

**Decree N° 31514-MINAE**  
**The President of the Republic**  
**And the Minister of the Environment and Energy**

In use of the faculties conferred by articles 46, 50, 140 clauses 3) and 18) and 146) of the Political Constitution, articles 46 and 47 of the Environment Organic Law Nr 7554 of October, 4<sup>th</sup>, 1995 and article 62 of the Biodiversity Law Nr 7788 of April, 30<sup>th</sup>, 1998,

**CONSIDERING:**

1. That article 15 of the Convention on Biological Diversity states that in recognition of the sovereign rights of the States over their natural resources, the faculty to regulate the access to genetic resources falls under the governments responsibilities and is subject to the national legislation and that each party will endeavor to create conditions to facilitate its access for environmentally sound uses.
2. That article 6 of the Biodiversity Law Nr 7788, stipulates that the biochemical and genetic properties of the wild and domesticated biodiversity elements are in the public domain and that the State will authorize the exploration, research, bioprospection, use and exploitation of the biodiversity elements which constitute public domain goods, as well as the utilization of all the genetic and biochemical resources, through the general rules for access.
3. That article 14 of the Biodiversity Law creates the National Commission on Biodiversity Management (CONAGEBIO, Spanish acronym).
4. That article 62 of this law, points out that: "The dispositions which the CONAGEBIO agrees on in this matter will constitute the General Rules for the Access to the Genetic and Biochemical Elements and for the protection of the Communitarian Intellectual Rights on biodiversity, to which the Administration and interested individuals should be subject to.
5. That the CONAGEBIO has taken into account for the elaboration of these rules, in addition to the Biodiversity Law, several international agreements, namely the Convention on Biological Diversity (CBD), the Bonn Guidelines on Access and Distribution of Benefits of the Convention on Biological Diversity, the Convention 169 on Indigenous and Tribal People (Law Nr 7316).
6. That in addition to the national and international legal provisions on access matters afore mentioned, the CONAGEBIO carried out consultations and workshops in several opportunities to get recommendations from experts, involved sectors and national institutions, for writing them, trying to accomplish this duty in the most effective, participatory and transparent way.

**THEREFORE:**

**WE DECREE**

**"General Rules for the Access to the Genetic and Biochemical  
Elements and Resources of the Biodiversity"**

**Chapter I. General Provisions**

**Article 1. Objectives**

The objectives of these rules are:

- a) Regulate the access to the genetic and biochemical elements and resources of the biodiversity and to the related traditional knowledge, innovations and practices.
- b) Regulate the fair and equitable distribution of the social, environmental and economic benefits derived from the use of the elements and biochemical and genetic resources of the biodiversity for all the sectors of society, with special attention to local communities and indigenous people.
- c) Foster of and protect the *sui generis* communitarian intellectual property rights.

- d) Facilitate the access to the genetic and biochemical elements and resources of the biodiversity and encourage the development of research and technology, if these activities neither put into risk the resources sustainability nor contravene the objectives of the Convention on Biological Diversity.
- e) Assure and facilitate the access to the technologies and their adequate, effective and selective transference, under fair, favorable and mutually agreed conditions so that the national capacity be improved.

#### **Article 2. Scope**

The rules of access will be applied on the elements and the genetic and biochemical resources of the biodiversity components, wild or domesticated, terrestrial, marine, freshwater or aerial, *in situ* or *ex situ*, which are found in the national territory as defined in Article 6 of the Political Constitution, either public or private property. Likewise, they will foster and regulate the protection of the related traditional knowledge and the fair and equitable distribution of the benefits derived from the use of such elements and resources.

#### **Article 3. Exclusions**

Notwithstanding what is stipulated in article 4 of the Biodiversity Law, the use of the biodiversity elements utilized as organic resources is excluded from the application of this rules which will continue under regulation by the Forest Law, the Wildlife Conservation Law, the INCOPECA creation Law, the Fishing and Marine Hunting Law, and other special laws.

#### **Article 4. Principles to apply the regulations**

When applying these regulations, the principles and criteria established in article 9 of the Biodiversity Law shall be observed.

