

Bolivia

Supreme Decree No. 24676, Regulation of Decision 391 on the Common Regime for Access to Genetic Resources (21 June, 1997).

Unofficial Private Translation

Title I X General Provisions

Chapter I X Objective and Aim

Article 1. - The present Supreme Decree implements Decision 391 of the Commission in the Agreement of Cartagena of the 22 of 1996 July relating to the Common Regime of Access to the Genetic Resources, establishes the obligation to sign a Contract of Access between the applicant and the Bolivian State to acquire genetic resources, to which the following Article makes reference, and this Contract determines the obligations and rights of the contracting parts.

Article 2. - The present Regulation applies to genetic resources of which Bolivia is the country of origin, their derivatives, their associated intangible components and to genetic resources of migratory species that by natural causes are in the national territory.

Article 3. - To implement Article 4(b) of Decision 391, it does not require the subscription of a prior Contract of Access, the signing of a contract is not required for the exchange of genetic resources, their derived products, the biological resources that they contain or the associated intangible components thereof, carried out by indigenous towns and communities farmers for their own consumption and in accordance with customary practices.

Title II X Institutional Framework

Chapter I X Competent National Authority

Article 4. - The Regime of Access to the Genetic Resources of the Nation is in the charge of the Ministry of Sustainable Development and the Environment, through the National Secretariat of Natural Resources and the Environment, as the Competent National Authority.

Article 5. - The Minister of Sustainable Development and the Environment, through the National Secretary of Natural Resources and the Environment, in accordance with Law No. 1493 of Ministries of the Executive Power, its Regulation, the present normative body and other connected provisions, has the following functions and competitions:

- a) To implement and enforce the present Regulation, the legal and contractual conditions for the access to genetic resources, its derivatives or their associated intangible components, and other connected legal dispositions,
- b) To formulate, define and implement national policies relating to the conservation, sustainable use and development of existing genetic resources in the national territory
- c) To guarantee the recognition of the rights of indigenous and campesino communities as providers of associated intangible components of genetic resources, in coordination with

- the National Secretariat of Ethnic Studies and Generations, and the representative organizations of these indigenous and campesino communities,
- d) To convene the Technical Advisory Body and to take responsibility of its operation,
 - e) To promote information dissemination on access to the genetic resources,
 - f) To develop the institutional capacity in order to guarantee the full implementation of 391 Decision and the present Regulation
 - g) To elevate, through the pertinent device of the Ministry of External Relations and Cult[ure?](culto), the pertinent recommendations to the General Secretariat of the Andean Community
 - h) To permit or to deny the access to the genetic resources.
 - i) To take and to maintain the technical files and the Public Registry of the Requests of Access to the Genetic Resources
 - j) To know and to solve the legal resources that correspond to him within the administrative process of access to the genetic resources, in case of denied requests.
 - k) To sanction infractions of 391 Decision and the present Regulation, against individuals or governmental officials,
 - l) To determine the suitability of the National Institution of Support that the applicant proposes,
 - m) To promote the creation of a national inventory of genetic resources of which Bolivia is the country of origin.

Chapter II X Prefecturas

Article 6. - The Prefectures in the Regime of Access to the Genetic Resources, have the following functions and attributes:

- a) To receive requests for the access to genetic resources.
- b) To inspect access activities, without preventing its normal unfolding, and submitting the respective information to the Competent National Authority.
- c) To promote within its jurisdictions, the development of programs, that contribute to the conservation, development and sustainable use of genetic resources, in coordination with the Municipalities.
- d) To supervise the full implementation of the terms and conditions of Contracts of Access, arranging in case of disobedience the preventive measures, and informing to the Competent National Authority in immediate form.

Chapter III X Technical Advisory Body

Article 7. - Create the Technical Advisory Body (CAT) as an organism responsibility for the following reasons in charge of advising and technical support to the Competent National Authority in subjects related to access to genetic resources.

Article 8. - The members of the CAT must have recognized scientific and technical experience, which will be endorsed by their respective curricula.

Article 9. - The Technical Advisory Body will be constituted of the following way:

1. one representative from the National Secretariat of Natural Resources
2. one representative for the National Secretariat of Agriculture and Ranching
3. one representative of the Secretary of Ethnic Subjects and Generations
4. one representative of the National Secretariat of Industry and Trade
5. one representative from the University System.

