

Decree No. 1.752, 20 December 1995
LAW NUMBER 8974, January 5, 1995

Enforcing Act items II and V of Paragraph 1, Article 225 of the Federal Constitution, sets standards for the use of genetic engineering techniques and for the environmental release of genetically modified organisms, authorizes the Executive Power to create, within the Presidency of the Republic, the National Technical Commission on Biosafety, and provides for other measures.

THE PRESIDENT OF THE REPUBLIC

Be it known that the National Congress decrees and I approve the following Law:

Article 1 - This law sets standards and means for controlling the use of genetic engineering techniques in the construction, cultivation, manipulation, transportation, marketing, consumption, release and disposal of genetically modified organisms (GMOs), with the objective of protecting the life and health of humans, animals and plants, as well as the environment.

Article 2 - The activities and projects, including those of teaching, scientific research, technological development and industrial production involving GMOs in Brazilian territory, are restricted to the domain of public or private legally established organizations, which shall be held responsible for obeying the precepts of this Law and of its regulations, as well as for whatever effects or consequences may arise from lack of compliance therewith.

Paragraph 1 - For the purposes of this Law, activities and projects in the domain of organizations are considered to be those carried out in their own facilities or in those of third parties under the technical or scientific responsibility of those organizations.

Paragraph 2 - The activities and projects referred to by this article are forbidden for physical persons as independent autonomous agents, even if they are employed or have any other relation to juridical persons.

Paragraph 3 - Public and private, national, foreign or international organizations which finance or sponsor the activities referred to by this article shall assure themselves of the technical and scientific competence and full compliance, by the body to be financed, sponsored or contracted, with the standards and safeguard mechanisms required by this Law, to which end they shall require presentation of the Certificate of Quality in Biosafety established in Article 6, item XIX, in order to avoid joint liability for whatever effects or consequences may arise from lack of compliance therewith.

Article 3 - For the purposes of this law, the following definitions shall hold:

I - organism - any biological entity capable of reproducing and/or transferring genetic material, including virus, prions and other classes which come to be known;

II - desoxyribonucleic acid (DNA), ribonucleic acid (RNA) - genetic material which contains information that determines hereditary characteristics that are transmittable to descendants.

III - recombinant DNA/RNA molecules - those which have been manipulated outside the living cells, through modification of natural or synthetic DNA/RNA segments and which can multiply in a living cell, and also the DNA/RNA molecules resulting from this multiplication. Synthetic DNA/RNA segments are also considered to be equivalent to those of natural DNA/RNA segments.

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

V - genetic engineering - the activity of manipulating recombinant DNA/RNA molecules.

Paragraph - GMOs do not include organisms arising from techniques that imply the direct introduction, into an organism, of hereditary material, when this does 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.

Article 4 - This Law is not applicable when the genetic modification is obtained through the following techniques, as long as they do not imply the use of a GMO as a receptor or donor:

I - mutagenesis;

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

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

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

Article 5 - [VETOED]

Article 6 - [VETOED]

Article 7 - The responsibilities of the inspection agencies of the Ministry of Health, of the Ministry of Agriculture, Supply and Agrarian Reform and of the Ministry of the Environment and the Legal Amazon, within their respective jurisdictions and considering the final technical opinion of the CTNBio and the mechanisms established in the regulations of this law.

I - [VETOED]

II - the control and inspection of all activities and projects related to Group II GMOs;

III - the issuance of registrations for products containing GMOs or derived from GMOs which are to be marketed for the human, animal or plant use or for release into the environment;

IV - the granting of authorization for the operation of laboratories, institutions or companies carrying out activities related to GMOs;

V - the issuance of authorization for the entry into the country of any product containing GMOs or derived from GMOs;

VI - maintenance of a register of all institutions and professionals carrying out activities and projects related to GMOs in the national territory;

VII - submission to the CTNBio, for the issuance of its technical opinion, of all procedures related to projects and activities involving GMOs;

VII - submission for publication in the Diário Oficial da União [Official Daily Federal Register] of the result of procedures judged by the agency, as well the conclusions of the technical opinion;

IX - application of penalties provided for by articles 11 and 12 of this Law.
Article 8 - The following activities related to GMOs are forbidden:

I - any genetic manipulation of living organisms or the *in vitro* handling of natural or recombinant DNA/RNA except under the standards provided by this Law;

II - genetic manipulation of human germ cells;

III - *in vivo* intervention in human germ cells, except for the treatment of genetic defects, obeying ethical principles such as the principle of autonomy and the principle of beneficence, and with the previous approval of the CTNBio;

IV - the production, storage or manipulation of human embryos 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, obeying ethical principles such as the principle of responsibility and the principle of prudence, and with the previous approval of the CTNBio;

VI - the release or disposal into the environment of GMOs other than under the standards set by the CTNBio as provided by the regulation of this Law.

