

**BRAZIL'S BILL ON "ACCESS TO GENETIC RESOURCES"**

**Bill of Law N: 306/95**

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 From: ("RFC-822": <cvw(a)isd.de>, SITE:INTERNET)  
 To:       MSSRF.MADRAS/SM8  
 Subj:     Brazil's access bill in English

RFC-822-Headers:

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Dear Prof. Swaminathan, I really regret that we could not manage a meeting. The following document may be of interest to you as chairman of the Committee which has submitted access legislation in India.

Yours sincerely, Christine von Weizsdcker

>Friends,

>

>Attached you should find a copy of the most recent version of Brazil's  
>bill to regulate Access to Genetic Resources.

>

>This is bill number 306/95, in the Federal Senate since October 1995.  
>Just last week, on Nov. 19, 1997, the Senate's Commission on Social  
>Affairs voted its approval for the bill, with three minor amendments  
>(incorporated into the attached translation).

>

>The bill will still have to go through one other Senate commission (on  
>education, which covers S&T), and no one is sure yet just how long  
>this may take. It may be a virtual formality, however, allowing the  
>bill to be sent to the lower house of Congress, the Chamber of  
>Deputies, in early 1998. In any case, few here are optimistic that the  
>bill will become law before the end of 1998.

>

>Several Brazilian NGOs wish to further develop the section on  
>traditional rights, while representatives of the Brazilian government  
>have made absolutely no public comment at all on the content of the  
>bill for about a year. It is known, however, that an inter-ministerial  
>working group headquartered in the President's office is preparing a  
>(considerably abbreviated) version of its own for this bill, to be  
>presented "soon".

>

>This translation was furnished by the Translation Service of the  
>Secretariat of Information and Documentation, at the Federal Senate.

>

>

>- David Hathaway, AS-PTA

>BRAZIL'S BILL ON "ACCESS TO GENETIC RESOURCES"

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>BILL OF LAW N: 306/95

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>Emended version presented by Rapporteur Senator Osmar Dias (PSDB/PR),  
>as approved by the Commission on Social Affairs  
>of the Federal Senate of Brazil,  
>on November 19, 1997

>

>Provides for the access to genetic resources and their derived products and  
>makes other provisions.

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>       THE NATIONAL CONGRESS decrees:

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>

>TITLE I

>

>PRELIMINARY PROVISIONS

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>       Article 1. This Act provides for rights and duties concerning the access  
>to genetic resources, genetic material, and derived products, in ex situ or

in situ conditions, existing in the Brazilian territory or having Brazil as their country of origin, to traditional knowledge possessed by indigenous populations and local communities, associated with genetic resources or derived products and with domesticated and semi-domesticated crops in Brazil.

>  
> Article 2. Genetic resources and derived products are considered public property of special use of the Brazilian Nation, and the contracts of access to them shall be carried out under the terms of this Act, without prejudice to material and immaterial property rights relating to:

>  
> I - the natural resources containing the genetic resource or derived product;

>  
> II - the lands traditionally inhabited by Indians and their exclusive enjoyment of the riches existing in such lands;

>  
> III - the private collection of genetic resources or derived products;

>  
> IV - the traditional knowledge possessed by indigenous populations and local communities, associated with genetic resources or derived products;

>  
> V - the domesticated and semi-domesticated crops in Brazil.

>  
> Sole paragraph. The owners and holders of goods and rights referred to in this article shall be ensured of the fair and equitable sharing of the benefits derived from the access to genetic resources, to the traditional knowledge possessed by indigenous populations and local communities associated with genetic resources and derived products, and to the domesticated and semi-domesticated crops in Brazil, under the terms of this Act.

>  
> Article 3. The legal classification presented in the previous article does not apply to the genetic resources and any components or substances of human beings, with due regard to the provisions of article 8 of this Act.

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>  
>TITLE II

>  
>DEFINITION OF TERMS AND GENERAL PROVISIONS

>  
>Chapter I

>  
>Definition of Terms

>  
> Article 4. For the purposes of this Act, the following definitions apply:

>  
>ACCESS TO GENETIC RESOURCES: acquisition and utilization of genetic resources, genetic material and derived products, in ex situ or in situ conditions, existing in the Brazilian territory or having Brazil as their country of origin, of knowledge possessed by indigenous populations and local communities associated with genetic resources or derived products, and of domesticated and semi-domesticated crops in Brazil, for purposes of research, bioprospecting, conservation, industrial application or commercial exploitation, among others.

>  
>COMPETENT AUTHORITY: public agency appointed by the Government to enter into contracts regarding the access to genetic resources, which must include benefit sharing and the access to and the transfer of technology, as set forth in this Act.

>  
>BIOTECHNOLOGY: any technological application which uses biological systems or living organisms, part of them or their derived products, to make or modify products or processes for specific utilization.

