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Report Highlights:
Brazil's national Congress approved on March 2, 2005 the so-called Biosafety Bill, which replaced the previous legal framework in use since 1995 under which agricultural biotechnology was developed in Brazil. Brazil's President Lula signed the Biosafety Bill on March 24, 2005, and it became law number 11,105. This law, which also includes provisions for stem cell research, became effective on March 28, 2005 and is expected to stimulate the use of biotechnology in Brazil's agricultural sector.

Includes PSD Changes: No
Includes Trade Matrix: No
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SECTION I. EXECUTIVE SUMMARY

The United States-Brazil bilateral agricultural trade reached a record of US$ 3.7 billion in 2004 with record Brazilian exports to the United States of US$ 3.4 billion. The United States agricultural exports to Brazil totaled nearly US$ 300 million, primarily agricultural commodities to meet local shortfalls. Historically, Brazil is a major producer and exporter of agricultural products, such as soybeans, cotton, sugar, cocoa, coffee, frozen concentrated orange juice, beef, poultry, pork, tobacco, hides and skins, fruits and nuts, fish products, and wood products. As a result, the United States and Brazil are often competitors in third markets, while the United States is a major destination of Brazil's exports of sugar, coffee, tobacco, orange juice, and wood products.

Brazil's national Congress approved on March 2, 2005 the so-called Biosafety Bill, which replaced the previous legal framework in use since 1995 under which agricultural biotechnology was developed in Brazil. Brazil's President Lula signed the Biosafety Bill on March 24, 2005, and it became law number 11,105. This law, which also includes provisions for stem cell research, became effective on March 28, 2005 after its publication in Brazil's official registry (Diario Oficial).

Although law 11,105 brings some rationality to the public debate and court battles occurring in Brazil for the past 7 years, there are still several steps and concerns regarding the full use of biotech crops in Brazil, and its implication for imports and exports of biotech products. The next hurdle is the current debate over the regulation of law 11,105, which will be established by a Presidential Decree. Other deadlocks include the application of the labeling regulations for biotech products, marketing restrictions in some states, and that the court case between Monsanto and environmental and consumer NGOs is still not closed. Also, on June 22, 2005, the Federal Public Prosecutor filed a lawsuit in Brazil's Supreme Court called Direct Action of Unconstitutionality (ADIN) against the new Biosafety Law. ADIN is a legal instrument based on Brazil's constitution to challenge in the highest court any law that is considered to be unconstitutional. Despite all these challenges, Brazilian farmers now have a major legal framework that is expected to boost the use of biotech crops, such as soybeans, cotton, and corn in the upcoming years

SECTION II. BIOTECHNOLOGY TRADE AND PRODUCTION

Status of Product Approvals

Crop	Trait Category	Applicant	Event	Trait Description	Reviewed Uses within Brazil
Cotton Gossypium hirsutum	Insect Restistant	Monsanto	BCE 531	Lepidoptora Order	Textile fibers Food and Feed
Soybeans Glycine max (L.) Merrill	Herbicide Tolerant	Monsanto (Monsoy)	TTS-40-3-2	Glyphosate Herbice Tolerant	Food and Feed
Corn Zea Mays	Insect Resistant Herbicide Resistant	AVIPE (Poultry Producers from Pernambuco	Cry 1a (c) Cry 1a (b) PAT/bar MEPSPS	Lepidopteran resistant Gluphosinate tolerant	Import/Processing /Feed

Source: CTNBio

Soybeans:

Soybean biotech seeds are also registered under the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and meet the requirements of Brazil's Plant Variety Protection Law. This means they can be legally used for planting. Due to the passage of the new biosafety law, Post expects that biotech soybean seeds will account for 40 to 45 percent of the upcoming 2005/06-crop. The following constraints impede biotech soybeans from expanding more rapidly:

1) Lack of biotech seed on hand. ABRASEM, the Brazilian Association of Seed Producers, estimates that there are 4.5 million bags of biotech seed for next year, enough to cover 30% of the current planted area in Brazil. The 2004/05-planted area is estimated at 15-20% biotech. Monsanto also reported that they do not have sufficient seed ready to supply next year's crop. The main producers of RR soybean seed in Brazil are Embrapa, with 20%, followed by Pioneer, Fundacep (Central Experiment and Research Foundation), and the Mato Grosso Foundation.