Paragraph 1 - Products containing GMOs which are destined to marketing or industrialization, originating in other countries, may only be introduced into Brazil following the previous final conclusion of the CTNBio and authorization by the pertinent control agency, with consideration to be given to technical opinions issued in other countries, when available.

Paragraph 2 - Products containing Group II GMOs, as defined in Appendix I of this Law, may only be introduced into Brazil following the previous final conclusion of the CTNBio and the authorization of the pertinent control agency.

Paragraph 3 - [VETOED]

Article 9 - Any organization using genetic engineering techniques and methods shall create an Internal Biosafety Commission/CIBio, in addition to naming a principle technical responsible for each specific project.

Article 10 - The Internal Biosafety Commission (CIBio), within the domain of the respective institution, is responsible for:

I - maintaining the employees, any person and the community informed, when they may be affected by the activity, with regards to all issues related to health and safety, as well as related to procedures in the event of accidents;

II - establishing prevention and inspection programs to assure the operation of facilities under their responsibility, within the rules and standards of biosafety, as defined by the CTNBio in the regulations of this Law;

III - submission to the CTNBio of documents to be listed in the regulations of this Law, in order to be analyzed and receive authorization from the pertinent agency whenever necessary;

IV - maintaining individual progress reports for each activity or project that is underway involving GMOs;

V - notifying the CTNBio, Public Health authorities and employees' organizations of the results of assessments of risk to which any exposed persons are submitted, as well as any accident or incident that may cause the dissemination of the biological agent;

VI - investigation of the occurrence of accidents and diseases possibly related to GMOs, and notification of the CTNBio regarding their conclusions and measures taken.

Article 11 - For the purposes of this law, all acts or omissions that constitute non-compliance with the precepts established herein, as well as the disobeyance of normative determinations made by the competent administrative agencies or authorities, constitute infractions, with the exception of Paragraph Paragraph 1 and 2 and items II to VI of article 8.

Article 12 - The CTNBio is authorized to set the value of fines of at least 16,110.80 UFIRs, to be applied by the inspection agencies referred to in article 7, proportionate to the direct or indirect damages, for the following infractions:

I - disobeyance of prevailing biosafety rules and standards;

II - execution of a project without previously registering the organization carrying out the research and manipulation of GMOs and the project's responsible technician, as well as the CTNBio;

III - environmental release of any GMO whose previous approval has not been published in the Diário Oficial da União [Official Daily Federal Register];

IV - operation of laboratories that manipulate GMOs without observing the biosafety standards set in the regulations of this Law;

V - failure to completely investigate accidents occurring in the course of research and projects in the area of genetic engineering, or failure to submit the respective report to the competent authority within a maximum of 5 (five) days following the date of the event;

VI - execution of a project without keeping individual progress reports;

VII - failure to notify the CTNBio and public health authorities immediately of any accident that may cause the dissemination of GMOs;

VIII - failure to adopt the means necessary to fully inform the CTNBio, public health authorities, the community and other employees of the institution or company regarding the risks to which they are exposed, as well as procedures to be followed in the event of accidents;

IX - any genetic manipulation of a living organism, or *in vitro* handling of natural or recombinant DNA/RNA, when not carried out in compliance with standards set in this Law and in its regulations.

Paragraph 1 - In cases of recurrence, the fine will be doubled.

Paragraph 2 - In cases of on-going infractions, characterized by continuation of the action or omission initially punished, the respective penalty will be applied daily until its cause ceases, with no prejudice to the competent authority's ability to halt the activity immediately and/or to interdict the laboratory or the responsible institution or company.

Article 13 - The following activities are considered crimes:

I - the genetic manipulation of human germ cells;

II - the *in vivo* intervention in human genetic material, except for the treatment of genetic defects, in obedience of ethical principles such as the principle of autonomy and the principle of beneficence, and with the previous approval of the CTNBio;
Penalty - imprisonment for three months to one year.

Paragraph 1 - If it results in:

- a) incapacity to perform habitual occupations for more than thirty days;
- b) peril of death;
- c) permanent debility of a member, sense or function;

d) acceleration of delivery;
Penalty - imprisonment for one to five years.

