YEAR XXXVII Nº 2012 LA PAZ - BOLIVIA

OFFICIAL BOLIVIAN GAZETTE

JUNE - 21 - 1997
SUPREME DECREE Nº 24676

REGULATION OF DECISION 391 OF THE COMMISSION OF THE CARTAGENA AGREEMENT AND OF THE BIOSAFETY

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PUBLISHED ON JULY 1, 1997

SUPREME DECREE Nº 24676

GONZALO SANCHEZ DE LOZADA
CONSTITUTIONAL PRESIDENT
OF THE REPUBLIC

WHEREAS:

Articles 136 of the Political Constitution of the Government and article 3 of Environmental Law No. 133 of April 27, 1992, determine that the Bolivian Government is sovereign in the use and exploitation of its natural resources.

In recognition of the sovereign rights of the States over their biological resources, the Biological Diversity Agreement subscribed in Rio de Janeiro in 1992 and ratified by means of Law of the Republic Nº 1580 of July 25th, 1994, determines that it is incumbent upon the national Governments to regulate the access to genetic resources.

The genetic resources, by constituting an strategic value in the national and international context for being the primary source of products and processes for the industry, Decision 391 of the Commission of the Cartagena Agreement instructs the Member Countries to elaborate a regulation related to their genetic resources, their by-products, and the intangible components associated to them, under conditions of equity and reciprocity between the Government, the suppliers of the genetic resources and the associated knowledge, and the individuals that accede to said resources.

Agreement 169 on Indigenous and Tribal Peoples in Independent Countries of the International Labour Organization, ratified by means of Law of the Republic No. 1257 of July 11th, 1991 and the Political Constitution of the Government recognizes and guarantees the rights of the indigenous peoples and Peasant communities to participate in the sustainable utilization and exploitation of the natural resources available in their common lands and therefore, the rights of these to participate in the benefits that the utilization of said resources may provide.

On the other hand, the Biological Diversity Agreement instructs the Contracting Parties to establish and maintain the means to regulate, administer and control the risks derived from the utilization and release of genetically modified organisms that could affect the human health, the environment and the sustainable conservation and utilization of the biological diversity.

The Commission of the Cartagena Agreement, by means of Decisions 345 y 391 instructs the Member Countries to adopt a Common Biosafety Regime, particularly in what is referred to the transborder movement of genetically modified organisms.

In accordance to Environmental Law 1333, it corresponds to the Government through its competent agencies, to

execute actions for the prevention, control and evaluation of the activities that are susceptible of degrading the environment and natural resources.

Likewise, it is necessary to establish a legal framework that regulates the introduction of genetically modified organisms to the national territory, as well as the carrying out of activities with the same.

THE COUNCIL OF MINISTERS

DECREES:

ARTICLE 1.- By means of this Supreme Decree, the Regulation of Decision 391 of the Commission of the Cartagena Agreement and the Biosafety Regulations are approved with their respective Annexes that form integral part of the same.

ARTICLE 2.- All legal provisions on the contrary to this Supreme Decree are hereby annulled.

The Minister of State in the Dispatch of Sustainable Development and the Environment is hereby in charge of the execution and enforcement of this Supreme Decree.

Given at the Government Palace of the city of La Paz, at the twenty first day of the month of June of the year nineteen ninety-seven.

Signed by GONZALO SANCHEZ DE LOZADA, Antonio Aranibar Quiroga, Victor Hugo Canelas Zannier, Alfonso Edwin Kreidler Guillaux, José Guillermo Justiniano Sandoval, MINISTER OF THE PRESIDENCY AND ALTERNATE MINISTER OF SUSTAINABLE DEVELOPMENT AND THE ENVIRONMENT, René Blattmann Bauer, Fernando Candia Castillo, Franklin Anaya Vasquez, Jorge España Smith, ALTERNATE LABOR MINISTER, Mauricio Antezana Villegas, Alfonso Revollo Thenier, and Jaime Villalobos Sanjinés.

REGULATION OF DECISION 391 COMMON ACCESS REGIME TO GENETIC RESOURCES

TITLE I
GENERAL PROVISIONS

CHAPTER I
OBJECT AND SCOPE

Article 1.- This Supreme Decree has the object of regulating Decision 391 of the Commission of the Commission of the Cartagena Agreement of July 22nd, 1996, that regulates the Common Regime of Access to Genetic Resources, establishing the mandate to subscribe an Access Contract between the petitioner and the Bolivian Government, to accede to any of the genetic resources referred to by the next Article, said Contract determines the obligations and scope of the rights of the Contracting Parties

Article 2.- This regulation shall be applied to the genetic resources of which Bolivia is a country of origin, its by-products, its intangible components associated to the genetic resources of the migrating species that due to natural causes are found in the national territory.

Article 3.- For purposes of the set forth by clause b) of Article 4 of Decision 391, the exchange of the genetic resources, its by-products, the biological resources that contain them or the intangible component associated to these, does not require the subscription of a prior Access Contract entered into by the indigenous peoples and peasant communities for their own consumption and based in customary methods.

CHAPTER I I
INSTITUTIONAL FRAMEWORK

CHAPTER I
COMPETENT NATIONAL AUTHORITY

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

Article 5.- The Ministry of Sustainable Development and the Environment, through the National Secretary's Office of Natural Resources and the Environment, in accordance with the established in Law No 1493 of the Ministries of the Executive, in its Regulations, this body of laws, and other related provisions, has the following functions and competence:

a) Fulfill and enforce this Regulation, the legal and contractual conditions for the access to genetic resources, its by-products or the intangible components associated to them, and other related legal provisions.

b) Formulate, define and implement national policies referred to the conservation, sustainable use and development of the genetic resources existent in the national territory.

c) Guarantee the acknowledgment of the rights of the indigenous peoples and peasant communities as suppliers of the intangible component associated to the genetic resources in coordination with the National Secretary's Office of Ethnic, Genre and Generational Affairs, and the organizations that are representatives of said indigenous peoples and peasant communities.

d) Summon the Body of Technical Advice and be responsible for its operation.

e) Promote the dissemination of information regarding access to genetic resources.

f) Develop the institutional capacity in order to guarantee faithful compliance of Decision 391 and this Regulation.

g) Promote the recommendations pertinent to the General Secretary's Office of the Andean Community through the pertinent branch of the Ministry of Foreign Affairs and Cult.

h) Grant or deny access to genetic resources.

i) Keep and maintain the technical files and the Public Registry of Petitions for Access to Genetic Resources.

j) Hear and resolve the legal appeals that correspond to it within the administrative actions of access to genetic resources, in the case of denied petitions.

k) Penalize the transgressors of Decision 391 and this Regulation, whether these be civilians or public officers.

1) Object the suitability of the National Support Institution proposed by the petitioner.

n) Promote the elaboration of a national inventory of genetic resources of which Bolivia is a country of origin.

CHAPTER 11
PREFECTURES

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

a) Receive the petition for access to genetic resources.

b) Inspect the access activities, without obstructing their normal unfolding, and elevate in front of the Competent National Authority the respective reports.

c) Promote within their jurisdictions, the development of programs that contribute to the conservation, development and sustainable use of the genetic resources, in coordination with the municipalities.

d) Supervise faithful compliance with the terms and conditions of the Access Contracts, disposing preventive measures in the event of infringement, and reporting to the Competent National Authority in immediate manner.

CHAPTER III
BODY OF TECHNICAL ADVICE

Article 7.- The Body of Technical Advice (BTA) is created as the organism in charge of rendering advice and technical support to the Competent National Authority in matters related with the access to genetic resources.

Article 8.- The members of the BTA must have a known scientific and technical trajectory which shall be backed up by the respective curricula.

Article 9.- The Body of Technical Advice shall be composed in the following manner:

1. A representative of the National Secretary's Office of Natural Resources and the Environment.
2. A representative of the National Secretary's Office of Agriculture and Livestock.
3. A representative of the National Secretary's Office of Ethnic, Gender and Generational Affairs.
4. A representative of the National Secretary's Office of Industry and Commerce.
5. A representative of the University System.

