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INFORMATION ON NATIONAL EXPERIENCES WITH THE INTELLECTUAL
PROPERTY PROTECTION OF TRADITIONAL KNOWLEDGE

Document prepared by the Secretariat

The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("the Committee") has requested for consideration at its fifth session a consolidated survey of national experience with the intellectual property protection of traditional knowledge (TK) (document WIPO/GRTKF/IC/5/7) and a composite study on TK protection (document WIPO/GRTKF/IC/5/8). The present information document provides detailed background information relevant to both these two studies, comprising information from the responses provided to two questionnaires on TK protection (WIPO/GRTKF/IC/2/5 and WIPO/GRTKF/IC/Q.1). This document contains responses and text of legislation received up to February 28, 2003, compiled as follows:

- Annex I: responses containing actual examples of the use of conventional intellectual property regimes to protect TK;
- Annex II: responses describing enacted or planned *sui generis* regimes; and
- Annex III: text of enacted laws communicated to the Secretariat that establish *sui generis* systems for the protection of TK.

[Annex I follows]

ANNEXI

EXAMPLES OF THE USE OF CONVENTIONAL
INTELLECTUAL PROPERTY LAW IN PROTECTING TK

This Annex contains responses to question (c) of document WIPO/GRTKF/IC/Q.1 and, where noted, similar responses to the earlier questionnaire WIPO/GRTKF/IC/2/5. Question (c) was as follows:

Could you please explain by means of concrete examples how currently available standards of intellectual property have been used to protect traditional knowledge.

Responses are provided from the following Member States:

Australia
Canada
Colombia
Costa Rica
France
Italy
Kazakhstan
Mexico
Republic of Moldova
New Zealand
Portugal
Russian Federation
Samoa
Venezuela
Vietnam

AUSTRALIA¹

There have been a number of cases which demonstrate the ability of the existing Australian intellectual property regime to protect traditional knowledge.

In *FostervMountford(1976)29FLR233* the Court used the common law doctrine of confidential information to prevent the publication of a book containing culturally sensitive information. The case concerned an anthropologist, Dr. Mountford, who undertook an expedition to the Northern Territory outback in 1940. Local Aboriginal people revealed to him tribal sites and objects possessing deep religious and cultural significance for them. The defendant recorded this information some of which he published in a book in 1976. The plaintiff successfully sought an interlocutory injunction restraining the publication of the book on the basis of breach of confidence. (The plaintiff could not bring an action for copyright infringement because the work in question - i.e. the book - had not been written by them and they had not acquired the copyright in it). The Court held that the publication of the book could disclose information of deep religious and cultural significance to the Aborigines that had been supplied to the defendant in confidence and the revelation of such information amounted to a breach of confidence.

MilpurrruvIndofurnPtyLtd(1995)30IPR209 ('carpets case') highlighted the Courts' capacity to award damages for infringement in a culturally appropriate manner. The case involved the importation of carpets manufactured in Vietnam which reproduced either all or part of well-known works, based on creation stories, created by Indigenous artists. At no stage did the artists give permission for their artwork to be reproduced on the carpets, nor for the carpets bearing the artwork to be imported into Australia. The artists successfully claimed infringement of copyright (by reason of the unauthorized importation of carpets). The artists were also successful in a trade practices action in respect of the labels attached to the carpets which claimed that the carpets had been designed by Aboriginal artists and that royalties were paid to the artists on every carpet sold.

The judgment recognizes the concepts of 'cultural harm' and 'aggregated damages'. The Court noted in its judgment that "the statutory remedies do not recognize the infringement of ownership rights of the kind which reside under Aboriginal law in the traditional owners of the dreaming stories and the imagery such as used in the artwork of the present applicants." The applicants were awarded a collective sum of damages, with the proceeds of the action to be distributed to "those traditional owners who have legitimate entitlements according to Aboriginal law to share compensation paid by someone who has without permission reproduced the artwork of an Aboriginal artist." The Court made an award of exemplary damages, in the sum of AU\$70,000 for cultural harm and which took into account the calculated and flagrant nature of the infringement.

In *BulunBulun&MilpurrruvR&TTextilesPtyLtd(1998)41IPR513* the Court found that an Indigenous person had a fiduciary duty to his community. The court found that the relationship between Mr. BulunBulun (the artist) and his community in regard to the creation of the painting was one of mutual trust and confidence which was found to be

¹ The delegation of Australia has provided the following examples in response to questionnaire WIPO/GRTKF/IC/2/5.

sufficient, under Australian law, for a fiduciary relationship between Mr. Bulun Bulun and his community to arise.

The judge found that, on the evidence of the customary law of the Ganalbingu people, Mr. Bulun Bulun owed two fiduciary obligations to his community. First, he was not to exploit the painting in a manner contrary to his community's customary law. Secondly, in the event of infringement by a third party, he was to take reasonable and appropriate action to restrain and remedy infringement of the copyright in the painting.

The court recognized two instances in which equitable relief in favor of a tribal community might be granted, in a court's discretion, in circumstances where copyright is infringed in a work embodying ritual knowledge: first, if the copyright owner fails or refuses to take appropriate action to enforce the copyright; and second, if the copyright owner cannot be identified or found.

In a further case called *Bulun Bulun v Flash Screenprinters* [see discussion in (1989) EIPR Vol 2, pp. 346-355], Mr. Bulun Bulun brought a copyright infringement action in relation to the unauthorized reproduction of his artistic works on t-shirts by Flash Screenprinters. This was a clear-cut case of copyright infringement and the case was settled out of court. The successful resolution of this matter suggests that protection under the Copyright Act can be as valuable to Aboriginal and Torres Strait Islander artists as it is to other artists.

Further information regarding these and other cases can be located at:
<<http://www.austlii.edu.au>>.

Australia does not have specific provisions in its patents, trademarks and designs legislation to protect traditional knowledge. However, certification trademarks have been used recently as a mechanism to help protect the interests of indigenous and traditional knowledge owners through identifying or authenticating products or services provided by indigenous owners or in collaboration with indigenous owners. The trademark system has also been used by, for example, arts centers as a mechanism to promote the arts and crafts of indigenous people. The design system has been used by traditional knowledge owners to protect indigenous designs.

CANADA

The *Copyright Act* is used by a range of Aboriginal artists, composers and writers to protect their tradition-based creations. Examples include woodcarvings of Pacific coast artists, silver jewelry of Haida artists, songs and sound recordings of Aboriginal artists, and sculptures of Inuit artists.

Trademarks, including certification marks, are often used by Aboriginal people to identify a wider range of traditional goods and services. These range from traditional art and artwork of food products, clothing, tourist services and enterprises run by First Nations. Many Aboriginal businesses and organizations have registered trademarks relating to traditional symbols and names. The number of unregistered trademarks used by Aboriginal businesses and organizations is considerably greater than those that are registered. Some trademarks are registered in order to prevent improper utilization of symbols or names.

For example, Snuneymuxw First Nation of Canada in 1999 used the Trademarks Act to protect ten petroglyph (ancient rock painting images). Because the petroglyph has special religious significance to the members of the First Nation, the unauthorized reproduction and commodification of the images was considered to be contrary to the cultural interests of the community, and the petroglyph images were registered in order to stop the sale of commercial items, such as T-shirts, jewelry and postcards, which bore those images. Members of the Snuneymuxw First Nation subsequently indicated that local merchants and commercial artisans had indeed stopped using the petroglyph images, and that the use of trade-mark protection, accompanied by an education campaign to make others aware of the significance of the petroglyph to the Snuneymuxw First Nation, had been very successful.

Aboriginal communities also rely upon trade secret protection, and, on occasion, use confidentiality agreements with governments and non-Aboriginal businesses when sharing their traditional knowledge.

A study produced for the Canadian government in 1999 provides an overview of areas of Canadian intellectual property law of most relevance to Aboriginal people. It sets out brief examples of Aboriginal peoples' use of, and their perspectives on, copyright, industrial design, trade-marks, patent and trade secret protection. This paper is available at: http://www.ainc-inac.gc.ca/pr/ra/intpro/intpro_e.html.

COLOMBIA²

Article 136(g) of Decision 486 of the Commission of the Andean Community provides that "signs, whose use in trade may unduly affect a third party right, may not be registered, in particular when they consist of the name of indigenous, Afro-American or local communities, denominations, words, letters, characters or signs used to distinguish their products, services, or the way in which they are processed, or constitute the expression of their culture or practice, except where the application is filed by the community itself for with its express consent."

In Colombia, a case has been presented in which the mark has been rejected as a result of the exception mentioned above. A description of that case follows.

Tairona Culture Case

Overview

The case basically consists of the application for registration as a mark of the expression Tairona, which coincides with an indigenous culture that inhabited Colombian territory.

² The delegation of Colombia has provided the following examples in response to questionnaire WIPO/GRTKF/IC/2/5.

Description of Tairona Traditional Culture

The Taironas were a pre-Hispanic Colombian culture which inhabited the lowlands of the foothills of the Sierra Nevada of Santa Marta. The dense population lived in large villages, many of which are worthy of the name of cities.

The main basis of subsistence was large-scale maize cultivation, but also cassava, pumpkins, beans and a large number of fruit trees were grown. Another important source of food was the sea and, in a number of regions, beekeeping was practiced. The Taironas practiced vertical control of environmental aspects and each river basin appeared to contain various redistribution centers in the form of cities.

At the beginning of the sixteenth century, a large number of Tairona populations had settled around two important urban centers and two federations therefore began to be established in the form of two small incipient opposing States; one center was Bonda, located in the flat part, close to which was Santa Marta, and the other was Pocigüica, located on the steep slopes and dominating the areas at the head of the rivers Frío and Don Diego. Rivalries existed between both centers; it is noted that a powerful class of priests were engaged in more or less open warfare with the civil chiefs. However, as is obvious the Tairona had not achieved the complete consolidation of a centralized government.

Secondly, the first large villages, which used extensive constructions of lithic foundations, were preferably built in defensive positions, although part of the population lived in low-lying areas. Thirdly, the search for the oldest phases of Tairona culture has been in vain; the architectonic complex appeared more suddenly around the eleventh or twelfth century, without any clear local precedents. This lack of continuity brings to mind the possibility that the Taironas are of Central American origin and that they reached the coast of Santa Marta by sea, since all the signs of a migration over land are absent. Also the current Kogi culture contains many ideological elements which recall a Meso-American origin and are essentially Maioid in nature.

Tairona ceramic of the protohistoric period are very elaborate. Characteristic are certain receptacles with shiny black surfaces, small vessels with four supports, cups and large plates. The decoration is generally modeled and cut, and almost never painted. Many plastic features are combined with the receptacles, representing animals such as cats, marsupials, bats, birds and reptiles.

Some of the Tairona-Kogi cosmological and religious concepts show a universe formed by various horizontal strata superimposed with the world, i.e. the Sierra Nevada, in the center. The Sun and the Moon are divinities which were created by the Magna Mater in order to establish and maintain a cyclical order in the world. The observance of this order, i.e. of the cycle of solstices and equinoxes, together with the formulation of an agricultural and ceremonial calendar, was the responsibility of the priests who constructed their temples and ceremonial centers on the basis of these astronomical and meteorological phenomena.

The archaeological remains of Tairona culture, which were badly damaged by looters, continue to offer great surprises. The investigations conducted in the first few decades of this century revealed a number of villages where the houses had stone foundations: series of roads,

containing walls, cultivation terraces and drainage channels. This complex is now known by the name of the Lost Buritic City 200, and is an important tourist attraction.¹

Decision

Considering that the denomination applied for the mark TAIRONA for distinguishing Class 30 products in the Nice International Classification coincided with the name of the indigenous culture which inhabited Colombian territory and of which relics still exist, as already noted in the previous paragraph, it was considered that the title with which they are distinguished was protected as part of its heritage and of the country as such. In that regard, only representatives of this culture or persons with the authorization of those representatives are entitled to request the expression in question for use as a distinctive sign and, in this particular case, as a mark.

Rights and remedies

It should be stated that the decision taken was not based on any opposition raised by representatives of the culture, governmental organization or third party concerned, but as part of the formal study conducted by the administration in the light of Decision 486 of the Commission of the Andean Community, which contains the rules governing the subject. In that regard:

Article 136(g) of Decision 486 of the Commission of the Andean Community states that signs may not be registered as marks, which consist of the name of indigenous, Afro-American or local communities, denominations, words, letters, characters or signs used to distinguish their products, services or the way in which they are processed, or which constitute the expression of their culture or practice, except where the application is filed by the community itself for with its express consent.

An important and integral feature of the country is the Tairona culture and the significance of its history in terms of the different ways of life and customs, knowledge, degree of artistic and scientific development, as well as traditions and customs, *inter alia*, of its people. All the above represent for the country an invaluable heritage which is worthy of protection and respect by society, thereby making it necessary to achieve consistency with the global vision and the mechanisms that have been developed to provide them with the guarantees allowing them to be preserved, especially if consideration is given to human groups which are weak and have a strong tendency to die out, thereby generating a necessary interest on the part of the different States which, together, ensure that they are protected and maintained.

However, industrial property has not been neglected and according to Decision 486 of the Commission of the Andean Community those characters, denominations or symbols specific to the indigenous communities relating to our region, such as those of Afro-American character (descendants of the African negroes who were transported to America) or local communities do not form part of the series of features that may be appropriated by individuals with a view to their use as trademarks, thereby protecting and maintaining them in an environment which ensures that they are respected.

COSTARICA

There are no specific examples of actual indigenous use, only registrations of livestock brands, in view of the fact that branding is the activity most frequently encountered in indigenous reservations; as for indigenous inventions, they are not registered.

FRANCE³

In France there is no specific intellectual property enactment that provides for the protection of traditional knowledge. However, classical intellectual property rights can serve indirectly to provide such protection.

Trademarks: The trademark is an intellectual property title that can lend some protection to traditional knowledge: by using a trademark to protect a sign for products manufactured according to traditional methods, one capitalizes on the accumulated know-how; in the case of know-how belonging to a particular corporate group, the most suitable instrument is the collective mark, which can be used by all members of the group. Collective marks are protected in France by both national and Community law.

At the national level, Articles L.715 -1 and following of the Intellectual Property Code govern collective marks and collective certification marks, which may be used by any person who abides by regulations for use laid down by the owner of the registration. The ordinary collective mark is a trademark like the others which allows a group of producers to publicize their existence to consumers and to promote their goods and services by means of collective advertising. As for the collective certification mark, it attests that the producer or service possesses certain characteristics or qualities; it may only be filed by a legal entity possessing a degree of independence. The owner therefore does not use the mark itself, but provides rather for its promotion and for its legal defense against infringers. The collective mark always has to meet the distinctiveness condition, meaning that it has to relate to an arbitrary, non-descriptive sign.

Articles 64 to 72 of Council Regulation (EC) No 40/94 of December 20, 1993, on the Community trademark are concerned with Community collective marks. Those marks have to be filed by associations of manufacturers, producers, traders or service providers. They allow the goods or services of the members of the association to be distinguished, and they are accompanied by regulations for their use which among other things lay down the conditions of membership of the association.

For instance, in France the semi-figurative collective mark “Laguiole Origine Garantie” has been filed by the “Association du cousteau Laguiole” for the protection of cutlery articles made in Laguiole, a commune in the Aveyron department.

Geographical indications: The protection of geographical indications also serves to afford indirect protection to local and traditional knowledge: the reputation of a geographical name used in relation to particular goods is generally connected with the particular know-how

³ The delegation of France has provided the following examples in response to questionnaire WIPO/GRTKF/IC/2/5.

of the manufacturers in the place named. Protection of the name against use to designate goods not originating in the place named thus contributes to the protection of the know-how. The appellation of origin gives stronger protection to goods whose characteristics are connected with human factors (know-how) but also with natural factors. The protection of indications of source and appellations of origin can thus be a factor of protection of the cultural heritage. By exploring and protecting geographical names, one helps to enhance local traditions and know-how.

French law protects in particular controlled appellations of origin (AOC): under Article L.115-1 of the Consumer Code, an appellation of origin is constituted by "the name of a country, region or locality serving to designate a product originating therein the quality or characteristics of which are due to the geographical environment, including both natural and human factors." Human factors are to be taken to mean traditional local production methods. AOCs are governed by decrees that regulate in detail the conditions for the manufacture of the products qualifying for them with respect to the production area and the techniques used. France is party to the Lisbon Agreement of October 31, 1958, and as such protects both French AOCs and the appellations of origin of the other States party to the Agreement.

French law also protects indications of source. Articles L.217-6 to L.217-9 of the Consumer Code allow criminal sanctions for fraud to be imposed in cases of deception committed by the use of false indications of source on goods that do not possess an AO.

For instance, Decree No. 92-340 of April 1, 1992, regulates the appellation of origin "Monoïde Tahiti."

ITALY

Specific laws protect exclusive rights regarding the commercial use of names related to specific goods (not services) which in certain cases could have been made using "Traditional Knowledge." That can be assumed referring to the protection of certificate of origin and geographical indications (i.e., "Prosciutto di Parma"). At the moment, this kind of protection for agricultural goods and food stuff is admitted only after the Community Registration of the certificate of origin issued by the European Commission: See Reg. 2081/92/CEE, dated July 14, 1992, in GUCEn.208L dated July 24, 1992.

KAZAKHSTAN⁴

Till now in the Republic of Kazakhstan there are no special Regulations or special Laws providing protection for traditional knowledge. However, the valid legislation on the intellectual property protection, namely, the Patent Law of the Republic of Kazakhstan of July 16, 1999, and the Law "On the Trademarks, Service Marks and Appellations of Origin of the Goods" of July 26, 1999, do not exclude the possibility to protect inventions, industrial designs, trademarks. All being based on traditional knowledge of Kazakh people.

⁴ The delegation of Kazakhstan has provided the following examples in response to questionnaire WIPO/GRTKF/IC/2/5.

Thus, for example, the patent protection is provided for “the method of producing kumis (mare’s milk),” “Kazakhstan,” Patent of the RK, No. 33; for “the method of producing shubat (female camel’s milk),” “Turkestan,” Patent of the RK, No. 6237, as for inventions. There is provided to grant patent protection for “the method “Kushkon” of manufacturing relief picture of leather,” Patent of the RK, No. 4619. All these are attributed to traditional knowledge.

The outward appearance of national outer clothes, headresses (saykele), carpets (tuskiiz), decorations of saddles, national dwellings (yurta) and their structural elements; women’s decorations in form of bracelets (blezik), national children’s scots -crib-cradles and tablewares (piala, torcyk) are protected as industrial designs.

The designations containing elements of Kazakh ornament are registered and protected as trademarks.

MEXICO⁵

Case 1: ARTESERI (registered trademark)

The Seri people is made up of a number of communities, and the clan structure plays an important part in its social organization. The intensity and depth of its relationship with the nature of the Gulf of California and the Sonora Desert has been abundantly documented (Felger & Moser, 1991). It is an effect of this ancient culture that the Seri have managed to survive in one of the driest regions of North America. In doing so they have taught themselves to eke out the available resources, and their creations include numerous articles of adornment for craft markets, which actually constitute an important source of income for families and communities. In the middle of 1993, a meeting was held in Bahía Kino, Sonora, to discuss the difficult circumstances of the Seri craftsmen who produced iron wood pieces, faced as they were with mass production by mestizo workers. So there was some discussion at the time on whether the appellation of origin might not be an appropriate medium of protection. The report on the meeting was signed by the Governor of the Seri tribe, Pedro Romero, and the Director of the Field Office of the National Institute of Indigenous Affairs in the region.

As a result of this process closer relations evolved with the Secretariat for Commerce and Industrial Promotion. In view of the fact that not just one process and one product were involved, the appellation of origin concept was eventually not adopted, and the trademark route was taken instead. In order to secure protection for the wider range of Seri products (baskets, necklaces, carvings in wood and stone, dolls, etc.), the Cooperative Consumer Society “Artesanos Los Seris” S.C.L. registered the trademark Arte Seri with the Mexican National Institute of Industrial Property in five different classes between 1994 and 1995. Although the trademark is still in force in the various categories, the Seri are not making use of it.

Some thoughts inspired by this case are recorded below.

⁵ The delegation of Mexico has provided the following examples in response to questionnaire WIPO/GRTKF/IC/2/5.

Classification of marks

The Arte Seri trademark was registered in five different classes

<i>TABLE. TRADEMARK CLASSES AND ARTESERI</i>	
<i>Classes and product covered</i>	<i>Article 59. Regulations under the Industrial Property Law</i>
14. Necklaces	Jewellery, precious stones
19. Sculpted rock	Building materials (non-metal)
20. Iron wood and elephant wood carvings	Furniture, mirrors, picture frames; goods (not included in other classes) of various natural materials
21. Clay carvings	Earthenware not included in other classes
28. Rag dolls	Games and playthings

Given the range of craft products, their uses and the materials of which they were made, it was necessary to register them in five different classes, and that in turn generated an administrative cost from a procedural standing as well as to their right owners. This example shows that a careful study should be made of the wisdom of creating a special class for goods produced by groups organized according to ethnic identity where the goods in question fall into very different classes of the present classification.

Ownership of the registration

The legislation in force did not and still does not recognize indigenous peoples as subjects of law, so a legal notion recognizable by law had to be created, which in this case was a cooperative, but it was alien to Seri forms of organizational structure. In the present situation, those Seri who do not form part of the cooperative are not entitled to make use of the trademark, owing to the fact that, in practice, a form of organization has been imposed that is alien to their practices and customs.

At present the rights of indigenous peoples and communities are the subject of intense debate in Mexico. This example shows clearly that there are areas of law in which recognition of these communities as subjects of law would enable them to join together as peoples and, for instance, exercise their right to have trademarks registered or apply to have appellations of origin legally protected. In that connection it could be mentioned that Mexico is party to Convention 169 of the International Labour Organization, and that the Convention has been ratified almost exclusively by Latin American countries. This has implications for the development of a *suigeneri* system in our countries.

Limitations of the Arte Seri trademark

Registration of the trademark in five classes in any event was insufficient, given the diversity of the traditional knowledge and practices of the Seri, if their goods were to be exploited in the market. For instance, the elephant wood basketwork of the Seri, while covered by the trademark, is a product that has all the features of an appellation of origin (namely the indissoluble link with their environment and culture), with about five local plants being used and an abundance of culturally specific skills applied (picking, *tatemado*, spinning, dyeing and weaving).

Innovation, tradition and environment

On the subject of the iron wood artefacts, Felger and Moser (1991) say that it was a craft industry that developed at the beginning of the 1960s and was neither traditional nor imported; it came in the wake of a drastic acclimatization exercise. In other words, this particular craft is a Seri innovation, a fact recognized even by Jose As torgawho pioneered it. As already mentioned, the trademark owes its origin to the concern generated by the mass production of machine-made imitations competing with those made by hand, which involved carving one of the hardest woods of the planet (*Olneya tesota*). These semi-industrial production has had a serious effect on the population of this species of tree, of which there are progressively fewer centenarian examples. Indeed it has already been written among the Seri that they will discontinue this craft because it destroys "such a hard and ancient tree, some live to be 700 years old, are felled in an instant, and we don't make sculptures for that reason," as Humberto Romero of the Kunkaak people puts it.

