Supreme Decree No. 24676

Regulations for Decision 391 of the Commission of the Cartagena Agreement and the Biosafety Agreement

TABLE OF CONTENTS

Regulations on Biosafety

Gonzalo Sanchez de Lozada
Constitutional President of the Republic

Whereas:

Article 136 of the Political Constitution of the State and Article 3 of Environmental Law No. 1333 of April 27, 1992, stipulate that the Bolivian Government has sovereignty over the use and exploitation of its natural resources;

In recognition of the sovereign rights of States over their biological resources, the Convention on Biological Diversity, signed in Rio de Janeiro in 1992 and ratified by means of Law of the Republic No. 1580 dated July 25, 1994, stipulates that it is incumbent upon national governments to regulate access to genetic resources;

Given that genetic resources constitute a strategic value in the national and international context as a primary source of products and processes for industry, Decision 391 of the Commission of the Cartagena Agreement instructs Member Countries to draw up regulations for access to their genetic resources, their by-products and the intangible components associated with them, under conditions of equity and reciprocity between the Government, the suppliers of the genetic resources and associated knowledge, and the persons accessing said resources;

Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of the International Labour Organization, ratified by virtue of Law of the Republic No. 1257 of July 11, 1991, and the Political Constitution of the State, recognize and guarantee the rights of indigenous peoples and local communities to share in the sustainable use and development of the natural resources available on their communal lands, and hence their right to share in the benefits that may arise from the utilization of said resources;

In addition, the Convention on Biological Diversity instructs Contracting Parties to establish or maintain means to regulate, manage or control the risks associated with the use and release of genetically modified organisms which are likely to have adverse impacts on human health and the environment, and on the conservation and sustainable use of biological diversity;

The Commission on the Cartagena Agreement, by means of Decisions 345 and 391, instructs Member Countries to adopt a Common Biosafety Regime, particularly with regard to transboundary movements of genetically modified organisms (GMOs);

In accordance with Environmental Law No. 1333, it falls to the Government, through its competent bodies, to take measures to prevent, control and evaluate activities likely to degrade the environment and natural resources;

Similarly, there is a need to establish a legal framework regulating the introduction of GMOs into the national territory, as well as activities carried out with GMOs;

In the Council of Ministers

It is hereby decreed:

1. By means of this Supreme Decree, the Regulations under Decision 391 of the Commission of the Cartagena Agreement and the Regulations on Biosafety, with their respective Annexes which form an integral part thereof, are adopted.

2. Any legal provisions contrary to this Supreme Decree are hereby repealed.

The Minister of State in the Office of Sustainable Development and the Environment shall remain responsible for executing and enforcing this Supreme Decree.

Done at the Palace of Government in the city of La Paz, on the twenty-first day of the month of June of the year one thousand nine hundred and ninety-seven.

Signed by Gonzalo Sanchez de Lozada, Antonio Aranibar Quiroga, Victor Hugo Canelas Zannier, Alfonso Erwin Kreidler Guillaux, José Guillermo Justiniano Sandoval, Prime Minister and Deputy Minister for Sustainable Development and the Environment, René Blattmann Bauer, Fernando Candia Castillo, Franklin Anaya Vásquez, Jorge España Smith, Deputy Minister of Labor, Mauricio Antezana Villegas, Alfonso Revollo Thenier, Jaime Villalobos Sanjinés.

Regulations for Decision 391
Common Regime for Access to Genetic Resources

Title I
General provisions

Chapter I
Purpose and scope

1. The purpose of this Supreme Decree is to regulate Decision 391 of the Commission of the Cartagena Agreement of July 2, 1996, which governs the Common Regime for Access to Genetic Resources, establishing an obligation for the applicant and the Bolivian Government to sign an access contract, in order to accede to any of the genetic resources referred to in the following Article; said Contract shall determine the obligations and scope of the rights of the Contracting Parties.

2. These Regulations shall apply to the genetic resources for which Bolivia is the country of origin, their by-products, their associated intangible components and the genetic resources of migratory species which, due to natural causes, are found on the national territory.

3. For the purposes of the provisions of Article 4*(b)* of Decision 391, the signature of a prior access contract shall not be required for the following: the exchange of genetic resources, their by-products, the biological resources containing them, or their associated intangible components, by indigenous peoples and local communities for their own consumption and based on customary practices.

Title II
Institutional framework

Chapter I
Competent National Authority

4. The rules for access to the genetic resources of the nation shall be the responsibility of the Ministry for Sustainable Development and Environment, through the Office of the National Secretary for Natural Resources and the Environment, as the Competent National Authority.

5. The Minister for Sustainable Development and the Environment, through the Office of the National Secretary for Natural Resources and the Environment, in accordance with the provisions of Law No. 1493 on the Ministries of the Executive, the Regulations thereunder, the present rules and regulations and other related provisions, shall have the following functions and powers:

(a) to comply with and enforce these Regulations, the legal and contractual conditions for access to genetic resources, their by-products or the intangible components associated with them, and other related legal provisions.

(b) to draft, define and implement national policies on the conservation, sustainable use and development of the genetic resources existing on the national territory.

(c) to guarantee recognition of the rights of indigenous peoples and local communities as suppliers of the intangible component associated with the genetic resources, in coordination with the Office of the National Secretary for Ethnic Affairs, Gender and Generations, and the organizations representing said indigenous peoples and local communities.

(d) to call meetings of the Technical Advisory Body and be responsible for its operation.

(e) to promote the dissemination of information on access to genetic resources.

(f) to build institutional capacity in order to ensure full compliance with Decision 391 and these Regulations.

(g) to submit, through the competent body of the Ministry for External Relations and Religion, the relevant recommendations to the Office of the General Secretary of the Andean Community.

(h) to grant or deny access to genetic resources.

(i) to keep and maintain the technical files and the Public Registry of Applications for Access to Genetic Resources.

(j) to hear and resolve legal appeals to it under the administrative process for access to genetic resources, in the case of denied applications.

(k) to punish those who infringe Decision 391 and these Regulations, whether they be private individuals or public officials.

(1) to object to the suitability of the National Support Institution proposed by the applicant.

(m) to promote the drawing-up of a national inventory of genetic resources for which Bolivia is the country of origin.

Chapter II
Prefectures

6. The prefectures in the rules for access to genetic resources shall have the following functions and powers:

(a) To receive applications for access to genetic resources.

(b) To inspect access activities, without impeding their normal conduct, and to submit the corresponding reports to the Competent National Authority.

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

(d) To monitor full compliance with the terms and conditions of the access contracts, providing for preventive measures in the event of infringement and immediately informing the Competent National Authority.

Chapter III

Technical Advisory Body

7. The Technical Advisory Body (TAB) is hereby created as the entity responsible for providing advice and technical support to the Competent National Authority on matters regarding access to genetic resources.