>  
>EX SITU CONSERVATION CENTER: institution recognized by the competent authority, which collects and conserves the components of biological diversity out of their natural habitats.

>

>TRADITIONAL KNOWLEDGE: any knowledge, innovation, or individual or collective practice of an indigenous population or local community, having real or potential value, associated with a genetic resource or derived product, protected or not by intellectual property legislation.

>

>LOCAL COMMUNITY AND INDIGENOUS POPULATION: human group differentiated by its social, cultural and economic conditions, organized, in total or in part, according to its own customs and traditions or by special legislation, and preserving, whatever juridical status it has, its own social, economic, and cultural institutions, or part of them.

>

>EX SITU CONDITIONS: conditions in which the components of biological diversity are conserved out of their natural habitats.

>

>IN SITU CONDITIONS: conditions in which genetic resources exist in ecosystems and natural habitats, and, in the case of domesticated and cultivated species, in the environments where they have developed their characteristic properties.

>

>CONTRACT OF ACCESS: agreement between the competent authority and individuals or corporate bodies, establishing the terms and conditions for their access to genetic resources and their subsequent utilization, which must include benefit sharing and the access to and the transfer of technology, as set forth in this Act.

>

>BIOLOGICAL DIVERSITY: variability of living organisms of all origins, comprising land and marine ecosystems and other water ecosystems, and the ecological complexes they integrate, as well as genetic diversity, the diversity of species and of ecosystems.

>

>GENETIC DIVERSITY: variability of genes and of genotypes among and in species; part or the whole of the genetic information contained in biological resources.

>

>ECOSYSTEM: a dynamic complex of plant, animal and microorganism communities, and their inorganic environment, which interact as a functional unit.

>

>GENETIC EROSION: loss or reduction of genetic diversity, due to anthropic action or natural causes.

>

>GENETIC MATERIAL: any biological material of plant, animal, microbial or other origin, which contains functional units of heredity.

>

>COUNTRY OF ORIGIN OF GENETIC RESOURCES: country which possesses these genetic resources in in situ conditions, including those which, having been in such conditions, are now in ex situ conditions under Brazilian jurisdiction.

>

>DERIVED PRODUCT: isolated natural product of biological origin, or structurally based on it, or having been in some way created from the utilization of a traditional knowledge associated with it.

>

>PROVIDER OF TRADITIONAL KNOWLEDGE: community or group empowered, under the terms of this Act and by means of the contract of access, to take part in the decision-making process regarding the provision of the traditional knowledge it possesses.

>

>PROVIDER OF GENETIC RESOURCE: individual or corporate body, indigenous population or local community, empowered, under the terms of this Act and by means of the contract of access, to take part in the decision-making process regarding the provision of a genetic resource, genetic material, or their derived products.

>

>BIOLOGICAL RESOURCES: organisms or parts of them, populations or any other biotic component of ecosystems, comprising genetic resources.

>

>GENETIC RESOURCES: genetic material of actual or potential value, including the genetic variability of species of plants, animals and microorganisms

which make up biological diversity, of present or potential social and economic interest, for immediate utilization or genetic improvement, in biotechnology, in other sciences or in related undertakings.

>

>BENEFIT SHARING: comprises measures to promote and ensure the distribution of outcomes, either economic or not, of research, development, commercialization or licensing derived from the access to genetic resources, including the access, transfer of technology and biotechnology, and the participation in research and development activities related to genetic resources.

>

>SUSTAINABLE USE: utilization of components of biological diversity in such a manner and in such a pace so as not to bring about the long-term reduction of biological diversity, thus preserving its potential to meet the needs and aspirations of the present and future generations.

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>

>Chapter II

>

>General Provisions

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> Article 5. It is incumbent upon every individual and corporate body, and upon the State, in particular, to preserve the genetic patrimony and the biological diversity of the Country, to promote their study and sustainable use and to control the activities of access to genetic resources, as well as to oversee the institutions engaged in prospecting, collection, research, conservation, manipulation, commercialization, among other activities related to such resources, under the terms of this Act, with due regard to the following principles:

>

> I - integrity of the genetic patrimony and of the biological diversity of the Country;

>

> II - national sovereignty over the genetic resources and their derived products, existing in the Brazilian territory;

>

> III - need of justified prior consent of the local communities and indigenous populations for the activities of access to the genetic resources located in the areas they inhabit, to their domesticated and semi-domesticated crops, and to the traditional knowledge they possess;

>

> IV - intellectual integrity of the traditional knowledge possessed by the local community or indigenous population, it being ensured the recognition, protection, fair and equitable compensation for its utilization, and freedom of exchange among their members and with other similar communities and populations;

