DECISION 391
Common Regime on Access to Genetic Resources

THE COMMISSION OF THE CARTAGENA AGREEMENT,

HAVING SEEN:

The Third Temporary Provision of Commission Decision 345 and Board Proposal 284/Rev. 1;

WHEREAS:

The Member Countries have sovereignty over the use and development of their resources, a principle that has also been ratified by the Agreement on Biological Diversity, signed in Rio de Janeiro in June 1992 and legalized by the five Member Countries;

The Member Countries possess a sizeable biological and genetic heritage that should be preserved and developed on a sustainable basis;

The Andean countries are characterized by their multi-ethnic and pluricultural nature;

The biological diversity, the genetic resources, their endemism and rarity, as well as the know-how, innovations and practices of the native, Afro-American and local communities associated with them, have a strategic value in the international context;

It is necessary to recognize the historic contribution made by the native, Afro-American, and local communities to the biological diversity, its conservation and development and the sustained use of its components, as well as to the benefits generated by that contribution;

A close interdependence exists between the native, Afro-American and local communities and the biological resources that should be reinforced, in keeping with the conservation of the biological diversity and the economic and social development of those communities and of the Member Countries;

It is necessary to strengthen integration and scientific, technical and cultural cooperation, while moving ahead with the harmonious and comprehensive development of the Member Countries;

Genetic resources have an enormous economic value as a primary source of products and processes for industry;

DECIDES:

To approve the following:

COMMON REGIME ON ACCESS TO GENETIC RESOURCES

TITLE I

ON THE DEFINITIONS

Article 1.- The following definitions shall apply for purposes of this Decision:

ACCESS: the obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things.

ACCESS CONTRACT: agreement between the Competent National Authority in representation of the State, and a person that establishes the terms and conditions for access to genetic resources, their by-products and, if applicable, the associated intangible component.

ACCESS RESOLUTION: an administrative order issued by the Competent National Authority that executes the access to genetic resources or their by-products, after having fulfilled all requirements or conditions stipulated in the access procedure.

BIOLOGICAL DIVERSITY: the variability of living organisms of any source whatsoever, including, among others, land and ocean ecosystems and other aquatic ecosystems, as well as the ecological complexes of which they are a part. Covers the diversity that exists within each species and between species and within ecosystems as a result of natural and cultural processes.

BIOLOGICAL RESOURCES: individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its by-products.

BIOTECHNOLOGY: any technological application that utilizes biological systems or live organisms, parts of them or their by-products, to create or modify products or processes for specific uses.

BY-PRODUCT: a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings.

COMPETENT NATIONAL AUTHORITY: State entity or public institution appointed by each Member Country, authorized to supply the genetic resource or its by-products and therefore to sign or supervise the access contracts, to take the actions provided for in this common regime and to ensure their

performance.

COUNTRY OF ORIGIN OF THE GENETIC RESOURCE: country that possesses genetic resources in in situ conditions, including those which, having been in in situ conditions, are now in ex situ conditions.

ECOSYSTEM: a dynamic complex of communities of human beings, plants, animals and micro-organisms and their non-living medium that interact as a functional unit.

EX SITU CONDITIONS: those in which the genetic resources are not found in in situ conditions.

EX SITU CONSERVATION CENTER: a person or institution recognized by the Competent National Authority that conserves and collects genetic resources or their by-products outside their in situ conditions.

GENETIC DIVERSITY: variation of genes and genotypes between and within species. Sum total of the genetic information contained in biological organisms.

GENETIC EROSION: the loss of or decrease in genetic diversity.

GENETIC RESOURCES: all biological material that contains genetic information of value or of real or potential use.

IN SITU CONDITIONS: those in which the genetic resources are found in their ecosystems and natural environments; in the case of domesticated or cultivated species or those having escaped domestication, in the environments where they developed their specific properties.

INTANGIBLE COMPONENT: all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes.

NATIONAL SUPPORT INSTITUTION: national institution devoted to biological research of a scientific or technical nature, that accompanies the applicant and participates jointly with it in the access activities.

