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## **Brazil**

# **Food and Agricultural Import Regulations and Standards**

## **State of Biotechnology in Brazil**

### **2001**

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#### **Report Highlights:**

**The approval and commercial release of GMO seeds and food products continues to be a controversial issue in Brazil. A new Provisional Measure, No. 2,137, dated December 28, 2000, providing legal standing and new authority to the National Technical Commission on Biosafety (CTNBio) to approve GMOs in Brazil will be contested in the federal court by consumer groups.**

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## SUMMARY

This report describes recent events and current issues affecting genetically modified organisms (GMOs) in Brazil. We provide examples of how these issues have been addressed within the current regulatory context, and the trends towards the use of this technology in Brazil. The most recent official measure is the publication of Provisional Measure Number 2,137, dated December 28, 2000 which is intended to provide the legal standing and authority to the National Technical Commission on Biosafety (CTNBio) in resolving problems related to the approval of GMOs in Brazil.

## LEGAL FRAMEWORK

Law 8,974 of January 5, 1995 provides the legal framework and sets the standards and means for production, importation, manipulation, transportation, marketing, and consumption of genetically modified organisms (GMOs). This law regulates clauses ii and v of the first paragraph, article 225, of the Brazilian constitution of 1998, and authorizes the executive branch to create the National Technical Commission on Biosafety (CTNBio).

In addition to the above law, a Presidential Decree number 1,752 of December 20, 1995 provides the regulatory framework to implement law 8,974/95 and to establish the National Technical Commission of Biosafety, under the scope of the Ministry of Science and Technology.

The Presidential Decree 1,752 charged, among other responsibilities, CTNBio with proposing a national policy for biosafety, proposing a code of ethics for genetic manipulation, classifying GMOs according to the degree of risk involved, establishing mechanisms for the operation of the Internal Biosafety Commission (IBC) in each company or organization working with GMOs, and issuing the Certificate of Quality in Biosafety (CQB), through which these companies and organizations can initiate their research activities involving GMOs or GMO-derivatives.

## THE REVIEW OF THE LEGAL FRAMEWORK

There is a general consensus in Brazil among the scientific community, consumer groups, and biotech companies that law 8,974/95 is modern and one of the best of its kind in the world.

However, the problem arises with Presidential Decree 1,752/95 which is under scrutiny by

different offices of the federal government and by the judiciary. On June 26, 2000, a federal judge in Brasilia declared unconstitutional clause xiv of article two of this decree. This ruling was confirmed on August 8, 2000 by the regional federal court in Brasilia, during Monsanto corporation's appeal of its court case on roundup ready soybeans (RRS). See Section III.

The major problem with clause xiv of article two relates to the Environmental Impact Study (EIA), and the respective Report of the Impact on the Environment, the so-called "EIA-RIMA."

In view of the growing concerns over the legal framework about GMOs and biotechnology in general, the chief of staff of the presidency began, last year, to coordinate the draft of a "Provisional Measure" (MP) to resolve the legal problems derived from the court battles involving the release of GMO varieties in Brazil, and the most recent court battles involving importation of GMO corn from Argentina.

*Note: Provisional Measure is an act issued by the president, under the powers and privileges granted to him by the 1998 Brazilian Constitution. It has the power of a law, until Congress gives final approval, and then, becomes a law. A Provisional Measure needs to be re-issued each 30 days after its first publication in the Diario Oficial (Brazil's equivalent of the Federal Register).*

The President issued this new Provisional Measure (MP) 2,137 on December 28, 2000. The purpose MP 2,137 is to add and alter some clauses of Law 8,974/95 to clearly define the role of CTNBio. The Article first provides CTNBio with the legal authority to issue final technical reports about the release of GMOs in Brazil, and redefines the functions of each Ministry within the federal government as it relates to GMOs.

## **THE MONSANTO COURT BATTLE OVER RRS**

Background: this case was initiated on September 15, 1998 when the Brazilian Institute of Consumer Protection (IDEC) filed an injunction against CTNBio's decision to release Monsanto's RRS without requesting environmental studies (EIA-RIMA). The point made by IDEC (with the assistance of Greenpeace) was that CTNBio did not have the legal authority to waive environmental impact studies, since it was mandatory according to the 1998 constitution. IDEC then alleged the unconstitutionality of decree 1,752/95. In addition, IDEC claimed that there are no federal requirements in force for food safety nor labeling regarding GMOs. Note: since the beginning of Monsanto's court case, the Brazilian Institute for Environmental and Renewable Resources (IBAMA), under the Ministry of the Environment, was a co-petitioner in IDEC's injunction against the government. During the court hearings on June 28, 2000, IBAMA through its general attorney of law, decided to withdraw from this case.

