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## Brazil

## Biotechnology

## Update on Biotechnology Issues in Brazil

### 2004

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**Report Highlights:**

Brazil is moving closer to a more complete authorization of the use of agricultural biotechnology. A recent court panel ruled in favor of the authority of the Brazilian Technical Commission of Biosafety (CTNBio) to waive environmental study reports, but upheld the ruling against Monsanto Round Up Ready Soybeans (RRS). Legal specialists believe that this decision will have a positive impact in the Senate where the biosafety bill approved in the House is currently under review. However, due to upcoming municipal elections in October and the mid-year Congressional recess, the bill may not be voted on until the end of the year.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
Unscheduled Report  
Brasilia [BR1]  
[BR]

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## Update on Biotech issues in Brazil

On June 28, 2004 a three-judge panel of the Regional Federal Court (TRF in Portuguese), decided on the merits of a previous rule by the 6<sup>th</sup> Federal Circuit ("lower court") on Monsanto's Round Up Ready Soybean (RRS) case. The final panel decision (two votes against one) ruled as follows:

- a) In favor of the legality (authority) of the National Technical Commission on Biosafety (CTNBio) to waive environmental impact studies and reports for biotech products. The lower court had ruled in 1999 that CTNBio had no authority to waive such environmental reports and ruled in favor of the Consumer Protection Institute (IDEC) of Sao Paulo and Greenpeace who filed the court case against Monsanto.
- b) In favor of the lower court case that ruled against Monsanto and required environmental study reports for their biotech product (RRS).

Monsanto already declared they will appeal against the decision of the court panel that requires environmental study reports for its RRS, and IDEC also declared they will appeal against the court panel for recognizing the authority of CTNBio for authorizing biotech products for commercial use. IDEC believes that CTNBio has only a "consultative" power, and not a deliberative power to approve the final use of biotech products. The appeal by both parties will be to the Superior Justice Court (TSJ, in Portuguese).

The TRF final decision (Attachment 1) is a victory for the Brazilian scientists that are lobbying for CTNBio to hold its authority to approve biotech products, without environmental study reports and a loss to Monsanto that continues to have its RRS prohibited by the courts, except for the 2004/05 crop year, which plantings are under the terms of law 10,814/03.

CTNBio has not publicly released any statement until its board meeting within 15 days. There are 15 biotech products pending approval by CTNBio.

Legal analysts in Brasilia believe that this recent decision by the three judges will have an impact on the current debate in the Senate regarding the Draft Bill on Biosafety approved in the House, which withdraws the power of CTNBio to approve commercial use of biotech products, and allowed CTNBio only to approve research projects on biotechnology. Attachment 2 provides a translation of the Draft Bill as sent by the Office of the President to Congress in October 2003.

The Senate may not have enough time to approve (or change) the Draft Bill approved by the House because Congress will go shortly into their mid-year recess and municipal elections in October will restrain Congress from voting on important issues. If this scenario materializes, a new Provisional Measure will need to be issued by the President of Brazil to allow the planting of the 2004/05 soybean crop, starting in late August or early September in some areas in the south region.

## Attachment 1: Court Decision

5<sup>th</sup> Panel of the TRF [Regional Federal Court] –1<sup>st</sup> Region closes decision on transgenic soybean  
Monday, June 28, 2004