NATIVE, AFRO-AMERICAN OR LOCAL COMMUNITY: a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them.

PROGRAM FOR THE LIBERALIZATION OF GOODS AND SERVICES: a program whose purpose is to eliminate levies and restrictions of all kinds on the importation of goods originating in the territory of any Member Country, pursuant to the provisions of the pertinent chapter of the Cartagena Agreement and all other applicable rules and regulations of its body of law.

SUPPLIER OF THE BIOLOGICAL RESOURCE: a person empowered by this Decision and complementary national legislation to supply the biological resource that contains the genetic resource or its by-products.

SUPPLIER OF THE INTANGIBLE COMPONENT: a person that, through an access contract and pursuant to this Decision and to complementary national legislation, is empowered to supply the intangible component associated with the genetic resource or its by-products.

SUSTAINABLE USE: use of the components of biological diversity in a way and at a rate that does not cause their reduction in the long term and that enables them to maintain their possibilities for satisfying the needs and the aspirations of existing and future generations.

SYNTHESIZED PRODUCT: a substance obtained through the artificial processing of genetic information or of information from other biological molecules. Includes semi-processed extracts and substances obtained by converting a by-product through an artificial process (hemisynthesis).

TITLE II

ON THE PURPOSE AND AIMS

Article 2.- The purpose of this Decision is to regulate access to the genetic resources of the Member Countries and their by-products, in order to:

a) Establish the conditions for just and equitable participation in the benefits of the access;

b) Lay the foundations for the recognition and valuation of the genetic resources and their by-products and of their associated intangible components, especially when native, Afro-American or local communities are involved;

c) Promote conservation of the biological diversity and the sustainable use of the biological resources that contain genetic resources;

d) Promote the consolidation and development of scientific, technological and technical capacities at the local, national and subregional levels; and

e) Strengthen the negotiating capacity of the Member Countries.

TITLE III

ON THE SCOPE

Article 3.- This Decision is applicable to genetic resources for which is the Member Countries are the countries of origin, to their by-products, to their intangible components and to the genetic resources of the migratory species that for natural reasons are found in the territories of the Member Countries.

Article 4.- The following are excluded from the scope of this Decision:

a) Human genetic resources and their by-products; and

b) The exchange of genetic resources, their by-products, the biological resources containing them, or their associated intangible components among native, Afro-American and local communities of the Member Countries for their own consumption, based on their customary practices.

TITLE IV

ON THE PRINCIPLES

CHAPTER I

ON THE SOVEREIGNTY OVER GENETIC RESOURCES AND THEIR BY-PRODUCTS

Article 5.- The Member Countries exercise sovereignty over their genetic resources and their by-products and consequently determine the conditions for access to them, pursuant to the provisions of this Decision.

The conservation and sustainable use of the genetic resources and their by-products are regulated by each Member Country in keeping with the principles and provisions of the Biological Diversity Agreement and of this Decision.

Article 6.- The genetic resources and their by-products which originated in the Member Countries are goods belonging to or the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation.

Those resources are inalienable, not subject to prescription and not subject to seizure or similar measures, without detriment to the property regimes applicable to the biological resources that contain those genetic resources, the land on which they are located or the associated intangible component.

CHAPTER II

ON THE RECOGNITION OF KNOW-HOW, INNOVATIONS AND TRADITIONAL PRACTICES

Article 7.- The Member Countries, in keeping with this Decision and their complementary national legislation, recognize and value the rights and the authority of the native, Afro-American and local communities to decide about their know-how, innovations and traditional practices associated with genetic resources and their by-products.

CHAPTER III

ON TRAINING, RESEARCH, DEVELOPMENT AND THE TRANSFER OF TECHNOLOGY

Article 8.- The Member Countries favor the establishment of scientific and technical training programs, as well as the execution of research projects that promote the identification, registration, characterization, conservation and sustainable use of the biological diversity and of the by-products of genetic resources that help to satisfy local and Subregional needs.