Paragraph 2 - If it results in:

- a) permanent incapacity to work;
- b) incurable disease;
- c) loss of use or loss of a member, sense or function;
- d) permanent disability;
- e) miscarriage;

Penalty - imprisonment for two to eight years.

Paragraph - If it results in death;

Penalty - imprisonment for six to twenty years.

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

Penalty - imprisonment for six to twenty years.

IV - *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, in obedience of ethical principles such as the principle of responsibility and the principle of prudence, and with the previous approval of the CTNBio;

Penalty - imprisonment for three months to one year.

V - the release or disposal into the environment of GMOs other than under the standards set by the CTNBio as provided by the regulation of this Law.

Penalty - imprisonment for one to three years.

Paragraph 1 - If it results in:

- a) minor corporal lesions;
- b) peril of death;
- c) permanent debility of a member, sense or function;
- d) acceleration of delivery;
- e) damage to the property of third parties;
- f) damage to the environment;

Penalty - imprisonment for one to five years.

Paragraph 2 - If it results in:

- a) permanent incapacity to work;
- b) incurable disease;
- c) loss of use or loss of a member, sense or function;
- d) permanent disability;
- e) miscarriage;
- d) destruction of the property of third parties;
- e) severe damage to the environment;

Penalty - imprisonment for two to eight years.

Paragraph 3 - If it results in death;

Penalty - imprisonment for six to twenty years.

Paragraph 4 - If the release, disposal in the environment or introduction into the environment of GMOs is culpable;
Penalty - imprisonment for one to two years.

Paragraph 5 - If the release, disposal in the environment or introduction into the country of GMOs is culpable, the penalty will be increased by one third if the crime arose from disobedience of a technical rule of the profession.

Paragraph 6 - The Public Ministry of the Union and of the States may legitimately propose suits for civil and criminal liability for damages caused to humans, to animals, to plants and to the environment, if this law is disobeyed.

Article 14 - Without prejudice to the application of the penalties provided by this Law, the author is obliged, independent of the existence of culpability, to make compensation or to repair damage caused to the environment and to third parties affected by the author's activity.

General and Transitional Provisions

Article 15 - This Law shall be regulated within 90 (ninety) days after its publication.

Article 16 - Organizations who are carrying out activities regulated by this Law on the date of its publication, shall adapt to its provisions within one hundred and twenty days, following the publication of the decree that regulates it, and shall present a detailed report on existing products and on research and projects underway involving GMOs.

Paragraph - If the existence of severe risks for the health of humans or of animals, for plants or for the environment are verified, the CTNBio will order the immediate paralyzation of such activity.

Article 17 - This Law is effective on the date of its publication.

Article 18 - All provisions to the contrary are revoked.

Brasília, January 5, 1996; 174th year of Independence and 107th year of the Republic.

FERNANDO HENRIQUE CARDOSO

Nelson Jobim

José Eduardo de Andrade Vieira

Paulo Renato Souza

Adib Jatene

José Israel Vargas

Gustavo Krause

APPENDIX I

For the purposes of this Law, genetically modified organisms are classified as follows:

Group I: includes organisms that fulfill the following criteria:

A. Receptor or parental organism:

- non-pathogenic;

- free of foreign agents;
- possessing a broad documented history of safe use, or the incorporation of biological barriers which, without interfering in the receptor or fermentor's optimal growth, allows for its limited survival and multiplication, with no negative effects for the environment.

B. Vector/insert

- must be adequately characterized and free of known harmful sequences;
- its size must be limited, to the extent possible, to the genetic sequences needed to carry out the function for which it was designed;
- must not increase the stability of the modified organism in the environment;
- must be barely movable;
- must not transmit any resistance marker to organisms which, according to available knowledge, do not acquire this resistance naturally.

C. Genetically modified organisms:

- non-pathogenic;
- offering the same safety as the receptor or parental organism in the reactor or fermentor, but with limited survival and/or multiplication, with no negative effects on the environment.

D. Other genetically modified organisms that could be included in Group I, as long as they combine the conditions stipulated in item C above:

- microorganisms constructed entirely from a single prokaryotic receptor (including plasmids and endogenous viruses) or from a single eukaryotic receptor (including its chloroplasts, mitochondria and plasmids, but excluding virus) and organisms composed entirely by genetic sequences from different species that exchange such sequences through known physiological processes.

Group II: all those not included in Group I.

