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

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POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL PROPERTY AND GENETIC RESOURCES: COMMUNICATION BY COLOMBIA

Document prepared by the Secretariat

1. At its fifteenth session, held from December 7 to 11, 2009, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee'):

> "invited Member States and observers to make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources before February 12, 2010, and requested the Secretariat to make these available as information documents for the next session of the Committee." […]

2. Further to the decision above, the WIPO Secretariat issued a circular to all Committee participants, dated January 15, 2010, recalling the decision and inviting participants to make their submissions before February 12, 2010.

3. Pursuant to the above decision, the Delegation of Colombia submitted a document entitled “Colombia’s Regional, National and Community Policies, Measures and Experiences regarding Intellectual Property and Genetic Resources” and requested it be made available as an information document for the sixteenth session of the Committee.

4. The document is reproduced in the form received and contained in the Annex to this document.

[Annex follows]

ANNEX

COLOMBIA'S REGIONAL, NATIONAL AND COMMUNITY POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL PROPERTY AND GENETIC RESOURCES

Interinstitutional Working Committee on Recommendation 17 of Document Conpes 3533 of 2008, "Foundations for a Plan of Action for Aligning the Intellectual Property System with National Competitiveness and Productivity"

Background

In the framework of document CONPES 3533 of 2008 "Foundations for a Plan of Action for Aligning the Intellectual Property System with National Competitiveness and Productivity", adopted on July 14, 2008, a recommendation was made to the Ministry of Environment, Housing and Territorial Development; the Ministry of Trade, Industry and Tourism; the Ministry of Agriculture and Rural Development; the Ministry of Foreign Affairs; the National Planning Department and Colciencias to set up a working group to review Decision 391 on the Common Regime on Access to Genetic Resources of the Andean Community of Nations (CAN) with the aim of drawing up proposed rules for and/or an amendment to Decision 391 in order to prevent illegal use of the Nation's genetic resources and streamline the research, development and commercial use of these resources.

Since June 2008, the Committee set up has been working on the subject, starting by hiring two firms of consultants.

The two firms of consultants agreed to highlight some of the problems in the implementation of Decision 391, for which they also offered solutions – in some cases these were similar and in others different – which were reviewed by the Committee to finalize the proposed rules and/or amendment. Some of the points raised were:

1. The issue of access to genetic resources should become a high political and national priority.

2. Conceptual problems:

– Definitions such as access, intangible component, genetic resources, by-products, ex situ conservation center, supplier of the intangible component, supplier of the biological resource and national support institution need to be reviewed and altered so that their scope is clear to the applicant.

– The scope of the object to be accessed needs to be clarified.

– Clarification is needed with regard to the supplier of the object to be accessed.

3. Problems related to the process (procedure):

– The timeframe for the process is unclear, not enough data has been collected to make a decision, and there is only one process for the different uses of the genetic resource.

– The procedures for monitoring and controlling access to genetic resources must be optimized. The following mechanisms have been proposed: setting up robust information systems which make it possible to monitor activities under Decision 391; limiting the length of time an accessed resource can be used; defining the purpose of use and in order to do so establishing a procedure for informing the competent authority of the change in the use of the resource (from research to commercial use, etc.); developing and promoting the taking of inventories of native flora, fauna and micro-organisms, which help determine whether the accessed resource is owned by the Colombian State; and hiring audit firms.

– Holding prior consultation with indigenous communities and communities of African descent delays the process since it falls within the competence of a different authority. This subject needs to be looked at in more depth.

4. Problems related to institutional capacity:

– Capacity-building is necessary, both in the relevant national authority and other institutions, in terms of genetic resources. There are shortcomings in terms of: staff specialized in legal, scientific and economic matters; the availability of services and information for evaluation; the ability to negotiate contracts that are in the interests of the country and meet its needs; the ability to promote projects and proposals to improve the capacity to use genetic resources (bioprospecting, inventories, ex situ collections, etc.).

5. Problems related to contractual arrangements:

– In line with other environmental standards, a permit for scientific research on biodiversity has also been established (Decree 309 of 2000 – different from the access contract) which authorizes activities such as collecting, gathering, capturing, hunting, fishing and manipulating the biological resource, and organizing these on national territory. Considering the lack of clarity in the scope of the Andean Decision and the overlap in activities which can be authorized under this Decree, it seems necessary to establish one system to regulate these activities, which could be differentiated depending on the use of the resource. Furthermore, this would impose a two-fold procedure on scientific research institutions.

– Sanctions are not clear.

– The guidelines on equitable benefit-sharing (monetary and non-monetary) must be adapted.