In accordance with the genetic resource which is desired to be acceded and the usefulness that is pretended to be given to the same, the BTA shall invite other specialists of known scientific and technical trajectory to participate in the evaluations, as well as representatives of technical institutions, legally incorporated scientific organizations, indigenous peoples and peasant communities that were involved as suppliers of the intangible component associated to the Genetic Resources, the Direction of the Protected Area when the resource to be acceded is found within its boundaries, non governmental legally incorporated organizations that carry out activities related to the genetic resources, and others related.

Article 10.- The representative of the National Secretary's Office of Natural Resources and the Environment shall exercise the Presidency of the Body of Technical Advice, carrying out the functions that shall be determined in the internal Regulations of the same.

Article 11.- The members of the Body of Technical Advice shall meet at the request of the Competent National Authority to carry out the study and technical evaluation of the requests that were put under their consideration.

Article 12.- The Body of Technical Advice has the following attributions and functions:

a) Elaborate its Internal Regulations.

b) Carry out the technical evaluation of the requests for access to genetic resources and submit the corresponding Technical Decision to the Competent National Authority.

c) Submit a technical proposal in front of the Competent National Authority for the establishment of partial or total limitations for the access being requested.

d) Rate the suitability of the National Support Institution proposed by the petitioner and suggest its substitution by another in the event of being necessary.

e) Recommend to the Competent National Authority the suitable institutions to deposit the duplicates of the genetic material that has been acceded.

f) Evaluate the potential of the genetic resources in other uses other than the requested use and warn the Competent National Authority regarding this.

Article 13.- The members of the BTA, in their position as advisors of the Competent National Authority, are responsible for the truthfulness and faithfulness of the information included in the reports, decisions and any other document they elaborate and subscribe in compliance with their functions and in accordance with the

established in the national legislation.

Article 14.- When some of the members of the BTA participate directly in the requested accessing, they must be excused from participating in the evaluation of the petition, in which case the institution which they represent shall designate another representative with temporary character and only for the evaluation of the Petition that had made room for to the excuse of the member of the BTA.

TITLE III
ACCESS REGIME TO GENETIC RESOURCES

CHAPTER I
CONDITIONS AND LIMITATIONS FOR THE ACCESS TO GENETIC RESOURCES

Article 15.- The Contracts for Access to Genetic Resources shall also include, other than the conditions pointed out in Article 17 of Decision 391, the following:

1. Participation of a National Support Institution in any investigation and/or experimentation the petitioner carries out with the acceded genetic material:

2. Fair and equal participation of the Bolivian Government in any economic, technological benefit or others of any nature given by the access to the genetic resources. Likewise, when the peasant or indigenous communities are involved as suppliers of the intangible component associated to the genetic resource which is to be acceded, the participation of those sectors in the benefits derived from the access to the genetic resource shall be agreed through their representative organizations.

3. Submit reports in front of the National Support Institution, with a copy to the Competent National Authority regarding the experimentation work or other studies made starting from the acceded genetic material. A copy of said report shall be sent to the peasant community or indigenous peoples, *ex situ* Center of Conservation, and/or involved Direction of the Protected Area, as it corresponds.

Article 16.- The limitations established in Article 45 of Decision 391 govern for the access to the genetic resources, and others that could be established by the competent instances of the Ministry of Sustainable Development and the Environment in merit of the studies on the situation of the species.

CHAPTER II
PROCEDURE FOR ACCESS TO GENETIC RESOURCES

Article 17.- The petitions of access to genetic resources referred to in Article 2 of this Regulation impetrated by natural or juridical foreign persons, shall be submitted in front of the Competent National Authority.

The natural or juridical national persons, which pretend to accede to any genetic resource referred to in Article 2 of this Regulation, shall submit their Petitions of Access in front of the Departmental or National Authority as convenient to them, when the access activities are carried out within the jurisdiction of only one Department. When the Petition comprises the realization of access activities in the jurisdiction of more than one Department,

this shall be submitted in front of the Competent National Authority.

Article 18.- The following documents must be submitted enclosed in the Petition:

1. Form for the Petition of access to genetic resources annexed to this Regulation.

2. Documents that proof the legal status and legal capacity of the petitioner in accordance with the national legislation in force.

All the information provided by the petitioner for purposes of the Access Petition, shall have the character of a Sworn Declaration.

Article 19.- The petitioner shall be able to request from the Competent National Authority the recognition of a confidential treatment to a determined information that has been provided, to this effect a justification of its petition shall be submitted accompanied by a non-confidential summary that shall form part of the public file in accordance with the established in Articles 19 and 20 of Decision 391.

The Competent National Authority and the members of the BTA are responsible for maintaining the confidentiality over the aspects that are the purpose of said treatment, which will remain in a reserved file that shall not be made public except by express order on the contrary.

Article 20.- The petitions submitted in front of the Departmental Authority shall be submitted within the day for the knowledge of the Competent National Authority for the corresponding admission and registration.

Article 21.- The completed Petition shall be admitted and registered in the Public Register of Petitions by the Competent National Authority, who shall dispose the opening of the corresponding technical file. If the Petition was incomplete, it shall be immediately returned to the petitioner in order for him to rectify the omissions or observations.

Article 22.- Once the petition has been admitted, and within the following five days of its registration in the Public Register, the Competent National Authority shall publish an excerpt of the same and a summary of the Profile for the Access Project in a written medium of communication of national circulation and in another oral medium of communication of the location where the access is to be carried out, with the purpose that any person that could supply additional information or knows of the existence of any impediment to perfect the requested access, would submit the same for the knowledge of the Competent National Authority.

Article 23.- Once the publication has been carried out, the Competent National Authority shall summon the BTA and shall dispose the remittance of the technical file for the knowledge of the same for the corresponding evaluation.

Article 24.- Within the following thirty working days to the registration of the Petition in the Public Register, the BTA shall carry out the technical evaluation of the Petition and the Profile of the Project. The term for the

evaluation could be postponed to 60 days by express request and justification from the BTA.

Article 25.- Once the evaluation period has been fulfilled, the BTA shall submit a Technical Decision in front of the Competent National Authority, in which it will recommend if the Petition and the Profile of the Project are in accordance to law or not. Said decision must contain:

1. An explanatory and reasoned statement of the aspects that were object of the evaluation.

2. Indication of the methodologies used in the evaluation, as well as of the exams, tests or highly specialized advice that were required.

3. Reasoned statement of the motives by which the petition has been declared according to law or not.

4. The observations and recommendations that it considers fit for the negotiation and elaboration of the Access Contract.

Article 26.- The Competent National Authority, in merit of the Technical Decision, shall accept or reject the legal conformity of the petition and shall dispose the notice to the petitioner within the following five days to proceed to the negotiation and elaboration of the Contract of Access to Genetic Resources.

If the Petition is rejected by the Competent National Authority, it shall communicate this decision to the petitioner by means of a Secretarial Resolution, the same that could be refuted in the way prescribed in the national legislation.

Article 27.- Once the Access Contract has been subscribed among the petitioner and the Under-Secretary's Office of Natural Resources, the National Secretary of Natural Resources and the Environment shall issue a Secretarial Resolution to confirm the Access Contract.

Article 28.- The Resolution referred to in the preceding Article shall be published along with an excerpt from the Contract in a written medium of communication of national circulation and considering from this moment that the Access Contract has been perfected.

Article 29.- The petitioner shall be responsible for the expenses of publication and evaluation necessary for the access to the genetic resources, for said purpose, the Competent National Authority shall dispose the opening of a special Fiscal Account in which the petitioner makes said deposit of the amount corresponding to the expenses indicated.

CHAPTER III
ACCESS TO GENETIC RESOURCES IN PROTECTED AREAS

Article 30.- The access to genetic resources in Protected Areas shall be carried out only prior to the signing of an Accessory Contract with the involved Direction of the Protected Area in accordance with its handling plan, the categorization and zoning of the same and the in force legal norms regarding Protected Areas.

Article 31.- The Director of the Protected Area is responsible of the follow-up and control of the access activities being carried out in it, having to report in immediate manner of any infraction or irregularity to the Competent National Authority, without prejudice of disposing the execution of the preventive measures he considers necessary.

Article 32.- When the involved Protected Area constitutes a Community Land of Origin and as long as the genetic resource which is to be acceded is in the geographical space occupied by some indigenous population of the region, the petitioner, without prejudice to the set forth in Article 30 of this Regulation, shall subscribe an Accessory Contract with the organization that represents the community or communities involved, in accordance with the established in Title IV of this Regulation.

