be considered to be an additional approach to ADR.

Common characteristics of ADR methods are that they are faster, less formal, cheaper and often less adversarial than a court trial. The general principle is that if disputes and conflicts can be resolved without recourse to the courts, this should be encouraged as a preferable alternative to reliance on the general legal system.

In the context of the protection of TBKIPs, customary laws and decision-making processes will generally be the means by which traditional communities are regulated and controlled. It follows, therefore, that these are likely to be the preferred means of dispute resolution as traditional communities will be accustomed to these practices. Many existing national laws for the protection of traditional knowledge make explicit reference to the use of customary laws and/or ADR. For example, in the Philippines, the Indigenous Peoples Rights Act provides that 'when disputes involve Indigenous Cultural Communities/Indigenous Peoples, customary laws and practices shall be used to resolve the dispute'.[32] Clause 33 of the Pacific Model Law specifies that disputes may be resolved using mediation, alternative dispute resolution procedures and customary law and practices.

For the purposes of the legislation, where ADR methods (including customary law and practices) are utilised, these would generally occur as alternatives to civil and criminal proceedings under the legislation. In this case, detailed provisions relating to ADR are not likely to be necessary and countries may take the approach of simply confirming that ADR is an available option.

Alternatively, countries may consider it necessary to establish a specific process in the legislation for resolving disputes. An important policy consideration in this context is that customary laws used for social control within traditional communities vary greatly. For example, policy-makers should not assume that the role of elders is the same or that similar procedures for resolving disputes are in use across different communities. Close consultation with traditional communities will be critical to ensure that any ADR process established under the legislation is an appropriate means to achieve reconciliation.[33]

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[31] In recent years, the term ADR has come to mean 'appropriate dispute resolution' to emphasise that ADR methods stand on their own as effective ways to resolve disputes and should not be seen simply as alternatives to a court action

[32] Section 65, Primacy of Customary Laws and Practices

[33] Wichard, J.C. & Wendland, W.B. 2006. Mediation as an option for resolving disputes between indigenous/traditional communities and industry concerning traditional knowledge'. In Hoffman, B.T. (ed.), *Art and Cultural Heritage: Law, Policy and Practice.* Cambridge: Cambridge University Press

3.12 Relationship with intellectual property protection

The IPR's that are of most relevance in the context of TBKIPs are patents and plant variety protection (also referred to as plant variety rights and plant breeders' rights). In considering the relationship of the TBKIP Model Law with existing IPR`s, it is important to recall that the model is a tool for countries that have determined that new, *sui generis* legislation is necessary in order to achieve their identified objectives of protection. In other words, existing mechanisms and systems are considered not to be sufficient to achieve those ends. The TBKIP Model Law provides positive protection for TBKIPs on the assumption that this cannot be appropriately and adequately achieved under conventional IP laws.

The key matter that policy-makers need concern themselves with is how the new form of protection for TBKIPs that is provided under the legislation interfaces with conventional IP laws. There is a generally accepted principle that new forms of protection for TBKIPs should be complementary to any applicable conventional IP protection. This is often referred to as 'filling the gap'. This is reflected in a guiding principle of the TBKIP Model Law which states that 'special protection for TBKIPs should be complementary to, and not replace or prejudice the acquisition of, any applicable conventional IP protection and derivatives thereof'.

The background section below explains two key relationships that policy-makers should be familiar with:

- the relationship between the protection available for TBKIPs under conventional IP laws and the protection that will be provided by the legislation; and

- the relationship between the legislation and conventional IP laws in terms of the protection available for new innovations derived from TBKIPs (derivative innovations).

Having a clear understanding of these relationships is critical, particularly when the legislation is promulgated to stakeholders. At a minimum, policy-makers should expect interested parties to enquire about the interface between the legislation and conventional IP laws.