8. TAB members must have a recognized scientific and technical background, substantiated by their respective CVs.

9. The Technical Advisory Body shall consist of the following:

1. A representative from the Office of the National Secretary for Natural Resources and the Environment;

2. A representative from the Office of the National Secretary for Agriculture and Stockbreeding;

3. A representative from the Office of the National Secretary for Ethnic Affairs, Gender and Generations;

4. A representative from the Office of the National Secretary for Industry and Trade;

5. A representative of the university system.

Depending on the genetic resource for which access is sought and the intended use, the TAB shall invite, to take part in the evaluations, other specialists with a recognized scientific and technical background, as well as representatives of technical institutions, legally incorporated scientific organizations, indigenous peoples and local communities which are involved as suppliers of the intangible component associated with the genetic resources, the directors of the protected area when the resource for which access is sought is found therein, legally incorporated non-governmental organizations which carry out activities related to the genetic resources, and other similar bodies.

10. The representative of the Office of the National Secretary for Natural Resources and the Environment shall act as Chair of the Technical Advisory Body, carrying out the functions set out in the Rules of Procedure of that Body.

11. TAD members shall meet at the request of the Competent National Authority to conduct a study and technical evaluation of the applications submitted to it for consideration.

12. The Technical Advisory Body shall have the following powers and functions:

(a) to draw up its Rules of Procedure;

(b) to conduct a technical evaluation of the applications for access to genetic resources and to submit the corresponding technical ruling to the Competent National Authority.

(c) to submit technical proposals to the Competent National Authority for the establishment of partial or total limitations on the access sought;

(d) to rate the suitability of the National Support Institution proposed by the applicant and suggest a replacement, as need be;

(e) to recommend to the Competent National Authority suitable institutions for the deposit of duplicates of the genetic material accessed.

(f) to evaluate the potential of the genetic resources for uses other than the one requested, and warn the Competent National Authority accordingly.

13. TAB members, in their capacity as advisors to the Competent National Authority, shall be responsible for the truthfulness and suitability of the information included in the reports, rulings and any other documents they prepare and sign in the performance of their duties and in accordance with the provisions of national legislation.

14. If a TAB member is directly involved in the requested access, he must recuse himself from participating in the evaluation of the application, in which case the institution he represents shall appoint another representative on a temporary basis, solely for the evaluation of the application which gave rise to the recusal of the TAD member.

Title III
Rules for access to genetic resources

Chapter I
Conditions for and limitations on access to genetic resources

15. In addition to the conditions set out in Article 17 of Decision 391, contracts for access to genetic resources shall include the following:

1. The participation of a National Support Institution in any research and/or experiment the applicant carries out with the genetic material accessed.

2. The just and equitable sharing of the Bolivian Government in any economic, technological or other benefit of any kind arising from access to the genetic resources. Similarly, when local or indigenous communities are involved as suppliers of the intangible component associated with the genetic resource for which access is sought, these sectors shall be authorized to share in the benefits arising from access to the genetic resource, through their representative organizations.

3. To submit reports to the National Support Institution, with a copy to the Competent National Authority, on the experiments or other studies carried out on the basis of the genetic material accessed. A copy of said reports shall be sent to the local community or indigenous people, the *ex situ* conservation center and/or the directors of the protected area concerned, as appropriate.

16. Access to the genetic resources shall be governed by the limitations set out in Article 45 of Decision 391, as well as any others that may be established by the competent bodies of the Ministry for Sustainable Development and the Environment on the basis of studies on the status of the species.

Chapter II
Procedure for access to genetic resources

17. Applications for access to the genetic resources referred to in Article 2 of these Regulations that have been lodged by foreign natural persons or legal entities, shall be filed with the Competent National Authority.

National natural persons or legal entities wishing to access any genetic resource covered by Article 2 of these Regulations shall submit their applications for access to the departmental or national authorities, as appropriate, when the access activities are carried out within a single department. When the application encompasses the conduct of access activities in the jurisdiction of more than one department, said application shall be filed with the Competent National Authority.

18. The following documents shall be filed in addition to the application:

1. Application form for access to genetic resources, annexed to these Regulations.

2. Documents proving the applicant's legal capacity and legal status, in accordance with existing national legislation.

All of the information provided by the applicant for purposes of the application for access shall be considered a sworn statement.

19. The applicant may request the Competent National Authority to give confidential treatment to specific information provided, and must to this end submit the justification for his request accompanied by a non-confidential summary that will become part of the public file, in accordance with the provisions of Articles 19 and 20 of Decision 391.

The Competent National Authority and the TAD members shall be responsible for maintaining confidentiality on the aspects that are subject to said treatment, which shall remain in a reserved file that may not be made public, barring a court order to the contrary.

20. Applications filed with the departmental authority shall be brought to the attention of the Competent National Authority that same day, for admission and registration.

21. Once the application is completed, it shall be admitted and entered in the Public Register of Applications by the Competent National Authority, which shall order that the corresponding technical file be opened. Should the application be incomplete, it shall immediately be sent back to the applicant for rectification of omissions or observations.

22. Once the application has been admitted, and within five days following its registration in the Public Registry, the Competent National Authority shall publish an excerpt thereof and a summary of the profile for the access project, in a written medium of communication with nationwide circulation and in another oral medium of communication from the locality where the access is to be carried out, so that anyone who could supply additional information or is aware of the existence of any impediment to the fulfillment of the access requested, may bring that to the attention of the Competent National Authority.

23. Once publication has taken place, the Competent National Authority shall call a meeting of the TAB and shall order the technical file to be brought to the attention of the TAB for the corresponding evaluation.

24. Within 30 working days following the registration of the application in the Public Registry, the TAB shall conduct the technical evaluation of the application and the project profile. The deadline for such evaluation may be extended to 60 days at the express, justified request of the TAB.

25. Once the deadline for evaluation has expired, the TAB shall issue a technical ruling to the Competent National Authority, recommending proceeding or not proceeding with the application and access project profile. Said ruling must contain:

1. An explanatory and reasoned statement of the aspects that formed the subject matter of the evaluation.

2. An indication of the methodologies used in the evaluation, as well as the highly specialized examinations, tests and advice required.

3. A reasoned statement of the grounds on which the recommendation to proceed or not to proceed with the application is made.

4. Any observations or recommendations it deems appropriate for the negotiation and drafting of the access contract.

26. On the basis of the technical ruling, the Competent National Authority shall accept or reject the recommendation to proceed with the application and shall notify the applicant accordingly within the following five days, in order to proceed with the negotiation and drafting of the contract on access to the genetic resources.

If the application is rejected, the Competent National Authority shall inform the applicant of such a decision by means of a Secretarial Resolution, which may be appealed as provided for by national legislation.

27. Once the access contract has been signed by the applicant and the Office of the National Undersecretary for Natural Resources, the National Secretary for Natural Resources and the Environment shall issue a secretarial resolution authorizing the access contract.

28. The resolution referred to in the previous Article shall be published together with an excerpt from the contract, in a written medium of communication with nationwide circulation, at which point the access contract shall be deemed to be finalized.

29. The applicant shall bear the costs of publication and evaluation that are necessary for the access to the genetic resources. For this purpose, the Competent National Authority shall order the opening of a Special Fiscal Account on which the applicant may deposit the amount corresponding to the costs indicated.