On June 26, 2000 federal judge Antonio Souza Prudente declared unconstitutional clause xiv of article two of law 1,752/95 during Monsanto's appeal of its court case. On August 8, 2000, this ruling was upheld by the Regional Federal Court (TRF) in Brasilia. Monsanto can still appeal one more time, but legal experts consider it virtually impossible for the Superior Justice Court (TSJ) to change the TRF decision.

The most important aspect of judge Prudente's judicial decision, which was confirmed by the superior court, was the action declaring clause xiv of article 2 of decree 1,752/95 as "unconstitutional." This has serious implications because it extends the prohibition to release RRS to other commodities and food products. In addition, the ruling requires that the federal government, within 90 days, (note: this deadline expired September 30, 2000) to elaborate rules on GMOs relative to (a) food safety, (b) labeling, and (c) environmental impact studies and reports.

Monsanto is not opposed to conducting environmental impact studies of RRS if required by CTNBio, but they will pursue their case until the last step in the court appeal. According to Brazilian legal specialists, the result, so far, of this court battle implies that there is a "moratorium" on GMOs in Brazil. Monsanto also has lost another crop year (the 2000/01 planting season began October 2000). However, with the recent issue of MP 2,137, Monsanto is optimistic about selling its RRS in Brazil, and are taking all steps to meet producers' deadlines for the next crop year, beginning September/October 2001.

## **CTNBIO DECISION ON GMO CORN FOR ANIMAL FEED**

On July 3, 2000 CTNBio published in the Diario Oficial (Brazil's federal register) Notice Number 133, dated June 30, 2000 with the conclusive technical recommendation allowing imports of 13 GMOS corn varieties for animal feed.

The conclusion was that the varieties approved are safe for humans consuming meat from animals raised using these corn varieties. CTNBio's decision was based on studies from Argentina, Canada and the United States. Environmental impact studies in Brazil were not conducted. CTNBio's technical recommendation was that corn imports were only for animal consumption, prescribed special security measures to ensure that the product would not escape from the milling process, and would only be allowed into the country under the inspection authority of the Ministry of Agriculture and Food Supply (MAA).

CTNBio's decision on GMO corn imports for animal feed was made at the request of the MAA, which was concerned with the supply of corn for the poultry and pork industry due to the losses from the prolonged dry spell during the planting of the summer crop, and frost during the development of the mid year corn crop, mostly in the state of Parana.

CTNBio's decision to allow GMO corn imports conflicted with the court decision of 6/26/00 against these imports, which the CTNBio said it had not officially received from the judiciary. After intensive press accounts about conflicting views on GMO corn imports, on June 7, 2000, the chief of staff of the presidency released an official government note of support to the CTNBio. The note was signed by 6 cabinet ministers, including the ministers of the civil cabinet of the presidency, agriculture and food supply, justice, environment, science and technology, and health. The purpose of this note was to give full support to the decision of the CTNBio regarding GMO corn imports and to inform the public that CTNBio is a serious commission, formed by Brazilian scientists, with the full support of the federal government. This note was a response to consumer groups that were seeking to undermine the credibility of CTNBio and to some Brazilian scientists that challenged the analysis procedures carried out by CTNBio on these corn

varieties.

Importation of GMO corn remains risky and is done only after intense court battles. The poultry industry in the Northeast is the most affected by this "uncertainty" derived from court decisions against GMO corn imports and CTNBio notice 113/00. The poultry industry of the south, which represents nearly 90 percent of Brazil's poultry exports, has taken a more conservative approach to GMO corn imports. Brazil's poultry exports to Europe could be jeopardized by the Greenpeace campaign in the European markets against imports of poultry meat derived from birds fed with GMO corn. In fact, according to some trade sources, poultry exporters in the south have pressured the ministry of agriculture to release GMO corn imports to the northeast states, allowing government corn stocks in the south for the major poultry processors and exporters.

## **CTNBIO PROPOSED RULE FOR GMO CORN FOR PLANTING**

On July 31, 2000 CTNBio published in the Diario Oficial the request from Norvatis to release GMOS bt.11 corn for commercial planting. This request is under public consultation, and is the second commercial request after Monsanto's request to CTNBio to approve RRS.

The Brazilian consumer group (IDEC) filed with CTNBbio a document against the release of bt 11 corn and is threatening the same legal procedure against CTNBio as in the RRS case. Again, IDEC cites the lack of the environmental impact studies and reports (EIA-RIMA).

Since 1997, CTNBio has approved 787 research projects with GMOs in Brazil, of which GMO corn accounts for 700 research projects (nearly 89 percent), followed by soybeans (44, or 6 percent), cotton (24, or 3 percent), and sugar cane (11, or one percent). Other GMO crop experiments include rice, potatoes, eucalyptus, tobacco, and papaya. There are no official commercial plantings of GMOs in Brazil due to the so-called "legal moratorium" (see the RRS court case above).