There is also an important policy question for policy-makers to address. The abovementioned guiding principle of the TBKIP Model Law specifies that special protection should be complementary to, and not replace or prejudice the acquisition of, any applicable IP protection. In other words, the policy question of whether IP rights in innovations derived from TBKIPs (derivative innovations) should be recognised has already been determined. However, this recognition can be qualified by the imposition of terms and conditions on the innovator. In developing this element, policy-makers will need to consider whether terms and conditions should be imposed, in what circumstances, and what the nature of those terms and conditions might be.

3.12.1 Background

a) What is the relationship between the legislation and existing IP laws in terms of the protection provided to TBKIPs?

Some of the needs of traditional communities regarding the protection of TBKIPs may be met by solutions existing already within current IP laws, including through appropriate extensions or adaptations of those laws such as disclosure of origin provisions within patent law. However, in terms of the provision of positive protection, as noted above, the TBKIP Model Law was developed to provide that on the assumption that it is not currently available under conventional IP laws.

The distinction is usefully explained by considering TBKIPs itself (referred to as 'pre-existing' or 'the base') and new innovations derived there from. The TBKIP Model Law has been developed to provide protection for the former, whereas the latter, assuming it meets the criteria for protection, could be protected by conventional IP laws.

Figure 1 illustrates the relationship between the protectable subject matter (the 'base') which is protected under the legislation and derivative innovations which could be protected under conventional IP laws.[34]

Figure 1: Relationship between the 'Base' and derivative works

Many national laws distinguish between pre-existing TK and new innovations derived there from. For example, with regard to traditional knowledge and traditional cultural expressions, the Tunis Model Law on Copyright for Developing Countries 1976 protects 'works derived from national folklore' as original copyright works, whereas folklore itself, described as 'works of national folklore' is accorded a *sui generis* type of copyright protection because they are unprotected by copyright. The Model Provisions 1982 make a similar distinction as do national laws in Hungary, Indonesia and many others.

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[34] Wendland, W., "Intellectual Property and the Protection of Cultural Expressions: The Work of the World Intellectual Property Organization (WIPO)" in F.Willem Grosheide and Jan Brinkhof (eds) *Articles on the Legal Protection of Cultural Expressions and Indigenous Knowledge* (Schoten, Intersentia, 2002) 101-138.

b) How can conventional IP laws support the objectives of the legislation?

Conventional IP laws such as patent law can be adapted to support the objectives of the legislation. For example, the database established under the TBKIP Model Law could be linked with the patent examination process and treated as prior art when examining for the novelty and inventiveness of an application. As well, an applicant seeking patent protection for an invention derived from TBKIPs could be required to meet a disclosure of origin requirement. That could include a requirement to produce evidence of compliance with the legislation's PIC regime. Similar proposals have been advanced in the context of promoting compliance with countries access and benefit sharing regimes. The implications of non-compliance are the subject of considerable debate, including the question of compatibility with TRIPS. Discussion on this matter falls beyond the scope of the guidelines however it is important context for policy-makers to be cognisant of.

3.12.2 Policy questions

The following questions are intended to assist policy-makers to develop a policy on the regulation of derivative works that is appropriate to their national circumstances. This is not an exhaustive list and policy-makers should note that there may be additional questions to be considered.

a) What terms and conditions should be imposed regarding derivative innovations?

The imposition of terms and conditions regarding derivative innovations can be a means of appropriately recognising the prior relationship, rights and interests of traditional communities with the TBKIPs that underpin those innovations. In the absence of such terms and conditions to ensure the community concerned has ongoing rights and interests in derivative innovations, a user can enjoy the benefits of IP rights without a requirement for benefits to be shared with the community concerned.

The imposition of terms and conditions is not uncommon particularly in the context of traditional knowledge associated with biological resources. Under Article 8(j) of the Convention on Biological Diversity, Parties are required to encourage the equitable sharing of the benefits arising from the utilisation of traditional knowledge, innovations and practices. There have been a number of examples where users (e.g. companies, collectors, researchers) have entered into agreements with Indigenous and traditional communities in this regard. Agreements have included provisions that in exchange for using and applying the traditional knowledge of traditional communities and being able to obtain IP rights over research outcomes, the user will fairly and equitably share the benefits that accrue from that utilisation with the community concerned.