CHAPTER IV
ACCESS TO THE GENETIC RESOURCES IN *EX SITU* CONSERVATION CENTERS

Article 33.- For the purposes of this Chapter it is understood as *ex situ* Conservation Center, the natural or juridical person recognized by the Competent National Authority that conserves and collects the genetic resources or its by-products outside of its *ex situ* conditions.

Article 31.- The Access Contracts subscribed with the *ex situ* Conservation Centers do not authorize the execution of missions for the collection of genetic resources for other entities located outside the country.

Article 35.- For the access to genetic resources that are in *ex situ* Conservation Centers by researchers and others, an Accessory Contract must be subscribed with the Director of said Center with the purpose of agreeing on the benefits the same will receive for the utilization of the genetic resource.

CHAPTER V
SUBSCRIPTION AND PERFECTING OF THE ACCESS CONTRACT

Article 36.- The Competent National Authority through the Under-Secretary's Office of Natural Resources, shall proceed to negotiate with the petitioner, the terms of the Access Contract regarding the benefits the access will provide, the form and opportunity of their distribution, the conditions for the determination of the holding of ownership of the intellectual property rights and the conditions for the commercialization of the results.

Article 37.- Once the negotiation has been carried out, an Access Contract shall be drafted in accordance with the established in Decision 391 and the national legislation, containing the same clauses referred to:

a) Identification of the Contracting Parties.

b) Justification of the Contract.

c) Determination of the object of the contract whose detail shall appear in the final access project that will form

integral part of the Access Contract.

d) Stipulation of the rights and obligations of the parties, subjected to the conditions and limitations established in Decision 391 and this Regulation, taking into consideration what was agreed in the negotiation stage.

e) Indication of the benefits that the petitioner is in condition to offer to the Bolivian Government and the form and opportunity of their distribution.

f) Indication of the guarantees of fulfillment that the petitioner had offered.

g) Stipulations of the term, effect operation and prorogation of the Contract.

h) Clauses of modification, suspension, rescission and abrogation of the Contract.

Article 38.- Once the Access Contract has been elaborated, the Under-Secretary of Natural Resources, in representation of the Executive, shall subscribe the same and submit it to the National Secretary of Natural Resources and the Environment for its approval by means of the corresponding Secretarial Resolution.

Article 39.- The Under-Secretary of Natural Resources shall be able to subscribe Framework Access Contracts with the petitioner, that protect the execution of various projects established in this Regulation.

CHAPTER VI
PARTICIPATION OF THE GOVERNMENT IN THE BENEFITS GIVEN BY THE ACCESS TO GENETIC RESOURCES

Article 40.- The Bolivian Government shall participate in fair and equal manner from the benefits given by the access to genetic resources referred to by Article 2 of this Regulation. Said benefits shall be destined to propitiate the conservation, sustainable use and development of the genetic resources in the national territory.

Article 41.- For purposes of the preceding Article, the benefits derived from the access to genetic resources shall be able to consist in:

a) The transfer of technologies and knowledge used in the investigation and/or experimentation, from the part of the person that accedes to the resource.

b) Development of the technical and scientific capabilities of national institutions.

c) The payment of royalties for the commercial use of the genetic resources, their by-products or the intangible component associated to these.

d) The franchises granted to the country by the marketers or processors of the acceded genetic resources.

e) Others that could be agreed among the parties subjected to Decision 391, this Regulation and other related provisions.

Article 42.- For the purposes of clause a) of the preceding Article, the following considerations shall be taken into account:

a) The transfer of technologies, methods, equipment, materials and others used in the research and/or experimentation work, shall be made to the National Support Institution as well as to other technical/scientific institutions with the object of strengthening the capacity of the same and preferably in the national territory.

b) The petitioner must guarantee the participation of personnel from the National Support Institution in works of research and/or experimentation under mutually agreed terms. When indigenous peoples or peasant communities participate as suppliers of the intangible component associated to the acceded genetic resource, the participation of a representation of the same shall be foreseen in this phase.

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

a) If the acceded resource is extracted from Community Lands of Origin, or when the community or indigenous people participates as a supplier of the intangible component associated to the acceded genetic resource, the payment shall be made to the communities through their representative organizations in accordance with the established in the Accessory Contract or Annex as it corresponds, in such a manner that the group rights of the community are recognized over the natural resources existent in their Community Lands of Origin and over the intangible component associated to these.

b) If the acceded genetic material is collected in a Protected Area, the payment shall be made to the Direction of the Protected Area and/or to the National System of Protected Areas in accordance with the legal norms of currently Protected Areas.

c) Without prejudice to the established in the preceding clauses, the Bolivian Government shall use the collected resources in the implementation of programs and conservation projects, the development and sustainable use of the genetic resources within the framework of the National System of Conservation and Development of the Genetic Resources of Bolivia (GRS).

TITLE IV
THE ANNEX AND THE ACCESSORY CONTRACTS

CHAPTER I
ANNEX

Article 44.- The Annex is the document subscribed among the petitioner and the supplier of the intangible component associated to the genetic resource, with the purpose of foreseeing the fair and equal distribution of the benefits arisen from the utilization of said component. The same shall form integral part of the Access Contract and constitutes a necessary requirement for its subscription.

Article 45.- The general norms established for the Access Contract are governed by the subscription of the Annex, as long as they are applicable.

Article 46.- The Annex shall establish a clause of precedent condition that subordinates its validity to the perfecting of the Access Contract.

Article 47.- The supplier of the intangible component shall participate in the distribution of the benefits derived from the access to the genetic resource in the manner foreseen in this Regulation, without prejudice to other agreements entered into by the supplier of the component with the petitioner and that do not contravene Decision 391 and this Regulation.

Article 48.- The Ministry of Sustainable Development and the Environment, through the National Secretary's Office of Natural Resources and the Environment, shall watch for the legality of the obligations and rights arising from the Annex, in consideration of the strategic value of the practices, knowledge and innovations of the indigenous peoples and peasant communities. Non fulfillment of this Annex is a reason for the abrogation and nullification of the Access Contract.

CHAPTER II
ACCESSORY CONTRACTS

Article 49.- Accessory Contracts are those that are entered into for the development of activities related with the access among the petitioner and third parties different from the Government and that do not participate as suppliers of the intangible component associated to the genetic resource. Said Accessory Contracts determine the obligations and rights of the Contracting Parties. The subscription, execution and fulfillment of the same are governed by the established in current national legislation and by the agreement among the parties.

Article 50.- The petitioner shall subscribe Accessory Contracts as it corresponds with:

a) The National Support Institution

b) The owner, holder or administrator of the piece of land where said biological resource is and that contains the genetic resource.

c) The *ex situ* Conservation Center that conserves and/or collects the genetic resource.

d) The owner, holder or administrator of the biological resource that contains the genetic resource.

e) The Direction of the Protected Area where the access activities are being carried out.

Article 51.- For the purposes of clause a) of the preceding Article, The National Support Institution is the National juridical person dedicated to biological research of scientific or technical nature that accompanies the petitioner and participates along with him in the access activities under mutually agreed terms. Without prejudice to the agreed in the Accessory Contract and independently from it, the National Support Institution is obligated to collaborate with the Competent National Authority in the follow-up and control of the activities of access to genetic resources, submitting periodical reports for this reason.

Article 52.- For the subscription of the Accessory Contract, the petitioner must supply a copy of the Project to the other contracting party, with the purpose of him having full knowledge regarding the same.

Article 53.- The Accessory Contracts shall be able to be subscribed up to and before the subscription of the Access Contract and shall subject its validity to the fulfillment of the precedent condition referred to in Article 47 of this Regulation.

Article 54.- The obligations and rights arising from the subscription of the Accessory Contracts shall be effective only among the Contracting Parties, having legal enforcement among them. The modification, suspension, rescission, abrogation or nullity of the Accessory Contract may have the same effects over the Access Contract when it would affect in a substantial manner the conditions established in the latter.

