Law No 11.105, of 24 March 2005

Regulates items II, IV and V of Paragraph 1 of Article 225 of the Federal Constitution, provides for safety norms and inspection mechanisms for activities that involve genetically modified organisms - – GMOs and their by-products, implements the National Biosafety Council (*CNBS*), re-structures the National Biosafety Technical Commission (*CTNBio)*, provides for the National Biosafety Policy (*PNB*), revokes Law no 8.974, of 5 January 1995, and Provisional Measure no 2.191-9, of 23 August 2001, and arts. 5, 6, 7, 8, 9, 10 and 16 of Law no 10.814, of 15 December 2003, and provides for other measures.

THE PRESIDENT OF THE REPUBLIC I declare that National Congress decrees and I sanction the following Law:

CHAPTER **I**

GENERAL AND PRELIMINARY PROVISIONS

Article 1. This Law provides for safety norms and inspection mechanisms for the construction, culture, production, manipulation, transportation, transfer, import, export, storage, research, marketing, environmental release and discharge of genetically modified organisms – GMOs and their by-products, guided by the drive for attaining scientific development in the biosafety and biotechnology area, the protection of life and human beings, of animal and plant health, and the compliance with the principal of environmental precaution.

Paragraph 1. Under this Law, a research activity is that which is carried out in a laboratory, in the contention or field regime, as part of the process to obtain GMOs and their by-products, or for the evaluation of biosafety for GMOs and their by-products, which encompasses at the experimental level the construction, production, manipulation, transportation, transfer, import, export, storage, research, marketing, the release onto the environment and the discharge of genetically modified organisms – GMOs and their by-products

Paragraph 2. Under this Law, a commercial use activity of GMOS and their by-products is that which does not fall under a research activity, and which governs the culture, production, manipulation, transportation, transfer, marketing, import, export, storage, consumption, the clearance and discharge of GMOs and their by-products for commercial purposes.

Article 2. Activities and projects involving GMOs and their by-products, where living organisms are manipulated for purposes of teaching, of scientific research, for technical development and for industrial production are limited to the scope of public or private legal entities, which will be responsible for complying with the provisos provided by this Law and its regulation, as well as eventual consequences or effects caused by its non-compliance.

Paragraph 1. Under this Law, activities and projects within the scope of entities are those which are carried out in the entities' own facilities or those which are under the entities administrative, technical or scientific responsibility.

Paragraph 2. Activities and projects which are provided by this article are forbidden for self-employed and independent individuals, notwithstanding their employment relationship or any other relationship, for that matter, with legal entities.

Paragraph 3. Any individual who is interested in carrying out an activity provided by this Law shall request permission to the National Biosafety Technical Commission (*CTNBio*), which shall reply within the time limit provided by the by-laws.

Paragraph 4. Public and private organisations, national, foreign or international, which finance or sponsor activities or projects mentioned under the caption of this article, must require a Biosafety Quality Certificate issued CTNBio, and will be subject to joint liability for any eventual effect arisen by non-complying with this Law or its regulation.

Article 3. Under this Law, it shall be considered:

I – an organism: each and every biological entity that is capable of reproducing or transferring genetic material, including virus and other classes that may be made known;

II – deoxyribonucleic acid - DNA, ribonucleic acid - RNA: genetic material which contains determining information about transmissible hereditary characters to progeny;

III – recombinant DNA/RNA molecules: molecules manipulated outside live cells through changes made to natural or synthetic DNA/RNA segments that can multiply in a live cell, or yet, DNA/RNA molecules resulting from this multiplication; DNA/RNA synthetic segments equivalent to natural DNA/RNA are also considered;

IV – genetic engineering: the activity of manipulating DNA/RNA recombinant molecules;

V – genetically modified organism - GMOs: an organism the genetic material of which – DNA/RNA has been modified by any genetic engineering technique;

VI –GMO by-product: a product obtained from a GMO and that is not capable of autonomously replicating, or that does not contain a feasible GMO form;

VII – human germinal cell: the mother cell responsible for forming gametes which are found in the female and male sexual glands and their direct progeny in any ploid degree;

VIII – cloning: an asexual reproduction process, artificially produced, based on a sole genetic patrimony, by using or not genetic engineering techniques;

IX – cloning for reproductive means: cloning the end purpose of which is to make an individual;

X – therapeutic cloning: cloning the end purpose of which is to produce embryonic stem cells for therapeutic purposes;

XI – embryonic stem cells: embryonic cells that are capable of modifying the cells of any organism tissue.