Section 11 of the TBKIP Model Law provides that where an owner gives its PIC to a proposed use, an agreement between the owner and user must be negotiated under the supervision of the Competent National Authority. This agreement is referred to as an 'Access and Benefit Sharing Agreement' and the TBKIP Model Law specifies that the agreement must set out the terms under which use is permitted. It includes a list of matters that should be given regard to and it includes IPR's. This list is intended as a guide and a country can modify as it chooses to.

11 Access and Benefit Sharing Agreement

(1) Where the owner gives its prior informed consent to the proposed use, an agreement between the owner and the user, to be known as an Access and Benefit-Sharing Agreement, must be negotiated under the supervision of the [Competent National Authority] setting out the terms under which use is permitted and having regard to the following matters, amongst others:

Knowledge, innovations and practices:

(a) restrictions on using knowledge in any other material form

(b) restrictions on reproduction, publication, translation, or broadcasting of knowledge

(c) restrictions on the quantity of an innovation to be obtained

(d) requirement for progress reports to be supplied at each stage of testing of an innovation

(e) rights regarding anything derived from research on an innovation.

General:

(a) fees or compensation for using the knowledge, innovation or practice

(b) obtaining of relevant permits

(c) duration of the Agreement

(d) choice of law upon breach of a term of the Agreement

(e) options upon breach of a term of the Agreement

(f) limits on transfer to third parties

(g) restrictions on fixation through any process such as making a sound recording or taking a photograph

(h) intellectual property rights

(i) recognition of moral rights

(j) benefit sharing, monetary and non-monetary, on the successful commercialisation of any aspect of the knowledge, innovation or practice

(2) The [Competent National Authority] is to ensure that the Agreement is not to the detriment of the owner.

(3) Nothing in subsection (1) is to be construed as preventing the promulgation of more detailed access and benefit regimes for knowledge or for innovations or for practices or for any combination of these elements.

Section 11, TBKIP Model Law

3.12.3 Further information

Another source of information regarding the relationship with IP protection is:

- WIPO. 2006. *The Protection of Traditional Knowledge: Revised Objectives and Principles.* WIPO/GRTKF/IC/9/5. Geneva: WIPO. Pages 42-44 of the Annex discusses the interface with other legal systems, including those regulating access to genetic resources.

3.13 Relationship with ABS regime

By virtue of the Convention on Biological Diversity (CBD), Parties have the authority to determine access to genetic resources in areas within their jurisdiction. The CBD came into force in 1993 and recognises the sovereign rights of states over their natural resources, including genetic resources, in areas within their jurisdiction.

A wide range of sectors undertake research and develop commercial products from genetic resources. They include the pharmaceutical, biotechnology, seed, crop protection, horticulture, cosmetic and personal care, fragrance and flavour, botanicals, and food and beverage industries.

It is frequently argued that industry groups have used TK as leads or short-cuts during the lengthy and costly product development phase. The protection of TBKIPs therefore inevitably interfaces with the legal systems regulating access to genetic resources.

It is important that in developing the legislation, policy-makers are not only cognisant of this relationship but take steps to ensure that there is as much consistency as possible between the legislation and laws and policies regulating access to genetic resources. As both will without doubt contain PIC procedures, policy-makers should seek to align the two regimes as much as possible, not only for administrative efficiency but to promote clarity and certainty for users and traditional communities as well. Similarly, benefit-sharing priorities and arrangements can also be aligned where appropriate.

Further, the interrelationship between the two regimes will need to be considered carefully, particularly the independence of PIC procedures for access to genetic resources from access to TK related to those resources. For example, it should be made clear to users that permission to access genetic resources does not imply permission to access and/or use traditional knowledge.

3.14 International and regional protection

Intellectual property has long had an international dimension, reflecting agreement in the mid-nineteenth century that effective and appropriate protection was dependent on a degree of international coordination and cooperation. This is also the case for the protection of TBKIPs.

