# PROVISIONAL ACT NO. 2,186-16, DATED AUGUST 23, 2001.

Regulates item II from Paragraph 1 and Paragraph 4 of Article 225 of the Constitution, Articles 1, 8, item "j", 10, item "c", 15 and 16, items 3 and 4 of the Convention on Biological Diversity, provides for the access to genetic heritage, protection and access to associated traditional knowledge, benefit-sharing and access to and transfer of technology for its conservation and use, and makes other provisions.

**THE PRESIDENT OF THE REPUBLIC**, making use of the prerogatives vested upon him by Article 62 of the Constitution, adopts the following legally binding Provisional Act:

#### TITLE I

#### **GENERAL PROVISIONS**

**Article 1.** This Provisional Act provides for assets, rights and obligations concerning:

- I Access to components of genetic heritage existing within the Brazilian territory, on the continental shelf and in the exclusive economic zone for purposes of scientific research, technological development or bioprospecting;
- II Access to traditional knowledge associated to genetic heritage, related to the conservation of biological diversity, to the integrity of the country's genetic heritage and to the use of its components;
- III The fair and equitable sharing of the benefits arising from the use of genetic heritage component and the associated traditional knowledge; and
- IV Access to technology and transfer of technology for the conservation and use of biological diversity.
- Paragraph 1. Access to components of genetic heritage for the purpose of scientific research, technological development or bioprospecting shall be carried out under the terms of this Provisional Act, without prejudice to material or intangible property rights that are incident upon the accessed genetic heritage components or upon the site of occurrence.
- Paragraph 2. Access to components of genetic heritage existing on the continental shelf shall comply with that provided for in Law No. 8,617, dated January 4, 1993.
- **Article 2.** Access to genetic heritage existing in the country shall only be take place with an authorization from the Federal Government and its use, commercialization and employment for any purpose shall be submitted to inspection, restrictions and sharing of benefits in the terms and conditions established in this Provisional Act and its complementary legislation.

- **Article 3.** This Provisional Act does not apply to human genetic heritage.
- **Article 4.** The exchange and dissemination of components of genetic heritage and of associated traditional knowledge practiced within indigenous communities and local communities for their own benefit and based on customary practices is hereby preserved.
- **Article 5.** Access to genetic heritage is hereby prohibited for practices that are harmful to the environment and to human health and for the development of biological and chemical weapons.
- **Article 6.** At any moment, in the light of scientific evidence denoting the risk of serious and irreparable damage to biological diversity, arising from activities carried out in the terms of this Provisional Act, the Government, through the Genetic Heritage Management Council, provided for in Article 10, based on criteria and technical assessments, shall determine measures intended to prevent such damage and may even stop the activity, observing the mandate of the agency responsible for the biosafety of genetically modified organisms.

#### TITLE II

## **DEFINITIONS**

- **Article 7.** In addition to the concepts and definitions contained in the Convention on Biological Diversity, the following terms are defined for the purposes of this Provisional Act:
- I Genetic heritage: information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal species, in the form of molecules and substances originating in the metabolism of these living beings, and in extracts obtained from *in situ* conditions, including domesticated, or kept in *ex situ* collections, if collected from *in situ* conditions, within the Brazilian territory, on the continental shelf or in the exclusive economic zone;
- II Associated traditional knowledge: individual or collective information or practice of the indigenous community or local community, with real or potential value, associated to genetic heritage;
- III Local community: human group, including descendants of *Quilombo* communities, differentiated by its cultural conditions, which is, traditionally, organized along successive generations and with its own customs, and preserves its social and economic institutions;
- IV Access to genetic heritage: acquisition of samples of genetic heritage components for the purpose of scientific research, technological development, or bioprospecting, with a view to its industrial or other application;
- V Access to associated traditional knowledge: acquisition of information on individual or collective knowledge or practice associated to genetic heritage, from an indigenous

community or local community, for the purpose of scientific research, technological development or bioprospecting, with a view to its industrial or other application;