Paragraph 1 It is not considered a GMO that which results from direct introduction techniques into an organisms, provided this does not entail the use of recombinant DNA/RNA molecules or GMOs, including in vitro fecundation, conjugation, transduction, transformation, polyploid induction and any other natural process.

Paragraph 2. It is not considered a GMO a chemically defined pure substance obtained from biological processes that do not contain GMOs, heterologous protein nor recombinant DNA.

Article 4. This Law is not applicable when a genetic modification results from the following techniques, provided they do not imply in using a GMO as the receiver or donator:

I – mutagenesis;

II – the formation and use of animal hybridome somatic cells;

III – cellular fusion, including plant cells protoplasm, which can be produced from traditional culture methods;

IV – the self-cloning of naturally processed non-pathogenic organisms.

Article 5. It is permitted for research and therapeutic purposes to use human embryonic stem cells produced from in vitro fertilisation, which are not used for the following procedures, provided these conditions are observed:

I – whether from unfeasible embryos, or;

II – from embryos that have been frozen for 3 (three) years or more, as of the date of publication of this Law, or that were frozen at the date of publication of this Law, after the 3 (three) year period has lapsed, as of the date when it was actually frozen.

Paragraph 1. In any of the cases, the parents must give their authorization.

Paragraph 2. Research institutions and health service providers that carry out research or therapy using human embryonic stem cells shall submit their projects to be analysed and approved by the relevant research ethics committees.

Paragraph 3 It is forbidden to sell biological material which is the subject-matter of this article, under the penalty of being charged with the crime typified in Article 15 of Law no 9.434, of 4 February 1997.

Article 6. It is forbidden to:

I – implement a GMOS-related project without maintaining individual monitoring records for that project;

II – perform genetic engineering on live organisms or manipulate natural or recombinant in vitro DNA/RNA, which do not comply with the norms provided by this Law;

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

V – perform human cloning

V – destroy or discharge onto the environment GMOs or their by-products, in disagreement with norms set forth by *CTNBio*, by registration and monitoring agencies and entities, referred to in Article 16 of this Law, and those which are part of this Law and its regulation;

VI – release onto the environment GMOs or their by-products, within the scope of research activities, without the favourable technical opinion granted by *CTNBio*, and in the cases of commercial clearance, without the favourable technical opinion granted by *CTNBio* or without

the licence granted by the responsible environmental agency or entity, whenever *CTNBio* deems the activity as a potential environmental degradation agent, or without the approval granted by the Biosafety National Council (*CNBS*), whenever the process has been mandated by that entity, under the terms of this Law and its regulation;

VII –use, sell, register, file for patent and licensing of limited use genetic technologies.

Sole paragraph. Under terms of this Law, it is understood that limited use genetic technology is any process by which human intervention generates or multiplies genetically modified plants to produce sterile reproductive structures, as well as any manner of genetic manipulation that aims at activating or deactivating fertility-related plant genes by using external chemical inducers.

Article 7. It is mandatory:

I – to investigate accidents occurred while genetic engineering-related research or projects were performed and to send the pertinent report to the relevant authority within 5 (five) days maximum, as of the date of the occurrence;

II – to immediately notify *CTNBio* and public health, agriculture and cattle-raising and environmental authorities about the accident that could result in the dissemination of GMOs and their by-products;

III – to adopt the required measures to fully inform *CTNBio*, public health, environmental and agriculture and cattle raising authorities, the community and all employees who work for the institution or company about the risks they could run, s well as the actions to be taken in the case of a GMO-related accident.

CHAPTER II

The National Biosafety Council (*CNBS*)

Article 8. The National Biosafety Council (*CNBS*) is hereof established, which is subject to the Office of the President of the Republic as a higher assistance agency of the President of the Republic for formulating and implementing the National Biosafety Policy (*PNB*).