>

> V - inalienability, restraint of mortgage, and imprescriptibility of rights relating to the traditional knowledge possessed by the local community or indigenous population and to their domesticated and semi-domesticated crops, their utilization being possible, however, with justified prior consent of the respective local community or indigenous population, and by means of fair and equitable compensation, under the terms of this Act;

>

> VI - national participation in the economic and social benefits arising from the activities of access, especially for the benefit of the sustainable development of the areas allowing access to genetic resources and of the local communities and indigenous populations providing traditional knowledge;

>

> VII - priority of implementation in the Brazilian territory to the processing, research and development related to the genetic resources to which access was granted;

>

> VIII - promotion of and support for the various forms of generation, to the benefit of the Country, of knowledge and technologies related to genetic resources and derived products;

>  
> IX - protection and encouragement of cultural diversity, highlighting  
the  
knowledge, innovations and practices of the local communities and indigenous  
populations related to the conservation, improvement, use, management, and  
exploitation of genetic resources and their derived products;  
>  
> X - compatibility with policies, principles and rules related to  
biosafety;  
>  
> XI - compatibility with policies, principles and rules related to food  
safety of the Country;  
>  
> XII - compatibility with policies, principles and rules related to the  
national policies of environmental protection;  
>  
> XIII - compliance with and strengthening of the Convention on Biological  
Diversity and other international agreements regarding the conservation and  
sustainable use of biodiversity.  
>  
> Article 6. The contracts of access to genetic resources, their control  
and  
oversight are aimed at the conservation, study and sustainable use of the  
biological diversity of the Country, the provisions of this Act being  
applied to all individuals or corporate bodies, either Brazilian or foreign,  
as well as to:  
>  
> I - any activity of extraction, use, exploitation, storing or  
commercialization, in the Brazilian territory, of genetic resources or their  
derived products; and,  
>  
> II - any agreement or contract, public or private, regarding genetic  
resources and derived products originating in the Country.  
>  
> Article 7. This Act applies to the inland, coastal, marine and island  
genetic resources and their derived products existing in the Brazilian  
territory or having Brazil as their country of origin, as well as to the  
associated traditional knowledge possessed by local communities and  
indigenous populations, and to the migrating species which, for natural  
causes, are present in the Brazilian territory.  
>  
> Article 8. This Act does not apply:  
>  
> I - to the genetic materials and any components or substances of human  
beings, with any collection or use of these resources, components or  
substances being subject to approval by the Executive Power, upon justified  
prior consent of the individual concerned, while a specific act regulating  
the matter does not come into force;  
>  
> II - to the exchange of genetic resources, derived products, traditional  
crops or associated traditional knowledge, carried out by the local  
communities and indigenous populations, among themselves, for their own  
purposes and based on their customary practices;  
>  
> Article 9. The use, either direct or indirect, of biological resources,  
genetic resources, or genetic materials and derived products in biological  
weapons or in practices which are harmful to the environment or to human  
health is forbidden.  
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>  
>TITLE III  
>  
>INSTITUTIONAL DUTIES  
>  
> Article 10. To ensure compliance with the provisions of this Act, the  
Federal Government shall appoint an agency of the Direct Administration to  
carry out the functions of competent authority and to be responsible for  
authorizing access to genetic resources.  
>

> Article 11. The decisions of the competent authority with respect to the national policy of access and to the authorizations of access shall be signed by a Genetic Resources Committee, to be established by the Executive Power, made up of representatives of the Federal Government, the state governments and the Federal District, the scientific community, the local communities and indigenous populations, the agencies of access, the non-governmental organizations and private companies, with parity of representation of members of the Government and of the communities and non-governmental institutions, the institutions of education and research being included among the latter.

>  
> Sole paragraph. The competent authority shall carry out the functions of executive secretariat of the Genetic Resources Committee, according to the regulations.

>  
> Article 12. In addition to signing contracts of access, it is incumbent upon the competent authority, upon opinion of the Genetic Resources Committee and with due regard to the provisions of this Act and of any other legislation and environmental policy tools:

>  
> I - to prepare, coordinate and carry out the national policy of access to genetic resources, with a view to preserving the diversity and integrity of the national genetic patrimony;

>  
> II - to oversee, control and assess the activities of access to genetic resources developed in the Country;

>  
> III - to support the issuing and updating of periodical reports about the degrees of threat to the national biodiversity and about the actual and potential impacts on its preservation;

>  
> IV - to cooperate with agencies of the Executive Power, international organizations, local communities and non-governmental organizations in the preparation of lists of biological resources threatened of extinction or of deterioration, and of areas in danger of serious loss of biodiversity, as well as in the definition of the necessary mechanisms of control;

>  
> V - to contribute to the disclosure of information regarding threats to the national biological diversity;

>  
> VI - to monitor and promote researches and inventories of the national biological diversity and develop mechanisms to organize and maintain this information;

>  
> VII - to contribute to the development of activities of ex situ conservation of genetic resources;

>  
> VIII - to identify priorities and promote the training of the personnel necessary to the activities of access, as well as to propose training programs.