#### **Article 5. Competent Authority**

The CONAGEBIO is the competent national authority to propose and coordinate the policies on access to the elements and the genetic and biochemical resources of the biodiversity and to the related traditional knowledge. This ensures the adequate scientific-technical transference and the fair and equitable distribution of the benefits derived from the access, through the present rules.

The CONAGEBIO will have a supporting Technical Office for, among other duties, transacting, approving, rejecting and controlling the applications for access to the genetic and biochemical elements and resources of the biodiversity as well as to the related traditional knowledge in the terms of these regulations.

The CONAGEBIO will act as focal point in the matter of access to the genetic and biochemical resources of the biodiversity and distribution of the benefits derived from such access before the Secretariat of the Convention on Biological Diversity.

To accomplish its duties, the CONAGEBIO will appoint *ad hoc* committees as advisors.

#### **Article 6. Definitions**

Additionally from the definitions included in article 7 of the Biodiversity Law, these general rules will use as reference the following:

##### **a) Material Transference Agreements**

Agreement held between the parties, either persons or corporations, for the exchange and transference of genetic and biochemical elements and resources of the biodiversity kept either in *ex situ* or *in situ* conditions. The Technical Office as stipulated in article 74 of the Biodiversity Law should authorize these agreements.

##### **b) Agreement between the interested person and the provider of elements or resources**

Agreement subscribed between the interested person and the provider of genetic and biochemical elements and resources of biodiversity as established in clause q) of this very article.

**c) Economic exploitation**

Utilization of natural resources for self-subsistence or commercial purposes.

**d) Bioprospection**

Systematic search, classification and research for commercial purposes of new sources of chemical compounds, genes, proteins, microorganisms and other products with actual or potential economic value, found in biodiversity.

**e) Preliminary identity card for access**

Official identity document issued by the Technical Office of the CONAGEBIO once the interested party has registered as potential user for access to genetic and biochemical elements and resources of biodiversity. Similarly, it assists the interested party to apply for the prior informed consent.

**f) Certificate of origin**

Official document issued by the Technical Office of the CONAGEBIO which certifies the legality of access to genetic and biochemical elements and resources of biodiversity and the observance of the terms on which the corresponding access permit was granted to the interested party.

**g) Local community**

Human population that cohabits a determined geographical area and share a collective identity, which includes knowledge, traditions, innovations and life practices, related to conservation and use of biological diversity. They can be rural, urban, coastal and river dwelling.

**h) Concession**

Authorization for constant access with commercial purposes to biochemical or genetic properties of the elements and resources of biodiversity, which the head of the Ministry of the Environment and Energy grants to the interested party, either national or foreign, once its application has been revised and transferred to the Technical Office of CONAGEBIO.

For the purposes of this definition, the term “constant use” will mean the interested party applies for access at least six times in a period of five years over the same genetic or biochemical resource.

Furthermore, concessions are neither exclusive nor excluding.

**i) Biodiversity related knowledge**

Resulting from intellectual activity over elements of biodiversity generated in a traditional way or following the scientific method.

**j) Traditional knowledge**

It is dynamic knowledge, which improves through constant innovation and experimentation. The traditional element refers to the way in which it is acquired, shared and utilized through a social learning process that is unique to each indigenous culture and local community.

**k) National counterpart**

National person or corporation, who in association with a foreign entity, participates in access to genetic and biochemical elements and resources of biodiversity, and in the duties of research, bioprospection or economic exploitation.

**l) Sui Generis Communitarian Intellectual Rights**

Knowledge, practices and innovations of the indigenous people and local communities related to the use of the biodiversity elements and related knowledge.

**m) Fair and equitable distribution of benefits**

Participation in the economic, environmental, scientific-technological, social or cultural benefits resulting from research, bioprospection or economic exploitation of the genetic and biochemical elements and resources of biodiversity among the parties involved in access and conservation of biochemical and genetic resources, with special attention to local communities and indigenous people.

**n) Basic research in biodiversity**

Activities tending to investigate, examine, classify or increase existing knowledge over biological elements in general or their genetic or biochemical characteristics in particular, without immediate interest in commercializing its results.

**o) Interested party or person**

Person or corporation, national or foreign, interested in obtaining an access permit to biochemical and genetic elements and resources of biodiversity found in the country. It can act through a legal representative.