The judgment on merits at the TRF – 1<sup>st</sup> Region that addresses the validity of the authorization for the growth and trade of transgenic soybean granted by CNTBio [National Technical Commission on Biosafety] in commercial scale was closed today at 09:00 p.m. The appeals court judges of the 5th panel decided, by majority of votes, to acknowledge the legality of CNTBio's work. The need for the performance of an environmental impact assessment prior to the release of the soybean was determined on a decision issued by a lower court judge. Dissatisfied with the decision, the Federal Government and Monsanto and Monsoy corporations appealed to the TRF. Once the trial started, the Appeals Court Judge Antônio Ezequiel da Silva requested an examination of the court records and today issued his decision stating that "it is incumbent upon CNTBio's discretion to decide on the need to request the performance of Environmental Impact Assessment (EIA) and of the Report on Impact on the Environment (RIMA), as a condition to release it in the environment and for commercial use of genetically modified organisms (GMOs)", thus regarding CNTBio's action as legal. Federal Associate Judge João Batista Gomes voted for the need of the Environmental Impact Assessment so that the democratic principle of protection to man and to the environment was complied with. The two opinions closed the judgment of the panel, since Federal Reporting Judge Selene Maria de Almeida had already issued her opinion favorable to the appeals, in which she was followed by Federal Associate Judge João Batista Moreira, whereby Federal Associate Judge João Batista Moreira was defeated. The Reporting Judge's opinion stated that the agency in charge of granting the authorizations, the National Commission on Biosafety – CNTBio – had been backed by a scientific study with all the necessary technical requests, which would render her opinion valid. Although Federal Associate Judge Antônio Ezequiel had voted likewise the Reporting Judge, he did not follow part of the vote that rendered null the initial decision granted in the preparatory injunction of the preparatory civil action filed by the Attorney General in the public interest, thus remaining defeated the reporting judge as far as the rejection of the injunction. With the pending injunction issue, the actual release and trade of transgenic soybean in commercial scale would depend on this latter. AC 1998.34.00.027682-0/DF Public Relations of the TRF-1<sup>st</sup> Region - Marília Maciel Costa

## Attachment 1: Draft Bill on Biosafety

### Note on Biosafety Bill

1. This Bill establishes safety standards and mechanisms for controlling the activities involving genetically modified organisms (GMOs) and their derivatives, creates the National Biosafety Council (CNBS), restructures the National Biosafety Commission (CTNBio), and provides for the National Biosafety Policy as well as other provisions.
2. The final text is the result of work conducted by an Inter-Ministerial Group established by President Lula in February 2003 which was stepped up as from last June.
3. The Bill is built on 8974/95 Law, the current Biosafety Law, and includes improvements resulting mostly from suggestions of the organized sectors of society through discussion seminars promoted by the Inter-Ministerial Group.
4. The purpose of the Bill is to give the country well defined, long-lasting legislation on Biosafety that can prevent future court disputes, encourage scientific research and protect people health and environment.
5. The National Biosafety Commission (CTNBio) will be made up of 26 members, including 10 from the scientific community, 8 from the Federal Government, and 8 from civil society. Since civil society and Federal Government representatives must necessarily have acknowledged professional competence in their areas of expertise, a high-level CTNBio will be ensured. And society's greater participation will allow the merit review to be as multidisciplinary as possible while keeping its technical-scientific character.
6. CTNBio will play a consulting and advisory role and will produce binding opinions for registration and inspection bodies when applications are not granted on the ground that the GMO is not biosafe. In cases of favorable opinions, registration and inspection bodies will work on a complementary basis according to their legally established competences.
7. The qualification of CTNBio's members and the increased representation of both scientific community and civil society will contribute decisively to restore CTNBio's credibility.
8. The Bill has maintained the competences of registration and inspection bodies, thus preventing competence conflict with CTNBio.
9. The twelve-minister National Biosafety Council (CNBS) has the major role of advising the President of the Republic on GMO issues. The Council is responsible for formulating the National Biosafety Policy and making strategic decisions.
10. CNBS's involvement in merit issues is not an option; such issues are the responsibility of CTNBio and registration and inspection bodies. Only by the order of the President of the Republic or at its members' request, will CNBS express its view about the convenience and opportuneness of cases involving GMO releases, when favorable views are presented by CTNBio and registration and inspection bodies.
11. The Bill provides that, whenever a risk is involved, a Precautionary Principle applies. The Precautionary Principle provision meets the claim of all those that expressed their views on the issue.

12. The Biosafety Information System (SIB) is also established to give publicity to actions and documents related to Biosafety in the country. This System will be managed by the Ministry of Science and Technology, which will also host CTNBio. SIB is intended to give greater publicity to CTNBio's actions.

13. The Bill provides that GMO research will have simplified treatment.

14. Funding from penalties enforcement will be allocated to public laboratories to conduct GMO research.

In the light of the foregoing, the Office of the Chief of Staff for the Presidency considers that, once passed, the released Biosafety Law Bill will put an end to the court dispute period that has been going on for years, as it will harmonize the current national legislation and assure that technical-scientific analyses will prevail over occasional political decisions related to the release of GMOs. Its provisions will give the country an adequate process of support for GMO research and licensing that will be able to ensure agility and safety in the treatment of this important technology.