2) Seed not yet developed for conditions outside the South. Seed brought in from Argentina across the southern border has worked well in the southern region. There are 38 varieties approved for use, including 19 developed by Monsanto, 10 by Embrapa, and 9 by other companies. But, according to ABRASEM and contacts at Embrapa, appropriate varieties for the warmer and more humid regions have begun to be researched more recently, and will not be ready for next year's crop. There are two projects currently targeting biotech seeds that are appropriate for the center-west and Amazon climates. One is a joint Monsanto/Embrapa project that takes conventional varieties already adapted for the region and adds the Glyphosate resistant gene. The expected launch of these biotech seeds is at least one year away. The other project, creating new transgenic seeds for the warmer climates outside of Southern Brazil, has just begun to be researched by Embrapa and BASF.

3) For the first year of legal biotech seed production for commercial use, dry weather is also creating a seed supply that leaves much to be desired. After negotiating with the government for seven years for approval to produce biotech seed, the sector now confronts dry weather that has cut its seed production 30%. According to the ABRASEM, an initial forecast of 5 million bags for next year's harvest has been cut to 3.5 million. This supply will plant 5 million hectares, which is approximately the same amount of area occupied with illegal biotech soy this year.

On the other hand, there are several points that support biotech soybean expansion in Brazil. The main motivator for growing biotech soybeans is lower production costs. DERAL has reported that biotech soybeans cut 20% of the costs of producing conventional varieties (see chart below), and this savings has been verified by other sources. Farmers in the south have been growing roundup ready soybeans for several years, both with and without paying royalties. They obviously continue to do it because it is cost-effective. In the case of Argentina, planting soybeans with RR seed began in 97/98, and within 5 years they were almost entirely biotech. A study performed by Nidera showed that Argentine farmers saved $1 billion per year with biotech seed.

Cotton:

On March 17, 2005, The National Technical Commission on Biosafety (CTNBio) legalized the planting and commercialization of a biotech cotton variety owned by Monsanto. The approval of the insect resistant BT variety was under deliberation by CTNBio since September with only the Ministry of Environment voting against planting and commercialization. It is no surprise that CTNBio voted in favor of the use of biotech cotton given that in November the commission approved the sale of cottonseeds with 1 percent biotech material. However, it is surprising to some in the industry that the decision by CTNBio came so soon. The Brazilian Cotton Producer's Association (ABRAPA) was not expecting approval of biotech cotton for several months or even years.

The Ministry of Environment and environmental NGO's are opposed to the release of biotech cottonseed due to the possibility of crossing with native cotton species. However, CTNBio did require that Monsanto prepare an impact study on the effects of planting the seed. Furthermore, some regions are prohibited from planting biotech seed and buffer zones on cotton farms are required.

In addition to this approval, current requests by Monsanto and Bayer are pending for approval of additional biotech cotton varieties. Currently, input costs in Brazil are very high and insecticides comprise about 40 percent of the production costs for cotton with producers spaying up to 14 times a year. It is estimated that use of biotech seed will reduce the cost of production by U.S. $130 per hectare. Therefore, it is expected that adoption of this biotech variety will make cotton even more attractive to producers in Mato Grosso and Bahia.

However, producers will not be able to plant biotech cottonseed this upcoming crop year. The new biotech seed must be registered with MAPA following studies on the value of the use of the seed. It is expected that this study and registration could take up to two years and thus some in the industry do not expect the sale of biotech seed before 2007. Nevertheless, some producers believe they will be able to buy imported seed from the United States and Australia for use in the upcoming crop. It is not yet clear whether CTNBio will authorize imports of biotech cottonseeds, but trade sources estimate that illegal planting of biotech cottonseed will be as high as 30 percent of the planted area.

