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Minambiente

**HANDBOOK
FOR ACCESS TO
GENETIC
RESOURCES
AND THEIR
BY-PRODUCTS
IN COLOMBIA**



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HANDBOOK FOR ACCESS TO GENETIC RESOURCES AND THEIR BY-PRODUCTS IN COLOMBIA

Ministerio de Ambiente y desarrollo Sostenible
Dirección de Bosques, Biodiversidad y Servicios Ecosistémicos
Grupo de Recursos Genéticos
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CONTEXT

Colombia is a megadiverse country, due to its location and geographical characteristics, and has a wide variety of biological species. Many of these species are as yet unstudied or undiscovered, as for example, most of Colombia's micro-organisms. The starting point for managing the sustainable use of Colombia's genetic resources in order to guarantee species conservation, is by first recognizing what we already have in terms of biodiversity. This will then contribute to the nation's economic development, by allowing access to genetic resources and any by-products derived from these species.

In Colombia, The Competent National Authority that promotes the sustainable use of genetic resources and their by-products is the Ministry of Environment and Sustainable Development (Minambiente). It ensures conformation to all legal and technical standards from both basic and applied research. This ensures that the generation of knowledge and development from these research projects are always based on models that guarantee a balance between conservation and economic development, and

are also competitive both in the region and in new markets. These projects generate “a sustainability database for future bio-prospecting”, which in turn can develop livelihood alternatives for the populations of the most mega-diverse regions of the country.

Consequently, the Ministry faces many challenges in the field of bioprospecting, including the creation of a national inventory of genetic resources, and the construction of a National Bioprospecting Strategy, which it has already begun to lead.

Colombia is a member of the Andean Community (CAN). One of the principal instruments for managing these nations’ bio-diverse genetic resources, is Andean Decision 391 of 1996 (on supranational rule). In the Decision, the mechanism for establishing Mutually Agreed Terms (MAT) between the State, as owner of the resource (provider), and the person requesting authorization for access and use of these resources¹ (user), is an Access Contract for ‘genetic resources and their by-products’ (Spanish: *recursos genéticos y sus productos derivados*), from here on referred to as an ‘Access Contract’. Through this mechanism, Colombia complies with the provisions of Article 15 of the Convention on Biological Diversity (CBD).

The Colombian Ministry of Environment and Sustainable Development, through the Directorate of Forests, Biodiversity and Ecosystem Services (DBBSE), has created a Genetic Resources Group (GRG) that promotes access to Colombian genetic resources and their by-products from a perspective of ‘sustainable use of biodiversity’. Increased access has been based on an improvement in response times; internal restructuring that facilitates the Access Contract application

1. Norms that support State ownership of its genetic resources: Decree 2811 of 1974, National Code of Renewable Natural Resources and Environmental Protection -CRN, Article 291, Colombian Constitution of 1991, Articles 8 and 81, Convention on Biological Diversity-CBD, Law 165 of 1994, Article 15, No. 1 and Andean Decision 391 of 1996, Articles 5 and 6.

process; reinforcing follow-up to authorized contracts; and technical guidelines to define which activities can be recognized as 'access to genetic resources and their by-products' within the current regulatory framework.

In addition, there has been consultation with academic, institutional and business sectors, and other legal entities whose procedures would be recognized within an Access Contract.

To date, the DBBSE Genetic Resources Group has signed over 373 individual and framework Access Contracts, for both research or commercial purposes. This handbook has been published with the aim of informing Access Contract applicants about:

- Regulations associated with access to genetic resources and their by-products
- The Access Contract application procedure
- The follow-up to signed contracts
- Technical and legal developments carried out by the Ministry of Environment and Sustainable Development.

This is a permanent consultation tool for those who want to carry out basic or applied research and/or the possibility of scaling up to a commercial or industrial level using species of Colombian origin. It is important to note that the texts in this handbook were produced under the current regulatory framework, and may therefore be subject to adjustment in cases of regulatory change.



01

**REGULATORY
FRAMEWORK**





1.1.**Colombian Constitution of 1991**

Article 81 of the Political Constitution of Colombia from 1991 establishes that “[...] the State will regulate usage of genetic resources, and their entry into and exit out of the country, in accordance with national interest [...]”.

1.2.**Convention on Biological Diversity (CBD)**

The Convention on Biological Diversity (CBD) adopted through Law 165 of 1994, recognizes the sovereign rights of states over their natural resources in areas within its jurisdiction. The parties to the convention, therefore, have the authority to determine access to genetic resources within their own territory, and the obligation to take appropriate measures to share the benefits derived from their use. Specifically, the third objective of the CBD (developed in Articles 15, 16 and 8j) is for the fair and equitable sharing of the benefits arising from use of genetic resources. This is to be achieved through adequate access to these resources, appropriate transfer of relevant technologies, and appropriate financing, taking into account the rights over those resources and those technologies.

1.3.

Andean Decision 391 from the Cartagena Agreement Commission

In July 1996, the five Andean countries (Bolivia, Colombia, Ecuador, Perú and Venezuela) signed Andean Decision 391 from the Cartagena Agreement Commission. The Andean Decision is intended to regulate access to genetic resources and their by-products or their intangible components (from any member countries which are their country of origin), in order to:

- a. Establish conditions for just and equitable sharing of any benefits from this access;
- b. Lay the foundations for the recognition and valuation of the genetic resources and their by-products and any associated intangible components, especially when native, Afro-American or local communities are involved;
- c. Promote conservation of biological diversity and sustainable use of biological resources that contain genetic resources;
- d. Promote the consolidation and development of scientific, technological and technical capacities at local, national and sub-regional levels;
- e. Strengthen the negotiating capacity of the Member Countries.²

2. The objectives of Andean Decision 391 of 1996 were added in the English version.



The Andean Decision is applicable to genetic resources (from any member countries which are their country of origin), their by-products and intangible components, as well as genetic resources from migratory species which, due to natural causes, occur in the territory of the member countries.

Within this supranational norm, genetic resources are conceived as assets or patrimony of the nation or state, in accordance with the provisions of their respective internal legislation.

In most cases, signing an Access Contract will be required³ in order to access these resources, as well as the issuance and publication of all corresponding Resolutions and registrations of any actions related to access activities.

1.4.

Concept No. 977 of August 8, 1997 of the Civil Service Chamber of the State Council

One of the concerns of the Competent National Authority in Environmental Matters was how to conceptualize genetic resources as a national asset, in order to determine whatever ownership rights the State had over those resources. For this

3. Contract for access to genetic resources signed between the Ministry of Environment and Sustainable Development and the interested party; authorization that allows access to genetic resources or their by-products for the purpose of biological prospecting, industrial application, commercial exploitation or basic research; when the activities are not molecular phylogenetics, ecology, evolution and molecular biogeography.

purpose, the Civil Service Chamber of the State Council was requested to provide such a concept.

This was pronounced as Concept No. 977 of August 8, 1997, which states that genetic resources are assets within the public domain and consequently, imprescriptible, unattachable and inalienable.

In addition, the State Council established that the principles given in Andean Decision 391 of 1996, are also applicable to genetic resources when isolated from their biological origins. In other cases, ecological function and public interest are the constitutional mechanisms by which the State protects its proprietary rights over genetic resources.

1.5.

National Code of Renewable Natural Resources and Environmental Protection

Item (g) in Article 8 of the National Code of Renewable Natural Resources and Environmental Protection of 1974, considers the extinction, or quantitative and/or qualitative decrease of animal and plant species or other genetic resources, to be among the principal factors that degrade the environment. Article 291 establishes the need to obtain special authorization for the import, production, sale, or purchase of hybrids or new species obtained through the use of genetic resources.



Additionally, Article 328 establishes that one of the purposes of Colombia's National Park System is to perpetuate in their natural state: our biotic communities, physiographic regions, biogeographic units, genetic resources or any wild species threatened with extinction. Article 329 therefore established that the National System of National Natural Parks, within its specified areas, is obligated to provide both *flora* sanctuaries (areas dedicated to the preservation of plant species and communities in order to conserve the nation's genetic flora resources), and *fauna* sanctuaries (areas dedicated to the preservation of species and communities of wild animals to conserve the nation's genetic fauna resources).

1.6.

Law 99 of 1993

Law 99 (Article 5) of 1993, established the Ministry of Environment and Sustainable Development (previously the Ministry of the Environment) as responsible for coordinating, promoting and guiding research activities concerning the environment and renewable natural resources; establishing the Environmental Information System, and organizing an inventory of biodiversity and national genetic resources (Article 20).

Likewise, it is held responsible for ensuring that national or non-national studies, exploration or research in respect to renewable natural resources, respect Colombia's national sovereignty and rights over its genetic resources (Article 38).

1.7.

Resolution 1348 of 2014

This Resolution specifies the activities that constitute 'access to genetic resources and their by-products' in Colombia, in accordance with Andean Decision 391 of 1996.

"Article 2. Activities that constitute access to genetic resources and their by-products.

The following activities carried out with native species, whether in their wild, domesticated, cultivated or feral forms, including viruses, viroids and the like, found in the national territory or outside of it:

- 1. Those activities that seek the isolation of functional and non-functional units of DNA and/or RNA, in all forms found in nature.*
- 2. Those activities that aim to isolate one or more molecules, understood as micro- or macro-molecules, produced by the metabolism of an organism.*
- 3. Whenever a patent is sought on an identified function or property of a molecule, which has not yet been isolated and purified".⁴*

4. Modified under Resolution 1352 of 2017: "When seeking a patent for products or procedures obtained or developed from genetic resources or their by-products, the applicant must submit to the competent national office, copy of the contract for access to genetic resources and their by-products, as stated in Andean Decision 486 of 2000".



1.8.

Decree 1076 of 2015

This decree compiles the Environmental and Sustainable Development Sector's pre-existing regulatory standards, including regulations for biological collections, permissions to collect wild specimens of biological diversity for non-commercial scientific research purposes, and study permits for scientific research purposes.

Within the scope of this decree, it also establishes that any basic scientific research activities involving:

**THIS
decree
COMPILES
PRE-EXISTING
REGULATORY
STANDARDS
FOR THE ENVI-
RONMENT AND
SUSTAINABLE
DEVELOPMENT
SECTOR**

- Molecular systematics
- Molecular ecology
- Evolution
- Biogeography

do not constitute access to genetic resources:

- When carried out with specimens obtained within the framework of a permission to collect specimens of wild species of biological diversity for non-commercial scientific research purposes,
- Or with specimens obtained from a biological collection⁵.

5. The clarification of the collection permission to collect specimens of wild species of biological diversity for non-commercial scientific research purposes and with specimens obtained from a biological collection, was done in the English version.

In order to access genetic resources from specimens deposited in biological collections, or collected from the environment for industrial, commercial or bioprospecting purposes, the interested party must sign an Access Contract, in accordance with current national legislation (Article 2.2.1.5.1.2, Article 2.2.2.9.1.4, paragraphs 1 and 2, and Article 2.2.2.8.1.2, paragraphs 5 and 6).

1.9.

Other relevant regulations

- **Andean Resolution 414**, Cartagena Agreement Commission, July 22nd of 1996, from which the Access Contract application form model was adopted.
- **Andean Resolution 415**, Cartagena Agreement Commission, July 22nd of 1996, from which the Access Contract model was adopted.
- **Andean Decision 486 of 2000**, of the Andean Community Commission, on the Common Regime on Industrial Property, establishes in Article 3 on Biological and Genetic Heritage and Traditional Knowledge, that "member countries will ensure that the protection conferred on industrial property elements will be granted safeguarding, and will have respect for its biological and genetic heritage, as well as for the traditional knowledge of its indigenous, African-American or local communities.

As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law.



The Member Countries recognize the right and the authority of indigenous, African-American, and local communities in respect of their collective knowledge.

The provisions of this Decision shall be applied and interpreted in such a way that they do not contravene the stipulations of Decision 391 and its effective amendments”.

- **Law 1333 of July 21st of 2009**, acknowledges the rights of environmental authorities to exercise sanctioning powers against any environmental offence regarding: violations of regulations that protect environmental and renewable natural resources; violations of administrative acts by the competent environmental authority, or by actual harm to the environment.

Genetic resources group functions

1.10.

Decree 730 of 1997

In this Decree, the Colombian Government designated the Ministry of Environment and Sustainable Development (previously known as the Minis-



try of the Environment) as the Competent National Authority in matters of access to genetic resources through Decree 730 of March 14th, 1997⁶.

1.11.