REASONS FOR THE VETO

Message Number 39

To the President of the Federal Senate,

I hereby advise you, under the terms of paragraph 1, article 66 of the Federal Constitution, that I have decided to partially veto Bill Number 114 from 1991 (Bill 2,560/92 in the Chamber of Deputies), which "Regulates items II and V of Paragraph 1 of Article 225 of the Federal Constitution, sets standards for the use of genetic engineering techniques and for the environmental release of genetically modified organisms, authorizes the Executive Branch to create, within the Presidency of the Republic, the National Technical Commission on Biosafety, and provides for other measures."

The Ministry of Science and Technology, based on the reasons presented as follows, has proposed the veto of the following provisions:

Article 5

Article 5 - The Executive Power is authorized to create, within the Office of the Presidency, the National Technical Commission on Biosafety, hereinafter called the CTNBio, with the purpose of supervising the development and the technical and scientific progress of genetic engineering, of biotechnology, of bioethics, of biosafety and of related areas, with strict regards to the safety of consumers and of the population in general, with constant care for the protection of the environment, and with the responsibility for promoting and proposing all complementary research and studies with the objective of assessing the potential risks of new methods and available products.

Paragraph 1 - The National Technical Commission on Biosafety - CTNBio, to be named by the President of the Republic, will be made up of full members and their alternates, as follows:

I - one representative of the Presidency of the Republic;

II - eight experts working in the field of biotechnology, two of them in the field of human health, two in the field of animal health, two in the area of agriculture and two in the area of the environment;

III - one representative of each of the following Ministries:

a) Ministry of Health;

b) Ministry of Agriculture, Supply and Agrarian Reform;

c) Ministry of the Environment and the Legal Amazon;

d) Ministry of Education and Sports;

e) Ministry of Science and Technology;

IV - one representative of an official consumer defense agency;

V - one representative of an official workers' health agency;

VI - one representative of companies related to the field of biotechnology, to be named from a list of three nominations presented by associations representing this sector, which are legally registered on the date that this law is published.

Paragraph 2 - The members of the CTNBio shall possess notable scientific and technical knowledge and will be renewed every three years, one third one time, and two thirds the next.

Paragraph 3 - The seat of the CTNBio shall be in Brasília, DF.

Paragraph 4 - The CTNBio shall meet periodically, in ordinary meetings, once per month, for a period to be set in the regulation, and in extraordinary meetings whenever convened by its Executive Secretary or by the absolute majority of its members, in writing, with justification.

Paragraph 5 - The functions and activities to be performed by the CTNBio shall be considered to be of great importance and honorific, and its members shall not receive any remuneration arising from these functions, with the exception of payment for travel and lodging expenses during the meetings.

Paragraph 6 - The deliberations of the CTNBio shall be made by a two-thirds majority of its members.

Paragraph 7 - The Executive Secretariat of the CTNBio shall be exercised by the Secretariat of Strategic Affairs of the Presidency of the Republic, which shall provide administrative support and whose budget shall include resources for the operation of the Commission.

Paragraph 8 - The positions of Executive Secretary and of Under Executive Secretary of the CTNBio are hereby created, respectively DAS 101.4 and 101.3, within the agency referred to in the preceding paragraph.

Reasons for the veto:

"The issuance of Provisional Measure 813, on January 1, 1995, on the organization of the Presidency of the Republic, arose from profound reflections on the most appropriate structure for the achievement of the objectives of the present Government. For this reason, the signing of Bill 114/91 without the exclusion of its Article 5, which amounts to the insertion of a National Technical Commission on Biosafety into the new organizational structure of the Presidency of the Republic, would upset the balance achieved by that Provisional Measure.

"The truth is that the organization of an appropriate commission and the definition of its attributes and linkages should be the object of a legal measure to be taken in timely fashion, in the light of studies on State reform which are now beginning.

"In addition, the creation, structure and attributes of public agencies can only be the subject matter of bills presented at the exclusive initiative of the President of the Republic (Constitution, Article 61, II, "e")."

Article 6

Article 6 - The National Technical Commission on Biosafety/CTNBio, among other attributes, will have the power to:

I - draft and approve its Bylaws within thirty days after it is named;

II - propose to the President of the Republic the National Biosafety Policy;

III - accompany the development and the technical-scientific progress in genetic engineering, in biotechnology, in biosafety and in related areas, with strict respect for the health and safety of workers, consumers, the population in general, the fauna, the flora and the environment.