>  
> Article 13. At any time, in case of danger of serious and irreparable damage deriving from activities carried out under the terms of this Act, the Government, based on a technical opinion and on proportionality criteria, shall adopt measures to prevent such damage and may even stop the activity, especially in the following cases:

>  
> I - endangered species, subspecies, lineages or varieties;

>  
> II - reasons of endemism or rarity;

>  
> III - vulnerable conditions of the structure or functioning of ecosystems;

>  
> IV - adverse effects on human health or on the quality of life or cultural identity of the local communities and indigenous populations;

>

> V - environmental impacts which are undesirable or difficult to control,  
upon urban and rural ecosystems;

>  
> VI - danger of genetic erosion or loss of ecosystems, of their resources  
or components, because of undue or uncontrolled collection of germplasm;

>  
> VII - non-compliance with biosafety or food safety rules and principles;  
and

>  
> VIII - use of resources for purposes contrary to national interests and  
to  
the agreements entered into by the Country.

>  
> Sole paragraph. The lack of absolute scientific certainty regarding the  
cause and effect relationship between the activity of access to genetic  
resources and the damage may not be presented as a reason to disregard the  
adoption of the necessary effective measures.

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>  
>TITLE IV

>  
>ACCESS TO GENETIC RESOURCES

>  
>Chapter I

>  
>Access to Resources in In situ Conditions

>  
> Article 14. Any procedure of access to genetic resources in the  
Brazilian  
territory, in in situ conditions, shall be subject to prior authorization of  
the competent authority and to the signing and publication of a contract  
between the competent authority and the individuals and corporate bodies  
concerned.

>  
> Sole paragraph. The competent authority shall keep a reference file of  
public institutions and non-profit private organizations which carry out  
activities related to the conservation and sustainable use of natural  
resources, referred to as "agencies of access" for the purposes of this Act,  
empowered to request access on behalf of third parties, discuss additional  
contracts and clauses for the protection of rights relating to traditional  
knowledge, and manage projects and investment of funds derived from  
contracts of access.

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>  
>Section I

>  
>The Petition and the Project of Access

>  
> Article 15. To obtain authorization and sign a contract of access to a  
genetic resource, the petitioner or the agency of access must present a  
petition, together with the project of access, including at least the  
following items:

>  
> I - curriculum vitae and complete identification, including those of the  
respective responsible persons:

>  
> a) of the petitioner of access, either an individual or a corporate body  
who will implement the access, and who must have both the legal capacity to  
sign a contract and proven technical capacity, including information about  
all the persons or institutions who will be involved in the procedures of  
access;

>  
> b) of the agency of access, including the file registration and the  
contract with the petitioner of access, as the case may be;

>  
> c) of the holder of the natural resource containing the genetic  
resource,  
or of the collection of genetic resources, as the case may be;

>

> d) of the provider of traditional knowledge;

>

> e) the name of the public institution of education, of research or of public interest domiciled in Brazil, in charge of monitoring the procedures of access.

>

> II - complete information on the timetable, budget and sources of financing for the activities scheduled;

>

> III - detailed and specified description of the genetic resources, derived products or traditional knowledge to which access is intended, including their current and potential uses, their environmental sustainability, and the risks which may arise from such access;

>

> IV - detailed description of the methods, techniques, collection systems and tools to be used;

>

> V - precise location of the areas where the procedures of access will be carried out;

>

> VI - indication of the destination of the material collected and of its probable future use.

>

> Paragraph 1. In the case of access to traditional knowledge, the project referred to in this article shall include an authorization to visit the local community or indigenous population, as well as the information collected, from an oral or a written source, related to the traditional knowledge concerned.

>

> Paragraph 2. The competent authority shall also, when it deems necessary, require the presentation of an environmental impact study and report related to the activities to be carried out.

>

> Article 16. If the petition and project of access are considered complete, the competent authority will grant it a date, hour and number of registration and, within 15 (fifteen) days as of such date, it will take the following steps:

>

> I - publication of an abstract of the petition and of the project of access in the Federal Official Gazette;

>

> II - publication of an abstract of the petition and of the project of access, for 3 (three) consecutive days, in the newspaper of highest circulation figures in the region where the access will take place;

>

> III - when the institution assigned by the petitioner or by the agency of access is not approved, indication of at least three institutions which may be assigned to monitor the procedures of access under the terms of this Act.

>

> Sole paragraph. If the petition and the project of access are deemed incomplete, they may not be accepted by the competent authority, who shall immediately return them for correction.