**p) Access passport to genetic and biochemical elements and resources of biodiversity**

Official document issued by the Technical Office, which entitles the interested party, once its access application has been approved, to enter the place where the corresponding activities will be carried out.

**q) Access permit for economic commercial exploitation**

Personal and non-transferable authorization, neither exclusive nor excluding, granted by the Technical Office of CONAGEBIO that allows the interested party to make occasional or constant use of the biochemical or genetic elements and resources of biodiversity for commercial purposes, without necessarily being preceded by a basic research or bioprospection program as part of the application. Should utilization be constant a concession process will be required according to article 11 of the present regulations.

**r) Provider of genetic and biochemical elements and biodiversity resources**

Person or corporation that owns, is responsible for, or possess goods where the genetic and biochemical elements and biodiversity resources are found, or is the owner of related traditional knowledge and might authorize its access, once the legal procedures established in these regulations have been fulfilled.

**s) Organic resource**

Any material from living beings, wild or domesticated, which may be utilized as such, as a whole or in its macroscopic parts.

**t) Biochemical resource**

Any material derived from living beings, sought or utilized for its actual or potential value, which has certain specific characteristics, special molecules or clues to design them. In contrast to the organic use of resources, the biochemical resource undergoes a greater technical-industrial transformation and exploitation, and generally contains a greater number of active ingredients.

**u) Genetic resource**

Any material from living beings which contains functional units of inheritance and which be conventionally managed or innovated by farmers and plant or zoo-breeders; as well as

investigated or exploited through modern biotechnological procedures, with actual or potential value.

**v) Conservation Areas National System**

Institutional, non-concentrated and participatory management and coordination Regime, which integrates the competences in forest, wildlife and protected areas matters of the Ministry of the Environment and Energy, which issues policies, plans and implements processes aimed at achieving the sustainability of natural resources management in Costa Rica.

**CHAPTER II. REQUIREMENTS AND PROCEDURES TO OBTAIN PERMITS, CONCESSIONS AND AGREEMENTS FOR ACCESS TO GENETIC AND BIOCHEMICAL ELEMENTS AND RESOURCES OF BIODIVERSITY**

**SECTION I. ACCESS PERMITS AND CONCESSIONS**

**Article 7. Access permits**

This chapter regulates the procedures and requirements to obtain three types of access permits to genetic and biochemical elements and resources of biodiversity or to the related traditional knowledge:

1. Basic research
2. Bioprospection
3. Commercial economic exploitation.

Definitions of such permits are given on clauses d), h), n) and q) of the latter article.

To apply for each type of permit, different requirements should be met.

From the moment the basic research begins to anticipate commercial or profitable purposes, the interested party should meet the requirements exacted for bioprospection. Likewise, the requirements for economic exploitation should be fulfilled when the access objective shifts from the exploratory type into the exploitation of biochemical or genetic material with commercial purposes.

The access permits will not be granted in an exclusive nor an excluding character.

**Article 8. Interested parties registry**

The interested party, either a person or a corporation, or its representative, should register at the Technical Office, before applying for any type of access permit, by filling to a form on which the following information should be supplied under oath:

-Name and complete identification of the interested party, including a place for notifications. If the applicant is not the interested party themselves, the representative should provide the document that accredits him/her as such.

-If the applicant(s) is a person or a corporation residing abroad, he/she will designate a legal representative, residing in the country.

-Type of permit for which he/she will apply for in first instance: basic research, bioprospection or economic exploitation.

Once the interested party has submitted this form, the Technical Office will issue a preliminary Identity Card as potential user for access to genetic and biochemical elements and resources of biodiversity; the interested party should bear such Identity Card when applying for the prior informed consent.

## **Article 9. General requirements to apply for access permit for basic research, bioprospection or economic exploitation**

The interested party or its representative, should duly complete the application form and the technical guidelines available at the Technical Office, as well as attaching the documents indicated by this article. All of them must be submitted in Spanish language.