## **THE GROWING DEBATE ON GMO FOOD PRODUCTS**

On June 20, 2000, the Brazilian Institute of Consumer Protection (IDEC) and Greenpeace released the results of 42 samples collected from Brazilian supermarkets of different food products (both domestic and imported food products) that were tested to verify the presence of GMO residues. IDEC sent 31 samples and Greenpeace sent 11 samples for testing, respectively, to Australian and Austrian labs. The presence of genetic material (DNA) in products was determined using the "polymerase chain reaction"(PCR) method. Nine samples of products collected by IDEC showed positive results for residues of GMO soybeans, of which the following were imported from the United States: Bac-o's (flavored bacon chips) and Cup o' noodles (chicken flavor). Three samples of products sent by the Greenpeace showed positive results for residues of GMO corn (bt176) or soybeans, of which the following were imported from the United States: Cup o' noodles, Pringles original, and McCormick bacon bits.

Based on the lab results, IDEC sent letters to several government offices in Brasilia, including the Ministries of Agriculture and Food Supply, Justice, and Health, alleging violations of the following legal instruments: a) code of consumer protection (article 66 of law 9,078/90); b)

biosafety law (article 13 of law 8,974/95; and, c) Ministry of Health food regulations (law 6,437/77, law 9,782/99, resolution 23/2000, and decree-law 986/69. Based on these legal documents, IDEC requested that the products found with traces of GMOs be removed from supermarkets shelves. Note: by federal law, only representatives of the Ministry of Health's Agency for Sanitary Surveillance (ANVISA), similar to the Food and Drug Administration, can carry out such actions. OAA was informed by ANVISA officials that their agents have advised supermarkets to voluntarily remove such products, since they have no legal power to take this type of action because of the lack of a national labeling law specific to GMO food products.

On August 1, 2000 the state of Sao Paulo public health authority ordered supermarkets to remove from their shelves the nine products that tested positive for GMO content. This decision was based on state law 10,467 of December 12, 1999 (which entered into force on March 21, 2000) and federal law 8,078 of September 1990 (Code of Consumer Protection).

The Brazilian Food Industry Association (ABIA) reacted to the Sao Paulo public health authorities and filed a court action of "unconstitutionality" (ADIN) with the Brazilian Supreme Court (STF) against law 10,467/99. The issue is that the state of Sao Paulo has no legal authority on matters that are the responsibility of the federal government. ABIA based its court claim on articles 22, 25 and 30 of the Brazilian Constitution.

ABIA has also published in major Brazilian newspapers a full page ad aimed at explaining to Brazilian consumers that all finished products imported by Brazil are subject to rigorous tests. The ABIA ad mentions the importance of the U.S. Food and Drug Administration (FDA), which is one of the most rigorous agencies in the world in regulating food products. They note that all imported food products in question have been marketed in many other countries for more than five years, without any evidence of injury or risk to consumers. ABIA is in favor of labeling GMO products. As soon as the federal legislation is approved (becomes law), ABIA will meet all labeling requirements.

The dispute between IDEC/Greenpeace and Brazilian food importers and manufacturers over GMO food products is growing. On September 22, 2000 Greenpeace released the results of lab tests on another batch of 11 food products collected in Brazilian supermarkets. According to Greenpeace, 4 products showed positive results for GMOs (traces of Monsanto's RRS and bt 176 corn from Norvatis). These products are popular brands in Brazil for powdered chicken soup, powdered cereals and cake mixes, and are produced by large Brazilian and U.S. food companies.

Despite the ABIA court action, some companies decided to remove their products from supermarket shelves to avoid retaliation and negative propaganda from Greenpeace. Some Brazilian supermarkets, such as those in Belo Horizonte and in Sao Paulo, are posting flyers with the text "product with transgenic content", while others are segregating those food products. IDEC and Greenpeace are using the Internet to ask Brazilian consumers to pressure food companies to remove their products with GMO content. IDEC has also started a national campaign with the slogan: "transgenics: do not swallow that." These organizations are basing their campaigns on the Brazilian Consumer Protection Code, which states that Brazilian consumers have the right to be informed about the content of any food product.

## NEW DIRECTIVE ON GMO FOOD LABELING

The first draft of an Interministerial Directive regarding GMO foods was published by the Ministry of Justice (who oversees consumer protection) on December 1, 1999, under public consultation number 2, with a deadline of 90 days, which was later extended for another 30 days. The Ministry of Justice received 178 comments, including those presented by the United States government and sent to the Ministry of Justice through the Office of Agricultural Affairs (OAA) in Brasilia.

The Brazilian government has reviewed all public comments and completed the draft of an Interministerial Directive (Portaria Interministerial) that would establish labeling standards for GMO foods. This final draft must be cleared by two Ministers - Agriculture and Health. There seems to be an internal dispute within the Brazilian government regarding tolerance levels. The release of this new Interministerial Directive has been postponed three times already, and government sources can not make an estimate of the time this Directive will be published. Some sources have indicated that the government is waiting for the final results of the court claims currently pending.