Paragraph 1. *CNBS* is responsible for:

I – establishing principles and guidelines for the administration of federal agencies and entities that have competence over the subject-matter;

II – analysing, upon *CTNBio*'s request, the social-economic convenience and opportunities and national interest entailed in the requests for clearing the commercial use of GMOs and their by-products;

III – mandating and deciding, in the last and final prosecution stages, based on *CTNBio*'s opinion and whenever deemed necessary, supported by agencies and entities referred to in Article 16 of this Law, within the scope of their competences, about proceedings related to activities which entail the commercial use of GMOs and their by-products;

IV – (VETOED)

Paragraph 2. (VETOED)

Paragraph 3. Whenever CNBS decides in favour of an activity that has been analysed, it shall forward its opinion to the registrations and inspection agencies and entities referred to in Article 16 of this Law.

Paragraph 4 Whenever CNBS decides against the activity that has been analysed it shall forward its opinion to *CTNBio*, who shall inform the applicant.

Article 9 *CNBS* is comprised by the following members:

I – The State Minister Chief of the Civil HouseTN1 to the President of the Republic, who will be the chairperson;

II – The State Minister for Science and Technology;

III – The State Minister for Land Development;

IV – The State Minister for Agriculture, Cattle-Raising and Supply;

V – The State Minister of Justice;

VI – The State Minister of Health;

VII – The State Minister for the Environment;

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

IX – The State Minister for Foreign Office;

X – The State Minister of Defence;

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

Paragraph 1. *CNBS* shall meet whenever called by the The State Minister Chief of the Civil House to the President of the Republic, or when called by the majority of its members.

Paragraph 2 (VETOED)

Paragraph 3. Representatives from the public sector and from civil society entities can be exceptionally invited to attend the meeting.

Paragraph 4. *CNBS* shall have an Executive Secretariat subject to the Civil House of the President of the Republic.

Paragraph 5. *CNBS*' meetings can be held with the participation of 6 (six) of its members and decisions will be made by voting by the absolute majority.

CHAPTER III

The National Biosafety Technical Commission (*CTNBio*)

Article 10. *CTNBio*, which is part of the Ministry of Science and Technology, is a consulting and deliberating multidisciplinary collegiate, that provides technical and assistance support to the Federal Government to formulate, update and implement the National Biosafety Policy for GMOs and their by-products, as well as establishes safety technical norms regarding the authorization of research-related activities and the commercial use of GMOs and their by-products, based on the evaluation of their zoo-phytosanitary, human health and environmental risk.

Sole paragraph. *CTNBio* shall monitor the development and technical-scientific progress attained by the biosafety, biotechnology, bioethics and related areas, with aims at increasing their capacity of protecting human, animal and plant health and the environment.

Article 11. *CTNBio*, which is comprised of incumbent members and their substitutes, who are appointed by the State Minister for Science and Technology, shall be comprised of 27 (twenty-seven) Brazilian citizens, the technical competence of which is acknowledged and the notable participation and scientific learning is recognised, and who hold a doctorate degree and who have been professionally active in the biosafety, biotechnology, biology, human and animal health areas and the environment, whereby:

I – 12 (twelve) are experts with notable scientific and technical learning, are currently active professionals, as follows:

a) 3 (three) in the human health area;

b) 3 (three) in the animal health area;

c) 3 (three) in the plant health area;

d) 3 (three) in the environment area;

II – one representative from the following agencies shall be appointed by their respective incumbents:

a) the Ministry of Science and Technology;

b) the Ministry of Agriculture, Cattle-Raising and Supply;

c) the Ministry of Health;

d) the Ministry for the Environment;

e) the Ministry for Land Development;

f) the Ministry for the Development, Industry and Foreign Trade;

g) the Ministry of Defence;

h) the Special Secretariat for Agriculture and Fisheries to the President of the Republic;

i) the Ministry of Foreign Office;

III – a consumer rights expert, appointed by the Minister of Justice;

IV – a health expert appointed by the Minister of Health;

V – an environment expert, appointed by the Minister for the Environment;

VI – a biotechnology expert, appointed by the Minister for Agriculture, Cattle Raising and Supply;

VII – an allotment farm expert, appointed by the Minister for Land Development;

VIII – a work health expert, appointed by the Minister of Labour and Employment.