### **1. Application form**

The following information and documentation must be provided:

- a) Name and complete identification of the interested party, including place for notifications. If it is not the interested party itself, the representative's data should be indicated and the authorization based on which he/she will carry out the application.
- b) If the applicant(s) is a person or corporation residing abroad, a legal representative, residing in the country, should be designated. Distinguishable national research institutions may serve as legal representatives.
- c) Type of permit applied for: basic research, bioprospection or economic exploitation.
- d) Title of the project of research, bioprospection or economic exploitation.
- e) The certification of incorporation instrument, if needed.
- f) Photocopy of national ID, passport or juridical ID of interested party and researcher responsible for the project.
- g) Documents or representation powers, if needed.
- h) Submit, if that is the case, the agreement or contract, as established in article 22 of these regulations.
- i) Voucher of the deposit made into CONAGEBIO's bank account, corresponding to the administrative rates stipulated by executive decree, according to article 17 of these regulations.

### **2. Technical Guidelines**

This form will contain the following information:

- a) Name and complete identification of the person or party interested in the access, or their representative.
- b) Name and complete identification of the main researcher or bioprospector of the respective project or of the responsible of the economic exploitation permit, when it is other than the interested party.
- c) Objectives and aim pursued by the project, and description of the scope of the research, of the bioprospection or the economic exploitation.
- d) Location of the geographical zone and of the site where the research, bioprospection or economic exploitation will be carried out, indicating the property's holder or owner, or the owner or responsible of the materials held in ex-situ conditions, including geographical co-ordinates and the declaration whether it is a protected wildlife area, an indigenous territory, a marine or freshwater area.
- e) The approximate time that the whole process will last and number of times that the site will be entered.
- f) The type of material of interest and the approximate quantity of material which is required, in the case of access to genetic and biochemical resources of biodiversity.
- g) The methods utilized for the collection of material, in the case of access to genetic and biochemical resources of biodiversity.
- h) Name and complete identification of the international or national counterpart in the activities of research, bioprospection or economic exploitation, if needed.
- i) Indication of the potential destination of the resources or related traditional knowledge and of their subsequent destinations.
- j) Indication of the utilization of the local or indigenous traditional knowledge related to the use of the resources of biodiversity, in the case of access to this type of knowledge.
- k) Indication of the studies or research which back up a previous knowledge upon the elements or resources or related traditional knowledge on which access is asked. If originally written in another language, they can be submitted in that language, but a summary in Spanish must be provided.

- l) Way in which the research, bioprospection or economic exploitation activities will contribute to species and ecosystems conservation.
- m) Possible risks of environmental or cultural impact that could occur due to access, extraction or processing of the material, due to the granting of the permit applied for access to the resources of biodiversity, such as genetic erosion, biodiversity loss, indirect damage over endangered species or with reduced population or forbidden hunting, or other.
- n) Work schedule.
- o) Copy of the project or project draft to be carried out.
- p) Manifestation that all declarations have been made under oath.

### **3. Prior informed consent and mutually agreed conditions.**

The prior informed consent and the mutually agreed conditions could be reached and negotiated according to the model contract prepared by the Technical Office, which among their recommended clauses include:

- a) The aims of the research, bioprospection or economic exploitation.
- b) The site or sites where the search or exploitation will be settled on.
- c) The number of researchers, bioprospectors or authorized persons which will enter the site and manner in which they might be identified. In case that guide and attendance by persons of local communities or indigenous people be required, these should be duly hired and paid for, if the parties so agree.
- d) The type of material of interest and the approximate quantity of material required.
- e) The methods utilized for the collection or exploitation of the material.
- f) The initial price for sample extracted, when applicable. This price and the number of samples will be the base for determining the percentage mentioned in section 4 of this Article.
- g) The approximate time which the whole process will last and number of times which the access site will be entered.
- h) The potential destination of the genetic and biochemical elements or resources and their subsequent destinations.
- i) Formal commitment, by the interested party, to provide evidence of the origin of the resources and the related knowledge, in any publication, procedure or further use of them.
- j) Agreed terms regarding the exchange of knowledge related to characteristics, qualities, uses, procedures and tending over the genetic and biochemical elements and resources of biodiversity, and how this knowledge will contribute to the conservation of species and ecosystems.
- k) Agreed terms about any other condition which the practice or the result of the participatory process of the local communities and indigenous people regulated in article 83 of the Biodiversity Law, indicate as required.
- l) Express manifestation by the interested party that the protection measures of the related knowledge, practices and innovations of the local communities and indigenous people will be respected, as established in the national legal system on *sui generis* Communitarian Intellectual Rights.
- m) Agreed terms on a possible study on cultural impact of the access, if required.
- n) Agreed terms on the type and ways of transference of technology or generation of information derived from the research, bioprospection or economic exploitation towards the national counterparts, local communities and indigenous people and the provider of the resource.
- o) Agreed terms on the equitable distribution of environmental, economic, social, scientific or spiritual benefits, including possible commercial profits at short, mid and long term, of any product or sub product derived from the acquired material. The Technical Office will verify the fulfillment of these terms according to the third objective of the Convention on Biological Diversity.
- p) Approximate estimate of the terms for the distribution of benefits.