Resolution 620 of 1997

Resolution 620 of July 1997⁷ established the internal procedure to process applications for access to genetic resources and their by-products.

1.12.

Decree 3570 of 2011

With this decree, the objectives and internal structure of the Ministry of Environment and Sustainable Development were modified, integrating the Administrative Sector of Environment and Sustainable Development. In addition, the Directorate of Forests, Biodiversity and Ecosystem Services

6. Decree 730 of 1997, through this Decree, the Ministry of the Environment, today the Ministry of Environment and Sustainable Development, was designated as the Competent National Authority for the effects enshrined in Decision 391 of the Commission of the Cartagena Agreement.

7. Resolution 620 of 1997 of the Ministry of the Environment, which delegates some functions contained in Decision 391 of the Commission of the Cartagena Agreement and establishes the internal procedure to process requests for access to genetic resources and their by-products.





IN 1997 THE INTERNAL PROCEDURE TO PROCESS REQUESTS FOR ACCESS TO GENETIC RESOURCES WAS ESTABLISHED

was directed to implement a process for dealing with applications for access to genetic resources, accepting or denying applications, resolving filed appeals for rescindment, and signing the corresponding contracts.

In addition, the Sustainable and Green Business Office was assigned the role of proposing and supporting the adoption of mechanisms for fair and equitable sharing of any benefits arising out of access to genetic resources (with the support of the Ministry's Sub-directorate of Education and Participation, when these mechanisms have associated traditional knowledge).

Likewise, the Office participates in the formulation of strategic elements to guarantee that intellectual property systems respect rights over Colombia's biological and genetic resources. This is implemented in coordination with the Directorate of Forests, Biodiversity and Ecosystem Services, and the Ministry 's Subdirectorate of Education and Participation.

1.13.

Resolution 766 of 2012

Resolution 766 of 2012 distributes the overall responsibilities of the Ministry of Environment and Sustainable Development throughout its various dependencies and internal work groups.

Based on this Resolution, the Directorate of Forests, Biodiversity and Ecosystem Services, holds all



responsibilities relating to Item 14 of Article 16 of Decree 3570 of 2011:

- Implementing the process for dealing with applications for access to genetic resources
- Accepting or denying those applications
- Resolving filed appeals for clarification, modification, addition or revocation of contracts
- Signing any corresponding contracts.

1.14.

Resolution 736 of 2015

Resolution 736 of 2015 created the internal working groups of the Directorate of Forests, Biodiversity and Ecosystem Services (DBBSE), including the Genetic Resources Group (GRG). It also determines these groups' functions, and appoints their coordinators.

In addition to processing Access Contracts, other functions assigned to the GRG include the evaluation and monitoring of policies, plans, programs, projects, and all regulations regarding the conservation, handling, and sustainable use of Colombian genetic resources and their by-products.

These regulations include:

- The definition of technical guidelines for the prevention and control of illegal access to Colombian genetic resources.
- The organization of a national inventory of genetic resources.
- The definition of technical, conceptual and legal guidelines for the implementation of biosecurity measures and the sustainable use of genetically modified organisms.





02

CONSIDERATIONS WHEN APPLYING FOR AN ACCESS CONTRACT





2.1.

Procedure

Applying for an 'Access Contract for Genetic Resources and their By-products' (Spanish: *Contrato de Acceso a Recursos Genéticos y sus Productos Derivados*).

2.2.

Who should apply for an access contract

Any national or foreign individual or legal entity, consortia or temporary group that seeks access to the genetic resources or their by-products or associate intangible components of any native species, including viruses, viroids and microorganisms isolated from the national territory⁸.

2.3.

When to apply for an access contract

An Access Contract **must** be requested whenever it is intended to carry out activities with any native species found in the national territory or outside of it, whether in their wild, domesticated, cultivated or feral forms. This includes viruses, viroids and micro-organisms isolated from the national

8. Text "microorganisms isolated from the national territory" added in the English version.

territory⁹, in accordance with the provisions of Article 2 of Resolution 1348 of 2014 (see Annex 1).

These activities are:

- Those that seek the isolation of functional and non-functional units of DNA and RNA, in all forms found in nature.
- Those that seek the isolation of one or several molecules, understood as micro- and macromolecules, produced by the metabolism of an organism.
- When seeking a patent for products or procedures obtained or developed from genetic resources or their by-products, the applicant must submit to the Competent National Office, a copy of the Access Contract, as stated in Andean Decision 486 of 2000¹⁰.

WHEN TO
apply
 FOR AN
 ACCESS
 CONTRACT

NOTE: If, after analyzing the project and having reviewed the three aforementioned activities and the specifications in the diagram in Annex 1, you are unable to identify whether or not the activities to be carried out require an Access Contract, you may request clarification/categorization from the Ministry of Environment and Sustainable Development. For that, you must provide your project title, objectives, methodology, extent of the research and your expected results. You can file this request in physical form at the following address:

9. Text "microorganisms isolated from the national territory" added in the English version.

10. Text added in the English version as modified under Resolution 1352 of 2017.





Directorate of Forests, Biodiversity and Ecosystem Services, Calle 37 No 8-40, Bogotá, or by email to:

- correspondencia@minambiente.gov.co or
- servicioalciudadano@minambiente.gov.co

specifying in the subject-line that the mail is addressed to:

- Genetic Resources Group of the Directorate of Forests, Biodiversity and Ecosystem Services.

2.4.

When NOT to apply for an access contract

An Access Contract is **not** required:

- When activities are carried out for basic research purposes that are limited to: molecular systematics, molecular ecology, evolution and molecular biogeography, as established in Decree 1076 of 2015. This is regardless of techniques used. This is also provided that the biological resource has been obtained under a Collection Permit for Wild Specimens of Biological Diversity for Non-commercial Scientific Research Purposes, or from a collection registered at the Alexander von Humboldt Biological Resources Research Institute.





- When activities are carried out with human genetic resources and their by-products, as established in Andean Decision 391 of 1996.
- When there is an exchange by indigenous, African-American or local communities of the member countries, of genetic resources, their by-products, the biological resources that contain them, or the intangible components associated with them. This must be between themselves and for their own consumption, based on their customary practices, as established in Andean Decision 391 of 1996.

2.5.

The competent national authority for access contracts

The Competent National Authority to grant Access Contracts is the Ministry of Environment and Sustainable Development, in accordance with the provisions of Decrees 730 of 1997 and 3570 of 2011.

2.6.

Types of access contract

Note that when applying for an Access Contract, there are two different types:

- The Individual Access Contract.
- The Framework Access Contract.



2.6.1

Individual access contract

THERE IS NO CHARGE FOR PROCESSING AN ACCESS CONTRACT

As previously stated, an Access Contract is an agreement between the Ministry of Environment and Sustainable Development and an individual or organisation, which establishes the terms and conditions for access to genetic resources, their by-products and, if applicable, their associated intangible components¹¹.

This contract can be established for industrial, commercial or biological prospecting (bioprospection) purposes, and allows for the development of access activities under a specified project.

The parties to an individual access contract are:

- The Ministry of Environment and Sustainable Development.
- The applicant.

2.6.2

Framework access contract

A Framework Access Contract is the same as an Individual Access Contract, but covers the execution of multiple access activities within the overall framework of diverse research projects.

11. Definition contained in Andean Decision 391 of 1996, Common Regime on Access to Genetic Resources.

Projects with different access activities can be included in the initial contract application, or added during the contract term through an amendment to the original Framework Contract. This type of contract is conducted between the Ministry of Environment and Sustainable Development and universities, research centers or recognized researchers¹², in accordance with the provisions of Decision 391 of 1996 and in accordance with the legislation of each member country¹³. In Colombia, the status of 'recognized research center and researcher' is established in accordance with the criteria adopted by the Ministry of Science, Technology and Innovation.

The parties to a framework access contract are:

- The Ministry of Environment and Sustainable Development.
- The applicant (a university, research center or recognized researcher).

12. A recognized researcher shall be understood as one who has the quality of leader of a research group, classified by the Ministry of Science, Technology and Innovation.

13. Article 36 of Andean Decision 391 of 1996, Common Regime on Access to Genetic Resources.





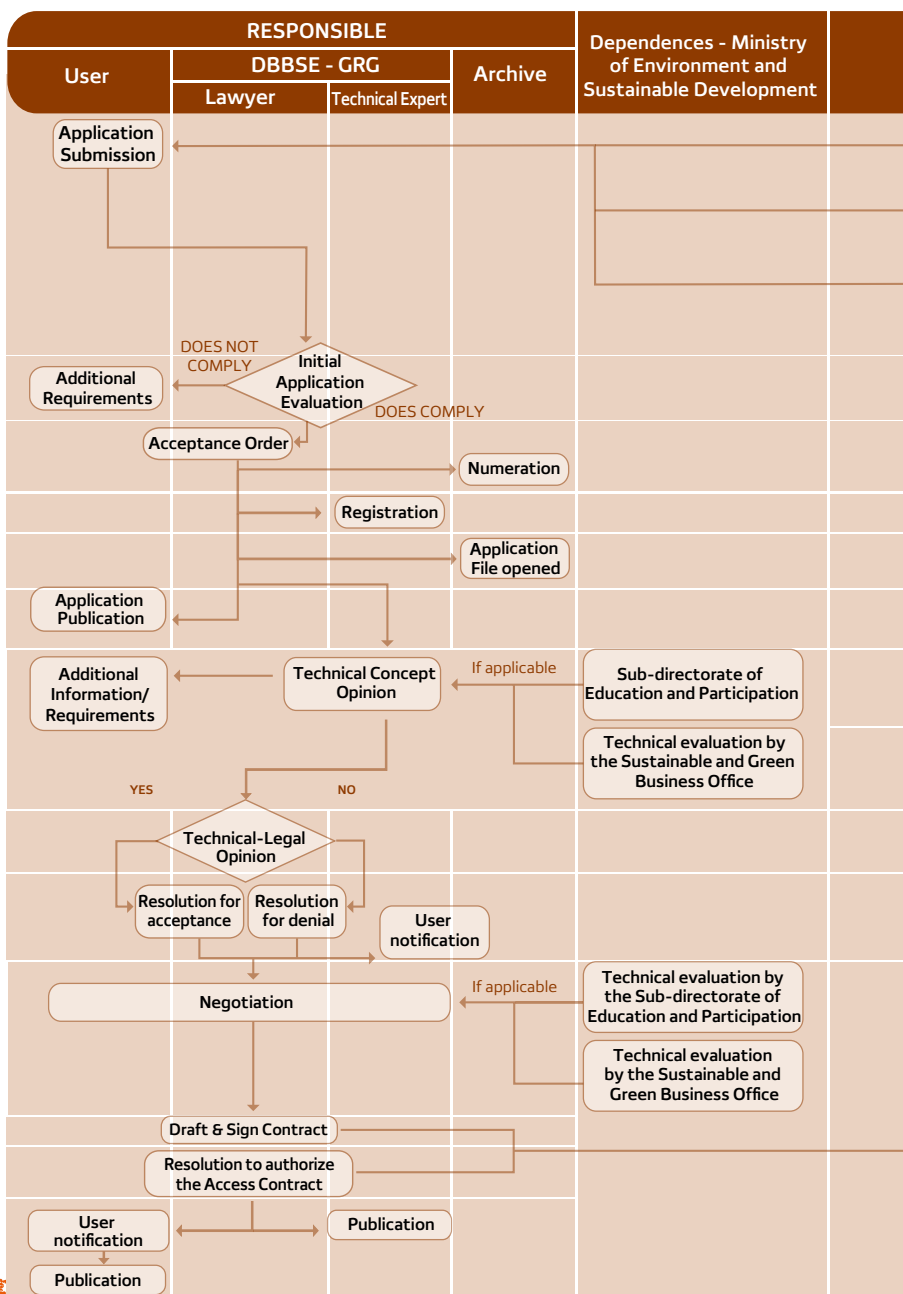
03

APPLICATION
PROCEDURE





Flow chart for processing the contract for access to genetic resources and their by-products



The flow is designed in accordance with the provisions of Resolution 620 of 1997 and Decree 3570 of 2011



| Ministries and others | TIME (BUSINESS DAYS) | OBSERVATIONS | PROCEDURE |
|---|----------------------|---|--|
| <p>Scientific research permit (ANLA-CAR-SPNN)</p> <p>Certificate of the presence of ethnic groups (Ministry of Interior)</p> <p>National Support Institution</p> <p>If there is presence →</p> <p>Certificate of land titles from Agencia Nacional de Tierras (ANT)</p> | | | Application submission |
| | 20 | | Preliminary analysis of the application Application Acceptance Application registration Application File opened |
| | | 5 days after registration | Application publication |
| | 30 | Up to 60 days after registration Request for information clarification or technical visits | Application evaluation Testing and information Technical-Legal Opinion |
| | 5 | | Resolution for acceptance or denial |
| <p>Superintendency of Industry and Commerce (in case the research is patentable)</p> | 10 | | Negotiation and Signing the contract Publication of Resolution authorizing Access Contract |

Directorate of Forests, Biodiversity and Ecosystem Services



The procedure is carried out in accordance with the provisions of Resolution 620 of 1997 and in accordance with the functions assigned to the Directorate of Forests, Biodiversity and Ecosystem Services through Decree 3570 of 2011, taking into account responsibilities and established time frames.