TITLE V
NATIONAL SYSTEM OF GENETIC RESOURCES OF BOLIVIA

Article 55.- The National System of Genetic Resources of Bolivia (GRS) has been created as a instrument to help with the conservation, development and sustainable use of the genetic resources of which Bolivia is a country of origin, through the implementation and execution of programs and projects within the framework of the current legal norms.

Article 56.- The National Secretary's Office of Natural Resources of the Environment, as governing body of the National System of Genetic Resources of Bolivia shall promote and support the establishment and operation of the same.

TITLE VI
INFRACTIONS AND SANCTIONS

Article 57.- Administrative infractions are all the conducts carried out by the petitioner, public officers or third parties, that contravene the provisions established in Decision 391 and this Regulation.

Article 58.- The infractions to this Regulation, according to their seriousness or degree of recidivism, shall cause sanctions without prejudice of the penal sanctions that might correspond when said conducts configure a violation of the law, in which case the files must be remitted to the knowledge of the authority called upon by law.

Article 59.- For purposes of evaluation of a sanction, the National Secretary of Natural Resources and the Environment, shall consider the following aspects jointly or separately:

a) The seriousness of the infraction.

b) If the infraction causes damage to public health.

c) The value of the genetic and biological diversity being affected.

d) The economic and financial cost of the project, or activity that causes the damage.

e) The economic and social benefit obtained as a result of the infracting activity.

f) The recidivism.

g) The nature of the infraction.

Article 60.- The sanctions shall be imposed by the National Secretary of Natural Resources and the Environment according to their classification and shall comprise the following measures:

a) Written warning when the infraction is not serious and is committed for the first time, granting the warned person with a procedural term in order to amend the same.

b) Progressive fines in case the infraction persists, a fine equivalent to 60 days of fine shall be imposed. In case the infraction persists or new infractions are being committed, the National Secretary of Natural Resources and the Environment shall increment the fine consecutively in a one hundred percent over the base of the previous fine, up to the limit of three cumulative fines.

c) Suspension of the access activities and preventive or final confiscations, in the event of flagrant infringements that imply alterations of the ecosystems and/or the biological diversity, the National Secretary of Natural Resources and the Environment shall dispose the immediate suspension of the access activities and the preventive or final confiscation of the assets and/or instruments of the transgressor.

d) Revocatory of authorization and ineligibility to request new accesses, in the event of recidivism or resistance to the fulfillment of the sanctions being imposed, the National Secretary of Natural Resources and the Environment may also dispose the revocatory of the access authorization and the ineligibility to request new accesses.

e) Abrogation of the Access Contract. Without prejudice of the preceding sanctions, the Competent National Authority shall be able to annul the Access Contract due to the following causes:

1. Nonfulfillment of the obligations established in the Access Contract, and in the Annex.

2. The transfer of the acceded genetic resource to third parties without authorization from the Competent National Authority.

3. Impossibility of reaching a satisfactory agreement among the parties of the Contract regarding the benefits subjected to a precedent condition.

Article 61.- For purposes of clause b) of the preceding Article, a day of fine shall be considered as the equivalent of one day of minimum salary.

Article 62.- The earnings arisen from the administrative sanctions by concept of fines shall be deposited in a special account administered by the National Fund for the Environment (FONAMA, abbrev. In Spanish), destined to the reparation of the environmental damages and/or conservation and development programs of the genetic resources.

Article 63.- The procedure and Abrogation of the administrative infractions shall be carried out in accordance with the established in the Environmental Law and its Regulations, resolving the objecting resources by Ministerial Resolution of the Ministry of Sustainable Development and the Environment.

TITLE VII
FINAL PROVISIONS

FIRST.- For purposes of the aforementioned in the First Transitory Provision of Decision 391, those who unlawfully keep with purposes of access the genetic resources of which Bolivia is a country of origin, their by-products or intangible associated components, shall pursue said access in accordance with Decision 391 of the Commission of the Cartagena Agreement and this Regulation, until June of 1998

SECOND.- For purposes of guaranteeing the effective and adequate fulfillment of this Regulation, the National Secretary's Office of Natural Resources and the Environment, shall establish the mechanisms of coordination with the National Secretary's Offices of Industry and Commerce, International Economic Relations, Ethnic Affairs, Gender and Generational, Agriculture and Livestock and other pertinent governmental entities.

THIRD.- The members of the BTA shall elaborate the Internal Regulations of the same, until ninety calendar days have passed of the coming into force of this Regulation, for which effect they must be guaranteed by their respective institutions within the term of thirty calendar days from the approval of this Regulation,

FOURTH.- For purposes of Article 29 of this Regulation, the Competent National Authority shall pursue the opening of the referred Special Fiscal Account, in the maximum term of 30 working days from the approval of it. The handling and management of said Special Fiscal Account shall be in charge of the National Secretary of Natural Resources and the Environment in coordination with the Body of Technical Advice.

FIFTH.- The rights granted to the petitioner shall not be transferred to third parties without express authorization from the Competent National Authority. The person to whom the rights are being transferred, automatically assumes the rights and obligations of the transferred with the Bolivian Government.

SIXTH.- The authorizations that protect the research, procurement, provision, commercialization or any other activity with biological resources, do not condition, presume nor determine the authorization of access to genetic resources contained in said biological resources. The same shall incorporate in their text the label "Not authorized to be used as genetic resources".

SEVENTH.- When the protection of a right of procurer of vegetal varieties or other right of intellectual property is being requested over any product and/or live organism, developed from genetic resources referred to in Article 2 of this Regulation, the corresponding National Authority in the subject, shall demand the presentation of the Secretarial Decision referred to in Article 27 of this Regulation as a requisite for the granting of said rights.

EIGHT.- When attempting to export biological resources of flora or fauna with the purpose of access to genetic resources, the National Secretary's Office of Agriculture and Livestock, through its corresponding branches, shall demand the Secretarial Decision referred to by Article 27 of this Regulation as a requisite for the drawing up of the Certificates of Vegetal and/or Animal Sanitation as it corresponds.

NINTH.- The National Secretary's Office of Natural Resources and the Environment will be able to respond to inquiries with normative character and universal effect, without exceeding the framework of their competencies.

ANNEX 1

PETITION FORM FOR ACCESS TO GENETIC RESOURCES

I. PETITIONER OR LEGAL REPRESENTATIVE

1. IDENTIFICATION

Name and Trade
Name. .....
Nationality .....
Legal Status .....
Identification Document .....
Legal Domicile .....
Telephone..... Fax..... Electronic Mail.....
Postal Office Box .....

II. TECHNICAL PERSON IN CHARGE OF THE PROJECT

1. IDENTIFICATION

Name and Trade
Name. .....
Nationality .....
Legal Status .....
Identification Document .....
Legal Domicile .....
Telephone..... Fax..... Electronic Mail.....

Postal Office Box .....

2. ACCESS ACTIVITIES CARRIED OUT BY THE TECHNICAL PERSON IN CHARGE IN THE LAST 5 YEARS.

YEAR	ACTIVITY	COUNTRY	COUNTERPART

3. CURRICULUM VITAE OF THE TECHNICAL PERSON IN CHARGE

4. WORK GROUP IN CHARGE OF THE ACCESS ACTIVITY

ADDRESS	NAME	SPECIALITY	ACADEMIC DEGREE

III. INFORMATION OF THE SUPPLIER OF THE BIOLOGICAL RESOURCE

1. IDENTIFICATION

Name and Trade Name/Legal Status
.....
Identification Document .....
Address .....
Indigenous People/Peasant
Community .....
Representative and/or corresponding Organization
.....
Department ..... Province .....
Telephone..... Fax..... Electronic Mail.....
Postal Office Box .....

IV. INFORMATION OF THE PERSON OR NATIONAL SUPPORT INSTITUTION

1. IDENTIFICATION

Name and Trade
Name .....
Position .....
Legal Domicile .....

Telephone..... Fax..... Electronic Mail.....
Postal Office Box .....

V. PROPOSAL FOR THE PROFILE OF THE PROJECT

1. **TITLE**
2. **OBJECTIVES**
3. **JUSTIFICATION**
4. **AREAS OF APPLICATION**
5. **TYPE OF ACTIVITY AND USES THAT WILL BE GIVEN TO THE RESOURCE**
6.