It is also important to mention that production based on natural raw materials (biological resources) is not necessarily sustainable just because it is the work of the Seri. That means that, without there being any intellectual property aspects, it is necessary to forge links between intellectual property and the rights and obligations associated with the conservation and development of biodiversity. Such matters have a direct connection with the Convention on Biological Diversity, especially its Article 8(j).

Case 2: OLINALÁ (appellation of origin)

The appellation of origin OLINALÁ relates to wooden articles made in the municipality of Olinalá in the state of Guerrero. This tradition has to do with Mexican lacquers which use natural raw materials, and the product is clearly an example of the connection between the environment and culture, which makes it eligible for the appellation.

The applicant for recognition of the denomination was the Unión de Artesanos Olinca, A.C., although in fact the declaration was made by, and the appellation belongs to, the State as a whole, which rules out the possibility of the arbitrary exclusion of other interested parties, as might happen in the case of the Arte Seri trademark. That fact indicates the importance of appellations of origin as elements of the national heritage which should be protected by the State. The articles in question are chests and crates made of wood from the Alo tree (*Bursera aeloxylon*), a tree endemic to the Upper Balsas region. The lacquering process involves additional raw materials such as fats of insect origin and mineral powders. The manufacture of Olinalá craft products is a local tradition that makes use of wood from a shrub that is a biological resource specific to the region.

Case 3: TEQUILA (appellation of origin)

Tequila is a spirit produced in various regions of Mexico by distillation of the fermented must derived from the heart of a plant known as the “blue agave,” the “*Azul*” variety of the *Agave tequilana* Weber. The name Tequila comes from the eponymous region in Jalisco, but the traditional production takes place in a number of municipalities in the states of Jalisco, Nayarit, Tamaulipas, Guanajuato and Michoacán.

The making of tequila involves knowledge that is traditional in the region and dates back to the middle of the sixteenth century, and it evolved into a full-scale industry at the end of the nineteenth. Tequila is considered the Mexican alcoholic beverage *par excellence*.

REPUBLIC OF MOLDOVA

Moldova provides for protection of elements of traditional knowledge, particularly by means of collective trademarks or geographical indications and in some cases by means of patents.

NEW ZEALAND⁶

Trademarks

There are currently no specific provisions contained in New Zealand’s intellectual property laws specifically directed to the protection of traditional knowledge. Aspects of traditional knowledge are, however, protected to an extent by intellectual property laws generally. For example, traditional literary or artistic works may qualify for protection as copyright works under the Copyright Act 1994. Certain works might also be registrable as registered designs under the Designs Act 1953.

A new Trade Marks Bill, currently being considered by Parliament, will if enacted allow the Commissioner of Trade Marks to refuse to register a trademark where its use or registration would be likely to offend a significant section of the community, including Maori.⁷ This provision would provide additional protection to some expressions of traditional knowledge by preventing the inappropriate registration of marks based on Maori text or imagery.

The Trade Marks Bill also provides that persons who are culturally aggrieved have standing to seek a declaration that a registered trademark is invalid because it is likely to offend a significant section of the community, including Maori.

⁶ The delegation of New Zealand has provided the following examples in response to questionnaire WIPO/GRTKF/IC/2/5.

⁷ This response makes reference to the term “Maori.” For the purpose of this document “Maori” is used to refer to the indigenous people of New Zealand.

To assist the Commissioner's consideration of whether a mark might be considered offensive to Maori, the Bill provides for the establishment of an advisory committee. The role of the advisory committee would be to advise whether the use or registration of a mark derivative of Maori text or imagery would be or is likely to be offensive to Maori.

While the above amendments have yet to be brought into effect (dependent on the Parliamentary process), the Intellectual Property Office has existing processes for the examination of trademarks containing Maori text and imagery. Where it has been determined that a trademark is of significance to a particular iwi (tribe), hapu (sub-tribe) or other Maori group, it is usually considered appropriate to require an applicant to seek consent from the relevant Maori authority (section 19 of the Trade Marks Act requires consent to registration in certain cases).

For example, where a trademark consists of or includes Maori words that are a iwi or hapu name, the name of a site of significance to a particular Maori group, or part of a traditional Maori proverbial saying, applicants will be advised that registration of the trademark "would appear" to be deceptive under Section 16 of the Trade Marks Act,⁸ as consumers may assume there is a connection between the applicant and its goods or services and the iwi or hapu concerned. Applicants are further advised in such cases that objection to registration may be overcome if consent of the relevant Maori authority is obtained. Any consent given is included as a condition of registration. Similar objections may be raised concerning devices with particular cultural or spiritual significance to Maori.

Also in the trademark area, the Government, through the Maori Arts Board of the Arts Council of New Zealand ("Creative New Zealand"), has funded the development of the "Maori Made Mark." The Maori Made Mark is a mark of authenticity and quality, which will indicate to consumers that the creator of works is of Maori descent and produces work of a particular quality. Creative New Zealand is the current owner of the trademark. It is anticipated that once the mark is well established it will be transferred to an autonomous Maori entity.

The Maori Made Mark was developed in response to concerns raised by Maori regarding the protection of cultural and intellectual property rights, the misuse and abuse of Maori concepts, styles and imagery and the lack of commercial benefits accruing back to Maori. The Mark is considered by many as an interim means of providing limited protection to Maori cultural property, by decreasing the market for copy-cat works produced by non-Maori.

Patents

New Zealand is also considering how aspects of the Patents Act 1953 might (where appropriate) be modified to address Maori concerns and interests. A comprehensive review of the Act is taking place, which will include consideration of exceptions to patentability. Public consultation will be undertaken this year which will, among other things, seek to

⁸ Section 16(1) of the Trade Marks Act 1953 provides that "It shall not be lawful to register as a trademark or part of a trademark any scandalous matter or any matter the use of which would be likely to deceive or cause confusion or would be contrary to law or morality or would otherwise be disentitled to protection in a Court of Justice."

ascertain views on the issues of interest to Maori, such as how patent examiners might be made aware of traditional knowledge which constitutes prior art.

Also in the patents area, the Government has agreed in principle to one of the recommendations of the Royal Commission on Genetic Modification⁹ that a "Maori Consultative Committee" be established.¹⁰ The precise role and functions of the Committee are, however, yet to be determined and are expected to be the subject of consultation as part of the review of the Patents Act more generally. Also in response to a recommendation of the Royal Commission on Genetic Modification, the Government has agreed that the Patents Act be amended by adding a specific exclusion to the patentability of human beings and the biological processes for its generation. This can in part be seen as a response to concerns raised by Maori about the patentability of human beings.

As with trademarks, the Intellectual Property Office has developed guidelines for patent examiners concerning patent applications of significance to Maori. The guidelines target inventions relating to, using or derived from indigenous flora and fauna, Maori individuals or groups, indigenous micro-organisms (including viruses, bacteria, fungi, algae where any line of research resulted from many traditional or local knowledge), and indigenous material derived from an inorganic source where research resulted from many traditional or local knowledge.

If an application falls into one of the above criteria an examiner is required to assess whether it is appropriate to raise an objection to registration under section 17 of the Patents Act (which allows the Commissioner of Patents to refuse an application where the use of the invention in question would be contrary to morality). In making this assessment, examiners are directed to consider the extent to which the application may have special cultural or spiritual significance for Maori, and whether or not the application is likely to be considered culturally offensive. Where an application may reasonably be considered to fall under section 17, applicants are to be advised accordingly and given the opportunity to obtain the consent of the competent Maori authority.

⁹ The Royal Commission on Genetic Modification was established to look into and report on the issues surrounding genetic modification in New Zealand. The Commission's warrant tasked that, among other things, it investigate and hear views on the intellectual property issues involved, now and in the future, in relation to the use in New Zealand of genetic modification, genetically modified organisms and products.

¹⁰ The Royal Commission on Genetic Modification recommended that the "Maori Consultative Committee" develop procedures for assessing patent applications, and facilitate consultation with the Maori community where appropriate.

Plant Varieties

A review of the Plant Variety Rights Act 1987 is currently being considered. The purpose of the review is to determine whether the 1987 Act provides adequate protection for new plant varieties. The Government's obligations under the Treaty of Waitangi, and Maori concerns regarding the exploitation of indigenous flora will be taken into account.

Measures such as those contained in the Trade Marks Bill are not able or intended to address the concerns of Maori about the use and protection of their "cultural and intellectual property." They do, however, seek to provide some practical measures that will contribute to this objective.

We are not aware of case law or practical examples in the industrial property or copyright areas which demonstrate the ability of the existing New Zealand intellectual property regime to protect traditional knowledge. While a search of the Intellectual Property Office's database reveals a number of patents (either granted or under examination) involving traditional uses of indigenous flora and fauna, these records do not contain information relating to the ethnicity of the applicant. Similarly, with trademarks, while all applications involving Maori text and imagery are flagged as type "Maori" there is no record of the ethnicity of the applicant.¹¹

PORTUGAL

The Industrial Property Code (CPI), approved by Decree-Law no. 16/95 of January 24, 1995 plays an important role in the absence of any specific legislation about traditional knowledge, for it protects various forms of intellectual property in general, such as trade, collective, and certification marks, appellations of origin and geographical indications.

It should therefore be pointed out, in the case of trademarks, that is forbidden to register signs that consist exclusively of the shape resulting from the nature of the product itself, the shape of the product necessary for obtaining a technical result or the shape that gives the product its own substantial value, as well as of signs or indications that may be used commercially to designate the kind, quality, quantity, purpose, value, geographical origin, the time of production of the product or of rendering of the service (CPI article 166). Consequently there is a form of indirect protection of the subject matter which for the most part seeks to avoid or prevent the registration of marks, or other distinctive signs, that relate to the designation of the traditional knowledge concerned.

A more visible form of protection of the traditional knowledge may be found in collective marks, signs or indications used commercially to designate the geographical origin of products or services (CPI article 172(2)), association marks, specific signs belonging to an association of natural or legal entities whose members usually have the intention of using the sign for products or services (CPI article 173), and certification marks, specific signs

¹¹ The Intellectual Property Office of New Zealand receives on average, about 2200 trademark applications per month. Of these, on average, around 12 contain Maori text and imagery. There are approximately 900 registered trademarks and 170 pending applications which contain Maori text and imagery.

belonging to a corporate body that controls the products or services or establishes the regulations that they must comply with; such sign is to be used in respect of products or services which are subject to the aforementioned control for which the regulations were established (CPI article 174).

In Portugal, for example, Arraiolos carpets, North Alentejo handicraft, striped cheese and Minho fiancées' handkerchiefs are registered as association marks as well as shoes from Portugal, Caldas da Rainha embroidery, Açores pine apple, cheese of Évora, Açores handicraft.

However, traditional knowledge has an even more direct form of protection under appellations of origin - the name of a region, a specific locality or in exceptional cases a country used to designate or identify the following types of products: (a) products originating from the region, specific locality or country in question; (b) products the quality or characteristics of which are essentially or exclusively due to the geographical environment, including natural and human factors, and the production, transformation and creation of which are carried out in the demarcated geographical area. Appellations of origin may also include certain traditional designations, whether geographical or not, indicating a product which comes from a region or specific locality (CPI article 249). A geographical indication is the name of a region, a specific locality or in exceptional cases a country used to designate or identify the following types of products: (a) products originating from the region, specific locality or country in question; (b) products the reputation, specific quality or other characteristics of which may be attributed to such geographical region and/or the production, transformation and creation of which are carried out in the demarcated geographical area (CPI article 249).

Portugal has a variety of rights of this kind protected such as wines of Porto, Madeira, Redondo, Dão; the cheeses of Serpa, Azeitão, S. Jorge, Serrada Estrela, Nisa; Madeira embroidery; honey of Alentejo, Açores.

Those rights, when registered, shall constitute the common property of the residents and may be used indiscriminately by any person who, in the respective area, works in any field of characteristic production.

RUSSIAN FEDERATION

We propose the following examples of the protection of traditional knowledge under the existing system of intellectual property protection.

Patents granted to national industrial enterprises:

- "Majolica paste": Patent no. 2153479. Applicant: "Gzhel" Association.
- "Porcelain glaze": Patent no. 2148570. Applicant: "Gzhel" Association.
- "Method for artistic-decorative articles made of wood (variants)": Patent no. 2156783. Applicant: "Khokhloma Painting" Association.

Patents granted for medicines:

- “Medicinal, cosmetic cream” (based on medicinal plants):
Patent no. 2049459. Applicant: M.M. Gafarov et al.
- “Immunomodulation means” (using grapevines, whey, etc.): Patent no. 2034542.
- “Diabetic mix” (based on medicinal plants):
Patent no. 2137491. Applicant: A.I. Sukhanov. ¹²

Examples of protection of works of national creation by means of patent law for industrial designs:

Many art products are made and considered to be industrial designs protected by the patent law of the Russian Federation.

Applications are filed by the closed stock company “Gzhel” from the Moscow region. Gzhel is an ancient mining region known as a major mining area from the 18th century onwards. Patents for industrial designs are granted for mining items such as the “Plate.” Patent No. 48143; “Kvasnik” (a container for kvass), Patent No. 48142; and a “Tea Service,” Patent No. 48144.

Decorative articles made of wood with Khokhloma painting are protected, including golden painted wooden plates and dishes, toys, matrioshka dolls and domestic utensils. In the 1970s, industrial design certificates were issued for the following painted articles: an “assemblable matrioshka” toy, Certificate No. 11052; a “matrioshka” musical toy, Certificate No. 11170; a “Khorovod” toy, Certificate No. 11358; and a “needle case,” Certificate No. 11528.

Protection of items of national creation using geographical appellations.

According to Article 35(1) of Law No. 3520-1 of the Russian Federation on “Trade Marks and Service Marks for Appellations of Origin” (September 23, 1992), a State Register of the Russian Federation on appellations of origin must be kept. The entry of an appellation of origin in the Register serves as a basis for granting to the applicant a certificate for the right to use this item, which is issued for ten years and may be extended for additional 10-year periods.

¹² In response to questionnaire WIPO/GRTKF/IC/2/5, the delegation of the Russian Federation has mentioned the following additional examples of patents granted for inventions based on TK:
RU2102078C1 “Means for invigorating the human organism;”
RU2102078C1 “Means for acting on acupuncture points for correcting the functional, psychological and emotional condition of an individual;”
RU2033798C1 “Means for apitherapy and apiculture preventive treatment.”

A number of ancient industries are registered, the articles for which are connected with designations claiming to protect as appellations of origin: Velikiy -Ustyugniello, Gorodets painting, Rostovenamel, Kargopolclaytoy, and a Filimonovtoy.

To date, Rospatent has received more than 150 applications.

SAMOA¹³

Samoa's Copyright Act 1998, the Patent Act 1972 and the Trademarks Act 1972 are the intellectual property laws currently enforced in Samoa. They do not have provisions to protect the traditional knowledge. The Copyright Act 1992 however, contains certain provisions on protection of moral rights and performers rights. These could be used to protect traditional knowledges such as cultural activities on dances, tattooing etc. being fixated on videotapes only to the extent that there is an infringement on the right of the registered author. The traditional knowledge holders may only claim royalties if they happen to be the performers of the traditional knowledge that was demonstrated and fixated on videotape. They may claim on the right of performers protected under the Copyright Act 1998, but this is a course of action that is rarely pursued.

The Village Fono Act 1990 provides for an institutional structure within the Village communities called "Village Fono" (Village Council), which is a traditional authority of government comprised of traditional chiefs ("matai"). They formulate customary village laws and enforce punishments according to village customs and usage. They also make rules, which govern the development and use of village land (including the rivers, springs and trees thereon) for the economic betterment of the village. The Village Fono Act 1990 indirectly yet effectively protects Samoa's traditional form of governance, customary laws and traditional forms of punishments. The Act primarily gives legal recognition to the Village Fono as the lawmaking body for the village in incidental matters. It enacts laws and penalties/punishments in accordance with the village custom and usage. The implementation of this Act by the Village Fono not only preserves the traditional form of government in Samoa (Village Fono), it also preserves traditional knowledge in customary laws and traditional punishments, thus protecting them from eroding.

VENEZUELA¹⁴

There are, in Venezuela real-life instances in which use has been made of modern industrial property provisions to protect traditional knowledge. One example is the institution of appellations of origin, which is extensively provided for in our legal order, and which indeed has served to protect a large amount of subject matter that can be assimilated to what traditional knowledge is generally understood to be.

¹³ The delegation of Samoa has provided the following examples in response to questionnaire WIPO/GRTKF/IC/2/5.

¹⁴ The delegation of Venezuela has provided the following examples in response to questionnaire WIPO/GRTKF/IC/2/5.

Example that can be quoted are highly relevant inasmuch as it is not only geographical conditions that have influenced the recognition of the appellations of origin granted to date, but rather human intervention, detected in the conduct of activities that themselves have had a potential effect on exploitation. One such example is Cocuy de Pe caya (aliquete extracted from the agave): not only does the area in which this type of plant is grown benefit from special conditions, but there is a manner in which the communities located there traditionally extract the product, using processes that have remained unchanged for centuries.

VIETNAM

Patent No. VN1017: Traditional preparation of medicinal plants used for assistance in stopping drug addiction was patented as it met all requirements for a patent to be protected of novelty, involving an inventive step and industrial applicability.

Trademark No. 30848: Traditional balm of medicinal plants registered as Truong Son Balsam was granted with trademark certificate as it was distinctive from others.

Appellation of Origin No. 1: Phu Quoc fish sauce has been protected as it is geographical name of an island where the fish sauce is produced and has peculiar characteristics or qualities attributed to geographical factors of the island.

[Annex II follows]

ANNEX II

DESCRIPTION OF *SUI GENERIS* SYSTEMS FOR THE PROTECTION OF TK

This Annex provides the responses given to question (f) of questionnaire WIPO/GRTKF/IC/Q.1 and similar responses to the earlier questionnaire (document WIPO/GRTKF/IC/2/5), concerning enacted or planned *sui generis* laws for the protection of TK. Question (f) was as follows:

If your answer to question (e) is yes, could you please describe how your law or regulation or administrative ruling of general application establishing a system of traditional knowledge protection is special ly adapted to its characteristics (a sui generis system)

- (i) *defines and/or identifies the policy objective of the protection;*
- (ii) *identifies its subject matter (scope of protection);*
- (iii) *identifies the criteria that the subject matter must meet as a condition for its protection;*
- (iv) *identifies the owner of the rights;*
- (v) *defines the rights conferred, including exceptions;*
- (vi) *establishes the procedures and formalities, if any, for the acquisition and maintenance of the rights conferred;*
- (vii) *sets forth the enforcement procedures so as to permit effective action against infringement of rights in traditional knowledge;*
- (viii) *defines how the rights are lost and how they expire (including invalidation or revocation of any registration);*
- (ix) *sets forth the interaction between the sui generis system and the existing standards of intellectual property, especially the extent to which they overlap or complement each other.*

Responses are provided from the following Member States:

Brazil
Panama
Peru
Portugal
Kenya
Philippines

BRAZIL¹⁵

Please indicate if there is a specific (suigeneris) law providing for intellectual property protection of traditional knowledge and, if so, the name and/or number of the law or regulation.

There is a specific law – Provisional Measure No. 2186 -16 of August 23, 2001, which regulates the protection of and access to traditional knowledge.

When did it come into force, or, in the case of a draft, at what stage is it in the process of legislative adoption?

Provisional Measure No. 2052 came into force following its publication in our Official Government Journal (*Diário Oficial da União*), dated June 29, 2000, and has been reprinted on several occasions, currently under No. 2.186, its sixteenth reprinting, dated August 23, 2001.

A copy of the law may be obtained at the following internet address:
<<http://www.planalto.gov.br/ccivil/mpv/2186-16.htm>>

There is also Decree No. 3945 which is on a directly related subject, i.e. the establishment of the Genetic Heritage Management Council. This can be found at the following internet address: < http://www.planalto.gov.br/ccivil_03/decreto/2001/d3945.htm>

Both texts are in Portuguese.

What are the stated purposes or objectives of the law or regulation?

The stated objectives are to legislate on access to the genetic heritage existing in the national territory, the continental platform and the exclusive economic area for scientific research, technological development or bioexploration purposes; access to traditional knowledge relating to the genetic heritage, relevant to the preservation of biological diversity, the integrity of the country's genetic heritage and the use of its components; the fair and equitable distribution of the benefits derived from the exploration of the genetic heritage and related traditional knowledge; access to technology and the transfer of technology for the preservation and use of biological diversity

What terms are used to determine the subject matter for which protection under the law or regulation may be obtained?

The terms are as follows: access to the genetic heritage, protection for and access to related traditional knowledge, benefit sharing and access to technology, and technology transfer.

¹⁵ The following information was provided by the delegation of Brazil in response to questionnaire WIPO/GRTKF/IC/2/5.

How is the subject matter defined or described in the law or regulation?

Article 7, the Chapter on Definitions, of Provisional Measure No. 2186 -16, contains a number of paragraphs that can be applied to traditional knowledge, including:

“(…)
II – Related traditional knowledge: information or individual or collective practice of the indigenous or local community, with real or potential value, relating to the genetic heritage;

III – Local community: human group, including the remnants of the *quilombos* communities, distinct in terms of its cultural conditions, and which is organized traditionally through successive generations and its own customs, and preserves its social and economic institutions;

V – Access to related traditional knowledge: obtaining information on individual or collective knowledge or practice, relating to the genetic heritage, from the indigenous or local community, for the purposes of scientific or technological research or bioexploration, with a view to its industrial or other application;

VI – Access to technology and technology transfer with a view to access, development and transfer of technology in order to preserve and use the biological diversity or technology developed from the sample of the related genetic heritage or traditional knowledge;

VII – Bioexploration: exploratory activity which aims to identify the genetic heritage and information on related traditional knowledge, with potential for commercial use; (...).

X – Authorization for Access and Shipping: a document which, subject to specific conditions, allows access to the genetic heritage sample and its shipping to the receiving institution, as well as access to related traditional knowledge;

XI – Special Authorization for Access and Shipping: a document which, subject to specific conditions, allows access to the genetic heritage sample and its shipping to the receiving institution, as well as access to related traditional knowledge, for a period of up to two years, renewable for equal amounts of time;

XII – Equipment Transfer Contract: accession instrument to be signed by the receiving institution prior to the shipping of any genetic heritage sample, indicating, where necessary, that access to related traditional knowledge was obtained;

XIII – Contract for Use of the Genetic Heritage and Benefit Sharing: multilateral legal instrument which describes the parties, purpose and conditions of access and shipping of the genetic heritage and related traditional knowledge, as well as the conditions for benefit sharing; (...).”

What criteria are used to determine whether subject matter qualifies for protection under the law or regulation?

As regards the protection of traditional knowledge by means of patents, it is important to observe the patentability requirements of novelty, inventive step and industrial applicability.

Is there any subject matter expressly excluded from protection?

Yes, there is. Article 3 of this Provisional Measure does not apply to the human genetic heritage.

What rights are granted by the law or regulation in respect of the protected subject matter (which acts in respect of the subject matter are subject to authorization or remuneration, as the case may be (see following question))?