Paragraph 1. Experts which are the subject-matter of item I under the caption of this article shall be chosen from a tripartite list, compiled by scientific associations, according to that which is provided by the by-laws.

Paragraph 2. Experts which are the subject-matter of items III and VIII under the caption of this article shall be chosen from a tripartite list, compiled by scientific associations, according to that which is set forth by the by-laws.

Paragraph 3. Each incumbent member shall have a substitute, who will join the works when the incumbent is absent.

Paragraph 4. *CTNBio* members shall be in office for 2 (two) years, which may be extended for 2 (two) additional consecutive periods.

Paragraph 5. The president of *CTNBio* shall be appointed among its members by the Minister for Science and Technology for a 2 (two) year term of office, extendable for the same period.

Paragraph 6 *CTNBio* members shall perform their duties within strict compliance of ethic-professional concepts, under which it is forbidden to participate in the trial of issues with which they are in any manner whatsoever professionally or personally involved, under penalty of loosing office, according to the by-laws.

Paragraph 7 *CTNBio* meetings can be held with the participation of 14 (fourteen) members, including at least one representative form each of the areas mentioned in item I of the caption of this article.

Paragraph 8 (VETOED))

Paragraph 9. Any agency or entity which is under the federal public administration has the right to request their attendance to a *CTNBio* meeting to discuss issues that are relevant to their interest, without holding voting rights.

Paragraph 10. Representatives from the scientific community, the public sector and civil society entities can be invited to attend meetings, without holding voting rights.

Article 12. The operation of *CTNBio* shall be provided by the regulation of this Law.

Paragraph 1. *CTNBio* shall have an Executive Secretariat and the Minister for Science and Technology shall be responsible for providing it with technical and administrative support.

Paragraph 2. (VETOED)

Article 13. *CTNBio* shall set up permanent sector sub commissions for human health, animal, plant and the environment areas, and is entitled to set up extraordinary sub-commissions to carry out the prior analysis of themes to be submitted to the Commission's plenary.

Paragraph 1. Both incumbent and substitute members shall take part in the sector sub-commissions and shall be responsible for receiving proceedings to be analysed.

Paragraph 2. The operation and co-ordination of works endeavoured by the sector and extraordinary sub-commissions shall be defined by *CTNBio*'s by-laws.

Article 14. *CTNBio* shall be responsible for:

I – determining norms for research carried out with GMOs and GMOs by-products;

II – determining norms for activities and projects related to GMOs and their by-products;

III – determining, within the scope of its competences, risk assessment and monitoring criteria for GMOs and their by-products;

IV – performing the risk assessment study, case-by-case, regarding activities and projects that entail GMOs and their by-products;

V – determining operation mechanisms for the Biosafety Internal Commissions (*CIBio*), within the scope of each institution that is dedicated to learning and scientific research and to technical development and industrial production which entail GMOs or their by-products;

VI – determining biosafety requirements to authorise the operation of laboratories, institutions or companies that carry out activities related to GMOs and their by-products;

VII – maintaining a relationship with biosafety institutions for GMOs and their by-products, within the national and international scope;

VIII – authorising, registering and monitoring research activities using GMOs or GMOs by-products, as prescribed by legislation in effect;

IX – authorising the import of GMOs and their by-products for research activities;

X – providing technical consulting and assistance support for *CNBS* to prescribe the Biosafety National Policy for GMOs and their by-products;

XI – issuing the Biosafety Quality Certificate (*CQB*) to carry out activities using GMOs and their by-products in laboratories, institutions or companies and to forward a copy of the file to the registration and inspection agencies referred to in Article 16 of this Law;

XII – issuing the technical opinion, case-by-case, about the biosafety of GMOs and their by-products within the scope of research and commercial use activities of the GMOs and their by-

products, including the classification of the required risk grade and biosafety level, as well as safety measures required and restrictions of use;

XIII – defining the biosafety level to be applied to GMOs and its uses, and relevant safety procedures and measures for using it, as prescribed by this Law, as well as for its by-products;