Corn:

CTNBio also approved biotech corn imports from Argentina for animal feed at the request of the Pernambuco Poultry Association (AVIPE). Other requests for corn imports have been turned down by the CNBS because CTNBio has its functions temporarily suspended pending the approval of a Presidential Decree. This decision effectively blocks all foreign supplies. The powerful pork and poultry industry pressures for corn imports, but want to segregate imported corn for internal use only, such as the Northeast of Brazil, to avoid market problems with their exports to the European Union.

SECTION III. BIOTECHNOLOGY POLICY

Regulatory Framework

The new regulatory framework for agricultural biotechnology in Brazil is outlined in law 11,105 and it is comprised of the following:

a) The National Biosafety Council (CNBS, in Portuguese). This council is under the Office of the President and is responsible for the formulation and implementation of the national biosafety policy (PNB, in Portuguese) in Brazil. It establishes the principles and directives of administrative actions for the federal agencies involved in biotechnology. It evaluates socio-economic implication and national interests regarding approval for commercial use of biotech products. No safety considerations are evaluated by CNBS. Under the presidency of the Chief of Staff of the Office of the President, 11 cabinet ministers comprise CNBS and a minimum quorum of 6 ministers is needed to approve any relevant issue.

b) The National Technical Commission of Biosafety (CTNBio, in Portuguese) was established in previous legislation. CTNBio had is authority confirmed by law 11,105 after intense public debate over the ability of a commission to waive environmental studies before approving a biotech product. CTNBio not only had its sole power confirmed, but had its membership enlarged from 18 to 27 members to include official representatives from 9 ministries of the federal government, 12 specialists with scientific and technical knowledge from 4 different areas including animal, plant, environment, and health (3 specialists from each area), and 6 other specialists from other areas such as consumer defense and family farming. Members of CTNBio are elected for two years with a possibility of being reelected for an additional two years. CTNBio is under the Ministry of Science and Technology.

Political and other social and economic factors that may influence regulatory decisions related to agricultural biotechnology are handled by the CNBS above. All technical related issues are debated and approved under CTNBio. Imports of any agricultural commodity for feed or for processing, or any ready-to-consume food products, and pet food containing biotech events must be pre-approved by CTNBio. Approvals are on a case-by-case basis

Although the new Bio safety law was approved by the Congress and signed by the President of Brazil, the Brazilian Consumer Protection Institute (IDEC, in Portuguese), from Sao Paulo, filed a petition with the Federal Public Prosecutor alledging that the new law is unconstitutional and requests that the Prosecutor file a law suit of unconstitutionality (ADIN, in Portuguese) in the Brazilian Supreme Court. On June 20, 2005, the Federal Public Prosecutor accepted the petition from IDEC and filed an ADIN in the Supreme Court alledging that the new Biosafety law could not authorize CTNBio to decide if new biotech varieties could be exempt from environmental impact assessments, which in their view, is not permitted under the Brazilian Constitution, and it is contrary to the “precautionary principle.”

Product Authorizations

In Brazil, a technology provider must file an application for approval to sell agricultural biotech products with CTNBio. A company must file a single application for each biotech event. CTNBio will evaluate the need for any further environmental impact studies. After the approval of CTNBio, three other ministers have an important role in the registration process: a) Ministry of Agriculture, Livestock, and Food Supply (MAPA) for products used in agriculture, livestock, and agribusiness (processing); b) Ministry of Health, regarding use of products for humans and pharmaceutical uses; and, c) Ministry of Environment for products that require registration and inspection for use in the natural ecosystem.

Note: On May 3, 2005 the National Technical Commission on Biotechnology (CTNBio) issued a public notice to declare that its normal functions are temporarily suspended because the new Biosafety Law Number 11,105, revoked Law Number 8,974 of January 5, 1995 and Provisional Measure Number 2,191 of August 23, 2001 under which the commission was operating. Also, according to Article 12 of the new Biosafety law a Presidential Decree, currently under review by CNBS, will define the new functions of CTNBio, which should be fully operational by the end of August 2005.