The law – Provisional Measure No. 2186 – 16 – contains two articles on this subject: Article 8 provides protection, through the Provisional Measure, for the traditional knowledge of indigenous and local communities, relating to the genetic heritage, against the use and unlawful exploration, and other acts that are prejudicial or unauthorized by the Management Council referred to in Article 10, or by an approved institution (...). Article 9 provides that

“The indigenous and local communities which generate, develop, hold or preserve the traditional knowledge relating to the genetic heritage are guaranteed the right to:

I – have the origin of the access to traditional knowledge stated in all publications, uses, explorations and disclosures;

II – prevent unauthorized third parties from:

(a) using, or carrying out tests, research or exploration relating to the relevant traditional knowledge;

(b) disclose, transmit or retransmit data or information contained in or constituting relevant traditional knowledge;

III – obtain benefits through economic exploration by third parties, either directly or indirectly, of the relevant traditional knowledge, whose rights are under their ownership, in terms of the Provisional Measure.”

There is also Chapter VII of the same Law – on benefit sharing – which deals with remuneration. In general, this must be fair and equitable, and may constitute a share of the profits; the payment of royalties; access to and transfer of technologies; licensing, free of charges, products and processes; and human resource training.

Chapters VI and VII should be highlighted, along with Article 31.

Are the rights granted exclusively rights or right to remuneration?

There are exclusive rights since the intellectual property subject matter is owned by the community. As for the right to remuneration, this is defined in Article 9, paragraph III of the Law (see also the above response).

Isthe protection granted by the law or regulation automatic upon the fulfillment of the criteria referred to above?

Yes.

Does the law or regulation make provision for the revocation or forfeiture of rights obtained? If yes, in what circumstances and at whose instance?

Yes, through Article 31 which establishes the interconnection between Provisional Measure 2.186 and the patents system, for which the duration of the protection obtained will follow the conditions established by the Industrial Property Law (LPI - 9.279).

Isthe protection afforded by your laws and regulations limited in time?

Yes.

(i) Traditional knowledge *strictusensu* is not a temporary concept. The inclusion of traditional knowledge in an invention protected by the patents system (Article 31 of Provisional Measure 2.186) shall have the periods of protection stipulated in Law 9.279.

(ii) The inclusion of traditional knowledge in an invention protected by the patents system (Article 31 of Provisional Measure 2.186) shall have the periods of protection stipulated in Law 9.279 (protection begins from the filing date, if the patent is granted).

(iii) There is a clear distinction between traditional knowledge *strictusensu*, which is fundamentally non-temporary, and the inventions stemming from its inventive use. What is in the public domain, once the patent has expired, is the invention stemming from the use of the traditional knowledge, not the traditional knowledge *per se*.

Does the law or regulation provide for retroactive protection? If yes, please explain how this provision works in practice, particularly in respect of pre-existing rights in overlapping subject matter previously obtained under intellectual property laws.

No, the law does not provide for retroactive protection.

Who is entitled to acquire the protection provided for?

Local communities such as those defined in law.

Does the law or regulation allow for the acquisition and exercise of the rights by a community or the collective?

Yes.

“Article 31. The granting of the industrial property right by the appropriate authorities for the processor product obtained from the genetic heritage sample is independent on the Provisional Measure being observed, for which reason the

applicant must provide information on the origin of the genetic material and related traditional knowledge, where necessary.

“Article 24. The benefits resulting from the economic development of the product or process created from the genetic heritage sample and the related traditional knowledge, obtained by a national institution or one which has its headquarters abroad, shall be shared in a fair and equitable manner, between the contracting parties, in accordance with the relevant regulations and legislation.”

Thus, the inventions developed from the genetic heritage and which serve as sources of information relating to relevant traditional knowledge shall clearly explain the origin of the genetic resource and the information relating thereto, as well as being based on a principle of equal sharing of benefits obtained through the economic development of such knowledge.

Does the law or regulation allow for the acquisition and exercise of the rights by more than one community?

Yes. There is no explicit limitation in the law on the number of communities which shall have the right over the benefits generated from the protection of a traditional knowledge item.

What exceptions, if any, are there in respect of the rights granted (such as customary use, use for scientific and academic purposes, prior use)?

“Article 43 - The provision contained in the previous article does not apply to:

- I – acts carried out by unauthorized third parties, for private purposes and with no commercial aim, without harming the economic interest of the patent owner;
- II – acts carried out by unauthorized third parties as experiments, relating to studies or scientific or technological research;
- III – the preparation of medicines based on a medical prescription for individual cases, drawn up by a skilled professional, as well as for the medicine thus prepared;
- IV - a product manufactured according to a process or product patent which has been placed on the domestic market directly by the patent owner or with his consent;
- V - third parties which, in the case of patents relating to living organisms, use, for non-economic purposes, the patented product as an initial source of variation or propagation in order to obtain other products; and
- VI - third parties which, in the case of patents relating to living organisms, use, circulate or market a patented product which has been lawfully traded by the patent owner or by a licensee holder, since the patented product has not been used for commercial propagation of the living organism in question.”

What are the legal consequences of breaches of the rights granted by the law or regulation?

Legal consequences: caution; fine; seizure of the genetic heritage samples and of the instruments used in the collection or processing of the products obtained from the information relating to the relevant traditional knowledge; seizure of the products derived from the sample of the genetic heritage or related traditional knowledge; suspension of the sale of the product derived from the sample of the genetic heritage or related traditional knowledge and its seizure; embargo on the activity; partial or total prohibition of the establishment, activity

or undertaking; suspension of the registration, patent, license or authorization; cancellation of the registration, patent, license or authorization; loss or restriction of the share in the funding line in an official credit institution; operation in the institution; prohibition on contracts with the Public Administration for a period of up to five years .

What civil, criminal or other sanctions and remedies are available in cases of breach?

The law provides for administrative sanctions, without prejudice to possible civil or criminal sanctions.

Do right holders have the right, under the law or regulation, to assign their rights and to conclude licensing contracts? Does the law or regulation provide for the grant of compulsory licenses? If yes, on what terms and in what circumstances?

Yes, owners may assign their rights and conclude licensing contracts. There are no provisions on compulsory licenses.

Does the law or regulation establish any institutional agencies, mechanisms or structures to manage or administer rights granted under the law or regulation? (such as the office of a registrar, ombudsman or “competent authority”)

Yes, the law provides for the creation of the Genetic Heritage Management Council (Provisional Measure 2186 -16, Article 10, regulated by Decree No. 3945). Article 10 reads:

“Within the Ministry of the Environment, the Genetic Heritage Management Council is hereby established, for discussion and standard -setting purposes – comprising the representatives of the bodies and entities of the Federal Public Administration, the jurisdiction of which covers the various activities dealt with by this Provisional Measure.”

Are there special provisions referring to or regulating the relationship between the forms of protection offered by the sui generis law or regulations and the protection provided for by existing intellectual property laws and regulations?

Yes. Those provisions are contained in Articles 8(4) and 31 of the Law, as follows:

“Article 8(4) – The protection introduced shall not affect, prejudice or limit the rights relating to intellectual property.”

“Article 31 – The grant of an industrial property right by the competent bodies, for a process or product obtained from the genetic heritage samples shall be determined according to whether this Provisional Measure is observed, and the applicant shall provide information on the origin of the genetic material and related traditional knowledge, where appropriate.”

PANAMA¹⁶

Please indicate if there is a specific (suigeneris) law providing for intellectual property protection of traditional knowledge and, if so, the name and/or number of the law or regulation.

Law No. 20 of June 26, 2000, regulated by Executive Decree No. 12 of March 20, 2001, entitled "Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples, for the Protection and Defense of their Cultural Identity and their Traditional Knowledge, and Other Provisions."

When did it come into force, or, in the case of a draft, at what stage is it in the process of legislative adoption?

It came into force on June 27, 2000, on being promulgated in Official Gazette No. 24,083.

What are the stated purposes or objectives of the law or regulation?

Protection and defense of the collective intellectual property rights and the traditional knowledge of indigenous peoples in relation to their creations, such as inventions, models, drawings and designs, innovations contained in images, figures, symbols, graphics, petroglyphs and other material, in addition to the cultural elements of their history, music, art and traditional artistic expressions that are suitable for commercial use, afforded by means of a special system of registration, promotion and commercialization of their rights, with a view to enhancing the socio-cultural values of indigenous culture and doing social justice to those peoples.

The cultural heritage of indigenous peoples may not be the subject of any form of exclusive rights in favor of third parties not authorized under the intellectual property system, such as copyright, industrial design and trademark rights, and the rights in geographical indications and other subject matter, except where the application is made by the indigenous people themselves.

What term is used to determine the subject matter for which protection under the law or regulation may be obtained?

Collective rights of indigenous peoples in their creations, traditional knowledge, cultural heritage, innovations and practices.

How is the subject matter defined or described in the law or regulation?

Collective indigenous rights: indigenous cultural and intellectual property rights that relate to art, music, literature, biological, medical and ecological knowledge and other subject matter and manifestations that have no known author or owner or date of origin, being the heritage of an entire indigenous people.

¹⁶ The following information was provided by the delegation of Panama in response to questionnaire WIPO/GRTKF/IC/2/5.

Comment: Work is currently proceeding on a draft law for the protection of the collective rights of local communities, which broadens the definition as follows: they are the intellectual property rights of indigenous peoples and local communities the subject matter of which is art, music, literature, biological, medical and ecological knowledge, rituals, games, cultural expressions, traditional science and technology, gastronomy, cultural traditions, beliefs and other aspects of the cultural heritage that are not dissociable from the cultural identity of a whole community.

What criteria are used to determine whether subject matter qualifies for protection under the law or regulation?

Indigenous peoples have developed knowledge that has been handed down and perpetuated throughout generations in Panama. That knowledge embodies an intellectual effort and is a contribution to society. It is well known to all that this scientific and biological knowledge, traditional medicine, art, culture, music, agriculture, traditional know-how and other subject matter of the cultural heritage is currently at risk of improper exploitation by persons and/or companies seeking to commercialize it, and that it is precisely that commercial exploitation based on it that is going to deter the creators of such knowledge and manifestations owing to the non-existence of national provisions with which to prevent it.

All this traditional knowledge constitutes the identity of an indigenous people. Panama is a signatory of the Convention on Biological Diversity, and as a Contracting Party is bound to respect, preserve and maintain the knowledge, innovations and practices of indigenous and local peoples that contribute to traditional lifestyles. That was the motivation for the enactment of special legislation to protect the collective rights of those peoples, and thereby to promote the preservation of biological diversity and the sustainable use of biological resources. Finally, all that knowledge is in everyday use by indigenous peoples and local communities. The provisions on collective and certification marks contained in Law 35 of 1996, which require the inclusion with the application for registration of rules for the use of the traditional knowledge or cultural manifestation, will be applied.

Is there any subject matter expressly excluded from protection?

Genetic resources.

What rights are granted by the law or regulation in respect of the protected subject matter (which acts in respect of the subject matter are subject to authorization or remuneration, as the case may be (see following question))?

Collective intellectual property rights of indigenous peoples.

Are the rights granted exclusive rights or rights to remuneration?

Exclusive rights, with the proviso that they may be the subject of exclusive third-party rights where therequest is filed by the indigenous peoples themselves.

Is the protection granted by the law or regulation automatic upon the fulfillment of the criteria referred to above?

Yes.

Does the law or regulation make provision for the revocation or forfeiture of rights obtained? If yes, in what circumstances and at whose instance?

Where the rights have been granted on the basis of false or inaccurate information.

Is the protection afforded by your laws and regulations limited in time?

No.

How is the starting point of protection determined?

As soon as registration of the collective rights has been granted by the Registry.

Does the law or regulation provide for retroactive protection? If yes, please explain how this provision works in practice, particularly in respect of pre-existing rights in overlapping subject matter previously obtained under intellectual property laws.

The Law provides that rights accorded previously under the relevant legislation shall be respected and shall not be affected.

Who is entitled to acquire the protection provided for?

The Traditional Indigenous Congress(es) or Authority(Authorities) of the indigenous peoples are entrusted with representing them and complying with the requirements laid down in the Regulations under the Law. The Regulations provide that there can be traditional knowledge of indigenous peoples in the form of creations shared between members of two or more communities, in which case the benefits accrue to both or all of them collectively.

Does the law or regulation allow for the acquisition and exercise of the rights by a community or other collective?

Yes.

Does the law or regulation allow for the acquisition and exercise of the rights by more than one community?

Yes. The Regulations under the Law provide that the collective rights of an indigenous people shall not prevent that people from continuing to exercise the rights within the indigenous community that hold the traditional knowledge, neither shall they affect the right of present and future generations to continue to make use of the collective knowledge and develop it.

What exceptions, if any, are there in respect of the rights granted (such as customary use, use for scientific and academic purposes, prior use)?

Law No. 20 of June 26, 2001, provides that traditional indigenous knowledge (*Naöbe-Bugle*) is excluded from it when acquired by non-indigenous communities by operation of

customary law but in respect of which those communities cannot claim their collective rights recognized by the said Law.

What are the legal consequences of breaches of the rights granted by the law or regulation?

In cases not provided for in either customs legislation or industrial property legislation, infringements of the Law are punished with fines ranging from 1,000 to 5,000 dollars, depending on their seriousness. In the event of a repeat offense, the amount of the fine is doubled. These sanctions provided for in the Law are applied in addition to the seizure and destruction of the materials used to commit the infringement.

What civil, criminal or other sanctions and remedies are available in cases of breach?

Appeals against registrations have to be filed in person with the representatives of the General Congresses or Traditional Indigenous Authorities. There is no evidence of appeals having been filed.

Do rightsholders have the right, under the law or regulation, to assign their rights and to conclude licensing contracts? Does the law or regulation provide for the grant of compulsory licenses? If yes, on what terms and in what circumstances?

Under the Law and its Regulations, the owners of rights do have the right to assign their rights by licensing the use of registered collective rights. There is no provision for the grant of compulsory licenses.

Does the law or regulation establish any institutional agencies, mechanisms or structures to manage or administer rights granted under the law or regulation? (such as the office of a registrar, ombudsman or "competent authority")

Law 20 of 2001 sets up the Department of Collective Rights and Expressions of Folklore within the Industrial Property Registry of the Ministry of Commerce and Industries (MICI), through which the collective rights of indigenous peoples and local communities will be granted.

The foregoing was ratified by Resolution No. 3 of July 31, 2001, of the Ministry of Commerce and Industries, which brought about the creation of the Department.

Are there special provisions referring to or regulating the relationship between the forms of protection offered by the sui generis law or regulations and the protection provided for by existing intellectual property laws and regulations?

Yes. Law No. 20 of 2001 provides that the provisions on collective and certification marks contained in Law No. 35 of 1996 shall be applicable insofar as they do not conflict with the rights provided for in Law No. 20 itself. The application for registrations should (1) include rules of use, which, in addition to the identifying particulars of the applicant authorities, should specify the grounds on which use of the collective rights may be denied to a member of the indigenous people, and (2) include a favorable report by the competent administrative body on the rules of use.

PERU

The objectives [of Law No. 27811 (2002)] are the following:

- (a) To promote respect for and the protection, preservation, wider application and development of the collective knowledge of indigenous peoples;
- (b) To promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge;
- (c) To promote the use of the knowledge for the benefit of the indigenous peoples and mankind in general;
- (d) To ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples;
- (e) To promote the strengthening and development of the potential of the indigenous peoples and of the machinery traditionally used by them to share and distribute collectively generated benefits under the terms of this regime;
- (f) To avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions.

The collective knowledge of indigenous peoples that is associated with genetic resources is eligible for protection.¹⁷

The owners of the rights are the indigenous peoples who have custody of the collective knowledge in question; they exercise those rights through their representative organizations.

¹⁷ “Article 2. -Definitions

For the purposes of this legislation:

- (a) ‘Indigenous peoples’ means aboriginal peoples holding rights that existed prior to the formation of the Peruvian State, maintaining a culture of their own, occupying a specific territorial area and recognizing themselves as such. They include peoples in voluntary isolation or with which contact has not been made, and also rural and native communities. *The term ‘indigenous’ shall encompass, and may be used as a synonym of, ‘aboriginal,’ ‘traditional,’ ‘ethnic,’ ‘ancestral,’ ‘native’ or other such word form.*
- (b) ‘Collective Knowledge’ means the accumulated, transgenerational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity. *The intangible components referred to in Decision 391 of the Commission of the Cartagena Agreement include this type of collective knowledge.*
- (...)
- (e) ‘Biological resources’ means genetic resources, organisms or parts thereof, populations or any other kinds of biotic component of ecosystem that are of real or potential value or use to mankind.”

Some of the provisions of the Law mentioned above that are considered relevant in determining the rights granted by it are reproduced below.

“Article 1. - Recognition of rights.

The Peruvian State recognizes the rights and power of indigenous peoples and communities to dispose of their collective knowledge as they see fit.”

“Article 6. - Conditions of access to collective knowledge.

Those interested in having access to collective knowledge for the purposes of scientific, commercial and industrial applications shall apply for the prior informed consent of the representative organizations of the indigenous peoples possessing collective knowledge. The organization of the indigenous peoples whose prior informed consent has been applied for shall inform the greatest possible number of indigenous peoples possessing the knowledge that it is engaging in negotiations and shall take due account of their interests and concerns, in particular those connected with their spiritual values or religious beliefs. (...)”

“Article 7. - Access for the purposes of commercial or industrial application

In the event of access for the purposes of commercial or industrial application, a license agreement¹⁸ shall be signed in which terms are provided that ensure due reward for the said access and in which the equitable distribution of the benefits deriving therefrom is guaranteed.”

“Article 38. - Access to the resources for the Fund for the Development of Indigenous Peoples and Communities.

Indigenous peoples have the right to draw on the resources of the Fund for the Development of Indigenous Peoples through their representative organizations for the purpose of development projects, subject to prior evaluation and approval by the Administrative Committee.”

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“Article 27. - Contents of the license contract.

For the purposes of this regime, contracts shall contain at least the following clauses:

- (a) Identification of the parties;
- (b) A description of the collective knowledge to which the contract relates;
- (c) A statement of the compensation that the indigenous peoples receive for the use of their collective knowledge; such compensation shall include an initial monetary or other equivalent payment for its sustainable development, and a percentage of not less than five percent of the value, before tax, of the gross sales resulting from the marketing of the goods developed directly and indirectly on the basis of the said collective knowledge, as the case may be;
- (d) The provision of sufficient information on the purposes, risks and implications of the said activity, including any uses of the collective knowledge and its value where applicable;
- (e) The obligation on the licensee to inform the licensor periodically, in general terms, of progress in the research on and industrialization and marketing of the goods developed from the collective knowledge to which the licensee relates;
- (f) The obligation on the licensee to contribute to the improvement of the ability of the indigenous peoples to make use of the collective knowledge relating to its biological resources. Where the contract embodies a safeguard obligation, it shall expressly state that INDECOP shall not register contracts that do not conform to the provisions of this Article.”

“Article 42. - Rights of indigenous peoples possessing collective knowledge
Indigenous peoples possessing collective knowledge shall be protected against the disclosure, acquisition or use of that collective knowledge without their consent and in an improper manner provided that the collective knowledge is not in the public domain. It shall likewise be protected against unauthorized disclosure where a third party has legitimately had access to collective knowledge covered by a safeguard clause.”

“Article 43. - Actions for violation of rights of indigenous peoples
Indigenous peoples possessing collective knowledge may bring infringement actions against persons who violate the right specified in the foregoing Article. An infringement action shall also be permissible where there is an immediate danger of such violation.
(...).”

“Article 45. - Actions claiming ownership and indemnification.
The representative organizations of indigenous peoples possessing collective knowledge may bring the actions claiming ownership and indemnification that are available to them under the laws in force against a third party who, in a manner contrary to the provisions of this regime, has directly or indirectly made use of the said collective knowledge.”

Collective knowledge that is in the public domain is exempted in some of the provisions of the above Law. The regime applicable to such knowledge is covered by Article 13, which reads as follows:

“Article 13. - Collective knowledge in the public domain.
For the purposes of this regime, it shall be understood that collective knowledge is in the public domain when it has been made accessible to persons other than the indigenous peoples by mass communication on media such as publication or, when the properties, uses or characteristics of a biological resource are concerned, where it has become extensively known outside the confines of the indigenous peoples and communities.”

“In cases where the collective knowledge has passed into the public domain within the previous 20 years, a percentage of the value, before tax, of the gross sales resulting from the marketing of the goods developed on the basis of that knowledge shall be set aside for the Fund for the Development of Indigenous Peoples provided for in Articles 37 *et seq.*”

There are no established formalities to be met for the acquisition and maintenance of rights.

It should nonetheless be mentioned that formalities and procedures do have to be observed for the (optional) registration of the collective knowledge and for the (mandatory) registration of license contracts.

Article 43 of the above Law provides that indigenous peoples possessing collective knowledge may bring infringement actions against persons who violate the rights specified in

the Article that precedes it. ¹⁹ Article 43 states moreover that an infringement action is also permissible where there is an immediate danger of violation, and that infringement actions may be brought *ex officio* by or der of INDECOPI.

The Law lays down the procedures and formalities to be observed in connection with infringement actions. It should be added that it is possible to have precautionary measures ordered to ensure compliance with the final ruling, including cessation of the acts proceeded against and confiscation, depositor immobilization of goods produced with the aid of the collective knowledge to which the action relates.

The rights of indigenous peoples in their collective knowledge neither expire nor lapse.

The registration of collective knowledge or of a license to use it may be cancelled. It should be borne in mind however that the registration of collective knowledge is not constitutive of rights.

This protection regime is independent of classical industrial property protection regimes.

The Second Complementary Provision ²⁰ does however establish a link between this protection regime and the one for patents.

PORTUGAL

Decree-law no. 118/2002 of April 20, establishes the legal regime of registration, conservation, safeguarding and transfer of autochthonous vegetable material with actual or potential interest for the agrarian, agriculture - forest activities and landscape, including local varieties and spontaneous material, as well as the knowledge to them associated.

Traditional knowledge is all the intangible elements associated to the commercial or industrial use of local varieties and other endogenous material developed by the local populations, collectively or individually, in a non-systematic manner and that are inserted in the cultural and spiritual traditions of those populations, including, but not limiting to, knowledge relating to methods, processes, products and denominations that are applicable in agriculture, food and industrial activities in general, including handicrafts, trade and services, informality associated to the use and preservation of local varieties and other endogenous and spontaneous material that is covered by the present statute.

¹⁹ See Article 42 in the reply to Question (f)(v).

²⁰ "SECOND.- Submission of the license contract as a requirement for obtaining a patent Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicants shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned."

Such knowledge shall be protected against its reproduction and/or commercial or industrial use, provided the following conditions of protection are met:

- (a) traditional knowledge shall be identified, described and registered in the Registry of Plant Genetic Resources (RPGR);
- (b) the description referred to in the previous subparagraph shall be made in a manner that allows for other persons to reproduce or use the traditional knowledge and to obtain results that are identical to those obtained by the knowledge holder.

Traditional knowledge holders may opt for keeping it in confidentiality, in which event the regulation will set forth the modality of its publication in the gazette of registration, which shall be limited to give notice of the existence of the knowledge and to identify the variety which it is associated, the protection conferred by the certificate being limited to the event it has been acquired by third parties in an unfair manner. esto

The registration of traditional knowledge which, by the date of the filing of the application, has not been the subject of utilization in industrial activities or has not become publicly known beyond the population or the local community in which it has been developed, shall confer on the respective holder the right:

- (a) To prevent unauthorized third parties from reproducing, imitating and/or using, directly or indirectly, for commercial purposes;
- (b) To assign, transfer or license the rights in traditional knowledge, including transfer by succession;
- (c) Traditional knowledge that is the subject matter of specific industrial property registrations is excluded from protection.