- VI Access to and transfer of technology: an action that aims to ensure access to, development and transfer of technology for the conservation and utilization of biological diversity or technology developed from samples of genetic heritage components or associated traditional knowledge;
- VII Bioprospecting: an exploratory activity that aims to identify genetic heritage components and information on associated traditional knowledge, with potential for commercial use;
- VIII Endangered species: species with a high risk of disappearing from nature in the near future, recognized as such by the competent authority;
- IX Domesticated species: species in which the evolutionary process has been influenced by humans to meet their needs;
- X Authorization for Access and Shipment: the document that allows, under specific conditions, access to samples of genetic heritage components and its shipment to the recipient institution and the access to associated traditional knowledge;
- X Authorization for Special Access and Shipment: the document that allows, under specific conditions, access to samples of genetic heritage components and its shipment to the recipient institution and the access to associated traditional knowledge, for a period of up to two years, renewable for equal periods;
- XI Material Transfer Agreement: accession instrument to be signed by the recipient institution before shipment of any sample of genetic heritage components, indicating, when appropriate, if there was access to associated traditional knowledge;
- XII Contract for Use of Genetic Heritage and Benefit-Sharing: the multilateral legal instrument that identifies the Parties, the object, the conditions of access and of shipment of a genetic heritage component and of associated traditional knowledge, as well as the conditions for benefit-sharing;
- XIV *Ex situ* condition: maintaining samples of genetic heritage components outside of their natural habitat, in living or preserved collections.

### TITLE III

## PROTECTION TO ASSOCIATED TRADITIONAL KNOWLEDGE

**Article 8.** This Provisional Act protects the traditional knowledge of the indigenous communities and of the local communities, associated to genetic heritage, from illicit use and exploitation and other harmful actions or those actions not authorized by the Management Council referred to in Article 10, or by an accredited institution.

Paragraph 1. The State recognizes the right of the indigenous communities and of the local communities to decide on the use of their traditional knowledge related to the genetic heritage of the country, in the terms of this Provisional Act and its complementary legislation.

Paragraph 2. The traditional knowledge related to genetic heritage provided for by this Provisional Act is an integral part of the Brazilian cultural heritage and may be registered, as provided for the Management Council or specific legislation.

Paragraph 3. The protection conferred by this Provisional Act may not be interpreted so as to become an obstacle to the preservation, utilization and development of traditional knowledge of an indigenous community or a local community.

Paragraph 4. The protection hereby established shall not affect, damage or limit rights related to intellectual property.

**Article 9.** The indigenous communities and local communities that create, develop, hold or conserve traditional knowledge associated to genetic heritage are assured the right to:

- I Have acknowledged the origin of the access to the traditional knowledge in all publications, uses, exploitations and dissemination;
- II Prevent non-authorized third-parties for:
- A) Use, test, research or exploit of associated traditional knowledge;
- b) Disseminate, transmit or forward data or information that constitute associated traditional knowledge, or part thereof;
- III Receive benefits from the economic use by third parties, directly or indirectly, of associated traditional knowledge to which they hold rights, in accordance with this Provisional Act.

Sole Paragraph. For the purposes of this Provisional Act, any traditional knowledge related to genetic heritage may be deemed to be held by the community even if only one member of this community holds this knowledge.

#### **TITLE IV**

# INSTITUTIONAL MANDATE AND COMPETENCE

**Article 10.** The Genetic Heritage Management Council is hereby established, under the Ministry of Environment, a regulatory and deliberative body, composed of representatives of Federal Government entities responsible for the various actions covered by this Provisional Act.

Paragraph 1. The Management Council shall be chaired by the representative of the Ministry of the Environment.

Paragraph 2. The Management Council shall have its composition and operation provided for in complementary legislation.

# **Article 11.** The Management Council is responsible for:

- I Coordinating implementation of genetic heritage management policies;
- II Establishing:
- a) Technical standards;
- b) Criteria for access and shipment authorizations;
- c) Guidelines for drafting the Contract for Use of Genetic Heritage and Benefit-Sharing;
- d) Criteria for creation of a database for recording information on associated traditional knowledge;
- III Overseeing, in coordination with other federal bodies, or by means of an agreement with other institutions, the activities of access and shipment of samples of genetic heritage components and access to associated traditional knowledge;