3.1.

Application submission

The procedure begins by submitting an application to the Ministry of Environment and Sustainable Development for an Access Contract. This is done by either entering the main Environmental Procedures page of VITAL,

<http://vital.anla.gov.co/Ventanillasilpa/> and filling out the application form, or by sending your request by e-mail:

- corespondencia@minambiente.gov.co or
- servicioalciudadano@minambiente.gov.co.

The application must contain the following documents:

1. Completed Access Contract application form (see Annex 2), as adopted by the Cartagena Agreement Board through Resolution 414 of 1996.
2. Project Proposal (when necessary or if the applicant considers annexing it).
3. Applicant's identification documents.



4. Certification and legal representation, if a national legal entity.
5. Certification and legal representation as a legal foreign entity in Colombia, authenticated by the Colombian consular officer or their substitute and in Spanish, if required.
6. Any legal empowerment duly granted, in the event that the individual or the legal representative of the legal entity does not act directly.
7. Constitutional documents for any consortium or temporary group, if requested through any of these forms.
8. Certification showing the presence of any ethnic groups in research areas, if required, or a document granted by the Ministry of Interior, stating that prior consultation is not required for the project.
9. In the event that the application involves the collection of biologic resources in areas where ethnic groups are present, or when there is traditional knowledge associated with the research, a formal record of prior consultation with ethnic groups (from the Ministry of the Interior) must be attached.



If this is not available during the initial application, it will not be a cause for rejection. However, it is a prerequisite for signing the contract, and must be provided for the application evaluation.¹⁴

10. Any previous permissions to collect wild specimens of biological diversity for non-commercial, scientific research purposes, when applicable.
11. A study permit for scientific research purposes in biological diversity, when applicable.
12. Where a collection permit is not held, a permit will either be granted within the Access Contract, or will be unnecessary if samples are taken from a biological collection.
13. If the collection of species is not needed, because samples will be taken from a collection, a copy of the collection register certificate from the Alexander von Humboldt Biological Resources Research Institute must be attached.
14. Accessory Contracts, where relevant, between the applicant and:
 - The owner, possessor or administrator of the property where the biological resource containing the genetic resource or its by-product is located. (In this case, the Accessory Contract is understood as a document showing that the owner, holder, or administrator of the property, authorizes entrance to their property and indicates the type and quantity of samples to be collected from the property).

14. According to Convention No. 169 on Indigenous and Tribal Peoples in Independent Countries (ILO).



- The owner, holder or administrator of a biological resource containing the genetic resource. (In this case, the Accessory Contract is understood as a document showing that the owner, holder, or administrator of the biological resource (e.g. the vendor of biological resources at a collection center) will deliver, sell, or donate, specific types and quantities of samples).
- The *ex situ* conservation center. (In this case, the Accessory Contract is understood as a document showing that the *ex situ* conservation center (for example, a biological collection registered with the Alexander von Humboldt Biological Resources Research Institute, a botanical garden, a zoo, etc.) will donate specified types and quantities of samples).

Note: Not having the Accessory Contract during the initial application will not be cause for rejection.

The Accessory Contract must clearly indicate the identity of the specimens (the scientific name of the specimen and an identification number in the case of an *ex situ* conservation center), from which the genetic resource and its by-products will be obtained, plus the number and type of samples to collect.

Note: When samples are to be taken from a biological collection, a copy of their registration with the Alexander von Humboldt Biological Resources Research Institute, must be attached. This registration must have been made within the two (2) years prior to the Access Contract date of application.



15. In the event that access to genetic resources or their by-products is requested with an intangible component that does not belong to an ethnic community, a signed document must be presented between the supplier of the intangible component and the access applicant. It may also be underwritten by the Competent National Authority, in accordance with the provisions of the national legislation of the member country. If the said annex is not signed by the Competent National Authority, the Access Contract will be subject to suspension. If unavailable at the time of application, this is not a cause for rejection. However, it is a prerequisite for signing the Access Contract.
- 16 Letter of commitment from a National Support Institution (Spanish acronym: INA), in accordance with the provisions of Andean Decision 391 of 1996, together with certification and legal representation from the same. The INA is a national legal entity, dedicated to biological research of a scientific or technical nature, that accompanies the applicant and participates with them in access activities.

The letter must clearly indicate that the INA - name of the institution or entity - , will support the Ministry of Environment and Sustainable Development in the activities of monitoring and control of genetic resources, by-products or synthesized products and associated intangible components, for project "x" – *"the name of the project"* that is subject to the Access Contract application, as established in Andean Decision 391 of 1996.



- 17** *Curriculum vitae* of the technical project manager (the technical project manager is whoever is accountable for all technical activities carried out under the contract and the suitability of the research and work team).

N.B. When submitting their application, the applicant may state whether all administrative notifications derived from the application process and subsequent execution of the contract, should be sent electronically by email (give email address).

3.1.1.

How to apply for an individual access contract

The following section gives a step by step explanation on how to complete the Access Contract application form, (see Annex 2a for the form and a completed example).

HOW TO FILL IN THE APPLICATION FORM FOR AN ACCESS CONTRACT

I. Applicant or legal representative

1. Identification

Fill in the name of the individual or legal entity applying for an Access Contract, together with their nationality, ID number, legal address (or residence address), telephone, work email and, if possible, personal



email. If, during the contract execution process, you change your contact information, please notify the appropriate office.

When the applicant is a legal entity (e.g. a company, university or research center), the name of the legal entity, followed by their legal representative, must be included.

II. Technical project manager

1. Identification

Fill in the company name or the name of the party responsible for the research project in which access to genetic resources and their by-products is required. Also include their: nationality, ID number, legal address (or residence address), telephone, work email and, if possible, personal email. If any information concerning the technical project manager changes during the term of the contract, please notify the appropriate office.

If the primary applicant is also the technical project manager, fill the same data in both spaces.

2. Access activities carried out in the last five (5) years by the technical project manager

Fill in the table, briefly describing any access activities to genetic resources, made in the last five years, including the country in which they were carried out, and the individual or legal entity for whom the described activities were carried out.



3. Description of previous studies undertaken by the technical project manager (three most important)

Fill in the table with any previous advanced studies carried out by the technical project manager (main researcher), with year, institution and place where these studies were carried out.

4. Publications by the technical project manager (three most important)

Fill in the table with the three most relevant publications (of a scientific nature) made by the technical project manager of the project (principal researcher).

5. Experience of the technical project manager (activities carried out in the last five years)

Fill in the table with work experience or academic activities carried out in the last five years (prior to the application), indicating in the first column the number of days or months spent in the activity or in a related position.

6. Working group responsible for the access activity

Fill in the table with the name, address, specialty and academic degrees of the people responsible for access to genetic resources with email addresses where possible.

In the event that the project requires **the collection of samples of native species**, whether in their wild, domesticated, cultivated or feral forms,



including viruses, viroids and micro-organisms¹⁵, the following should be indicated:

- 1. Personal data:** Basic contact information of those who will carry out the activity.
- 2. Academic training:** Academic programs, courses or training related to the research or project to be carried out and with activities related to the capture and handling of specimens.
- 3. Specific experience on the subject:** Experience in specimen collection, including methods of sampling, capture, handling and preservation of specimens.

NOTE: When applying for a Framework Access Contract, the working group responsible for the access activities should not be given. This information should only be given when requesting the addition of specific activities under specific projects.

15. Text "microorganisms" added in the English version.

III. Resource provider details

1. Identification

Fill in the name of the supplier of the natural, biological, genetic resources and their by-products, or associated intangible component, their ID number, and legal address. Likewise, attach any documents certifying that the aforementioned supplier is the authorized supplier of the resource (in this case, a biological resource). For example, if it is a biological collection, you must include the registration certificate from the Alexander von Humboldt Biological Resources Research Institute, indicating the total number and identity of requested resources.

IV. Details of the Person or National Scientific or Cultural Support Entity (INA)

1. Identification

Fill in the name, ID number and legal address of the National Support Institution (INA) (person or legal entity) dedicated to biological research of a scientific or technical nature, that accompanies the applicant and will participate together with them in access activities.

V. Project proposal

1. Title

Enter the title of the project within which access to genetic resources or their by-products will be carried out. This will define the framework under which all activities will be carried out and must be coherent to the project objective.



NOTE: When completing a Framework Access Contract application, the title should correspond to the name of the institutional program under which the specific access activities of the various projects will be added. In this sense, the name should be coherent with the access activities that are intended to be carried out within the specific projects.

2. Justification, objectives and technical literature

The justification for the project should be outlined and described, specifying:

- What is being carried out and why
- What are the project's benefits
- Who the project's beneficiaries

The project's goals, objectives and expected outcomes must also be clearly given, along with any supportive or pertinent technical literature, concisely expressed.

If the project includes the collection of biological resources, this must also be included in the objectives, as this activity is required for access to genetic resources.

NOTE: When completing an application form for a Framework Access Contract, the justification, objectives and technical literature information must correspond to the institution's own program.



3. Application area

Here, specify the knowledge or application area for which the project is being developed.

NOTE: When completing a Framework Access Contract application, the specific knowledge or application area should not be given. This information should only be given when requesting the addition of activities for specific projects.

4. Type of activity and uses of the resource

Define whether access will be for industrial, commercial or 'biological prospecting' purposes. Biological prospecting is understood as "bioprospecting", defined in the CONPES 3697 National Planning Department 2011 document as " the systematic and sustainable exploration of biodiversity to identify and obtain new sources of chemical compounds, genes, proteins, microorganisms and other products that have the potential to be used commercially (Rocha, 2009)."¹⁶

NOTE: When completing a Framework Access Contract application, the type of activity and uses to be given to the resource should not be outlined. This information should only be given when requesting the addition of activities under specific projects.

16. Rocha P. (2009). Proposal for strengthening the national bioprospecting capacity with the use of biotechnological tools, in areas of interest for the development of products with commercial impact. National Planning Department.

5. Reference list of genetic resources, by-products and associated intangible components, to which access is sought (scientific name, common name and number of samples)

This reference list is the description of biological resources, genetic resources, by-products, and intangible components that the applicant intends to access. It indicates the level at which the genetic resource and its by-products will be accessed. In the event that the project involves activities to collect biological samples, the following must be given:

- **Scientific name:** Taxonomic identity (with the highest possible level of detail) of the species to be collected, from which it is intended to access the genetic resource and/or its by-products. The level of detail depends on the nature and objectives of the project to be carried out.
- **Sample type:** Refers to the specimen: e.g. skin, liquid sample, botanical sample (exsiccated or dry), feathers, tissue sample (muscle, heart, liver), blood, feces, 250 ml water sample, surface scraping of 1 cm², batch, etc.
- **Total number of specimens to be collected:** Maximum number of specimens, and the type of samples to be collected. Please note that this number should be established with consideration for locality and type of sample. Remember to include within the total quantity, sufficient material for a duplicate sample



that you should deposit in a collection registered with the Alexander von Humboldt Biological Resources Research Institute during the execution of the access contract.

- **Polygon number:** Numbering the localities given in Point 6. Please note you should link the identity and number of specimens you intend to collect to each of the sampling localities.



THE
INFORMATION
MUST BE
CLEAR
AND
COMPLETE.
IT WILL SPEED
UP THE
PROCESS
AND WILL
FACILITATE THE
EVALUATION OF
THE REQUEST
FOR ACCESS TO
GENETIC
RESOURCES
AND THEIR
BY-PRODUCTS

- **Special categories:** If you intend to carry out species collection activities within the following special categories, indicate the special category to which they belong according to:
 - a) Endemic species: write “yes” or “no”.
 - b) Endangered species: write “CR” for species classified as Critically Endangered, “EN” for Endangered species or “VU” for Vulnerable species, depending on the species’ category of threat.
 - c) Animals within a closed season: write “regional” or “national” according to the species’ appropriate closure category.
- **Permission/resolution number:** Enter the permission or authorization ID registration number to collect species in special categories, from the Ministry of Environment and Sustainable Development, or another environmental authority.