Brasília, October 31, 2003  
Office of the Chief of Staff for the Presidency

### **Proposed Bill**

Sets up safety standards and inspection mechanisms to control activities involving genetically modified organisms - GMOs and GMO derivatives, establishes the National Biosafety Council - CNBS, restructures the National Biosafety Commission - CTNBio, establishes the National Biosafety Policy and makes other provisions.

THE NATIONAL CONGRESS decrees:

#### CHAPTER I

##### PRELIMINARY PROVISIONS

Art.1· This Law establishes safety standards and mechanisms for inspection of GMOs and GMO derivative construction, cultivation, production, handling, transport, transfer, commercialization, import, export, storage, research, consumption, release or disposal, aiming at protection of human, animal and plant life and health and the environment.

Art.2·The activities mentioned in art. 1 must comply with this Law and Law no. 6.938, of August 31, 1981 and its regulations to effectively prevent and mitigate threats to human health and the environment under precautionary principles.

Art.3· Activities and projects related to education involving manipulation of living organisms, scientific research, technological development, and industrial production involving GMOs and their derivatives shall be conducted by public or private entities which shall be held responsible for securing compliance with this Law and its regulations, as well as for potential effects or consequences arising from non compliance.

§1 For the purposes of this Law, activities and projects conducted by public or private entities are those carried out in the facilities of such public or private entities or elsewhere under their technical or scientific responsibility.

§ 2 The activities and projects in this article shall not be carried out by individuals as independent autonomous agents even if they have an employment relationship or any other type of relationship with companies or other entities.

§3 Without prejudice to the application of biosafety standards set forth in this Law, the Government shall adopt simplified treatment to research activities respecting the purpose of the activity, and the type and class of GMO risk, as provided for in the proper regulation.

§4 Domestic, foreign or international public or private organizations that fund or sponsor the activities or projects mentioned in this article shall require the proper Specific Business License issued by the relevant registration and inspection agencies and entities listed in art.14, otherwise they shall be held co-responsible for the effects of non compliance with such provisions.

Art.4 For the effects of this Law, the following definitions shall apply:

I-organism: any biological entity capable of reproducing or transferring genetic material, including viruses, prions and other classes that may come to be known;

II-deoxyribonucleic acid (DNA), ribonucleic acid (RNA): genetic material that encodes genetic information determining inheritance of specific traits by offspring;

III-recombinant DNA/RNA molecules: molecules resulting from modification of natural or synthetic DNA/RNA segments, as well as those resulting from their multiplication;

IV-genetically modified organism (GMO): an organism whose genetic material (DNA/RNA) has been modified by any genetic engineering technique;

V-genetic engineering: production and manipulation of recombinant DNA/RNA molecules;

VI - GMO derivative: product obtained from GMO that lacks capacity for autonomous replication or does not include any viable GMO form;

VII- human germ cell: parent cell that produces gametes found in male and female glands and its direct descendants in any degree of ploidy.

Sole paragraph - GMOs do not include organisms resulting from techniques that involve direct introduction into an organism of hereditary material, provided that such techniques do not involve the use of recombinant DNA/RNA molecules or GMOs, such as: in vitro insemination, conjugation, transduction, transformation, polyploid induction and any other natural process.

Art. 5 This Law shall not apply when genetic modification is obtained through the following techniques, provided the GMO is not used as receptor or donor.

I- mutagenesis;

II- formation and use of somatic cells from an animal hybridome;

III-cell fusion, including protoplasm fusion, of plant cells, which can be produced through traditional culture techniques;

IV- self-cloning of non-pathogenic organisms when processed in a natural fashion.

