Presidency of the Republic

Civil Cabinet

Sub-Office of Legal Affairs

LAW NO. 11.105 OF MARCH 24, 2005

Veto Message

Regulations

Regulates Items II, IV and V of §1 of Article 225 of the Federal Constitution, sets out safety standards and inspection mechanisms for activities involving Genetically modified organisms – GMOs – and their derivatives, creates the National Biosecurity Council (CNBS), restructures the National Biosecurity Technical Commission (CTNBio), and rearranges the National Biosecurity Policy (PNB), revokes Law No. 8.974 of January 5, 1995 and Provisional Measure No. 2.191-9 of August 23, 2001, and Articles 5, 6, 7, 8, 9, 10 and 16 of Law No. 10.814 of December 15, 2003, and provides other measures.

THE PRESIDENT OF THE REPUBLIC. I hereby make known that the National Congress has decreed and I sanction the following Law:

CHAPTER I

PRELIMINARY AND GENERAL PROVISIONS

Article 1

This Law establishes the security standards and inspection mechanisms on the building, cultivation, production, handling, transport, transfer, import, export, storage, research, commercialization, consumption, release into the environment and disposal of genetically modified organisms – GMOs and their derivatives, based on the guiding principles of the promotion of scientific advances in the areas of biosecurity and biotechnology, protection of human, animal and plant life and health, and observance of the precautionary principle for the protection of the environment.

§1 For the purposes of this Law, activities which take place in the laboratory, containment regime or field, as part of the process of obtaining GMOs and their derivatives or the

assessment of the biosecurity of GMOs and their derivatives, which includes in the fields of experimentation, building, cultivation, handling, transport, transfer, commercialization, import, export, storage, release into the environment and disposal of GMOs and their derivatives shall be deemed research activities.

§2 For the purposes of this Law, activities considered commercial use of GMOs and their derivatives, shall be those which do not fall within the framework of research activities and which cover cultivation, production, handling, transport, transfer, commercialization, import, export, storage, consumption, release and disposal of GMOs and their derivatives for commercial purposes.

Article 2
Activities and projects involving GMOs and their derivatives, relating to teaching with the handling of living organisms, scientific research, technological development and industrial production shall remain limited to the scope of public or private legal entities, which shall be responsible for compliance with the precepts of this Law and the Regulations thereunder, as well as for the possible consequences or effects resulting from failure to comply.

§1 For the purposes of this Law, activities and projects within the scope of entities shall be considered to be those conducted in premises of the entities, or under the administration, technical or scientific responsibility of the entity.

§2 The activities and projects covered by this Article shall be prohibited to individuals acting autonomously or independently, even if they have an employment or any other link with legal entities.

§3 Those interested in carrying out activities provided for by this Law shall request authorization from the National Biosecurity Technical Commission (CTNBio), which shall give its opinion within the period set out in the Regulations.

§4 Public and private, national, foreign or international organizations, financers or sponsors of activities or projects referred to in the **main body** of this Article shall require the presentation of the Certificate of Biosecurity Quality, issued by CTNBio, lest they become jointly liable for possible effects resulting from the failure to comply with this Law or the Regulations thereunder.

Article 3
For the purposes of this Law, the following definitions shall apply:

I – organism: any biological entity capable of reproducing or transferring genetic material, including viruses and other classes which are as yet unknown;

II - deoxyribonucleic acid – DNA, ribonucleic acid – RNA: genetic material containing information determining hereditary characteristics transmissible to descendants;

III – recombinant DNA/RNA molecular: molecules handled outside living cells through the modification of segments of natural or synthetic DNA/RNA and which are capable of multiplying in a living cell, or even DNA/RNA molecules resulting from this multiplication; segments of synthetic DNA/RNA shall also be considered equivalent to natural DNA/RNA segments;

IV – genetic engineering: the activity of the production or handling of recombinant DNA/RNA molecules:

V – genetically Modified Organism – GMOs: organism whose genetic material – DNA/RNA has been modified by any genetic engineering technique;

VI – GMO derivative: product obtained from a GMO and which does not have an autonomous replication capacity or which does not contain a viable form of GMO;

VII –human germ cell: mother cell responsible for the formation of gametes present in the male and female sexual glands and their direct descendants at any level of ploidy;

VIII – cloning: asexual reproduction process, artificially produced, based on a single genetic heritage, with or without use of genetic engineering techniques;

IX – cloning for reproductive purposes: cloning with the intention of obtaining an individual;

X – therapeutic cloning: cloning for the purposes of production of embryonic stem cells for therapeutic use;

XI – embryonic stem cells: embryo cells which have the capacity to become cells of any tissue of an organism.