XIV – classifying GMOs according to risk class, observing criteria prescribed by this Law;

XV – monitoring the technical-scientific development and progress of biosafety for the GMOs and their by-products;

XVI – issuing normative resolutions about matters under its competence;

XVII – providing technical support to relevant agencies for accident and disease prevention and investigation processes, checking the course of projects and activities which employ recombinant DNA/RNA techniques;

XVIII – providing technical support to registration and inspection agencies and entities referred to in Article 16 of this Law, when performing activities related to GMOs and their by-products;

XIX – publishing in the Federal Gazette, prior to the study, the abstract of proceedings and at a later date, of the opinion for each proceedings to it submitted, as well and disseminating fully in the Biosafety Information Systems (*SIB*) its agenda, procedural steps of cases, minutes of meetings and other information pertaining its activities, except for confidential commercial information, thus classified by the applicant and deemed as such by *CTNBio*;

XX – identifying activities and products derived from the use of GMOs and their by-products which are potential environmental degrading agents or can pose a risk to human health;

XXI – readdressing their technical opinion as requested by its members or by an appeal filed by registration and inspection agencies and entities, based on facts or novel scientific knowledge, which is relevant to the biosafety of GMOs or their by-products, under the terms of this Law and its rulings;

XXII – suggesting scientific biosafety research and studies for GMOs and their by-products;

XXIII – presenting the by-laws draft to the Minister for Science and Technology.

Paragraph 1. In regards to the biosafety aspects of GMOs and their by-products, *CTNBio*'s technical opinion binds the other administration agencies and entities to it.

Paragraph 2. When analyzing the commercial use, among other duties, such as the analysis of technical aspects whenever requested by *CTNBio*, registration and inspection agencies and entities shall comply with *CTNBio*'s technical opinion regarding the biosafety aspects of GMOs and their by-products.

Paragraph 3. In cases when a favourable technical opinion is granted for research activities, *CTNBio* shall forward the relevant proceedings to the agencies and entities referred to in Article 16 of this Law, when performing their duties.

Paragraph 4. *CTNBio* technical opinion shall provide an abstract of the technical basis, detailing safety measures and restrictions for using GMOs and their by-products and shall take into account the peculiarities inherent to the different Brazilian regions, with aims at providing guidance and support to registration and inspection agencies and entities referred to Article 16 of this Law, when performing their duties.

Paragraph 5. GMOs already approved by *CTNBio* shall not be subject to the latter's analysis and technical opinion report.

Paragraph 6. Individuals or corporations involved in any stage of the agricultural production, marketing or transportation of a genetically modified product, which were granted clearance for commercial use are wavered from presenting the *CQB* and setting up a *CIBio*, except when ruled otherwise by *CTNBio*.

Article 15. *CTNBio* can carry out public hearings where civil society participation is assured, under the terms of the law.

Sole paragraph. In cases of commercial clearance, a public hearing can be requested by the interested parties, among which can be included civil society organizations that can give proof of their relevant interest in the subject-matter, under the terms of the law.

CHAPTER IV

Registration and inspection agencies and entities

Article 16. Registration and inspection agencies and entities under the Ministry of Health, the Ministry of Agriculture, Cattle Raising and Supply, the Ministry for the Environment and the Special Secretariat for Aquaculture and Fisheries to the Office of the President of the Republic are responsible for, among their other duties within their field of competence and in compliance with *CTNBio*'s technical opinions, the rulings of *CNBS* and mechanisms provided by this Law and its regulation, shall be responsible for:

I – inspecting research activities for GMOs and their by-products;

II – registering and inspecting the commercial clearance of GMOs and their by-products;

III – granting authorisation for importing GMOs and their by-products for commercial use;

IV – keeping updated information in the Biosafety Information Systems (*SIB*) of institutions and technical responsible individuals that carry out activities and projects related to GMOs and their by-products;

V – disclosing to the public, including the *SIB*, granted registrations and authorisations;

VI – enforcing penalties which are the subject-matter of this Law;

VII – assisting *CTNBio* in defining biosafety assessment parameters for GMOs and their by-products.