IV - maintain relations with institutions dedicated to genetic engineering and biosafety nationally and internationally;

V - propose to the President of the Republic a Code of Ethics for activities involving Genetic Manipulation;

VI - propose research and studies to assess the potential benefits and risks of new methods and products in the field of genetic engineering;

VII - establish the operating mechanisms of the Institutional Biosafety Commissions (CIBios) within each institution dedicated to teaching, researching, developing and using genetic engineering techniques;

VIII - set rules and standards regarding activities and projects related to GMOs, with the aim of constantly updating this legislation;

IX - receive the documentation required by the regulations of this Law from all the projects and activities related to GMOs, and verify their correct classification, as defined in Appendix I of this Law;

X - classify GMOs by degree of risk, defining the level of biosafety based on standards set in the regulations of this Law, as well as defining activities considered unhealthy and hazardous;

XI - issue conclusive technical opinions on projects involving GMOs belonging to Group II, based on Appendix I of this Law, and present them to the competent agencies;

XII - provide technical support for the competent agencies in the process of investigating accidents and diseases occurring in the course of projects and activities in the area of genetic engineering, as well as in the control and monitoring of these projects and activities;

XIII - propose regulations for the transportation, storage, release and disposal of GMOs;

XIV - issue previous conclusive technical opinions on any environmental release of GMOs, and present them to the competent agency;

XV - recruit *ad hoc* consultants, when it deems necessary;

XVI - publish in the Diário Oficial da União [Official Daily Federal Register], previous to the judgment process, for society to take note, a representative summary of applications presented to the CTNBio that involve activities and projects implying the environmental release of GMOs, excluding any information identified as secret by the applicant and considered as such by the CTNBio;

XVII - issue previous conclusive technical opinion on the records and use of products containing GMOs or derived from GMOs, presenting them to the competent control agency;

XVIII - require, as additional documentation, if it deems necessary, the Environmental Impact Study (EIS) and the respective Environmental Impact Report (EIR) for projects and applications involving the environmental release of GMOs, in addition to requirements specific to the level of risk as established in the regulation of this Law;

XIX - issue Certificates of Quality in Biosafety for facilities destined for any activity or project involving GMOs, previous to their operation, or whenever there are changes in any component that may modify pre-established safety conditions;

XX - propose the regulations for this Law.

Reasons for the veto:

Same as those for the veto of Article 5.

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Item I of article 7

"Article 7 -

I - the issuance of previous authorization for activities or projects related to GMOs belonging to Group II."

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Reasons for the veto

"Previous authorization is both innocuous and risky, for the following reasons:

- a) The agencies of the Executive Branch mentioned in article 7 are responsible for authorizing activities related to GMOs in general (IV): "considering the final technical opinion of the CTNBio." Therefore, previous authorization does not exclude the need for analysis by the CTNBio, which will issue its conclusive technical opinion on the application, to be considered by the competent agencies;
- b) The group II organisms referred to by article 7, I are precisely those which demand the greatest care with respect to biosafety. Previous authorization of an activity or project whose safety has not been assessed means assuming an unwarranted risk."

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Paragraph 3 of article 8

"Article 8 -

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Paragraph 3 - The entry into Brazil of products containing GMOs to be used in research or teaching and belonging to Group I as defined in Appendix I of this Law shall only be allowed with the previous authorization of the competent control agency."

Reasons for the Veto

"The consequences of this paragraph will be an unnecessary delay for all teaching and research projects and activities relative to genetic engineering in the country.

Appendix I of the Law makes it clear that Group I organisms are: 'non-pathogenic, free of foreign agents, and possessing a broad documented history of safe use.'

Around the world, these organisms have been used safely, based on guidelines originally formulated by the National Institutes of Health, and which have already been translated and adapted to the conditions of Brazil. In addition, the actions provided for in the Law for the competent agencies (article 7, IV), for the CTNBio (article 6) and for the Internal Biosafety Commissions (article 10) are more than sufficient instruments to assure the safe use of Group I organisms and products, there being no need for the authorization mentioned in paragraph 3 of article 8."

These, Mr. President, are the reasons that caused me to partially veto this bill, and I hereby submit them for examination by the Members of the National Congress.

Brasília, January 5, 1995

FERNANDO HENRIQUE CARDOSO

Decree No. 1,752, December 20, 1995

Enforcing Law No. 8,974 of January 5, 1995, on the hierarchy, jurisdiction, and structure of the National Technical Commission on Biosafety - CTNBio - and making other provisions.

The Vice President of the Republic, acting in the office of President of the Republic, with the authority invested in him under Article 84, sections IV and VI of the Constitution, and in view of Law No. 8,974 of January 5, 1995,

So decrees:

Chapter I

On the Hierarchy of the CTNBio

Article 1. The National Technical Commission on Biosafety - CTNBio, is part of the Executive Secretariat of the Ministry of Science and Technology.