>

> Article 17. Within 60 (sixty) days as of the publication of the petition and project of access, the competent authority shall start its examination, analyzing the information provided according to article 15, carrying out the necessary inspections, and, based upon a technical-juridical opinion and upon the opinions expressed by any interested party, submitted within the legal time period, it shall make a decision whether to accept the petition or not.

>

> Paragraph 1. The deadline stipulated in the caption may be extended, at the discretion of the competent authority.

>

> Paragraph 2. The petitions of access to take place in conservation units

shall be subject to an opinion of the competent agencies, to be issued without prejudice to the deadline stipulated in the caption.

>  
> Paragraph 3. The petitions of access to take place in indigenous areas shall be subject to an opinion of the competent agencies, to be issued without prejudice to the deadline stipulated in the caption, as well as to the justified prior consent of the indigenous community concerned, under the terms of this Act.

>  
> Article 18. Before the end of the time period for examination, the competent authority, based on the opinion provided for in the previous article, shall grant or dismiss the petition by means of a justified decision.

>  
> Paragraph 1. The decision to dismiss shall be communicated to the interested party and shall be the final step of the procedures, without prejudice to the admissible administrative or judicial appeals.

>  
> Paragraph 2. The decision to grant the petition shall be communicated to the interested party within 10 (ten) days and published in the Official Gazette and in the newspaper of highest circulation figures in the region where the access will take place, being followed by the discussion and preparation of the contract of access.

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>  
>Section II

>  
>The Contract of Access

>  
> Article 19. The following are the parties to the contract of access:

- >  
> a) the State, represented by the competent authority;  
>  
> b) the petitioner of access;  
>  
> c) the agency of access;  
>  
> d) the provider of traditional knowledge or domesticated crop, in the case of contracts of access involving such components.

>  
> Article 20. When the petition of access involves a traditional knowledge or domesticated crop, the contract of access shall include, as an integral part, an annex referred to as a supplementary contract on the utilization of traditional knowledge or domesticated crop, undersigned by the competent authority, by the provider of traditional knowledge or domesticated crop, by the petitioner and the agency of access, as the case may be, stipulating a fair and equitable compensation with respect to the benefits arising from such utilization, the form of such participation being expressly indicated.

>  
> Article 21. During the stage of discussion of the contract of access, the petitioner or agency of access shall submit to the competent authority the additional contracts they may have entered into with third parties, under the terms of this Act.

>  
> Paragraph 1. The public or private institution operating as national support, under an additional contract set forth in this Act, shall be accepted by the competent authority.

>  
> Paragraph 2. The acceptance set forth in the previous paragraph shall not, by any means, render the competent authority responsible for compliance with the respective additional contract.

>  
> Article 22. The contract of access, as determined by the terms and clauses mutually agreed upon by the parties, shall include, in addition to the information provided by the petitioner or the agency of access, all of the

conditions and duties to be fulfilled, as follows:

- >
- > I - definition of the object of the contract, as registered in the petition and project of access;
- >
- > II - determination of the holders of possible intellectual property rights and the commercialization of products and processes obtained, as well as of the conditions for the granting of licenses;
- >
- > III - obligation of the petitioner and of the agency of access not to forego or transfer to third parties the access, management or utilization of genetic resources and their derived products without the express consent of the competent authority, and, as the case may be, of the local communities or indigenous populations who possess the traditional knowledge or domesticated crop, subject to a procedure of access;
- >
- > IV - commitment of the petitioner and of the agency of access to give prior notice to the competent authority about the researches and utilization of the genetic resources and derived products subject to access;
- >
- > V - commitment of the petitioner and of the agency of access to submit to the competent authority the reports and other publications prepared about the genetic resources and derived products subject to access;
- >
- > VI - commitment of the petitioner and of the agency of access to give prior notice to the competent authority about new products or processes obtained, or products or processes different from those stated in the contract;
- >
- > VII - obligation of the petitioner and of the agency of access to submit to the competent authority regular reports of the results attained;
- >
- > VIII - commitment of the petitioner and of the agency of access to request prior authorization of the competent authority for the transfer or transportation of genetic resources and derived products to areas other than those assigned for the procedure of access;
- >
- > IX - obligation to deposit samples of the genetic resource and derived products subject to access, including any associated material, at an institution assigned by the competent authority, single samples being expressly prohibited to leave the Country;
- >
- > X - eventual commitments of confidentiality, without prejudice to the rights arising from traditional knowledge and to the juridical status provided for access by this Act;
- >
- > XI - eventual commitments of exclusive access for the petitioner and the agency of access, provided that they are in compliance with the national legislation on free competition, without prejudice to the rights arising from traditional knowledge and to the juridical status adopted for access by this Act;
- >
- > XII - stipulation of a guarantee which ensures compensation, in the case of non-compliance with the clauses of the contract by the petitioner and by the agency of access;
- >
- > XIII - stipulation of compensation clauses in the case of lack of fulfillment of contract and extra-contract duties, as well as of damages to the environment;
- >
- > XIV - compliance with any other national rules, especially those regarding sanitation control, biosafety, protection of the environment and customs.
- >
- > Article 23. The term of the contract of access shall be determined by the competent authority, the maximum period being 3 (three) years as of the date

of its signing, renewable for periods of the same length as the first one.