The holder of this authorization will be responsible for guaranteeing best practices in relation to the total number of samples, sampling location and frequency, so that collection does not negatively affect either species or ecosystems.

Note: When completing an application for a Framework Access Contract, the reference list of genetic resources, by-products, and intangible

components should not be given. This information should only be given when requesting the addition of activities for specific projects.

6. Location of access areas and access activities (coordinates)

a) Collection

Specify the geographical area with its respective geographic coordinates, in the Magna-Sirgas Origin Bogotá system (preferably as a delimited polygon); the name of the municipality and department where the collection, capture, hunting and fishing activities will be carried out. Also give what biological resources containing the genetic resources and their by-products will be accessed, with a respective description of the files (GDB and SHP), according to the base thematic cartography of the Geographical Institute Agustín Codazzi (IGAC), using a work table scale.

b) Location of access area

Indicate whether the biological resources that contain genetic resources and their by-products are *in situ* or in *ex situ* collections.

c) Location of genetic material processing and use

Specify the place and the geographical area where the access activities will be carried out, such as laboratories, research centers, etc.

In case of *ex situ* resources, relevant information about the *ex situ* conservation or commercialization center should be included.

Note: When filling out the form for a Framework Access Contract, the location of the access areas and the execution of the access activities should not be indicated. This information should only be related when requesting the addition of activities in specific projects.

7. Indicative timeline

Complete the table with all activities, times and places involved with the project. As for approximate durations, the contract should cover all stages of the project until the specific objectives are met.

NOTE: When completing the form for a Framework Access Contract, it is not necessary to give an indicative timeline, as this information should only be given when requesting the addition of activities of specific projects. However, the final deadline for the framework contract for the development of projects within the institutional program should be given.

8. Materials and methods

Give details of the methodology, techniques and tools that will be used to carry out the access activities.

NOTE: When completing the form for a Framework Access Contract, the materials and methods should not be given. This information should only be given when requesting the addition of activities for specific projects.

9. Exploration and collection procedure

Give details of the methods for collecting, capturing, hunting or fishing, the biological resources that contain the genetic resources and by-products to be accessed.

A clear description of the methodologies used to collect specimens or samples (capture, removal, temporary or permanent extraction from the natural environment) of biological material should be given with full details. Specimen capture, collection, handling and preservation methods must be included, specifying the duration and frequency of sampling (a schedule showing how many collections and the number of specimens or samples within each collection).

The proposed methodology must guarantee a reasonable use of the biological resource, avoiding overcollection. In any case, it should show that the collection will not negatively affect species and ecosystems, including breeding locations, biological cycles and wild population habitats.



In the event that research requires laboratory livestocking or slaughter, the methodology must be specified in either case. The transport of collected material within the country should be given, including all journeys taken. This information will be included in the Access Contract and in the final Resolution, which will act as a safe-conduct to transport the specimens or samples.

NOTE: When completing the form for a Framework Access Contract, the exploration and collection procedure should not be given. This information should only be given when requesting the addition of activities for specific projects.

10. Management of Samples

Describe the handling of sample(s), from the moment of collection (if applicable), through processing, to final disposal. Remember that any duplicate of a sample to be consigned to a registered biological collection, must comply with the appropriate conditions for its consignment. There should be consultation with the aforementioned biological collection on their set conditions, so there are no grounds for rejection.

NOTE: When completing the form for a Framework Access Contract, sample handling should not be described. This information should only be given when requesting the addition of activities for specific projects.



11. Expected results

These are the results expected at the conclusion of the project.

NOTE: When completing the form for a Framework Access Contract, the expected results of the institutional program must be described.

12. Initial budget

Refers to the financial resources required for the development of the project.

NOTE: When completing the form for a Framework Access Contract, the budget should not be given. This information should only be given when the addition of activities for specific projects is requested.

13. Other Documents for Inclusion

Other documents, in addition to the above, that should be included with the application.

VI. Letter of acceptance in principle or contract from the provider of biological resources, genetic resources or intangible components

Described in Section 3.1.14: Accessory contracts to the Access Contract.

VII. Letter of commitment from a National Support Institution (INA), person or legal entity

This letter is described in Section 3.1.16 on accessory documents to be included in the application.



3.1.2.

Applying for a framework access contract

The application should contain the following documents:

- Certification and legal representation or ID of the applicant (person or legal entity), with an issue date not exceeding 30 days prior to the date the application is filed.

- In the event that the applicant is a higher education institution, they must attach certification as such, from the Ministry of National Education.
- Completed Access Contract application form (Resolution 414 of 1996) (see Annex 2).
- Identification of a National Support Institution.
- Documentation as described in the previous section.
- It is necessary to emphasize that, when access activities are carried out in cooperation with international entities and necessitate transport of samples abroad, a copy of the cooperation agreement, or letter of understanding, must be attached to the application in which are specified:
 - 1) How this cooperation functions in terms of access activities;
 - 2) How cooperation functions in terms of handling the genetic materials and by-products;
 - 3) In all cases, it must be specified that, if samples remain, they will be returned to the country of origin and deposited in a registered collection, as no later use should be made of any information obtained from the samples, nor the samples *per se*.

It is important to emphasize that, for both cooperative activities as described in the previous paragraph, and also for analysis abroad of the sample, genetic resource, or its by-products (e.g. sequen-



cing, isolated elements, etc.), it is necessary to acquire the respective export permit (CITES¹⁷ or NO CITES) so that samples can leave the country.

The Ministry of Environment and Sustainable Development is the authority responsible for processing CITES export permits, which apply to the species cited in its three appendices. The National Authority for Environmental Licenses (ANLA) is the authority responsible for processing NO CITES export permits, which apply to species not mentioned in the CITES appendices.

The application form for an Access Contract, must conclude with an alphabetic list of all bibliographic and document references consulted in the development of the application.

NOTE: The applicant must provide all other environmental permits or licenses required by national regulations to carry out the activities described in the project.

The above is necessary, since the Access Contract only authorizes the obtention and use of genetic resources or their by-products and, as established in Decree 1076 of 2015, the collection of wild specimens. It does not authorize their export out of Colombia.

In the event that the confidentiality of certain information is necessary, it will only apply to that established in Article 19 of the Andean

17. CITES, Convention on International Trade in Endangered Species of Wild Fauna and Flora.



Decision 391 of 1996, by submitting a justification and petition for the confidentiality required, accompanied by a non-confidential summary that will be part of the public file, and expressly indicating the information concerned.

3.2.

Preliminary analysis of the application

When an application for an Access Contract is submitted to the Ministry of Environment and Sustainable Development, a preliminary analysis of the application is made in order to determine if it is complete.

This analysis consists of a formal review of the application content and presentation of the respective annexes and is conducted within fifteen (15) working days after the date of receipt.

3.3.

Acceptance of the application

If, within fifteen (15) working days, the preliminary analysis determines that the application is complete, an Initiation Order will be issued by which the application is accepted for evaluation, and the process will begin. The same administrative act will also sanction the registration, publication and opening of the application file.





A summons is sent by which the applicant can choose whether notification is made electronically or in person at the Ministry of Environment and Sustainable Development. Once the means for notification have been agreed, the applicant is notified of the Initiation Order accepting the application for evaluation. (If the applicant chooses electronic notification, they must confirm receipt).

NOTE: The applicant may, at this first summons, state whether they prefer to be notified electronically of any following administrative acts that arise within the application process.

3.4.

Application registration

The Genetic Resources Group will keep a public record, to include among other information: the Initiation Order, any resolutions that accept or reject the application, subscription dates, modifications, suspensions or termination of the Access Contract; date and number of the Resolution that awards it; date and number of any Resolution or Award or any judgement that imposes rejection or sanctions.

This registration can be found on the Ministry of Environment and Sustainable Development website, as follows:



www.minambiente.gov.co

↳ "Topics"

↳ "Environment and Sustainable Development"

↳ "Forests, Biodiversity and Ecosystem Services"

↳ "Genetic resources"

↳ "Documents of interest"

↳ "Status of requests for a contract for access to genetic resources"

3.5.

Opening of the application file

With the issuance of the Initiation Order, a file is opened containing the documents and information provided by the applicant.

3.6.

Publication of the application

Within five (5) working days of the registration date of the Application, in the Public Record of Access to Genetic Resources and their By-Products, the applicant must, at their own expense, publish an extract of their Application in a communication medium (e.g. a newspaper or periodical) at the locality in which the access will be carried out, so that interested persons can submit any other pertinent information.

Proof of publication must be sent to the Ministry of Environment and Sustainable Development, to be included in the Application file.



3.7.

Technical-legal opinion

Within thirty (30) working days following the publication of the Application, the Genetic Resources Group will evaluate the Access Application, in a process called the “Technical-Legal Opinion”.

This period may be extended for up to sixty (60) working days, if deemed necessary. Any extension will be issued by an administrative act of the Ministry of Environment and Sustainable Development.

Based on this technical evaluation, additional information may be requested, in order to complete all information necessary to make the Contract application viable.

The applicant will be granted a period of fifteen (15) working days to provide this additional information. This period may be extended at the request of the applicant, as the Application would be considered withdrawn if the required information was not provided.

During the Application evaluation period, the Directorate of Forests, Biodiversity and Ecosystem Services may also ask for tests and information *ex officio*, or at the request of other interested parties, and, if deemed necessary, may conduct a technical-legal visit with the applicant. Within this period, the applicant must provide the Application file with a copy of all permits for the exploitation, use or affect of natural resources, or the environmental licenses required to carry out any activities related to access to genetic resources and/or their by-products, wherever required by national regulations. However, the applicant may be granted a supplementary period to present them, by an administrative act.

3.8.

Analyses and statements from other ministry departments

For an Access Contract for commercial purposes, the Genetic Resources Group of the DBBSE will require an analysis and statement from the Sustainable and Green Business Office, to determine conditions for a fair and equitable sharing of monetary and/or non-monetary benefits. If the Sustainable and Green Business Office requires additional information or documents, prior to this



analysis, this will be requested from the applicant by the Genetic Resources Group.

The application for access to genetic resources and their by-products may also involve associated traditional knowledge, or be required to carry out prior consultation with ethnic communities. In such cases, the Genetic Resources Group will ask the Sub-directorate of Education and Participation for a statement to determine negotiating conditions from the Ministry, in order to guarantee the rights of related ethnic communities in relation to the project. This will take place simultaneously with the technical and legal evaluation of the application.

3.9.

Resolution granting application acceptance or denial

Based on the results from the evaluations, consultation minutes, information provided by third parties, evidence from the Application file, and other documents, a draft Resolution will be prepared by which the Application is either accepted or denied. This should be signed preferably by the Director of the DBBSE.

The applicant must then be notified of the Resolution under the terms of Law 1437 of 2011, by which the Code of Administrative Procedure and Administrative Litigation is issued.

The applicant will thus be notified of the Resolution regarding acceptance or denial of their Application (understood as an administrative act).





First, a summons will be sent in which the applicant can choose whether notification is made electronically or in person at the facilities of the Ministry of Environment and Sustainable Development. Once the means by which the notification will be made have been defined, the respective notification will be made.

It should be noted that an appeal (against this administrative act) for reinstatement is possible at this point (please review 'Legal Recourses' at the end of this chapter). Otherwise, the applicant may waive their entitlement to appeal and the resolution will be made final. Any appeal should be made within ten (10) working days after notification. If no appeal is made within this time, it will be assumed that the applicant has accepted the Resolution and it will be made final. (When an applicant chooses to be notified electronically, they must confirm receipt).

NOTE: The applicant may, in this second communication, state whether they prefer to be notified by electronic means of any further administrative acts that may arise within the application process.



3.10.

Signing the contract

Once the application is accepted, the Genetic Resources Group draws up a detailed draft of the Contract and sends it to the applicant via email, so that they can make any specific comments. The GRG also schedules a date for a meeting at the Ministry of Environment and Sustainable Development to sign and negotiate the Access Contract.

Prior to the meeting, the GRG will consider any comments from the applicant.