Paragraph 1. After *CTNBio* or *CNBS* have given their favourable opinion, in the case of mandate or appeal, as a result of the specific analysis and ensuing decision:

I – the Ministry of Agriculture, Cattle Raising and Supply shall grant authorisations and registration and shall monitor products and activities that use GMOs and their by-products for animal, agriculture, cattle-raising, agro industry use and in similar areas, according to the legislation in effect and under the terms of this Law;

II – the relevant agency under the Ministry of Health shall grant authorisations and registration and shall inspect products and activities that use GMOs and their by-products for human, pharmaceutical, household cleaning use and similar areas, according to the legislation in effect and under the terms of this Law;

III – the relevant agency under the Ministry for the Environment shall grant authorisations and registration and shall inspect products and activities that use GMOS and their by-products to be discharged into natural ecosystems, according to the legislation in effect and under the terms of this Law, as well as licensing, in cases where CTNBio resolves, under the of this Law, that the GMOS is a potential environmental degradation agent;

IV – the Special Secretariat for Aquaculture and Fisheries of the Office of the President of the Republic shall grant authorisations and registration for products that use GMOs and their by-products, to be used in fisheries and aquaculture, according to the legislation in effect and under the terms of this Law.

Paragraph 2. Provisions set forth by items I and II of Article 8 and under the caption of Article 10 of Law no 6.938, of 31 August 1981, shall be applicable only when *CTNBio* determines that the GMO is a potential environmental degradation agent.

Paragraph 3. *CTNBio* shall rule, at the last and final jurisdiction, on cases when the activity is a potential or effective environmental degradation agent, as well as to the need of environmental licensing.

Paragraph 4. Environmental registrations, authorisations and licensing mentioned in this Law shall be granted within a maximum of 120 (one-hundred and twenty) days.

Paragraph 5. The deadline provided by Par. 4 of this article shall be postponed for up to 180 (one-hundred and eighty) days, while the applicant is drafting studies or providing other required clarification.

Paragraph 6. Authorisations and registrations provided by this article shall be bound to *CTNBio*'s relevant technical opinion, whereby any technical requirement for biosafety-related aspects that might exceed the conditions provided by that opinion is forbidden.

Paragraph 7. Whenever there is a dissention regarding *CTNBio*'s technical opinion on the commercial clearance of GMOs and their by-products, registration and inspection agencies and entities, within their scope of competence, shall present the appeal to *CNBS* within a maximum of 30 (thirty) days, as of the date of publication of *CTNBio*'s technical opinion.

CHAPTER V

Biosafety Internal Commission (*CIBio*)

Article 17. Any institution which uses genetic engineering techniques and methods, or that carries out research using GMOs and their by-products shall set up a Biosafety Internal

Commission (*CIBio*) and shall also appoint a principal technician who will be responsible for each specific project

Article 18. Within the scope of the institution where it has been set up, the *CIBio* shall be responsible for:

I – keeping workers and member of that community informed, whenever they are liable of being affected by the activity, on health and safety issues, as well as on the procedures should an accident occur;

II – implementing preventive and inspection programmes to ensure the operation of facilities for which they are responsible, within biosafety standards and norms, defined by *CTNBio* under the terms of this Law;

III – forwarding to *CTNBio* all documents that will be determined upon the regulation of this Law, for analysis, registration or authorisation purposes by the relevant agency, when applicable;

IV – maintaining the record of individual monitoring for each activity or project being developed that entails GMOs or their by-products;

V – notifying *CTNBio*, registration and inspection agencies and entities referred to in Article 16 of this Law, and labour unions, the results of risk assessment for individuals who become exposed, as well as any accident or incident that may cause the dissemination of a biological agent;

VI – investigating accident occurrences and diseases possibly related to GMOs and their by-products and informing their conclusions and measures taken to *CTNBio*.

CHAPTER VI

Biosafety Information System (*SIB*)

Article 19. The Biosafety Information System (SIB) is established within the scope of the Ministry of Science and Technology, to generate information resulting from analyses, authorisation, registration, monitoring and observation activities which entail GMOs and their by-products.