# IV - Deliberating on:

- a) Authorizations for access and shipment of samples of genetic heritage components, with prior consent of its holder;
- b) Authorizations for access to associated traditional knowledge, with the prior consent of its holder;
- c) Special authorizations for access and shipment of samples of genetic heritage components to the Brazilian institution, public or private, that carries out research and development activities in biological and related areas, and to the Brazilian university, public or private, for a period of up to two years, renewable for equal periods, in accordance with complementary legislation;
- d) Special authorization for access to associated traditional knowledge to a Brazilian institution, public or private, that carries out research and development activities in biological and related areas, and to a Brazilian university, public or private, for a period of up to two years, renewable for equal periods, in accordance with complementary legislation;

- e) Accreditation of a Brazilian public research and development institution or a federal public management institution to authorize another Brazilian institution, public or private, that carries out research and development activities in biological and related areas:
- 1. To access samples of genetic heritage components and of associated traditional knowledge;
- 2. To ship samples of genetic heritage components to a Brazilian institution, public or private, or to a foreign-based institution;
- f) Accreditation of a Brazilian public institution to be the trustee of samples of genetic heritage components;
- V Approving Contracts for Use of Genetic Heritage and Benefit-Sharing with regard to their complying with the requirements of this Provisional Act and its complementary legislation;
- VI Promoting debates and public hearings on the issues covered by this Provisional Act;
- VII Operating as the highest appeals body in regard to decisions of an accredited institution and the acts arising from the enforcement of this Provisional Act;
- VIII Approving its bylaws.
- Paragraph 1. The decisions of the Management Council are subject to appeal in the plenary, in accordance with the complementary legislation.
- Paragraph 2. The Management Council may be organized in thematic chambers to assist plenary decisions.
- **Article 12.** When the activity of collecting genetic heritage components and of accessing associated traditional knowledge, which contributes to the progress of knowledge and which is not associated to bioprospecting, involves the participation of a foreign legal entity, shall be authorized by the body responsible for the Brazilian scientific and technological research policy, in keeping with the terms of this Provisional Act and legislation in force.

Sole Paragraph. The authorization provided for in the chapeau of this article shall comply with the technical standards defined by the Management Council, which shall oversee these activities.

**Article 13.** The Chairperson of the Management Council is responsible for signing, on behalf of the Federal Government, Contracts for Use of Genetic Heritage and Benefit-Sharing.

Paragraph 1. Within the mandate provided for in the chapeau of this article, the Chairperson of the Management Council shall delegate to the head of a federal research and development public institution, or a public federal management institution, the competence provided for in the chapeau of this article, in accordance with its respective area of action.

Paragraph 2. When the institution provided for in Paragraph 1 above is an interested party in the contract, the contract shall be signed by the Chairperson of the Management Council.

- **Article 14.** The accredited institution provided for in numbers 1 and 2 of item "e" of Paragraph IV of Article 11 of this Provisional Act, shall undertake one or more of the following responsibilities, in compliance with the guidelines of the Management Council:
- I To analyze requests and issue authorization to third parties for:
- a) Accessing samples of genetic heritage components existing in *in situ* conditions, within the Brazilian territory, on the continental shelf and in the exclusive economic zone, with prior consent of its holders;
- b) Accessing associated traditional knowledge, with the prior consent of its holders;
- c) Shipping samples of genetic heritage components to a Brazilian institution, public or private, or to a foreign-based institution;
- II To oversee, in coordination with federal entities, or by means of an agreement with other institutions, the activities of access and shipment of samples of genetic heritage components and access to associated traditional knowledge;
- III To create and maintain:
- a) A register of *ex situ* collections, as provided for in Article 18 of this Provisional Act;
- b) A database to record information obtained during the collection of samples of genetic heritage components;
- c) A database with information on the Authorizations of Access and Shipment, Material Transfer Agreements and Contracts for Use of Genetic Heritage and Benefit-Sharing, in accordance with complimentary legislation;
- IV To disclose, periodically, a list of the Authorizations of Access and Shipment, Material Transfer Agreements and Contracts for Use of Genetic Heritage and Benefit-Sharing;
- V To oversee the implementation of the Material Transfer Agreement and the Contracts for Use of Genetic Heritage and Benefit-Sharing related to the cases it authorizes.