The entities that are entitled to register traditional knowledge are any public or private, individual or collective entity that represents the interests of the geographical zone where the local variety is more dispersed or where the spontaneous autochthonous material presents the highest genetic variability.

The registration of traditional knowledge shall provide effects for a period of 50 years from the date of the application, renewable for an identical period.

(g) *If your answer to question (e) is no, is your country planning to establish a system of traditional knowledge protection especially adapted to its characteristics (a sui generis system)? If yes, could you please describe it in accordance with the scheme of elements contained in question (f)?*

KENYA

The delegation of Kenya has informed that its future *sui generis* statute on TK protection will contain the following features:

Policy objectives: *Ex-situ* conservation of wild plant/animal species within the Tropics that are of known traditional values and to negate the threat of their extinction.

Subject matter: Traditional knowledge of plants and animals of likely commercial value (medicinal, agricultural, environmental conservation).

Criteria for protection: A *sui-generis* like system of protection that will be unique to traditional knowledge bearing in mind the problem of inventiveness and novelty.

Right owners: The system should clearly define benefits to the traditional knowledge holder (individual or communal ownership).

Rights conferred: Rights conferred are as stipulated in the CBD, on access to genetic resources.

Procedures and formalities: Procedures and formalities will be based on the CBD provisions and the kind of arrangement existing between Kenya and the Royal Botanic Gardens, Kew.

Enforcement: It is on agreement basis, where both parties should observe the agreement terms.

Loss and expiry of rights: Not yet clearly deliberate d.

Relationship with other IP standards: The system should compliment the existing Intellectual Property regimes (patents) with an understanding on the novelty and inventiveness.

PHILIPPINES

Yes. Senate Bill No. 101 entitled "An Act Providing for the Establishment of a System of Community Intellectual Rights Protection" is pending before the Philippine Senate. The Bill is in its very raw state is still at the Committee level.

(i) The Bill is rooted on the policy of the State recognizing the origin and rights of indigenous peoples and local communities over plant and genetic resources, traditional medicines, agricultural methods and local technologies they have discovered and developed.

(ii) The subject matters include, parent strains, genetic materials, seeds and reproductivematerials, agricultural practices and devices, medicinal products and processes, cultural products from cultural communities.

- (iii) Basically, to be entitled to protection, the subject matter must originate from indigenous and local communities and from all other sectors, especially those who do not have a written tradition or culture, without the usual access to journals of scientific, business and academic communities.
- (iv) A community shall become the general owners of a form of product of traditional knowledge, once it is entered in any of the registers created under the proposed legislation. A community, as defined in the Bill, is any group of people living in a geographically defined area with common history and definitive patterns of relationship.
- (v) As general owners, the community is entitled to collect justifiable percentage from all profits derived from the commercial use of their knowledge, for a period of 10 years starting from the date of registration.
- (vi) The procedures and formalities for the acquisition and maintenance of the rights conferred shall be provided by the implementing rules and regulations to be promulgated by the implementing agency.
- (vii) The lead agency to enforce the proposed legislation is the National Commission on Plant Genetic Resources to be created under the Bill. For cultural products and heritage, the National Museum shall keep and maintain the register. As far as indigenous inventions, designs and utility models are concerned, the Intellectual Property Office is tasked to maintain the respective register.
- (viii) The protection accorded to communities under the Bill is separate and distinct from the patents granted under the Intellectual Property Code of the Philippines. However, the IPO is given the function to handle the registration insofar as indigenous inventions, designs and utility models are concerned considering their relevance and the technical expertise the Office has in these matters.

[Annex III follows]

ANNEX III

ENACTED LEGISLATION ESTABLISHING *SUI GENERIS* REGIMES FOR THE
PROTECTION OF TK

This Annex contains the text of national laws for the *sui generis* protection of TK that have been provided to the Secretariat in the context of the work of the Committee.

Brazil

Provisional Measure No. 2.186 -16, of August 23, 2001.....page 2

Panama

Law No. 20, of June 26, 2000.....page 16

Executive Decree No. 20, of March 20, 2001.....page 22

Peru

Law No. 27811 (published on August 10, 2002).....page 35

Portugal

Decree-Law No. 118/2002, of April 20, 2002.....page 53

BRAZIL

PROVISIONAL MEASURE No. 2.186 - 16 OF AUGUST 23, 2001

Enacting provisions under paragraphs (1)(ii) and (4) of Article 225 of the Constitution, Articles 1, 8(j), 10(c), 15 and 16(3) and (4) of the Convention on Biological Diversity, regulating access to the genetic heritage, protection of and access to associated traditional knowledge, sharing of benefits and access to and transfer of technology for their conservation and use, and introducing other provisions.

THE PRESIDENT OF THE REPUBLIC, by virtue of the powers invested in him by Article 62 of the Constitution, adopts the following Provisional Measure, with force of law:

CHAPTER I

GENERAL PROVISIONS

Article 1. This Provisional Measure provides for the benefits, rights and obligations concerning:

- I. access to components of the genetic heritage on the national territory, on the continental shelf and in the exclusive economic zone for purposes of scientific research, technological development or biological prospection;
- II. access to traditional knowledge relating to the genetic heritage that is relevant to the conservation of biological diversity, the integrity of the Country's genetic heritage and the use of its components;
- III. the fair and equitable sharing of the benefits deriving from exploitation of components of the genetic heritage and the associated traditional knowledge; and
- IV. access to and transfer of technology for the conservation and use of biological diversity.

§1. Access to components of the genetic heritage for purposes of scientific research, technological development or bioprospection shall be had in accordance with this Provisional Measure, without prejudice to any material property rights that might subsist in components of the genetic resources accessed, or the location where access is had.

§2. Access to components of the genetic heritage on the continental shelf shall be subject to the provisions of Law No. 8.617 of January 4, 1993.

Article 2. Access to components of the genetic heritage within national boundaries shall only be had with the authority of the Union and its use, marketing and exploitation for whatever purposes shall be subject to inspection, restrictions and benefit-sharing on the terms and conditions established in this Provisional Measure and in the regulations under it.

Article 3. This Provisional Measure does not apply to human genetic resources.

Article 4. The exchange and dissemination of components of the genetic heritage and associated traditional knowledge practised within indigenous and local communities for their own benefit and based on customary usage are preserved.

Article 5. Access to the genetic heritage for purposes that are harmful to the environment and to human health, and for the development of biological and chemical weapons, is prohibited.

Article 6. If at any time there is scientific evidence to suggest a risk of serious and irreversible damage to biological diversity resulting from activities provided for in this Provisional Measure, the public authorities, acting through the Council for the Management of the Genetic Heritage provided for in Article 10, shall, on the basis of technical opinion and criteria, decide on measures to prevent the damage, which may include suspension of the activity, due regard being had to the competence of the body responsible for the biological security of genetically modified organisms.

CHAPTER II

DEFINITIONS

Article 7. In addition to the concepts and standard definitions in the Convention on Biological Diversity, the following definitions shall apply for the purposes of this Provisional Measure:

- I. Genetic heritage: information of genetic origin contained in samples of all or part of plant, fungal, microbial or animal specimens, in the form of molecules and substances deriving from the metabolism of such living beings and extracts obtained from such organisms, live or dead, encountered *in situ*, including domestic situations, or kept in *ex situ* collections after *in situ* collection within the national territory, on the continental shelf or in the exclusive economic zone;
- II. Associated traditional knowledge: information or individual or collective practices of an indigenous or local community having real or potential value and associated with the genetic heritage;
- III. Local community: human group, including remnants of Quilomboc communities, distinguished by its cultural conditions, that traditionally organizes itself throughout successive generations and through its own customs and preserves its social and economic institutions;
- IV. Access to the genetic heritage: acquisition of samples of components of the genetic heritage for purposes of scientific research, technological development or bioprospection, with a view to its application in industry or elsewhere;
- V. Access to associated traditional knowledge: acquisition of information pertaining to knowledge or individual or collective practices, associated with the genetic heritage, of an indigenous or local community for purposes of scientific research, technological development or biological prospecting, with a view to its application in industry or elsewhere;
- VI. Access to and transfer of technology: action whose purpose is access to and the development and transfer of technology for the preservation and use of biological diversity or technology developed from samples of components of the genetic heritage or from associated traditional knowledge;
- VII. Bioprospection: exploratory activity aimed at identifying components of the genetic heritage and information on associated traditional knowledge with potential for commercial use;

- VIII. Species threatened with extinction: species carrying a high risk of disappearance from nature in the near future, and recognized as such by the competent authority;
- IX. Domesticated species: a species in whose course of evolution human beings have intervened in order to meet their own needs;
- X. Authorization of Access and Dispatch: document that allows, under specific conditions, access to samples of components of the genetic heritage and the dispatch thereof to a receiving institution, and access to associated traditional knowledge;
- XI. Special Authorization of Access and Dispatch: document that allows, under specific conditions, access to samples of components of the genetic heritage and the dispatch thereof to a receiving institution, and access to associated traditional knowledge, for a period of up to two years, renewable for equal periods;
- XII. Instrument of Material Transfer: formal document to be signed by the receiving institution before any samples of components of the genetic heritage are dispatched, with a mention where appropriate of whether access has been had to associated traditional knowledge;
- XIII. Contract for Use of the Genetic Heritage and Benefit-Sharing: multilateral legal instrument which gives the particulars of the parties, the purpose and the conditions of access to and dispatch of components of the genetic heritage and associated traditional knowledge, and also the conditions for the sharing of benefits;
- XIV. *Ex situ* state: maintenance of samples of components of the nation's genetic resources outside their natural habitat, in collections of live or dead material.

CHAPTER III

PROTECTION OF ASSOCIATED TRADITIONAL KNOWLEDGE

Article 8. Traditional knowledge of indigenous and local communities relating to the genetic heritage is protected by this Provisional Measure against illegal use and exploitation and other actions that are harmful or have not been authorized by the Management Council referred to in Article 10 or by an accredited institution.

- I. The State recognizes the right of indigenous and local communities to decide on the use of their traditional knowledge associated with the genetic heritage, as provided in this Provisional Measure and the regulations under it.
- II. The traditional knowledge associated with genetic heritage that is covered by this Provisional Measure encompasses the cultural heritage of Brazil and may be subject to a cadastral record, as directed by the Management Council or provided in specific legislation.
- III. The protection afforded by this Provisional Measure may not be interpreted in such a way as to impede the preservation, use and development of traditional knowledge of an indigenous or local community.
- IV. The protection here instituted shall not affect, prejudice or limit rights pertaining to intellectual property.

Article 9. Indigenous or local communities that create, develop, hold or preserve traditional knowledge associated with the genetic heritage are guaranteed the right to:

- I. have the origin of the access to traditional knowledge mentioned in all publications, uses, exploitation and disclosures;
- II. prevent unauthorized third parties from:
 - (a) using or carrying out tests, research or investigations relating to associated traditional knowledge;
 - (b) disclosing, broadcasting or otherwise broadcasting data or information that incorporate or constitute associated traditional knowledge;
- III. derive profit from economic exploitation by third parties of associated traditional knowledge the rights in which are owned by the community as provided in this Provisional Measure.

Sole Paragraph: For the purposes of this Provisional Measure, any traditional knowledge associated with the genetic heritage may be owned by the community, even if only one single member of the community holds that knowledge.

CHAPTER IV

INSTITUTIONAL COMPETENCIES AND POWERS

Article 10. The Council for the Management of Genetic Resources is hereby created within the Ministry of the Environment, being deliberative and normative in nature and composed of representatives of organs and agencies of the Federal Public Administration that are competent to perform the various actions provided for in this Provisional Measure.

§1. The Management Council shall be presided over by the representative of the Ministry of the Environment.

§2. The composition and action of the Management Council shall be laid down in the regulations.

Article 11. The Management Council shall be competent to:

- I. coordinate the implementation of policies for the management of the genetic heritage;
- II. establish:
 - (a) technical standards;
 - (b) criteria for authorization of access and dispatch;
 - (c) directives for drafting the Contract for Use of the Genetic Heritage and Benefit-Sharing;
 - (d) criteria for the creation of a database for recording information on associated traditional knowledge;
- III. take part, in concert with Federal bodies or by agreement with other institutions, in the work of accessing and dispatching samples of components of the genetic heritage, and accessing associated traditional knowledge;
- IV. deliberate on:
 - (a) authorization of access and dispatch of samples of components of the genetic heritage, subject to the prior consent of the owner;

- (b) authorization of access to associated traditional knowledge, subject to the prior consent of the owner;
 - (c) special authorization of access to and dispatch of samples of components of the genetic heritage for a national institution, whether public or private, which carries on research and development activities in the areas of biology and related subjects, and for a national university, whether public or private, for a term of up to two years, renewable for equal periods, as provided in the regulations;
 - (d) special authorization of access to associated traditional knowledge for a national institution, whether public or private, that carries on research and development activities in the biological and related fields, and for a national university, whether public or private, for a term of up to two years, renewable for equal periods, as provided in the regulations;
 - (e) accreditation of a national public research and development institution or Federal public management institution for authorizing another national institution, whether public or private, which carries on research and development activities in the biological and related fields, to:
 1. access samples of components of the genetic heritage and associated traditional knowledge;
 2. dispatch samples of components of the genetic heritage to a national institution, whether public or private, or to an institution with its headquarters abroad;
 - (f) accreditation of a national public institution as a depository of samples of components of the genetic heritage.
- V. approve Contracts for the Use of the Genetic Heritage and Benefit-Sharing as complying with the requirements of this Provisional Measure and the regulations under it;
- VI. promote discussion and public consultation on the subjects provided for in this Provisional Measure;
- VII. function as a higher court of appeal in relation to decisions of an accredited institution and acts resulting from the application of this Provisional Measure;
- VIII. approve its statutes.

§1. Decisions of the Management Council may be referred to the plenary session, as provided in the regulations.

§2. The Management Council may organize itself into subject groups to prepare decisions of the plenary session.

Article 12. The activity of collecting components of the genetic heritage and access to associated traditional knowledge that contributes to the advancement of bioprospection shall, when it involves the participation of a foreign legal entity, require authorization by the body responsible for national policy on scientific and technological research, subject to the terms of this Provisional Measure and the laws in force.

Sole Paragraph. The aforesaid authorizations shall conform to the technical standards laid down by the Management Council, which shall oversee such activities.

Article 13. The Chairman of the Management Council shall be competent to sign, in the name of the Union, the Contract for the Use of the Genetic Heritage and Benefit-Sharing.

§1. While retaining the competences specified in the heading of this Article, the Chairman of the Management Council may delegate that competence to the incumbent of a Federal public research and development institution or Federal public management institution, depending on the area of activity with which it is concerned.

§2 Where the institution mentioned in the preceding paragraph has an interest in the contract, the contract shall be signed by the Chairman of the Management Council.

Article 14. The accredited institution referred to in Article 11.IV(e)1 and 2 of this Provisional Measure may be accorded one or more of the following powers, as directed by the Management Council:

- I. to analyze applications and to issue authorizations to third parties for:
 - (a) access to samples of components of the genetic heritage existing *in situ* within the national territory, on the continental shelf and in the exclusive economic zone, subject to the prior consent of the owners;
 - (b) access to associated traditional knowledge, subject to the prior consent of the owners from the area;
 - (c) dispatch of samples of components of the genetic heritage to a national institution, whether public or private, or to an institution with its headquarters abroad;
- II. With Federal bodies, or by agreement with other institutions, to take part in the work of access to and dispatch of samples of components of the genetic heritage and access to associated traditional knowledge;
- III. to create and maintain:
 - (a) a register of *ex situ* collections, as provided in Article 18 of this Provisional Measure;
 - (b) a database for recording information obtained during the collection of samples of components of the genetic heritage;
 - (c) a database of Authorizations of Access and Dispatch, Terms of Transfer of Material and Contracts for the Use of Genetic Heritage and Benefit -Sharing, as provided in the regulations;
- IV. to disclose periodically a list of Authorizations of Access and Dispatch, Terms of Transfer of Material and Contracts for the Use of the Genetic Heritage and Benefit-Sharing;
- V. to take part in the implementation of Terms of Transfer of Material and Contracts for the Use of the Genetic Heritage and Benefit -Sharing in the case of processes that it has itself authorized.

§1. An accredited institution shall every year report fully on its activity to the Management Council and supply a copy of its database to the executive body provided for in Article 15.

§2. An accredited institution under Article 11 shall comply with the terms of this Provisional Measure, the regulations under it and the decisions of the Management Council, on pain of forfeiture of its accreditation and liability also, where applicable, to the penalties provided for in Article 30 and in the relevant legislation.

Article 15. The creation is authorized, within the Ministry of the Environment, of an executive body which shall exercise the function of executive secretariat of the Management

Council provided for in Article 10 of this Provisional Measure, and which shall have the following powers, among others:

- I. to implement the resolutions of the Management Council;
- II. to give support to the accredited institutions;
- III. to issue, in accordance with the resolutions of the Management Council and its name:
 - (a) Authorizations of Access and Dispatch;
 - (b) Special Authorizations of Access and Dispatch;
- IV. to take part, in concert with other Federal bodies, in the work of accessing and dispatching samples of components of the genetic heritage and accessing associated traditional knowledge;
- V. to give accreditation, in accordance with resolutions of the Management Council and its name, to a national public research and development institution or a Federal public management institution for authorizing a national institution, whether public or private, to:
 - (a) access samples of components of the genetic heritage and associated traditional knowledge;
 - (b) dispatch samples of components of the genetic heritage to a national institution, whether public or private, or to an institution with its headquarters abroad, subject to the requirements of Article 19 of this Provisional Measure;
- VI. to give accreditation, in accordance with resolutions of the Management Council and its name, to a national public institution as depositary of samples of components of the genetic heritage;
- VII. to register Contracts for Use of the Genetic Heritage and Benefit - Sharing, following their approval by the Management Council;
- VIII. to disclose a list of species designated for facilitated exchange in international agreements, including those relating to food safety, of which the country is a signatory, in accordance with Article 19.II of this Provisional Measure;
- IX. to create and maintain:
 - (a) a register of *ex situ* collections, as provided in Article 18;
 - (b) a database for recording information obtained during the collection of samples of components of the genetic heritage;
 - (c) a database of Authorizations of Access and Dispatch, Terms of Transfer of Material and Contracts for Use of the Genetic Heritage and Benefit - Sharing;
- X. to disclose periodically a list of Authorizations of Access and Dispatch, Terms of Transfer of Material and Contracts for Use of the Genetic Heritage and Benefit - Sharing.

CHAPTER V

ACCESS AND DISPATCH

Article 16. Access to components of the genetic heritage existing *in situ* within the national territory, on the continental shelf or in the exclusive economic zone, and to associated traditional knowledge, shall be had by collection of samples and information respectively, and authorizations shall only be given to a national institution, whether public or private, that carries on research and development activities in the biological and related fields by prior authorization, as provided in this Provisional Measure.

§1. The person responsible for the expedition to collect samples shall, at the end of his work in each area accessed, sign with the owner or representative thereof a declaration listing the material accessed, as provided in the regulations.

§2. In exceptional cases, where the owner of the area or his representative was not identified or located when the expedition to collect samples took place, the declaration listing the material accessed shall be signed by the person responsible for the expedition and sent to the Management Council.

§3. A representative sub-sample of each accessed population constituting a component of the genetic heritage shall be deposited *ex situ* with an accredited depositary, described in Article 11.IV(f) of this Provisional Measure, as provided in the regulations.

§4. When there is a prospect of commercial use, *in situ* access to samples of components of the genetic heritage and to associated traditional knowledge may only occur after the Contract for Use of the Genetic Heritage and Benefit -Sharing has been signed.

§5. If potential for economic use has been identified in either a product or a process, whether or not it qualifies for intellectual protection on the basis of a sample of a component of the genetic heritage and information derived from associated traditional knowledge, accessed by virtue of authorization that did not establish that hypothesis, the benefiting institution is obliged to communicate with the Management Council, or the institution with which the process of access and dispatch originated, for execution of the Contract for the Use of the Genetic Heritage and Benefit -Sharing.

§6. Participation of a foreign legal entity in an expedition to collect samples of components of the genetic heritage *in situ* and to gain access to associated traditional knowledge shall only be authorized when it is to be in conjunction with a national public institution, which shall compulsorily be responsible for the coordination of activities, and provided that all institutions involved carry out research and development activities in biological and other related fields.

§7. Research on components of the genetic heritage shall preferably be done on the national territory.

§8. The Authorization of Access to and Dispatch of samples of components of the genetic heritage in the case of species that are strictly endemic or threatened with extinction shall be dependent on the prior consent of the competent body.

§9. Authorization of Access and Dispatch shall be granted with the prior consent of:

- I. the indigenous community involved, the views of its official representative body having been heard where access occurs on indigenous territory;
- II. the competent body where access occurs in a protected area;
- III. the owner where access occurs on private land;
- IV. the National Defense Council where access occurs in an area indispensable to national security;
- V. the maritime authority where access occurs in Brazilian territorial waters, or the continental shelf for the exclusive economic zone.

§10. The holder of an Authorization of Access and Dispatch under §9.1 to V of this Article is responsible for indemnifying the owner of the area for any damage or harm that has been duly proved.

§11. An institution holding a Special Authorization of Access and Dispatch shall send to the Management Council the consents referred to in paragraphs §8 and §9 of this Article before or on the occasion of collection expeditions to be carried out during the period of validity of the Authorization, and failure to do so shall result in its cancellation.

Article 17. In the event of relevant public interest, as defined by the Management Council, entry into a public or private area for access to samples of components of the genetic heritage shall not require prior authorization by its owners, who shall be assured of the benefits provided for in Articles 24 and 25 of this Provisional Measure.

§1. In the case provided for in the heading of this Article the indigenous community, local community or owners shall be given advance notice.

§2. In cases involving indigenous lands, the provisions of Article 231(6) of the Federal Constitution shall apply.

Article 18. The *ex situ* preservation of samples of components of the genetic heritage shall take place on the national territory, provided that it may take place abroad at the discretion of the Management Council.

§1. *Ex situ* collection of samples of components of the genetic heritage must be registered with the executive body of the Management Council, as provided in the regulations.

§2. The Management Council may delegate registration under paragraph (1) of this Article to one or more institutions accredited as provided in Article 11.IV(d) and (e) of this Provisional Measure.

Article 19. The dispatch of samples of components of the genetic heritage by a national institution, whether public or private, to another national institution, whether public or private, shall make use of material held *ex situ* subject to information on the intended use and cumulative compliance with the following conditions, in addition to other that the Management Council might establish:

- I. deposit of a representative sub-sample of components of the genetic heritage in a collection maintained by an accredited institution, even if the provisions of Article 16§3 of this Provisional Measure have not been complied with;
- II. where samples of components of the genetic heritage have been accessed *in situ* before the publication of this Provisional Measure, the deposit referred to in the preceding paragraph shall be made in the form accessed, if still available, as provided in the regulations;
- III. provision of information obtained during collection of samples of components of the genetic heritage for recording in the database mentioned in Article 14.III(b) and Article 15.IX(b) of this Provisional Measure;
- IV. prior signature of the Terms of Transfer of Material.