Field Testing

Field testing of biotech crops is allowed in Brazil, but this research must be previously approved by CTNBio. The technology provider must obtain from the National Technical Commission on Biosafety (CTNBio) the so-called CQBs (Certificate of Quality in Bio Safety) to perform field testing.

Field testing approved by CTNBio for biotech crops in 2004 totaled 21 trials, of which, 11 were for corn, followed by soybeans 3, eucalyptus 3, cotton 2, and rice and dry edible beans, one each. Information on traits being tested is available only for corn:

Field-testing, 2004: Corn

Trait Category	Quantity
Insect resistance/Gluflosinate tolerant	2
Amonia Glufosinate Tolerant	1
Insect Resistance	5
Glufosinate tolerant	3

Source: CTNBio

Coexistence of biotech and non-biotech crops

There is no national policy in place regarding the coexistence of biotech and non-biotech crops in Brazil. Law 11,105 of March 2005 established the legal framework under which biotech crops can be produced and marketed in Brazil. Conventional or non-biotech crops are produced throughout the country with agricultural zoning and environmental limitations mostly applicable in the Amazon region.

Law 9,456 of April 25, 1997, the so-called Plant Variety Protection law establishes the legal framework for registration of both biotech and non-biotech seeds, but the law does not favor one over the other.

Decree 2,366 of November 5, 1997, established the National Plant Varieties Protection Service under the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and regulates the registration of biotech and non-biotech seeds.

Organic agriculture is growing rapidly in Brazil. Growth is estimated at 20 percent per year, but commercial production is still limited mostly to grains and vegetables, although it is increasing in the meat and dairy sectors. The growth in organics in Brazil has been recently boosted by the interest of the Brazilian supermarkets in providing organic products. There are approximately 1,200 certified farmers and two private institutions with the authority to certify organic products. There are no official trade statistics about organic products either for imports or exports.

The rapid growth of organic farming in Brazil has prompted the Brazilian government to regulate the sector. On May 19, 1999, the Minister of Agriculture, Livestock, and Food Supply (MAPA) published in the Diario Oficial (Brazil's Federal Register) Normative Instruction Number 7, which contains the standards for production, classification, processing, packaging, imports, distribution, identification, and certification of the quality of organic products, of both animal and plant origin.

Both domestic and imported organic products must be labeled with the term "organic product" and the name and registration number of the certifying organization. For bulk products, a "certificate of organic quality" must accompany the shipment. The Office of Agricultural Protection (SDA) of the Ministry of Agriculture, Livestock, and Food Supply (MAPA) has the authority to approve imported organic products.

Technology Fees

The new Biosafety Law, which provides a clear regulatory framework for the research and marketing of new biotechnology crops in the country, has encouraged Brazil's federal government to embrace and protect new technologies that benefit agriculture.

After 5 months of intense negotiations, Monsanto reached a 2-year agreement with entities that represent farmers on the point of delivery system the company had developed. Under this system, Monsanto collects post-harvest fees for those soybeans that have been planted from seed for which royalties have not been paid.

For this season, the price will be 1% for declared and 3% for non-declared RR soy. For the 2005/2006 crop season the price will be 2% declared and 3% non-declared. At current soy prices (near historical average) the fee is about $2.10 per ton this season and $4.20 per ton next season declared and $6.30 per ton non-declared. The compensation fee for the non-authorized use of Roundup Ready technology is a legal right supported by the Brazilian federal constitution, Brazilian patent law, and the TRIPS international Agreement.

For the 2005/06-crop year, Monsanto was not able to reach an agreement with Brazil's Seed Producer's Association regarding collection of royalties. The new strategy of Monsanto is to negotiate directly with the so-called "seed multipliers" and a preliminary agreement was reached to collect a fee of R$ 0.88 per kilogram of RRS seed (equivalent to R$ 35.20 per bag of 40 kilograms). Trade sources indicate that this is equivalent to US$ 8.00 per acre, nearly half of the value paid by U.S. soybean producers.

Labeling

On April 24, 2003 the President of Brazil published in Brazil's Federal Register (Diario Oficial) Executive Order (Decreto) number 4,680/03 establishing a tolerance limit of one percent (see note below) for food and food ingredients destined for human or animal consumption containing or being produced with biotech events. The Executive Order also declared that consumers needed to be informed of the biotech nature of the product.