6. REFERENCE LIST OF GENETIC RESOURCES, BY-PRODUCTS AND INTANGIBLE ASSOCIATED COMPONENTS, TO WHICH IT IS ATTEMPTED TO ACCEDE (SCIENTIFIC NAME, COMMON NAME, AND QUANTITY OF SAMPLES) :

7. LOCATION OF THE ACCESS AREAS AND OF CARRYING OUT OF THE ACCESS ACTIVITIES (COORDINATES - MAP)

a) Collection areas

In Situ_____ Ex situ_____

Coordinates

Detail :

- In case of an *ex situ* resource, the information of the *ex situ* conservation center shall be included.

- In case of *in situ* resources, the information of the towns of peasant communities involved as suppliers of the intangible component associated to the genetic resource and/or the biological resource, shall be included.

c) Processing site and/or use of the genetic material, location.

8. INDICATIVE CHRONOGRAM

ACTIVITIES	TIME	PLACE	METHODOLOGIES
EXPLORATION			
COLLECTION			
EXTRACTION			
HANDLING			
RESEARCH			

Approximate Duration

Type and size of the sample, design of samples and type of characterization

9. MATERIALS AND METHODS

10. EXPLORATION AND COLLECTION PROCEDURE

11. HANDLING OF THE SAMPLE

12. EXPECTED RESULTS

13. BUDGET OF THE PROJECT

14. BENEFITS AND GUARANTEES THAT MAY BE OFFERED TO THE GOVERNMENT

15. TECHNICAL LITERATURE

16. OTHERS

VI. ANNEXED DOCUMENTS

1. LETTER OF ACCEPTANCE IN PRINCIPLE OF THE SUPPLIER OF THE INTANGIBLE COMPONENT (PEASANT COMMUNITY AND/OR INDIGENOUS PEOPLES) OR ANNEX PROJECT.

2. LETTER OF ACCEPTANCE IN PRINCIPLE OF THE PERSON OR NATIONAL SUPPORT ENTITY, SUPPLIER OF THE BIOLOGICAL RESOURCE, OWNER OF THE PIECE OF LAND, DIRECTOR OF THE INVOLVED PROTECTED AREA, EX SITU CONSERVATION CENTER OR OTHERS, OR PROJECT OF AN ACCESSORY CONTRACT.

3. LETTER OF INSTITUTIONAL ACCREDITATION OF THE PERSON RESPONSIBLE OF THE PROJECT

VII. SWORN DECLARATION.

For purposes as may be required, I swear the truthfulness of the information supplied in this form.

Name .....
Full Name .....
Identification Document .....
Position (Holder or Legal Representative) .....
Date .....

REGULATION ON BIOSAFETY

TITLE I
GENERAL PROVISIONS

CHAPTER I
OBJECT, PURPOSES AND SCOPE

Article 1.- This Supreme Decree has the object of regulating clause g) of Article 80 and numerals 3) and 4) of Article 19 of the Biological Diversity Agreement, ratified by means of Law No. 1580 of July 25, 1994.

Article 2.- The purpose of this Regulation is to minimize the risks and avoid the negative environmental impact that the activities referred in the following Article may cause to human health, the environment, and the biological diversity.

Article 3.- This Regulation shall be applied to activities of introduction, research, manipulation, production, utilization, transportation, storage, conservation, commercialization, use and release of genetically modified organisms (OGM's) obtained through genetic engineering techniques, their by-products and/or the organisms that contain them.

Article 4.- This Regulation does not apply to organisms whose genetic modification is obtained through conventional techniques and traditional methods, as long as they do not imply the manipulation of molecules of recombinant deoxy-ribonucleic acid (DNA) or the utilization of GMO's as receptive or parental organisms.

CHAPTER II
DEFINITIONS

Article 5.- For purposes of this Regulation it shall be understood as:

1. **Deoxy-Ribonucleic Acid (DNA) and Ribonucleic Acid (RNA):** Genetic material that contains determinant information of the heritable characters transmittable to lineage.

2. **Storage:** Accumulate OGM with some purpose.

3. **Accident:** Any accident that implies a significant or involuntary release of OGM's during a specific activity that is carried out with it and that may imply a danger of immediate or retarded effect and risks for the human health, the environment, and the biological diversity.

4. **Biosafety:** All the actions or safety measures required to minimize the risks derived from the handling of a GMO, and the utilization and the technology of recombinant DNA (genetic engineering) and other modern molecular techniques.

5. **Biotechnology:** Every technological application that uses biological systems and live organisms or their by-products for the creation or modification of products or processes for specific uses.

6. **Confinement:** Prevention of the dispersion of organisms outside of the facilities that may be achieved by means of physical confinement (application of suitable work practices, use of appropriate equipment and good design of the facilities) and/or biologic confinement (use of organisms that have a reduced ability to survive or breed in the natural media).

7. **Biological diversity:** The variability of live organisms of any source, including the terrestrial, marine ecosystems and other aquatic ecosystems and the ecological complexes of which they form part, comprises the diversity within each species, among the species and of the ecosystems.

8. **Evaluation of risks:** Estimation of possible damages and probability of occurrence in activities with GMO's.

9. **Management of risks:** Implementation of appropriate measures to minimize the identified risks and the ones that may arise during the process of carrying out of a determined activity with the GMO.

10. **Genetic engineering:** Process by which the gene of an organism is transferred to another through the manipulation of the genetic information (genes).

11. **Insert:** Nucleic Acid (DNA or RNA).

12. **Introduction of a GMO:** The introduction of a GMO in the country by natural or juridical persons, public or private, with purposes of handling.

13. **Intentional or deliberate Release:** Deliberate release into the environment of a GMO or a combination of GMO's without taking measures of containment or isolation, such as the physical and/or chemical and/or biological barriers used to limit their contact with the population in general, the biological diversity and the environment.

14. **Handling of a GMO:** Action that implies activities of research, manipulation, production, utilization, transportation, storage, conservation, commercialization, use and release of a GMO.

15. **Organism:** Any biological entity capable of breeding or of transferring genetic material, including the microbiological entities within this concept, whether they be cellular or not.

16. **Genetically modified organism (GMO):** Any organism whose genetic material has been modified by any

technique of genetic engineering.

17. Host organism: Organism in which the genetic material is being altered by means of the modification of part of its own material and/or the insertion of foreign genetic material.

18. Parental organisms: Organisms from which an organism with new traits is being derived.

19 Confined utilization: Any operation that implies activities with organisms controlled by physical barriers or a combination of physical and/or biological barriers that limit their contact with the potentially receptive surroundings (that includes human beings) or their effects in it.

20. User: Any natural person or public or private institution in charge of the development, production, commissioning, commercialization and distribution of genetically modified organisms.

21. Vector: Organism or object used to transfer genetic material of a donor organism to a receptive organism.

TITLE II
INSTITUTIONAL FRAMEWORK

CHAPTER I
COMPETENT NATIONAL AUTHORITY

Article 6.- The Ministry of Sustainable Development and the Environment, through the National Secretary's Office of Natural Resources and the Environment, in accordance with the established in Law No 1493 of the Ministries of the Executive, the Supreme Decree No 23660 Regulative of the Law of Ministries of the Executive, Environmental Law No 1333 and Supreme Decree No 24176 Regulations to the Environmental Law, is the Competent Authority at a national level.

Article 7.- The Minister of Sustainable Development and the Environment, through the National Secretary's Office of Natural Resources and the Environment, has the following functions.

a) Fulfill and enforce the provisions referring to Biosafety established in the Convention on Biological Diversity, this Regulation and other complementary provisions, national or international.

b) Formulate and implement national policies referred to the Biosafety in coordination with the sectorial instances involved.

c) Create and maintain a Public Registry of the public or private natural and juridical persons that carry out activities with GMO's.

d) Create and maintain a registry of the GMO's, their by-products and the products that contain them, whose introduction to the country with purposes of carrying out any of the activities stipulated in Article 3, had been

authorized and/or rejected.

e) Delegate functions of control and surveillance over activities with GMO's to public and/or private technical institutions, maintaining the responsibility and direction of said supervision.

f) Promote the development of the coordination ability of the sectorial institutions involved in order to guarantee full compliance with this Regulation.

g) Verify if the institutions that carry out any of the activities foreseen in Article 2, have the norms of internal biosafety for this effect.

h) Elaborate norms complementary to this Regulation.

i) Summon the National Biosafety Committee and be responsible for its performance.

j) Grant or deny the authorization for the carrying out of activities with GMO's in the national territory.

k) Keep and maintain the technical files of the petitions for the carrying out of activities with GMO's.

l) Spread out information regarding the risks and benefits derived from the handling of GMO's through its instances of promotion, diffusion and pertinent education.

m) Promote the elaboration of a Code of Ethics of the Biotechnology.

n) Control the fulfillment of the measures of management of risk proposed by the petitioner, for the carrying out of the authorized activity.

o) In the event of non-fulfillment of this Regulation, dispose in immediate manner the execution of preventive and corrective measures and pertinent sanctions.