Chapter III
Access to genetic resources in protected areas

30. Access to genetic resources in protected areas shall require the prior signature of an accessory contract with the directors of the protected area in question, in accordance with their plan for managing, categorizing and zoning that area and the existing legal rules on protected areas.

31. The Director of the Protected Area shall be responsible for monitoring and controlling the access activities carried out within said area; he must immediately inform the Competent National Authority of any infringement or irregularity, without prejudice to ordering the execution of any preventive measures he deems necessary.

32. When the protected area in question is also a community land of origin and when the genetic resource to which access is sought is found in the geographical area occupied by a population indigenous to the region, the applicant, without prejudice to the provisions of Article 30 of these Regulations, shall sign an accessory contract with the organization representing the community or communities in question, in accordance with the provisions of Title IV of these Regulations.

Chapter IV
Access to genetic resources in ex situ c*onservation centers*

33. For the purposes of this Chapter, *ex situ* conservation center shall mean the natural person or legal entity recognized by the Competent National Authority that conserves and collects the genetic resources or their by-products outside their *in situ* conditions.

34. Access contracts signed with *ex situ* conservation centers shall not authorize the carrying-out of tasks for the collection of genetic resources for other entities located outside the country.

35. For researchers and others to access the genetic resources located at *ex situ* conservation centers, they shall sign an access contract with the Director of said center with a view to granting the benefits the center will receive for the use of the genetic resources.

Chapter V
Signing and finalization of access contracts

36. The Competent National Authority, through the Office of the Undersecretary for Natural Resources, shall proceed to negotiate with the applicant the terms of the access contract relating to the benefits arising from the access, the form and opportunity of their distribution, the conditions for the determination of ownership of the intellectual property rights, and the conditions for the commercialization of the results.

37. Once the negotiations have been completed, the access contract shall be drawn up in accordance with the provisions of Decision 391 and the national legislation, and shall contain the same clauses referring to:

(a) identification of the Contracting Parties;

(b) justification of the contract;

(c) determination of the purpose of the contract, the details of which shall appear in the final access project that shall form an integral part of the access contract;

(d) stipulation of the rights and obligations of the Contracting Parties, subject to the conditions and limitations established in Decision 391 and the present Regulations, taking into consideration what was agreed at the negotiating stage;

(e) indication of the benefits that the applicant is in a position to offer the Bolivian Government and the form and timeliness of their distribution;

(f) indication of the contract performance guarantees offered by the applicant;

(g) stipulation of the term, validity and extension of the contract;

(h) clauses for amendment, suspension, cancellation or termination of the contract.

38. Once the Access Contract has been drawn up, the Undersecretary for Natural Resources, representing the Executive, shall sign the contract and submit it to the National Secretary for Natural Resources and the Environment for his approval by means of the corresponding secretarial resolution.

39. The Undersecretary for Natural Resources may enter into framework access contracts with the applicant covering the execution of various access projects, in accordance with Article 36 of Decision 391 and the provisions of these Regulations.

Chapter VI
State share of the benefits arising from access to the genetic resources

40. The Bolivian Government shall share in a just and equitable fashion in the benefits of any kind arising from access to genetic resources referred to in Article 2 of these Regulations. Said benefits shall be intended for promoting the conservation, sustainable use and development of the genetic resources on the national territory.

41. For the purposes of the previous Article, the benefits arising from access to genetic resources may consist of:

(a) Transfer of the technologies and knowledge used in the research and/or experiments by the person accessing the resource;

(b) Development of the technical and scientific capacities of national institutions;

(c) Freezing of royalties for the commercial use of genetic resources, their by-products or the intangible component associated therewith;

(d) The franchises granted to the country by the marketers or processors of the genetic resources accessed;

(e) Any other provisions the parties may agree, subject to Decision 391, these Regulations and other related provisions.

42. For the purposes of clause *(a)* of the previous Article, the following considerations shall be taken into account:

(a) The transfer of technologies, methods, equipment, materials, etc. used in the research work and/or experiments, shall take place both at the National Support Institution and at other technical and scientific institutions with a view to strengthening their capacity, preferably on the national territory;

(b) The applicant must guarantee that the staff of the National Support Institution participate in the research work and/or experiments, on mutually agreed terms. When indigenous peoples or local communities participate as suppliers of the intangible component associated with the genetic resource accessed, provision shall be made for a representative thereof to participate in this phase.

43. With regard to the distribution of the benefits referred to in Article 41(c), the following aspects shall be taken into consideration:

(a) If the resource accessed has been taken from community lands of origin, or if the indigenous community or people participates as a supplier of the intangible component associated with the genetic resource accessed, payment shall be made to the communities through their representative organizations, in accordance with the provisions of the accessory contract or annex, as appropriate, so as to ensure recognition of the collective rights of the community in the natural resources existing on their community lands of origin and in the intangible component associated therewith.

(b) If the genetic material accessed has been collected in a protected area, payment shall be made to the directors of the protected area and/or to the National System of Protected Areas, in accordance with existing legal rules on protected areas.

(c) Without prejudice to the provisions of the previous subparagraphs, the Bolivian Government shall use the resources collected to implement programs and projects for the conservation, development and sustainable use of genetic resources within the framework of

the National System for Conservation and Development of the Genetic Resources of Bolivia (SRG).

Title IV
Annexes and accessory contracts

Chapter I
Annexes

44. The Annex is the document signed by the applicant and the supplier of the intangible component associated with the genetic resource, for the purpose of providing for the fair and equitable distribution of the benefits arising from the use of said component. The Annex shall form an integral part of the access contract and shall be a prerequisite for its signature.

45. The signature of the annex shall be governed by the general rules established for the access contract, as applicable.

46. The annex shall stipulate a condition precedent making its effectiveness contingent upon the finalization of the access contract.

47. The supplier of the intangible component shall share in the distribution of the benefits arising from access to the genetic resource in the form provided for by these Regulations, without prejudice to any other agreements which the supplier of the component may have entered into with the applicant that do not contravene Decision 391 or these Regulations.

48. The Minister for Sustainable Development and Environment, through the Office of the National Secretary for Natural Resources and the Environment, shall ensure the lawfulness of the obligations and rights arising from the Annex, bearing in mind the strategic value of the practices, knowledge and innovations of the indigenous peoples and local communities. Non-compliance with the Annex shall be grounds for termination and invalidation of the Access Contract.

Chapter II
Accessory contracts

49. Accessory contracts are documents signed for the conduct of access-related activities, by the applicant and third parties different from the Government that do not participate as suppliers of the intangible component associated with the genetic resource. Said accessory contracts shall determine the rights and duties of the Contracting Parties. The signature, execution and fulfillment thereof shall be governed by the provisions of existing national legislation and by agreement among the parties.

50. The applicant shall sign accessory contracts, as appropriate, with:

(a) the National Support Institution;

(b) the owner, holder or administrator of the land on which the biological resource containing the genetic resource is found;

(c) the *ex situ* conservation center that conserves and/or collects the genetic resource;

(d) the owner, possessor or management of the biological resource containing the genetic resource;

(e) the directors of the protected area where the access activities are being carried out.