Paragraph 1. The CTNBio will have an Executive Secretariat, which will provide technical and administrative support for the Commission.

Chapter II

On the Jurisdiction of the CTNBio

Article 2. It is the responsibility of the CTNBio:

I. to propose a National Biosafety Policy;

II. to monitor the development and technical and scientific progress of biosafety and related areas, aimed at the safety of consumers and the general population, with constant surveillance to protect the environment;

III. to deal with institutions devoted to genetic engineering and biosafety at the national and international levels;

IV. to propose a Code of Ethics for Genetic Manipulation;

V. to establish standards and regulations for activities and projects involving the making, culture, handling, use, transportation, storage, marketing, consumption, release and disposal of genetically modified organisms (GMOs);

VI. to classify GMOs according to their degree of risk, defining biosafety levels assigned to them and to what are considered unhealthy and dangerous activities;

VII. to establish mechanisms for operations of the Internal Biosafety Committees - CIBio's - within each institution and which are devoted to research on and teaching, development, and utilization of genetic engineering techniques;

VIII. to issue expert technical opinions on projects related to GMOs pertaining to Group II, as defined in Appendix I of Act No. 8,974, of 1995, referring them to the competent agencies;

IX. to provide technical support for the competent agencies in the process of investigating accidents and diseases observed over the course of projects and activities in the area of genetic engineering, as well as to inspect and monitor such projects and activities;

X. to issue a conclusive prior expert technical opinion on the release of any GMO into the environment, referring it to the competent agency;

XI. to publish in the *Diário Oficial da União* [Official Daily Federal Register], prior to the process of analysis, the list of petitions submitted for approval and referring to the release of GMOs into the environment, excluding confidential information of

commercial interest, the object of intellectual property, identified by the applicant and thus considered by the Commission;

XII. to issue a conclusive prior expert technical opinion on the registration, use, transportation, storage, marketing, consumption, release, and disposal of any product containing GMO or derivative, referring it to the competent inspection agency;

XIII. to publish in the *Diário Oficial da União* [Official Daily Federal Register] the results of cases submitted to it for judgment;

XIV. to demand as additional documentation, whenever it deems necessary, an Environmental Impact Study (EIS) and the respective Environmental Impact Report (EIR) for projects and applications involving the release of GMOs into the environment, in addition to specific requirements for the applicable risk level;

XV. to issue, at the request of the applicant, a Biosafety Quality Certificate (BQC), referring to installations devoted to any activity or project involving GMOs or derivatives;

XVI. to recruit ad hoc consultants whenever necessary;

XVII. to propose changes in the enforcement of Act No. 8,974 of 1995;

XVIII. to draft and approve its internal statutes within 30 days after being established.

Chapter III

On the Structure of the CTNBio

Article 3. The CTNBio, made up of full members and alternates designated by the President of the Republic, will be constituted as follows:

I. eight renowned scientific and technical specialists active in the field of biotechnology, two of whom from the human sciences, two from the animal sciences, two from the plant sciences, and two from the environmental sciences;

II. one representative from each of the following Ministries, named by the respective Ministers:

a) Science and Technology;

b) Health;

c) Environment, Water Resources, and Legal Amazonia;

d) Education and Sports;

e) Foreign Relations;

III. two representatives from the Ministry of Agriculture, Supply, and Agrarian Reform, including one from agriculture and one from livestock, named by the respective Minister;

IV. one representative from a legally established consumer defense agency;

V. one representative from legally established associations representing the biotechnology business sector, to be named by the Minister of Science and Technology based on a list of three names submitted by the above-mentioned associations;

VI. one representative from a legally established agency for protection of workers' health.

Paragraph 1. Candidates named to membership in the CTNBio should have the proper credentials and professional experience in the biotechnology field, as demonstrated by their respective resumé.

Paragraph 2. Specialists referred to in section I will be named by the Minister of Science and Technology from among scientists with doctoral degrees who are recommended by scientific and technological institutions and associations from the biotechnology field.

Paragraph 3. Nominations mentioned in the previous paragraph will be made within thirty days from receipt of the consultation issued by the Executive Secretariat of the CTNBio and within the same period whenever a vacancy occurs.

Paragraph 4. In the case of non-approval of names submitted, the Minister of Science and Technology may solicit indication of alternative candidates.

Paragraph 5. The representative referred to in section IV of this article will be named by the Minister of Science and Technology from a list of three candidates from public or non-governmental consumer defense institutions, following the same process of consultation and indication provided for under paragraph 3.