§1 The GMO category shall not include that which results from techniques which imply the direct introduction, into an organism, of hereditary material, as long as they do not involve the use of recombinant DNA/RNA molecules or GMOs, including **in vitro** fertilization, conjugation, transduction, transformation, polyploidy induction and any other natural process.

§2 The GMO derivative category shall not include a pure substance, chemically defined, obtained by means of biological processes and which does not contain a GMO, heterologous protein or recombinant DNA.

Article 4
This Law shall not apply if the genetic modification was obtained by the following techniques, as long as they do not involve the use of a GMO as receiver or donor:

I – Mutagenesis;

II – Formation and use of somatic cells of an animal hybridoma;

III – Cellular fusion, including that of protoplasm, plant cells which could be produced through traditional cultivation methods;

IV – Autocloning of non-pathogenic organisms processed in a natural manner.

Article 5
For research and therapy purposes, the use of embryonic stem cells obtained from human embryos produced by **in vitro** fertilization and not used in the respective procedure, shall be allowed under the following conditions:

I – they are unviable embryos; or

II – they are embryos frozen 3 (three) or more years ago, at the date of the publication of this Law, or if, already frozen at the time of publication of the Law, at the end of 3 (three) years, starting from the date of freezing.

§1 In any case, the consent of the parents shall be necessary.

§2 Research institutions and health services which carry out research or therapy with human embryonic stem cells shall submit their projects for assessment and approval to the respective committees on research ethics.

§3 The commercialization of biological material referred to in this Article shall be prohibited and its practice shall involve the crime characterized in Article 15 of Law No. 9.434 of February 4, 1997.

Article 6
The following shall be prohibited:

I – implementation of a project related to a GMO without maintenance of the registration of its individual accompaniment;

II – genetic engineering on a living organism or **in vitro** handling of natural or recombinant DNA/RNA, carried out contrary to the standards set out in this Law;

III – genetic engineering on human germ cells, human zygotes or human embryos;

IV – human cloning;

V – destruction or disposal in the environment of GMOs and their derivatives contrary to the standards established by CTNBio, by the bodies and entities for registration and inspection, referred to in Article 16 of this Law, and the standards of this Law and the Regulations thereunder;

VI – release into the environment of GMOs or their derivatives, within the area of research activities, without the positive technical decision of CTNBio and, in the event of commercial release, without the positive technical opinion of CTNBio, or without the licensing of the responsible environmental body or entity, if CTNBio considers the activity a potential cause of environmental degradation, or without the approval of the National Biosecurity Council – (CNBS), if the process was called back by it, in the form of this Law and the Regulations thereunder;

VII – the use, commercialization, registration, patenting and or licensing of genetic technologies of restricted use.

Single paragraph
For the purposes of this Law, genetic technologies of restricted use shall be deemed to be any process of human intervention for generation or multiplication of genetically modified plants for the production of reproductively sterile structures, as well as any form of genetic manipulation which aims to activate or deactivate genes related to fertility of plants via external chemical inducers.

Article 7
The following shall be compulsory:

I – investigation of accidents which occurred during research and projects in the field of genetic engineering and the sending of the respective report to the competent authority within a maximum period of 5 (five) days starting from the date of the event;

II – immediate notification to CTNBio and the public health, agricultural and environmental protection authorities, about the accident which could cause the dissemination of GMOs and their derivatives;

III – the adoption of means necessary to inform fully CTNBio, the public health authorities, environmental and agricultural protection authorities, the community and the other employees of the institution or company about the risks to which they may be exposed, as well as the measures to be taken in the event of accidents involving GMOs.