- Paragraph 1. The accredited institution shall, every year, by means of a report, fully inform the Management Council about the executed activities and send a copy of the database to the executing unit provided for in Article 15.
- Paragraph 2. The accredited institution, in the terms of Article 11, shall comply with the provisions of this Provisional Act, its complementary legislation and the decisions of the Management Council, under penalty of removal of its accreditation, and further subject to the penalties provided for in Article 30 and legislation in force, as appropriate.
- **Article 15.** The creation of an executing unit, to operate as the executive secretariat of the Management Council, provided for in Article 10 of this Provisional Act, is hereby authorized, under the Ministry of Environment, with the following responsibilities, among others:
- I Implementing the decisions of the Management Council;
- II Providing support to accredited institutions;
- III Issuing, in accordance with Management Council decisions, and on its behalf:
- a) Authorization for Access and Shipment;
- b) Special Authorization for Access and Shipment;
- IV Overseeing, in coordination with other federal entities, the activities of access and shipment of samples of genetic heritage components and access to associated traditional knowledge;
- V Accrediting, in accordance with Management Council decision and on its behalf, a Brazilian public research and development institution or a federal public management institution to authorize a Brazilian institution, public or private:
- a) To access samples of genetic heritage components and associated traditional knowledge;
- b) To ship samples of genetic heritage components to a Brazilian institution, public or private, or to a foreign-based institution, observing the requirements of Article 19 of this Provisional Act;
- VI Accrediting, in accordance with Management Council decision and on its behalf, a Brazilian public institution to be the trustee of samples of genetic heritage components;
- VII Registering the Contracts for Use of Genetic Heritage and Benefit-Sharing, upon Management Council consent;

VIII - Publishing a list of species with facilitated exchange contained in international agreements, including on food safety, of which the country is signatory, in accordance with Paragraph 2 of Article 19 of this Provisional Act;

IX - creating and maintaining:

- a) Register of ex situ collections, as provided for in Article 18;
- b) A database to record information obtained during the collection of samples of genetic heritage components;
- c) A database with information on the Authorizations of Access and Shipment, Material Transfer Agreements and Contracts for Use of Genetic Heritage and Benefit-Sharing;
- X Disclosing, periodically, a list of the Authorizations of Access and Shipment, Material Transfer Agreements and Contracts for Use of Genetic Heritage and Benefit-Sharing;

#### TITLE V

#### **ACCESS AND SHIPMENT**

**Article 16.** Access to genetic heritage components existing in *in situ* conditions, within the Brazilian territory, on the continental shelf and in the exclusive economic zone, and to associated traditional knowledge shall take place by collecting samples and information, respectively, and shall only Brazilian, public or private, institutions that carry out research and development in biological and related areas, shall be authorized to do so, in accordance with this Provisional Act.

Paragraph 1. The person responsible for a collection expedition shall, at the conclusion of his activities in each accessed area, sign with the landholder, or his representative, a declaration containing a list of the accessed material, in accordance with complementary legislation.

Paragraph 2. Exceptionally, when the landholder of the area or his representative is not identified or found during the collection expedition, the declaration containing the list of the accessed material shall be signed by the person responsible for the expedition and forwarded to the Management Council.

Paragraph 3. A representative sub-sample of the accessed genetic heritage component shall be deposited in *ex situ* condition at an institution accredited as trustee, as provided for in item "f" of Paragraph IV of Article 11 of this Provisional Act, in accordance with complementary legislation.

Paragraph 4. When probability of commercial use is apparent, access to samples of genetic heritage components, in *in situ* conditions, and to the associated traditional knowledge may only take place after signing a Contract for Use of Genetic Heritage and Benefit-Sharing.

Paragraph 5. If potential for economic use is identified in a product or process, liable or not to intellectual property protection, originating in a sample of a genetic heritage component and in information arising from associated traditional knowledge, accessed with authorization in which this hypothesis was not established, the recipient institution undertakes the commitment to inform the Management Council or the institution where the process for access and shipment originated, to formalize a Contract for Use of Genetic Heritage and Benefit-Sharing.

Paragraph 6. Participation of a foreign legal entity in an expedition to collect *in situ* samples of genetic heritage components and to access associated traditional knowledge shall be authorized only when it is joined by a Brazilian public institution, the latter having mandatory coordination of activities and so long as all institutions concerned carry out research and development activities in biological and related areas.