51. For the purposes of clause *(a)* of the previous Article, the National Support Institution shall be the national legal entity devoted to biological research of a scientific or technical nature, which accompanies the applicant and participates along with him in the access activities on mutually agreed terms. Without prejudice to what has been agreed in the accessory contract and independently thereof, the National Support Institution shall be obliged to collaborate with the Competent National Authority in following up and monitoring activities involving access to genetic resources, and shall submit periodic reports to this end.

52. For the signature of the accessory contract, the applicant must provide a copy of the project to the other Contracting Party, in order to ensure that the Party has full knowledge thereof.

53. Accessory contracts may be signed up until the signature of the access contract; their execution shall be subject to the condition precedent referred to in Article 47 of these Regulations.

54. The rights and obligations arising from the signature of the accessory contracts shall only apply between the Contracting Parties and shall be binding upon them. The amendment, suspension, cancellation, termination or invalidation of the Accessory Contract may have the same effect on the Accessory Contract, if it substantially affects the conditions set out in that Contract

Title V
National Genetic Resources System of Bolivia

55. The National Genetic Resources System (SRG) of Bolivia is hereby established as an instrument for promoting 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 within the framework of existing legal rules.

56. The Office of the National Secretary for Natural Resources and the Environment, as the supervisory body for the National Genetic Resources System of Bolivia, shall promote and support the establishment and functioning thereof.

Title VI
Violations and punishment

57. Administrative violations shall be any kind of conduct by the applicant, public officials or third parties that contravenes the provisions established in Decision 391 and these Regulations.

58. Depending on their gravity or the degree of recidivism, violations of these Regulations shall give rise to sanctions, without prejudice to criminal punishment that may apply when said conduct constitutes a criminal offense, in which case they shall be brought to the attention of the authority designated by law.

59. For the purposes of evaluating the punishment, the National Secretary for Natural Resources and the Environment shall consider the following aspects, either separately or jointly:

(a) the gravity of the violation;

(b) whether the violation has caused damage to public health;

(c) the value of the genetic and biological diversity affected;

(d) the economic and social costs of the project or activity causing the damage;

(e) the economic and social benefit obtained as a result of the infringing activity;

(f) recidivism;

(g) the nature of the violation.

60. Punishment shall be meted out by the National Secretary for Natural Resources and the Environment depending on his evaluation, and shall comprise the following measures:

(a) A written warning when the infringement is minor and is committed for the first time, giving the person warned a peremptory deadline to rectify matters.

(b) Progressive fines; should the infringement persist, a fine equivalent to 60 days' fine shall be imposed. In case the infringement persists or new infringements are being committed, the National Secretary for Natural Resources and the Environment shall increase the fine successively by 100 per cent on the basis of the previous fine, up to a maximum of three cumulative fines.

(c) Suspension of the access activities and preventive or final confiscation; in case of flagrant infringements that imply alterations to the ecosystems and/or biological diversity, the National Secretary for Natural Resources and the Environment shall order the immediate suspension of the access activities and the preventive or final confiscation of the assets and/or instruments of the infringer.

(d) Revocation of authorization and disqualification from applying for new access; in cases of recidivism or failure to comply with the punishment imposed, the National Secretary for Natural Resources and the Environment shall further order the revocation of the access authorization and disqualification from applying for new access.

(e) Termination of the access contract. Without prejudice to the previous sanctions, the Competent National Authority may terminate the access contract on the following grounds:

1. Failure to comply with the obligations set out in the access contract and the annex.

2. Transfer of the genetic resources to third parties, without the authorization of the Competent National Authority.

3. Inability of the Contracting Parties to reach a satisfactory agreement in relation to the benefits subject to the condition precedent.

61. For the purposes of clause *(b)* of the previous Article, a day of fine shall be considered the equivalent of one day of minimum salary.

62. Revenue from administrative sanctions administered in the form of fines shall be deposited into a special account managed by the National Fund for the Environment (FONAMA), and shall be destined for repairing environmental damage and/or programs for the conservation and development of genetic resources.

63. The procedure for and termination of administrative violations shall take place in accordance with the provisions of the Environmental Law and its Regulations, and the disputed appeals shall be resolved via ministerial decision of the Ministry for Sustainable Development and the Environment.

Title VII
Final provisions

One. For the purposes of the content of the First Transitional Provision of Decision 391, anyone who holds, for purposes of access, genetic resources of which Bolivia is the country of origin, their by-products or associated intangible components, shall manage such access in accordance with Decision 391 of the Commission of the Cartagena Agreement and these Regulations, up to June 1998.

Two. To ensure full and effective compliance with these Regulations, the Office of the National Secretary for Natural Resources and the Environment shall set up coordination mechanisms with the Offices of the National Secretaries for Industry and Trade, International Economic Relations, Ethnic Affairs, Gender and Generations, Agriculture and Livestock, and other relevant State activities.

Three. The members of the TAB shall draw up the Body's Rules of Procedure, within 90 calendar days following the entry into force of these Regulations, and shall therefore be accredited by their respective institutions within 30 calendar days from the adoption of these Regulations.

Four. For the purposes of Article 29 of these Regulations, the Competent National Authority shall take steps to open the above-mentioned Special Fiscal Account, within 30 working days following the adoption of these Regulations. The management and administration of said Special Fiscal Account shall be the responsibility of the National Secretary for Natural Resources and the Environment, in coordination with the Technical Advisory Body.

Five. The rights granted to the applicant may not be transferred to third parties without the express authorization of the Competent National Authority. The person to whom the rights are transferred shall automatically assume the rights and duties of the transferor with the Bolivian State.

Six. The authorizations covering research, procurement, provision, commercialization or any other activity with biological resources shall not condition, presume or determine the authorization for access to the genetic resources contained in said biological resources. The text of such authorizations shall incorporate the inscription "Not authorized for use as genetic resources".

Seven. When protection is sought for a plant breeder's right or other intellectual property right in any product and/or living organism developed from the genetic resources referred to in Article 2 of these Regulations, the Competent National Authority shall require, as a prerequisite for the granting of said rights, the presentation of the secretarial decision referred to in Article 27 of these Regulations.

Eight. Where the intention is to export plant or animal biological resources for purposes of access to genetic resources, the Office of the National Secretary for Agriculture and Livestock, through its corresponding bodies, shall require the secretarial decision referred to in Article 27 of these Regulations, as a prerequisite for the issuing of the Plant and/or Animal Health Certificates, as the case may be.

Nine. The Office of the National Secretary for Natural Resources and the Environment may commission consultations of a normative nature and with universal effect, without overstepping the bounds of its powers.

ANNEX 1

APPLICATION FORM FOR ACCESS TO GENETIC RESOURCES

I. APPLICANT AND LEGAL REPRESENTATIVE

1. IDENTIFICATION

Name and business name .....
Nationality .....
Legal status .....
Identity card .....
Legal residence .....
Telephone ..... Fax ..... E-mail .....
P.O. Box .....

II. TECHNICAL PROJECT OFFICER

1. IDENTIFICATION

Name and business name .....
Nationality .....
Identity card .....
Legal residence .....
Telephone ..... Fax ..... E-mail .....
P.O. Box .....