Article 9.- The Member Countries, recognizing that technology, including biotechnology, and both the access to it and its transfer are essential to the attainment of the objectives of this Decision, shall ensure and facilitate, through the corresponding contracts, the access to technologies that utilize genetic resources and their by-products, that are appropriate for the conservation and sustainable use of the biological diversity and that do not cause damage to the environment.

CHAPTER IV

ON SUBREGIONAL COOPERATION

Article 10.- The Member Countries shall define mechanisms for cooperation on matters of common interest concerning the conservation and sustainable use of genetic resources and their by-products and the associated intangible components.

They shall also establish Subregional technical and scientific training programs on the information, follow-up, control and evaluation of activities connected with those genetic resources and their by-products and for the performance of joint research.

CHAPTER V

ON NATIONAL TREATMENT AND RECIPROCITY

Article 11.- The Member Countries grant each other national, and not discriminatory, treatment in matters relating to access to genetic resources.

Article 12.- The Member Countries may grant national and non-discriminatory treatment to third countries that give them equal treatment.

CHAPTER VI

ON PRECAUTION

Article 13.- The Member Countries may adopt measures aimed to impeding genetic erosion or the degradation of the environment and of the natural resources. If the danger of serious and irreversible damage exists, the lack of scientific certainty should not be seized upon as a reason for postponing the adoption of effective measures.

The principle of precaution should be applied in keeping with the provisions in the Chapter on the Liberalization Program of the Cartagena Agreement and the other applicable rules and regulations of the body of law of this Agreement.

CHAPTER VII

ON FREE SUBREGIONAL TRAFFIC IN BIOLOGICAL RESOURCES

Article 14.- Provided that there is no access to the genetic resources contained in the biological resources referred to in this Decision, the provisions of this regime shall not hinder the use of and free movement of in those biological resources, nor the fulfillment of the provisions of the CITES Convention on health, food security, biosecurity and the obligations stemming from the Program of Liberalization of goods and services among Member Countries.

CHAPTER VIII

ON JURIDICAL SECURITY AND TRANPARENCY

Article 15.- Provisions, procedures and acts of government authorities of the Member Countries with regard to access, shall be clear, effective, well-grounded and lawful.

The actions performed and information provided by individuals shall likewise be lawful, complete and truthful.

TITLE V

ON THE ACCESS PROCEDURE

CHAPTER I

ON THE GENERAL ASPECTS

Article 16.- All access procedures shall require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the declarative registration of the acts connected with that access.

Article 17.- The applications for access and access contracts and, if appropriate, accessory contracts shall include conditions like the following:

a) The participation of Subregional nationals in the research on genetic resources and their by-products and on the associated intangible component;

b) Support for research within the jurisdiction of the Member Country of origin of the genetic resource or in any other Subregional Member Country that contributes to the conservation and sustainable use of the biological diversity;

c) The strengthening of mechanisms for the transfer of know-how and technology, including biotechnology, that is culturally, socially and environmentally healthy and safe;

d) The supply of information about the background and status of the science and about other matters that would contribute to a better knowledge of the situation regarding the genetic resource that originated in the Member Country, its by-product or synthesized product and its associated intangible component;

e) The strengthening and development of the institutional capacity of the country or the Subregion in regard to genetic resources and their by-products;

f) The strengthening and development of the capacities of the native, Afro-American and local communities with relation to the associated intangible components, the genetic resources and their by-products;

g) The compulsory deposit of duplicates of all material collected, at institutions designated by the Competent National Authority;

h) The obligation to inform the Competent National Authority about the results of the research carried out; and

i) The terms for the transfer of the material to which third parties are given access.

Article 18.- The documents connected with the access procedure shall appear in a public file that the Competent National Authority shall keep.

That file shall consist of the following, at least: the application; the identification of the applicant, the resource supplier, and the national support person or institution; the site or area to which the access applies; the access methodology; the project proposal; the parts of the access contract that are not subject to confidentiality; the opinion about and registry of visits; and, if applicable, the evaluation studies of the economic, social and environmental impact or of the environmental permits.