Paragraph 1. The provision of legal, regulating and administrative acts that modify, complement that have any effect of the biosafety legislation for GMOs and their by-products shall be disseminated by the *SIB* at the same date when those acts are in effect.

Paragraph 2. Registration and inspection agencies and entities referred to in Article 16 of this Law shall provide input for the *SIB* in the form of activity-related information under the terms of this Law, processed within the scope of its competence.

CHAPTER VII

Civil and Administrative Responsibility

Article 20. Without loss to the application of punishment under the terms of this Law, those who are accountable for environmental damages and third parties shall hold joint and several liability and shall pay compensation or full recovery, regardless of culpability.

Article 21. An administrative infringement is every action or omission which violates the norms provided by this Law and other pertinent legal provisos.

Sole paragraph. The administrative infringement shall be punished under the terms of this law, regardless of provisional measures to seize the product, suspend product marketing and the embargo of activities, to which the following sanctions shall be applied:

I – admonishment;

II – fine;

III – seizure of GMOs and their by-products;

IV – suspension of marketing GMOs and their by-products;

V – activity embargo;

VI – partial or full disability of facilities, activity or enterprise;

VII – suspension of registration, licence or authorisation;

VIII – cancellation of registration, licence or authorisation;

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

X – loss or suspension of credit line with an official credit institution;

XI – intervention in the facilities;

XII – prohibition of entering any agreement with public administration for up to 5 (five) years.

Article 22. Registration and inspection agencies and entities, referred to in Article 16 of this Law are responsible for defining criteria, amounts and to collect fines ranging from R$ 2,000.00 (two thousand reais) to R$ 1,500,000.00 (one million five-hundred reais), proportional to the seriousness of the infringement.

Paragraph 1. Fines can be applied at a cumulative basis in conjunction with other sanctions provided by this article.

Paragraph 2. In cases of repeated infringement the fine shall be doubled.

Paragraph 3. In cases of continuous infringement, characterised by the permanence of the action or omission previously punished, the relevant punishment shall be applied on a daily basis until the cause is stopped, without loss of immediately halting the activity or disabling the responsible laboratory or the institution or the company.

Article 23. Fines established under the terms of this Law shall be applied by the registration and inspection agencies and entities under the Ministries of Agriculture, Cattle Raising and Supply, of Health, for the Environment and the Special Secretariat for Aquaculture and Fisheries to the Office of the President of the Republic referred to Article 16 of this Law, according to their respective competences.

Paragraph 1. Income yielded from the collection of fines shall be allocated to the registration and inspection agencies and entities referred to Article 16 of this Law, which have applied the fine.

Paragraph 2. Federal public administration inspection agencies and entities can enter agreements with the States, the Federal District and Municipalities in order to carry out services related to the inspection as provided by this Law and can transfer a part of the income obtained from the payment of fines.

Paragraph 3. The inspection authority shall forward a copy of the infringement record to *CTNBio*.

Paragraph 4 When the infringement is a crime or a misdemeanour, or is damaging to the Federal Public Finances or the consumer, the inspection authority shall represent with the relevant agency to investigate the administrative and penal accountability.

CHAPTER VIII

Crimes and Punishment

Article 24. For using a human embryo in breach with that which is provisioned by Article 5 of this Law:

Punishment by confinement from 1 (one) to 3 (three) years and fine.

Article 25. For performing genetic engineering on a human germinal cell, human zygote or human embryo:

Punishment by confinement from 1 (one) to 4 (four) years and fine.

Article 26. For performing human cloning:

Punishment by confinement from 2 (two) to 5 (five) years and fine.

Article 27. For releasing or discharging GMOs onto the environment, breaching norms set forth by *CTNBio* and registration and inspection agencies and entities:

Punishment by confinement from 1 (one) to 4 (four) years and fine.

Paragraph 1. (VETOED)

Paragraph 2 Punishment will be aggravated:

I – by 1/6 (one sixth) to 1/3 (one third), if a third party asset is damaged;

II – by 1/3 (one third) to one-half if the environment is damaged;

III – by one-half to 2/3 (two thirds), if third-parties are seriously physically injured;

IV – by 2/3 ((two thirds) to twice the amount if a third-party dies.