2. ACCESS ACTIVITIES CARRIED OUT BY THE PROJECT OFFICER OVER THE PAST FIVE YEARS

YEAR	ACTIVITY	COUNTRY	COUNTERPART

3. CURRICULUM VITAE OF THE TECHNICAL OFFICER

4. WORKING GROUP RESPONSIBLE FOR THE ACCESS ACTIVITY

RESIDENCE	NAME	SPECIALITY	ACADEM. LEVEL

III. INFORMATION ON THE BIOLOGICAL RESOURCE SUPPLIER

1. IDENTIFICATION

Name and business name/Legal status .....

Identity card.....
Address.....
Indigenous people/Local community.....
Representative and/or corresponding organization.....
Department..... Province .....
Telephone..... Fax ..... E-mail.....
P.O. Box.....

IV. INFORMATION ON THE NATIONAL SUPPORT PERSON OR INSTITUTION

1. IDENTIFICATION

Name and business name .....
Position.....
Legal residence.....
Telephone..... Fax ..... E-mail.....
P.O. Box.....

V. PROJECT PROFILE PROPOSAL

1. **TITLE**
2. **GOALS**
3. **JUSTIFICATION**
4. **AREAS OF APPLICATION**
5. **TYPE OF ACTIVITY AND USES FOR THE RESOURCE**
6. **REFERENCE LIST OF GENETIC RESOURCES, BY-PRODUCTS AND ASSOCIATED INTANGIBLE COMPONENTS TO WHICH ACCESS IS SOUGHT (SCIENTIFIC NAME, COMMON NAME AND SAMPLE NUMBER)**
7. **LOCATION OF THE AREAS FOR ACCESS AND CONDUCT OF THE ACCESS ACTIVITIES (COORDINATES — MAP)**

(a) Collection areas

In situ _____ *Ex situ*_____

Coordinates.

Details:

— In the case of *ex situ* resources, information shall be included on the *ex situ* conservation center.

— In the case of *in situ* resources, information shall be included on the indigenous peoples and/or local communities participating as suppliers of the intangible component associated with the genetic resource and/or biological resource.

(b) Site for the processing and/or use of the genetic material, location

8. INDICATIVE SCHEDULE

ACTIVITIES	TIME	PLACE	METHODOLOGY

EXPLORATION			
COLLECTION			
EXTRACTION			
HANDLING			
RESEARCH			

Approximate duration
Sample type and size, sample design and characterization type

9. MATERIALS AND METHODS
10. PROCEDURES FOR EXPLORATION AND COLLECTION
11. HANDLING OF THE SAMPLE
12. EXPECTED RESULTS
13. PROJECT BUDGET
14. BENEFITS AND GUARANTEES AVAILABLE TO THE GOVERNMENT
15. TECHNICAL LITERATURE
16. OTHER

VI. ATTACHED DOCUMENTS

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

2. LETTER FOR THE ACCEPTANCE IN PRINCIPLE OF THE NATIONAL SUPPORT PERSON OR INSTITUTION. SUPPLIER OF THE BIOLOGICAL RESOURCES, ESTATE OWNER, DIRECTOR OF THE PROTECTED AREA CONCERNED, *EX SITU* CONSERVATION CENTER AND OTHERS, OR DRAFT ACCESSORY CONTRACT.

3. LETTER OF INSTITUTIONAL ACCREDITATION FOR THE PROJECT OFFICER

VII. SWORN STATEMENT

For the following purposes, I hereby attest to the truthfulness of the information provided in this form

Signature .....
Full name .....
Identity card .....
Position (titular or legal representative).....
Date.....

Regulations on Biosafety

Title I
General provisions

Chapter I
Purpose, aims and scope

1. The purpose of this Supreme Decree shall be to regulate clause *(g)* of Article 8 and subparagraphs (3) and (4) of Article 19 of the Convention on Biological Diversity, ratified by means of Law No. 1580 of July 25, 1994.

2. These Regulations shall aim to minimize the risks and prevent the negative environmental impacts that the activities referred to in the following Article may have on human health, the environment, and biological diversity.

3. These Regulations shall apply to activities relating to the introduction, research, handling, production, utilization, transport, storage, conservation, commercialization, use and release of genetically modified organisms (GMOs) obtained through genetic engineering, their by-products and the organisms that contain them.

4. These Regulations shall not apply to organisms whose genetic modification is obtained through conventional techniques and traditional methods, as long as they do not involve the manipulation of molecules of recombinant deoxyribonucleic acid (DNA) or the utilization of GMOs as receiving or parent organisms.

Chapter II
Definitions

5. For the purposes of these Regulations, the following definitions shall apply:

1. Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA): Genetic material that contains the genetic instructions for the hereditary traits transmissible to descendants.

2. Storage: Accumulation of GMOs for some purpose.

3. Accident: Any incident that involves a significant or involuntary release of GMOs during a specific activity which is carried out with it and which may entail a danger, either immediate or delayed, and risks to human health, the environment and biological diversity.

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

5. Biotechnology: Any technological application that uses biological systems and living 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 installations, which can be achieved by means of physical confinement (application of suitable work practices, use of appropriate equipment and properly designed facilities) and/or biological confinement (use of organisms with a reduced capacity to survive or reproduce in the environment).

7. Biological diversity: The variability of living organisms from any source, including land ecosystems and marine and other aquatic ecosystems, and the ecological complexes of which they form a part, means the diversity within each species, among species and among ecosystems.

8. Risk evaluation: Estimation of possible damage and likelihood of occurrence, in activities with GMOs.

9. Risk management: Implementation of appropriate measures to minimize the risks identified and those which may arise during the process of carrying out a specific activity with the GMO.

10. Genetic engineering: Process whereby the gene of one 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 into the country by public or private natural persons or legal entities, for the purposes of handling.

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

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

15. Organism: Any biological entity capable of reproducing or 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 altered 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. Parent organisms: Organisms from which an organism with new traits is derived.

19. Confined utilization: Any operation that involves activities with organisms controlled by physical barriers or a combination or physical and/or chemical and/or biological barriers that limit their contract with the potentially receptive surroundings (that include human beings) or their effects on it.

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

21. Vector: Organism or object used to transfer genetic material from a donor organism to a receiving organism.

Title II
Institutional framework

Chapter I
Competent National Authority

6. The Ministry of Sustainable Development and the Environment, through the Office of the National Secretary for Natural Resources and the Environment, in accordance with the provisions of Law No. 1493 of the Ministries of the Executive, Supreme Regulatory Decree No. 23660 of the Law of Ministries of the Executive, Environmental Law No. 1333 and Supreme Regulatory Decree No. 24176 thereon, shall be the Competent Authority at the national level.

7. The Minister of Sustainable Development and the Environment, through the Office of the National Secretary for Natural Resources and the Environment, shall have the following functions:

(a) To fulfill and enforce the provisions referring to biosafety established in the Convention on Biological Diversity, these Regulations and other complementary national or international provisions.

(b) To draft and implement national policies relating to biosafety, in coordination with the sectoral bodies involved.