§1. Whenever there is a prospect of commercial use of a product or process resulting from the use of components of the genetic heritage, the Contract for Use of the Genetic Heritage and Benefit-Sharing shall be signed in advance.

§2. Dispatch of samples of components of the genetic heritage in the case of species designated for facilitated exchange in international agreements, including those on food safety, of which the country is a signatory, shall be carried out in accordance with the conditions defined therein, the requirements of such agreements being constantly observed.

§3. Dispatch of any sample of components of the genetic heritage by a national institution, whether public or private, to an institution with its headquarters abroad, shall make use of *ex situ* material, subject to information on the intended use, prior authorization by the Management Council or the accredited institution and cumulative compliance with all the conditions laid down in subparagraphs I to IV and paragraphs §1 and §2 of this Article.

Article 20. The format of the Terms of Transfer of Materials shall be approved by the Management Council.

CHAPTER VI

ACCESS TO AND TRANSFER OF TECHNOLOGY

Article 21. The institution receiving samples of components of the genetic heritage or associated traditional knowledge shall facilitate access to and transfer of technology for the preservation and use of that heritage or knowledge for the national institution responsible for access and dispatch of samples and information on the knowledge, or an institution specified by it.

Article 22. Access to and transfer of technology between the national research and development institution, whether public or private, and an institution with its headquarters abroad may be achieved, among other activities, by means of:

- I. scientific research and technological development;
- II. basic and specialized training of human resources;
- III. exchange of information;
- IV. exchange between the national research institution and the research institution with its headquarters abroad;
- V. consolidation of the infrastructure for scientific research and technological development;
- VI. economic exploitation, in partnership, of a process or product derived from the use of components of the genetic heritage; and
- VII. establishment of a technology-based joint venture.

Article 23. A company that invests in research and development activity in the Country in the process of affording access to and transfer of technology to a national institution, whether public or private, responsible for access to and dispatch of samples of components of the genetic heritage and for access to information on associated traditional knowledge shall qualify for tax incentives for technological training in industry, agriculture and livestock breeding and for other incentives in accordance with relevant legislation.

CHAPTER VII

BENEFIT-SHARING

Article 24. The benefits arising from economic exploitation of a product or process developed from samples of components of the genetic heritage and associated traditional knowledge, obtained by a national institution or an institution with its headquarters abroad shall be shared in a fair and equitable way between the contracting parties, as provided in the regulations and relevant legislation.

Sole paragraph. When the Union is not a party to the Contract for Use of Genetic Heritage and Benefit-Sharing, it shall be assured where applicable of a share in the benefits referred to in the heading of this Article, as provided in the regulations.

Article 25. The benefits derived from the economic exploitation of a product or process developed from samples of the genetic heritage or associated traditional knowledge may consist of the following among other things:

- I. division of profits;
- II. payment of royalties;
- III. technology access and transfer;
- IV. unrestricted licensing of products or services; and
- V. training of human resources.

Article 26. Economic exploitation of a product or process developed from samples of components of the genetic heritage or associated traditional knowledge that have been accessed in a manner not conforming to the terms of this Provisional Measure shall make the guilty party liable to payment of an indemnity equivalent to a minimum of twenty percent of the gross invoiced amount obtained through the marketing of the product or of royalties obtained from third parties by the guilty party as a result of the licensing of the product or process or the use of the technology, whether or not protected by intellectual property, without prejudice to administrative sanctions and appropriate penalties.

Article 27. The Contract for Use of the Genetic Heritage and Benefit-Sharing shall mention and clearly identify the contracting parties, being on the one hand the owner of the public or private area or the representative of the indigenous community and the official indigenous body, or the representative of the local community and, on the other hand, the national institution authorized to have access and the receiving institution.

Article 28. Essential clauses in the Contract for Use of the Genetic Heritage and Benefit-Sharing, as provided in the regulations, and without prejudice to others, are those that relate to:

- I. purpose, elements, quantification of samples and intended use;
- II. duration;
- III. method of fair and equitable sharing of benefits and, where applicable, access to and transfer of technology;
- IV. rights and responsibilities of the parties;
- V. intellectual property rights;

- VI. cancellation;
- VII. penalties;
- VIII. jurisdiction in Brazil.

Sole Paragraph. When the Union is a party to the contract referred to in the heading of this Article, it shall be governed by the provisions of public law.

Article 29. Contracts for Use of the Genetic Heritage and Benefit - Sharing shall be submitted to the Management Council for registration and shall only become effective once approved.

Sole paragraph. Contracts for Use of the Genetic Heritage and Benefit - Sharing that are signed in a manner not conforming to the terms of this Provisional Measure and the regulations shall be null and void of legal effect.

CHAPTER VIII

ADMINISTRATIVE SANCTIONS

Article 30. Any actor or mission that contravenes the terms of this Provisional Measure and other relevant legal provisions shall be considered an administrative offense against the genetic heritage and associated traditional knowledge.

§ 1. Administrative offenses shall be punished, as provided in the regulations under this Provisional Measure, with the following sanctions:

- I. a warning;
- II. a fine;
- III. confiscation of samples of components of the genetic heritage and of instruments used for collecting or processing them, or of products obtained on the basis of information relating to associated traditional knowledge;
- IV. confiscation of products derived from samples of components of the genetic heritage or associated traditional knowledge;
- V. suspension of sales of the product derived from the sample of components of the genetic heritage or the associated traditional knowledge, and confiscation thereof;
- VI. activities;
- VII. partial or total prohibition of the establishment, activity or undertaking;
- VIII. suspension of registration, patent, license or authorization;
- IX. cancellation of registration, patent, license or authorization;
- X. loss or restriction of tax incentives and benefits accorded by the Government;
- XI. loss or suspension of financing arrangements with an official credit establishment;
- XII. intervention in the establishment;
- XIII. prohibition on signing contracts with public authorities for a period of up to five years.

§ 2. The fate of the samples, products and instruments referred to in subparagraphs III, IV and V of paragraph § 1 of this Article shall be determined by the Management Council.

§ 3. Sanctions provided for in this Article shall be applied according to the procedure set out in the regulations under this Provisional Measure, without prejudice to civil sanctions or appropriate penalties.

§4. The fines referred to in subparagraph II of paragraph § 1 of this Article shall be determined by the competent authority according to the gravity of the offense and as provided in the regulations, and may vary from R\$200 (two hundred reais) to R\$100,000 (one hundred thousand reais) in the case of a natural person.

§5. If the offense was committed by a legal entity or with its consent, the fines shall be from R\$10,000 (ten thousand reais) to R\$50,000,000 (fifty million reais), as determined by the competent authority, according to the gravity of the offense and as provided in the regulations.

§6. In the event of a repeat offense, the fines shall be doubled.

CHAPTER IX

FINAL PROVISIONS

Article 31. The grant of industrial property rights by the competent bodies for a processor product obtained using samples of components of the genetic heritage is contingent on the observance of this Provisional Measure, the applicant being obliged to specify the origin of the genetic material and the associated traditional knowledge, as the case may be.

Article 32. The competent Federal bodies shall carry out inspection, interception and confiscation of samples of components of the genetic heritage or of products obtained from information on associated traditional knowledge that have been accessed in a manner not conforming to the provisions of this Provisional Measure, it being possible to decentralize those activities by agreement, as provided in the regulations.

Article 33. The portion of income and royalties payable to the Union as a result of the economic exploitation of a processor product developed on the basis of a sample of components of the genetic heritage, as well as the value of fines and indemnities provided for in this Provisional Measure, shall be credited to the National Environment Fund created by Law No. 7.797 of July 10, 1989, to the Naval Fund created by Decree No. 20.923 of January 8, 1932, and to the National Fund for Scientific and Technological Development created by Decree - Law No. 7.19 of July 31, 1969, and confirmed by Law No. 8.172 of January 18, 1991, as provided in the regulations.

Sole Paragraph. The resources to which this Article refers shall be used exclusively for the conservation of biological diversity, recovery and the creation and maintenance of depositary institutions, for the furtherance of scientific research, for technological development associated with genetic resources and for the training of human resources associated with the conduct of activities relating to the use and conservation of genetic resources.

Article 34. Any person using or economically exploiting components of the genetic heritage and associated traditional knowledge shall ensure that other activities conform to the standards laid down in this Provisional Measure and the regulations under it.

Article 35. The Government shall regulate this Provisional Measure up to December 30, 2001.

Article 36. The provisions of this Provisional Measure shall not apply to material regulated by Law No. 8.974 of January 5, 1995.

Article 37. Acts based on Provisional Measure No. 2.186 -15 of June 26, 2001, shall remain valid.

Article 38. This Provisional Measure shall enter into force on the date of its publication.

Brasilia, August 23, 2001; 180th year of Independence and 113th year of the Republic.

FERNANDO HENRIQUE CARDOSO

José Gregori

José Serra

Ronaldo Mota Sardenberg

José Sarney Filho

PANAMA

LEGISLATIVE ASSEMBLY

LAW No. 20
(of June 26, 2000)

On the special intellectual property regime upon collective rights of indigenous communities, for the protection of their cultural identities and traditional knowledge, and whereby set forth other provisions.

THE LEGISLATIVE ASSEMBLY

DECREES:

CHAPTER I

PURPOSE

Article 1. The purpose of this law is to protect the collective rights of intellectual property and traditional knowledge of the indigenous communities upon their creations such as inventions, models, drawings and designs, innovations contained in the pictures, figures, symbols, illustrations, old carved stones and others; likewise, the cultural elements of their history, music, art and traditional artistic expressions, capable of commercial use, through a special registration system, promotion, commercialization of their rights in order to stand out the value of the indigenous cultures and to apply social justice.

Article 2. The customs, traditions, beliefs, spirituality, religiosity, folkloric expressions, artistic manifestations, traditional knowledge and any other type of traditional expressions of the indigenous communities, constitute part of their cultural assets: consequently, cannot be object of any form of exclusive right by unauthorized third parties under the intellectual property systems such as copyrights, industrial models, trademarks, geographical indications and others, unless the application is filed by the indigenous community. However, rights previously recognized under the legislation on the matter will be respected and will not be affected.

CHAPTER II

OBJECTS SUSCEPTIBLE OF PROTECTION

Article 3. It is recognized as traditional dresses of indigenous communities, those used by the communities of Kuna, Ngobe and Bugle, Embera and Wounaan, Naso and Brebre, such as:

1. *Dule Mor*. It consists in the combined use of the garment by which the Kuna men and women identify the culture, history and representation of their community. Mor Sen, Saburedi, Olassu and Winiconstitute this.

2. *Jio*. It consists in the combined use of the garment by which the Emberas and the Wounaan men and women identify the culture, history and representation of their community. The women use Ua (Paruma), Boró Barí, Dyidi Dyidi, Kondita, Neta, Parata Kerá, Manía, Soritja Kipará (Jagua), Karichí (achiote), and Kera Patura. The men use the same garments with exception of the Paruma, and also use ear flap, breast strap, Amburá and Andía.
3. *Nahua*. It consists in the garment by which the Ngobes and Buglés identify the culture, history and representation of their community. This dress is of a single piece. It is wide and it covers half of the leg; it is made with plain cloths of attractive colors, decorated with geometric applications of the cloths of contrasting colors and it includes a wide neck lace made with chaquiras. The technical description of these traditional dresses will be contained in their respective registrations.

Article 4. The collective rights of the indigenous communities are recognized on their musical instruments, music, dances or form of performance, oral and written expressions contained in their tradition that constitute their historical, cosmological and cultural expression.

The application for registration of these collective rights shall be filed by the respective general congresses or indigenous traditional authorities, before the General Office for the Registry of the Industrial Property of the Ministry of the Commerce and Industry hereinafter referred to as DIGERPI or before the National Copyright Office of the Ministry of Education, depending on the case, for its approval and registration.

Article 5. The collective rights of the indigenous communities are recognized on their work instruments and traditional art, as well as the technique for making them, expressed in the national basic materials, through the elements of the nature, their method of process, elaboration, combination of natural dyes, such as the carved tagua (ivory plant) and wood (coco bolo and nazareno), traditional baskets, nuchus, chaquiras, chacaras and any other cultural expression of traditional aspects of these communities.

The registration of these rights shall be requested by the general congresses or indigenous traditional authorities before the offices mentioned in the previous article.

Article 6. Registrable objects susceptible of protection, as this Law determines to protect their originality and authenticity, are deemed to be collective rights.

CHAPTER III

REGISTRATION OF COLLECTIVE RIGHTS

Article 7. The department of Collective Rights and Folkloric Expressions shall be created within DIGERPI, through which will be granted, among others, the registration of the collective rights of the indigenous communities.

This registration shall be requested by the general congresses or indigenous traditional authorities in order to protect their dresses, arts, music and any other traditional rights susceptible of protection.

The registrations of the collective rights of the indigenous communities will not expire, neither will have duration. The procedure before DIGERPI will not require the service of a lawyer and it is exempt of any payment. The administrative appeals against this registration shall be notified personally to the representative of the general congresses or indigenous traditional authorities.

Article 8. The provisions on collective marks and guarantees contained in the Law 35 of 1996 will be applicable to the present regime, as long as they do not harm the rights recognized in the present Law.

Article 9. DIGERPI will create a position of examiner on indigenous collective rights, for the protection of the intellectual property and other traditional rights of the indigenous communities. This public officer will have the power to examine all the applications that are filed before DIGERPI related with the collective rights of the indigenous communities, so the registration will not be granted against this law.

CHAPTER IV

PROMOTION OF THE INDI GENOUS ARTS AND CULTURAL EXPRESSIONS

Article 10. The arts, the craftsmanship, the dresses and other forms of cultural expression of the indigenous community, will be object of promotion and development by General Office for the Registry of the Industrial Property of the Ministry of the Commerce and Industry.

The General Directorate of National Craftsmanship or the Provincial Directorate of the mentioned Ministry, with awareness of the local indigenous authorities and by the request of interest party, will seal, print or stamp, without any cost, a certification in the artistic work, dress, craft or other protected forms of industrial property or copyright, in which shows that it has been elaborated by means of the traditional indigenous procedures and/or by indigenous hands. For this purpose, the Directorate that issues the certificate is authorized to inspect the workshops, materials, finished products and procedures used.

Article 11. The Ministry of Commerce and Industry shall do the necessary task in order to assure the participation of the indigenous craftsmen in the national and international fairs and to expose their handcrafts. The General Directorate of National Craftsmanship will do the required to carry out the celebration of the indigenous artisan's day with the sponsor of this Ministry.

Article 12. In the national and international presentations of the Panamanian indigenous culture, the exhibition of their dresses, dances and traditions will be mandatory.

Articles 13. The Ministry of Education shall include in the school curriculum contents related to the indigenous artistic expressions, as an integral part of the national culture.

Article 14. The public institutions vested with legal power are authorized to disclose and to promote, in agreement with the general congresses and indigenous traditional authorities, the history, customs, values and artistic and traditional expressions (including the garments) of the indigenous communities, as an integral part of the national culture.

The exhibits on sale of indigenous crafts elaborated by students shall be allowed in the school fairs for the benefit of their school center.

CHAPTER V

RIGHTS OF USE AND COMMERCIALIZATION

Article 15. The rights of use and commercialization of the art, crafts and other cultural expressions based on the tradition of the indigenous community, must be governed by the regulation of each indigenous community, approved and registered in DIGERPI or in the National Copyright Office of the Ministry of Education, according to the case.

Article 16. The folkloric dance groups that perform artistic presentations in the national and international level will be exempt of the compliance of the previous article. However, the natural or legal person that organizes artistic presentation to stand out the indigenous culture, whole or in part, he (she) shall include members of this communities for this performance. If the recruiting of these is not possible, the authorization of the respective general congress or indigenous traditional authority is required, in order to preserve its authenticity. The National Institute of Culture will look after for the compliance of this obligation.

CHAPTER VI

PROHIBITIONS AND SANCTIONS

Article 17. The literal j is added to the article 439 of the Fiscal Code, amending as follows:

Article 439. Foreign goods originating from all countries can be imported except the following:

- j. The non-original products, recorded, embroidered, weave or any other articles that imitate, in whole or partly, the making of the traditional dresses of the indigenous communities, as well as musical instruments and traditional artistic works of these communities.

Article 18. The numeral 7 is added to the article 16 of the Law 30 of 1984, amending as follows:

Article 16. The following acts constitute the crime of smuggling:

7. The possession of not expressed, neither declared, neither authorized transitory goods, under the custom regulation, of the not original products that imitate in whole or partly, the traditional dresses of the Panamanian indigenous communities, as well as the materials and musical instruments and artistic or handmade works of these communities.

Article 19. An additional paragraph is added to the article 55 of the Law 30 of 1984, amending as follows:

Article 55....

When it is concerned with custom crimes of goods that imitate products belonging to the Panamanian indigenous communities, from fifty percent (50%) of the fine, not transferable to the informer and accusers mentioned in this article, fifty percent (50%) will be destined for the benefit of the National Treasure, and the other fifty percent (50%) will be dedicated to cover the investment expenses of the respective indigenous community or district, according to the procedures that establish the law.

Article 20. The industrial reproduction, either total or partial, of the traditional dresses and other collective rights recognized in this Law, is forbidden, unless it is authorized by the Ministry of Commerce and Industry, with the previous and express consent of the general congresses and indigenous council, and if it is not against the provisions established hereon.

Article 21. In the cases not contemplated in the custom legislation and in that of industrial property, the infringement of this Law will be sanctioned, depending on the seriousness of the act, with the fine of a thousand dollars (\$1,000.00) to five thousand dollars (B/.5,000.00). In the repeating event, the fine will be double of the previous quantity. The sanctions established hereon will be applied in addition to the forfeiture and destruction of the products in violation of this law.

The fifty percent (50%) of the imposed fine according to this article will be assigned for the benefit of the National Treasure and the other fifty percent (50%) will be dedicated to cover the investment expenses of the districts or correspondent indigenous communities.

Article 22. The following authorities are vested with the legal power to persecute the offenders of this Law, to take preventive measures on the respective products and goods, and to forward them to the corresponding appointed public officers:

1. The regional governor or the county governor, in case the first one does not exist.
2. The general congress of the corresponding district. For such effects, the traditional authorities will be able to request the cooperation and the support of the Public Force.

Article 23. The small non-indigenous artisans that dedicate to the manufacture, production and sale of the reproduction of crafts belonging to indigenous Ngobes and Buglé that reside in the districts of Tolé, Remedios, San Félix and San Lorenzo of the Province of Chiriqui are exempt of this law. These small non-indigenous artisans will be able to manufacture and to market these reproductions, but they will not be able to claim the collective rights recognized by this Law to the indigenous group.

CHAPTER VII

FINAL PROVISIONS

Article 24. At the day in force of the present law, the small not indigenous artisans who dedicate to the elaboration, reproduction and sale of traditional indigenous crafts registered in the General Office of National Craftsmanship, will be able to carry out these activities, with the awareness of the indigenous traditional authorities.

The Ministry of Commerce and Industry, previous verification of the registration date and issuance of license, will issue the permits and respective authorizations. However, the Panamanian indigenous artisans shall affix, print, write or identify in any visible way that the product is a reproduction, as well as its origin place.

Article 25. For the effects of the protection, use and marketing of the intellectual property collective rights of the indigenous communities contained in this Law, the artistic and traditional expressions of other countries will have the same benefits set forth in hereon, whenever they are made by means of reciprocal international agreements with these countries.

Article 26. This Law will be regulated by the Executive Branch through the Ministry of Commerce and Industry.

Article 27. The present Law adds to the Law 30 of November 8 of 1984, the number 7 to the article 16 and a paragraph to the article 55, as well as the literal j to the article 439 of the Fiscal Code, and it abolishes any disposition contrary to this law.

Article 28. This Law shall enter into force from its promulgation .

LET IT BE KNOWN AND EXECUTED,

Approved in third debate, in the Justo Arosemena Palace, City of Panama, on the fifteenth days of the month of May of the year two thousand.

President

The General Secretary

ENRIQUE AROSEMENA

JOSÉ GÓMEZ NUÑEZ

NATIONAL EXECUTIVE BRANCH - PRESIDENCY OF THE REPUBLIC. -
PANAMA, REPUBLIC OF PANAMA, JUNE 26TH, 2000.

MIREYA MOSCOSO
President of the Republic

JOAQUÍN JACOMETEN
Minister of Commerce and Industry

MINISTRY OF TRADE AND INDUSTRIES

EXECUTIVE DECREE NO. 12
(of March 20, 2001)

“Regulating Law No. 20 of June 26, 2000, on the Special Intellectual Property Regime Governing the Collective Rights of Indigenous Peoples for the Protection and Defense of their Cultural Identity and their Traditional Knowledge, and Enacting Other Provisions.”

THE PRESIDENT OF THE REPUBLIC
In exercise of her constitutional and legal powers

CONSIDERING:

That Law No. 20 of June 26, 2000, has as its purpose the protection of the collective intellectual property rights and the traditional knowledge of indigenous peoples embodied in their creations, such as inventions, models, designs and drawings, innovations contained in images, figures, graphics symbols, petroglyphs and other material, and also the cultural elements of their history, music, art and traditional artistic expressions susceptible of commercial use, which is to be done through a special system of registration, promotion and marketing of their rights in such a way as to give prominence to the indigenous socio-cultural values and do them social justice;

That, by virtue of the regulatory power conferred upon it by Article 26 by Law No. 20 of June 26, 2000, published in *Gaceta Oficial* No. 24,083 of June 27, 2000, the Executive, acting through the Ministry of Commerce and Industries, has to regulate Law No. 20 of June 26, 2000, for the better implementation thereof without departing in any case from either its text or its spirit;

That the Executive, acting through the Ministry of Commerce and Industries, following consultation with the sectors connected with the promotion, production and marketing of the arts and handicraft, and also with the holders of indigenous traditional knowledge and especially with the indigenous authorities, 2000, has directed that such Regulations be adopted by this Executive Decree with a view to facilitating the procedures and formalities for the protection and defense of the collective rights, cultural identity and traditional knowledge of indigenous peoples,

Decreases as follows:

CHAPTER I

PURPOSE

Article 1. The purpose of this Decree is to regulate the protection of the collective intellectual property rights and the traditional knowledge of indigenous peoples embodied in their creations, such as inventions, models, designs and drawings, innovations contained in

images, figures, graphics symbols, petroglyphs and other material, and also the cultural elements of their history, music, art and traditional artistic expressions, as well as other provisions contained in Law No. 20 of June 26, 2000.