In developing this element, policy-makers will need to consider the recognition of the rights of foreign rights holders regarding TBKIPs in national systems of protection, including in what circumstances foreign right holders would have access to national protection systems and the nature and extent of rights granted to foreign nationals. Practical mechanisms to facilitate the obtaining and administration of rights regarding TBKIPs may also need to be addressed if foreign right holders experience difficulties. However, this will be difficult to anticipate prior to the legislation coming into force.

3.14.1 Background

IP is essentially protected through rights recognised and exercised under national laws. As a rule, it is at the national level that rights holders are recognised as having legal identity (or legal personality), that they are given standing to take legal action, and that they are considered entitled to be granted or to hold an IP right. It is ultimately under national law that IP rights are legally recognised (though international arrangements can facilitate applying for rights, can facilitate their registration and recording and, in some jurisdictions, can form the basis for rights directly exercised by individual right holders), and national legal mechanisms allow IP right holders to take action to restrain infringement of their rights and to secure other remedies such as damages. Contracts and agreements that affect the ownership, licensing of and other dealing in IP rights are also concluded and enforced under national laws.[35]

Similarly, the protection of TBKIPs - whether through conventional IP rights, *sui generis* adaptations of IP rights, or distinct *sui generis* systems such as the TBKIP Model Law - ultimately takes place at the national level. Any general approach to the IP protection of this subject matter, including its international dimension, involves consideration of what legal tools and mechanisms are required at the national level, how they should operate, and what legal and operational contributions the international dimension can make to protection at the national level. It also requires a shared understanding of the role, and the limits on the role, of international mechanisms, whether they are legal, policy, administrative or capacity-building mechanisms. This is not to diminish the international dimension of IP protection, but to set it in a practical and operational context. [36]

Nonetheless, even if its protection is ultimately dependent on the operation of national laws, the nature of IP has long demanded international cooperation, including through international legal instruments, but also through a wide range of other international systems and processes.

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[35] WIPO IGC 6/6 pg 4
[36] WIPO IGC 6/6 pg 5

3.14.2 Policy considerations

Coordination and clarification of linkages with related elements of international law is important. With respect to TBKIPs, these areas would include access to genetic resources and benefit-sharing thereof, cultural heritage, human rights, Indigenous peoples' issues and trade and industry. International legal instruments of particular relevance to TBKIPs include the Convention on Biological Diversity and the Declaration on the Rights of Indigenous Peoples.

Substantive standards are under development within international fora such as under the CBD and this is likely to have an impact on national laws for the protection of TBKIPs. Nonetheless, it is likely that such international standards will continue to respect national discretion as has been the case with existing international IP laws. Countries are likely to have a wide discretion in giving effect to any international standards that emerge.

3.14.3 Policy questions

a) How can the rights and interests of foreign holders of rights be recognised?

As a rule, the international standard is for relatively open access to IP systems for foreign nationals (provided that they are nationals of a country with relevant treaty commitments), a rule that dates back to the first international conventions in the 1800s. By virtue of the obligations under the Paris Convention, the Berne Convention, TRIPS and other IP treaties, the principle of national treatment applies to most categories of IP protection (subject to certain exceptions). In addition, WTO Members are required (also subject to certain exceptions) to apply the most-favoured nation principle at least in relation to the IP protection required under the WTO TRIPS Agreement. Some specific aspects of IP protection (such as the duration of term of copyright protection) may also be determined in certain circumstances by the principle of reciprocity.

The protection of foreign holders of rights in TBKIPs is, however, a complex question particularly where different customary laws are at play and also where TBKIPs are part of the shared cultural heritage of countries. Moreover, there is currently no international instrument establishing obligations and undertakings regarding the recognition of the rights and interests of foreign holders of rights regarding TBKIPs. Existing *sui generis* national laws either do not protect foreign right holders at all or show a mix of approaches Some systems of registration and recognition of *sui generis* rights in TBKIPs appear to be focused on rights holders who are nationals of the country of protection, or that are communities recognised in that country. One model that has been applied has been for reciprocal protection to apply. For example, the Panama Law of 2000 and the Pacific Model Law 2002 provide for protection of foreign materials. The Model Provisions 1982 provide protection for expressions of culture of foreign origin either according to a reciprocity principle or on the basis of international treaties.[37]

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[37] Section 14.