Art.6 The following activities related to GMOs and GMO derivatives are forbidden:

I-any genetic manipulation of living organisms or *in vitro* handling of natural or recombinant DNA/RNA carried out outside the standards provided for in this Law;

II- genetic manipulation of human germ cells;

III- *in vivo* intervention in human genetic material, except for required diagnostic, prevention or treatment procedures for diseases or defects, as previously approved by the National Biosafety Commission - CTNBio and relevant registration and inspection agencies; in cases of clinical research approval by the National Commission for Ethics in Research - Conep -of the Ministry of Health National Health Council is required;

IV- production, storage or manipulation of human embryos intended to be used as available biological material;

V *in vivo* intervention in the genetic material of animals, except for cases in which such intervention constitutes a significant advance in scientific research and in technological development, according to ethical principles such as the principle of responsibility and the principle of prudence, and as previously approved by CTNBio;

VI- release or disposal into the environment of GMOs and their derivatives in violation of standards set by CTNBio and registration and inspection agencies and entities, and as provided for by the regulation of this Law;

VII- supplying products without proper information to users as to release criteria and technical requirements applicable to biosafety maintenance;

VIII- project implementation without previous registration of the GMO research institution and its technician in charge and CIBio;

IX- environmental release of any GMO and GMO derivatives without CNTBio approval or licensing from the responsible environmental agency or entity as published in the Federal Official Journal;

X- operation of laboratories, vivaria, greenhouses and trial stations that manipulate GMOs and their derivatives without proper observation of the standards provided for in this law and biosafety legislation;

XI-absence of adequate activities related to investigation of accidents occurred in the course of research and projects in genetic engineering or failure to submit the accident report to the relevant authority within a maximum of five days from occurrence;

XII- project implementation without recording project progress and follow-up;

XIII- failure to promptly notify CTNbio and public health and environmental authorities about accidents that may result in dissemination of GMO and their derivatives;

XIV- absence of the necessary means to provide communication to CTNBio and health, environmental and plant and animal health protection authorities, the public, and institution or company employees on potential risks and actions to be taken in the occurrence of hazards.

## CHAPTER II

### NATIONAL BIOSAFETY COUNCIL - CNBS

Art.7. It is hereby established the National Biosafety Council - CNBS, a counseling body to the President to formulate and implement the National Biosafety Policy –PNB. CNBS shall set the principles and guidelines for administrative action by relevant federal agencies and entities, provide appraisal, if necessary, as a body of last resort on aspects involving the convenience and opportuneness of requests for authorization of activities involving construction, cultivation, production, manipulation, transport, transfer, commercialization, import, export, storage, research, consumption, release or disposal of GMO and their derivatives.

Sole paragraph. CNBS´s decisions as a body of last resort on aspects involving the convenience and opportuneness of activities shall require previous favorable opinion by CTNBio and relevant registration and inspection agencies and entities, as well as determination by the President or request from any of its members.

Art.8·CNBS comprises the following members:

I- Minister and Chief of Staff for the Presidency who will be the chair;

II-Secretary for Government Communication and Strategic Management of the Office of the President;

III-Minister of Science and Technology;

IV-Minister of Agrarian Development;

V-Minister of Agriculture;

VI-Minister of Justice;

VII-Minister of Health;

VIII-Special Minister for Food Security and Combating Hunger;

IX-Minister of the Environment;

X-Minister of Foreign Relations;

XI-Minister of Development, Industry and Trade; and

XII-Special Secretariat of Aquaculture and Fisheries.

§1 CNBS shall meet any time when summoned by the Minister and Chief of Staff for the Presidency, or by request of four of its member, and shall issue decisions as resolutions.

§2 CNBS may invite representatives from other agencies or public and private entities to participate in the meetings.

### CHAPTER III

#### NATIONAL BIOSAFETY COMMISSION - CTNBio

Art.9 CTNBio is a collegial, consultative and deliberative body within the Ministry of Science and Technology that supplies technical support and counsel to the Federal Government in the formulation, updating and implementation of the national biosafety policy (PNB) for GMOs and their derivatives, as well as establishment of safety standards and technical opinion on protection of human, animal and plant health and the environment in activities that involve construction, cultivation, production, manipulation, transport, transfer, commercialization, import, export, storage, research, consumption, release or disposal of GMO and their derivatives.

Sole paragraph. CTNBio shall exert its jurisdiction by monitoring technical progress and development in biosafety, biotechnology, bioethics and related areas, aiming at protection of human, animal and plant life and health and the environment.