Note: The previous regulation (Executive Order Number 3,871 of July 18, 2001) established a four percent threshold, which was considered too high by environmentalists and consumer groups. Executive Order 4,680 revoked Executive Order 3,871.

The Ministry of Justice published on October 3, 2003 in their home page Public Consultation Number 1, which regulates Article 2, Paragraph One, of Executive Order Number 4,680 of April 24, 2003 regarding the symbol (logo) for transgenic products.

Note: For further details on Public Consultation Number 1, please see GAIN 3614, dated 10/17/2003. The Brazilian government failed to notify the World Trade Organization (WTO) about this public consultation. In addition, the period for public comments (15 days) was not in compliance with WTO rules. Public Consultation Number 1 received 157 written comments, of which 88 favorable to the logo, 54 unfavorable, and 15 related to questions and doubts.

On December 26, the Ministry of Justice published in Brazil's Diario Oficial, Directive (Portaria) Number 2,658/03 approving the regulations for the use of the transgenic logo, which basically was the same as reported in our GAIN BR3614. As per Article Two of Directive (Portaria) 2,658/03 use of the new logo required would be effective as of February 23, 2004 (60 days after the publication in the Diario Oficial of Directive 2,658/03). It applies for biotech products for both human and animal consumption with biotech content above one percent. On February 27, 2004 The Ministry of Justice published in the Diario Oficial Directive Number 786 that extended for another 30 days the effective date of Directive 2,658/03. The new effective date was March 27, 2004.

On April 2, 2004, the Civil Cabinet of the Presidency published Normative Instruction Number 1, signed by 4 cabinet ministers (Civil Cabinet, Justice, Agriculture, and Health) that established the conditions by which Directive 2,658/03 will enforce the labeling of products containing biotech events above the one percent limit. In addition to the federal agencies, Normative Instruction Number 1 also authorizes the state and municipal consumer defense officials to enforce the new labeling requirements.

SECTION IV. Marketing Issues

There is a publicity public campaign "Brazil Better Without Transgenics" against the use of biotech crops in Brazil sponsored by Greenpeace and supported by environmental and consumer groups, including government officials within the Ministry of Environment, some political parties, the Catholic Church, and the Landless Movement. However, the acceptance of biotech crops in Brazil is strong among producers. According to the Brazilian Farm Bureau (CNA), the latest survey among Brazilian farmers dated from 2001 showed an 80 percent acceptance rate of biotech crops.

Acceptance is low among meat processors and the food processing industry. These groups fear the publicity campaign against their products sponsored by Greenpeace and other environmental and consumer groups. However, tests conducted by Greenpeace showed a minimum of biotech residues in several consumer ready products. Brazilian retailers also are reluctant to accept biotech products, especially the large supermarkets under French ownership. Reliable information about consumer acceptance of biotech products in Brazil is currently not available.

U.S. corn exporters have been disadvantaged by the reluctance of Brazilian food products companies to use biotech (meat processors and food industry in general). Even with the approval of the new Brazilian Biosafety law, all biotech corn imports (including those from Argentina under the Mercosul Free Trade Agreement) must have a formal approval from CTNBio on a case-by-case basis. This can be a lengthy and expensive process. In addition, the current suspension of CTNBio activities (see note under policy section) has banned biotech corn imports until the new Presidential Decree is published which may not occur until late in 2005.

SECTION VI: Capacity Building and Outreach

Post has developed and implemented two major outreach activities over the past three years that were important in the development of biotech regulations in Brazil.

1. First Biotechnology Workshop, August 20-21, 2002 for a select group of Brazilian scientists from various ministries, universities, and scientific foundations;
2. Brazilian Congressional Visit to the United States in 2004 with representatives from select Brazilian NGOs and institutes.

As part of an ongoing effort to build a stronger public diplomacy strategy on biotechnology, post has provided technical support, such as bringing U.S. scientists and speakers, to various Brazilian workshops on biotechnology. This strategy has proved successful in promoting science-based biotechnology policies among different interest groups in Brazil.