- q) Special emphasis should be made so that granting of the prior informed consent is carried out, as far as possible, with an equitable participation of both genders.
- r) Signature or finger-print of the provider and applicant thus formalizing their agreement with the terms of access.
- s) In the cases of basic research or bioprospection, the resources provider: the Regional Council or the Director of the specific Conservation Area- in case of a State property- the authorities of the local communities or indigenous people, owners of farms, or owners or responsible of materials kept in *ex situ* conditions, and the interested party, will determine an amount of cash money, up to a 10% of the research or bioprospection budget, as stipulated in clause c) of section D of this Article.
- t) Other terms agreed.

The interested party or its duly registered legal representative, will go to the representatives of the site where access to the genetic and biochemical elements or resources of biodiversity will be carried out, be it: Regional Council, Conservation Area Director -in case of a State property-, landowners, authorities of the local communities or indigenous peoples and the owners or responsible of the materials kept in *ex situ* conditions, to have an in depth discussion on the meaning and scope of the access, the terms of protection of the related knowledge demanded by them, and the practical, economic and logistic aspects of the access, as stipulated in the present article and transitory 2 of these regulations.

If access is going to be carried out in a coastal-marine area, which is not included in the definition of *wetland* of article 40 of the Environment's Organic Law or is not included within the limits of a protected area so declared, the prior informed consent should be applied for at INCOPESCA, which will request advice to the Scientific-Technical Commission attached to that institution.

If access is going to be carried out alongside public roads and sidewalks, or in rivers, lagoons and *wetlands*, the prior informed consent should be applied for before the Regional Council or the corresponding Conservation Area Director.

In the case of indigenous territories, the information will be regulated as stipulated by the Convention 169 of ILO, Law Nr 7316 of Costa Rica. The prior informed consent should be submitted in the corresponding indigenous language as well, if so demanded by the involved party.

#### **4. For basic research or bioprospection**

Aside from what is indicated in sections 1, 2 and 3, the interested party should:

- a) Submit written formal commitment manifesting that, in case of modification of the permit's aims whether for bioprospection or economic exploitation, the requirements established for each case will be fulfilled.
- b) Deliver three copies of the final results of the basic research, bioprospection or the scientific papers and publications derived from them, on which the country's contribution and the knowledge related to the respective resource or resources will be acknowledged. The copies will be delivered as follows: one to the Technical Office, one to the corresponding Conservation Area and one to the property's owner or provider. If the research project's document is in a language other than Spanish, an executive summary should be attached
- c) The interest party should deposit up to 10% of the research or bioprospection's budget. This percentage will be established according to the parties will and will be deposited in a bank account or other indicated by the direct provider of the genetic or biochemical elements or resources of biodiversity. In the resolution which grants the access permit, the Technical Office will establish the acquired obligation and will allow a term of eight workdays, after notification of this resolution, for the researcher or bioprospector to

make the deposit as agreed. The percentage indicated will depend on the number and price of the samples applied for.