Also included in the file are the Resolution executing the access, the reports supplied by the national support person or institution, and the follow-up and supervisory reports provided by the Competent National Authority or the entity delegated to perform that task. That file is open to consultation by any person.

Article 19.- The Competent National Authority may give confidential treatment to data and information supplied to it in the course of the access procedure or the contract performance, and not previously disclosed, which could be put to unfair commercial use by third parties, unless the knowledge of this data and information by the public is necessary to protect the social interest or the environment.

Accordingly, the applicant should state the grounds for its petition, accompanied by a non-confidential summary that will become a part of the public file.

The information or documents referred to in the second paragraph of Article 18 of this Decision cannot be made confidential.

The confidential aspects shall be covered in a separate file, in the custody of the Competent National Authority, and may not be disclosed to third parties, unless that is judicially ordered.

Article 20.- If the petition for confidential treatment fails to comply with the requirements established in the previous article, the Competent National Authority shall deny it as a matter of right.

Article 21.- The Competent National Authority shall keep a public registry where the following information shall be entered, among other data: the Resolution that may possibly deny the petition, the access contract signing, amendment, suspension and termination dates, the date and number of the Resolution executing or canceling it, the date and number of the Resolution, award or sentence determining the nullity or imposing penalties, with an indication of their kind and the parties, and accessory contract signing, amendment, suspension, termination and nullification dates.

That registry shall be of a declaratory nature.

Article 22.- As stipulated in Article 15, the execution of the access is dependent upon the provision of full and reliable information by the applicant, as called for by law.

In this connection, the applicant should present the Competent National Authority with all of the information about the genetic resource and its by-products that it knows or is in a position to know at the moment the application is presented. That information shall include the present and potential uses of the resource, by-product or intangible component, their sustainability and the risks that could result from the access.

The statements made by the applicant in the application and in the contract, including their respective annexes, shall be in the nature of a sworn statement.

Article 23.- The permits, authorizations and other documents that support the investigation, obtaining, provision, transfer, etc., of biological resources, shall not determine, qualify or presume the authorization of the access.

Article 24.- It is forbidden to use genetic resources and their by-products in biological weapons or for practices that are harmful to the environment or to human health.

Article 25.- The transfer of technology shall be carried out in accordance with the provisions contained in the body of law of the Cartagena Agreement, complementary national provisions and such rules and regulations on biosecurity and the environment as the Member Countries may approve.

Article 26.- The access to and transfer of technology subject to patents or other intellectual property rights, shall be accomplished in keeping with the Subregional and complementary national provisions regulating that area.

CHAPTER II

ON THE APPLICATION FOR ACCESS

Article 26.- The procedure starts with the presentation to the Competent National Authority of an application for access which should contain:

a) Identification of the applicant and, if pertinent, documents that accredit its legal capacity to make a contract;

b) Identification of the supplier of the genetic and biological resources and their by-products or of the associated intangible component;

c) Identification of the national support person or institution;

d) Identification and curriculum vitae of the person responsible for the project and of his working group;

e) The access activity applied for; and

f) The location or area where the access is to be carried out, with an indication of its geographical coordinates.

The application shall be accompanied by the project proposal, considering the referential model the Board approves through a Resolution.

Article 27.- If the application with its accompanying project proposal is complete, the Competent National Authority shall accept it, assign it a presentation or filing date, record it in the report and enter it with a declarative intent in the public registry it shall keep for that purpose and open the corresponding file.

Were the application to be incomplete, the Competent National Authority would return it without delay, indicating the information that is missing, so that it might be completed.

Article 28.- Within five working days following the date of entry of the application in the public registry referred to in the previous article, an extract of that application shall be published in a newspaper with broad national circulation and in another medium of the place where the access is to be effected, so that those that wish to might supply information to the Competent National Authority.