According to the genetic resource for which access is request and the intended utility of that resource, the CAT will invite other specialists of recognize scientific and technical expertise to participate in the evaluation, as well as representatives of technical institutions and legally constituted scientific organizations, indigenous and campesino communities that are involved as providers of the associated intangible components of genetic resources, the director of the Protected Area when the resource is found there, and legally constituted non-governmental organizations that have activities related to genetic resources, and others.

Article 10. - The representative of the National Secretariat of Natural Resources and the Environment ejercerà the Presidency of the Body of Technical Advising, performing the functions that are determined in the Internal Regulation.

Article 11. - The members of the Technical Advisory Body will meet at request of the Competent National Authority to undertake a study and technical evaluation of the requests that were put to their consideration.

Article 12. - The Technical Advisory Body has the following attributes and functions:

- a) To create its Internal Regulation.
- b) To effect the technical evaluation of the requests of access to genetic resources and to raise/prepare the corresponding Technical Opinion to the Competent National Authority.
- c) To raise technical proposals to the Competent National Authority for the establishment of partial or total limitations to requested access.
- d) To gauge the suitability of the National Institution of Support proposed by the applicant and to suggest a different one, if necessary.
- e) To recommend to the Competent National Authority the suitable institutions for the deposit of duplicates of the accessed genetic material.

- f) To raise the potentiality of genetic resources in other uses aside from the requested one and to come up about this to the Competent National Authority.

Article 13. - The members of the CAT, in their position as advisers to the Competent National Authority, are responsible by the veracity and cabalidad for the information including in the forms, opinions and any other document that elaborates and sign in implementation of their functions in agreement as established in national legislation.

Article 14. - When some of the members of the CAT participate directly in the request for access, they must be excused from participation in the evaluation of the request, in which case the institution which represents will designate another representative with transitory and single character for the evaluation of the Request that had given rise to CAT member's recusal.

Title III X Regime of Access to Genetic Resources

Chapter I X Conditions and Limitations for Access to Genetic Resources

Article 15. - Contracts of Access to Genetic Resources will include, in addition to the conditions indicated in Article 17 of Decision 391, the following:

1. Participation of a National Institution of Support in any investigation and/or experimentation carried out by the applicant with the accessed genetic material;
2. The just and equitable participation of the Bolivian State in any economic, technological or other benefit or another one of any nature that derive from the access to the genetic resources. Likewise, when indigenous and campesino communities become involved as providers of associated intangible component of genetic resources to which access is requested, they are accorded participation in the benefits derived from the access to the genetic resource through its representative organizations.
3. To bring reports before the National Institution of Support, with copy to the Competent National Authority on the work of experimentation or other studies done from the accessed genetic material. A copy of these reports will be sent to the indigenous and campesino communities, the ex situ Conservation Center, and/or Director of the Area Protected involved, as applicable.

Article 16. - To govern access to genetic resources, the limitations established in Article 45 of the Decision 391, and others that could be established by the Ministry of Sustainable Development and the Environment as merited by the circumstances to studies on the situation of the species. ??

Chapter II X Procedures for Access to Genetic Resources

Article 17. - The requests for access to genetic resources to which Article 2 of the present Regulation refers impetradas by natural persons or legal foreigners, must be submitted to the Competent National Authority.

Natural persons or legal nationals, that intend to access any genetic resource to which Article 2 of the present Regulation refers, must present his Requests of Access before the Departmental or National Authority, according to his advice, when the access activities are made in the jurisdiction of a single Department. When the Request involves access activities in the jurisdiction of more than one Department, the Request must be submitted to the Competent National Authority.

Article 18. - The Request must include the following documents:

1. Form of Request of access to the genetic resources annexed to the present regulation.
2. Documents that identify the legal capacity and legal function and position of the applicant in accordance with applicable national legislation.

All the information provided by the Applicant relating to the Request of Access, will have the character of a Sworn Declaration.

Article 19. - The applicant may request the Competent National Authority to make certain information confidential, whose must present the justification of its request accompanied by a nonconfidential summary that will comprise of the public file, in accordance with Articles 19 and 20 of Decision 391.

The Competent National Authority and the members of the CAT are responsible for maintaining the confidentiality of this proceeding, which will remain in a reserved file which cannot be disclosed except by judicial order.