The following parties participate in the Access Contract negotiation: the applicant, the main researcher, the Genetic Resources Group, the Sustainable and Green Business Office (for access contracts for commercial purposes), the Sub-directorate of Education and Participation (when there is an association between the genetic resource or its by-products and traditional knowledge), or any other Ministry department, that, due to its competence or functions, may have an interest in the Access Contract.

Likewise, when deemed necessary, the National Support Institution (participation by the INA is not mandatory), the Ministries of Interior, Foreign Trade and Agriculture, and other public entities, may participate in the negotiation in any matters within their respective areas of competence and that are related to the subject matter of the contract. The applicant may be accompanied by their institution's legal representative. The GRG will summon all participants and take minutes of the meeting, which will form part of the record.

3.11.

Publication of the resolution finalizing the access contract

This resolution is understood as finalizing authorization for access, and must be published within five (5) days following the date of contract registration in the Public Record for Access to Genetic Resources and their By-products. The Ministry will publish the Resolution on the legal entity's own page.

The applicant will be notified of the Resolution (understood as an administrative act) that finalises the Access Contract. As in previous administrative acts, a summons will first be sent, in which the applicant will be able to choose whether the notification is made electronically or in person at the Ministry of Environment and Sustainable Development. The notification will be made once the communication means have been defined.

It should be noted that, at this point, there is a right to appeal (against this administrative act), for a review of the application's final details (please review 'Legal Recourses' at the end of this chapter), or the applicant may waive this right and the resolution will be made final. Any appeal should be made within ten (10) working days after notification. If no appeal is made within this time, it will be assumed that the applicant has waived this right of appeal and the Resolution will be made final. (When an applicant chooses to be notified electronically, they must confirm receipt).

NOTE: The applicant may, in this summons, state whether they prefer to be notified by electronic means of any further administrative acts that arise within the follow-up to the Contract.

Once the applicant has been notified, an executive order will be passed by the Ministry of Environment and Sustainable Development and the applicant informed. It is from the date of this executive order that access activities to genetic resources and their by-products can begin, and if applicable, specimen collection activities could be started.

3.12.

Legal recourses within the application process

In accordance with current regulations, appeals against administrative acts issued within the process of applying for an Access Contract proceed in accordance with the provisions of Article

74 and following Law 1437 of 2011, by which the Administrative Procedure and Administrative Litigation Code was issued.

THE PERIOD FOR
IN-DEPTH RESOLUTION
OF AN APPEAL MAY NOT
EXCEED THIRTY

(30)
WORKING
DAYS

During the application procedure, two Resolutions are issued. The first is the Resolution by which the application is accepted or denied. The second gives the details



under which the contract to access genetic resources is granted. This is open to negotiation through appeals from the applicant for clarification, modification or addition before signing.

Applicants can appeal against either Resolution. All appeals are decided by the Director of the Directorate of Forests, Biodiversity and Ecosystem Services.

Appeal time limit

Appeals against a Resolution must be in writing and either filed personally or sent within ten (10) working days following notification of the Resolution or at the expiration of the publication term, as the case may be.

Once an appeal has been presented in accordance with current regulations and its provenance is evaluated by the Ministry's legal counterpart, if required, it will be transferred to the Ministry's technical department to issue the respective concept statement. In all cases, the term to settle the respective appeal may not exceed thirty (30) working days.





04

**FOLLOW-UP
FOR ACCESS
CONTRACTS**





As the National Competent Authority granting access to genetic resources and their by-products, the Ministry of Environment and Sustainable Development also has an obligation to supervise all signed contracts and ensure their fulfillment. This is in order to:

- Protect the rights of providers of biological and genetic resources and their intangible components.
- Modify, suspend, resolve or terminate access contracts, and provide for their cancellation, in accordance with the terms of the said contracts, by Andean Decision 391 of 1996 and internal legislation.
- Supervise and control compliance of the conditions of the contracts with the provisions of Andean Decision 391 of 1996.

To fulfill this obligation, the Ministry must trace, control, and establish follow-up and evaluation mechanisms as it deems appropriate. Likewise, the appointed National Support Institution is obliged to collaborate with the Ministry in regard to the tracing and control of access to genetic resources, their by-products or synthesized products and associated intangible components. They must also submit reports on the activities in their charge or responsibility, in a form and at times to be determined by the Ministry.



4.1.

Trace and control of access contracts

Once the contract for access to genetic resources and their by-products has been signed and authorized, a process begins for tracing and controlling the activities agreed in the said contract (see Annex 3).

The Ministry will control the tracing database and verify that reports are delivered in a timely manner. Likewise, in order to provide information, a delivery status report for each signed contract will be published on the Ministry's website, on the following page:

www.minambiente.gov.co

- ↳ "Topics"
 - ↳ "Environment and Sustainable Development"
 - ↳ "Forests, Biodiversity and Ecosystem Services"
 - ↳ "Genetic resources"
 - ↳ "Documents of interest"
 - ↳ "Status of requests for a contract for access to genetic resources"



The Ministry will endeavor to carry out technical and legal visits to the location where the access activities are carried out. This is in order to establish direct communication with the contract user, provide guidance for the fulfillment of the contract, and update on its state of progress. Visits can be arranged in advance with the parties involved.





4.2.

Information the user must present in activity reports

Given that the delivery of regular reports to the Ministry of Environment and Sustainable Development is agreed in the Access Contract, these reports must be numbered (e.g. Report #1, 2, ... Final report) and contain at least:

1. Name of the project, name of the applicant, name of the technical project manager, access contract number.
2. Mention each of the objectives set forth in the Access Contract application. Indicate how each objective has been developed in as much detail as possible, showing methodologies used and results obtained up to that moment. Also describe the handling and management of all samples subject to the Access Contract (if applicable, include annexes).
3. A list of each of the obligations agreed in the contract by the user, indicating whether they were fulfilled or not at the time of the report, and justifying them as appropriate (if applicable, the corresponding evidence should be attached: for example, if one of the obligations requires the export of biological samples, genetic resources or by-products for its analysis, a copy of the respective export permits must be attached). If there are obligations that, at the time of making the report, are not being fulfilled, you must justify why not, or show that they do not apply for that stage.



**THE
USER
MAY SUBMIT
ADDITIONAL
INFORMATION
THAT THEY
CONSIDER
RELEVANT**

4. When access contracts involve collection activities, you must remember the information required in the report for each of the agreed obligations within the contract related to this specific activity. In addition, it is important to mention all sites (with their respective coordinates in the established coordinate system), where samples were actually collected. Likewise, if during the access contract period, accessory contracts were not annexed (e.g. with the owners of the premises where the samples were to be collected, or the supplier of the biological, genetic resource or by-product), you must present them at this stage of contract tracing.
5. Since there is no set format to present the activity reports of the contract, the user may submit any relevant additional information that was not mentioned in previous paragraphs.

The report must be addressed to the Genetic Resources Group of the Directorate of Forests, Biodiversity and Ecosystem Services. It also should include a cover letter stating that a specific activity report or final activity report is being delivered, and indicate any annexes included, the contents of each annex, and, if possible at the end of the cover letter, the total number of report pages delivered.



The information can be filed in physical form at the address:

- Directorate of Forests, Biodiversity and Ecosystem Services Calle 37 No 8-40, Bogotá

or by email to:

- correspondencia@minambiente.gov.co

specifying in the subject-line that the mail is addressed to:

- Genetic Resources Group
- Directorate of Forests, Biodiversity and Ecosystem Services.





4.3.

Modifications to access contracts

Once the contract is duly signed and legalized, the user may request, within the time stipulated in their contract, modifications to the contract related to the time-frame, species, number of species, etc. However, these modifications may not relate to the overall object or nature of the project, i.e. it may not involve substantive changes.

The procedure for modifying an Access Contract are as follows:

4.3.1.

Modification request

The user must file a contract modification request with the Ministry of Environment and Sustainable Development, in which they must indicate and justify any aspects that require modification.

4.3.2.

Technical and legal evaluation

From the submitted request, an evaluation of its legal viability is made. If appropriate, it is transferred to the Ministry's technical division who will provide a resolution to the viability of the request by issuing a concept statement. If necessary, based on the technical evaluation,





requests for additional information or clarification by letter may be sent in order to complement the information necessary to make the modification of the contract feasible.

For this purpose, the user is granted a term of fifteen (15) working days, which may be extended at the request of the party, under penalty of considering the request withdrawn if the required information is not submitted.

4.3.3.

Modifications as addendums to the contract

Once the information is complete and whenever the request for modification is deemed viable, an addendum is prepared, which is signed by the director of the Directorate of Forests, Biodiversity and Ecosystem Services and the user, and then incorporated into the file. With the signing by both parties, the addendum is understood to be legalized.

4.4.

Adding projects to an access framework contract

When adding specific project activities to a Framework Contract, the user should follow the same process for requesting modification to an Access Contract described in Section 4.3.



In this case, a covering letter should indicate that the request is for the addition of project activities to a Framework Contract. Consequently, some of the documents listed in section 3.1. should also be attached to the request. These documents are those indicated by numbers 1, 2, 3 (for this, include the technical project manager's ID documents), 8, 9, 10, 11, 12, 13, 14, 15 and 17.

4.5.

Termination and settlement of contracts

Contracts may be terminated at the following events:

1. End of agreed contract term
2. Miscompliance of the agreed terms by the researcher
3. Force majeure or fortuitous event
4. Assignment of the contract without Ministry authorization
5. Proof of falsity or fraud in submitted documents
6. Request for termination by the researcher
7. Death of the researcher
8. Mutual agreement between both parties
9. Damages caused by the access activities that affect human health, biodiversity, genetic resources, ecosystems or the assets of third parties.



In the case of (1), the end of the agreed contract term, the status of implementation and compliance will be reviewed. When compliance of the terms, obligations and commitments agreed in the contract is shown in a final tracing report, a Liquidation Order is prepared by the Ministry's legal department, which is then signed by all parties in this case, the Director of the Directorate of Forests, Biodiversity and Ecosystem Services and the user.

In the other events, the Ministry's technical departments must assess the status of compliance with the contract in order to determine if there are pending obligations and commitments to be completed. In such cases, additional information may be required.

Once it is available, a final compliance report will be prepared, based on which the legal department will prepare a Termination and Liquidation Report, which must be signed by the Director of the Directorate of Forests, Biodiversity and Ecosystem Services and the user.