6. Decision 391 is insufficiently disseminated and users of genetic resources are not aware of its existence.

The National Planning Department – DNP

A. Law 165 of 1994 adopts the "Convention on Biological Diversity – CBD" done at Rio de Janeiro on June 5, 1992. Its aims are the conservation of biological diversity, the sustainable use of its components, the fair and equitable sharing of benefits arising from the use of genetic resources by ensuring, *inter alia*, adequate access to those resources, the appropriate transfer of the relevant technologies, taking into account all rights over those resources and technologies, and the appropriate funding.

B. Decision 391 of 1996 of the Andean Community of Nations (CAN) on the Common Regime on Access to Genetic Resources, means that Colombia, in its capacity as a CAN member, has to implement the Convention on Biological Diversity (CBD).

The following developments to the Andean Decision have been made:

– Resolution 414 of the Board of the Cartagena Agreement of July 22, 1996, which adopts the reference model for applications for access to genetic resources.

– Decree 730 of March 14, 1997, which designates the Ministry of Environment, Housing and Territorial Development as the competent national authority on matters related to access to genetic resources. In 1997, the internal procedure for the processing of applications for access to genetic resources and their by-products was also established under Resolution 620 of July 1997 of what is now the Ministry of Environment, Housing and Territorial Development.

– Decree 216 of 2003 sets out the objectives, organizational structure of the Ministry of Environment, Housing and Territorial Development, and other provisions. The Directorate for Ecosystems is responsible for ensuring that national sovereignty and the rights of the Nation over its genetic resources are observed in the study, exploration and research of natural genetic resources by nationals and foreigners, and drafting and developing a legal framework for genetic resources.

– Resolution 1393 of 2007 establishes that the Ministry of Environment, Housing and Territorial Development's duties include speeding up the application process for access to genetic resources, accepting or rejecting an application and settling appeals for reversal by the Advisor, Code 1020, grade 13 of the Directorate for Licenses, Permits and Environmental Procedures and signing contracts for access to genetic resources at the Directorate for Licenses, Permits and Environmental Procedures.

– Decree 309 of 2000 on research on biological resources establishes study permits for scientific research purposes on biological diversity. This standard seeks to develop the freedom of teaching, learning and research, and the duty of the State to protect environmental diversity and integrity (Article 79 of the Political Constitution of 1991).

C. CAN Decision 486 of 2000 on the Common Regime on Industrial Property, stipulates that the protection of industrial property is granted while safeguarding and respecting

biological and genetic heritage, and the traditional knowledge of its indigenous, Afro-American or local communities.

Article 26 therefore provides that patent applications must include a copy of the access contract where products or procedures for the application have been obtained or developed on the basis of genetic resources or their by-products whose country of origin is a Member State. A copy of the document granting the license or authorization for use of traditional knowledge of indigenous, Afro-American or local communities of the Member States is also required when products or procedures for which protection is requested have been obtained or developed on the basis of the said knowledge.

In order for the said requirement to be effective, Article 75 of the aforementioned Decision states that the competent national authority shall declare either *ex oficio* or at the request of any person at any time that a patent is null and void where copies of each of the requisite documents were not submitted.

D. Decision 523 of 2002 on the Regional Biodiversity Strategy for the Tropical Andean Countries adopts this strategy, mandates the Andean Committee of Environmental Authorities (CAAAM) to update and strengthen the strategy, to draft a plan of action and a roadmap for projects on the basis of the approaches to the implementation of the strategy and to submit reports to the Andean Council on the progress of the updating process. The strategy, in annex to the Decision, includes an assessment, comprehensive framework, a vision, principles, strategic approaches and objectives, courses of action and results, instruments and an analysis of the feasibility of the strategy.

Ministry of Interior – Directorate for Indigenous, Minority and Roma Affairs

The phrase “intellectual property” covers all the creations of the human mind and is linked to the “right to ownership”, which can be applied to these creations. They are the product of the intellect: sculptures, literary works, musical works, inventions, designs, videos, integrated circuits, computer programs, scientific works, etc.

The intellectual property system in Colombia is primarily regulated by the Supervisory Authority for Industry and Trade and the National Directorate of Copyright.

This system is principally governed by the following standards:

A. Legal standards under the Constitution:

- Political Constitution of Colombia: Articles 15, 61, 150-24 and 188-27.

B. Internal legal standards:

– Civil Code of Colombia: Article 671.

– Law 23 on Copyright of January 28, 1982.

– Law 44 of February 5, 1993, amending Law 23 of 1982 and Law 29 of 1944.

– Law 719 of 2001, amending Law 23 of 1982 and Law 44 of 1993. Ruling C-975.2002 of the Constitutional Court of November 13 declared this Law could not be implemented.

– Decree 1184 of 1999 ordered the National Directorate of Copyright attached to the Ministry of Interior to be suspended and dissolved, and its duties transferred to the Supervisory Authority for Industry and Trade and a Superintendent appointed for industrial property matters.