With regard to possible mechanisms to enable nationals of one country to enjoy rights in a foreign jurisdiction, policy-makers may wish to refer to the following approaches:

- National treatment: This principle can be defined as granting the same protection to foreign rights holders that are granted to domestic nationals (subject to exceptions and limitations), or *at least* the same form of protection. Examples include the Berne Convention, the Rome Convention 1961[38] and the WPPT 1996.[39].

- Reciprocity: Instead of national treatment, or supplementing it, other international legal mechanisms have been used to recognise the IP rights of foreign nationals. Under 'reciprocity' (or reciprocal recognition), whether a country grants protection to nationals of a foreign country depends on whether that country in turn extends protection to nationals of the first country; the duration or nature of protection may also be determined by the same principle. Under a 'mutual recognition' approach, a right recognised in one country would be recognised in a foreign country by virtue of an agreement between the two countries.

- Most-Favoured-Nation: Also of potential application to the recognition of rights of foreign rights holders, is the 'most-favoured-nation' principle. The TRIPS Agreement provides (subject to exceptions) that with regard to the protection of IP, any advantage, favour, privilege or immunity granted by a [WTO] member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other members.

While a national treatment approach would appear to be an appropriate starting point, the very nature of TBKIPs suggests that national treatment be supplemented by certain exceptions and limitations or other principles, such as mutual recognition, reciprocity and assimilation, especially when this concerns the legal status and customary laws of beneficiaries of protection. For example, it is broadly accepted that the beneficiaries of protection should be the traditional communities in whom the custody, care and safeguarding of TBKIPs are entrusted in accordance with the customary laws and practices of the communities. Under one strict conception of national treatment, a foreign court in the country of protection would have recourse to its own laws, including its own customary laws, to determine whether a foreign community qualifies as a beneficiary. This may not satisfactorily address the situation from the community's viewpoint; the community would, reasonably, wish for its own customary laws to be referred to. Under mutual recognition and assimilation principles, a foreign court in the country of protection could accept that a community from the country of origin of the TBKIPs has legal standing to take action in country A as the beneficiary of protection because it has such legal standing in the country of origin. Therefore, while national treatment might be appropriate as a general rule, it may be that mutual recognition, for example, would be the appropriate principle to address certain issues such as legal standing.[40]

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[38] Article 2 of the Rome Convention 1961

[39] The WPPT 1996 states that: "Each Contracting Party shall accord to nationals of other Contracting Parties, as defined in Article 3(2), the treatment it accords to its own nationals with regard to the exclusive rights specifically granted in this Treaty, and to the right to equitable remuneration provided for in Article 15 of this Treaty."

[40] WIPO. 2006. *The Protection of Traditional Knowledge: Revised Objectives and Principles* WIPO/GRTKF/IC/9/5. p46

In considering which approach to use, policy-makers may wish to refer to the TBKIP Model Law which uses a reciprocal approach. Section 17 states that the Act may provide the same protection for knowledge, innovations and practices originating in countries or territories with whom it has entered into reciprocal agreements with. As a practical example of how this would work, if Samoa and Vanuatu have a reciprocal arrangement, the beneficiaries of protection in Fiji will enjoy the same rights and interests regarding their TBKIPs in Vanuatu as they do under Fiji's law, and vice versa.

Reciprocal agreements

In accordance with reciprocal agreements entered into with other countries or territories, this Act may provide the same protection for knowledge, innovations and practices originating in those countries or territories as it provides for knowledge, innovations and practices originating in [the enacting country].

Section 17, TBKIP Model Law

The legislation could also specify that the rights and benefits arising from the protection of TBKIPs under the legislation should be available to all eligible beneficiaries who are nationals or habitual residents of a prescribed country, depending on whether a national treatment or reciprocity approach is taken.

b) What should recognition of the rights of foreign nationals consist of?