CHAPTER II
OF THE NATIONAL BIOSAFETY COMMITTEE

Article 8.- The National Biosafety Committee is hereby created as an organism in charge of offering consulting and technical support to the Competent National Authority on activities regarding the Biosafety.

Article 9.- The National Biosafety Committee shall be constituted by the following members:

a) Two representatives of the National Secretary's Office of Natural Resources and the Environment

b) A representative of the National Secretary's Office of International Economic Relations.

c) Two representatives of the National Secretary's Office of Agriculture and Livestock.

d) A representative of the National Secretary's Office of Industry and Commerce.

c) A representative of the National Secretary's Office of Health

C) Two representatives of the University System

In accordance with the Petition to be evaluated, the National Biosafety Committee shall invite as a minimum, four specialists of known scientific and technical trajectory with practice in the area of biotechnology, being the same of the areas of human, animal, vegetal health, and the environment. The Committee will also be capable of inviting representatives of scientific research institutions, business institutions of the area of biotechnology, legally incorporated non-governmental organizations that carry out activities related with the environment, health, agriculture, the biological diversity, and others that are similar.

Article 10.- The Competent National Authority shall designate one of the representatives of the National Secretary's Office of Natural Resources and the Environment to exercise the Presidency of the National Biosafety Committee, performing the functions that are determined in the Internal Regulation of the same.

Article 11.- For purposes of this Regulation, the members of the National Biosafety Committee, must be professionals of high qualification with experience in the areas of competency of the institutions they represent, which shall be backed up by the respective curricula.

Article 12.- The members of the National Biosafety Committee shall meet when the Competent National Authority summons them to carry out the technical evaluation of the Petitions.

Article 13.- The National Biosafety Committee has the following functions and attributions:

a) Elaborate, approve and update its Internal Regulations.

b) Advise the Competent National Authority in matters related with the handling of GMO's and Biosafety.

c) Carry out the study and technical evaluation of the Petitions for the carrying out of activities with GMO's and issue the corresponding Technical Report.

d) Propose norms to the Competent National Authority that are complementary to this Regulation.

e) Establish relations with public and private institutions that carry out activities related with genetic engineering and Biosafety at a national and international level, and establish with them mechanisms of exchange of information on subjects related to the evaluation of the risks, management of the risks and the approvals granted for the commercialization of GMO's, their by-products or the products that contain them.

Article 14.- The members of the National Biosafety Committee, in their condition as advisors of the Competent National Authority, are responsible for the truthfulness and faithfulness of the information included in the reports, decisions and any other document they elaborate and subscribe in compliance with their functions and in accordance with the established in the national legislation.

TITLE III
EVALUATION, CATEGORIZATION AND MANAGEMENT OF THE RISKS

CHAPTER I
EVALUATION OF THE RISKS

Article 15.- The evaluation of the risks shall be carried out with the purpose of determining:

1. The possible negative effects for human health, the environment and the biological diversity derived from the activity that is being carried out with the GMO.

2. The feasibility of management of the risks based on the measures of management proposed by the petitioner.

3. The classification of the GMO according to the groups established in this Regulation.

Article 16.- The evaluation of the risks shall be carried out based on a thorough examination of the information provided by the petitioner on the following parameters:

1. The characteristics of the GMO:

a) The receptor/parental or host organism.
b) The donor organism and the vector being used.
c) The insert and the coded trait.
d) The center of origin.

2. The utilization it is destined to, that is the specific application of the confined utilization or the intentional release or the incorporation to the market with the inclusion of the foreseen scale and the procedures of management and treatment of waste, among others.

3. The potential receptor environment

Article 17.- The information required to carry out the evaluation of risks in adequate manner shall include the elements contained in the Petition Form of Annex I of this Regulation, as well as the attached documents supplied by the petitioner and other additional information that could be required.

CHAPTER II
CLASSIFICATION OF THE RISKS

Article 18.- For the determination of the possible risks derived from the handling of the genetically modified

organisms, these shall be classified in one of the following groups according to the criteria established next:

Group 1: A GMO shall be classified in this group and considered of low risk according to the following criteria:

i) There is no probability that the receptor or parental organism provokes disease to human beings, animals or plants;
ii) The nature of the vector and of the insert is such that it does not furnish the GMO with a genotype that will probably cause diseases to human beings, animals or plants, or that will probably have adverse effects on the environment.
iii) It is not likely that the GMO causes disease to human beings, animals or plants, and it is very unlikely that it has adverse effects for the environment.

Group 2: A GMO shall be classified in this group and considered of high risk when it does not meet the requisites established in Group 1, that is that the receptor or parental organism, the nature of the vector and the insert as well as the GMO or one of them, causes diseases for humans, animals and plants and has adverse effects for the environment.

CHAPTER III
MANAGEMENT OF THE RISKS

Article 19.- The management of the risks shall be carried out with the objective of reducing and controlling the negative impact of the GMO on human health, the environment and the biological diversity during the carrying out of a specific activity with the same, that is why the same shall be carried out by the petitioner in systematic manner during the entire process of carrying out of the activity with the GMO.

Article 20.- Prior to the evaluation of risks carried out by the National Biosafety Committee according to the activity being requested and in function of the classification of the GMO and in accordance with the established in this Regulation, the petitioner shall establish the corresponding measures of management of risks, as well as the mechanisms through which the same shall be applied.

TITLE IV
AUTHORIZATION FOR THE CARRYING OUT OF ACTIVITIES WITH GMO's

CHAPTER I
INFORMATION AND ESTABLISHED CONSENT PRIOR TO THE INTRODUCTION OF GMO's

Article 21.- Every natural or juridical public or private person, national or foreign that pretends to introduce GMO's to the national territory for the carrying out of any of the activities foreseen in Article 3 of this Regulation, shall submit their Petition in front of the National Secretary's Office of Natural Resources and the Environment.

Article 22.- The National Secretary of Natural Resources and the Environment shall remit the Petition in the same day to the Direction of Evaluation of Environmental Impact, so that this Direction, in coordination with the National Direction of Conservation of the Biodiversity, and another involved sectorial organism, carry out the

basic evaluation of the information provided by the petitioner, identifying the risks to human health, the environment and the biological diversity, with the object of:

a) Rejecting the introduction of the GMO to the national territory.

b) Admit the carrying out of the evaluation of risks of the petition for the authorization or rejection of the introduction of the GMO to the national territory.

Article 23.- Once the basic evaluation of the information provided by the petitioner has been carried out, the National Secretary of Natural Resources and the Environment, in the term of ten working days, shall communicate the petitioner by means of a Secretarial Decision in the case of clause a) of the preceding Article, and by means of Administrative Resolution in the case of clause b) of the preceding Article.

The Secretarial Decision by means of which the introduction of GMO's to the national territory is rejected, shall be registered in the Public Register by the Competent National Authority for said effect.

CHAPTER II
PROCEDURE

Article 24.- The natural or juridical public or private person, national or foreign, that pretends to carry out any of the activities foreseen in Article 3 of this Regulation, shall submit its Petition in front of the National Secretary of Natural Resources and the Environment in person or by means of a legal representative.

Article 25.- The following documents shall be submitted enclosed to the Petition:

1. Petition Form.

2. Documents that prove the legal capability and legal status of the petitioner.

3. Documents that prove the technical ability of the person responsible for the project.

4. Letter of Institutional Accreditation for the person responsible of the project, in the event of juridical persons.

5. Administrative Resolution that authorizes the carrying out of the evaluation of risks of the petition in the event of introduction of the GMO to the national territory for the carrying out of any of the activities established in Article 2 of this Regulation.