Article 20. - The requests presented to the Departmental Authority will be sent in the day to knowledge of the Competent National Authority for the admission and corresponding registry.

Article 21. - The completed Request, will be admitted and registered in the Public Registry of Requests by the Competent National Authority, that will have the opening the corresponding technical file. If the request is incomplete, it will be given back to the applicant immediately, so that it may be corrected.

Article 22. - Upon admission of the request, and within the five following days to its entry in the Public Registry, the Competent National Authority will publish an abstract of the Request and a summary of the Profile of Project of access, in written mass media of national circulation and in another oral mass media in the locality where access is requested, so that any person may provide additional information regarding the existence of some impediment so that the asked for access is perfected, to the Competent National Authority.

Article 23. - Perfected by this publication, the Competent National Authority will summon the CAT and will remit the technical file for the knowledge of the CAT for an evaluation.

Article 24. - Within thirty working days following the entry of the Request in the Public Registry, the CAT will make the technical evaluation of the Request and the Profile of Project. The end of the evaluation could be extended to 60 days at the express and justified request of the CAT.

Article 25. - Upon completion of the evaluation, the CAT will provide a Technical Opinion to the Competent National Authority, in which it will recommend the appropriateness or inappropriateness of the Request and the Profile of Project of Access. This opinion must contain:

1. An explicit and fundamental explanation of the aspects evaluated,
2. An indication of the methodologies used in the evaluation, as well as of the examinations, tests or advice of high specialization that were required.

3. A fundamental explanation of the reasons by which the appropriateness or inappropriateness of the request is pronounced.
4. The observations and recommendations considered advisable for the negotiation and processing of the Contract of Access.

Article 26. - The Competent National Authority, taking into account the Technical Opinion, will accept or reject the origin of the request and will notify the applicant within the five following days, to negotiate and process the Contract from Access to genetic resources.

If the application is denied, the Competent National Authority will communicate this decision to the applicant by means of Secretarial Resolution, which can be opposed in the form anticipated in the national legislation.

Article 27. - The signed Contract of Access between the applicant and the National Undersecretary's office of Natural Resources, the National Secretary of Natural Resources and the Environment will transmit a Secretarial resolution, that ratifies the Contract of Access.

Article 28. - The Resolution referred to in the preceding Article will be published with an abstract of the Contract, in mass media written of national circulation, at which time the Contract of Access is perfected/comes into force.

Article 29. - The applicant will pay the expenses of publication and necessary evaluations for access to the genetic resources, to this effect the Competent National Authority will open Special Fiscal Account in which the applicant carries out the deposit of the amount, corresponding to the indicated expenses.

Chapter III X Access to Genetic Resources in Protected Areas

Article 30. - Access to genetic resources in Protected Areas, requires the signing of an Accessory Contract with the Director of the Area Protected involved, in accordance with its plan of handling, categorization and zonification for the Protected Area and the effective legal norms on Protected Areas.

Article 31. - The Director of the Protected Area is responsible for the pursuit and control of the access activities that are made within the Protected Area, and must inform the Competent National Authority immediately of any infraction or irregularity, without prejudice to the execution of the preventive measures that are considered necessary.

Article 32. - When the Protected Area involved also constitute communal lands, and whenever the genetic resource to which access is requested is located in the geographic space occupied by some indigenous population of the region, the applicant, without prejudice to Article 30 of the present Regulation, must sign with the representative organization of the community or involved communities, an Accessory Contract in conformity with Title IV of the present Regulation.

Chapter IV X Access to Genetic Resources in *Ex Situ* Conservation Centers

Article 33. - For the purpose of this chapter, it is understood that *ex situ* Conservation Centers are the natural or legal persons recognized by the Competent National Authority that conserve and collect the genetic resources or their derived products outside *in situ* conditions.

Article 34. - The Contracts of Access signed with ex situ Conservation Centers do not authorize the execution of missions/trips to collect genetic resources for other organizations that are found outside the country.

Article 35. - For access to genetic resources that are in ex situ Conservation Centers on the part of investigators or others, an Accessory Contract with the Director of this Center must be signed with the object of agreeing on the anticipated benefits from the use of the genetic resource.