CHAPTER II

National Biosecurity Council – CNBS

Article 8
The National Biosecurity Council (CNBS) shall be created, linked to the Presidency of the Republic, as the highest assessment body of the President of the Republic for the formulation and implementation of the National Biosecurity Policy – (PNB).

§1 It shall be the responsibility of CNBS to:

I – set principles and guidelines for the administrative actions of the federal bodies and entities with a remit in this area;

II –analyze, at the request of CTNBio, requests to release GMOs and their derivatives for commercial use, with regard to the desirability, suitability in social and economic terms, and the national interest;

III – advocate and decide, as the final and ultimate authority, on the basis of the opinion of CTNBio and, if it considers it necessary, the bodies and entities referred to in Article 16 of this Law, within their areas of competency, on the processes relating to activities involving the commercial use of GMOs and their derivatives;

IV – VETOED

§2 VETOED

§3 Whenever CNBS decides in favor of the carrying-out of the activity evaluated, it shall deliver its decision to the registration and inspection bodies and entities referred to in Article 16 of this Law.

§4 Whenever CNBS decides against the activity evaluated, it shall deliver its decision to CTNBio which shall inform the applicant.

Article 9
CNBS shall be made up of the following members:

I – Minister of State Presidential Chief-of-Staff of the Presidency of the Republic, who shall act as chair;

II – Minister of State for Science and Technology;

III – Minister of State for Agrarian Development;

IV – Minister of State for Agriculture, Farming and Food Supply;

V – Minister of State for Justice;

VI – Minister of State for Health;

VII – Minister of State for the Environment;

VIII – Minister of State for Development, Industry and Foreign Trade;

IX – Minister of State for Foreign Affairs;

X – Minister of State for Defense;

XI – Special Secretary for Aquaculture and Fisheries of the Presidency of the Republic.

§1 CNBS shall meet whenever convened by the Minister of State Presidential Chief-of-Staff of the Presidency of the Republic, or at the request of the majority of its members.

§2 VETOED

§3 Representatives of the public sector and of civil society entities may, exceptionally, be invited to participate in meetings.

§4 CNBS shall have an Executive Secretary, linked to the Office of the Presidency of the Republic.

§5 A meeting of the CNBS may take place with the presence of 6 (six) of its members and decisions shall be taken by an absolute majority of votes in favor.

CHAPTER III

National Biosecurity Technical Commission – CTNBio

Article 10
CTNBio, part of the Ministry of Science and Technology, is a multidisciplinary collegiate authority, of a consultative and deliberative nature, for the provision of technical advice and support to the Federal Government in the formulation, updating and implementation of PNB for GMOs and their derivatives, as well as in the establishment of technical safety standards and technical opinions referring to authorization for activities involving research and commercial use of GMOs and their derivatives, based on the evaluation of the zoosanitary and phytosanitary risks to human health and the environment.

Single paragraph
CTNBio shall follow up the development and technical and scientific advances in the areas of biosecurity, biotechnology, bioethics and related matters, with the aim of capacity building for the protection of human, animal and plant health and the environment.

Article 11
CTNBio, made up of titular members and alternates, nominated by the Minister of State for Science and Technology, shall consist of 27 (twenty seven) Brazilian citizens with recognized technical competency, with known actions and scientific knowledge, with the academic status of doctor and with distinguished professional activity in the areas of biosecurity, biotechnology, biology, human and animal health or the environment, as follows:

I – 12 (twelve) specialists of renowned scientific and technical knowledge, in effective professional practice:

(a) 3 (three) from the field of human health;
(b) 3 (three) from the field of animal health;
(c) 3 (three) from the field of plants;
(d) 3 (three) from the field of the environment;

II – a representative from each of the following bodies, nominated by the respective titular members:

(a) Ministry of Science and Technology;
(b) Ministry of Agriculture, Farming and Food Supply;
(c) Ministry of Health;
(d) Ministry of the Environment;
(e) Ministry of Agrarian Development;
(f) Ministry of Development, Industry and Foreign Trade;
(g) Ministry of Defense;
(h) Special Secretary for Aquaculture and Fisheries of the Presidency of the Republic;
(i) Ministry of Foreign Affairs;

III – one specialist in consumer rights, nominated by the Minister for Justice;

IV – one specialist in the area of Health, nominated by the Minister for Health;

V – one specialist on the environment, nominated by the Minister for the Environment;

VI – one specialist in biotechnology, nominated by the Minister for Agriculture, Farming and Food Supply;

VII – one specialist in family farming, nominated by the Minister for Agrarian Development;

VIII – one specialist in worker health, nominated by the Minister for Work and Employment.