Art.10. CTNBio comprises incumbent members and deputies nominated by the Minister of Science and Technology forming a body of twenty-six Brazilian citizens of widely recognized expertise and outstanding professional activity in areas such as biology, molecular biology, immunology, ecology, bioethics, genetic, virology, entomology, public health, labor safety and health, biochemistry, pharmacology, animal and plant pathology, microbiology, toxicology, biotechnology or biosafety:

I- ten specialists of well-known technical and scientific expertise and full professional activity representing scientific societies, two members being nominated by CNBS for each of the following areas: human health, animal health, plant health, environment and social science;

II- one representative of each of the following bodies nominated by the relevant authority:

- a) Ministry of Science and Technology;
- b) Ministry of Health;
- c) Ministry of Environment;
- d) Ministry of Agrarian Development;
- e) Ministry of Agriculture;
- f) Ministry of Development, Industry and Trade;
- g) Special Secretariat of Aquaculture and Fisheries;
- h) Special Ministry for Food Security and Combating Hunger;

III - a representative of legally established institution in the area of consumer protection;

IV - a representative of legally established institution in the biotechnology business sector;

V - a representative of legally established institution in the area of health;

VI - a representative of legally established environment protection institution;

VII - a representative of legally established institution in the area of bioethics;

VIII - a representative of legally established institution in the agribusiness sector;

IX - a representative of legally established family farming protection institution;

X - a representative of legally established workers' protection institution.

§1 Each incumbent member shall have a deputy that will participate in activities in case of incumbent member impossibility to participate.

§2-This Law will define the operating aspects of CTNBio and the nomination procedures of CTNBio members, mentioned in subsection I and subsections III to X.

§3 CTNBio members must be guided by the strict observation of ethical and professional concepts, and shall abstain from deliberations that would meet their professional or personal interests, under penalty of losing their mandate, as defined by the regulation.

§4 Quorum for CTNBio deliberations shall be 17 favorable votes.

§5 Quorum for CTNBio meetings shall be 17 members, including, necessarily, the presence of at least one representative of each area mentioned in subsection I of this article.

§6 When necessary, bodies and entities of the Administration may request their participation in CTNBio meetings in order to address subjects of their special interest.

§7 Exceptionally, members of the scientific community, the public sector and the civil society may be invited to attend the meetings, with the rights of voice, but no rights to vote.

§8 The Minister of Science and Technology will appoint the chairman of the Committee, from a list made by the Committee, for a two-year mandate, renewable for up to two consecutive periods.

Art. 11 CTNBio will constitute sectoral and permanent subcommissions on human health, animal, plant and environment, besides extraordinary subcommissions intended for previous analysis of themes to be submitted to the plenary of the Commission.

§1. Both incumbent members and deputies take part in the sectoral subcommissions, and are in charge of distributing the proceedings for analysis.

§2. Operation and coordination of sectoral subcommissions shall be set in the CTNBio bylaws.

Art.12.CTNBio has the authority to:

I- provide consultative technical support and counsel to CNBS in formulation of PNB for GMOs and their derivatives;

II- set up, according to its jurisdiction, risk assessment and monitoring criteria for GMOs and their derivatives;

III- conduct risk assessments, on a per-case basis, for activities and projects involving GMOs and their derivatives submitted to its analyses;