Chapter V X The Signing and Entry into Force of the Contract of Access

Article 36. - The Competent National Authority, through the Undersecretary's office of Natural Resources, will sign with the applicant the terms of the Contract of Access taking into account: the benefits that derive from the access, the form and opportunity of its distribution, the conditions for the determination of the owner/holder of the intellectual property rights and the conditions for the commercialization of the results.

Article 37. - The Contract of Access must be prepared in conformity with Decision 391 and national legislation, containing clauses such as:

- a) Identification of the contracting parts.
- b) Justification of the Contract.
- c) Determination of the object of the contract whose detail will appear in the definitive project of access that will comprise integral of the Contract of Access.
- d) Stipulation of the rights and obligations of the parties, consistent with the conditions and limitations established in 391 Decision and the present regulation, taking in consideration the agreements of the negotiating stage.
- e) Indication of the benefits, that the applicant is in condition to offer to the Bolivian State and the form and opportunity of the distribution of benefits
- f) Indication of the implementation guarantees offered by the applicant.
- g) Stipulation of the duration, use and extension of time of the contract.
- h) Clauses of modification, suspension, rescission, and resolution of the Contract.

Article 38. - In the preparation of the Contract of Access, the Undersecretary of Natural Resources, representing of the Executive Power, will sign the contract and send it to the National Secretary of Natural Resources and the Environment for his ratification through the corresponding Secretarial Resolution.

Article 39. - The Undersecretary of Natural Resources can sign with the Applicant a Framework Contract of Access that protects in the execution of various projects of access, in accordance with Article 36 of Decision 391 and the present Regulation.

Chapter VI X Participation of the State in the Benefits Deriving from Access to Genetic Resources

Article 40. - The Bolivian State will participate in the just and equitable form of the benefits of any nature that derive from the access to the genetic resources referred to in Article 2 of the present Regulation. These benefits will be distributed for conservation, the sustainable use and development of genetic resources in the national territory.

Article 41. - To implement the preceding Article, the benefits derived from the access to the genetic resources will consist of:

- a) The transfer of technologies and knowledge used in the investigation and/or experimentation, relating to access to the resource.
- b) Development of technical and scientific capacities of national institutions.
- c) the cancellation of royalties for the commercial use of the genetic resources, its derivatives or their associated intangible component.
- d) tax exemptions that the drug dealers or processors of the accessed genetic resources grant to the country.
- e) Others that could decide under Decision 391, the present Regulation and other connected dispositions.

Article 42. - To implement paragraph a) of the preceding Article, one will consider the following:

- a) The transfer of technologies, methods, equipment, materials or others used in the work of the investigation and/or experimentation, to strengthen the capacity of the National Institution of Support and other scientific and technical institutions, preferably within the National territory.
- b) the applicant must guarantee the participation of personnel of the National Institution of Support in the work of investigation and/or experimentation, under mutually agreed terms. When indigenous and campesino communities participate as providers of the associated intangible component of the accessed genetic resource, the applicant will call for the participation of one representative of these groups in this phase.

Article 43. - For the distribution of the benefits referred to in paragraph c) of Article 41, the following aspects will be considered:

- 2) If the accessed resource is extracted from communal lands, or when the community or indigenous community participates as a provider of the associated intangible component of the acquired genetic resource, the payment will be made to the communities through its representative organizations in conformity with the Accessory or Annex Contract, as appropriate, so that the collective rights of the community are recognized in the existing natural resources in their communal lands and in associated intangible component of the biological resources.
- b) If the accessed genetic material is collected in a Protected Area, the payment will be made to the Director of the Protected Area and/or to the National System of Areas Protected in accordance with the legal norms on Protected Areas effective.

- c) Without prejudice to the preceding paragraphs, the Bolivian Government will use the resources collected in the implementation of programs and projects relating to conservation, development and sustainable use of the genetic resources in the framework of the National System of Conservation and Development of the Genetic Resources of Bolivia (SRG).

Title IV X Annexed and Accessory Contracts

Chapter I X Annex

Article 44. - The Annex is signed between the applicant and the provider of the associated intangible component to the genetic resource, with the object of anticipating the just and equitable distribution of the benefits deriving from the use of this component. The same parties constitute indispensable members of the Contract of Access.

Article 45. - For the signing of the Annex, the established general norms for the Contract of Access govern, when they are applicable.