(c) To set up and maintain a public registry of the public or private natural persons and legal entities carrying out activities with GMOs.

(d) To set up and maintain a registry of GMOs, their by-products and the products that contain them, whose introduction into the country for the purpose of carrying out any of the activities stipulated in Article 3, had been authorized and/or rejected.

(e) To delegate the monitoring and surveillance of activities with GMOs to public and/or private technical institutions, maintaining the responsibility and direction of said monitoring.

(f) To promote the development of the coordination capacity of the sectoral institutions involved in order to ensure full compliance with these Regulations.

(g) To verify whether the institutions carrying out any of the activities provided for in Article 2, have internal biosafety rules for this purpose.

(h) To draw up rules complementary to these Regulations.

(i) To call meetings of the National Biosafety Committee and be responsible for its operation.

(j) To grant or deny authorization for carrying out activities with GMOs on the national territory.

(k) To keep and maintain the technical files of applications for carrying out activities with GMOs.

(l) To disseminate information on the risks and benefits arising from the handling of GMOs through its relevant bodies for promotion, dissemination and education.

(m) To promote the drafting of a Biotechnology Code of Ethics.

(n) To monitor compliance with the risk management measures proposed by the applicant, for the carrying out of the authorized activity.

(o) To take immediately appropriate preventive and corrective measures and sanctions in the event of non-compliance with these Regulations.

Chapter II
National Biosafety Committee

8. The National Biosafety Committee is hereby created as a body in charge of offering advice and technical support to the Competent National Authority on activities relating to biosafety.

9. The National Biosafety Committee shall be composed of the following members:

(a) Two representatives from the Office of the National Secretary for Natural Resources and the Environment.

(b) One representative from the Office of the National Secretary for International Economic Relations.

(c) Two representatives from the Office of the National Secretary for Agriculture and Livestock.

(d) One representative from the Office of the National Secretary for Industry and Trade.

(e) One representative from the Office of the National Secretary for Health.

(f) Two representatives of the university system.

In accordance with the application to be evaluated, the National Biosafety Committee shall invite a minimum of four specialists with a recognized scientific and technical background and experience in the area of biotechnology; the same practice shall be followed for the fields of human, animal and plant health, and the environment. The Committee may also invite representatives of scientific research institutions, business institutions from the area of biotechnology, legally incorporated non-governmental organizations that carry out activities relating to the environment, health, agriculture, biological diversity, and other similar activities.

10. The Competent National Authority shall designate one of the representatives from the Office of the National Secretary for Natural Resources and the Environment to act as the Chair of the National Biosafety Committee, performing the functions that are specified in the Committee's Rules of Procedure.

11. For the purposes of these Regulations, the members of the National Biosafety Committee must be highly qualified professionals with experience in the areas of competency of the institutions they represent, as substantiated by their respective curricula vitae.

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

13. The National Biosafety Committee shall have the following functions and powers:

(a) To draw up, adopt and update its Rules of Procedure.

(b) To advise the Competent National Authority on matters relating to the handling of GMOs and biosafety.

(c) To carry out the study and technical evaluation of applications for the conduct of activities with GMOs and issue the corresponding technical reports.

(d) To propose rules to the Competent National Authority that are complementary to these Regulations.

(e) To establish relations with public and private institutions that carry out activities relating to genetic engineering and biosafety at the national and international level, and establish with them mechanisms for the exchange of information on subjects relating to risk

evaluation and management, and approvals granted for the commercialization of GMOs, their by-products or the products that contain them.

14. The members of the National Biosafety Committee, in their capacity as advisors to the Competent National Authority, shall be responsible for the truthfulness and faithfulness of the information included in the reports, decisions and any other document they prepare and sign in the performance of their duties and in accordance with the provisions of national legislation.

Title III
Evaluation, categorization and management of risks

Chapter I
Evaluation of risks

15. Risks shall be evaluated for the purpose of determining:

1. The possible negative impacts on human health, the environment and biological diversity arising from the activity carried out with the GMO.

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

3. The classification of the GMO according to the groups established in these Regulations.

16. Risks shall be evaluated on the basis of a thorough examination of the information provided by the applicant with regard to the following parameters:

1. The characteristics of the GMO;

(a) The receiving/parent or host organism;

(b) The donor organism and the vector used;

(c) The insert and the coded trait;

(d) The center of origin.

2. The utilization for which it is intended, that is, the specific application of the confined utilization or the intentional release or the incorporation into the market, with the inclusion of the planned scale and the procedures for waste management and treatment, inter alia.

3. The potential receiving environment.

17. The information required to evaluate the risks properly shall include the elements contained in the application form in Annex I of these Regulations, as well as the attached documents supplied by the applicant and any other additional information that could be required.

Chapter II
Classification of risks

18. With a view to determining the possible risks arising from the handling of the genetically modified organisms, these shall be classified in one of the following groups, according to the criteria established below:

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

(i) There is no likelihood that the receiving or parent organism could cause disease in human beings, animals or plants;

(ii) The nature of the vector and of the insert is such that it does not supply the GMO with a genotype that is likely to cause disease in human beings, animals or plants, or that is likely to have adverse impacts on the environment;

(iii) It is not likely that the GMO will cause disease in human beings, animals or plants, and it is highly unlikely that it will have adverse effects on the environment.

Group 2: A GMO shall be classified in this group and considered of high risk when it does not meet the requirements established in Group 1, that is, the receiving or parent organism, the nature of the vector and the insert as well as the GMO or one of them, causes disease in human beings, animals and plants, and has adverse impacts on the environment.

Chapter III
Management of risks

19. Risks shall be managed with the objective of reducing and controlling the negative impacts of the GMO on human health, the environment and biological diversity during the carrying-out of a specific activity therewith; for that reason, the activity shall be implemented systematically by the applicant during the entire process of the conduct of the activity with the GMO.

20. Prior to the evaluation of the risks carried out by the National Biosafety Committee according to the requested activity and depending on the classification of the GMO and in accordance with the provisions of these Regulations, the applicant shall establish the corresponding measures for the management of risks, as well as the mechanisms through which those measures shall be applied.

Title IV
Authorization for the implementation of activities with GMOs

Chapter I
Information on and prior informed consent for the introduction of GMOs

21. Any natural person or legal entity, public or private, national or foreign, seeking to introduce GMOs into the national territory for carrying out any of the activities provided for in Article 3 of these Regulations, shall submit an application to the Office of the National Secretary for Natural Resources and the Environment.

22. The National Secretary for Natural Resources and the Environment shall forward the application that same day to the Office for Environmental Impact Assessment, so that that body, in coordination with the National Office for the Conservation of Biodiversity, and any other sectoral body involved, may carry out a basic evaluation of the information provided by the applicant, identifying the risks to human health, the environment and biological diversity, with a view to:

(a) Rejecting the introduction of the GMO onto the national territory.

(b) Allowing the conduct of the evaluation of risks of the application for the authorization or rejection of the introduction of the GMO onto the national territory.

23. Once the basic evaluation of the information provided by the applicant has been carried out, the National Secretary for Natural Resources and the Environment shall, within 10 working days, communicate with the applicant by means of a secretarial decision in the case of clause *(a)* of the preceding Article, and by means of administrative decision in the case of clause *(b)* of the preceding Article.