Paragraph 6. Such public or private consumer defense institutions will be those registered at the Department of Consumer Protection and Defense, Secretariat of Economic Law, Ministry of Justice.

Paragraph 7. Each of the representative associations from the biotechnology business sector that is legally established and registered with the Executive Secretariat of the CTNBio will submit a list of three candidates for selection of the representative mentioned in section V, following the same process of consultation and indication provided for under paragraph 3.

Paragraph 8. The representative referred to in section VI of this article will be named by the Minister of Science and Technology, based on suggestions from the Ministries of Health and Labor and non-governmental organizations for the protection of workers' health, following the same process of consultation and indication provided for under paragraph 3.

Chapter IV

On the Term of Office CTNBio Members

Article 4. Members of the CTNBio will serve a term of three years and may be reelected only once.

Paragraph 1. Every three years there will be a turnover of half the members of the CTNBio, such that at the end of the first term four of the eight specialists referred to in Section I, Article 3, will necessarily be reelected.

Article 5. The Minister of Science and Technology will designate one member of the CTNBio as chairperson of the Commission, from a list of three names drafted by the board during its inaugural session.

Paragraph 1. The Chairperson of the CTNBio will serve a term of one year, which may be renewed as many as two times.

Article 6. Functions and activities developed by CTNBio members will be considered highly relevant and honorific but will not involve any form of remuneration, except for payment of transportation and food and lodging during meetings.

Chapter V

On CTNBio Standards and the Biosafety Quality Certificate

Article 7. Standards and provisions to be issued by the CTNBio and pertaining to activities and projects related to GMOs and derivatives will include the making, culture, handling, use, transportation, storage, marketing, consumption, release, and disposal of same, with a view especially towards safety with the material and protection of living beings and the environment.

Article 8. The Biosafety Quality Certificate, or BQC, referred to in Paragraph 3, Article 2, of Act No. 8,974 of 1995 is required of domestic, foreign, or international organizations in order to develop activities related to GMOs and derivatives and must be requested by the applicant and issued by the CTNBio.

Paragraph 1. Included among the organizations referred to in this article are those devoted to teaching, scientific research, and technological development and provision of services involving GMOs and derivatives inside Brazilian national territory.

Paragraph 2. In order to fund or sponsor activities or projects provided for under this article, even through agreements or contracts, public and private domestic, foreign, or international organizations must require the BQC of the beneficiary institutions operating in Brazilian territory, or else they may be considered accessories to effects resulting from non-compliance with this requirement.

Paragraph 3. The application for obtaining a BQC should include documents referring to the constitution of the respective legal entity, its location, financial competence, purpose, detailed description of installations and personnel, and other information to be specified on a form to be defined by the CTNBio with normative instructions.

Paragraph 4. A new BQC will be required whenever there is a change in any part that may modify the previously approved conditions.

Paragraph 5. After receiving a request for a BQC, the Executive Secretariat of the CTNBio will have a period of thirty days to manifest itself on the documentation submitted to it, drafting whatever requirements it deems necessary. Once the requirements have been met and the inspection made whenever necessary by a member of the CTNBio or a specialized person or firm accredited and hired for this purpose, the CTNBio will issue the BQC within a period of thirty days.

Chapter VI

On the Functioning of the CTNBio

Article 9. Petitions related to activities with GMOs or derivatives, including registration of products, should be submitted to the CTNBio on a specific form to be defined under normative instructions.

Article 10. The CTNBio will set up - among its full members and alternates - Specific Sectoral Committees to provide technical support for inspection agencies from the Ministries of Health, Agriculture, Supply, and Agrarian Reform, and Environment, Water Resources, and Legal Amazonia, with regard to the jurisdictions ascribed to them under Law No. 8,974 of 1995.

Paragraph 1. Each Committee referred to in the heading to this Article will be made up of a representative from the respective Ministry in charge of the specific sector in relation to the CTNBio and who will chair it and CTNBio members related to that sector.

Paragraph 2. Members of the Specific Sectoral Committees, both full and alternate, will serve a term of three years, and may be reelected. The term in the Committee will end together with the term served in the CTNBio.

Paragraph 3. The Specific Sectoral Committees will function as an extension of the CTNBio and will have an adequate structure for their functioning in the respective Ministries.

Paragraph 4. The Specific Sectoral Committees may recruit ad hoc consultants whenever necessary.