C. Legal standards of the Andean Community:

– Decision 351 on the Common Provisions on Copyright and Neighboring Rights, regulating Law No. 23 of January 28, 1982, and Law No. 44 of February 5, 1993.

– Decision 244 on the Common Regime on Industrial Property.

– Decision 486 on the Common Regime on Industrial Property, which entered into force on December 1, 2000.

– Decree 0575 of April 3, 1992, which partially regulates Decision 313 of the Commission of the Cartagena Agreement, Official Journal 40412 of April 8, 1992.

– Decree 0117 of January 14, 1994, which regulates Decision 344 of the Commission of the Cartagena Agreement, Official Journal 41174 of January 14, 1994.

– Decree 0698 of March 14, 1997, which regulates Article 107 of Decision 344 of 1993 of the Commission of the Cartagena Agreement, Official Journal 43006, March 19, 1997.

– Decision 345 on the Common Provisions on the Protection of Rights of Breeders of New Plant Varieties.

– Decision 391 on the Common Regime on Access to Genetic Resources.

D. International legal standards; Treaties signed by Colombia:

– Geneva Treaty on the International Registration of Audiovisual Works; Law 26 of 1992.

– Berne Convention for the Protection of Literary and Artistic Works; Decree 1042 of 1994.

Similarly, the National Economic and Social Policy Council produced the document CONPES 3533 entitled “Foundations for a Plan of Action for Aligning the Intellectual Property System with National Competitiveness and Productivity for 2008-2010”, which outlines six concrete strategies to bring the intellectual property system in line with international standards, and which ensure the intellectual property system’s effectiveness and efficiency.

Colombia has not adopted any domestic legislation with regard to genetic resources. The only precedent is Decision 391 on the Common Regime on Access to Genetic Resources, which was adopted in the framework of the Andean Community of Nations. The negotiations on Colombia's position are also moving forward in the framework of the CBD.

Regional measures have not been adopted, which is why every legal or administrative measure which is to be adopted and which has a direct or indirect impact on ethnic groups must first undergo the prior consultation process

The Ministry of Social Protection - INVIMA

Pursuant to Decision 486 of the Andean Community of Nations, Colombia issued Decree 2085 of 2002, which regulates aspects related to the protection of test data from the information collected in order to draw up a health register for drugs, as this is the applicable legal framework for the protection of test data in Colombia.

In implementing the said Decree of 2002, the National Institute of Food and Drug Monitoring (INVIMA) has granted protection for test data of different molecules. In 2009, 16 molecules were granted data protection for undisclosed information.

INVIMA is constantly working on the protection and enforcement of intellectual property rights. By way of summary, the following actions which have been undertaken for the protection of pharmaceuticals and similar products derived from research on genetic resources are particularly noteworthy:

Colombia is now making headway thanks to INVIMA with regard to penal proceedings brought before its Office of the Legal Counsel; it has 3,082 ongoing cases, of which 148 are penal proceedings which have been brought for drugs, but only 18 of which are for counterfeit drugs.

Decree 677 of 1995, which is also the legal framework for processing health registrations of drugs, does not include the definition of counterfeit drugs, which is why these investigations are conducted by the Public Prosecutor's Office. Nevertheless, penal proceedings were started for counterfeit drugs pursuant to Article 2 of Decree 677 of 1995.

In 2009, 729 visits for inspection, monitoring and control purposes were carried out and 51 health safety measures were issued, including seizures, denaturation, freezing, total suspension of activity and suspension of advertising; all of these cases were for non-compliance with the Sanitary Standard for Products from Manufacturing Establishments in force.

In the light of this, it is worth mentioning that Colombia implements mechanisms for combating the scourge of counterfeiting and adulteration of drugs. Some examples of the progress made in the past few years are the progress with regard to legal issues and groups set up to work exclusively on these issues; sanctions have become stricter for persons committing this type of infringement and a standard is being developed which allows for the use of electronic tagging of drugs, the purpose of which is to address the issue of counterfeit drugs. The National Convention to Combat Drugs on the Illegal Market was created, which seeks to eradicate the illegal production and marketing of drugs which are counterfeit,

adulterated, pilfered, smuggled or have changed commercial channels. Industrial Associations, the Government and various government bodies and any Colombian buying drugs in an authorized establishment are involved in this.

Work is constantly being done to ensure greater cooperation and coordination, not only between the various state agencies concerned with this issue, but also with other countries in the region, in order to develop strategies to combat infringements of this type more effectively.