>

> Sole paragraph. Without prejudice to other rescissory clauses agreed upon, the competent authority may rescind the contract of access at any time by virtue of a provision of this Act.

>

> Article 24. The data and information contained in the petition, proposal, authorization and in the contract of access may be subject to confidential treatment, in case third parties may make unfair commercial use of them, except when their disclosure is necessary to the protection of public interest, of the environment or of rights regarding traditional knowledge.

>

> Paragraph 1. For the purposes stated in the caption, the petitioner or the agency of access shall submit a justified petition, together with a non-confidential summary, to be part of the published documents.

>

> Paragraph 2. The confidential data shall be kept by the competent authority and may not be disclosed to third parties, except by means of a court order.

>

> Paragraph 3. Confidentiality may not be applied to the information referred to in items I, IV and V of article 15.

>

> Article 25. The competent authority may sign, with state-owned or public utility research centers and universities, domiciled in the Country, agreements to provide for the carrying out of one or more contracts of access, in compliance with the procedures stated in this Act, it being waived, in such cases, the need to assign an institution to monitor the activities of access, in accordance with the provisions of articles 15 and 16.

>

> Article 26. The contracts signed in violation of this Act shall be null and void, and their nullity may be decreed ex officio by the competent authority, or at the petition of any person.

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>Section III

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>The Provisional Bioprospecting Contract

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> Article 27. Authorizations may be requested and contracts of access may be signed without compliance with items III and VI of article 15, in which case they shall be referred to as provisional authorizations and contracts, in areas having their location and size defined by the competent authority, with due regard to the ecological zoning of the Country, the following being observed:

>

> I - the contract mentioned in this article shall be in force for not more than 1 (one) year as of the date of its signing, not being renewable;

>

> II - the contract mentioned in this article shall provide for a detailed report of the bioprospecting which was carried out, to be submitted to the competent authority within 120 (one hundred and twenty) days as of the date of expiration of the contract, and which will be considered confidential for 1 (one) year as of the expiration of the contract;

>

> III - the commercial utilization of products or processes obtained from procedures of access carried out under the terms of provisional contracts shall not be authorized;

>

> IV - the access to the genetic resources found in the area shall be subject to an authorization and a contract prepared in accordance with the previous articles;

>

> V - the party to the contract mentioned in this article shall have priority to receive authorization and to sign a contract of access to the

genetic resources prospected in the area, and this priority may be used within 1 (one) year as of the expiration of the contract.

>

>Section IV

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>The Additional Contracts of Access

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> Article 28. The additional contracts of access are those necessary to the implementation and development of activities relating to access to genetic resources, and that have been entered into by the petitioner or the agency of access and:

>

> a) the owner or holder of the natural resource which contains the genetic resource;

>

> b) the holder of a collection of genetic resources in ex situ or in situ conditions;

>

> c) the public or private institution assigned, under the terms of this Act, to monitor the activities of access, involving obligations which should not be part of the contract of access.

>

> Sole paragraph. The additional contracts shall stipulate a fair and equitable share for the parties in the benefits arising from access to the genetic resource, the form of such sharing being expressly indicated.

>

> Article 29. Without prejudice to the provisions of the additional contract and notwithstanding such a contract, the public or private institution shall be required to cooperate with the competent authority in the monitoring and controlling of the activities of access, and to submit reports about the activities under its responsibility, in the manner and as often as the authority determines, the suitability to the nature of the activities under the contract being ensured.

>

> Article 30. The signing of an additional contract does not authorize access to a genetic resource, and its contents must be compatible with the provisions of the contract of access and of this Act.

>

> Article 31. The additional contracts shall include a suspensive clause, conditioning their implementation to the carrying out of the contract of access.

>

> Article 32. The nullity of the contract of access causes the nullity of the additional contract.

>

> Paragraph 1. The competent authority may rescind the contract of access when the nullity of the additional contract is declared, if the latter is essential to the completion of the access.

>

> Paragraph 2. The alteration, suspension, or rescission of the additional contract may imply the alteration, suspension, or rescission of the contract of access by the competent authority, if they have a substantial effect on the conditions of the latter.

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>Section V

>

>The Implementation and Monitoring of the Contracts of Access

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> Article 33. The procedures of access must be monitored by a Brazilian institution of education or of research, either public or private, of undisputed repute in the area subject to the procedure, approved by the competent authority and hired by the petitioner or by the agency of access, before the authorization.