#### **5. For occasional or regular economic exploitation**

Aside from what is indicated in sections 1, 2 and 3, the interested party should submit:

- a) Description of the commercial use of the genetic and biochemical elements or resources of biodiversity intended to be extracted or the related traditional knowledge.
- b) General information about the project's economic feasibility.
- c) Obligation to pay up to 50% of the royalties obtained by the interested party on behalf of: the Conservation Areas National System, local communities or indigenous people, the landowners, owners or responsible of the materials kept in *ex situ* conditions, where the economic exploitation will be carried out, as defined or established in the contract foreseen by the prior informed consent with the Technical Office's endorsement.

In case of constant utilization, according to what is stipulated in Article 6, clause h), once authorized by the Technical Office, the application for concession established in article 11 of the present regulations will be additionally required. In the case of national parks and biological reserves, concessions cannot be granted.

### **SECTION II: PROCEDURE FOR AUTHORIZATION OF PERMITS, FOLLOW-UP AND CONTROL**

#### **Article 10. Terms for approval of applications**

Once the interested party submits the requirements pointed out in article 9, according to the type of permit applied for, the Technical Office will concede the interested party a maximum of 10 workdays to submit the omitted requirements or documents to process the application.

Once the interested party submits the omitted requirements and documents, or in case that an omission has not been indicated, the Technical Office will have a maximal term of 30 natural days to resolve the application.

If the omitted documents are not submitted by the stipulated deadline, the Technical Office will cancel the application.

#### **Article 11. Procedure to grant concessions**

In the cases of granting an access permit for economic exploitation which becomes constant, i.e. the interested party has applied for the access at least six times within a five-year period upon the same genetic or biochemical resource with commercial purposes, getting a concession will be required hereafter. CONAGEBIO's Technical Office will process the application and will remit the file with the respective recommendation, to the Minister's office for its eventual approval and signing.

#### **Article 12. Endorsement of the prior informed consent**

The Technical Office should endorse the prior informed consent and in if necessary will make field consultations, to verify the terms agreed upon.

#### **Article 13. Resolution of approval or rejection**

The resolution issued by the Technical Office, should clearly indicate whether the application was approved or rejected and the technical, social or environmental justifications this act is based upon.

Once the access permit is approved, the Technical Office will issue an "access passport" which will allow the interested party to enter the site where the activities authorized by the corresponding resolution will be carried out, and on which, the activities will be consigned.

In the approval resolution, the following conditions, among others, will be stipulated:

- a) Duration of the permit
- b) Obligation of the interested party to deposit up to 10% of the research budget and up to 50% of the royalties charged, on behalf of the resources provider, if applicable. As well as any other benefit or technology transference, that is part of the prior informed consent.
- c) Obligation of the interested party to submit reports and their periodicity.
- d) Any other condition or restriction which the Technical Office considers necessary.

**Article 14. Additional criteria for evaluation or approval of the application**

In the evaluation or approval of the application, the Technical Office will consider the public interest criterion and the precautionary principle found in the international agreements, regional protocols and national laws to guarantee:

- a) the development options for the future generations,
- b) the food security and sovereignty,
- c) the ecosystems conservation,
- d) the protection of human health,
- e) the improvement of quality of life of the citizens,
- f) the gender equity and,
- g) the objectives of conservation, sustainable utilization and fair and equitable distribution of the benefits derived from access to the genetic and biochemical elements and resources and the related traditional knowledge.

It is understood that what is stipulated in this Article does not imply that the applications submitted have to meet every single criterion indicated.

**Article 15. Publication of the applications and resolutions**

A summary of the applications and their final resolutions, once they are definite, will be published in the CONAGEBIO's web page within the following eight workdays, respecting the confidentiality and the commercial and industrial secrets pointed out as such by the interested party in the information supplied in the permit access application as well as in the attached documents, and according to the Non-Divulged Information Law Nr 7975.

Likewise, the Technical Office will elaborate an annual report on the access permits granted in the country, and will forward it to the Clearing-House Mechanism of the Convention on Biological Diversity.

**Article 16. Revocation and appeal resorts**

If the Technical Office rejects a permit or there is unconformity by the interested party or the resource provider regarding the resolution issued by the Technical Office, they will have three workdays to pose a written revocation request before the Technical Office and one of appeal before CONAGEBIO, who will finalize the administrative appeal process. The deadline will run from the following working day after the notification of the resolution.

In the case of concessions, a revocation request will be applicable according to Article 344, clause 2 of the Public Administration General Law.