Article 29.- Within thirty working days after its registration, the Competent National Authority shall evaluate the application, make the visits it deems necessary and issue a technical and legal opinion about its propriety or invalidity. That period may be extended to up to sixty working days if the Competent National Authority considers it desirable.

Article 30.- When the time limit stipulated in the previous article expires, or before that, if appropriate, the Competent National Authority shall accept or deny the application, based on the results of the opinion, the records of visits, the information supplied by third parties, and the fulfillment of the conditions established in this Decision.

The applicant shall be advised about the acceptance of the application and project proposal within five working days after this occurs. The access contract shall then be immediately drawn up and negotiated.

In the event that the application and project proposal are denied, this shall be communicated through a justified Resolution and the matter shall be considered finished. This does not, however, preclude the filing of such objections as are in order, according to the procedures established in the national legislation of Member Countries.

Article 31.- If required by the national law of the Member Country or if the Competent National Authority deems it necessary, the applicant shall comply with environmental provisions in effect.

The procedures that should be followed in that event shall be independent from those stipulated in this Decision and may be started beforehand. Nonetheless, they must be concluded before the expiration of the time limit stipulated in Article 29 and must be considered by the Competent National Authority in making its evaluation.

Were the Competent National Authority to require such studies, it could grant the applicant a supplementary period set exclusively in accordance with the time needed to complete and submit them for its consideration.

CHAPTER III

ON THE ACCESS CONTRACT

Article 32.- The parties to the access contract are:

a) The State, represented by the Competent National Authority; and

b) The applicant requesting the access.

The applicant must be legally empowered to make a contract in the Member Country in which it requests the access.

Article 33.- The terms of the access contract must be in keeping with the provisions of this Decision and Member Country national legislation.

Article 34.- The access contract shall bear in mind the rights and interests of the suppliers of genetic resources and their by-products, the biological resources that contain them and the intangible component as applicable, in accordance with the corresponding contracts.

Article 35.- When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of the profits from use of that component.

The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the Competent National Authority, in accordance with the provisions of national law of the Member Country. If that annex is not signed by the Competent National Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision.

Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.

Article 36.- The Competent National Authority may enter into access contracts with universities, research centers or well-known researchers to support the execution of several projects, as provided for in this Decision and in keeping with the national legislation of each Member Country.

Article 37.- The ex-situ conservation centers or other institutions that perform activities involving access to genetic resources or their by-products and, if appropriate, the associated intangible component, should enter into access contracts with the Competent National Authority, pursuant to this Decision.

That Authority may likewise sign access contracts with third parties in regard to genetic resources of which the Member Country is the country of origin and which have been deposited at those centers, bearing in mind the rights and interests referred to in Article 34.

CHAPTER IV

ON THE EXECUTION OF THE ACCESS

Article 38.- Once the contract has been adopted and signed, the corresponding Resolution shall be issued in a joint act. This resolution shall then be published together with an extract of the contract, in the Official Newspaper or a newspaper with wide national circulation. As of that moment, the

access shall be considered to have been granted.

Article 39.- Such contracts as are signed in violation of the provisions of this regime shall be null and void. The nullification procedure shall be subject to the national provisions of the Member Country in which it is invoked.

Article 40.- The rescission or resolution of the contract shall be motive for the official cancellation of the registration by the Competent National Authority.

TITLE VI

ON THE ANCILLARY CONTRACTS TO THE ACCESS CONTRACT

Article 41.- Ancillary contracts are those that are signed in order to carry out activities connected with the genetic resource or its by-products, between the applicant and:

a) The owner, possessor or manager of the land where the biological resource containing the genetic resource is located;

b) The ex situ conservation center;

c) The owner, possessor or manager of the biological resource containing the genetic resource; or

d) The national support institution, with regard to activities that it should perform and that are not a part of the access contract.

Making an ancillary contract does not authorize access to the genetic resource or its by-product, and its contents are subject to the stipulations of the access contract as provided for in this Decision.

The national support institution must be accepted by the Competent National Authority.