Paragraph 7. Research on genetic heritage components should preferably be carried out on Brazilian territory.

Paragraph 8. Authorization for Access and Shipment of samples of genetic heritage components of an endemic or an endangered species shall depend on the prior consent of the competent body.

Paragraph 9. Authorization for Access and Shipment shall be given after prior consent of:

- I The indigenous community concerned, after consulting the official Indian Affairs body, when the access occurs in indigenous lands;
- II The competent body, when access occurs in protected area;
- III The owner of the private area, when the access occurs there;
- IV The National Defense Council, when the access takes place in an area essential for national security;
- V The maritime authority, when the access takes place in Brazilian jurisdictional waters, on the continental shelf and in the exclusive economic zone.

Paragraph 10. The holder of the Authorization for Access and Shipment referred to in items I to V of Paragraph 9 of this Article is responsible for compensating the owner of the area for any incurred damage or harm, if duly proven.

Paragraph 11. The institution holding the Special Authorization for Access and Shipment shall forward to the Management Council the consents referred to in Paragraphs 8 and 9 of this Article before or during the collection expeditions to be carried out during the period in which the Authorization is in force, where non-compliance shall result in its cancellation.

**Article 17.** In the instances of relevant public interest, so defined by the Management Council, entrance into public or private area for access to samples of genetic heritage components shall be done so without the prior consent of titleholders, assuring them that provided for in Articles 24 and 25 of this Provisional Act.

Paragraph 1. In the instance provided for in the chapeau of this Article, the indigenous community, the local community or the landowners shall receive prior notice.

Paragraph 2. If the area is in indigenous lands, the provisions of Paragraph 6 of Article 231 of the Federal Constitution must be observed.

**Article 18.** Ex situ conservation of samples of genetic heritage components is to be carried out in Brazilian territory, and may also, in a complementary fashion, at the discretion of the Management Council, be carried out abroad.

Paragraph 1. The *ex situ* collections of samples of a genetic heritage component shall be registered at the executing unit of the Management Council, in accordance with complementary legislation.

Paragraph 2. The Management Council may delegate the registration referred to in Paragraph 1 of this Article to one or more accredited institutions in the terms of items "d" and "e" of Paragraph IV of Article 11 of this Provisional Act.

- **Article 19.** Shipment of samples of genetic heritage components from a Brazilian institution, public or private, to another Brazilian institution, public or private, shall be carried out based on material in *ex situ* conditions, and on receipt of information on the intended use, in cumulative compliance with the following conditions, in addition to others that the Management Council may establish:
- I Deposit of a representative sub-sample of the genetic heritage component in a collection maintained by an accredited institution, should that provided for in Paragraph 3 of Article 16 of this Provisional Act not yet have been met;
- II In the instances when the samples of genetic heritage components were accessed in *in situ* conditions before the enactment of this Provisional Act, the deposit referred to in the previous paragraph shall be carried out in the accessed form, if still available, in accordance with complementary legislation;
- III Provide information obtained during the collection of samples of genetic heritage components, for recording in the database mentioned in item "b" of Paragraph IX of Article 15 of this Provisional Act;
- IV Prior signing of the Material Transfer Agreement.

Paragraph 1. Every time the probability of commercial use is apparent of the product or process arising from genetic heritage components, prior signing of a Contract for Use of Genetic Heritage and Benefit-Sharing shall be required.

Paragraph 2. Shipment of samples of genetic heritage components of species that have facilitated exchange in interBrazilian agreements, including on food safety, of which Brazil is signatory, shall be carried out according to the conditions defined therein, maintaining the requirements of the items therein.

Paragraph 3. Shipment of any sample of genetic heritage components from a Brazilian institution, public or private, to a foreign-based institution, shall be carried out based on material in *ex situ* conditions, and on receipt of information on the intended use and the prior authorization of the Management Council or an accredited institution, observing the cumulative compliance of the conditions established in items I to IV and Paragraphs 1 and 2 of this Article.