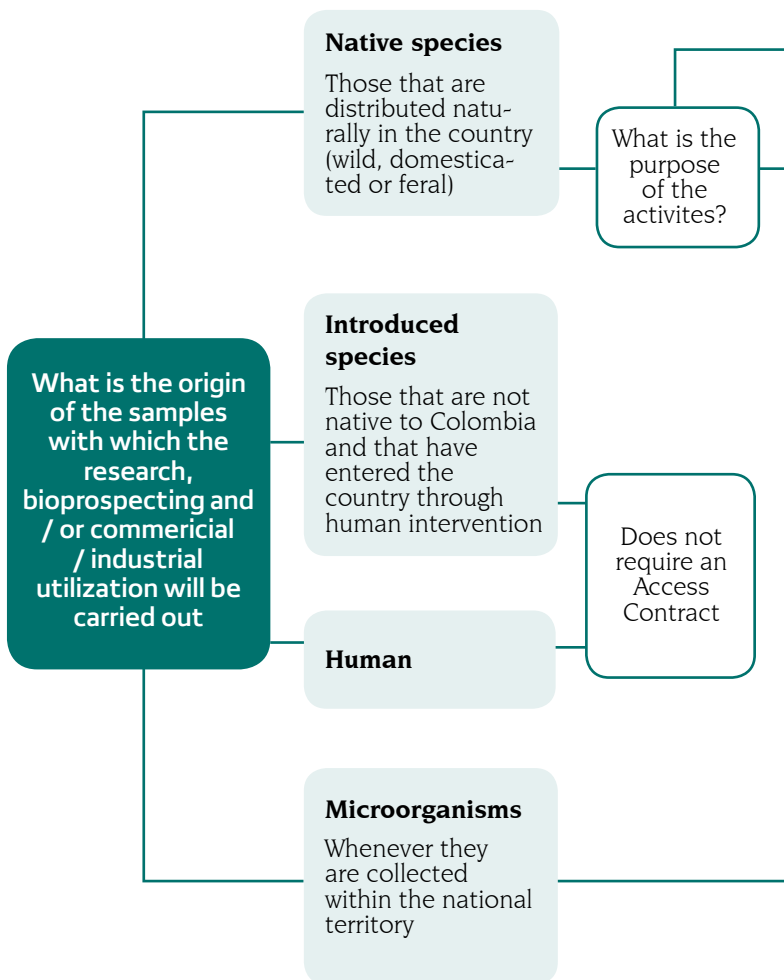
ANNEXES

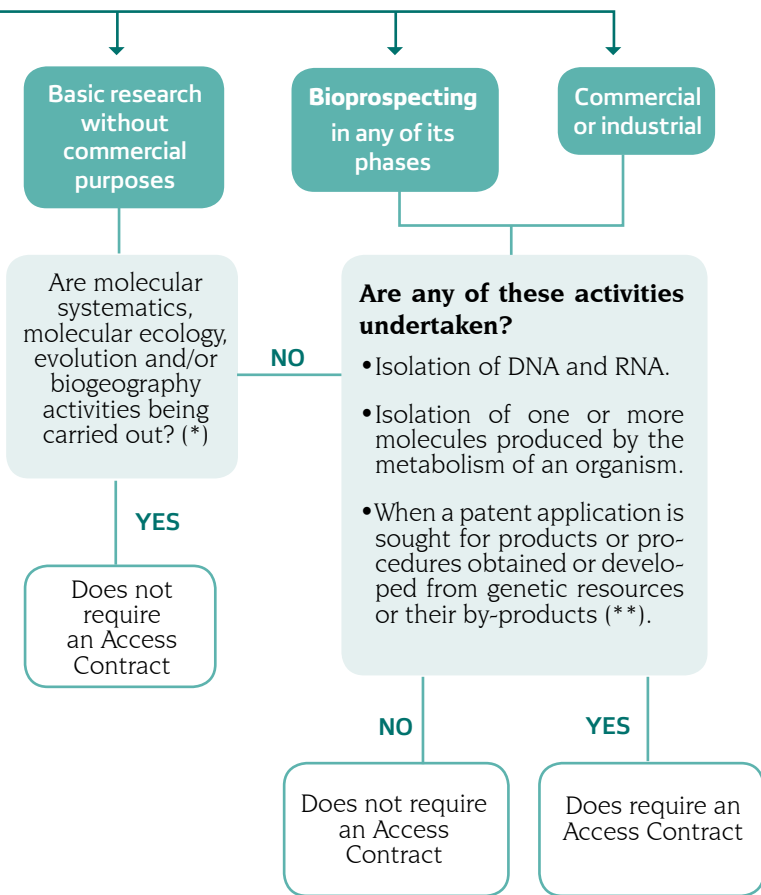




Annex 1

Diagram for the identification of activities that DO or DO NOT configure access to genetic resources and their by-products





(*) These activities are excluded from the contract for access to genetic resources, in accordance with the provisions of articles 2.2.2.8.1.2, Paragraph 5 and 2.2.2.9.1.4, Paragraph 1 of Decree 1076 of 2015.

(**) Resolution 1348 of 2014 issued by the Ministry of Environment and Sustainable Development establishes the activities that configure access to genetic resources and their by-products.



Annex 2 Application form

**APPLICATION TO ACCESS
GENETIC RESOURCES**

IDENTIFICATION

I. APPLICANT OR LEGAL REPRESENTATIVE

1. IDENTIFICATION

Name or business name

.....

Nationality

Identity Document

Address

Telephone Fax

Email

II. TECHNICAL PROJECT MANAGER

1. IDENTIFICATION

Name or business name

.....

Nationality

Identity Document

Address

Telephone Fax

Email



2. ACCESS ACTIVITIES CARRIED OUT IN THE LAST FIVE (5) YEARS BY THE TECHNICAL PROJECT MANAGER

| YEAR | ACTIVITY | COUNTRY | COUNTERPART |
|------|----------|---------|-------------|
| | | | |
| | | | |
| | | | |
| | | | |

3. DESCRIPTION OF STUDIES UNDERTAKEN BY THE TECHNICAL PROJECT MANAGER

| YEAR | HIGHER EDUCATION (SPECIALTY) | DEGREE | INSTITUTION | LOCATION |
|------|------------------------------|--------|-------------|----------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

4. PUBLICATIONS BY THE TECHNICAL PROJECT MANAGER (three most important)

| TITLE | YEAR | JOURNAL/BOOK |
|-------|------|--------------|
| | | |
| | | |
| | | |
| | | |



5. EXPERIENCE OF THE TECHNICAL PROJECT MANAGER
(activities carried out in the last five years)

| YEAR | ACTIVITY OR POSITION | QUANTITY | COUNTRY |
|------|----------------------|----------|---------|
| | | | |
| | | | |
| | | | |

6. WORKING GROUP RESPONSIBLE FOR THE ACCESS ACTIVITY

| ADDRESS | NAME | SPECIALITY | ACADEMIC DEGREE |
|---------|------|------------|-----------------|
| | | | |
| | | | |

III. RESOURCE PROVIDER DETAILS

1. IDENTIFICATION

Name or business name

Nationality

Identity Document

Address

Telephone Fax

Email

IV. DETAILS OF THE PERSON OR NATIONAL SCIENTIFIC OR CULTURAL SUPPORT ENTITY (INA)

1. IDENTIFICATION

Name or business name

Address

Telephone Fax

Email

V. PROJECT PROPOSAL

1. Title
2. Justification, objectives and technical literature
3. Application area
4. Type of activity and uses of the resource
5. Reference list of genetic resources, by-products and associated intangible components, to which access is sought (scientific name, common name and number of samples)
6. Location of access areas and access activities (coordinates)

a) Collection

b) Location of access area

In situ *Ex situ* Coordinates

c) Location of genetic material processing and use

- In the case of *ex situ* resources, relevant information about the *ex situ* conservation or commercialization center should be included



7. INDICATIVE TIMELINE

| ACTIVITIES | TIME | LOCATION | METHODOLOGY* |
|-------------|------|----------|--------------|
| Exploration | | | |
| Collection | | | |
| Extraction | | | |
| Handling | | | |
| Research | | | |

* Type and size of the sample, design and sampling, and characterization type

Approximate duration _____

8. Materials and methods
9. Exploration and collection procedure
10. Sample management
11. Expected results
12. Initial budget
13. Other documents for inclusion

VI. LETTER OF ACCEPTANCE IN PRINCIPLE OR CONTRACT FROM THE PROVIDER OF BIOLOGICAL RESOURCES, GENETIC RESOURCES OR INTANGIBLE COMPONENTS

VII. LETTER OF COMMITMENT FROM A NATIONAL SUPPORT INSTITUTION PERSON OR ENTITY

VIII. AFFIDAVIT OF THE APPLICANT, RECORDING THE TRUTHFULNESS OF THE DETAILS NOTED IN THE APPLICATION

Annex 2a Example of completed application form for an access contract

Below is an example of a completed application form for an Individual Access Contract.

I. APPLICANT OR LEGAL REPRESENTATIVE

1. IDENTIFICATION

| | | | |
|-----------------------|---|---------------------------|------------|
| Name or business name | Mauricio Andrés Giraldo | | |
| Nationality | Colombiana | | |
| Identity Document | C.C. 2.001.000.111 | | |
| Address | Calle 1, Carrera 10, Casa 2. Chía, Cundinamarca | | |
| Telephone | 1 +123567 | Fax | 1+89101112 |
| Email | angiraldo@gmail.com | mgiraldo@unibogota.com.co | |

II. TECHNICAL PROJECT MANAGER

The individual who will manage the project or research. This could also be the applicant when the applicant is also the project manager.

1. IDENTIFICATION

| | | | |
|-----------------------|---|---------------------------|------------|
| Name or business name | Mauricio Andrés Giraldo | | |
| Nationality | Colombiana | | |
| Identity Document | C.C. 2.001.000.111 | | |
| Address | Calle 1, Carrera 10, Casa 2. Chía, Cundinamarca | | |
| Telephone | 1 +123567 | Fax | 1+89101112 |
| Email | angiraldo@gmail.com | mgiraldo@unibogota.com.co | |



2. ACCESS ACTIVITIES UNDERTAKEN IN THE LAST FIVE (5) YEARS BY THE TECHNICAL PROJECT MANAGER

| YEAR | ACTIVITY | COUNTRY | COUNTERPART |
|-----------|--|----------|----------------------|
| 2011-2014 | Fractioning of essential oils and extracts, isolation of bioactive compounds | Colombia | University of Bogotá |

3. DESCRIPTION OF STUDIES UNDERTAKEN BY THE TECHNICAL PROJECT MANAGER

| YEAR | HIGHER EDUCATION (SPECIALITY) | DEGREE | INSTITUTION | LOCATION |
|------|--------------------------------|-----------|---------------------------------|----------|
| 2007 | Master's in Analytic Chemistry | Master | University of Barcelona | Spain |
| 2010 | Doctorate in Applied Chemistry | Doctorate | Autonomous University of Madrid | Spain |

4. PUBLICATIONS BY THE TECHNICAL PROJECT MANAGER (three most important)

| TITLE | YEAR | JOURNAL/BOOK |
|--|------|--|
| GC-MS study of compounds isolated from <i>Ocimum gratissimum</i> flowers by different extraction techniques | 2010 | <i>Journal of Separation Science</i> 2014, 40(17), 2301-2316 |
| Chromatographic and mass spectrometric characterization of essential oils and extracts from <i>Silene</i> (<i>Caryophyllaceae</i>) | 2012 | <i>Journal of Separation Science</i> 2014, 20, 100-115 |
| Analysis of volatile secondary metabolites from <i>Rubia tinctorum</i> and evaluation of their in vitro astringent activity | 2014 | <i>Journal of Separation Science</i> 2015, 36, 190-202 |



2. ACCESS ACTIVITIES CARRIED OUT IN THE LAST FIVE (5) YEARS BY THE TECHNICAL PROJECT MANAGER

| YEAR | ACTIVITY | COUNTRY | COUNTERPART |
|------|----------|---------|-------------|
| | | | |
| | | | |
| | | | |

3. DESCRIPTION OF STUDIES UNDERTAKEN BY THE TECHNICAL PROJECT MANAGER

| YEAR | HIGHER EDUCATION (SPECIALTY) | DEGREE | INSTITUTION | LOCATION |
|------|------------------------------|--------|-------------|----------|
| | | | | |
| | | | | |
| | | | | |

4. PUBLICATIONS BY THE TECHNICAL PROJECT MANAGER (three most important)

| TITLE | YEAR | JOURNAL/BOOK |
|-------|------|--------------|
| | | |
| | | |
| | | |

5. EXPERIENCE OF THE TECHNICAL PROJECT MANAGER (activities carried out in the last five years)

| YEAR | ACTIVITY OR POSITION | QUANTITY | COUNTRY |
|-----------|---|----------|----------|
| 2008-2015 | Head Professor, University of Bogotá | 5 years | Colombia |
| 2009-2015 | Director of the Biomolecular Research Center - University of Bogotá | 8 years | Colombia |

6. WORKING GROUP RESPONSIBLE FOR THE ACCESS ACTIVITY

| ADDRESS | NAME | SPECIALITY | ACADEMIC DEGREE |
|---------------------------------|---|--|---------------------------|
| Calle 40 #10- 12. Bogotá | Julio Castro Orjuela jcastro@gmail.com | Mass spectrometry and chromatographic analysis applied to different chemical areas. | Chemistry, PhD |
| Calle 120 #7- 01. Bogotá | Sandra Pérez sperez@ubogota.com | Environmental toxicology. Mechanisms of xenobiotic toxicity. Biochemistry and molecular biology. Signal transduction. Computational chemistry. Molecular modeling. Structure-toxicity relationships. Analytical chemistry. Modeling chromatographic processes. | Basic sciences, PhD |
| Carrera 8 #90- 70. Bogotá | Andrés Molina amolina@gmail.com | Biology undergraduate student, with experience in plant species collection. | Degree work |

III. RESOURCE PROVIDER DETAILS



In case a collection permit is required, the biological resource provider must also be indicated.

1. IDENTIFICATION

Name or business name Ministerio de Ambiente y Desarrollo Sostenible

Nationality Colombiana

Identity Document NIT 830115395-1

Address Calle 37 N.° 8-40. Bogotá D.C.