The secretarial decision whereby the introduction of GMOs onto the national territory is rejected, shall be recorded in the Public Registry by the Competent National Authority for said effect.

Chapter II
Procedure

24. Any natural person or legal entity, public or private, national or foreign, seeking to carry out any of the activities provided for in ARTICLE 3 of these Regulations, shall submit an application to the National Secretary for Natural Resources and the Environment in person or through a legal representative.

25. The following documents shall be submitted attached to the application:

1. Application form.

2. Documents substantiating the applicant's legal capacity and legal status.

3. Documents substantiating the project officer's technical capacities.

4. A letter of institutional accreditation for the project officer, in the case of legal entities.

5. The administrative decision authorizing the conduct of the evaluation of risks of the application in the event that the GMO is introduced onto the national territory with a view to carrying out any of the activities established in Article 2 of these Regulations.

6. A copy of the project for carrying out the requested activity.

All of the information provided by the applicant for the purposes of the application shall be deemed to be a sworn statement.

26. The National Secretary for Natural Resources and the Environment, through the Undersecretary for the Environment, shall review the application and all of the attached documents. Once the application is complete, he shall admit it within five working days and shall order that the corresponding technical file be opened. If the application is incomplete, it shall be returned to the applicant for rectification of omissions and observations.

27. Within five working days following the admission of the application, the National Secretary for Natural Resources and the Environment shall call a meeting of the National Biosafety Committee and shall bring the technical file to the Committee's attention , for its consideration and corresponding technical evaluation.

Simultaneously, the National Secretary for Natural Resources and the Environment shall publish a summary of the application in two written communication media with nationwide circulation, one of them being of a technical specialized character, so that the persons or institutions who or which could provide information with respect to the GMOs with which it is sought to carry out any of the activities provided for in Article 3, may make the information known to the National Biosafety Committee.

28. The National Biosafety Committee shall study the application and the attached documents and evaluate the risks as provided for by Title II of these Regulations within 90

calendar days; this term may only be extended once at the request of the National Biosafety Committee, depending on the GMO involved, the requested activity or the type of evaluation required.

29. Once the evaluation of the application has been completed, the National Biosafety Committee shall submit a technical report to the National Secretary for Natural Resources and the Environment. Said report shall contain a reasoned statement of the following aspects:

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

2. The classification of the risks, indicating whether the GMO belongs to Group 1 or Group 2.

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

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

5. The possible economic benefits that the activities with the GMO may yield.

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

30. Within the term of 20 working days starting from the remittance of the technical report to be brought to the attention of the National Secretary for Natural Resources and the Environment, the Secretary, by means of a secretarial decision, shall authorize or refuse the application and shall order its publication in a written medium of communication with nationwide circulation.

31. If the application is refused, the applicant may appeal the decision issued by the National Secretary for Natural Resources and the Environment, as provided for by national legislation.

32. The secretarial decision authorizing or refusing the application shall be entered in the Public Registry and implemented by the Competent National Authority for that purpose.

33. The Competent National Authority, for purposes of granting authorization for the activities regulated in this Supreme Decree, shall require the applicant to pay the amount corresponding to the costs of publication, evaluation, study and analysis necessary for the granting of said authorization.

Chapter III
Confidential treatment

34. The applicant may petition the Competent National Authority to grant confidential treatment for specific information provided by it for the purpose of requesting authorization for the carrying-out of activities with the GMO, which could be subject to unfair commercial use by individuals foreign to the procedure established in these Regulations. Said petition shall be accompanied by the corresponding justification and a non-confidential summary that shall form part of the public file.

35. Information relating to the identification of the holder and project officer, the purpose of the activity and the location at which it will be carried out, the systems and the

emergency and control measures, as well as the evaluation of risks to human health and the environment, may not be of a confidential nature.

36. The National Secretary for Natural Resources and the Environment may grant the requested confidential treatment and shall refrain from supplying information to third parties, except when public knowledge thereof is necessary to protect the environment, biological diversity and human health.

Those aspects which are subject to confidential treatment shall remain in a reserved file in the custody of the Competent National Authority and may not be made known, barring a court order to the contrary.

Title V
Violations and punishment

37. For the purposes of these Regulations, the following shall be considered violations:

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. Failure to comply with the conditions established in the secretarial decision for the carrying-out of the requested activity.

3. The carrying-out of activities with a GMO without due authorization.

4. Failure to comply with the measures for supervision, control and management of risks proposed by the applicant for the carrying-out of the authorized activity.

5. Failure to inform the Competent National Authority of accidents due to the carrying-out of the authorized activity that might have caused damage to health, the environment or biological diversity.

6. Any other action or omission by the applicant, public officials or third parties, which infringe the provisions established in these Regulations.

38. For purposes of determining the punishment for any action or omission by the applicant, public officials or third parties, that infringes the provisions established in these Regulations, the National Secretary for Natural Resources and the Environment shall consider the following aspects jointly or separately:

1. The gravity of the infringement.

2. Whether the infringement causes damage to human health, the environment or biological diversity.

3. The nature of the infringement.

39. Infringements of these Regulations shall give rise to the following punishment:

1. Suspension of the activities with a GMO; depending on the gravity of the infringement, the Competent National Authority shall order the temporary or permanent suspension of the activities with a GMO and shall give the infringer a specific deadline to amend the infringement.

2. Fines; independently of the previous punishment, the Competent National Authority shall impose a fine equivalent to 60 days’ fine.

3. Revocation of authorization; if it is clear the infringement is deliberate and in the event of severe and irreversible damage to human health, biodiversity or the environment, the Competent National Authority shall order the revocation of the authorization for carrying out the authorized activities and disqualify the infringer from filing further applications.

40. For the purposes of subparagraph 2 of the previous Article, a day of fine shall be considered equivalent to one day of the minimum salary.

41. The punishment referred to in Article 39 shall be imposed by the National Secretary for Natural Resources and the Environment unless said conduct constitutes a criminal offense, in which case the files shall be submitted to the authority designated by law for the imposition of the corresponding criminal punishment.

42. Without prejudice to the provisions of Article 39, and if there has been damage to biological diversity, the environment or human health, the National Secretary for Natural Resources and the Environment shall order the opening of investigation proceedings to determine the gravity of the damage caused, the degree of responsibility of the infringers and the compensation due to the Bolivian State for the damage caused, excluding the rights of aggrieved third parties, who may claim their rights under existing national legislation.

Title VI
Final provisions

One. The genetic manipulation of human germinal and/or somatic cells and human embryos as biological material available for the production of GMOs shall be subject to specialized regulations, which must be drawn up by the competent bodies in the health sector.

Two. Those institutions carrying out activities with GMOs on their national territory when these Regulations come into force shall draw up their technical rules for internal biosafety, which shall be validated by the Competent National Authority prior to a technical report by the National Biosafety Committee within 90 calendar days following the adoption of these Regulations.