**Article 20.** The Material Transfer Agreement shall have its model approved by the Management Council.

## **TITLE VI**

#### ACCESS TO AND TRANSFER OF TECHNOLOGY

- **Article 21.** The institution that receives samples of genetic heritage components or associated traditional knowledge shall facilitate the access to and transfer of technology for the conservation and use of this heritage or this knowledge, to the Brazilian institution responsible for the access and shipment of the sample and information on the knowledge, or to an institution it indicates.
- **Article 22.** The access to and transfer of technology between a Brazilian research and development institution, public or private, and a foreign-based institution, may be carried out through the following activities, among others:
- I Scientific research and technological development;
- II Training and capacity building of human resources;
- III Exchange of information;
- IV Exchange between a Brazilian research institution and a foreign-based research institution;
- V Consolidation of scientific research and technological development infrastructure;
- VI Economic use, in partnership, of process and product arising from the use of a genetic heritage component; and

VII – Establishment of joint technologically based undertaking.

**Article 23.** The company that, as it ensures the access to and transfer of technology to a Brazilian institution, public or private, responsible for the access to and shipment of a samples of genetic heritage components and for the access to information on associated traditional knowledge, invests in research and development in Brazil shall be able to apply for fiscal incentives for technological capacity building of industry and agriculture and for other incentive instruments, in accordance with the relevant legislation.

# **TITLE VII**

# **BENEFIT-SHARING**

**Article 24.** The benefits arising from the economic use of the product or process developed from samples of genetic heritage components and associated traditional knowledge, obtained by a Brazilian or foreign-based institution, shall be shared in a fair and equitable manner among the contracting parties, as defined in complementary and relevant legislation.

Sole Paragraph. When the Federal Government is not a party to the Contract for Use of Genetic Heritage and Benefit-Sharing, it shall be assured participation in these benefits, as provided for in the chapeau of this article, as appropriate, in accordance with complementary legislation.

- **Article 25.** The benefits arising from the economic use of the product or process developed from a sample of a genetic heritage component or from associated traditional knowledge, may be, among others:
- I Sharing of profits;
- II Payment of royalties;
- III Access and transfer of technologies;
- IV licensing, without cost, of products and processes; and
- V Capacity building of human resources;

Article 26. The economic use of a product or process developed from samples of genetic heritage components or from associated traditional knowledge, accessed in a manner contrary to the provisions of this Provisional Act, shall subject the offender to payment of compensation corresponding to at least twenty percent of the gross income obtained from commercialization of the product or of the royalties obtained from third parties by the offender, as a result of licensing the product or process or use of the technology, whether or not they are protected by intellectual property, without prejudice to administrative sanctions and the appropriate penalties.

**Article 27.** The Contract for Use of Genetic Heritage and Benefit-Sharing should clearly indicate and qualify the contracting parties, namely, on the one side the owner of the public or private area or the representative of the indigenous community and the official Indian Affairs body, or the representative of the local community and, on the other side, the Brazilian institution authorized to carry out the access and the recipient institution.

**Article 28.** The clauses that are mandatory in the Contract for Use of Genetic Heritage and Benefit-Sharing, in accordance with complementary legislation, without prejudice to others, are those that provide for:

I – The object, its elements, quantification of the sample and intended use;

II – Period of duration;

III – Manner of fair and equitable sharing of benefits, and when appropriate, access to and transfer of technology;

IV – Rights and responsibilities of the parties;

V – Intellectual property rights;

VI - Withdrawal;

VII - Penalties:

VIII - Court jurisdiction in Brazil.

Sole Paragraph. When the Federal Government is a party, the contract mentioned in the chapeau of this Article shall be ruled by the public law.

**Article 29.** The Contracts for Use of Genetic Heritage and Benefit-Sharing shall be submitted for registration with the Management Council and shall only enter into force after its consent.

Sole Paragraph. The Contracts for Use of Genetic Heritage and Benefit-Sharing shall be considered null and void, without any legal standing, when they are signed contrary to the provisions of this Provisional Act and its complementary legislation.

#### **TITLE VIII**

# **ADMINISTRATIVE SANCTIONS**

**Article 30.** An administrative violation against the genetic heritage or the associated traditional knowledge is considered to be every act or omission that violates the rules provided for in this Provisional Act and other relevant legal provisions.