- IV – follow-up development and scientific progress in biosafety of GMOs and their derivatives;
- V- establish contacts with national and international institutions engaged in GMO biosafety;
- VI - set up standards for activities and projects related to GMOs and their derivatives;
- VII –propose studies and research in the field of GMO and GMO derivative biosafety;
- VIII –establish operation mechanisms for Internal Biosafety Commissions within institutions involved in education, scientific research, technological development and industrial production related to GMOs and their derivatives;
- X- issue opinions on quality assurance in biosafety in respect to the Specific Business License set forth in art. 14, II, for development of activities involving GMOs and their derivatives in laboratories, institutions or companies;
- X- establish biosafety requirements for the authorization of operation for laboratories, institutions or companies that will develop activities related to GMOs and their derivatives;
- XI – establish the biosafety level to be applied to GMOs and their uses, and the respective safety measures and procedures for GM and GMO derivative use, according to standards set forth in the regulation of this Law;
- XII- classify GMOs according to risk classes in accordance with criteria established in the regulation of this Law;
- XIII-issue preliminary and conclusive technical opinions, on a case-by-case basis, regarding the activities, consumption or release of GMO and GMO derivatives, including their classification pursuant to risk degree and biosafety level requirements, as well as the safety measures required and restrictions for use, forwarding it to the relevant registration and inspection agencies and entities;
- XIV- issue normative resolutions on issues within its jurisdiction;
- XV-give technical support to the relevant agencies in investigating accidents and illnesses, identified during projects and activities applying DNA/RNA recombinant techniques.
- XVI-give technical support to inspection agencies and entities in the exercise of their duties related to GMOs and GMO derivatives;
- XVII-publish in the Federal Official Journal the requests preceding the analyses and the opinions on the proceedings under its consideration, and give full publicity, through the Biosafety Information System (SIB), to its agenda, on-going proceedings, annual reports, minutes of meetings and any other non-confidential information of commercial interest, pointed out by the applicant and deemed so by CTNBio;
- XVIII-identify, in order to give subsidies to the agencies and entities set forth in art. 14, the activities and products originating from GMOs and GMO derivatives that potentially cause significant damage to the environment and may cause risks to human health;
- XIX-provide additional information to the technical opinion, at request of registration and inspection agencies and entities, in order to clarify specific issues concerning GMOs and GMO derivatives;

XX-reconsider its decisions, at its own discretion or at request of CNBS or any registration and inspection agencies and entities, based in new scientific facts or knowledge deemed as relevant to GMO or GMO derivative biosafety, at the time and manner set forth in the bylaws;

XXI-present a bylaw proposal to the Minister of Science and Technology.

§1 CTNBio technical and conclusive opinion binds, if unfavorable, the other administration agencies and entities pursuant to GMO and GMO derivative biosafety aspects under its consideration.

§2 By issuing an opinion favorable to its continuation, CTNBio will forward the corresponding proceeding to the agencies and entities set forth in art. 14 herein, for possible registration and licensing under the applicable law.

§3 As part of the discovery procedure, CTNBio must request to registration and inspection agencies and entities a term of reference with biosafety requirements for assessment of GMOs and GMO derivatives.

§4 CTNBio's conclusive technical opinion must provide a summary of its technical rationale and document compliance with the terms of reference, highlighting the safety measures and restrictions for use of GMOs and GMO derivatives in the light of the particularities of each region in the country, in order to guide and give subsidies to registration and inspection agencies and entities in the exercise of their duties.

§ 5 Derivatives whose GMO has been approved by CTNBio will not be submitted to CTNBio analysis and technical opinion.

§ 6 Individual or legal entities participating in any phases of crop production, commercialization or transport of GMOs that were granted a favorable, conclusive and preliminary technical opinion by CTNBio and a favorable commercialization decision issued by the agencies and entities set forth in art. 14 herein are waived from presenting the Specific Business License set forth in subsection IX of this article.

Art.13 CTNBio may conduct public hearings, which are compulsory for commercial clearance requests.

## CHAPTER V

### REGISTRATION AND INSPECTION AGENCIES AND ENTITIES

Art. 14 Registration and inspection agencies and entities from the Ministries of Health, Agriculture, Environment and the Special Secretariat of Aquaculture and Fisheries, according to CTNBio technical opinion, CNBS deliberations and the mechanisms established during regulation of this Law must perform, among other competencies:

I–registration, authorization, licensing, inspection and monitoring of the activities and projects related to research and technological development, production and manipulation of GMOs and GMO derivatives;

II- issue of Specific Business License for laboratories, institutions or companies intending to develop activities related to GMOs and GMO derivatives;

III- issue of registration and authorization or licensing for commercialization of products containing GMOs or GMO derivatives intended for human and animal consumption, plant use or release into the environment;

IV- issue of authorization/licensing required for any product containing GMO and GMO derivatives entering the country;

V-keep the SIB posted with update information on the institutions and technicians in charge of activities and projects related to GMOs and GMO derivatives in the national territory;

VI-forward granted registrations and authorizations to the Federal Official Journal and SIB for publication;

VII-apply the penalties set forth in this Law;

VIII-issue temporary authorization for field trials with GMOs and GMO derivatives;

IX-submit to CTNBio term of reference with biosafety requirements for biosafety assessment of GMOs and GMO derivatives and

X-assess the need of monitoring and risk management of derivatives accordingly to subsections I, II, III and IX.