§1 The specialists mentioned in item I of the **main body** of this Article shall be selected from a triplicate list, drawn up with the participation of scientific societies, in accordance with the provisions of the Regulations.

§2 The specialists mentioned in items III to VIII of the **main body** of this Article shall be selected from a triplicate list, drawn up by civil society organizations, in accordance with the provisions of the Regulations.

§3 Each effective member shall have an alternate, who shall participate in the work in the absence of the titular member.

§4 The members of CTNBio shall have a mandate of 2 (two) years, renewable for up to another 2 (two) consecutive periods.

§5 The president of CTNBio shall be nominated, from the members, by the Minister for Science and Technology for a term of 2 (two) years, renewable for an equal period.

§6 The members of CTNBio shall guide their actions through the strict observance of concepts of professional ethics, and they shall be prohibited from participating in the judgment of issues in which they have any involvement, professional or personal, otherwise they shall lose their mandate, in accordance with the Regulations.

§7 A meeting of the CTNBio may take place with the presence of 14 (fourteen) of its members, including at least one representative of each of the areas referred to in item I of the **main body** of this Article.

§8 VETOED

§8 The decisions of CTNBio shall be by an absolute majority vote of members in favor. (Included by Law No. 11.460 of 2007)

§9 Federal public administration bodies and entities may request to participate in CTNBio meetings to deal with matters of particular interest to them, without voting rights.

§10 Representatives of the scientific community and public sector and of civil society entities may, exceptionally, be invited to participate in meetings, without voting rights.

Article 12
The functioning of CTNBio shall be defined by the Regulations under this Law.

§1 CTNBio shall have an Executive Secretary and the Ministry of Science and Technology shall provide technical and administrative support.

§2 VETOED

Article 13
CTNBio shall set up permanent sectoral subcommittees in the areas of human health, animal health, plants and the environment, and it may set up extraordinary subcommittees, for prior analysis of the subjects which shall be submitted to the Commission plenary.

§1 Both titular members and alternates shall participate in the sectoral subcommittees and all shall receive distribution of the procedures for analysis.

§2 The functioning and coordination of the work in the sectoral and extraordinary subcommittees shall be defined by the internal rules of procedure of CTNBio:

Article 14

CTNBio shall:

I – establish standards for research in GMOs and GMO derivatives;

II – establish standards relating to activities and projects related to GMOs and their derivatives;

III – establish, within their area of competence, criteria for assessment and monitoring of risk in GMOs and their derivatives;

IV – analyze risk assessment, on a case-by-case basis, in relation to activities and projects involving GMOs and their derivatives;

V – establish the mechanisms for the functioning of the Internal Biosecurity Commissions (CIBio), within each institution involved in teaching, scientific research, technological development and industrial production involving GMOs and their derivatives;

VI – establish requirements relating to biosecurity for authorization of the functioning of laboratories, institutions and companies developing activities related to GMOs and their derivatives;

VII – communicate with institutions working on the biosecurity of GMOs and their derivatives, in the national and international arena;

VIII – authorize, register and follow up research activities with GMOs or GMO derivatives, under the terms of legislation in force;

IX – authorize the importation of GMOs and their derivatives for research activities;

X – provide technical consultation and advice to CNBS in the formulation of PNB for GMOs and their derivatives;

XI – issue the Certificate of Biosecurity Quality – CQB for the development of activities with GMOs and their derivatives, in laboratories, institutions or companies and send copies of the report to the registration and inspection bodies referred to in Article 16 of this Law;