**Article 17. Payment of administrative rates**

All the applicants of research permits, of bioprospection or economic exploitation will have to pay the amounts established by the Technical Office corresponding to procedures, administrative rates or other expenses. The resources collected this way must be deposited in the CONAGEBIO's bank account and the corresponding voucher must be attached to the application.

**Article 18. Export**

With the granting of the access permit, the interested party is not exonerated from the fulfillment of the obligations stipulated in the national legislation regarding the export of plants, animals, seeds, microorganisms or parts of these obtained from access.

#### **Article 19. Certificate of origin**

In order to certify the legality of access, the Technical Office will issue to the applicant a certificate of origin, also denominated "legal origin certificate" which includes: place and date of access, owner of the elements or resources of biodiversity, the obtained material, quantity, and the person, community or communities that have contributed or will contribute with their related knowledge, innovations and traditional practices. Furthermore, it will indicate whether the interested party fulfilled the regulations established for the prior informed consent and the mutually agreed conditions for the basic research, bioprospection or economic exploitation, as well as the date and number of the corresponding resolution. The Technical Office will design the corresponding format.

#### **Article 20. Verification and control**

The Technical Office according to the terms of the granted permit, will carry out the verification and control duties. For such work, when it is considered as necessary, the Technical Office will coordinate with the interested party or the resource provider.

The Technical Office officers could carry out inspections in the site on which the access will be granted, at any time while the respective permit is in force or once the activities it includes are finished.

The officers will write records of their control visits. The Technical Office will also receive accusations and will investigate the possible violation of the terms of the prior informed consent or of the terms of the access permit.

The unfulfilment of the agreements and commitments will cause the permit cancellation as stipulated in Article 27 of these regulations.

### **SECTION III. FRAME AGREEMENTS, CONTRACTS AND AGREEMENTS BETWEEN INDIVIDUALS**

#### **Article 21. Frame agreements**

The public universities and other research centers duly registered could periodically submit for the Technical Office's approval, frame agreements for access to the genetic or biochemical elements or resources of biodiversity or to the related knowledge, for basic research, bioprospection or economic exploitation and submit the respective reports of operations.

In these cases, the legal representatives of the universities or institutions which apply for this benefit, will be criminally and civilly responsible for the use given to the agreements.

#### **Article 22. Authorization of agreements and contracts between individuals**

The Technical Office of CONAGEBIO will authorize the agreements and contracts subscribed between national or foreign individuals, or between them and the institutions registered for that effect, if they comprises access to the country's genetic and biochemical elements and resources.

To process and approve them, they will have to fulfill what is stipulated in the present regulations, and in the articles 63, 64, 65, 69, 70 and 71 of the Biodiversity Law, whether it is basic research, bioprospection or economic exploitation. Their revision and approval will be carried out taking into consideration the Non-Divulged Information Law Nr 7975.

In case that the agreement or contract be carried out after the access permit applied for has been granted, the permit holder should submit it before the Technical Office for due authorization. Otherwise, the granted permit will be cancelled.

## **SECTION IV. RESTRICTIONS, CANCELLATIONS AND SANCTIONS**

### **Article 23. Duration of permits and concessions**

The access permits, either for basic research or bioprospection and economic exploitation, as well as the concessions, will be established for a maximum term of three years, which could be extended by the Technical Office or Minister, respectively.

Any extension should be processed before the Technical Office.

### **Article 24. Restrictions to the access permits, concessions or agreements**

Permits of any kind, for basic research, bioprospection or economic exploitation, will be granted to the person or corporation who applies for, or on whose behalf it is applied for; they are personal and non-transferable; they are materially limited to the genetic or biochemical elements or resources authorized and could only be utilized in the area or territory explicitly indicated on them, and under the terms pointed out in the resolution issued by the Technical Office.

In the resolution of the access permit application, the Technical Office could impose total or partial restrictions to the access to the genetic or biochemical elements or resources of biodiversity to ensure their conservation and sustainable use. Thus it could prohibit its access, condition it, set limits and regulate the collection methods, among others, or applying the precautionary principle mentioned in article 11.2 of the Biodiversity Law.