Access by foreign right holders regarding TBKIPs to national *sui generis* protection systems may entail various forms of recognition. For instance, it may concern:

- recognition as eligible Indigenous or local communities, or recognition of the legal identity of a collective or community as rights holder;
- entitlement to be granted a right relating to TBKIPs, including entitlement for TBKIPs or related subject matter to be entered on a register, where applicable;
- participation in any official mechanisms for the collective administration of rights;
- participation in benefit-sharing arrangements or other funds concerning the exploitation of TBKIPs; and
- entitlements concerning enforcement of rights, including *ex officio* enforcement action taken by national authorities or public prosecutors.

Under some national laws, rights in TBKIPs may be specifically reserved for certain classes of individuals or communities, identified and recognised under domestic law – for example, 'Indians' in the US Indian Arts and Crafts Act 1990, or certain local or Indigenous communities. Hence, the availability of such rights to foreign individual or collective claimants may also be dependent on their compliance with similar or adapted criteria to be eligible rights holders. This may entail clarifying whether eligibility of foreign rights holders for rights or benefits reserved for particular categories of TBKIPs holders would be assessed according to the laws of the country of origin, or the laws of the country in which protection is claimed.

c) How should practical impediments, if any, to foreign right holders be addressed?

The practical exercise and enforcement of IP rights can also pose major difficulties for rights holders, especially when multiple jurisdictions are involved and when rights holders have limited resources. This has given the administration of IP rights an international dimension. If the validity of a patent, trade mark or industrial design right depended on the timely filing of applications, then applicants would face considerable hurdles in securing the early filing date necessary to safeguard their rights in countries other than their own. Hence the notion of a right of priority was introduced into the Paris Convention for such industrial property rights, so that a filing date in one country would have effect in another Paris Union country, provided an application was filed within a certain period of time. International systems such as the Madrid and Hague international registration systems, and the Patent Cooperation Treaty are, in essence, developments of this important mechanism, motivated by the recognition that seeking IP rights in multiple jurisdictions creates practical burdens both for applicants and for national authorities, and entails considerable duplication of administrative activities by various authorities. Such developments provide public benefits by reducing the investment of public resources in duplicative administration and the checking of formalities, and creating more effective and useful public information resources. There is, similarly, an international dimension to the question of making more practicable the exercise of IP rights covering TBKIPs subject matter for the benefit of traditional communities.

The difficulty of enforcement of IP rights in multiple jurisdictions has also led to the development of quasi-international mechanisms for alternative dispute resolution. Alternative dispute resolution procedures respond in part to practical difficulties with conventional litigation for parties in more than one jurisdiction, and the international aspect of disputes over such IP-related subject matter as internet domain names.

As the TBKIP Model Law has introduced a comparatively new approach, and in the absence of practical experience regarding its implementation, it is difficult to gauge at this point whether administrative measures are needed to address practical impediments. Even so, the development of cooperative mechanisms would most likely occur at the regional level for subsequent implementation at the national level. If and when this occurs, countries wishing to implement measures to address practical impediments may need to make amendments to their legislation for the protection of TBKIPs.

3.14.4 Further information

Another source of information regarding the relationship with international and regional protection is:

- WIPO. 2006. *The Protection of Traditional Knowledge: Revised Objectives and Principles* WIPO/GRTKF/IC/9/5. Pages 45-47 of the Annex provide information on the relationship with international and regional protection.

PART 4. ADDITIONAL LEGISLATIVE FEATURES

Following the development of the legal elements of protection of the legislation, there are a number of additional legislative features that policy-makers will need to address. The majority of these features will be shaped by national legislative practices. The Guidelines focus only on complex matters in which policy-makers are likely to require assistance: the development of transitional measures and regulatory making powers.