>

> Sole paragraph. The institution so assigned has joint and several liability for the fulfillment of the obligations undertaken by the

individual or corporate body authorized to carry out the procedure of access.

>  
> Article 34. It is incumbent upon the competent authority, together with the institution assigned to monitor the authorized activities, to monitor the compliance with the provisions of the authorization and of the contract of access and, especially, to ensure that:

>  
> I - access is obtained exclusively to the authorized genetic resources and derived products, when it is not the case of a provisional contract, and in the established area;

>  
> II - the environmental conditions of the region where the activities take place are preserved;

>  
> III - there is permanent direct participation of an expert from the monitoring institution;

>  
> IV - a detailed account of the activities carried out and of the destination of the samples collected is presented;

>  
> V - samples of the species collected are handed over to be conserved *ex situ* by the institution assigned by the competent authority.

>Section VI

>Compensation

>  
> Article 35. In addition to the payments and sharing of benefits agreed upon by the petitioner, the agency of access, the providers of traditional knowledge and the other parties to the additional contracts, a fair compensation is ensured to the State, in the form of money or commercialization rights, in the manner stipulated by the contract of access signed by the competent authority and the other parties.

>  
> Article 36. The forms of compensation stated in this section shall make up a special fund for the conservation, research and inventory of the genetic patrimony, designed to be a tool of financial support to projects related to the access to and the conservation of genetic resources and to the knowledge associated with genetic resources.

>  
> Sole paragraph. The projects stated in this article shall be selected by the competent authority, whose decision shall be confirmed by the Genetic Resources Committee, subject to the availability of funds and to compatibility with the principles established in this Act.

>Section VII

>General Provisions for the Contracts of Access

>  
> Article 37. The permits, authorizations, licenses, contracts and other documents regarding the research, collection, acquisition, storing, transportation, or any other similar activity related to the access to genetic resources, in force at the date of publication of this Act, in accordance or not with the provisions thereof, do not condition neither presuppose the authorization for access.

>  
> Article 38. The individuals or corporate bodies authorized to develop activities of access to genetic resources are required to transmit to the competent authority any information regarding the transportation of the material collected, and they also have civil, criminal and administrative responsibility for the inadequate use or handling of such material and for the adverse effects of such activities.

>  
> Article 39. The authorization or contract of access to genetic resources do not imply authorization to remit them abroad, in which case authorization

must be previously requested and justified before the competent authority.

>

> Sole paragraph. It is totally forbidden to remit single samples abroad, without due regard to the provisions concerning the mandatory deposit of samples of every genetic resource or derived product which may have been subject to access.

>

> Article 40. It is illegal to use genetic resources and derived products for purposes of research, conservation, industrial or commercial applications, or any other purposes, if the access has not taken place according to the provisions of this Act.

>

> Article 41. The rights upon genetic resources and derived products obtained or used in violation of this Act shall not be recognized, and the certificates of intellectual property or similar certificates upon such resources or derived products or upon products or processes resulting from access under such circumstances shall not be considered valid.

>

> Sole Paragraph. The depositors of intellectual creations subject to protection by copyright, industrial property, crops or any other mode of intellectual property, being based on any genetic resources or traditional knowledge, as well as those based on the cultural or artistic traditions of local communities or indigenous populations, must present a certificate of approval by the communities or populations, to be obtained before requesting legal protection of the creation and in compliance with the laws of the country of origin of the genetic resource or of the traditional knowledge.

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>Chapter II

>

>The Access to Resources in Ex situ Conditions

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> Article 42. The competent authority may sign contracts of access to genetic resources which are deposited in ex situ conservation centers located in the Brazilian territory, or in other countries, provided that Brazil is the country of origin of the resources.

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> Sole paragraph. The provisions regarding access to resources in in situ conditions shall apply, where appropriate, to access to resources in ex situ conditions.

>

> Article 43. The genetic material transfer agreements or similar agreements between ex situ conservation centers or between such centers and third parties, either within the Brazilian territory or through importation or exportation, constitute modes of contracts of access.

>

> Paragraph 1. The conservation center providing the genetic resource shall submit a petition of access to the competent authority, who will publish an extract of the petition in the Official Gazette within 15 (fifteen) days as of the respective date.

>

> Paragraph 2. The agreements stated in the caption shall be valid provided that they are compatible with the conditions agreed upon in the original contract of access to the resource exchanged, and with the intellectual property rights concerned.

>

> Paragraph 3. In its analysis of the petition of access, the competent authority may demand financial compensation, under the terms of this Act, which compensation shall be mentioned in the genetic material transfer agreement or similar agreement.

>

> Paragraph 4. In its analysis of the petition of access, the competent authority must take into consideration the opinions presented by any interested party.