Three. Those persons or entities who or which, at the date of the entry into force of these Regulations, are carrying out any of the activities provided for in Article 3, must regularize their status with the Competent National Authority, in accordance with Title IV of these Regulations, within 60 working days.

Four. Within 60 working days following the adoption of these Regulations, the National Biosafety Committee shall draw up and adopt its Rules of Procedure. For this purpose, the government institutions shall accredit their representatives to the Committee within 15 working days.

Five. In the case of activities involving transgenic seeds, the National Seed Department of the Office of the National Secretary for Agriculture and Livestock shall require due authorization as mentioned in Title IV of these Regulations, to proceed with the fulfillment of the established registrations, requirements and procedures.

Six. When it receives requests for the importation of GMOs of plant and/or animal origin, the Office of the National Secretary for Agriculture and Livestock, through its corresponding bodies, shall require the secretarial decision referred to in Article 30 of these Regulations as a prerequisite for issuing the Certificate of Plant and/or Animal Health.

Seven. All institutions wishing to carry out activities with GMOs on the national territory shall register with the Public Registry, which shall be set up for this purpose by the Competent National Authority within 15 working days.

Eight. For the purposes of clause *(d)* of Article 7 of these Regulations, the Competent National Authority shall set up, within 15 working days, a Public Registry of GMOs, their by-products and the products that contain them, whose introduction into the country with the purpose of carrying out any of the activities stipulated in Article 3, had been authorized and/or rejected.

Nine. For the purposes of the provisions of Article 33, the Competent National Authority shall arrange for the opening of a Special Fiscal Account within 30 working days following the adoption of these Regulations.

ANNEX 1

APPLICATION FORM FOR CARRYING OUT ACTIVITIES WITH GENETICALLY MODIFIED ORGANISMS IN BOLIVIA

1. GENERAL INFORMATION

1.1 Identification

Name of applicant.....
Nationality .....
Identity document .....
Legal status .....
Address .....
Telephone..... Fax ..... E-mail .....
Name of the technical officer responsible for the requested activity .....
Nationality .....
Identity document .....
Legal status .....
Address .....
Telephone..... Fax ..... E-mail .....

1.2 Type of activity requested (please tick):

( ) Large-scale field test
( ) Small-scale field test
( ) Production
( ) Research
( ) Transportation
( ) Storage
( ) Commercialization
( ) Other

1.3 Type of application before the Competent National Authority:

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

2. INFORMATION REGARDING THE PROJECT

The project must contain information on the following aspects:

1. Title
2. Description of the project
3. Justification and objectives
4. Area of application of the project, indicating the location, canton, province, department (latitude and longitude reference coordinates)
5. Type of activity/activities to be carried out with the GMO
6. Indicative schedule of activities
7. Materials and methods

8. Expected results
9. Budget or total investment
10. Technical literature
11. Other

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

3.1 Name of the GMO to be introduced

	SCIENTIFIC NAME	COMMON NAME	COMMERCIAL NAME	OTHER DESIGNATION
Donor organism				
Receiving organism				
Vector or vector agents				
GMO or product				

3.2 Means of transportation by which the GMO is to be introduced (please tick)

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

3.3 Quantity of GMO to be introduced

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

3.5 Purpose of the introduction

3.6 Program of proposed introductions (schedule)

Date of introduction of the GMO into 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 at which the requested activity is to be carried out

3.9 Description of any biological material (for example, cultivation medium) or host material accompanying the GMO

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

Name	Academic rank	Specialization	Address

Note: In addition to the information requested under this item the respective curricula vitae substantiating the technical abilities of each of the persons shall be attached to this form.

5. INFORMATION REQUIRED FOR RISK EVALUATION

5.1 INFORMATION RELATING TO THE ORGANISM WITH NEW TRAITS

(A) Characteristics of the organism from which the GMO is derived (receiving/parent/host organism):

1. Name and identity 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 reproduce and spread in the environment
9. Medium of transfer of genetic material to other organisms

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

1. Pathogenicity
2. Toxicity
3. Allergenicity

(C) Characteristics of the vector:

1. Identity
2. Origin and natural habitat
3. Relevant safety characteristics
4. Frequency of mobilization or ability to transfer to other organisms
5. Factors that could influence the vector's ability to establish itself in other hosts

(D) Characteristics of the inserted nucleic acid (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 gene product or products

(E) Characteristics of the organism with new traits:

1. Pathogenicity, toxicity and allergenicity, for human beings and other organisms
2. Capacity to survive in the environment
3. Capacity to persist in the environment
4. Capacity to compete in and spread into the environment
5. Other relevant interactions
6. Capacity to transfer genetic material and potential dissemination routes
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 its area of ecological expansion
10. Characterization of the products(s) of the inserted gene(s)
11. Characterization of the stability of the modification

5.2 INFORMATION RELATING TO THE PLANNED USE

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

1. Quantity or volume of the GMO(s) that will be used
2. Scale of the operation
3. Proposed confinement measures, including verification of their operation
4. Training and supervision of the staff who will carry out the work
5. Waste control plans
6. Plans to protect the health of the staff who will carry out the work
7. Plans to control and monitor accidents and unforeseen events
8. Relevant information from previous utilizations

(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 areas and human activity
4. Method and frequency of release
5. Training and supervision of the staff who will carry out the work
6. Possibility of transborder movements
7. Time and duration of release
8. Environmental conditions provided for during the release
9. Proposed risk management measures, including verification of their operation
10. Subsequent treatment of the site and waste control plans
11. Plans to control accidents and unforeseen events/disasters
12. Relevant information from any previous releases

5.3 INFORMATION RELATING TO THE CHARACTERISTICS OF THE POTENTIAL RECEIVING ENVIRONMENT

1. Geographical location of the site.
2. Identity and any special characteristic of the receiving environment that makes it vulnerable to damage.
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, endangered or endemic specific, potential competitive species and non-target organisms.
5. Potential of any organism that is found in the potential receiving environment to receive genes from the released organism.

6. IN THE EVENT THAT THE REQUESTED ACTIVITY IS THE COMMERCIALIZATION OF A GMO OR THE PRODUCT THAT CONTAINS IT, THE FOLLOWING INFORMATION SHALL BE SPECIFIED

6.1 Name of the product and names of the GMOs that contain it
6.2 Name of the manufacturer or distributor
6.3 Specificity of the product
6.4 Exact conditions of use, including the type of environment and/or geographical areas in which the product will be commercialized
6.5 Type of planned use
( ) Industry
( ) Agriculture
( ) Consumption by the general public
( ) Other specialized activities
6.6 Measures to be adopted in the event of unintentional release or improper use

6.7 Specific instructions or recommendations for storage and handling
6.8 Proposed container
6.9 Proposed labeling
6.10 If there are intellectual property rights in the GMO, specify:
(a) Name of patent
(b) Registration number
(c) Holder
(d) Date of grant
(e) Date of application

7. CONFIDENTIAL INFORMATION

In the event of confidential information, supply the particulars thereof and attach to this form.

8. SWORN STATEMENT

For the following purposes, I hereby swear that the information provided in this form is true.

Signature .....
Full name .....
Identity document .....
Position (holder or legal representative) .....
Date