Paragraph 1. The administrative violations shall be punished as provided for in the complementary legislation of this Provisional Act, with the following sanctions:

I - Warning;

II – Fine;

III - Seizure of samples of the genetic heritage components and the instruments used in the collection or processing or the products obtained as a result of information on associated traditional knowledge;

IV - Seizure of all products derived from a sample of a genetic heritage component or of associated traditional knowledge;

V - Suspension of the sale of the product derived from the sample of the genetic heritage component or of the associated traditional knowledge and its seizure;

VI - Embargo of the activity;

VII - Partial or total closure of the business, activity or undertaking;

VIII – Suspension of the register, patent, license or authorization;

IX – Canceling of the register, patent, license or authorization;

X - Loss or reduction of fiscal incentives and benefits granted by the government;

XI - Loss or suspension of the right to receive financing from an official financing agency;

XII – Intervention in the establishment;

XIII – Prohibition of entering into contracts with the Public Administration for a period of up to five years;

Paragraph 2. The samples, products and instruments referred to by items III, IV and V of Paragraph 1 of this Article shall have their destination defined by the Management Council.

Paragraph 3. The sanctions established in this Article shall be applied in the procedural manner established in the complementary legislation to this Provisional Act, without prejudice to applicable civil or criminal sanctions.

Paragraph 4. The fines referred to by item II of Paragraph 1 of this Article shall be decided by the competent authority according to the severity of the violation and pursuant to complementary legislation, and can vary from R\$200.00 (two hundred reals) to R\$100,000.00 (one hundred thousand reals), when an individual is involved.

Paragraph 5. If the violation is committed by a corporation, or with its abetment, the fine shall be from R\$10,000.00 (ten thousand reals) to R\$50,000,000.00 (fifty million reals), to be decided by the competent authority, according to the severity of the violation, pursuant to the complementary legislation.

Paragraph 6. In the case of repeating incidence, the fine shall be doubled.

#### TITLE IX

## **FINAL PROVISIONS**

**Article 31.** Granting of industrial property rights by the competent bodies over the process or product obtained from samples of genetic heritage components is subject to compliance with this Provisional Act. The person or institution applying for the property rights must inform the origin of the genetic material and the genetic knowledge and the associated traditional knowledge, as appropriate.

Article 32. Competent federal bodies shall be responsible for supervision, interception and seizing of samples of genetic heritage components or of product obtained from information on associated traditional knowledge, accessed in manner contrary to the provisions of this Provisional Act, pursuant to complementary legislation, and, furthermore, said activities may be decentralized by means of agreements.

Article 33. The share of profits and royalties owed to the Federal Government, resulting from the economic use of a process or products developed from samples of genetic heritage components, as well as the fines and compensations dealt with by this Provisional Act shall be intended for the National Environment Fund, created by Law No. 7797, dated July 10, 1989, and for the Navy Fund, created by Decree No. 20,923, dated January 8, 1932, and for the National Scientific and Technological Development Fund, created by Decree-Law No. 719, dated July 31, 1969 and reestablished by Law No. 8712, dated January 18, 1991, pursuant to complementary legislation.

Sole Paragraph. The resources referred to by this Article shall be used exclusively in the conservation of biological diversity, including the recovery, creation and maintenance of depositary banks, in fostering scientific research, in the technological development associated to genetic heritage and in the capacity building of human resources associated to the development of activities related to the use and conservation of genetic heritage.

**Article 34.** The person who uses or makes economic use of the components of genetic heritage and associated traditional knowledge should make their activities compatible with the provisions of this Provisional Act and its complementary legislation.

**Article 35.** The Federal Government shall enact complementary legislation to this Provisional Act by December 30, 2001.

**Article 36.** The provisions of this Provisional Act do not apply to matter regulated by Law No. 8974, dated January 5, 1995.

**Article 37.** The acts practiced in accordance with Provisional Act No 2,186-15, dated July 26, 2001 are hereby validated.

**Article 38.** This Provisional Act enters into force on the day of its publication.

Brasília, 23rd of August 2001; 180th Year of the Independence and 113th Year of the Republic.

FERNANDO HENRIQUE CARDOSO

José Gregori José Serra Ronaldo Mota Sardenberg José Sarney Filho