To establish total or partial restrictions the following, among others, must be considered:

- a) Extinction danger of species, subspecies, races and varieties.
- b) Reasons of endemism, little abundance or rarity.
- c) Vulnerability or fragility conditions in the structure or functioning of ecosystems.
- d) Adverse effects on human health, species or ecosystems or on essential elements of the autonomy or cultural identity of the indigenous people and local communities.
- e) Genetic resources or geographical areas qualified as strategic.

In all cases the access to the biochemical and genetic resources or elements of biodiversity and to the related traditional knowledge for military, terrorist or denaturalizing purposes by use of genetic use restriction technologies (GURT) is prohibited.

Existing restrictions in the National Parks and Biological Preserves will also be taken into consideration, according to Law 6084 from August, 24th, 1977, on Creation of the National Parks Service and the specific laws of each protected area.

### **Article 25. Intellectual rights**

The Technical Office will oppose registration of patent, commercial secrets, plant breeder rights, *sui generis* communitarian intellectual rights, author's rights, farmers' rights and others, if the institutions authorized by the laws in force to grant these protections, do not fulfill what is established in Article 80 of the Biodiversity Law.

For this purpose, the Technical Office will take into account what is established and delimited on this subject in Articles 77 (Acknowledgement of invention forms), 78 (Protection Form and Limits), 81 (Licenses) and 82 (*Sui generis* communitarian intellectual rights of the Biodiversity Law); as well as the national laws on non-divulged information, patents and author's rights.

### **Article 26. Criteria to request an Environmental Impact Evaluation**

When the Technical Office considers that the access activities to the biochemical and genetic elements or resources of biodiversity derived from a specific permit could cause the erosion of the resource applied for or of the related or adjacent resources, including the soil and its microorganisms; or may cause pollution or other type of environmental impact, submission of the document requested by SETENA will be required of the interested party or its legal representative

to determine the Environmental Impact Evaluation needed. Depending on the results, the Technical Office will proceed to approve, reject or cancel the permit access.

**Article 27. Cancellation of the access permits**

If after due process, the Technical Office comes to prove the noncompliance of the conditions under which the permit was granted, it will suspend it temporarily, and will allow to the interested party a peremptory term to carry out the corresponding corrective measures. In case that the proved noncompliance should be serious, or that in the granted term the corrective measures have not been taken, the Technical Office will cancel the granted permit.

It will be considered a serious noncompliance, that which causes a substantial violation of the prior informed consent and the conditions mutually agreed, of the *sui generis* communitarian rights, and of the conservation of species and ecosystems; or that the documents used for granting the permit are found to be false.

**Article 28. Sanctions for non-authorized access**

Whoever carries out exploration, bioprospection or has access to the elements and resources of biodiversity, without being authorized by the Commission's Technical Office, or over extends the terms on which the permit was granted, will be imposed with a fine which will range between the equivalent to a salary established in article 2 of Law Nr 7337, up to the equivalent to twelve of such salaries, according to article 112 of the Biodiversity Law.

**CHAPTER III. FINAL AND TRANSITORY DISPOSITIONS**

**Transitory 1. For the biochemical and genetic resources and elements of biodiversity kept in *ex situ* conditions**

Once these regulations are published and within a six- month term, CONAGEBIO with the support of specialized persons and technical groups will set the procedure for the access to the biochemical and genetic resources and elements of biodiversity kept in *ex situ* conditions according to article 69 of the Biodiversity Law. As long as there is no such regulations no access permits will be granted for bioprospection or economic exploitation for material found in these conditions.

**Transitory 2. Knowledge, innovations and practices of the local communities and indigenous people**

No access permits for basic research, bioprospection or economic exploitation will be granted, when they involve knowledge, innovations and practices of the local communities and indigenous people on the use of the biochemical and genetic resources of biodiversity, as long as the procedure to establish their rights is not complied, according to articles 66, and articles 82 to 85 of the Biodiversity Law.

**Article 29.** These regulations are in force once published.

Given at the Presidency of the Republic at the three days of the month of April of year 2003.

**ABEL PACHECO DE LA ESPRIELLA**

**CARLOS MANUEL RODRIGUEZ ECHANDI**