§1 Licensing, registration, authorization and inspection agencies and entities provided for in this article must observe biosafety aspects concerning GMOs and GMO derivatives set forth in CTNBio preliminary conclusive technical opinion.

§ 2 in case of disagreement with CTNBio's technical opinion, registration and inspection agencies and entities may request a review provided that science-based rationale is given under subsection XX of article 11.

§ 3 The applicants for the authorization of activities provided for in this Law must require the consideration of CTNBio, which will forward a conclusive technical opinion to the agencies and entities set forth in this article within the time frame set in regulation and, when is the case, observing the CNBS decision.

§ 4 After favorable CTNBio opinion:

I- the Ministry of Agriculture must issue authorizations and registrations, inspect products and activities related to GMOs and GMO derivatives intended for animal use, agriculture, livestock, agribusiness and related activities, according to the legislation in force and the provisions in this Law;

II- the competent agency of the Ministry of Health must issue authorizations, registrations and inspect products and activities related to GMOs and GMO derivatives intended for human consumption, pharmacological use and household and public sanitation purposes, among other uses, according to the legislation in force and the provisions in this Law;

III- the competent agency of the Ministry of Environment must issue authorizations, registrations and licenses, besides inspecting products and activities related to GMOs and GMO derivatives intended for release into the ecosystems, according to the legislation in force and the provisions in this Law;

IV-the Special Secretariat of Aquaculture and Fisheries must issue the authorizations and registrations provided for in this article, related to GMOs and GMO derivatives intended for fishery and aquaculture purposes, according to the legislation in force and the provisions in this Law; .

§ 5 Registration and inspection agencies and entities are granted unlimited access to all information contained in applications submitted to CTNBio.

## CHAPTER VI

### THE INTERNAL BIOSAFETY COMMISSION - CIBio

Art.15 Each institution applying genetic engineering techniques and methods or using GMOs and GMO derivatives must implement a CIBio and appoint one technician in charge of each specific project.

Art.16 The CIBio, within the institution where it was constituted, must:

I- keep workers and other members of the community that might be affected by the activity posted on all health and safety issues and procedures required in case of accidents;

II- implement preventive and inspection programs to assure that the facilities under its responsibility are in compliance with biosafety standards and rules defined by CTNBio and the regulation of this Law;

III-forward to CTNBio the documentation to be defined in the regulation of this Law, intended for analysis, registration or authorization of the competent body, when applicable:

IV-monitor each activity or on-going project regarding GMOs and GMO derivatives;

V-notify CTNBio, registration and inspection agencies and entities and labor organizations of the risks people are exposed, as well as any accidents or incidents that may cause dissemination of biological agents;

VI- investigate the occurrence of accidents and illnesses possibly related to GMOs and GMO derivatives, forwarding its conclusions and provisions to CTNBio.

## CHAPTER VII

### THE BIOSAFETY INFORMATION SYSTEM - SIB

Art.17 It is hereby established, within the scope of the Ministry of Science and Technology, the Biosafety Information System - SIB, an information management system for the analysis, authorization, registration, monitoring and follow-up of activities related to GMOs and GMO derivatives.

§1 Legal, regulatory and administrative provisions that change, complement or produce any effects on biosafety legislation regarding GMOs and GMO derivatives must be published in the SIB concurrently to the date these provisions come into force.

§2 Registration and inspection agencies and entities must feed the SIB with information related to the activities mentioned herein, processed within the scope of their competencies.

## CHAPTER VIII

## CIVIL AND ADMINISTRATIVE LIABILITIES

Art.18 Without prejudice to the application of penalties provided for in this Law, people held responsible for damage to the environment will be jointly liable to compensation or full indemnification, regardless of fault.

Art.19 Administrative infringement is understood as every action or inaction that violates the rules provided for in this Law and other relevant legal provisions.

Sole paragraph. Penalties for administrative infringements will be imposed according to this Law, regardless of the precautionary action demanding seizure of products, suspension of sales licensing and embargo of activities, with the following sanctions:

I-warning;

II-fine;

III-seizure of GMOs and GMO derivatives;

IV-suspension of sales of GMOs and GMO derivatives;

V-embargo on the activity;

VI-partial or full quarantine of establishment, activity or business;

VII-suspension of registration, license or authorization;

VIII-cancellation of registration, license or authorization;

IX-removal or restriction on federal tax support and tax relief;

X-removal or suspension of credit lines available at federal credit institutions;

XI-intervention in the establishment;

XII-five-year prohibition of contracts signed with the Administration.