Article 46. - The Annex will establish clauses for suspending the contract of access that subordinates its efficacy to the improvement of the contract of Access.

Article 47. - The provider of the intangible component will participate in the distribution of the benefits derived from the access to the genetic resource in the form anticipated by this Regulation, without prejudice to other agreements between the provider and the applicant, provided that the agreements do not contravene Decision 391 and the present Regulation.

Article 48. - The Ministry of Sustainable Development and the Environment through the National Secretariat of Natural Resources and the Environment, will ensure the legality of the obligations and emergent rights of the Annex, in consideration to the strategic value of the practices, knowledge and innovations of the indigenous and campesino communities. The breach of the Annex is cause for resolution and invalidity of the Contract of Access.

Chapter II X Accessory Contracts

Article 49. - Accessory Contracts must be signed relating to the development of access activities between the applicant and third people different from the State who do not participate as providers of associated intangible components to genetic resources. These Accessory Contracts determine the obligations and rights of the contracting parts. The signing, execution and implementation of these contracts are governed by applicable national legislation and the agreement of the parties.

Article 50. - The applicant will sign an Accessory Contracts, as applicable, with:

- a) The National Institution of Support.

- b) the owner, possessor or administrator of the property on which the biological resource that contains the genetic resource is found.
- c) the ex situ Conservation Center that conserves and/or collects the genetic resource.
- d) the proprietor, possessor or administrator of the biological resource that contains the genetic resource.
- e) The Director of the Protected Area where the access activities are made.

Article 51. - To implement paragraph a) of the preceding Article, the National Institution of Support is the national legal person dedicated to the biological investigation of scientific or technical reasons that accompanies the applicant and participates in the activities of access under mutually agreed terms Without prejudice to the agreements included in the Accessory Contract, the National Institution of Support must collaborate with the Competent National Authority in the pursuit and control of the activities of access to genetic resources, presenting it periodically in a form decided upon by the Authority.

Article 52. - For the signing of the Accessory Contract, the applicant must provide a copy of the Project to the other contracting party, in order to provide the other party with knowledge of the project.

Article 53. - The Accessory Contracts can be signed before the signing of the Contract of Access and will hold their effectiveness to the fulfillment of the suspensive condition referred to in Article 47 of the present Regulation.

Article 54. - The obligations and emergent rights of the signed Accessory Contracts will have effect only between the contracting parties, having among them the force of law. The modification, suspension, rescission, resolution or invalidity of the Accessory Contract can such have effects on the Contract of Access when it affects of established substantial way conditions in this last one.

Title V X National System of Genetic Resources of Bolivia

Article 55. - It is created the National System of Genetic Resources of Bolivia (SRG) as an instrument that helps to the conservation, development and sustainable use of the genetic resources of which Bolivia is the country of origin, through the implementation and execution of programs and projects in the framework of the effective legal norms.

Article 56. - The National Secretariat of Natural Resources and the Environment as the governing body of the National System of Genetic Resources of Bolivia promotes and supports the establishment and operation of the National System of Genetic Resources.

Title VI X Infractions and Sanctions

Article 57. - All conduct of the applicant, governmental officials or third parties that contravene the provisions established in 391 Decision and this Regulation are administrative infractions.

Article 58. - Infractions of the present Regulation, according to their gravity or grade of recidivism will give rise to sanctions, without damage of the penal sanctions that could correspond when these conducts form a crime, in which case, it must be sent to the authority called by law.

Article 59. - With the object of describing the sanction, the National Secretary of Natural Resources and the Environment will consider, together or separately, the following aspects:

- a) The gravity of the infraction.
- b) If the infraction causes damages to the public health.
- c) the value of the affected genetic and biological diversity.
- d) the social economic cost of the project or activity causing the damage.
- e) the economic and social benefit obtained as a product of the infraction.
- f) recidivism.
- g) the nature of the infraction.