XII – issue technical decisions, on a case-by-case basis, on the biosecurity of GMOs and their derivatives in the area of research and commercial use activities for GMOs and their derivatives, including classification with regard to the degree of risk and the level of biosecurity demanded, as well as security measures required and restrictions on use;

XIII – define the level of biosecurity to be applied to GMOs and their uses, and the respective security procedures and measures with regard to such uses, in accordance with the standards established in the Regulations under this Law, as well as for their derivatives;

XIV – classify GMOs in accordance with the class of risk, based on the criteria established in the Regulations under this Law;

XV – follow up the development and the technical and scientific progress in the biosecurity of GMOs and their derivatives;

XVI – issue resolutions, of a normative nature, on the issues within its competence;

XVII –technically support the competent bodies in the process of prevention and investigation of accidents and diseases, discovered during projects and activities with recombinant DNA/RNA techniques;

XVIII – technically support the registration and inspection bodies and entities referred to in Article 16 of this Law, in the exercise of their activities related to GMOs and their derivatives;

XIX – disclose in the Official Journal of the Union, prior to analysis, the extracts of cases and, afterwards, the opinions on the processes submitted to it, as well as to provide broad circulation in the Biosecurity Information System – SIB, of its agenda, cases being processed, annual reports, minutes of meetings and other information on its activities, excluding confidential information, of commercial interest, noted by the proposer and thus considered by CTNBio;

XX – identify activities and products resulting from the use of GMOs and their derivatives which potentially could cause environmental degradation or which could cause human health risks;

XXI –reassess its technical decisions at the request of its members or by appeal from the registration and inspection bodies and entities, based on new scientific facts or knowledge, which are relevant to the biosecurity of GMOs or their derivatives, in accordance with this Law and the Regulations thereunder;

XXII – propose the carrying-out of research and scientific studies in the area of the biosecurity of GMO and their derivatives;

XXIII – present a proposal for the internal rules of procedure to the Ministry of Science and Technology.

§1 With regard to the aspects of the biosecurity of GMOs and their derivatives, the technical decisions of CTNBio shall be binding on the other administrative bodies and entities.

§2 In cases of commercial use, among other technical aspects of analysis, the registration and inspection bodies, in the exercise of their tasks where requested by CTNBio, shall respect the technical decision of CTNBio, with regard to the biosecurity of GMOs and their derivatives.

§3 In the case of a favorable technical decision on biosecurity in the area of research activity, CTNBio shall send the respective file to the bodies and entities referred to in Article 16 of this Law, for the exercise of their duties.

§4 A technical decision of CTNBio shall contain the summary of the technical grounds, set out the security measures and restrictions on the use of GMOs and their derivatives, and consider the specific features of the different regions of the country, with the aim of guiding and assisting the registration and inspection bodies and entities referred to in Article 16 of this Law, in the exercise of their duties.

§5 Derivatives whose GMOs have already been approved by CTNBio shall not be submitted to it for analysis and issuance of a technical opinion.

§6 Natural or legal persons involved in any of the stages of the process of agricultural production, commercialization or transport of a genetically modified product which has been released for commercial use shall be granted dispensation from presentation of CQB and the constitution of CIBio, unless otherwise decided by CTNBio.

Article 15
CTNBio may hold public hearings, guaranteeing the participation of civil society, in accordance with the Regulations.

Sole paragraph
In cases of commercial release, interested parties may request a public hearing, including civil society organizations which demonstrate an interest related to the subject, in accordance with the Regulations.

CHAPTER IV

Registration and Inspection Bodies and Entities

Article 16
Registration and inspection bodies and entities of the Ministry of Health, Ministry of Agriculture, Farming and Food Supply and the Ministry of the Environment, and the Special Secretariat for Aquaculture and Fisheries of the Presidency of the Republic shall, among other duties, in their areas of competence, having observed the technical decisions of CTNBio, the deliberations of CNBS and mechanisms established by this Law and in the Regulations thereunder, also:

I – inspect research activities for GMOs and their derivatives;

II – register and inspect the commercial release of GMOs and their derivatives;

III – issue authorization for the import of GMOs and their derivatives for commercial use;

IV – keep up-to-date the SIB register of the institutions and the professional technicians responsible for activities and projects related to GMOs and their derivatives;

V – make public, including in SIB, the registrations and authorizations granted;

VI – apply the penalties covered by this Law;

VII – assist CTNBio in the definition of evaluation issues for the biosecurity of GMOs and their derivatives.