6. Copy of the Project for the carrying out of the requested activity.

All the information provided by the petitioner for purposes of the Petition shall have the character of a Sworn Declaration.

Article 26.- The National Secretary of Natural Resources and the Environment, through the Vice-Secretary's Office of the Environment, shall review the Petition and all the enclosed documents. The completed Petition shall be admitted in the term of five working days and shall dispose the opening of the corresponding technical

file. If the Petition was incomplete, it shall be returned to the petitioner to correct what is missing or observed.

Article 27.- In the term of the five working days following to the admission of the Petition, the National Secretary of Natural Resources and the Environment shall convoke the National Biosafety Committee and remit the technical file to the knowledge of the same for its consideration and corresponding technical evaluation.

Simultaneously, the National Secretary of Natural Resources and the Environment, shall publish a synthesis of the Petition in two written media of communication of national circulation, being one of them of technical specialized character with the purpose that the persons or institutions that could provide information with respect to the GMO with which it is pretended to carry out any of the activities foreseen in Article 3, may make the same known to the National Biosafety Committee.

Article 28.- The National Biosafety Committee shall carry out the study of the petition and the attached documents as well as the evaluation of risks in the form foreseen in Title II of this Regulation in the term of 90 calendar days, being able to be postponed for only one time at the request of the National Biosafety Committee depending of the GMO being dealt with, the requested activity or the type of evaluation being required.

Article 29.- Once the evaluation of the Petition has been carried out, the National Biosafety Committee shall submit a technical report to the National Secretary of Natural Resources and the Environment. Said report shall contain an established declaration of the following aspects:

1. The possible risks the release of the GMO may have for human health, the environment and the biological diversity.

2. The classification of the risks, indicating if the GMO belongs to Group I or Group 2.

3. The conditions in which the GMO shall be released, that is if they are adequate or not.

4. The feasibility of the measures of management of the risk proposed by the petitioner.

5. The possible economic benefits the activities with the GMO may render.

6. Finally, and based on the previously mentioned aspects, the National Biosafety Committee shall recommend the Competent National Authority to authorize or deny the carrying out of the requested activity and shall propose additional conditions under which said activity shall be carried out.

Article 30.- Within the term of 20 working days starting from the remittance of the Technical Report to be known by the National Secretary of Natural Resources and the Environment, the Secretary, by means of a Secretarial Decision shall authorize or deny the Petition and shall dispose its publication in a written means of communication of national diffusion.

Article 31.- If the Petition is denied, the petitioner may impugn the Resolution issued by the National Secretary of Natural Resources and the Environment in the form foreseen in the national legislation.

Article 32.- The Secretarial Decision that authorizes or rejects the petition shall be registered in the Public

Register and carried out by the Competent National Authority for said purpose.

Article 33.- The Competent Authority, for purposes of granting the authorizations for the activities regulated in this Supreme Decree, shall demand from the petitioner, the payment of the amount corresponding to the expenses of publication, evaluation, study and analysis necessary to concede said authorization.

CHAPTER III
CONFIDENTIAL TREATMENT

Article 34.- The petitioner may request from the Competent National Authority the recognition of a confidential treatment for determined information that it had provided with the purpose of requesting the authorization for the carrying out of activities with the GMO, which could be the subject of disloyal commercial use by individuals foreign to the procedure established in this Regulation. Said petition must be accompanied by the corresponding justification and a non-confidential summary that shall form part of the public file.

Article 35.- The information related to the identification of the holder and person responsible for the project, the aim and location in which the activity will be carried out, the systems and the emergency and control measures, and the evaluation of risks for human health and the environment, shall not have confidential character.

Article 36.- The National Secretary of Natural Resources and the Environment shall be able to recognize the requested confidential treatment and shall abstain from supplying information to third parties, except when its public knowledge is necessary to protect the environment, the biological diversity and human health.

The aspects that are object of confidential treatment shall remain in a reserved file under the custody of the Competent National Authority and shall not be capable of being divulged except by court order on the contrary.

TITLE V
INFRACTIONS AND SANCTIONS

Article 37.- For purposes of this Regulation, the following shall be considered as infractions:

1. Modification of the conditions established in the Secretarial Decision that authorizes the carrying out of the requested activity without the consent of the Competent National Authority.

2. Unfulfillment of the conditions established in the Secretarial Decision for the carrying out of the requested activity.

3. Carrying out of activities with a GMO without due authorization.

4. Unfulfillment of the measures of supervision, control and management of risk proposed by the petitioner for the carrying out of the authorized activity.

5. No handing over of information to the Competent National Authority regarding accidents provoked by the carrying out of the authorized activity and that had caused damages to the health, the environment or the biological diversity.

6. Any other action or omission carried out by the petitioner, public officers or third parties, that contravene the provisions established in this Regulation.

Article 38.- For purposes of determining the sanction for any action or omission carried out by the petitioner, public officers or third parties, that contravene the provisions established in this Regulation, the National Secretary of Natural Resources and the Environment shall consider the following aspects jointly or separately:

1. The gravity of the infraction.

2. If the infraction causes damage to human health, the environment and the biological diversity.

3. The nature of the infraction.

Article 39.- The infractions to this Regulation shall cause the following sanctions:

1. Suspension of the activities with a GMO, depending on the gravity of the infraction, the Competent National Authority shall dispose the temporary or final suspension of the activities with a GMO and shall grant the transgressor a determined term so he may amend the same.

2. Fines, independently from the prior sanction, the Competent National Authority shall impose a fine equivalent to 60 days fine.

3. Revocatory of Authorization. Being evident the premeditation of the infraction and in the event that the same causes serious and irreversible damage to the human health, the biodiversity or the environment, the Competent National Authority shall dispose the revocatory of the authorization for the carrying out of the authorized activity and the ineligibility of the transgressor to carry out new petitions.

Article 40.- For purposes of numeral 2 of the preceding Article, it shall be considered as a day of fine, the equivalent to one day of the minimum salary.

Article 41.- The sanctions referred in Article 9, shall be imposed by the National Secretary of Natural Resources and the Environment, except if said conduct configures a transgression, in which case the files must be remitted to the authority called upon by law for the imposition of the corresponding sanctions.

Article 42.- Without prejudice to the established in Article 39 and as long as damages had been caused to the biological diversity, the environment or health of the population, the National Secretary of Natural Resources and the Environment shall dispose the proceeding of an investigative process with the purpose of determining the gravity of the damage caused, the degree of responsibility of the transgressors and the indemnization to the

Bolivian Government by the damage caused, defending the rights of the third injured parties who may claim their rights in pursuance of the current national legislation.

TITLE VI
FINAL PROVISIONS

FIRST.- The genetic manipulation of human germinal and/or somatic cells and human embryos as biological material available for the production of GMO's, shall be the object of specialized regulations, being the elaboration of the same the obligation of competent organisms in the Health Area.

SECOND.- The institutions that are carrying out activities with GMO's in the national territory at the time of the coming into force of this Regulation, shall elaborate their technical norms of internal biosafety, which shall be validated by the Competent National Authority prior to a Technical Report from the National Biosafety Committee in the term of 90 calendar days starting from the approval of this Regulation.

THIRD.- Those who at the date of the coming into force of this Regulation, carry out any of the activities foreseen in Article 3, must adjust their situation in front of the Competent National Authority in accordance with Title IV of this Regulation, in the term of 60 working days.

FOURTH.- The National Biosafety Committee, until 60 working days have passed since the approval of this Regulation, shall elaborate and approve its internal Regulations. For this effect, the governmental institutions shall accredit their representatives in front of the Committee in the term of 15 working days.

FIFTH.- When the activities with transgenic seeds are being carried out, the National Direction of Seeds of the National Secretary's Office of Agriculture and Livestock, shall demand the due authorization mentioned in Tittle IV of this Regulation to proceed with the fulfillment of the established registries, requirements and procedures.

SIXTH.- When pretending to import GMO's of vegetal and/or animal origin, the National Secretary's Office of Agriculture and Livestock, through their corresponding branches, shall demand as a requisite for the drawing up of the Certificate of Vegetal and/or Animal Sanitation, the Secretarial Decision referred to in Article 30 of this Regulation.