Article 60. - Sanctions will be imposed by the National Secretary of Natural Resources and the Environment according to their qualification and will include the following measures:

- a) Written reprimand when the infraction is slight and committed for the first time, granting to him to admonished a fixed term, to amend the same one.
- b) progressive fines, in case of a persisting infraction, a fine equivalent to 60 days fines will be given. In case of a persisting infraction or the commission of new infractions, the National Secretary of Natural Resources and the Environment will successively increase the fine in a one hundred percent on the base of the previous fine, until the limit of three cumulative fines.
- c) Suspension of the activities of access and preventive or definitive seizures, in case of flagrant contraventions that they imply alterations to the ecosystems and/or the biological diversity, the National Secretary of Natural Resources and the Environment will have the immediate suspension the access activities and the preventive or definitive seizure of the goods and/or instruments of the violator.

- d) Revocatory of authorization and Incapacitation to ask for new accesses, in cases of recidivism or resistance to the fulfillment of the imposed sanctions, the National Secretary of Natural Resources and the Environment will be able in addition, to have revocatory the authorization to access and the incapacitation to ask for new accesses.
- e) Resolution of the Contract of Access. Without damage of the preceding sanctions the Competent National Authority will be able To solve the Contract of Access by causal the following ones:
 - 1. Breach of the obligations established in the Contract of Access, and the Annex.
 - 2, The transference of the acceded genetic resource to third, without the authorization of the Competent National Authority.
 - 3. Impossibility to reach a satisfactory agreement between the parts of the Contract in relation to the subject benefits on condition that suspensive.

Article 61. - To implement paragraph b) of the preceding Article, a fine of one day is considered the equivalent to a day of minimum wage.

Article 62. - The income from administrative sanctions deriving from fines will be deposited in a special account administered by the National Fund for the Environment (FONAMA) and destined for the compensation of environmental damages and/or to programs for conservation and development of the genetic resources.

Article 63. - The proceeding and Resolution of the administrative infractions will take place in accordance with the Law of the Environment and the its Regulations, being solved the impugnatorios resources by Ministerial Resolution of the Ministry of Sustainable Development and the Environment.

Title VII X Final Provisions

FIRST. - To effectuate the First Interim Provision of Decision 391, for those holding genetic resources of which Bolivia is origin country, its derived products or associated intangible components, such access must be managed in conformity to Decision 391 of the Commission in the Agreement of Cartagena and Regulation, until June of 1998.

SECOND. - To effectuate the guarantee the effective and adequate implementation of the present Regulation, the National Secretariat of Natural Resources and the Environment will establish mechanisms to coordinate with the National Secretariats of Industry and Commerce; International Economic Relations; Generational Ethnic Subjects and Generations; State Agriculture and Cattle Ranching; and other pertinent organizations.

THIRD. - The members of the CAT will process their Internal Regulation, within ninety calendar days of the present Regulation taking effect, whose effect will have to be credited by their respective institutions, within the term of thirty days calendar of the approval of the present Regulation.

FOURTH. - To effectuate Article 29 of the present Regulation, the Competent National Authority will manage the opening of the referred Special Account Fiscal, in the maximum term of 30 working days from the approval of this regulation. The handling and administration of this Special Fiscal Account will be in charge of the National Secretary of Natural Resources and the Environment in coordination with the Body of Technical Advising.

FIFTH. - The rights granted to the applicant can not be transferred to third parties without express authorization of the Competent National Authority. The person to whom rights are transferred automatically assumes the rights and obligations of the transferee with the Bolivian State.

SIXTH. - The authorizations that protect the investigation, obtaining, provision, commercialization or any other activity with biological resources, do not condition, presume nor determine the authorization of access to the contained genetic resources in these biological resources. Those authorizations will incorporate in their text the legend "not authorized for use as genetic resources".

SEVENTH. - When one asks for the protection of a right of obtentor of vegetal varieties or another right of intellectual property on any product and/or alive organism, developed from genetic resources to which Article 2 of the present Regulation talks about, the corresponding National Authority in the matter, it will demand like requirement for the granting of right sayings, the presentation of the Secretarial Resolution to which Article 27 makes reference of the present Regulation.

EIGHTH. - When it is tried to export biological resources of flora or fauna with aims of access to genetic resources, the National Secretariat of Agriculture and Ranching through his corresponding devices, it will demand as requisite for the extension of Certificates of Vegetal Health and/or Animal according to corresponds, the Secretarial Resolution to which makes reference Article 27 of the present Regulation.

NINTH. - The National Secretariat of Natural Resources and the Environment can absorb consultations with normative character and universal effect, without exceeding its authority.