4.1 Transitional measures

4.1.1 Policy questions

The following questions are intended to assist policy-makers to develop a policy on transitional measures that is appropriate to their national circumstances. This is not an exhaustive list and policy-makers should note that there may be additional questions to be considered.

d) Should protection operate retroactively or prospectively?

Most countries have general transitional provisions, but these provisions may not provide the result intended in the context of TBKIPs. A key issue for policy-makers is whether protection should operate retroactively or prospectively, and in particular how to deal with utilisations of TBKIPs that are continuing when the legislation enters into force and that had lawfully commenced before then.

In terms of policy considerations, it is an accepted principle that laws should respect, as far as possible, rights previously lawfully acquired. That said, it has also been noted that prior and ongoing uses of TBKIPs should be regulated as far as possible within a certain period of protection measures coming into force.[41]

Existing laws utilise a range of approaches:[42]

i. Retroactivity of the law, which means that all previous, ongoing and new utilisations would become subject to authorisation under the new law or regulation.

ii. Non-retroactivity, which means that the only utilisations that would come under the legislation would be those that had not been commenced before the law's entry into force. For example, the Panama Law 2000 provides that rights previously obtained shall be respected and not affected by the legislation.

iii. An intermediate solution, in terms of which utilisations that become subject to authorisation under the law or regulation, but were commenced without authorisation before the entry into force, should be brought to an end before the expiry of a certain period.

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[41] WIPO 2005 The Protection of Traditional Cultural Expressions/Expressions of Folklore: Revised Objectives and Principles WIPO/GRTKF/IC/8/4, Geneva, 40

[42] Ibid

The TBKIP Model Law uses a combination of these approaches. Section 3(2) provides that the Act has retrospective effect with regard to moral rights. Economic rights, on the other hand, only have prospective application.

The practical implications of the retroactive application of moral rights need to be considered carefully by policy-makers. In effect, it would mean that all previous and ongoing (as well as new utilisations) would become subject to the moral rights provisions under the new law. These comprise the right of attribution of ownership, the right not to have ownership of TBKIPs falsely attributed, and the right not to have TBKIPs subject to derogatory treatment. Therefore, once the legislation is in force, a user would need to ensure that their use of TBKIPs does not contravene these moral rights. There is flexibility for countries to modify this aspect of the TBKIP Model Law if they so wish so that moral rights only have prospective application.

The Pacific Model Law 2002 (which takes a different approach to the TBKIP Model Law) follows the intermediate solution identified above whereby a user has 60 days from the commencement of the Act to obtain the PIC of the traditional owners to continue to use the particular traditional knowledge and expression of culture. Such a provision can facilitate smoother transitional arrangements. If a country wishes to follow this intermediate approach, it is useful to refer to clause 35 of the Pacific Model Law 2002 below for guidance.

Procedure for transitional arrangements

(1) ….this section applies to a person if, immediately before the commencement of this Act, the person was making a non-customary use of traditional knowledge or an expression of culture;

(2) The provisions of this Act do not apply to the person during the period of 60 days (the "application period") starting on the commencement of this Act;

(3) During the application period, the person must apply…to the Cultural Authority to obtain prior and informed consent from the traditional owners to continue to use the traditional knowledge or expression of culture;

(4) If the person does not apply to the Cultural Authority…the Act applies to the person on and after the end of the application period;

(5) If a person has applied to the Cultural Authority…the Act continues not to apply to the person until the traditional owners reject the application or enter into an authorised user agreement with the person, whichever first occurs.

Clause 35, Pacific Model Law

Further, it is advisable that policy-makers develop the 'Application' provision within the TBKIP Model Law in more detail. This might include clarifying that economic rights are non-retrospective and also the application of the legislation to TBKIPs in existence before the commencement of the legislation and those developed after that commencement. A useful example to refer to is the 'Application' provision in the Pacific Model Law 2002.

Application

(1) This Act applies to traditional knowledge and expressions of culture that:

(a) were in existence before the commencement of this Act; and

(b) are created on or after that commencement.

(2) This Act does not affect or apply to rights that exist immediately before the commencement of this Act, including intellectual property rights.