Article 42.- Such ancillary contracts as are signed shall include a condition that subjects their execution to that of the access contract.

As of that moment, they shall become effective and binding and shall be governed by the mutually agreed terms, the provisions of this Decision and applicable Subregional and national legislation. The responsibility for their execution and compliance lies only with the parties to the contract.

Article 43.- Without detriment to what has been agreed upon in the accessory contract and independently of it, the national support institution shall be obliged to collaborate with the Competent National Authority in the follow-up and supervision of the genetic resources, by-products or synthesized products and associated intangible components, and to submit reports about the activities for which it is responsible, in the way or with the frequency that the Authority stipulates, according to the access activity.

Article 44.- The nullity of the access contract produces the nullity of the ancillary contract.

The Competent National Authority may also terminate the access contract when the nullity of the ancillary contract is declared, if the latter is essential for the access.

Its amendment, suspension, rescission or resolution may likewise produce the amendment, suspension, rescission or resolution of the access contract by the Competent National Authority if it substantially affects the conditions of the latter contract.

TITLE VII

ON THE LIMITATIONS TO ACCESS

Article 45.- Member Countries may establish, through an express legal rule, partial or total limitations on access to genetic resources or their by-products in the following cases:

a) Endemism, rarity or danger of extinction of species, subspecies, varieties or races or breeds;

b) Vulnerability or fragility of the structure or functioning of the ecosystems that could worsen as a result of access activities;

c) Adverse effects of access activities on human health or on elements essential to the cultural identity of nations;

d) Undesirable or not easily controlled environmental effects of access activities on the ecosystems;

e) Danger of genetic erosion caused by access activities;

f) Regulations on biosecurity; or

g) Genetic resources or geographic areas rated as strategic.

TITLE VIII

ON VIOLATIONS AND SANCTIONS

Article 46.- Any person performing access activities without the respective authorization shall be liable for punishment.

Also to be sanctioned is any person carrying out transactions with regard to by-products or synthesized products of such genetic resources or the associated intangible component, that is not protected by the corresponding contracts, signed in keeping with the provisions of this Decision.

Article 47.- The Competent National Authority, pursuant to the procedure provided for in its own national legislation, may apply administrative sanctions, such as fines, preventive or definitive confiscation, temporary or definitive closing-down of establishments and disqualification of the violator from applying for new accesses in cases of violation of this regime.

Those sanctions shall be applied without detriment to the suspension, cancellation of nullification of the access, the payment of compensation for such damages and losses as are incurred, including those caused to the biological diversity, and the civil and criminal sanctions that may possibly be in order.

TITLE IX

ON THE NOTIFICATIONS BETWEEN MEMBER COUNTRIES

Article 48.- The Member Countries shall notify each other immediately through the Board, of all applications for access and access resolutions and authorizations, as well as of the suspension and termination of such contracts as are signed.

They shall also advise each other about the signing of any bilateral or multilateral agreement on the subject, which must be in keeping with the provisions of this Decision.

Article 49.- Without prejudice to the stipulations of the previous article, the Member Countries shall immediately inform each other through the Board of all provisions, decisions, regulations, judgments, resolutions and other rules and acts adopted nationally that have to do with the provisions of this Decision.

TITLE X

ON THE COMPETENT NATIONAL AUTHORITY

Article 50.- The Competent National Authority shall perform all of the functions conferred on it in this Decision and in Member Country national legislation. In this connection, it shall be empowered to:

a) Issue the necessary internal administrative provisions to comply with this Decision and, until the appropriate Community rules and regulations are enacted, stipulate how the genetic resources and their by-products shall be identified and packed;

b) Receive, evaluate, accept or deny applications for access;

c) Negotiate, sign and authorize access contracts and issue the corresponding access resolutions;

d) Ensure the rights of suppliers of biological resources that contain genetic resources and of the intangible component;

e) Keep the technical files and the Public Registry of Access to Genetic Resources and their by-products;