Telephone 1 +3323400

Fax 1 +3323400

Email correspondencia@minambiente.gov.co



5. EXPERIENCE OF THE TECHNICAL PROJECT MANAGER (activities carried out in the last five years)

| YEAR | ACTIVITY OR POSITION | QUANTITY | COUNTRY |
|------|----------------------|----------|---------|
| | | | |
| | | | |
| | | | |
| | | | |

6. WORKING GROUP RESPONSIBLE FOR THE ACCESS ACTIVITY

| ADDRESS | NAME | SPECIALITY | ACADEMIC DEGREE |
|---------|------|------------|-----------------|
| | | | |
| | | | |
| | | | |

III. RESOURCE PROVIDER DETAILS

1. IDENTIFICATION

Name or business name

Nationality

Identity Document

Address

Telephone Fax

Email

IV. DETAILS OF THE PERSON OR NATIONAL SCIENTIFIC OR CULTURAL SUPPORT ENTITY (INA)

1. IDENTIFICATION

Name or business name Universidad Nacional de Colombia – Sede Bogotá

Address Carrera 45 N.º 26-85, Edificio Uriel Gutiérrez, Bogotá D.C.

Telephone 1+3165000

Fax 1+3165107

Email rectotiaun@unal.edu.co

V. PROJECT PROPOSAL

1. TITLE

Bioprospecting and development of natural ingredients for the cosmetic, pharmaceutical and toilet products industries from plants.

2. JUSTIFICATION, OBJECTIVES AND TECHNICAL LITERATURE

2.1 Justification

Biodiversity is a great opportunity for Colombia to study, take advantage of and to hold. The challenge is how to transform this comparative advantage into a competitive advantage. The answer proposed in this program is the generation of knowledge on the different stages of development of a biodiversity-based application ...

Secondary metabolites of plant species, isolated as mixtures are subject to evaluation tests of various types of biological activities, of particular relevance to pharmaceuticals and cosmetics. Fractionation processes and chromatographic analysis to achieve their detailed characterization are proposed as the mechanisms to identify the bioactive compounds ...

Through heterogeneous catalysis for terpene oxyfunctionalization and simple reactions of low environmental impact, major components of high availability essential oils will be modified. Several stages of the development process of a new cosmetic will be advanced, which uses products from biodiversity as ingredients ...

... so that biodiversity not only leads to limited economic development generated by the sale of raw materials, but that its isolation, transformation and use in processed products may also constitute a real competitive advantage.

2.2 Objectives

2.2.1 General objective

To develop a strategy for applying knowledge to the sustainable use of biodiversity



IV. DETAILS OF THE PERSON OR NATIONAL SCIENTIFIC OR CULTURAL SUPPORT ENTITY (INA)

1. IDENTIFICATION

Name or business name

Address

Telephone Fax

Email

V. PROJECT PROPOSAL

1. Title
2. Justification, objectives and technical literature
3. Application area
4. Type of activity and uses of the resource
5. Reference list of genetic resources, by-products and associated intangible components, to which access is sought (scientific name, common name and number of samples)
6. Location of access areas and access activities (coordinates)

a) Collection

b) Location of access area

In situ *Ex situ* Coordinate

c) Location of genetic material processing and use

- In case of *ex situ* resources, relevant information about the *ex situ* conservation or commercialization center should be included



2.2.2 Specific objectives

- To apply existing results to the development of new cosmetic products on useful ingredients derived from endemic tropical species.
- To detect useful natural components by computational methods.
- To characterize and know the allergenic, antigenotoxic, anti-inflammatory, antimicrobial, antioxidant, antitumor, cytotoxic and immunomodulatory activities of extracts, essential oils and their fractions, isolated from plant species collected in the Andean Region of Colombia.
- To assess semio-chemical relationship in order to detect promising natural ingredients for products from the pharmaceutical, cosmetic and toiletry product industries.

2.3 Technical literature

Bioprospecting is the examination of biological material of wild origin that is practiced for the purpose of finding substances with special bioactivity properties, that will eventually improve human well-being. The character of these expected results suggests that bioprospection is also a tool for the conservation of biodiversity. Biodiversity is huge, but internally it contains another great diversity, and that is chemical diversity. It is estimated that approximately 1% of plant species have been subject of detailed phytochemical studies. However, for the South American region, this fraction is 10 times less, at 0.1% [1]. This shows the size of what there is to explore, which, only at the macroscopic level, already shows a great variety. Before examining such a large number of objects, the use of some essentials is required; the experience gained in reviewing the results of plant families is useful, since some plant families stand out for having species with a good proportion of essential oil. Analysis of secondary metabolites has revealed the existence of chemotypes, which are morphologically indistinguishable species, but which possess essential oils of completely different composition. This is another level of diversity resulting from the conjugation of biological and chemical diversities [2]. Moving from macroscopic to molecular examination, there is another great expansion in the diversity of possibilities, since there are geometric and enantiomeric isomeries, for example, and they make the bioactivity of the molecules quite different. As an illustration of this diversity, serves the case of tangerine essential oil (*Citrus deliciosa*), in whose analysis the number of components detected increases by 13 when an analytical system capable of distinguishing enantiomers is used [3]. Just as certain selection criteria are required for the bioprospection of plant species, in the exploration of the great chemical diversity and in search of substances of interest to the pharmaceutical, cosmetics and toiletry industries, there are types of substances within which we are more likely to find a good candidate.

Bioprospecting requires a set of analytical tools as support to be able to deliver reliable results on the composition of isolated secondary plant material metabolites. In the past two decades ...

IV. DETAILS OF THE PERSON OR NATIONAL SCIENTIFIC OR CULTURAL SUPPORT ENTITY (INA)

1. IDENTIFICATION


Name or business name

Address

Telephone Fax

Email

V. PROJECT PROPOSAL

- 
1. Title
 2. Justification, objectives and technical literature
 3. Application area
 4. Type of activity and uses of the resource
 5. Reference list of genetic resources, by-products and associated intangible components, to which access is sought (scientific name, common name and number of samples)
 6. Location of access areas and access activities (coordinates)

a) Collection

b) Location of access area

In situ *Ex situ* Coordinate

c) Location of genetic material processing and use

- In case of *ex situ* resources, relevant information about the *ex situ* conservation or commercialization center should be included



3. APPLICATION AREA

Applied and basic science: Chemistry, Chemical Engineering, Biology; Health Sciences; industries: companies in the cosmetic, pharmaceutical and toilet product sectors.

4. TYPE OF ACTIVITY AND USES OF THE RESOURCE

The plant species collected during field trips in the different municipalities of Colombia will be used to obtain essential oils through the extraction technique "Microwave-assisted Hydro-distillation (MAHD)" and to obtain organic extracts, using solvents and extraction with supercritical fluid (SFE). The essential oils and extracts obtained will be tested for biological activity, namely antioxidant, antigenotoxic, cytotoxic, allergenic, antimicrobial, immunomodulatory, antitumor and repellency / insect attraction, and anti-inflammatory.

As a result of the bioactivity screening that will be developed, there will be a small number (~ 5-10) of oils and extracts that stand out for their performance in these tests. These samples will undergo a detailed chemical characterization that will involve the use of triple quadrupole mass spectrometry techniques (QqQ) and liquid chromatography coupled to mass spectrometry. Through a fractional distillation medium under reduced pressure (B / R Instruments distiller, model 8000 available in CIBIMOL), fractions of the oils will be obtained, which will be chemically characterized for the evaluation of their bioactivity.

IV. DETAILS OF THE PERSON OR NATIONAL SCIENTIFIC OR CULTURAL SUPPORT ENTITY (INA)

1. IDENTIFICATION

Name or business name

Address

Telephone Fax

Email

V. PROJECT PROPOSAL

1. Title
2. Justification, objectives and technical literature
3. Application area
4. Type of activity and uses of the resource
5. Reference list of genetic resources, by-products and associated intangible components, to which access is sought (scientific name, common name and number of samples)
6. Location of access areas and access activities (coordinates)
 - a) Collection
 - b) Location of access area

In situ *Ex situ* Coordinate
 - c) Location of genetic material processing and use
 - In case of *ex situ* resources, relevant information about the *ex situ* conservation or commercialization center should be included

5. REFERENCE LIST OF GENETIC RESOURCES, BY-PRODUCTS AND ASSOCIATED INTANGIBLE COMPONENTS, TO WHICH ACCESS IS SOUGHT (SCIENTIFIC NAME, COMMON NAME AND NUMBER OF SAMPLES)

| REFERENCE LIST OF BIOLOGICAL RESOURCES | | | | |
|--|---|-------------------------------------|--------------------------------------|----------|
| Scientific name | Type of sample | Quantity of species to be collected | Quantity to be collected per species | Location |
| Siparunaceae | Leaves, stems, fruits, flowers, exsiccata | 3 | 10-30 kg | all |
| Burseraceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Lamiaceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Aristolochiaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Piperaceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Lauraceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Verbenaceae | Leaves, stems, fruits, flowers, exsiccata | 20 | 10-30 kg | all |
| Orchidaceae | Leaves, stems, fruits, flowers, exsiccata | 10 | 10-30 kg | all |
| Boraginaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Tumeraceae | Leaves, stems, fruits, flowers, exsiccata | 20 | 10-30 kg | all |
| Myrtaceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Asteraceae | Leaves, stems, fruits, flowers, exsiccata | 20 | 10-30 kg | all |
| Anacardiaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Bignoniaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Caesalpiniaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Euforbiaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Labiatae | Leaves, stems, fruits, flowers, exsiccata | 20 | 10-30 kg | all |
| Myristicaceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Annonaceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Apiaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Fabaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Ghenopodiaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Gramineae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Magnoliaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Melastomataceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Monimiaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Moraceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Ocotea | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Passifloraceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Polygalaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |
| Rubiaceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Rutaceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Urticaceae | Leaves, stems, fruits, flowers, exsiccata | 15 | 10-30 kg | all |
| Valerianaceae | Leaves, stems, fruits, flowers, exsiccata | 5 | 10-30 kg | all |

From the species list, the by-product that is intended to be accessed is understood as essential oil, an organic extract and, finally, the isolation of the secondary metabolites of interest.

IV. DETAILS OF THE PERSON OR NATIONAL SCIENTIFIC OR CULTURAL SUPPORT ENTITY (INA)

1. IDENTIFICATION

Name or business name

Address

Telephone Fax

Email

V. PROJECT PROPOSAL

1. Title
2. Justification, objectives and technical literature
3. Application area
4. Type of activity and uses of the resource
5. Reference list of genetic resources, by-products and associated intangible components, to which access is sought (scientific name, common name and number of samples)
6. Location of access areas and access activities (coordinates)

a) Collection

b) Location of access area

In situ *Ex situ* Coordinate

c) Location of genetic material processing and use

- In case of *ex situ* resources, relevant information about the *ex situ* conservation or commercialization center should be included

6. LOCATION OF ACCESS AREAS AND ACCESS ACTIVITIES (COORDINATES)

a) Collection

| COLLECTION LOCATIONS - DATUM COORDINATE SYSTEM MAGNA-SIRGAS ORIGIN BOGOTÁ | | | |
|--|--------|---------|---------|
| Department - Location | East | North | Polygon |
| Cauca | 661992 | 725621 | 1 |
| Cauca | 690249 | 758799 | |
| Cauca | 723428 | 766737 | |
| Cauca | 723745 | 762609 | |
| Cauca | 717554 | 750544 | |
| Cauca | 713585 | 733717 | |
| Cauca | 674850 | 685933 | |
| Cauca | 648022 | 687203 | |
| Cauca | 655391 | 706359 | |
| Valle del Cauca | 768834 | 883679 | 2 |
| Valle del Cauca | 705175 | 898999 | |
| Valle del Cauca | 704068 | 909319 | |
| Valle del Cauca | 709756 | 912229 | |
| Valle del Cauca | 754609 | 918888 | |
| Valle del Cauca | 776702 | 919880 | |
| Valle del Cauca | 786888 | 920277 | |
| Valle del Cauca | 797009 | 921732 | |
| Valle del Cauca | 701513 | 908194 | |
| Valle del Cauca | 768865 | 883641 | |
| Atlántico | 912476 | 1699561 | 3 |
| Atlántico | 910253 | 1694375 | |
| Atlántico | 902799 | 1690093 | |
| Atlántico | 891626 | 1677653 | |
| Atlántico | 884006 | 1681569 | |
| Atlántico | 890145 | 1688872 | |
| Atlántico | 803108 | 1691200 | |
| Atlántico | 899670 | 1698079 | |
| Atlántico | 912476 | 1699561 | |

b) Location of access area

In situ *Ex situ* Coordinate

c) Location of genetic material processing and usage

| Department | Location | Datum Coordinate System - Magna-Sirgas Origen Bogotá | | Name of place |
|--------------|-------------|---|--------|----------------------|
| | | East | North | |
| Cundinamarca | Bogotá D.C. | 968574 | 987678 | University of Bogotá |