OAA has obtained a copy of the final draft and is currently analyzing the terms of the Directive. A copy in Portuguese will be mailed to FAS Washington for dissemination within USG agencies. After one year of intense internal discussions, the Brazilian government decided to develop its own model for GM food labeling. A brief analysis done by the Office of Agricultural Affairs (OAA) shows that the new draft regulation requires:

- A) mandatory labeling for all genetically modified foods;
- B) that information on GMO foods be identified in a way that is clear, readily visible, and printed in bold;
- C) that information on the label must be in Portuguese;
- D) that tolerance levels will be established by means of annexes to the technical regulation, and will be published case by case as the technical-scientific studies of each product are concluded;
- E) that the first tolerance level established was one percent for glyphosate herbicide for soybeans (glycine max l.), as per CTNBio Note Number 54, dated October 1, 1998. An Interministerial Commission is also created as part of the new regulation on GMO labeling, which will periodically evaluate the changes in the technology of GMOs.

The new Directive on labeling does not specify any tolerance levels for any other product, except for glycine max l. This could create a major legal loophole for imported food products tested positive for bt corn.

## COMMENTS

The overall conclusion is that IDEC and Greenpeace managed to delay the normal path of approval of GMOs in Brazil by exploiting the current "gaps" in the federal legislation. Trade sources called this situation a "legal moratorium" on GMOs. The strategy adopted by these groups are focused on the following:

(A) exploiting the "gaps" on the federal legislation regarding the environmental impact studies and reports (EIA-RIMA);  
(B) the alleged lack of transparency of CTNBio decisions;  
(C) the lack of GMO labeling requirements;  
(D) the lack of regulations on health safety of GMO foods. IDEC attempted to open a Congressional Investigation Committee (the so-called CPI) to investigate the federal government's actions regarding GMOs, including the actions of CTNBio. In addition, IDEC is working with some congressmen to establish a five-year moratorium on all GMO products.

The most recent strategy adopted by IDEC/Greenpeace involved a seminar in the national congress to discuss the health concerns of GMO foods. The seminar had attempted to: (a) to discredit the Food and Drug Administration (FDA) of the United States, (b) to show that the Brazilian government has no control over the surveillance of GMO foods in Brazil, and (c) to initiate a national aggressive campaign against GMO foods (including imported foods) with the slogan: "transgenics, do not swallow that." IDEC's strategy to discredit the FDA included a speech in the National Congress by Steven Drucker, Executive Director of Alliance for Biointegrity, Fairfield, Iowa.

The Brazilian government has reacted slowly to IDEC/Greenpeace strategies against GMOs in Brazil. However, the federal government is now focusing on the following:

(A) correcting the "gaps" in the current federal legislation on GMOs, which was partially done by issuing Provisional Measure Number 2,137 of December 28, 2000;  
(B) publishing a new Directive on GMO food labeling, which is currently postponed for an indefinite period of time;  
(C) increasing transparency of government activities and the actions of CTNBio, and preserving CTNBio's reputation, and  
(D) educating the consumer, and the media, about GMOs and the importance of this new technology for Brazil.

The federal government is also facing two other major challenges: smuggling of GMO seeds from Argentina and the lack of inspection by federal officials of the experimental fields with GMOs, approved by CTNBio (over 800 field trials). Smuggling of GMO seeds is in addition to the old problem in Brazil, where non-certified seeds have a market share of 30 percent. According to our contact at the Brazilian Seed Association in Brasilia, this is a growing trend mostly among seed and corn producers. The lack of inspection of field trials is basically a problem of lack of funds and personnel. According to our source in the Ministry of Agriculture, less than 40 percent of all GMO trials approved by CTNBio are inspected by agriculture officials. Less than 20 agricultural officials have the skills to inspect GMOs in the entire country. In addition, the Ministry of Agriculture has insufficient funds for travel and inspection.

The federal government is also trying to increase coordination among federal agencies (Ministries) on this issue to avoid public disputes, such as those between CTNBio and the Ministry of the Environment. The new Provisional Measure (MP) 2,137/00 was intended to correct this situation by specifying the legal competency of each Ministry. However, IDEC and Greenpeace legal advisers have already found some loopholes in the new MP. The major point against MP 2,137/00 is that CTNBio is a technical consultative committee to the federal

government, and should have no power to make conclusive decisions or recommendation. These groups support the independence of each government agency, such as the Ministry of the Environment to request environment impact reports from any company, such as Monsanto. One other major argument is that because "legally" speaking CTNBio did not exist (according to the federal judge decision last year), all previous decisions of CTNBio (such as the release of Monsanto's RRS) are not valid, and need to be reappraised and reapproved.