Article 2. For the purposes of this Decree, the following definitions apply:

- (i) “Law” means Law 20 of June 26, 2000.
- (ii) “Intellectual property” means the right that creators and owners have in the products of their intellect, which, on being recognized by the Law, prohibit third parties from availing themselves thereof without the owner’s consent.
- (iii) “Traditional knowledge” means the collective knowledge of an indigenous people based on the traditions of centuries, and indeed millennia, which are at once tangible and intangible expressions encompassing their science, technology and cultural manifestations, including their genetic resources, medicines and seeds, their knowledge of the properties of fauna and flora, oral traditions, designs and visual and representative arts.
- (iv) “Cosm vision” means the conception that indigenous peoples have, both collectively and individually, of the physical and spiritual world and the environment in which they conduct their lives.
- (v) “Collective indigenous rights” means the indigenous cultural and intellectual property rights relating to art, music, literature, biological, medical and ecological knowledge and other subject matter and manifestations that have no known author or owner and no date of origin and constitute the heritage of an entire indigenous people.
- (vi) “MICI” means the Ministry of Commerce and Industries.
- (vii) “DIGERPI” means the Directorate General of the Industrial Property Registry.
- (viii) “Copyright” means the intellectual protection of the rights of authors in their literary, educational, scientific or artistic works, regardless of type, medium of expression, merit or purpose thereof.
- (ix) “Collective intellectual property registration” means the exclusive right granted by the State, by virtue of an administrative instrument, to prohibit third parties from the exploitation of collective rights deriving from traditional knowledge or an expression of folklore, the effects and limitations of which shall be determined by the law and this Decree.
- (x) “General congresses or traditional authorities” constitutes State recognition of the existence of general congresses or traditional authorities as agencies of maximum expression, decision, consultation and administration adopted by indigenous peoples in accordance with their traditions and the Law Creating the Indigenous Districts and Their Organizational Charter, subject to the safeguards written into the Constitution and laws of the Republic.

- (xi) “Representative” means the person or persons designated by the general congress(es) or the traditional authority (authorities) for the management of the registration of collective rights.
- (xii) “Rules of use” means the rules that specify the characteristics common to traditional knowledge and subject matter eligible for registration as intellectual property. They are the substantiation of the traditional character of a collective right and its implementation in relation to indigenous peoples. ght
- (xiii) “License contract” means the right of the indigenous people or people to grant third parties, by written contract, a registered collective right to the use of knowledge.
- (xiv) “Replicas” means reproductions of original objects where their similarity in some way evokes traditional and autochthonous objects, including copies of an artistic work.
- (xv) “Royalties” means pecuniary rights, exclusive privileges of economic character or grants.
- (xvi) “Council of Elders” means the assembly or decision-making body of the Naso people.
- (xvii) “Industrial reproduction” means, for the purpose of the implementation of the Law, the production of goods by virtue of a collective right that is registered under and/or covered by the Law, and also the procedures engaged in by virtue of the collective rights of the indigenous people or peoples. Third-party use of registered collective rights for commercial, industrial and scientific purposes, shall be appropriate when it has been authorized by MICI with the express prior consent of the general congresses, traditional authorities or Councils of Elders, as the case may be.
- (xviii) “Cognitive processes” means knowledge acquired over time through observation of and experimentation with the environment in which man conducts his existence. It is a specific, special, rich knowledge derived from the relationship of man and nature and also from the need to dominate the environment.

CHAPTER II

SUBJECT MATTER ELIGIBLE FOR PROTECTION

Article 3. DIGERPI shall classify subject matter eligible for protection in accordance with the rules of use of indigenous collective rights submitted by the general congress(es) or traditional authority (authorities), which subject matters shall be that described in Article 3, 4 and 5 of the Law and those that are specified below:

- (1) Paruma:wa (in the Emberá tongue) hapkajúa (in the Wounaan tongue): this is a clothing article worn round the hips by native Emberá and Wounaan women which consists of a measured amount of palm bark fabric (previously rubber-tree bark), soaked and crushed, or of the textile material currently used.
- (2) Olua’ a: oval rings or hoops that Kunawomen use as clothing accessories (earrings).

- (3) Orbirid: pectoral garments made of several sections joined by li nksto as sizes sufficient to cover the entire chest of the native Kunawoman. Chest protectors.
- (4) Nuchu: carving in balsawood (*Ochromalimonensis*), used in religious and cultural ceremonies by Kuna natives. Anthropomorphic figure.
- (5) Chaqaira: Muñon -Kus (in Ngöbe), Crade (in Buglé): necklace of two or more rows produced by threading small colored beads to produce abstract designs. Neckwear used by Ngöbe and Buglé natives.
- (6) Wigo: necklace made of small multicolored beads, used as an article of clothing by native Ngöbe and Buglé women.
- (7) Canoa/Cayuco/Piragua, Jap (in Wounaan), Jambá (in Emberá): small boat made of a single tree trunk and propelled by oars or sails; mode of transport used at sea or on rivers by Panamanian natives and rural communities.
- (8) Ca: purses or bags woven with threads made of various fibers, decorated with traditional designs and patterns and used in various ways by the Ngöbe and Bugle people.
- (9) Canalete or Remo, döi (in Wounaan), Dobi (in Emberá): a paddle made of wood and used by natives and rural people to propel a small boat.
- (10) Pikiu (in Wounaan), pikiw' a (in Emberá): basket made of reeds by Emberá and Wounaan natives).
- (11) Dichaardi: hostelry, cabin or hut of the Wounaan native.
- (12) Medicinestick or baton of frank: Barra (in Emberá) Papörmie (in Wounaan): zoomorphic and anthropomorphic figures carved in wood, forming part of ritual accoutrement.
- (13) Hajua (in Wounaan), Antia (in Emberá) or Wuayuco: article of clothing used by natives of Emberá and Wounaan culture. Loin cloth or cache -sexe consisting of a narrow strip of cloth secured by a cord (p'ösié) and worn round the hips. The raw material is derived from a palm called ferjuby the natives.
- (14) Mola (Morrain Kuna); a women's blouse; application of a small decorative piece to a larger piece of fabric with working on the back. A combination of fabrics of many different, striking colors. The technique used is derived from the craft of embroidery (or appliqué). These are hand -made by native Kunawomen, and they consist of one or more layers of fabric cut and sewn together in such a way that the color of each of the lower layers shows through. The designs on a Mola are based on cosmovision, while others merely use geometric shape.
- (15) Jiw' a (in Emberá), Hosigdi (in Wounaan); chungá basket: small basket made of the tender leaves of the *Astrocaryum standlerianum* palm (or chungá). The tresses are sown together; they may be white or colored, forming a design. The Emberá make masks

- from this fiber.
- (16) Jirak: basket woven from stems of the Jirak bush, made by Wounaan natives.
 - (17) Kigá: thread or fiber from the Achmean mafdalena plant, extracted by means of a non-industrial process and used by the Ngöben natives to make bags.
 - (18) Kuas (in Wounaan), Jumpe (in Emberá), Pescao Uacuco: name of one of the many baskets made by Emberá and Wounaan natives.
 - (19) Küchuur (in Wounaan), sweeping basket: funnel-shaped basket, closed at one end, made by Emberá and Wounaan natives.
 - (20) Turpas: native Kunan name given to the hanging part of the breasts.
 - (21) Wini: beaded necklace, serving as bracelets and anklets, used by native Kunan women as clothing accessories.
 - (22) Meudau ó Pat'eenb (in Wounaan), N'edau (in Emberá): pieces carved in the wood of the cocobolo (*Delbergia retusa*) by Emberá and Wounaan natives. The designs carved on the articles are based on flora and fauna and human manifestations.
 - (23) H[^]rp: baskets manufactured by Wounaan natives, woven from the fibers of the reed of the same name.
 - (24) Jagua: K'ipaar (in Wounaan), Kipar'a (in Emberá): after a handicraft process, the black dye obtained from the fruit of the Genipa americana tree is used as a body paint and today the fibers of baskets and the ivory nut articles of Panamanian natives.
 - (25) Nimim (in Emberá), Titiimie (in Wounaan): black dye used by natives for basketwork and ivory nut objects. It is obtained from the Arrabida chicareed by means of a craft process.
 - (26) Nukuata: plant-based cloth manufactured by the Ngöben natives for making clothes. It is obtained from the bark of the rubber tree (*Castilla elastica*).
 - (27) Chir Chir (in Wounaan), Cha (in Emberá): earrings made of silver.
 - (28) Choo K'ier (in Wounaan): arrows made by Emberá and Wounaan natives.
 - (29) Choop' o (in Wounaan), Enedruma (in Emberá): bow (throwing weapon used by Emberá and Wounaan natives).
 - (30) Hik' oo (in Wounaan), M'ania (in Emberá): bracelet of conical shape made of silver, worn on both hands by Emberá and Wounaan natives.
 - (31) H[^]rrsir: flute: musical instrument used by Wounaan natives in their religious ceremonies.

- (32) Hesapdau: writing, Wounaan alph abet.
- (33) Jait: tool used by the Wounaan for making dugout canoes or pirogues.
- (34) Orejer (in Wounaan). Orej'era (in Emberá): oval -shaped silver earrings used by Emberá and Wounaan natives.
- (35) Sortik (in Wounaan). Sort'ia (in Emberá): ring made of silver, copper or ivory palm seeds.
- (36) Pörsir: type of crown made of gold or another precious metal by Wounaan natives. Used by men who exercise ancestral authority.
- (37) T'ur (in Wounaan), Zokó (in Emberá): large vessel of white clay in which Emberá and Wounaan native skeep their alcoholic and other beverages and water. Also used for cooking.
- (38) Teerjú: bed made of the bark of a palm. This raw material undergoes initial processing, and is used thereafter as a bed by the Wounaan native.
- (39) Taudau: figures carved in ivory palm seeds (*Phytelephas seemannii*), a craft that distinguishes the Wounaan carver.
- (40) Pazadö (in Wounaan), Miaz'u (in Emberá): type of spear used by Emberá and Wounaan natives for hunting.
- (41) P'ensir: toy for Wounaan boys. Type of rattle.
- (42) Pörk'au (in Wounaan), Antougué (in Emberá): Type of bench made of a single tree trunk. Used as a seat or headrest by natives.
- (43) Nangún: one -piece garment made of variously colored fabrics with traditional applications and designs, used by Ngöbe and Buglé women.
- (44) Drü: musical instrument used by the Ngöbe and Buglé people in their ritual activities and traditional entertainments. It is made of material extracted from the vegetation available locally.
- (45) Ka: traditional Ngöbe and Buglé songs used to enliven celebrations, rituals and other activities.
- (46) Picheer (in Wounaan): chest protecting garment, made by mixing glass beads with silver.
- (47) Tamburr (in Wounaan), T'ono'a (in Wounaan): drum.
- (48) P'ip'an (in Wounaan): three -holed flute.
- (49) T'okeemie (in Wounaan), Chir'u (in Emberá): set of minor flutes.

- (50) H[^]rrsir(inWounaan).Pi'pano(inEmberá):majorflute.
- (51) Haguaserit:musicoftheWounaannatives.
- (52) K'arichipar:Wounaandances.
- (53) J[^]di(inWounaan):sharpeningstone.
- (54) U'gu(inEmberá),Patt'ër(inWounaan):blowpipe:reedortubeforfiringdartsor arrows.Huntingimplementwhosemanufactureinvolvesthecuttingofchungaleaves.
- (55) Döt'ur(inWounaan):pitcher.
- (56) Dearad'e(inEmberá):traditionalEmberáhousemadeofwoodandlocalvegetation.
- (57) Jirab'a(inEmberá): Indianhammockmadeoflianas,knownbythenativesasa pinuguilla.
- (58) J'uepor'o(inEmberá),Terjú(inWounaan):sleepingmat(Esterilla)madebyEmberá andWounaannativesfromthebarkoftherubbertree.
- (59) Ch'a:arrowmadeofwhitecane.Weaponforhunting,propelledwithabowby Emberánatives.
- (60) Jegui:danceoftheNgöbeandBuglénatives.
- (61) JaTogoJuDogwobta:rhythmofaNgöbeandBuglésong.SongofMantarraya.
- (62) NoroTregue(squeezingtheflutes):openingsongtoinitiateadanceoftheNgobé and Buglénativepeoples.
- (63) Noro:flute:musicalinstrumentusedbytheNgobéandBuglénatives.
- (64) Balsería:asportoftheNgobéandBuglénatives.Practicedonfestiveoccasions.
- (65) Amb'ura(inEmberá).P'öcieCam(inWounaan):necklace -typeornament wornonthe hipsbymenoftheEmberáandWounaanpeoples.Madeofbeads.
- (66) Ne':drawingandartisticskillsoftheEmberápeople.
- (67) K'arl:dance.SpiritualperformanceoftheEmberápeople.
- (68) K'achir'u:bambooshellusedbythemedicinemenoftheEmber ápeopleintheir curingritual.
- (69) Borob'ari:crownmadeofgoldandsilver.UsedbyEmberáwomen.
- (70) K'ewasoso:acraftprocessthatmakesuseofalocalclimbingplantandproducesablue dye,whichtheEmberáandWounaanusefortheirbasketsandivory palmwork.

- (71) J'orop'o: baskets whose manufacture involves the use of the bark and fruit of the "nawala." Indigenous craft of the Emberá and Wounaan peoples.
- (72) Nek'a (in Emberá): Basket made by the Emberá and Wounaan natives out of fibers of the chungale af (Astrocaryum standlerianum) and the "nawala." Characterized by the variegated colors and designs used by the artisans in making them.
- (73) Jebdop (in Wounaan): Clay bowl made by Wounaan and Emberá natives.
- (74) Sip'inpa (in Wounaan): fishing rod of the Emberá and Wounaan natives.
- (75) Pir: works wrought in gold and silver by the Wounaan people. Rings.
- (76) Som Dau (in Wounaan): necklaces of beads worn by native Emberá and Wounaan women.
- (77) Paj'g Dee (in Wounaan): perfume extracted from plants.

Article 4. Applications for the registration of collective native rights may be filed with the traditional native authorities where the applicant indigenous community does not have a general congress.

Article 5. Objects eligible for protection may come from two or more indigenous communities, but registration with DIGERPI shall be the responsibility of the congress(es) or traditional native authority (authorities), as the case may be, which meets or meet the prescribed requirements.

Sole Paragraph: The traditional knowledge of indigenous peoples consists of creations shared by the members of several communities, and the benefits are construed as accruing to all of them collectively.

CHAPTER III

REGISTRATION OF COLLECTIVE RIGHTS

Article 6. The application for registration of collective rights shall specify the following:

- that a collective right is involved;
- that it belongs to one of the indigenous peoples of the country;
- the technique used (in the case of an object);
- history (tradition) and brief description; this shall be accompanied by the agreement (or record) constituting the application for registration of the collective right with the departments designated by the Law. The applications shall be supported by the inclusion of a copy of the rules of use of the indigenous collective right.

Article 7. The rules of use of the collective rights shall be drawn upon a form which shall be manufactured by the Registry, and with which the following particulars and materials shall be enclosed:

- (i) the indigenous people or peoples applying for registration of their traditional knowledge of an object eligible for registration;
- (ii) the general congress(es) or traditional native authority (authorities) filing the application for registration;
- (iii) the indigenous collective right filed for registration; it should be identified by its name and content in the native language, with a literal translation in Spanish;
- (iv) the use or uses that are made of the traditional knowledge of the object qualifying for protection;
- (v) the history (tradition) of the collective right;
- (vi) the dependent communities and population benefited;
- (vii) a specimen of the traditional object qualifying for registration.

Article 8. The registration authorities designated by the Law shall satisfy themselves, within a period of 30 days of the filing of the application, that it contains all the submissions required under the foregoing Article. Where any required particular or document has been omitted, the general congress(es) or traditional native authority (authorities), hereinafter referred to as "the representative," of the indigenous people or people that have applied for registration shall be informed accordingly, in order that the filing may be completed within a period not exceeding six months following the filing of the application. Following that date they shall file a new application with the documentation in question. Where the submissions required have been made and verified by the authorized national agencies, registration of the collective right applied for shall proceed.

Article 9. The indigenous representatives shall file with the Registries authorized by the Law the application for registration of the collective right in respect of each of the objects or all of the traditional knowledge eligible for registration.

Article 10. Appeals against such registrations shall be notified in person to the representatives of the collective rights in the manner laid down in Article 7 of the Law, once publication has taken place in the Official Bulletin of Industrial Property (BOPI).

Article 11. Registration of the collective rights in an object or in traditional knowledge shall not affect the traditional exchange of the object or knowledge in question between indigenous peoples.

Article 12. Access to the register of collective rights shall be public, with the exception of the experiments and cognitive processes conducted by the indigenous peoples and the traditional production techniques or methods used.

Nevertheless, registries may publicize statistics and cultural data of interest to educational centers, culture researchers and communal custodians of culture, trade and industry.

Article 13. For the purposes of Article 7 of the Law, and in order to facilitate the registration of the collective rights of indigenous peoples, DIGERPI may send officials from the

Department of Collective Rights and Expressions of Folklore to the indigenous communities with a view to gathering the information necessary for the prosecution of such applications for registration as they may wish to file.

Article 14. The Department of Collective Rights and Expressions of Folklore created by the Law shall have the following general objective: to coordinate, develop, guide and register, in a general manner, the work of protecting the collective rights of the holders of traditional knowledge and expressions of folklore.

To that end it shall perform the following functions among others:

- (a) examination of applications filed for the registration of collective indigenous rights and expressions of folklore;
- (b) creation of a manual and an automated archive of traditional knowledge and expressions of folklore, with preference being given to the country, which shall contain registrations (the information permitted by the rules), data, publications, oral transmissions, the practice of traditions and other elements;
- (c) creation of a standardized typology of collective rights and expressions of folklore;
- (d) monitoring of compliance with existing laws relating to the protection of collective intellectual property rights in traditional knowledge and expressions of folklore, and promotion of the enactment of new laws on the subject;
- (e) promotion of the program of intellectual property protection for collective rights and expressions of folklore;
- (f) technical support and training in the field of the intellectual property protection of traditional knowledge and expressions of folklore for the peoples in possession of such knowledge and expressions;
- (g) coordination with domestic and international organizations and agencies concerned with conducting programs for the intellectual property protection of traditional knowledge and expressions of folklore;
- (h) close cooperation between our country and others with a view to ensuring, at the international level, the benefits of the pecuniary rights deriving from the registration of the collective rights in traditional knowledge and expressions of folklore of the peoples and the holders of such knowledge and expressions.

CHAPTER IV

PROMOTION OF INDIGENOUS ART AND EXPRESSIONS OF CULTURE

Article 15. For the purposes of Article 10 of the Law, which provides for the development and promotion of traditional indigenous art, handicraft and clothing, those concepts are provided for in Law 27 of July 30, 1997 "Establishing the Protection, Promotion and Development of Handicraft." With regard to the other cultural expressions of indigenous peoples, and specifically the certification issued by the Directorate General of Handicraft for

the Provincial Directorates of MICI, with the consent of the indigenous authorities, recourse shall be had to the advice and assistance of the National Directorate of Historical Heritage of the National Institute of Culture (INAC), authorized by Law No. 14 of May 5, 1982 Enacting Measures on the Custody, Conservation and Administration of the Historical Heritage of the Nation.

The certification of the artistic work, garment, craftwork or other subject matter protected by industrial property shall be issued by the Directorate General of National Handicraft (DGAN) of the Ministry of Commerce and Industry (MICI) and shall attest that the subject matter is:

- (i) a work of indigenous traditional art or handicraft;
- (ii) handmade by natives.

CHAPTER V

RIGHTS OF USE AND MARKETING

Article 16. For the purposes of Article 15 of the Law, the rules of use of each indigenous people shall be submitted to the authorized Registries together with the filing of the application for registration of collective rights in respect of each of the objects and all of the traditional knowledge eligible for protection.

CHAPTER VI

PROHIBITIONS AND SANCTIONS

Article 17. For the purposes of Article 20 of the Law, the Ministry of Commerce and Industry, with the express prior consent of the general congresses, traditional authorities and councils, shall authorize industrial reproduction, either total or partial, under the registered collective rights. That authorization shall be issued by the Directorate General of National Handicraft of MICI, responsible for the promotion and development of handicraft, after the Registries authorized by law have studied and analyzed the submissions by the owners of the registration, which, in addition to the express consent and the application itself, the following documentation:

- (a) a record of the agreement or express authorization of the congresses, indigenous authority or, failing that, the indigenous council that is holding the registered traditional indigenous knowledge, which shall specify that the use of the collective rights shall be licensed to third parties by contract;
- (b) a copy of the license contract for use of the registered collective rights;
- (c) the identity of the representative(s) of the congress(es) or indigenous authority (authorities) of the indigenous community (communities) holding the registered traditional knowledge expression of folklore, who have signed the contract;
- (d) the identity of the other parties to the contract and of their representatives;
- (e) the use that is to be made of the traditional knowledge expression of folklore.

Article 18. A license contract for the use of collective rights shall be registered only where the following requirements have been met:

- (a) identification of the parties;
- (b) description of the registered collective rights to which the contract relates;
- (c) specification of the royalties that the indigenous peoples will receive for the use of the collective rights; those royalties shall include an initial payment or some form of immediate, direct compensation to the indigenous peoples, and a percentage of the value of the sales resulting from the marketing of products developed on the basis of the said collective rights;
- (d) provision of sufficient information on the purposes, risks and implications of the activity concerned, the periods of use, including possible uses of the collective rights, and the value thereof where applicable;
- (e) the obligation on the licensee to give a periodical account to the licensor, in general terms, on the progress made in research and industrialization and the marketing of the goods developed on the basis of the licensed collective rights; where the contract contains a reserved rights obligation, that fact shall be expressly stated.

Article 19. License contracts for uses shall be entered in a register kept for the purpose by DIGERPI.

Article 20. The Registry shall satisfy itself, within a period of 30 days from the filing of the application, that the said application embodies all the data and documents specified in Article 17 of the relevant legislation. Where an omission has occurred, the person applying for the registration shall be informed so that the application may be completed within a period of six months, subject to a warning that otherwise it shall be considered abandoned.

Article 21. The license for the use of the collective rights of an indigenous people shall not prevent that people from continuing to use it in the indigenous communities that possess the traditional knowledge, neither shall it affect the right of present and future generations to continue to use it and develop it on the basis of the collective knowledge. The license likewise shall not prevent other people that hold the same registered collective rights, but have not signed the contract, from licensing them.

Article 22. Sublicensing may only take place with the authorization of MICI and the express prior consent of the owner or owners of the registered collective rights whom meet the requirements prescribed in Article 1 of the Regulations.

Article 23. The Registry shall, *ex officio* at the request of one of the parties to the contract, cancel the license for the use of collective rights, after the parties concerned have been heard, where:

- (a) it has been granted in violation of any of the provisions of this enactment;
- (b) it has been granted on the basis of false or inaccurate data contained in the application which are essential.

Article 24. The request for cancellation of a registration shall specify or submit, as the case may be, the following:

- (a) identity of the party requesting cancellation;
- (b) identity of the representative;
- (c) registration of the collective right of which the cancellation is requested;
- (d) a statement of the grounds for the action;
- (e) evidence proving the reasons submitted for the cancellation;
- (f) domicile of the representatives;
- (g) copy of the instrument or agreement by which the congress or indigenous authority or Council of Elders has revoked the license contract for use.

Article 25. The files shall be submitted for settlement within a period of 30 days.

Article 26. For the purposes of Article 23 of the Law, artisans who are not natives of Tolé, Remedios, San Félix and San Lorenzo in the province of Chiriquí who devote themselves to the production of replicas of traditional indigenous handicraft shall carry an artisan's identity card issued by the Directorate General of Handicraft of MICI, and shall in addition print, write, fix or otherwise identify on every work or product, clearly and in a visible place, the place of origin, as provided in Articles 18, 19 and 20 of Law No. 27 of July 30, 1997.

CHAPTER VII

FINAL PROVISIONS

Article 27. MICI, acting through the Directorate General of Handicraft, shall issue permits and authorizations to non-indigenous artisans who are registered and hold the artisan's identity card and devote themselves to the development and production of replicas of traditional indigenous handicraft at the time of the entry into force of the Law. To that end the Directorate General of National Handicraft shall send the list of authorized artisans to the congresses, Council of Elders or traditional indigenous authorities.