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> Paragraph 5. The agreement may only be signed by the conservation center

and the interested party after validation of the proposal of agreement by the competent authority.

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>TITLE IV

>

>THE PROTECTION OF TRADITIONAL KNOWLEDGE

>ASSOCIATED WITH GENETIC RESOURCES

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> Article 44. The State recognizes and protects the rights of local communities and indigenous populations to benefit from their traditional knowledge collectively, and to receive compensation for the conservation of genetic resources, by means of payments in money, goods, services, intellectual property rights or other mechanisms.

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> Paragraph 1. It is incumbent upon the Public Prosecution to take judicial and extrajudicial measures to protect Brazilian genetic resources and to defend the interests and rights of local communities and of indigenous populations.

>

> Paragraph 2. The competent authority shall create a national reference file, where the local communities, the indigenous populations, and any other interested party may deposit records of knowledge associated with genetic resources.

>

> Paragraph 3. Every record deposited in the national reference file shall be submitted to an ethnologic appraisal, and shall be used as a basis for decisions concerning the terms of the contract of access.

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> Paragraph 4. By means of agreements, the collections of traditional knowledge belonging to other institutions, either Brazilian or foreign, may be deposited in the national reference file, for the same purpose of the preceding paragraph.

>

> Paragraph 5. The records mentioned in this article are not mandatory, and their non-existence are not a condition for, neither does it preclude the exercise of any right set forth in this Act.

>

> Article 45. The local communities and indigenous populations have exclusive rights over their traditional knowledge, and they alone are entitled to surrender them, by means of the types of contract set forth in this Act.

>

> Sole paragraph. The proposal of contract of access may only be accepted if it is preceded by justified prior consent of the local community or indigenous population, obtained according to clear and precise rules which shall be stipulated for this procedure by the competent authority.

>

> Article 46. The local communities and indigenous populations are ensured of the right to the benefits arising from access to genetic resources carried out in the areas they inhabit, defined under an additional contract referred to in this Act, and following justified prior consent as stated in the preceding article.

>

> Sole paragraph. The local communities and indigenous populations may request that the competent authority deny access to genetic resources in the areas they inhabit, if they believe that such activities threaten the integrity of their natural or cultural patrimony.

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> Article 47. Intellectual property rights with respect to products or processes related to traditional knowledge associated with genetic resources or derived products shall not be recognized if the access has not taken place according to the provisions of this Act.

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>TITLE V •

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>TECHNOLOGY DEVELOPMENT AND TRANSFER

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> Article 48. The State shall promote and support the development of national sustainable technologies for the study, use and improvement of autochthonous species, lineages and varieties, and shall support the traditional uses and practices of local communities and indigenous populations.

>

> Sole paragraph. For the purposes of this article, the State shall promote the survey and evaluation of national and traditional biotechnologies.

>

> Article 49. The use of foreign biotechnologies will be permitted, whenever these comply with this Act and with other regulations on biosafety, and the interested company takes full responsibility for any damage to health, the environment or traditional cultures.

>

> Article 50. Arrangements shall be set up to guarantee and facilitate, for the national researchers and providers of genetic resources, the access to and transfer of technologies that are relevant to the conservation and sustainable use of biological diversity, or that use genetic resources without harming the natural and cultural environment of the Country.

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> Article 51. In the case of technologies which are subject to patents or other intellectual property rights, it shall be guaranteed that the procedures of access and transfer of technology shall be effected with adequate protection to such rights.

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>TITLE VI

>

>VIOLATIONS AND ADMINISTRATIVE AND CRIMINAL SANCTIONS

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> Article 52. The conducts and activities which violate the provisions of this Act shall be punished with administrative and criminal sanctions.

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> Sole paragraph. The administrative and criminal sanctions may be cumulative, being independent from each other.

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> Article 53. As to the violations defined in this Act, liability falls upon the abettor, principal, director, administrator, member of the board and of the technical agency, auditor, manager, representative, or agent of a corporate body who, being informed or having the duty to be informed of the criminal conduct of a third person, fails to prevent such a conduct while having the power to act to prevent it.

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> Article 54. The corporate bodies shall be sentenced as provided in this Act, whenever the violation is perpetrated upon decision taken by their legal or contractual representatives, or by their collegiate bodies, in the interest or to the benefit of such entities.

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> Sole paragraph. The liability of corporate bodies does not preclude that of individuals, authors, co-authors, or persons participating in the same action.

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> Article 55. Without prejudice to the provisions of this Act, the agent, whether he is guilty or not, is required to compensate the damages caused to the environment and to third parties affected by his actions.

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> Article 56. The acquisition and commercialization of genetic resources and derived products, as well as their remittance abroad, and the use of traditional knowledge, without the authorization stated in this Act, constitute a crime subject to imprisonment of 1 (one) to 4 (four) years,