§1 Following a positive decision by CTNBio, or by CNBS, in the event of a call-back or appeal, as a result of specific analysis or relevant decision the following shall fall to:

I – the Ministry of Agriculture, Farming and Food Supply to issue the authorizations and registrations and to inspect products and activities which use GMOs and their derivatives destined for use with animals, in agriculture, farming, agroindustry and related areas, in accordance with the legislation in force and with the Regulations under this Law;

II – the competent body of the Ministry of Health to issue the authorizations and registrations and to inspect products and activities with GMOs and their derivatives for human and pharmacological use, and in household cleaning products and related areas, in accordance with the legislation in force and with the Regulations under this Law;

III – the competent body of the Ministry of the Environment to issue the authorizations and registrations and to inspect products and activities with GMOs and their derivatives which are to be released into natural ecosystems, in accordance with the legislation in force and with the Regulations under this Law, as well as the licensing, in cases which CTNBio considers, in accordance with this Law, GMOs are potentially a cause of significant degradation of the environment;

IV – the Special Secretariat for Aquaculture and Fisheries of the Presidency of the Republic, to issue the authorizations and registrations and to inspect products and activities with GMOs and their derivatives destined for use in fishing and aquaculture, in accordance with the legislation in force and with the Regulations under this Law.

§2 The provisions of items I and II of Article 8 and the **main body** of Article 10 of Law No. 6.938 of August 31, 1981, shall only apply to cases in which CTNBio considers that a GMO is potentially a cause of significant environmental degradation.

§3 CTNBio deliberates, as final and ultimate authority, on cases in which the activity is potentially or effectively a cause of environmental degradation, as well as on the need for environmental licensing.

§4 The issuance of registrations, authorizations and environmental licensing referred to in this Law shall take place within a maximum period of 120 (one hundred and twenty) days.

§5 The counting of the period provided for in §4 of this Article shall be suspended, for up to 180 (one hundred and eighty) days, during the preparation, by the applicant, of the studies or clarifications necessary.

§6 The authorizations and registrations dealt with in this Article shall be linked to the respective technical decision of CTNBio, and technical demands which are outside the sphere of the conditions set out in that decision shall be prohibited, for aspects relating to biosecurity.

§7 In the event of divergence with regard to a technical decision of CTNBio on the commercial release of GMOs derivatives, the registration and inspection bodies and entities, within their competences, may lodge an appeal with CNBS, within a period of 30 (thirty) days from the date of publication of the technical decision of CTNBio.

CHAPTER V

Internal Biosecurity Commission – CIBio

Article 17
Any institution which uses genetic engineering techniques and methods or carries out research with GMOs and their derivatives shall create an Internal Biosecurity Commission – CIBio, in addition to nominating a senior professional technician responsible for each specific project.

Article 18
Within the institution where it is constituted, the CIBio shall:

I – keep the workers and other members of the community informed, if they are liable to be affected by the activity, on the issues related to health and safety, as well as on the procedures in the event of accidents;

II – establish preventive and inspection programs to ensure the functioning of the premises under their responsibility, within the framework and standards for biosecurity, defined by CTNBio in the Regulations under this Law;

III – deliver to CTNBio the documents which the Regulations under this Law shall set out to be reported, for the purposes of analysis, registration or authorization by the competent body, where necessary;

IV – maintain a register for the individual follow-up of each activity or project under development which involves GMOs and their derivatives;

V – notify CTNBio, the registration and inspection bodies and entities, referred to in Article 16 of this Law, and workers' entities of the outcome of the assessments of risks to which persons exposed are subject, as well as of any accident or incident which could cause the dissemination of the biological agent;

VI – investigate the occurrence of accidents or diseases potentially related to GMOs and their derivatives and notify CTNBio of their conclusions and measures.