SEVENTH.- All the institutions that carry out activities with GMO's in the national territory must register in the Public Register which shall be implemented by the Competent National Authority for said effect in the term of 15 working days.

EIGHT.- For purposes of Clause d) of Article 7 of this Regulation, the Competent National Authority shall implement in the term of 15 working days, a Public Register of the GMO's, their by-products, and the products that contain them, whose introduction to the country with the purpose of carrying out any of the activities stipulated in Article 3, had been authorized and/or rejected.

NINTH.- For purposes of the established by Article 33, the Competent National Authority shall arrange the opening of a Special Fiscal Account in the term of 30 working days of having approved this Regulation.

ANNEX I

PETITION FORM FOR THE CARRYING OUT OF ACTIVITIES WITH GENETICALLY MODIFIED ORGANISMS IN BOLIVIA

I. GENERAL INFORMATION

1.1. Identification

Name of the
petitioner .....
Nationality .....
Identification Document .....
Legal Status .....
Address .....
Telephone ..... Fax ..... Elect. Mail .....

Name of the person responsible for the requested

activity .....
Nationality .....
Identification Document .....
Legal Status .....
Address .....
Telephone ..... Fax ..... Elect. Mail .....

1.2. Type of activity being requested (mark with a cross):

( ) Field test in a large scale
( ) Field test in a small scale
( ) Production
( ) Research
( ) Transportation
( ) Storage
( ) Commercialization
( ) Other

1.3. Type of petition in front of the Competent National Authority :

( ) New
( ) Renewal
( ) Extension or modification of the prior current petition

2. INFORMATION REGARDING THE PROJECT

The project must contain information regarding the following aspects:

1. Tittle
2. Description of the project
3. Justification, Objectives
4. Area of application of the project indicating the location, canton, province, department (coordinates of reference, latitude and longitude)
5. Type of activity(ies) that will be carried out with the GMO
6. Indicative chronogram of activities
7. Materials and Methods
8. Expected results
9. Budget or total investment
10. Technical literature
11. Others

3. IN THE EVENT OF INTRODUCTION OF A GMO IN THE COUNTRY, SPECIFY:

3.1 Name of the GMO that is pretended to be introduced

	SCIENTIFIC NAME	COMMON NAME	COMMERCIAL NAME	OTHER DESIGNATION
Donor organism				
Receptor organism				
Vector or vector agents				

GMO or product				

3.2 Medium of transportation in which the GMO will be introduced (mark with a cross)

( ) Material locally developed
( ) Official mail
( ) By hand or luggage
( ) Other

3.3 Quantity of GMO to be introduced

3.4 Type of GMO to be introduced (animal, vegetal or microorganism)

3.5 Purpose of the Introduction

3.6 Program of proposed introductions (chronogram)

Date of Introduction of the GMO in the country
Date of transfers within the country

3.7 Country, site and institution of origin of the GMO

3.8 Port of arrival, destination within the country and/or location in which the requested activity shall be carried out

3.9 Description of any biological material (for example, medium of cultivation) or host material that accompanies al GMO.

4. PERSON OR WORK GROUP IN CHARGE OF THE REQUESTED ACTIVITY

Name	Academic Degree	Specialty	Address

Note: In addition to the information requested in this point, the respective curricula vitae that proves the technical ability of each one of the persons shall be attached to this Form.

5. INFORMATION REQUIRED TO CARRY OUT THE EVALUATION OF RISKS

8.1 INFORMATION RELATED TO THE ORGANISM WITH NEW TRAITS

A) Characteristics of the organism from which the GMO is derived from (receptor/parental/host organism):

1. Name and identification of the organism
2. Pathogenicity
3. Toxicity
4. Allergenicity
5. Natural habitat and geographic origin of the organism
6. Distribution and function in the environment

7. Mechanisms the organism uses to survive in the environment
8. Mechanisms the organism uses to breed and disseminate in the environment
9. Mediums of transfer of genetic material to other organisms

B) Characteristics of the organism or of the organisms from which the nucleic acids are obtained (the donor) :

1. Pathogenicity
2. Toxicity
2. Allergenicity

C) Characteristics of the Vector :

1. Identification
2. Origin and natural habitat
3. Characteristics of pertinent safety
4. Frequency of mobilization or the ability to transfer to other organisms
5. Factors that could influence in the ability of the vector to establish itself in other hosts

D) Characteristics of the inserted nucleic acid (the insert) :

1. Functions coded by the inserted nucleic acid, with the inclusion of any residual vector.
2. Expression of the inserted nucleic acid
3. Activity of the product or products of the gene

E) Characteristics of the organism with new traits :

1. Pathogenicity, toxicity and allergenicity for human beings and other organisms
2. Survival capability in the environment
3. Persistence capability in the environment
4. Competitivity and diffusion capability in the environment
5. Other pertinent interactions
6. Capability to transfer genetic material and routes of potential diffusion
7. Methods to detect the organism in the environment
8. Methods to detect the transfer of the donated nucleic acid
9. Functions that could affect your area of ecological extension
10. Characterization of the product or the products of the inserted gene or genes
11. Characterization of the stability of the modification

5.2 INFORMATION RELATED TO THE FORESEEN UTILIZATION

A) In the event of confined utilization of the GMO specify:

1. Quantity or volume of the GMO or GMO's that will be used
2. Scale of the operation
3. Measures of proposed confinement, including the verification of its operation
4. Training and supervision of he personnel that will carry out the work
5. Plans for the control of the waste

6. Plans for the protection of the health of the personnel that will carry out the work
7. Plans for the control and follow-up of accidents and unforeseen events
8. Pertinent information coming from prior uses

B) In the event of deliberate releases of the GMO, specify:

1. Purpose and scale of the release
2. Description and geographical location of the release
3. Proximity to residential zones and human activities
4. Method and frequency of the release
5. Training and supervision of he personnel that will carry out the work
6. Possibility of transborder movements
7. Moment and duration of the release
8. Environmental conditions foreseen during the release

9. Proposed measures of management of risk, including the verification of its operation
10. Subsequent treatment of the site and plans relative to the control of waste
11. Plans for the control of accidents and unforeseen events/disasters
12. Pertinent information coming from any previous releases

5.3 INFORMATION RELATIVE TO THE CHARACTERISTICS OF THE POTENTIAL RECEPTOR ENVIRONMENT

1. Geographical position of the site
2. Identity and any special characteristic of the receptor environment that exposes it to damages
3. Proximity of the site to human beings and important biota
4. Flora, fauna or ecosystems that could be affected by the release, with the inclusion of fundamental species, in danger of extinction or endemic, potentially competitive species and non-destinatory organisms.
5. Potential of any organism that is found in the potential receptor environment to receive genes from the released organism.

6. <u>IN THE EVENT THAT REQUESTED ACTIVITY IS THE COMMERCIALIZATION OF A GMO OR THE PRODUCT THAT CONTAINS IT, THE FOLLOWING INFORMATION WILL BE SPECIFIED</u>

6.1 Name of the product and names of the GMO's it contains
6.2 Name of the manufacturer or distributor
6.3 Specificity of the product
6.4 Precise conditions of use, including the type of environment and/or geographical zones where it will be commercialized.
6.5 Type of foreseen use
( ) Industry
( ) Agriculture
( ) Consumption by the population in general
( ) Other specialized activities
6.6 Measure to be adopted in the event of a unintentional release or of improper use

6.7 Specific instructions or recommendations of storage and manipulation
6.8 Proposed Container
6.9 Proposed Labeling
6.10 In the event of existing Rights of Intellectual Property upon the GMO specify:
a) Name of the patent
b) No. of registration
c) Holder
d) Date of concession
e) Date of petition

7. CONFIDENTIAL INFORMATION

In the event of existing confidential information, make a detail list of the same and attach to this form.

8. SWORN DECLARATION

For purpose as may be required I swear the truthfulness of the information provided in this form

Signature .....
Full Name ....
Identification Document .....
Position (Title or Legal Representative) .....
Date .....

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Printed in the printing shop of the Official
Bolivian Gazette
Calle Ayacucho 453
TELEPHONE 359792 – 369285
P.O. BOX N°4007