f) Keep a directory of persons or institutions pre-qualified to perform scientific or cultural support tasks;

g) Amend, suspend, nullify or terminate access contracts and arrange their cancellation, as the case may be, in keeping with the terms of those contracts, this Decision and Member Country legislation;

h) Oppose the suitability of the national support institution proposed by the applicant and demand its replacement by another, suitable one;

i) Supervise and control compliance with the contractual conditions and the provisions of this Decision and accordingly establish such monitoring and evaluation mechanisms as it deems advisable;

j) Review, in keeping with this Decision, contracts involving access already signed with other institutions or persons and carry out the corresponding actions for repossession;

k) Delegate supervisory activities to other institutions, while keeping the responsibility and direction over that supervision, in conformity with national legislation;

l) Supervise the state of conservation of the biological resources containing the genetic resources;

m) Coordinate continuously with its respective liaison institutions all matters having to do with fulfillment of the provisions of this Decision;

n) Keep the national inventory of genetic resources and their by-products;

o) Keep in continuous contact with the competent national offices for industrial property and set up appropriate information systems with them; and

p) All such other functions as the domestic legislation of the Member Country itself may assign it.

TITLE XI

ON THE ANDEAN COMMITTEE ON GENETIC RESOURCES

Article 51.- The Andean Committee on Genetic Resources is hereby created, such to be comprised of the Directors of the Competent National Authorities on matters of Access to Genetic Resources or their representatives, their advisors and such representatives of other interested sectors as each Member Country may designate.

The Committee shall be responsible for:

a) Issuing national and Subregional recommendations for the best possible fulfillment of this Decision;

b) Issuing technical recommendations on such matters as the Member Countries may submit for its consideration;

c) Recommending the mechanisms for establishing an Andean information network on applications for access and access contracts in the Subregion;

d) Recommending and promoting joint actions to strengthen Member Country capacity in research, management and transfer of technology connected with genetic resources and their by-products;

e) Recommending to the Board for adoption through Resolutions, common documentation models, particularly those that will make it possible to easily verify the coding and identification of genetic resources and their by-products, as well as the legality of the access;

f) Promoting management, surveillance, control and supervision of access authorizations relating to genetic resources and their by-products that exist in two or more Member Countries;

g) Recommending and promoting joint emergency plans and warning mechanisms to prevent or resolve problems relating to access to genetic resources or their by-products;

h) Taking cooperative actions with regard to genetic resources or their by-products;

i) Drawing up their own internal regulations;

j) Writing an explanatory manual of this Decision; and

k) Such other functions as the Member Countries may assign to them.

COMPLEMENTARY PROVISIONS

FIRST.- The Member Countries shall, in keeping with their national legislation, set up or reinforce funds or other types of financial mechanisms financed by the profits from the access and resources from other sources to promote compliance with the aims of this Decision, under the direction of the Competent National Authority.

Through the Andean Committee on Genetic Resources, the Member Countries shall design and implement joint programs for the conservation of genetic resources and shall study the viability and desirability of creating an Andean Fund for their conservation.

SECOND.- The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.

Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.

THIRD.- The Competent National Offices on Intellectual Property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries.

The Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.

FOURTH.- Such health certificates supporting the export of biological resources as are issued in accordance with Commission Decision 328, its amendments or addenda, shall incorporate the following statement at the end of the format: "Use of this product as a genetic resource is not authorized."

FIFTH.- The Competent National Authority may enter into, with the institutions referred to in Article 36, contracts for the deposit of genetic resources or their by-products or of the biological resources containing them, exclusively for purposes of their care, keeping those resources under its jurisdiction and control.

Likewise, it may make contracts that do not involve access, such as intermediation or administration contracts, in relation to genetic resources or their by-products or synthesized products, in keeping with the provisions of this Regime.

SIXTH.- When requesting access to genetic resources from protected areas or their by-products, the applicant must fulfill, in addition to the stipulations of this Decision, also the special national legislation on the subject.