Attachment: Brazil's Biosafety Law

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 Bio safety Council (*CNBS*), re-structures the National Bio safety Technical Commission (*CTNBio)*, provides for the National Bio safety 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 the 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 bio safety 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 bio safety 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 Bio safety Technical Commission (*CTNBio*), which shall reply within the time limit provided by the by-laws.

Paragraph 4. Public and private organizations, national, foreign or international, which finance or sponsor activities or projects mentioned under the **caption** of this article, must require a Bio safety 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 plaid 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, transudation, transformation**,** polyphonic 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, heterogonous 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** fertilization, 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 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 analyzed 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 favorable technical opinion granted by *CTNBio*, and in the cases of commercial clearance, without the favorable technical opinion granted by *CTNBio* or without the license 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 Bio safety 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, and 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 Bio safety Council (*CNBS*)

Article 8. The National Bio safety 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 Bio safety 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 – analyzing, 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 favor of an activity that has been analyzed, 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 analyzed 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 House[TN1] 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 Defense;
XI – Special Secretary for Aquaculture and Fisheries to the President of the Republic.

Paragraph 1. *CNBS* shall meet whenever called by 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 voting by the absolute majority will make decisions.

CHAPTER III
The National Bio safety 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 Bio safety 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 bio safety, 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 recognized, and who hold a doctorate degree and who have been professionally active in the bio safety, 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) 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 Defense;
h) The Special Secretariat for Agriculture and Fisheries to the President of the Republic;
I) The Ministry of Foreign Affairs;
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 Labor 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 Minister shall appoint the president of CTNBio among its members 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 analyzed.

Paragraph 2. The operation and co-ordination of works endeavored 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 Bio safety 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 bio safety requirements to authorize the operation of laboratories, institutions or companies that carry out activities related to GMOs and their by-products;
VII – maintaining a relationship with bio safety institutions for GMOs and their by-products, within the national and international scope;
VIII – authorizing, registering and monitoring research activities using GMOs or GMOs by-products, as prescribed by legislation in effect;
IX – authorizing the import of GMOs and their by-products for research activities;
X – providing technical consulting and assistance support for *CNBS* to prescribe the Bio safety National Policy for GMOs and their by-products;
XI – issuing the Bio safety 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 bio safety 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 bio safety level, as well as safety measures required and restrictions of use;
XIII – defining the bio safety 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 bio safety 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 Bio safety 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 bio safety of GMOs or their by-products, under the terms of this Law and its rulings;
XXII – suggesting scientific bio safety 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 bio safety 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 bio safety aspects of GMOs and their by-products.

Paragraph 3. In cases when a favorable 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 authorization for importing GMOs and their by-products for commercial use;
IV – keeping updated information in the Bio safety 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 authorizations;
VI – enforcing penalties, which are the subject matter of this Law;
VII – assisting *CTNBio* in defining bio safety assessment parameters for GMOs and their by-products.

Paragraph 1. After *CTNBio* or *CNBS* have given their favorable 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 authorizations 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 authorizations 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 authorizations 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 authorizations 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, authorizations 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. Authorizations and registrations provided by this article shall be bound to *CTNBio*'s relevant technical opinion, whereby any technical requirement for related-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
Related 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 Related 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 programmers to ensure the operation of facilities for which they are responsible, within bio safety 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 authorization 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 labor 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
Bio safety Information System (*SIB*)

Article 19. The Bio safety Information System (SIB) is established within the scope of the Ministry of Science and Technology, to generate information resulting from analyses, authorization, 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 bio safety 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 liabilities 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, license or authorization;
VIII – cancellation of registration, license or authorization;
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, characterized 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 misdemeanor, 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-authorized 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 favorable technical opinion by CTNBio authorizing 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 shall still CTNBio support valid, as well as statutory acts 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 authorized to produce and market glyph sate-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 authorized to grow glyphosate-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 authorization, 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
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This text does not replace that which was published in the Federal Gazette of 28.3.2005.