Article 28. This Decree shall enter into force on its promulgation.

The foregoing shall be published and implemented.

JOAQUINE JACOMEDIEZ
Minister of Commerce and Industry

MIREYA MOSCOSO
President of the Republic

PERU

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LAW INTRODUCING A PROTECTION REGIME FOR THE COLLECTIVE
KNOWLEDGE OF INDIGENOUS PEOPLES DERIVED FROM BIOLOGICAL
RESOURCES

TITLE I

RECOGNITION OF THE RIGHTS OF INDIGENOUS PEOPLES IN THEIR COLLECTIVE
KNOWLEDGE

Article 1. - Recognition of rights

The Peruvian State recognizes the rights and power of indigenous peoples and communities to dispose of their collective knowledge as they see fit.

TITLE II

DEFINITIONS

Article 2. - Definitions

For the purposes of this legislation:

(a) “Indigenous peoples” means aboriginal peoples holding rights that existed prior to the formation of the Peruvian State, maintaining a culture of their own, occupying a specific territorial area and recognizing themselves as such. These include peoples in voluntary isolation or with which contact has not been made, and also rural and native communities. The term “indigenous” shall encompass, and may be used as a synonym of, “aboriginal,” “traditional,” “ethnic,” “ancestral,” “native” or other such word form.

(b) “Collective knowledge” means the accumulated, transgenerational knowledge evolved by indigenous peoples and communities concerning the properties, uses and characteristics of biological diversity. The intangible components referred to in Decision 391 of the Commission of the Cartagena Agreement include this type of collective knowledge.

(c) “Prior informed consent” means authorization given under this protection regime, by the representative organization of the indigenous people possessing collective knowledge and in accordance with provisions recognized by them, for the conduct of a particular activity that entails access to and use of the said collective knowledge, subject to the provision of sufficient information on the purposes, risks or implications of the said activity, including any uses that might be made of the knowledge, and where applicable on its value.

(d) “License contract for the use of collective knowledge” means an express agreement concluded between the organization of indigenous peoples possessing collective

knowledge and a third party that incorporate terms and conditions for the use of the said collective knowledge. Such contracts may constitute an annex to the contract mentioned in Article 34 of Decision 391 of the Commission of the Cartagena Agreement introducing the Common Regime on Access to Genetic Resources.

(e) "Biological resources" means genetic resources, organisms or parts thereof, populations or any other kinds of biotic component of an ecosystem that have or have potential value or use to mankind.

TITLE III

SCOPE OF PROTECTION

Article 3. - Scope of protection afforded by this legislation

This legislation establishes a special protection regime for the collective knowledge of indigenous peoples that is connected with biological resources.

Article 4. - Exception to the regime

This regime shall not affect the traditional exchange between indigenous peoples of the collective knowledge protected under this regime.

TITLE IV

OBJECTIVES

Article 5. - Objectives of the regime

The following shall be the objectives of this regime:

- (a) To promote respect for and the protection, preservation, wider application and development of the collective knowledge of indigenous peoples;
- (b) To promote the fair and equitable distribution of the benefits derived from the use of that collective knowledge;
- (c) To promote the use of the knowledge for the benefit of the indigenous peoples and mankind in general;
- (d) To ensure that the use of the knowledge takes place with the prior informed consent of the indigenous peoples;
- (e) To promote the strengthening and development of the potential of the indigenous peoples and of the machinery traditionally used by them to share and distribute collectively generated benefits under the terms of this regime;
- (f) To avoid situations where patents are granted for inventions made or developed on the basis of collective knowledge of the indigenous peoples of Peru without any account

being taken of that knowledge as prior art in the examination of the novelty and inventiveness of the said inventions.

TITLE V

GENERAL PRINCIPLES

Article 6. - Conditions of access to collective knowledge

Those interested in having access to collective knowledge for the purposes of scientific, commercial and industrial applications shall apply for the prior informed consent of the representative organizations of the indigenous peoples possessing collective knowledge. The organization of the indigenous peoples whose prior informed consent has been applied for shall inform the greatest possible number of indigenous peoples possessing the knowledge that it is engaging in negotiations and shall take due account of their interests and concerns, in particular those connected with their spiritual values or religious beliefs. The information supplied shall be confined to the biological resource to which the collective knowledge under negotiation relates in order to safeguard the other party's interest in keeping the details of the negotiation secret.

Article 7. - Access for the purposes of commercial or industrial application

In the event of access for the purposes of commercial or industrial application, a license agreement shall be signed in which terms are provided that ensure due reward for the said access and in which the equitable distribution of the benefits deriving therefrom is guaranteed.

Article 8. - Percentage accruing to the Fund for the Development of Indigenous Peoples

A percentage which shall not be less than ten percent of the value, before tax, of the gross sales resulting from the marketing of goods developed on the basis of collective knowledge shall be set aside for the Fund of the Development of Indigenous Peoples provided for in Articles 37 *et seq.* The parties may agree on a greater percentage according to the degree of direct use or incorporation of the said knowledge in the resulting end product and the degree to which the said knowledge contributed to the reduction of the cost of research and development work on derived products, among other things.

Article 9. - Role of present generations

The present generations of the indigenous peoples shall preserve, develop and administer their collective knowledge for the benefit of future generations as well as for their own benefit.

Article 10. - Collective nature of the knowledge

The protective knowledge protected under this regime shall be that which belongs to an indigenous people and not to particular individuals forming part of that people. It may belong to two or more indigenous peoples. The rights shall be independent of those that may come into being within the indigenous peoples, which may have recourse to their traditional systems for the purposes of the distribution of benefits.

Article 11. -Collective knowledge and cultural heritage

Collective knowledge forms part of the cultural heritage of indigenous peoples.

Article 12. -Inalienability and indefeasibility of rights

Because they form part of the cultural heritage, the rights of indigenous peoples in their collective knowledge shall be inalienable and indefeasible.

Article 13. -Collective knowledge in the public domain

For the purposes of this regime, it shall be understood that collective knowledge is in the public domain when it has been made accessible to persons other than the indigenous peoples by mass communication media such as publication or, when the properties, uses or characteristics of a biological resource are concerned, where it has become extensively known outside the confines of the indigenous peoples and communities. In cases where the collective knowledge has passed into the public domain within the previous 20 years, a percentage of the value, before tax, of the gross sales resulting from the marketing of the goods developed on the basis of that knowledge shall be set aside for the Fund for the Development of Indigenous Peoples provided for in Articles 37 *et seq.*

Article 14. -Representatives of indigenous peoples

For the purposes of this regime, indigenous peoples shall be represented by their representative organizations, due regard being had to the traditional forms of organization of the indigenous peoples.

TITLE VI

REGISTERS OF THE COLLECTIVE KNOWLEDGE
OF INDIGENOUS PEOPLES

Article 15. -Registers of the collective knowledge of indigenous peoples

The collective knowledge of indigenous peoples may be entered in three types of register:

- (a) Public National Register of Collective Knowledge of Indigenous Peoples;
- (b) Confidential National Register of Collective Knowledge of Indigenous Peoples;
- (c) Local Registers of Collective Knowledge of Indigenous Peoples.

The Public National Register of Collective Knowledge of Indigenous Peoples and the Confidential National Register of Collective Knowledge of Indigenous Peoples shall be under the responsibility of INDECOPI.

Article 16. -Purpose of the Registers of Collective Knowledge

The purposes of the Registers of Collective Knowledge of Indigenous Peoples shall be the following, as the case may be:

(a) to preserve and safeguard the collective knowledge of indigenous peoples and their rights therein ;

(b) to provide INDECOPI with such information as enables it to defend the interests of indigenous peoples where their collective knowledge is concerned.

Article 17. - Character of the Public National Register of Collective Knowledge of Indigenous Peoples

The Public National Register of Collective Knowledge of Indigenous Peoples shall contain such collective knowledge as is in the public domain. INDECOPI shall register the collective knowledge that is in the public domain in the Public National Register of Collective Knowledge of Indigenous Peoples.

Article 18. - Character of the Confidential National Register of Collective Knowledge of Indigenous Peoples

The Confidential National Register of Collective Knowledge of Indigenous Peoples may not be consulted by third parties.

Article 19. - Registration at the request of indigenous people s

Any people may, through its representative organization, apply to INDECOPI for the registration of collective knowledge possessed by it in the Public National Register or in the Confidential National Register.

Article 20. - Applications for the registration of collective knowledge

Applications for the registration of collective knowledge of indigenous peoples shall be filed with INDECOPI through the representative organizations of the said peoples, and shall contain the following:

- (a) Identity of the indigenous people applying for registration of its knowledge;
- (b) Identity of the representative;
- (c) Designation of the biological resource to which the collective knowledge relates, it being possible to use the indigenous name;
- (d) A mention of the use or uses that are made of the biological resource concerned;
- (e) A clear and full description of the collective knowledge to be registered;
- (f) The instrument embodying the agreement of the indigenous people to the registration of the knowledge.

The applications shall be accompanied by a sample or specimen of the biological resource to which the collective knowledge to be registered relates. In cases where the sample or specimen is difficult to transport or manipulate, the indigenous people applying for

registration may request INDECOPi to exempt it from the submission of the said sample or specimen and to allow it to file instead photographs that allow the characteristics of the biological resource to which the collective knowledge relates to be ascertained. The said sample or specimen, or as the case may be the said photographs, shall enable INDECOPi to identify unmistakably the biological resource concerned and to enter the scientific name thereof in the file.

Article 21. - Processing of the application

INDECOPi shall satisfy itself, within a period of ten days after the filing of the application, that the said application contains all the data specified in the foregoing Article. Where anything has been omitted, the indigenous people applying for registration shall be served notice to complete the application within a period of six months, which period may be renewed at its request, with a warning that otherwise the application shall be declared abandoned. Once INDECOPi has satisfied itself that the application contains all the data specified in the foregoing Article, it shall proceed to register the collective knowledge in question.

Article 22. - Sending of representatives of INDECOPi

In order to make the registration of collective knowledge of indigenous people easier, INDECOPi may send duly accredited representatives to the various indigenous peoples for the purpose of gathering the information necessary for the prosecution of such applications for registration as they may wish to file.

Article 23. - Obligation on INDECOPi to send the information contained in the Public National Register to the main patent offices of the world

With a view to its opposing pending patent applications, disputing granted patents or otherwise intervening in the grant of patents for goods or processes produced or developed on the basis of collective knowledge, 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.

Article 24. - Local registers of collective knowledge of indigenous peoples

Indigenous peoples may organize local registers of collective knowledge in accordance with their practices and customs. INDECOPi shall lend technical assistance in the organization of such registers at the request of the indigenous peoples.

TITLE VII

LICENSING

Article 25. - Compulsory registration of license contracts

License contracts shall be entered in a register kept for the purpose by INDECOPi.

Article 26. - Compulsory written form for license contracts

The representative organization of indigenous peoples in possession of collective knowledge may license third parties to use the said collective knowledge only by written contract, in the native language and in Spanish, for a renewable period of not less than one year or more than three years.

Article 27. - Contents of the license contract

For the purposes of this regime, contracts shall contain at least the following clauses:

- (a) Identification of the parties;
- (b) A description of the collective knowledge to which the contract relates;
- (c) A statement of the compensation that the indigenous peoples receive for the use of their collective knowledge; such compensation shall include an initial monetary or other equivalent payment for its sustainable development, and a percentage of not less than five percent of the value, before tax, of the gross sales resulting from the marketing of the goods developed directly and indirectly on the basis of the said collective knowledge, as the case may be;
- (d) The provision of sufficient information on the purposes, risks and implications of the said activity, including any uses of the collective knowledge and its value where applicable;
- (e) The obligation on the licensee to inform the licensor periodically, in general terms, of progress in the research on and industrialization and marketing of the goods developed from the collective knowledge to which the licensee relates;
- (f) The obligation on the licensee to contribute to the improvement of the ability of the indigenous peoples to make use of the collective knowledge relating to its biological resources.

Where the contract embodies a safeguard obligation, it shall expressly state.

INDECOPi shall not register contracts that do not conform to the provisions of this Article.

Article 28. - Applications for registration of license contracts. Confidentiality of the contract

Applications for the registration of a license contract filed with INDECOPi shall enclose the following:

- (a) Identity of the indigenous peoples party to the contract and their representatives;
- (b) Identity of the other parties to the contract and their representatives;
- (c) A copy of the contract;
- (d) The instrument evidencing agreement to enter into a license contract on the part of the indigenous peoples party to the contract.

The contract may not be consulted by third parties except with the express permission of both parties.

Article 29. -Processing of the application

INDECOPI shall satisfy itself within ten days of the filing of the application that it contains all the data specified in the foregoing Article. If anything has been omitted it shall serve notice on the party who applied for the registration to complete the application within a period of six months, which period may be renewed at this request, with the warning that otherwise the applications shall be declared abandoned.

Article 30. -Verification of the contents of the contract

With a view to the registration of a license INDECOPI shall, within 30 days of the filing of the application, satisfy itself that the clauses mentioned in Article 27 have been included.

Article 31. -Additional information on environmental impact

INDECOPI shall request additional information, either at the request of a party or *ex officio*, in cases where it considers that there is risk of the balance of the environment being affected in the territories inhabited by the indigenous peoples as a result of the contract filed for registration. Registration of the contract shall be refused if such a risk is detected and where the parties fail to undertake to do what is necessary to avoid it to the extent required by the national authority responsible for environmental concerns.

Article 32. -Scope of licenses for use

The licensing of the use of the collective knowledge of an indigenous people shall not prevent others from using or licensing the same knowledge, nor shall it affect the right of present and future generations to continue to use and develop collective knowledge.

Article 33. -Prohibition of sublicensing

Sublicensing shall be allowed only with the express permission of the representative organization of the indigenous people that granted the license.

TITLE VIII

CANCELLATION OF REGISTRATION

Article 34. - Causes of cancellation

INDECOPI may, either *ex officio* or at the request of a party, cancel registration of collective knowledge or a license, after the parties concerned have been heard, where:

- (a) the registration or license has been granted in violation of any of the provisions of this regime;
- (b) it is shown that the essential data contained in the application are false or inaccurate.

Cancellation actions arising out of this Article may be initiated at any time.

Article 35. - Request for cancellation

The request for cancellation of a registration shall record or enclose, as the case may be, the following:

- (a) Identity of the party requesting cancellation;
- (b) Identity of the representative or agent, if any;
- (c) Registration affected by the cancellation;
- (d) A statement of the legal grounds for the action;
- (e) Evidence substantiating the grounds for cancellation invoked;
- (f) Address at which notice was served on the owner of the registration whose cancellation is requested;
- (g) Where appropriate, copies of whatever powers of attorney are necessary;
- (h) Copies of the application and its enclosures for the owner of the registration.

Article 36. - Processing of the request

The request for cancellation shall be notified to the owner of the registration, who shall be allowed a period of 30 days to make his rebuttal. After that period, INDECOPI shall settle the issue with or without the relevant rebuttal.

TITLE IX

FUND FOR THE DEVELOPMENT OF INDIGENOUS PEOPLES

Article 37. - Purpose of the Fund for the Development of Indigenous Peoples

The Fund for the Development of Indigenous Peoples and Communities is hereby created for the purpose of contributing to the comprehensive development of indigenous peoples through the financing of projects and other activities. The Fund shall enjoy technical, economic, administrative and financial autonomy.

Article 38. - Access to the resources for the Fund for the Development of Indigenous Peoples and Communities

Indigenous peoples shall have the right to draw on the resources of the Fund for the Development of Indigenous Peoples through their representative organizations for the purpose of development projects, subject to prior evaluation and approval by the Administrative Committee.

Article 39. - Administration of the Fund for the Development of Indigenous Peoples

The Fund for the Development of Indigenous Peoples shall be administered by five members of representative organizations of indigenous peoples and two members of the National Commission for the Andean, Amazonian and Afro-Peruvian Peoples, who shall constitute the Administrative Committee. The Committee shall to the extent possible use the machinery traditionally used — by indigenous peoples — for allocating and distributing collectively-generated benefits. The Administrative Committee shall give the representative organizations of indigenous peoples quarterly information on funds received.

Article 40. - Obligation on members of the Administrative Committee to submit sworn statements

The members of the Administrative Committee shall, on taking up their duties and annually thereafter, submit a sworn statement of assets and income to the National Commission for the Andean, Amazonian and Afro-Peruvian Peoples.

Article 41. - Resources of the Fund for the Development of Indigenous Peoples

The resources of the Fund for the Development of Indigenous Peoples shall be derived from the State budget, international technical cooperation, donations, the percentage of economic benefits referred to in Articles 8 and 13, the fines referred to in Article 62 and other sources.

TITLE X

PROTECTION CONFERRED BY THIS REGIME

Article 42. - Rights of indigenous peoples possessing collective knowledge

Indigenous peoples possessing collective knowledge shall be protected against the disclosure, acquisition or use of that collective knowledge without their consent and in an improper manner provided that the collective knowledge is not in the public domain. It shall likewise be protected against unauthorized disclosure where a third party has legitimately had access to collective knowledge covered by a safeguard clause.

Article 43. - Actions for violation of rights of indigenous peoples

Indigenous peoples possessing collective knowledge may bring infringement actions against persons who violate the rights specified in the foregoing Article. An infringement action shall also be permissible where there is an immediate danger of such violation. Infringement actions may be brought *ex officio* by order of INECOPI.

Article 44. - Reversal of the burden of proof

Where infringement of the rights of an indigenous people possessing specific collective knowledge is alleged, the burden of proof shall be on the defendant.

Article 45. - Actions claiming ownership and indemnification

The representative organizations of indigenous peoples possessing collective knowledge may bring the actions claiming ownership and indemnification that are available to them under the laws in force against a third party who, in a manner contrary to the provisions of this regime, has directly or indirectly made use of the said collective knowledge.

Article 46. - Settlement of disputes between indigenous peoples

In order to settle such disputes as may arise between indigenous peoples in connection with the implementation of this regime, including those concerning the compliance, on the part of the indigenous people that has negotiated a license contract for the use of its collective knowledge, with the provisions of the second paragraph of Article 6 of this Law, they may have recourse to the law of equity and to their traditional forms of dispute settlement, it being possible to apply to a higher-ranking indigenous organization for mediation.

TITLE XI

INFRINGEMENT ACTIONS

Article 47. - Contents of the complaint

Indigenous peoples wishing to bring an infringement action shall submit an application, through their representative organization, to the Office of Inventions and New Technology, which shall contain:

- (a) the identity of the representative organization of the indigenous peoples bringing the action, and that of their representatives;
- (b) the identity and address of the party committing the infringement;
- (c) a mention of the registration number assigned to the rights of the complainant or, failing that, a description of the collective knowledge and a mention of the biological resource to which the collective knowledge at issue relates;
- (d) an account of the facts constituting the infringement, with a mention of the place and of the means actually or presumably used, and any other relevant information;
- (e) a submission or offer of proof;
- (f) an express mention of the provisional measure applied for.

Article 48. - Processing of the complaint

Once the complaint has been accepted for processing, it shall be conveyed to the defendant so that the latter may submit this rebuttal. The period for the filing of the rebuttal shall be five years following notification, on the expiry of which the administrative authority of INDECOPi shall declare the defendant who has failed to file it to be in contempt. In the case of *ex officio* procedures, the period for the filing of rebuttals shall start on the date on which the administrative authority notifies the defendant of the circumstances being investigated, and also the nature and description of the alleged infringement. The administrative authority of INDECOPi may make such inspections and investigations as it considers necessary before sending the said notification. The complaint may be notified at the same time as an inspection is made, either at the request of the plaintiff or *ex officio*, where the administrative authority of INDECOPi considers such a step judicious.

Article 49. - Provisional measures

At any stage in the proceedings, either *ex officio* or at the request of a party, the administrative authority of INDECOPi may, within the limits of its relevant competence, order one or more of the following provisional measures in order to ensure compliance with the final ruling:

- (a) Cessation of the acts that gave rise to the action;
- (b) The seizure, confiscation or immobilization of the goods produced using the collective knowledge to which the action relates;
- (c) The adoption of the measures necessary to ensure that the customs authorities prevent the entry into the country and the departure from it of goods produced using the collective knowledge to which the action relates;
- (d) The temporary closure of the defendant's premises;
- (e) Any other measure whose purpose is to avoid the occurrence of any prejudice deriving from the act to which the action relates, or to bring about the cessation of that act.

The administrative authority of INDECOPi may, if it sees fit, order a provisional measure different from that requested by the interested party. The party against whom a provisional measure is ordered may file a request with INDECOPi to have it modified or lifted where new evidence comes to light that justifies such a step.

Article 50. - Failure to comply with a provisional measure

Where the party required to comply with a provisional measure ordered by the administrative authority of INDECOPi fails to do so, he shall be automatically subjected to a sanction not exceeding the maximum of the permitted fine, for the gradation of which due regard shall be had to the criteria used by the administrative authority of INDECOPi for handing down final rulings. That fine shall be paid within a period of five days of notification, on the expiry of which enforced collections shall be ordered. Where the party under obligation persists in failing to comply, he shall be subjected to further fines successively doubling, without limitation, the amount of the previous fine imposed until the provisional measure ordered is complied with, and without prejudice to the possibility of the party responsible being reported to the Public Prosecutor with a view to the latter ordering the appropriate criminal proceedings. The fines imposed shall not prevent the administrative

authority of INDECOPI from imposing a different fine or other sanction at the end of the proceedings.

Article 51. - Conciliation

At any stage in the proceedings, until such time as the complaint is entertained, the competent administrative authority of INDECOPI may summon the parties to a conciliation hearing. If both parties arrive at an agreement on the complaint, an instrument shall be drawn up recording the agreement concerned, which will have the effect of an out-of-court settlement. The administrative authority of INDECOPI may in any event continue with the proceedings *ex officio* if it considers, on analyzing the circumstances reported, that third-party interests might still be affected.

Article 52. - Alternative disputes settlement mechanisms

At any stage in the proceedings, until such time as the complaint is entertained, the parties may submit to arbitration, mediation or conciliation or mixed disputes settlement arrangements conducted by third parties. Where the parties decide to submit to arbitration, they may immediately sign the appropriate arbitration convention in accordance with the rules that the governing body of INDECOPI shall have approved for the purpose. The administrative authority of INDECOPI may in any event continue with the proceedings *ex officio* if it considers, on analyzing the circumstances reported, that third-party interests might still be affected.

Article 53. - Evidence

The parties may submit the following forms of evidence:

- (a) Expert opinion;
- (b) Documents, including all kinds of written or printed matter, photocopies, plans, tables, drawings, x-rays, cinema film and other audio and video reproductions, computer-based communications in general and other subject matter and property that encompasses, contains or represents any factor of human activity or the result thereof;
- (c) Inspection.

Evidence different from that mentioned may be submitted as an exceptional measure, but only if, in the judgment of the competent administrative authority, it is of particular importance to the settlement of the case.

Article 54. - Inspection

In the event of an inspection being necessary, it shall be conducted by the competent administrative authority of INDECOPI. Whenever an inspection is conducted, a record shall be taken which shall be signed by the party in charge of it and also by the interested parties or those representing them, or by the appointed representative of the establishment concerned. Where the defendant, his representative or the appointed representative of the establishment refuses to sign, that fact shall be recorded.