FINAL PROVISIONS

FIRST.- Any disputes that may arise among Member Countries shall be settled as stipulated in the Andean body of law.

Any disputes that arise with third countries must be settled according to the provisions of this Decision. If a dispute arises with a third country party to the Agreement on Biological Diversity, signed in Rio de Janeiro on June 5, 1992, the solution adopted must also abide by the principles established in that Agreement.

SECOND.- In negotiating the terms of access contracts to genetic resources that originated in more than one Member Country or to their by-products and in carrying out activities connected with that access, the Competent National Authority shall bear in mind the interests of the other Member Countries, which may present their viewpoints and such information as they deem advisable.

THIRD.- The Board, through a Resolution and after hearing the opinion of the Andean Committee on Genetic Resources, may execute or adjust the procedure stipulated in Title V, Chapters I and II of this Decision.

FOURTH.- This Decision shall become effective on the date of its publication in the Official Newspaper of the Cartagena Agreement.

TEMPORARY PROVISIONS

FIRST.- On the date this Decision enters into force, those which possess, for purposes of access, genetic resources originated in the Member Countries, their by-products or associated intangible components, shall negotiate that access with the Competent National Authority pursuant to the provisions of this Decision. Accordingly, the Competent National Authorities shall set the time limits, which cannot exceed twenty-four months as of the date this Decision becomes effective.

Until this requirement is fulfilled, the Member Countries may disqualify such persons, as well as the institutions they represent or on whose account they act, from applying for new accesses to genetic resources or their by-products in the Subregion. This does not preclude the application of such sanctions as are in order once the time limit referred to in the previous paragraph expires.

SECOND.- Contracts or agreements signed by Member Countries or their public or State institutions with third parties in regard to genetic resources, their by-products, the biological resources containing them or associated intangible components, that are not in conformity with this Decision, may be renegotiated or may fail to be renewed, as applicable.

The renegotiation of such contracts or agreements, as well as the signing of new ones, shall be accomplished by common agreement among the Member Countries. To this end, the Andean Committee on Genetic Resources shall establish the common criteria.

THIRD.- The Member Countries may take such legal action as they deem advisable for the repossession of genetic resources of which they are the countries of origin, their by-products and the associated intangible components and for the collection of any damages and compensation to which they are entitled.

Only the State has the legal entitlement to the action for repossession of those genetic resources and their by-products.

FOURTH.- The Board, through a Resolution and after hearing the opinion of the Andean Committee on Genetic Resources, shall establish the necessary systems for the identification and packing of the genetic resources and, if applicable, their by-products.

FIFTH.- Within a period of no more than 30 working days after this Decision enters into force, the Member Countries shall designate the Competent National Authority on access to genetic resources and shall accredit it before the Board.

SIXTH.- The Member Countries, within a period of no more than 30 working days after this Decision enters into force, shall accredit before the Board their representatives to the Andean Committee on Genetic Resources.

SEVENTH.- The Member Countries shall adopt a common regime on biosecurity within the framework of the Agreement on Diversity. To that end, the Member Countries, in coordination with the Board, shall start the respective studies, particularly with regard to the cross-border movement of modified live organisms produced by biotechnology.

EIGHTH.- The Board shall draw up, within a period of three months after the Member Countries present their national studies, a proposal to establish a special regime or a harmonization regulation, as applicable, aimed at reinforcing the protection of know-how, innovations and traditional practices of native, Afro-American and local communities, in keeping with the provision of Article 7 of this Decision, ILO Convention 169 and the Agreement on Biological Diversity.

To that end, the Member Countries should present their respective national studies during the year after this Decision enters into effect.

NINTH.- The Member Countries shall design a training program to strength the capacity of the native, Afro-American and local communities to negotiate the intangible component within the context of access to genetic resources.

TENTH.- The Board, through a Resolution, shall adopt the reference models for the application for access to genetic resources and the access contract, within a period of no more than fifteen days after this Decision comes into effect.

Signed in the city of Caracas, Venezuela on the second of July of nineteen ninety-six.