In addition to this, it should be noted that the responsibility for combating the illegal trade of drugs in Colombia, does not lie solely in the State. INVIMA is developing strategies that contribute to this combat, in which the following players should also be actively involved:

– The various establishments involved in the manufacture, intermediate and final marketing of products: manufacturers, wholesalers, healthcare institutions, drug stores, distributors, supermarkets, etc

– Patients or users of the products: there is no black market if no one buys these products. You can make a difference by buying such products in authorized establishments. Timely reporting is therefore the most effective tool that the State has for inspection, monitoring and control.

– At the community level, INVIMA has created a policy which involves the community in the monitoring process, that is to say, users survey the market.

However, despite considerable effort and investment in this area, some problems still persist. One of the problems identified is the counterfeiting of expensive drugs, mainly those to treat cancer and HIV/AIDS and some of the new generation of antibiotics, which is in keeping with the world-wide trend for these types of illegal products. This has been identified as a threat, and various international organizations have already reported on the Internet marketing of drugs and other products which have a direct impact on consumer health, which is administered remotely and is difficult to control.

REGIONAL, NATIONAL AND COMMUNITY EXPERIENCES REGARDING INTELLECTUAL PROPERTY AND GENETIC RESOURCES

Ministry of Interior – Directorate for Indigenous, Minority and Roma Affairs

The indigenous peoples of Colombia have expressed the importance of the said standards on intellectual property and genetic resources on the national and international stage but have also stated that these are insufficient and inadequate for real and effective protection of their traditional knowledge given that these standards are based on the recognition of individual rights, which do not take into account the importance of indigenous peoples' collective knowledge. That is to say, there are no individual inventors in indigenous communities but rather traditional knowledge and practices are created and transformed in collective fashion. The indigenous peoples of Colombia therefore demand the effective protection of their traditional knowledge through a special *sui generis* system which provides for the importance of collective rights.

Document CONPES 3533 of July 2008 recommends that a public policy be drawn up on the protection of traditional knowledge and recognition of a *sui generis* system. In order to do this, the Directorate for Indigenous Affairs of the Ministry of Interior has linked the process to the Comprehensive Public Policy for the Indigenous Peoples of Colombia in the framework of the Standing Committee on National Consultation.

The first area covered in the Comprehensive Public Policy for Indigenous Peoples is "territory". It looks at the importance of developing and establishing rules regulating the use, management and conservation of natural resources and the design and implementation of multi-criteria assessment systems for the components of biodiversity and the equitable sharing of benefits. Other areas covered in this policy are traditional knowledge, genetic resources and biodiversity as an integral part of the protection of indigenous rights and the survival of ancestral cultural systems. Thus, the part entitled "self-government" covers the need to strengthen the specific forms of self-government with the aim, *inter alia*, of recovering and protecting values and knowledge of the elders and the wise men and women of indigenous communities. Similarly, areas such as health and food sovereignty are also closely linked to the protection of ancestral knowledge and respect for different forms of understanding and relating to the environment and territory.

On the whole, the draft of the Comprehensive Public Policy for Indigenous Peoples includes the integral protection of traditional knowledge and genetic resources because they are fundamental to the physical and cultural survival of communities.

Currently, the approaches in the Comprehensive Public Policy are being discussed in the Standing Committee on National Consultation together with national indigenous organizations and the indigenous authorities of all the peoples in the country.

In terms of the community experience related to genetic resources and intellectual property, the "Higher Law" in particular stands out, which was enacted by the Guambiano Indigenous People; its purpose is to promote the respect, protection and conservation of the Guambiano territory, including biodiversity, by ensuring the cultural preservation of the people and the protection of their collective knowledge and wisdom.

The law prohibits *inter alia*:

– The use of the Guambiano territory to introduce, sow, use and market seeds and transgenic products and their derivatives, as well as plants whose purpose is contrary to the natural order and culture.

– Access, research, output, use and marketing of the genetic resources of the Guambiano people.

– Studies and research that lead to the misappropriation and privatization of any element of the Guambiano natural or cultural heritage.

– Any form of misappropriation and privatization of the components of natural, biological, genetic, mineral, water resources, whether tangible or intangible, and material and non-material cultural elements which exist in our people and territory.

– Making available genetic resources in contracts, agreements or environmental service projects or any other type of project, including licensing and sale documents, or the extracting of information about their use and management.

– Any kind of intellectual or industrial property rights granted on the basis of genes or any product obtained through their genetic manipulation, on elements of biodiversity, its genetic content, or any product derived from its genetic manipulation or similar, and on elements of the Guambiano identity.

Although the application of the Guambiano law is limited in accordance with the institutional capacities of traditional authorities of this people, it is important to mention this case as it shows that there is an awareness of the issue within indigenous communities and the importance they attach to the issue. It also describes their demands to enforce the protection of ancestral knowledge and related genetic resources.

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