Article 28. For using, marketing, registering, filing for patent registration and licensing restricted use genetic technologies:

Punishment by confinement from 1 (one) to 4 (four) years and fine

Article 29. For the non-authorised production, storage, transportation, marketing, import or export of GMOs and their by-products, breaching the norms provided by *CTNBio* and by registration and inspection agencies and entities:

Punishment by confinement from 1 (one) to 2 (two) years and fine.

CHAPTER IX

Final and Temporary Provisions

Article 30. GMOs which have been granted a favourable technical opinion by *CTNBio* authorising their commercial clearance until this Law is enacted can be registered and marketed, except when *CNBS* pronounces itself against it, within 60 (sixty) days as of the date when this Law is published.

Article 31. *CTNBio* and the registration and inspection agencies and entities referred to in Article 16 of this Law shall review their normative deliberations within 120 (one-hundred and twenty) days, in order to align them to the provisions of this Law.

Article 32. Biosafety Quality Certificates, communiqués and technical opinions already granted by *CTNBio* shall still be valid, as well as statutory acts supported by Law no 8.974, of January 1995, provided they are not conflicting with the terms of this.

Article 33. Institutions which carried out activities regulated by this Law on the day when it was published shall align their provisions within 120 (one-hundred and twenty) days, as of the publication of the enactment decree.

Article 34. Temporary registrations granted under Law no 10.814, of 15 December 2003 are hereof co-validated.

Article 35. It is hereof authorised to produce and market gluphosate-tolerant genetically modified sowing soybean seeds that are registered with the National Seed Registration (*RNC*) under the Ministry of Agriculture, Cattle-Raising and Supply.

Article 36. It is hereof authorised to grow gluphosate-tolerant genetically modified sowing soybean seeds, which have been reserved by rural producers for their own use, for the 2004/2005 crop, and it is forbidden to sell the production as seed.

Sole paragraph. The Executive Power has the right to extend the authorisation which is the subject-matter of the caption of this article.

Article 37. The description of Code 20 of Appendix VIII of Law no 6.938, of 31 August 1981, added to by Law no 10.165, of 27 December 2000, is now in effect with the following wording:

"APPENDIX VIII

Code	Category	Description	Pp/gu
....	.....	.....	.....
20	Use of Natural Resources	Forestry; economic exploitation of wood or firewood and forestry by-products, import or export of Brazilian native fauna and flora; breeding activity and economic exploitation of exotic fauna and wild fauna; the use of natural genetic heritage; exploitation of live water resources; the introduction of exotic species, except those used to improve plant genetics and used in agriculture; the introduction of genetically modified species previously identified by *CTNBio* as a potential and significant environmental degradation agent; the use of biological diversity by biotechnology in activities previously identified by *CTNBio* as a potential and significant environmental degradation agent.	Medium
.....	.....	.....	.....

Article 38. (VETOED)

Article 39. It is not applicable to GMOs and their by-products that which is provided by Law no 7.802, of 11 July 1989, and its amendments, except in cases where they are developed to be used as raw material to produce pesticides.

Article 40. Foodstuff and food ingredients for human or animal consumption which contain or are produced with GMOs or their by-products shall show this information on their label, according to regulation.

Article 41. This Law shall be in effect on the date when it is published.

Article 42. The following are revoked: Law no 8.974, of 5 January 1995, Provisional Measure no 2.191-9, of 23 August 2001, and arts. 5, 6, 7, 8, 9, 10 and 16 of Law no 10.814, of 15 December 2003.

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

LUIZ INÁCIO LULA DA SILVA
Márcio Thomaz Bastos
Celso Luiz Nunes Amorim
Humberto Sérgio Costa Lima
Luiz Fernando Furlan
Patrus Ananias
Eduardo Campos
Marina Silva

Miguel Soldatelli Rossetto
José Dirceu de Oliveira e Silva

This text does not replace that which was published in the Federal Gazette of 28.3.2005.

Fuente: Comisión Técnica Nacional de Bioseguridad- Brasil, http://www.ctnbio.gov.br/index.php/content/view/12847.html, revisado 12 de mayo del 2010