(3) This Act does not affect or apply to contracts, licences or other agreements entered into by traditional owners before the commencement of this Act in relation to the use of traditional knowledge or expressions of culture.

Clause 3, Pacific Model Law

4.2 Regulatory making power

There is a general principle that matters of policy should be included in the empowering statute (primary legislation) while matters of detail should be left to delegated legislation (secondary legislation). This interface has been characterised as that between the principle and the detail, between policy and its implementation.[43]

As there is a considerable operational dimension to the protection approach taken in the TBKIP Model Law, secondary legislation will be needed to provide guidance on these matters. In order to make secondary legislation, a regulatory making power will need to be included in the primary legislation (referred to as an 'empowering clause'). This segment of the Guidelines provides guidance in this regard.

4.2.1 Policy questions

e) Who is the appropriate person to make the delegation to?

The empowering clause will need to delegate power to an appropriate person to make regulations. The person to whom the power is given should have an appropriate degree of responsibility. Law-making powers are often delegated to the governor-general, ministers or officials. Lawmaking powers can also be given to professional bodies to regulate particular industries.

If the law-making power will potentially impact on individual rights and liberties, careful consideration must be given to the person that should exercise the power. It may be appropriate for the governor-general or an equivalent to exercise the power.[44] If the law-making power involves prescribing technical matters which will not impact upon individual rights, an official may be the appropriate person to exercise the power. For the purposes of the legislation, the matters prescribed will relate mostly to procedural matters rather than matters that could impact on individual rights and freedoms. Therefore, it may

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[43] Legislation Advisory Committee (2001) *Guidelines on Process and Content of Legislation* Wellington: Ministry of Justice 125

[44] Ibid at 126

be appropriate for a minister rather than a governor-general to exercise the law-making power, recognising that this is a matter for individual countries to determine based on their national circumstances and practices.

The empowering clause in the TBKIP Model Law is contained in section 18, however, it does not specify to which minister the law-making power will be delegated; this is left blank as it is a matter for each country to determine. Portfolios that are relevant to the legislation include but are not limited to environment, culture and justice.

Regulations

The [insert] acting upon the advice of [insert] may make regulations for giving full effect to the provisions of this Act and for its due administration.

Section 18, TBKIP Model Law

f) What should be the scope of the delegation?

Within the empowering clause, the limits of the law-making power should be specified as clearly as possible. It is common for countries to have standard wording providing for the making of regulations and the specific purposes for the regulations are simply inserted. In terms of the legislation, the scope of the delegation will be influenced by the policy decisions taken in Part 3. It is therefore, difficult to define the necessary scope in the Guidelines. The following non-exhaustive list is intended to provide guidance to policy-makers on the types of matters that could be covered in regulations:

- Management of rights:
    - the form and procedures for applications for authorisation to the Competent National Authority;
    - the information any application for authorisation has to contain;
    - fees, if any, that the state body may charge for its services;
    - public notification procedures;
    - the procedures that must be followed by the Competent National Authority in advising the relevant social group of any application for authorisation;
    - the policies and procedures that any social group claiming ownership must follow to satisfy the Competent National Authority of its claim to ownership;
    - the terms and conditions upon which authorisations may be granted by the state body;
    - the procedures that must be followed by the Competent National Authority in informing the prospective user of the identify of an owner;
    - the resolution of disputes.

- Formalities:
    - the manner in which applications for registration should be made;
    - to what extent and for what purposes applications for registration are examined by the office, including timeframes;
    - measures to ensure that registration or notification is accessible and affordable;
    - appeals against the registration or notification of particular TBKIPs;
    - the resolution by the registration office of disputes relating to which community or communities should be entitled to benefit from the protection;
    - the legal effect of registration or notification.

4.2.2 Further information

Another source of information regarding regulatory making powers is:

- Legislation Advisory Committee. 2001. *Guidelines on Process and Content of Legislation* Wellington: Ministry of Justice. See Chapter 10: Delegation of Lawmaking Power which provides information on empowering clauses.

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