CHAPTER VI

Biosecurity Information System – SIB

Article 19
The Biosecurity Information System – SIB shall be created within the Ministry of Science and Technology, to manage information resulting from activities in the analysis, authorization, registration, monitoring and follow-up of activities involving GMOs and their derivatives.

§1 The provisions of the legal, regulatory, and administrative acts which change, complement or produce effects on biosecurity legislation concerning GMOs and their derivatives shall be disclosed in the related SIB when these acts come into force.

§2 The registration and inspection bodies and entities, referred to in Article 16 of this Law, must provide SIB with information relating to the activities which this Law deals with, processed within the area of their competence.

CHAPTER VII

Civil and Administrative Liability

Article 20
Without prejudice to the application of the penalties provided for by this Law, those responsible for damage to the environment and to third parties shall be liable, jointly, for full indemnification or reparation, independently of the existence of blame.

Article 21
All actions or omissions which violate the standards set out in this Law and in the other relevant legal provisions shall be deemed administrative violations.

Sole paragraph
Administrative violations shall be punished in the way established in the Regulations under this Law, independently of the precautionary measures for seizure of products, suspension of sale of the products and embargoes on the activities, with the following sanctions:

I – warning;

II – fine;

III – seizure of GMOs and their derivatives;

IV – suspension of the sale of GMOs and their derivatives;

V – embargo on activity;

VI – partial or total ban of the establishment, activity or undertaking;

VII – suspension of registration, license or authorization;

VIII – cancellation of registration, license or authorization;

IX – loss or restriction of the fiscal incentive or benefit granted by the government;

X – loss or suspension of the participation in the line of funding at an official credit establishment;

XI – intervention in the establishment;

XII – ban on contracting with the public administration, for a period of up to 5 (five) years.

Article 22
It shall fall to the registration and inspection bodies and entities, referred to in Article 16 of this Law, to define the criteria and values and to apply fines of R$2,000.00 (two thousand reais) to R$1,5000,000.00 (one million five hundred thousand reais), in proportion to the severity of the violation.

§1 The fines may be applied cumulatively with the other sanctions provided for in this Article.

§2 In the event of a repeat offense, the fine shall be doubled.

§3 In the event of continued violation, characterized by the persistent nature of the action or omission initially punished, the respective penalty shall be applied daily until cessation of the cause, without prejudice to the immediate stopping of the activity or of the ban on the laboratory or the institution or company responsible.

Article 23
The fines set out in this Law shall be applied by the registration and inspection bodies and entities of the Ministries of Agriculture, Farming and Food Supply, of Health and the Environment, and the Special Secretariat for Aquaculture and Fisheries of the Presidency of the Republic, referred to in Article 16 of this Law, in accordance with their respective competencies.

§1 The resources raised with the application of fines shall go to the registration and inspection bodies and entities referred to in Article 16 of this Law, which apply the fine.

§2 The inspection bodies and entities of the federal public administration shall sign agreements with the States, Federal District and Municipalities for the execution of services

related to the inspection activities set out in this Law and may pass on installments of the revenues obtained through the application of fines.

§3 The inspection authority shall deliver a copy of the record of the violation to CTNBio.

§4 If the violation constitutes a crime or contravention, or damage to the tax authorities or the consumer, the inspection authority shall appear together with the competent body for determination of the administrative and penal responsibilities.

CHAPTER VIII

Crimes and Penalties

Article 24
Use of a human embryo contrary to the provisions of Article 5 of this Law:

Penalty – detention, from 1 (one) to 3 (three) years, and a fine.

Article 25
Practice genetic engineering in a human germ cell, human zygote or human embryo:

Penalty – confinement, from 1 (one) to 4 (four) years, and a fine.

Article 26
Carry out human cloning:

Penalty – confinement, from 2 (two) to 5 (five) years, and a fine.

Article 27
Release or dispose of GMOs into the environment, contrary to the standards established by CTNBio and by the registration and inspection bodies and entities:

Penalty – confinement, from 1 (one) to 4 (four) years, and a fine.