Article 55. - Assistance of the National Police

The administrative authority of INDECOPI may, both for the administration of evidence and for the making of representations, request the intervention of the National Police, without prior notification being necessary, in order to ensure that it is able to carry out its functions.

Article 56. - Administration of evidence. Insufficiency of evidence

Where, on inspection of the information submitted, the administrative authority of INDECOPI considers it necessary to procure strong evidence, it shall serve notice on the parties to respond to the comments made within the period that the said authority shall specify, or shall administer *ex officio* such evidence as it considers necessary. The parties shall respond to the comments in writing, and shall submit such supporting evidence as they consider appropriate.

Article 57. - Oral report

The administrative authority of INDECOPI shall notify the parties that the case is ready for settlement. The parties may request the conduct of an oral proceeding before the said authority within five days. The acceptance or refusal of the said request shall be at the discretion of the administrative authority of INDECOPI, depending on the importance and implications of the case.

Article 58. - Calculation basis for fines

The amount of the fines imposed by the administrative authority of INDECOPI shall be calculated on the basis of the tax unit (UIT) applicable on the day of voluntary payment, or on the date on which enforced collection takes place.

Article 59. - Reduction of the fine

The fine applicable shall be reduced by 25 percent where the infringer pays the amount thereof prior to the expiry of the period for appealing against the ruling that concluded the proceedings, provided that no appeal against the ruling has been filed.

Article 60. - Expenses for administration of evidence

The cost of experts' reports, the administration of evidence and inspections, and other costs arising from the conduct of the proceedings shall be initially borne by INDECOPI. In all cases the final ruling shall determine whether the costs should be borne by one or other of the parties and refunded to INDECOPI in addition to the payment of any fine that may have been imposed.

Article 61. - Register of sanctions

INDECOPI shall keep a register of sanctions imposed for the information of the public and also in order to detect instances of recidivism.

Article 62. -Sanctions

Violations of the rights of indigenous peoples possessing collective knowledges shall give rise to the imposition of a fine, without prejudice to such measures as may be ordered to cause the infringing acts to cease or to prevent them from being committed. The fines that may be imposed shall be up to 150 tax units. The imposition and gradation of fines shall be determined according to the economic benefit secured by the infringer, the economic prejudice caused the indigenous peoples and communities and the conduct of the infringer throughout the proceedings. Recidivism shall be considered an aggravating circumstance, and the sanction applicable shall therefore not be less severe than the previous one. Where the defendant fails to comply within a period of three days with the terms of the ruling that concludes a proceeding, he shall be subjected to a sanction not exceeding the maximum of the fine allowed, according to the criteria referred to in the foregoing Article, and enforced collections shall be ordered. Where the defendant persists in failing to comply, the fine imposed may be successively doubled without limitation until such time as compliance occurs without prejudice to the possibility of the party responsible being reported to the Public Prosecutor with a view to the latter initiating the appropriate criminal proceedings.

TITLE XII

COMPETENT NATIONAL AUTHORITY AND INDIGENOUS KNOWLEDGE PROTECTION BOARD

Article 63. -Competent National Authority

The Office of Inventions and New Technology of the National Institute for the Defense of Competition and Intellectual Property (INDECOPI) shall be competent to hear and settle in the first instance all matters concerning the protection of the collective knowledge of indigenous peoples. The Intellectual Property Chamber of the Tribunal for the Defense of Competition and Intellectual Property of INDECOPI shall hear and settle all appeals in the second and last administrative instance.

Article 64. -Functions of the Office of Inventions and New Technology

The following shall be the functions of the Office of Inventions and New Technology of INDECOPI:

- (a) To maintain the Register of Collective Knowledge of Indigenous Peoples and keep it up to date;
- (b) To maintain the Register of Licenses for the Use of Collective Knowledge and keep it up to date;
- (c) To assess the validity of contracts for the licensing of collective knowledge of indigenous peoples, taking due account of the opinion of the Indigenous Knowledge Protection Board;
- (d) To perform such other functions as may be entrusted to it under these provisions.

Article 65. - Indigenous Knowledge Protection Board

The Indigenous Knowledge Protection Board shall be composed of five persons specialized in the subject, three of them designated by the representative organizations of indigenous peoples and two designated by the National Commission for the Andean, Amazonian and Afro-Peruvian Peoples, whose membership of the Board shall be honorary in character.

Article 66. - Functions of the Indigenous Knowledge Protection Board

The following shall be the functions of the Indigenous Knowledge Protection Board:

- (a) To monitor and oversee the implementation of this protection regime;
- (b) To support the Administrative Committee of the Fund for the Development of Indigenous Peoples and the Office of Inventions and New Technology of INDECOPI in the performance of their functions;
- (c) To give its opinion on the validity of contracts for the licensing of the collective knowledge of indigenous peoples;
- (d) To give advice and assistance to the representatives of indigenous peoples whose request regarding matters connected with this regime, and in particular in the planning and implementation of projects within the framework thereof;
- (e) To supervise the Administrative Committee of the Fund for the Development of Indigenous Peoples in the exercise of its functions.

To that end it may demand of the Administrative Committee any kind of information relating to the Fund's administration, order inspections or audits, examine its books and documents and appoint a representative who shall attend its meetings with the right to speak but not to vote. The decision ordering the conduct of an audit shall be accompanied by a statement of reasons. It shall be empowered to impose sanctions on them, including warnings, temporary suspension from the exercise of their functions or final dismissal from their positions, where they infringe the provisions of this regime or regulations under it, or where they are implicated in cases that affect the interests of indigenous peoples and communities, without prejudice to any criminal sanctions or civil actions that may be appropriate.

TITLE XIII

ADMINISTRATIVE APPEALS

Article 67. - Request for review

A request for the review of decisions handed down by the Office of Inventions and New Technology may be filed within 15 days following the notification thereof, and shall be accompanied by new evidence.

Article 68. -Appeal

An appeal, which shall be solely against a decision concluding proceedings that is handed down by the Office of Inventions and New Technology, may be lodged within 15 days following notification of the said decision. An appeal may not be lodged against first-instance rulings that impose provisional or precautionary measures.

Article 69. -Substantiation of appeals

Appeals shall be lodged when the challenger relies on a different interpretation of the evidence produced, or where purely legal questions are involved, the latter having to be substantiated before the Office of Inventions and New Technology. On verification of the requirements laid down in this Article and in the Single Text on Administrative Procedure (TUPA) of INDECOPI, the Offices shall allow the appeal and raise the case to the second administrative level.

TITLE XIV

PROCEDURE BEFORE THE TRIBUNAL

Article 70. -Second -instance procedure

When the file on the case has been received by the Intellectual Property Chamber of the Tribunal for the Defense of Competition and Intellectual Property of INDECOPI, the appeal shall be conveyed to the other party, who shall be required to submit his rebuttal within a period of 15 days.

Article 71. -Evidence and oral report

No evidence shall be allowed other than documents. Nevertheless, any of the parties may ask to speak, and shall be required to specify whether matters of fact or of law will be raised. The grant or refusal of the request shall be at the discretion of the Chamber of the Tribunal. Where the parties are summoned to an oral proceeding, it shall be conducted in the presence of those who attend it.

COMPLEMENTARY PROVISIONS

FIRST. -Independence of current intellectual property legislation. This special protection regime is independent of that provided for in Decisions 345 of the Commission of the Cartagena Agreement and 486 of the Commission of the Andean Community, in Legislative Decrees Nos. 822 and 823 and in Supreme Decree No. 008 -96-ITINCI.

SECOND. - Submission of the license contract as a requirement for obtaining a patent. Where a patent is applied for in respect of goods or processes produced or developed on the basis of collective knowledge, the applicant shall be obliged to submit a copy of the license contract as a prior requirement for the grant of the rights concerned, except where the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be a cause of refusal or invalidation, as the case may be, of the patent concerned.

TRANSITIONAL PROVISION

SOLE PROVISION. -Composition of the Administrative Committee of the Fund for the Development of Indigenous Peoples. The designation of the members of the Administrative Committee of the Fund for the Development of Indigenous Peoples shall be the responsibility of the National Commission for the Andean, Amazonian and Afro-Peruvian Peoples, and shall be coordinated with the representative organizations of the indigenous peoples.

FINAL PROVISION

SOLE PROVISION. -Rules of the Fund for the Development of Indigenous Peoples. Within a period of 90 days following the entry into force of this Law, the representative organizations of indigenous peoples shall submit draft rules to the Administrative Committee of the Fund for the Development of Indigenous Peoples, referred to in Article 39 of this Law, for approval. The said rules shall govern the organization and operation of the Fund for the Development of Indigenous Peoples, and shall determine the maximum amount or percentage of the Fund's resources that may be used to defray expenses incurred in its administration.

PORTUGAL

DECREE-LAW NO. 118/2002
April 20, 2002

The sovereign rights of States over their genetic resources and the fair and equitable allocation of benefits arising from their use are specified in the Convention on Biological Diversity, under which all Contracting Parties shall, as far as possible and as appropriate, promote the preparation of legislation and other regulatory provisions to protect species diversity and genetic resources.

Furthermore, paragraph 203(e) of the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture, adopted by the FAO International Technical Conference on Plant Genetic Resources in Leipzig in 1996, provides that governments shall consider legislative measures allowing the distribution and commercialization of local varieties.

Among these resources, and specifically with respect to plant material of agrarian, agroforestry and landscape interest, local varieties constitute a distinct part within the national genetic heritage. The adaptation of those varieties is promoted by the action of successive generations of farmers who recognize the importance of such material for adding economic value to the region, particularly through sustainable rural development.

In addition to this material, the genetic wealth embodied in spontaneously occurring autochthonous material is an equally important basis for the promotion of sustainable agrarian, agroforestry and landscape systems, particularly for the maintenance and development of agrobiodiversity.

The establishment of a mechanism for the legal registration of the aforementioned types of material – applicants for which may be public or private bodies of any kind, such as self-supporting businesses, farmers' associations, regional development associations or individuals – which relies on an adequate description and draws on reference collections specifically designated for the purpose, constitutes a valid basis for the identification of the material and consequently for its correct conservation *in situ* and *ex situ*.

The description of this material, the identity of which shall be defined in *suu generis* terms according to the particular characteristics of the population to which it belongs, further reinforces the grounds for formulating processes with which to protect appellations of origin and geographical indications and afford some kind of protection against any misappropriation of the material.

This instrument will likewise form the basis for the fair allocation of the benefits generated by the use of this material among the parties involved in their differentiation or maintenance or both. Finally, it will also make a positive contribution to the promotion of the secure interchange of plant genetic resources, at the same time ensuring the protection and preservation of the cultural diversity of local populations that is associated with the plant genetic resources of communities that have not had access to proper intellectual property machinery and so have seen innumerable technical contributions fall into the public domain or be appropriated by third parties without deriving any benefit therefrom.

The adoption and publication of this draft Decree -Law assumes the utmost importance and urgency on account of the obligations arising from the Convention on Biological Diversity signed by the EC on June 13, 1992, and approved on December 21, 1993, to which Portugal is party, and under which the signatory States undertook to adopt adequate legislative measures to allow the distribution and commercialization of local varieties.

Similarly, it is only through the adoption and publication of this regime of registration and protection of autochthonous plant material can measures be taken that allow certain specific plant genetic resources to be protected and safeguarded, thus ensuring the cultural diversity of local populations.

Under this Decree conditions may also be established for the collection of specific material with the aim of preventing its extinction.

Therefore:

By virtue of Article 198.1(a) of the Constitution, the Government decrees as follows:

ARTICLE 1. OBJECT

(1) This Decree establishes the legal regime for the registration, conservation, legal safeguarding and transfer of autochthonous plant material of current or potential interest to agrarian, agroforestry and landscape activity, including the local varieties and spontaneously occurring material referred to in Article 2, as well as associated knowledge, without prejudice to the provisions of Decree -Laws 316/89 of September 22 and 140/99 of April 24.

(2) The plant material covered by the application of this Decree, as defined in Articles 2(1) and (2), is considered a phyto-genetic resource of the utmost importance, since its access and use depend on the provisions established in this Decree and the regulations under it, without prejudice to current special legislation.

ARTICLE 2. SCOPE

(1) This Decree -Law applies to all local varieties and others spontaneously occurring autochthonous material of plant species that are of current or potential interest to agricultural, agroforestry or landscape activity, regardless of their genotypical composition, with the exception of varieties protected by intellectual property rights or concerning which the grant of such protection is pending.

(2) For the purposes of Articles 4 and 15, the species shall be fixed by joint decree of the Minister of Agriculture, Rural Development and Fisheries and the Minister of the Environment and Land Management on a proposal by the Directorate General for Crop Protection (DGPC) after the Technical Council of the Ministry of Agriculture, Rural Development and Fisheries on Agrarian Genetic Resources, Fisheries and Aquaculture (CoTeRGAPA) has been heard.

(3) Any plant material collected that is not included in the species referred to in paragraph (2) must be described by the collector, who shall supply free of charge a description and a representative sample of the material collected to the bodies authorizing the

collection or, in their absence, to the Regional Agricultural Directorate (DRA) of the geographical region in which the collection took place.

ARTICLE 3. TRADITION AL KNOWLEDGE

(1) Traditional knowledge comprises all intangible elements associated with the commercial or industrial utilization of local varieties and other autochthonous material developed in a non-systematic manner by local populations, either collectively or individually, which form part of the cultural and spiritual traditions of those populations. That includes, but is not limited to, knowledge of methods, processes, products and designations with applications in agriculture, food and industrial activities in general, including traditional crafts, commerce and services, informally associated with the use and preservation of local varieties and other spontaneously occurring autochthonous material covered by this Decree.

(2) That knowledge shall be protected against reproduction or commercial or industrial use or both as long as the following conditions of protection are met:

(a) the traditional knowledge shall be identified, described and registered in the Register of Plant Genetic Resources (RRGV);

(b) the description referred to above shall be so phrased that third parties may reproduce or utilize the traditional knowledge and obtain results identical to those obtained by the owner of the knowledge.

(3) The owners of the traditional knowledge may choose to keep it confidential, in which case the regulations shall provide for publication in the registration bulletin referred to in Article 12, which shall be limited to disclosure of the existence of the knowledge and identification of the varieties to which it relates, with the protection conferred by registration being limited to cases in which it is unfairly acquired by third parties.

(4) The registration of traditional knowledge that until it is requested has not been used in industrial activities or is not publicly known outside the population or local community in which it originated shall afford its owner the right to:

(i) object to its direct or indirect reproduction, imitation and/or use by unauthorized third parties for commercial purposes;

(ii) assign, transfer or license the rights in the traditional knowledge, including transfer by succession;

(iii) exclude from protection any traditional knowledge that may be covered by specific industrial property registrations.

(5) The entities defined in Article 9 of this Decree have the right to register traditional knowledge.

(6) The registration of traditional knowledge shall be effective for a period of 50 years from the application therefor, and may be renewed for an identical period.

(7) The provisions of Articles 7, 9, 10, 12, 13 and 14 shall apply *mutatis mutandis* to traditional knowledge.

ARTICLE 4. REGISTRATION OF PLANT MATERIAL

- (1) Plant material that falls within the scope of this Decree, as defined in Articles 2(1) and (2), may be registered in the RRGV, which shall be kept at the DGPC's National Center for the Registration of Protected Varieties.
- (2) Registered plant material must possess a designation and description that satisfy the conditions established by decree of the Minister of Agriculture, Rural Development and Fisheries.
- (3) The description of the plant material on which registration was based shall become the official description thereof for the purposes of this legislation.
- (4) The registration of the material referred to in paragraph (1) confers on the owner thereof the right to share in the benefits derived from its use, as provided in Article 7.
- (5) Registrations shall be granted by the Director General of Crop Protection, after CoTeRGAPA has been heard, in accordance with the conditions to be defined by joint decree of the Minister of Agriculture, Rural Development and Fisheries and the Minister of the Environment and Land Management.
- (6) Once registration of the specific plant material has been granted, it shall be included in the National Directory of Registrations of Plant Genetic Resources (LNRGV), for which the RRGV is responsible.

ARTICLE 5. DURATION OF REGISTRATION

Registrations shall be valid for a period of ten years and renewed for subsequent periods of the same duration, provided that the conditions required for the registration to be granted are maintained, on pain of termination.

ARTICLE 6. GOODS WITH AN APPELLATION OF ORIGIN OR GEOGRAPHICAL INDICATION

The plant material used in making goods with a protected appellation of origin or geographical indication must be registered, insofar as they are covered by this Decree, and then be entered in the directory referred to in Article 4(6).

ARTICLE 7. ACCESS TO AND ALLOCATION OF BENEFITS

- (1) Access to the germplasm of the plant material referred to in Articles 2(1) and (2) for the purposes of study, research, improvement or biotechnological applications shall be subject to prior authorization by CoTeRGAPA, the owner of the registration having been heard.
- (2) The use, for industrial or biotechnological purposes, of plants or parts thereof included in the plant material referred to in Articles 2(1) and (2), either directly or through application of the active ingredients contained in them, shall also be subject to prior authorization by CoTeRGAPA, and where appropriate by the competent body of the Ministry of the Environment and Land Management, the owner of the registration having been heard.

(3) In order to prevent them from becoming extinct, specific restrictions may apply at a local or national level to the collection or uprooting of plants of the species in question or of parts thereof, as determined by joint decree of the Minister of Agriculture, Rural Development and Fisheries and the Minister of the Environment and Land Management.

(4) Access as defined in paragraphs (1) and (2) requires a fair allocation of the benefits resulting from such use, by prior agreement with the owner of the registration.

ARTICLE 8. COMMERCIALIZATION

The rules governing the commercialization of seeds or propagules of plants included in the material mentioned in Articles 2(1) and (2) shall be the subject of a joint decree of the Minister of the Economy, the Minister of Agriculture, Rural Development and Fisheries and the Minister of the Environment and Land Management.

ARTICLE 9. APPLICANT FOR REGISTRATION

(1) An application for the registration of plant material covered by the provisions of Article 4(1) may be filed by any entity, whether public or private, individual or corporate, that fulfils the following conditions:

- (a) as required by paragraph (2) below, it represents the interests of the geographical area in which the local variety is most widely found or where the spontaneously occurring autochthonous material displays the greatest genetic variability;
- (b) it complies with the provisions of Article 10(3).

(2) To satisfy the conditions mentioned in (1)(a) above, the applicant shall be recognized by the competent municipal chamber by means of a document affirming the entity's fitness to protect the interests referred to in paragraph (1).

(3) The municipal chamber competent to confirm the recognition referred to above shall be that designated by CoTeRGAPA, the permanent representatives of the DRA having been heard, or by the competent body of the Ministry of the Environment and Land Management in the case of autochthonous wild species.

(4) In order to prove that the essential conditions for meeting the requirements of paragraph (1)(b) are present, the applicant shall submit a supporting document, approved by the DRA of the area in which the plant material in question is to be maintained.

ARTICLE 10. RIGHTS AND OBLIGATIONS OF THE OWNER OF THE REGISTRATION

(1) The entity owning the registration has the right to receive part of any benefits resulting from the use provided for in Articles 7(1) and (2).

(2) The performance of any of the acts provided for in Article 7(1) in the case of registered plant material may only be authorized after the owner of the registration has been heard.

(3) The owner of the registrations shall be responsible for the maintenance *in situ* of the registered plant material and for ensuring that it remains consistent with its official description, provided for in Article 4(3), and with the technical conditions laid down by CoTeRGAPA, and may delegate the performance of that task to others, in which case the RRGV shall be notified of the entity chosen for the purpose.

(4) For the purpose of inclusion in the reference collection or replacement of existing material, the owner of the registrations shall be obliged to provide the entity responsible for the coordination of reference collections, at its request and in the places specified by it, with propagating material corresponding to the registration that has the characteristics specified by the DGPC and conform to the official description referred to in Article 4(3).

ARTICLE 11. REFERENCE COLLECTION

(1) The entity responsible for the technical supervision of reference collections shall be the DGPC, and CoTeRGAPA shall promote and coordinate the establishment and maintenance of the reference collections, which must include all material registered at the regional or the national level, depending on what is most appropriate in each specific case.

(2) In the case of material registered or in the process of being registered, the owner of the reference collection may not supply it to third parties without authorization from the registration owner or applicant and a favorable ruling from CoTeRGAPA.

ARTICLE 12. REGISTRATION BULLETIN

The DGPC shall from time to time publish a bulletin reporting all materials submitted for registration and that which has already been registered in the LNRGV, and also traditional knowledge registered in accordance with the provisions of Article 3.

ARTICLE 13. VIOLATIONS

(1) The use of plants or parts thereof that constitute plant material within the meaning of Article 2(1) and (2) in a manner contrary to the provisions of Articles 7(1), (2) and (3) and to the regulation under this Decree, and also infringement of the provisions on traditional knowledge contained in Article 3, constitute violations punishable with a fine of between €100 and €2,500.

(2) Negligence is punishable.

(3) In the event of responsibility for the violation resting with a corporate entity, the maximum amount of fines shall be €30,000.

(4) The proceeds from fines shall revert to the DGPC (20%), the National Agrarian Research Institute (10%) and the DRA concerned (10%), with the remainder going to State funds.

(5) The DRA shall be competent to manage the violation proceedings provided for in this Article, and the Director General for Crop Protection shall be competent to impose the corresponding fines and accompanying sanctions.

ARTICLE 14 .ACCOMPANYING SANCTIONS

Depending on the seriousness of the violation and the degree of guilt of the party who committed it, the following accompanying sanctions may be imposed in addition to the fine according to the provisions of the general regime governing violations:

- (a) loss of the guilty party's property;
- (b) prohibition from the exercise of a profession or activity that requires a public enactment or the approval of a public authority;
- (c) removal of the right to participate in fairs and markets;
- (d) removal of the right to bid or to participate in tenders or public competitions in connection with the award of contracts for the execution of public works, the supply of goods and services, the rendering of public services and for the award of licenses and permits;
- (e) closure of an establishment that relies for its operation on authorization or licensing by an administrative authority;
- (f) suspension of authorizations, licenses and permits.

ARTICLE 15. CIVIL LIABILITY

The imposition of the fines referred to in the preceding Articles shall not prevent the owner from claiming his rights under Articles 7 and 10, and specifically the right to compensation and a share in benefits.

ARTICLE 16. FEES

Registration in the LNRGV or the RRGV is subject to the payment of fees to be fixed by joint decree of the Minister of Agriculture, Rural Development and Fisheries and the Minister of Finance.

ARTICLE 17. REGULATIONS

Implementing regulations under this Decree shall be enacted by joint decree of the Minister of Agriculture, Rural Development and Fisheries and the Minister of the Environment and Land Management.

Seen and approved in the Council of Ministers on January 23, 2002.

António Manuel de Oliveira Guterres
Guilherme de Oliveira Martins
António Luís Santos Costa
Luís Manuel Capoulas Santos
José Sócrates Carvalho Pinto de Sousa.

Promulgated on April 5, 2002.

Publication of the foregoing is hereby ordered.

The President of the Republic, JORGES AMPAIO.

Countersigned on April 5, 2002.

The Prime Minister, *António Manuel de Oliveira Guterres*.

[End of Annex III and of document]