Art.20 Registration and inspection agencies and entities shall define the applicable criteria and amounts, in order to apply fines that vary from R\$ 2,000.00 (two thousand reais) to R\$ 1,500,000.00 (one million and five thousand reais), accordingly to the seriousness of the infringement.

§ 1-Fines are cumulative and may be added to the other sanctions set forth in this article.

§2 In case of recidivism, fines will double.

§3 In case of continuing infringement, characterized by continuation of action or inaction after punishment, the corresponding penalty will be applied daily until its cause ceases, without prejudice to immediate suspension of the activity or quarantine of laboratory, institution or company in charge.

§ 4 Fine collection resources will be allocated to federal laboratories in charge of bioengineered food analysis, to registration and inspection agencies and entities that had issued the fine and to CTNBio.

Art.21 Fines set forth in this Law will be applied by registration and inspection agencies and entities of the Ministries of Agriculture, Health, Environment and the Special Secretariat of Aquaculture and Fisheries, according to their corresponding competencies.

§ 1 Inspection agencies and entities of the Administration may sign agreements with States, the Federal District and Municipalities for the inspection activities set forth in this Law, and may transfer to them the revenues originating from fine collection.

§ 2 The inspecting authority will send CTNBio a copy of the notice of violation.

§ 3 When violation constitutes a crime, misdemeanor or damage to the Public Treasury or to consumers, the inspecting authority will represent to the competent body in order to ascertain criminal and administrative liabilities.

## CHAPTER IX

### FINAL AND TEMPORARY PROVISIONS

Art. 22 Food and food products intended for human or animal consumption containing or being produced from genetically modified products must display all relevant information on their labels, pursuant to the regulation, without prejudice to compliance with the labeling legislation in force.

§1 The information mentioned in this article must also be included in the invoice, so that the product or ingredient will be accompanied by such information at all stages of the productive chain.

§ 2 A regulation may establish a minimum quantity of GMOs that is waived compliance with the provisions in this article.

Art.23 CTNBio shall review its normative decisions within a time frame of 120 days in order to promote its adequacy for the provisions of this Law.

Art.24 Institutions developing activities ruled by this Law on the date of its publication must comply with its provisions within the time frame of 120 days from the date the ruling decree was published, and present a detailed report on the existing products and GMO on-going researches or projects.

Art.25 CTNBio will count on an executive secretariat, and the Ministry of Science and Technology shall provide it with technical and administrative support.

Art.26.Art. 13 of Law n<sup>o</sup> 8.974, of January 5, 1995, is hereby in force added by the following subsection:

VI- construction, cultivation, production, transportation, transfer, commercialization, import, export or storage of genetically modified organism or GMO derivative, without authorization or in disagreement with legal or regulatory determination.

Penalty - one to three years of confinement." (NR)

Art.27 Description of Code 20, Appendix VIII of Law n<sup>o</sup> 6.938, of August 31, 1981, is hereby in force and will read as follows:

Code 20, Description: forestry; economical exploitation of wood or loose wood and forest byproducts; importation or exportation of Brazilian wild flora and fauna specimens; breeding and economical exploitation of the exotic and wild fauna; use of natural genetic assets, exploitation of live aquatic resources; introduction of exotic species, except for genetic improvement of plants and agricultural purposes; introduction of genetically modified species previously identified by the registration and inspection agency or entity of the Ministry of Environment as potentially harmful to the environment; use of the biological diversity by the biotechnology in activities previously identified by the registration and inspection agency and entity of the Ministry of Environment as potentially harmful to the environment."

Art.28 This Law will be regulated within 90 days from the date of its publication.

Art.29 This Law comes into force on the date of its publication.

Art.30 Law no. 8.974, of January 5, 1995, except art.13, and Provisional Measure no. 2,191-9, of August 23, 2001 are hereby revoked.

OFFICE OF THE PRESIDENCY OF THE REPUBLIC