§1 VETOED

§2 The penalty shall worsen:

I – by 1/6 (one sixth) to 1/3 (one third), if there is damage to the property of another person;

II – by 1/3 (one third) up to half, if there is damage to the environment;

III – by half up to 2/3 (two thirds), if there is physical injury of a serious nature to another person;

IV – by 2/3 (two thirds) up to double, if there is the death of another person.

Article 28

Using, commercializing, registering, patenting and licensing genetic technologies for restriction of use: Penalty – confinement, from 2 (two) to 5 (five) years, and a fine.

Article 29
Producing, storing, transporting, commercializing, importing and exporting GMOs and their derivatives, without authorization or contrary to the standards established by CTNBio and by the registration and inspection bodies and entities:

Penalty – confinement, from 1 (one) to 2 (two) years, and a fine.

CHAPTER IX

Final and Transitional Provisions

Article 30
GMOs which have obtained a technical decision from CTNBio favorable to their commercial release up until the entry into force of this Law may be registered and commercialized, unless there is a demonstration to the contrary from CNBS, within a period of up to 60 (sixty) days, starting from the date of publication of this Law.

Article 31
CTNBio and the registration and inspection bodies and entities, referred to in Article 16 of this Law, must review their normative deliberations, within a period of 120 (one hundred and twenty) days, in order to promote their adaptation to the provisions of this Law.

Article 32
Biosecurity Quality Certificates, communications of technical decisions already issued by CTNBio, as well as, in so far as they are not contrary to the provisions of this Law, standardization acts issued under Law No. 8.974 of January 5, 1995, shall remain in force.

Article 33
Institutions which carry out activities regulated by this Law at the time of its publication shall adapt to its provisions within 120 (one hundred and twenty) days, starting from the publication of the Decree which regulates it.

Article 34
Provisional registrations granted under Law No. 10.814 of December 15, 2003, shall be validated and become permanent.

Article 35
The production and commercialization of seeds of genetically modified glyphosate tolerant soya cultivars registered in the National Cultivars Registry – RNC of the Ministry of Agriculture, Farming and Food Supply shall be authorized.

Article 36
The planting of grains of genetically modified glyphosate tolerant soya shall be authorized, and limited to rural producers for personal use, in the 2004/2005 harvest, and the commercialization of the production as seed shall be banned (See Decree No. 5.534 of 2005).

Sole paragraph
The Executive may extend the authorization dealt with in the **main body** of this Article.

Article 37

The description of Code 20 of Annex VIII of Law No. 6.938 of August 31, 1981, added to by Law No. 10.165 of December 27, 2000, shall be effective with the following wording:

"ANNEX VIII

Code	Category	Description	Pp/gu
20	Use of natural resources	Silviculture: economic exploitation of wood or timber and forestry subproducts; import and export of native Brazilian flora and fauna; creation and economic exploitation activity of exotic fauna and wild fauna; use of the natural genetic heritage; exploitation of living aquatic resources; introduction of exotic species, except for improvement of plant genetics and use in agriculture; introduction of genetically modified species previously identified by CTNBio as potentially the cause of significant degradation of the environment; use of biological diversity for biotechnology in activities previously identified by CTNBio as potentially the cause of significant degradation of the environment.	Medium

Article 38 (VETOED)

Article 39
The provisions of Law No. 7.802 of July 11, 1989 and the amendments thereto, shall not apply to GMOs and their derivatives, except in cases in which they were developed to serve as raw material for the production of pesticides.

Article 40

Food and food ingredients for human or animal consumption which contain or are produced from GMOs or derivatives shall contain this information on their packaging, in accordance with the Regulations.

Article 41
This Law shall come into force on the date of its publication.

Article 42
Law No. 8.974 of January 5, 1995, Provisional Measure No. 2.191-9 of August 23, 2001 and Articles 5, 6, 7, 8, 9, 10 and 16 of Law No. 10.814 of December 15, 2003 are hereby revoked.

Brasilia, March 24, 2005; 184th Year of Independence and 117th Year of the Republic.

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This text shall not replace that published in the Official Journal of March 28, 2005.