IV. DETAILS OF THE PERSON OR NATIONAL SCIENTIFIC OR CULTURAL SUPPORT ENTITY (INA)

1. IDENTIFICATION

Name or business name

Address

Telephone Fax

Email

V. PROJECT PROPOSAL

1. Title
2. Justification, objectives and technical literature
3. Application area
4. Type of activity and uses of the resource
5. Reference list of genetic resources, by-products and associated intangible components, to which access is sought (scientific name, common name and number of samples)
6. Location of access areas and access activities (coordinates)

a) Collection

b) Location of access area

In situ *Ex situ* Coordinate

c) Location of genetic material processing and use

- In case of *ex situ* resources, relevant information about the *ex situ* conservation or commercialization center should be included

7. INDICATIVE TIMELINE

| ACTIVITIES | TIME | PLACE | METHODOLOGY |
|-------------|-------------|--|--|
| Exploration | 1-12 months | Atlántico, Cauca y Valle del Cauca | Tours will be made for observing the conditions of the areas to sample in order to observe if, in these areas, the necessary plant material will be obtained. |
| Collection | 1-12 months | Atlántico, Cauca y Valle del Cauca | Wild plant material (10-30 kg); assembly of <i>Exsiccata</i> to send to Colombian National Herbarium. |
| Extraction | 2-18 months | Laboratory of the University of Bogotá | Dried and chopped plant material (ca. 10 kg). Essential oils will be obtained by Microwave Assisted Hydrodistillation, using Thar SFE-2000 equipment. |
| Handling | 3-24 months | Laboratory of the University of Bogotá | The characterization of the AE will be carried out through gas chromatography-spectrometry mass (GC-MS), using apolar (DB-5MS) and polar (Carbowax) columns, 60 m x 0.25 mm, D.I x 0.25 mm, df. For characterization by liquid chromatography, a detector of diode array (DAD) will be used. |
| Research | 6-30 months | Laboratory of the University of Bogotá | Assessment of biological activities: antioxidant, antigenotoxic, cytotoxic, allergenic, antimicrobial, immunomodulatory, antitumor and repellency / attraction of insects, anti-inflammatory. Fractioning of essential oils that show biological activity. Detailed chemical characterization of essential oils and extracts that show biological activity (LC-MS-TOF; GCxGC-MS-TOF; GCMSQqQ). |

Approximate duration:

30 months (within which 12 months are planned to carry out the collection activities). The methodology is expanded in section 8.

7. INDICATIVE TIMELINE

| ACTIVITIES | TIME | PLACE | METHODOLOGY* |
|-------------|------|-------|--------------|
| Exploration | | | |
| Collection | | | |
| Extraction | | | |
| Handling | | | |
| Research | | | |

* Type and size of the sample, design and sampling, and type of characterization

Approximate duration _____

8. Materials and methods
9. Exploration and collection procedure
10. Sample management
11. Expected results
12. Initial budget
13. Other documents for inclusion

VI. LETTER OF ACCEPTANCE IN PRINCIPLE OR CONTRACT FROM THE PROVIDER OF BIOLOGICAL RESOURCES, GENETIC RESOURCES OR INTANGIBLE COMPONENTS

VII. LETTER OF COMMITMENT FROM A NATIONAL SUPPORT INSTITUTION (INA) PERSON OR LEGAL ENTITY

8. MATERIALS AND METHODS

8.1 Extraction, characterization and fractioning of essential oils and extracts

Plant species will be used to obtain essential oils through the technique of ... The plant material received from the collections will be subjected to environmental drying and then to chopping processes for size reduction of particles. Each batch of plant material will be divided into equal parts for the extraction of essential oils and obtaining extracts ...

8.2 Bioactivity evaluation of extracts and bioactive compounds

The essential oils and extracts obtained will be subject to biological activity tests, namely antioxidant, antigenotoxic, photoprotection, cytotoxic, allergenic ...

Antioxidant activity: SFE extracts and essential oils ...

Antigenotoxic activity and photoprotection: the identification and analysis of the expression of genes that could be involved in photoprotection ...

Cytotoxicity: the MTT method will be used ...

Screening for the allergenic effect: the assay is based on the quantification of the enzyme ...

8.3 General chemical characterization by GC-MS and LC of essential oils and supercritical extracts

All essential oils and extracts of the plant species will be chromatographically analyzed. All oils..

8.4 Division and detailed characterization

As a result of the bioactivity screening that will be developed, there will be a reduced number ...

9. EXPLORATION AND COLLECTION PROCEDURE

The plant material will be collected through the use of pruning shears for herbs or shrubs. A gutter will be used in the event of subarboreal, lower arboreal stratum or superior arboreal, depending, for all the cases, on previous observation of the phenological state of the vegetation and its availability, so that the population is not affected. For herbarium collections, it will be taken ...

10. SAMPLE MANAGEMENT

The plant species collected during field trips in the different locations will be received by the University of Bogotá laboratories.. The plant material received by the collections will be subject to environmental drying and, later, the extracts that exhibit high bioactivity will undergo certain operations ...



7. INDICATIVE TIMELINE

| ACTIVITIES | TIME | PLACE | METHODOLOGY* |
|-------------|------|-------|--------------|
| Exploration | | | |
| Collection | | | |
| Extraction | | | |
| Handling | | | |
| Research | | | |

* Type and size of the sample, design and sampling, and type of characterization

Approximate duration _____

8. Materials and methods
9. Exploration and collection procedure
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VIII. AFFIDAVIT FROM THE APPLICANT, RECORDING THE TRUTHFULNESS OF THE DETAILS IN THE APPLICATION

11. EXPECTED RESULTS

- Herbarium samples with their botanical description and collection site.
- Essential oils and supercritical extracts obtained from plant species collected.
- Characterization of at least 40 essential oils and supercritical extracts.
- Evaluation of the biological activity of at least 40 essential oils and supercritical extracts.
- ...

12. INITIAL BUDGET

| GLOBAL PROJECT BUDGET | | | |
|---------------------------------|---|-------------------------|-------------------------|
| Field | Financing by the Department of Science, Technology and Innovation | Others | Total |
| Bibliography | 0,00 | 10.000.000,00 | 10.000.000,00 |
| Administrative Costs | 300.000.000,00 | 0,00 | 300.000.000,00 |
| Equipment | 500.000.000,00 | 1.000.000.000,00 | 1.500.000.000,00 |
| Academic events | 28.000.000,00 | 0,00 | 28.000.000,00 |
| Contingencies | 0,00 | 30.000.000,00 | 30.000.000,00 |
| Infrastructure | 0,00 | 20.000.000,00 | 20.000.000,00 |
| Materials | 820.000.000,00 | 140.000.000,00 | 960.000.000,00 |
| Provision of technical services | 40.000.000,00 | 15.000.000,00 | 55.000.000,00 |
| Publications | 15.000.000,00 | 5.000.000,00 | 20.000.000,00 |
| Human Resources for CTI | 980.000.000,00 | 50.000.000,00 | 1.030.000.000,00 |
| Field Trips | 40.000.000,00 | 3.000.000,00 | 43.000.000,00 |
| Technical services | 27.000.000,00 | 0,00 | 27.000.000,00 |
| Software | 1.300.000,00 | 22.000.000,00 | 23.300.000,00 |
| Travel and travel expenses | 95.000.000,00 | 21.000.000,00 | 116.000.000,00 |
| TOTAL | 2.846.300.000,00 | 1.316.000.000,00 | 4.162.300.000,00 |

BIBLIOGRAPHY

- Desmarchelier C., F. Witting Schaus. 2000. Sixty medicinal plants from the Peruvian Amazon: Ecology, ethnomedicine and bioactivity. Proterra. Lima, Perú. 114 pp.
- Stashenko E., C.A. Ruíz, G. Arias, D.C. Durán, W. Salgar, M. Cala, J.R. Martínez. 2010. Lippia organoides chemotype differentiation based on essential oil GC-MS analysis. *Journal of Separata Science*, 33(1), 93-103.

7. INDICATIVE TIMELINE

| ACTIVITIES | TIME | PLACE | METHODOLOGY* |
|-------------|------|-------|--------------|
| Exploration | | | |
| Collection | | | |
| Extraction | | | |
| Handling | | | |
| Research | | | |

* Type and size of the sample, design and sampling, and type of characterization

Approximate duration _____

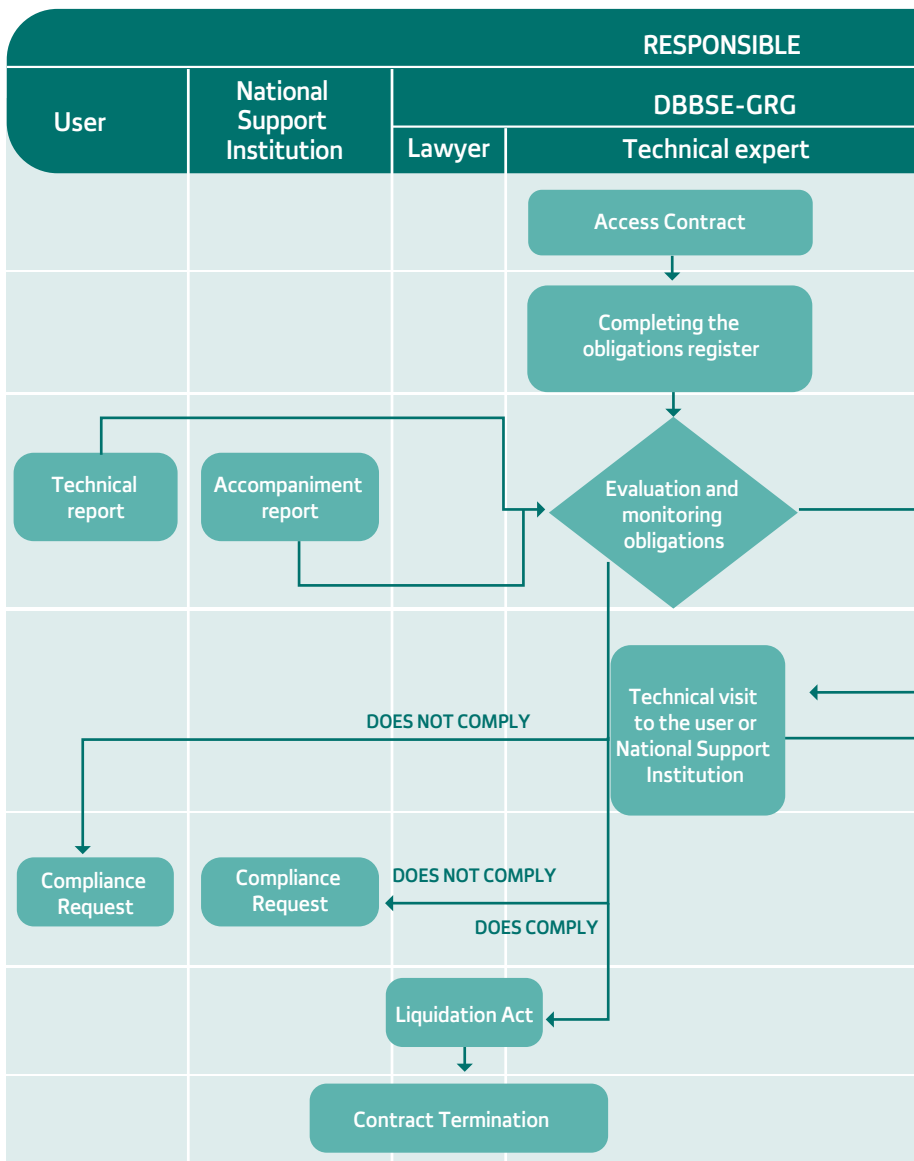
8. Materials and methods
9. Exploration and collection procedure
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VIII. AFFIDAVIT FROM THE APPLICANT, RECORDING THE TRUTHFULNESS OF THE DETAILS IN THE APPLICATION

Annex 3 Flow chart for the control and monitoring of access contracts





| | DIRECTORATES OF THE MINISTRY OF ENVIRONMENT AND SUSTAINABLE DEVELOPMENT | TIME IN BUSINESS DAYS | OBSERVATIONS |
|---------------|---|-----------------------|--|
| | | 5 | |
| IF APPLICABLE | <p>IF APPLICABLE</p> | 15 | This cycle repeats itself depending on the duration of the contract and the number of reports that the user must deliver |
| | | 10 | |



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El ambiente
es de todos

Minambiente



50
AÑOS

Al servicio de las personas y las naciones.