Article II. The following agencies will be responsible for the registration, transportation, marketing, handling, and release of products containing GMOs or derivatives, based on an opinion issued by the CTNBio:

I. in the Ministry of Health, the Secretariat for Health Surveillance;

II. in the Ministry of the Environment, Water Resources, and Legal Amazonia, the Secretariat for Coordination of Environmental Issues;

III. in the Ministry of Agriculture, Supply, and Agrarian Reform, the Secretariat for Agricultural and Livestock Defense;

Article 12. Inspection and monitoring of activities referred to in the previous Article will be conducted by the Specific Sectoral Committees in the respective Ministries, in accordance with the competent inspection agencies.

Paragraph 1. Activities related to research and development with GMOs and derivatives will have their inspection mechanisms defined by the CTNBio.

Article 13. It will be up to the CTNBio to refer the petitions to the Specific Sectoral Committees in charge of writing up conclusive opinions to be sent to the competent agency referred to in Article 12 of the Decree for the proper action.

Paragraph 1. Having performed the necessary review, the Specific Sectoral Committees will return the cases to the CTNBio, which will inform the interested party of the result of the petition and will provide for publication of same.

Article 14. The CTNBio will convene and deliberate with the presence of at least two-thirds of its members.

Chapter VII

On the Publication of Projects

Article 15. When promoting the publication of projects related to the release of GMOs into the environment and submitted for its approval, the CTNBio will examine the points that the applicant considers confidential and thus to be excluded from disclosure.

Paragraph 1. If it does agree with such exclusion, the CTNBio will issue a confidential notice to this effect to the applicant, who will have a period of ten days to respond.

Paragraph 2. If the CTNBio maintains its understanding regarding non-exclusion, it will submit the issue, through a confidential notice, for deliberation by the National Council on Science and Technology in the Ministry of Science and Technology, with its justification, and the final decision will be made within thirty days.

Paragraph 3. Members of the CTNBio must maintain confidentiality with regard to issues submitted to the Commission's plenary.

Chapter VIII

On Transitory Measures

Article 16. Institutions developing activities and projects with GMOs or derivatives on the date of publication of this Decree will have 90 days to request the BQC of the CTNBio.

Paragraph 1. The CTNBio will have a period of ninety days to issue the BQC, and inspection of the applicant institution will be open to the Commission.

Chapter IX

Final Measures

Article 17. The Ministry of Science and Technology will take the necessary measures to include specific resources in its budget for the functioning of the CTNBio, including remuneration of the ad hoc consultants it may come to hire.

Article 18. The deadlines referred to in this Decree which depend on normative instructions to be issued by the CTNBio that enter into effect on the date of publication of same.

Article 19. This Decree enters into effect on the date of its publication.

Article 20. Decree No. 1,520 of June 12, 1995, is hereby revoked.

Brasília, December 20, 1995, 174th Anniversary of Independence and 107th Anniversary of the Republic

Marco Antônio de Oliveira Maciel

Sebastião de Rego Barros Netto

José Eduardo de Andrade Vieira

Paulo Renato Souza

Adib Jatene

Lindolpho de Carvalho Dias

Gustavo Krause

DECREE NUMBER 2.577, APRIL 10, 1998

Provides new wording for Article 3 of Decree no. 1.752 of December 20, 1995, enforcing Law No. 8,974 of January 5, 1995, on the hierarchy, jurisdiction, and structure of the National Technical Commission on Biosafety (CTNBio).

The President of the Republic, with the authority invested in him under Article 84, sections IV and VI of the Constitution, and in view of Act No. 8,974 of January 5, 1995.

SO DECREES:

Article 3. The CTNBio, made up of full members and alternates designated by the Minister of Science and Technology, will be constituted as follows:

.....
V. one representative from legally established associations representing the biotechnology business sector, to be named by the Minister of Science and Technology based on a list of three names submitted by the above-mentioned associations;

.....
Paragraph 2. Specialists referred to in section I will be named by the Minister of Science and Technology from among scientists with doctoral degrees who are recommended by scientific and technological institutions and associations from the biotechnology field.

Paragraph 5. The representative referred to in section IV of this article will be named by the Minister of Science and Technology from a list of three candidates from public or non-governmental consumer defense institutions, following the same process of consultation and indication provided for under paragraph 3.

.....
Paragraph 8. The representative referred to in section VI of this article will be named by the Minister of Science and Technology, based on suggestions from the Ministries of Health and Labor and non-governmental organizations for the protection of workers' health, following the same process of consultation and indication provided for under paragraph 3. (NR)

Art. 2 This Decree enters into effect on the date of its publication.

Brasília, April 30, 1998, 177th Anniversary of Independence and 110th Anniversary of the Republic.

FERNANDO HENRIQUE CARDOSO

José Israel Vargas