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## Nicaragua

## Biotechnology

## Annual Report

## 2005

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**Report Highlights:**

Nicaragua is implementing the provisions of the Cartagena Protocol. The GON requires a risk analysis for the import of biotechnology products. The risk analysis has not stopped trade between the United States and Nicaragua.

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Includes PSD Changes: No  
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## SECTION I EXECUTIVE SUMMARY

Yellow corn for animal feed is the main biotechnology crop exported from the United States to Nicaragua. The GON is implementing the provisions of the Cartagena Protocol. It requires notifications of imports of biotechnology products and risk analysis for such imports. Currently, the Commission for Risk Analysis of Genetically Modified Organisms (CONARGEN) is conducting risk analyses for processing and feed uses for all genetic events authorized by the United States for yellow corn. The CONARGEN is expected to continue performing science-based risk analysis on other biotechnology products.

## SECTION II BIOTECHNOLOGY TRADE AND PRODUCTION

Nicaragua does not produce any biotechnology crops and does not have the technical resources to develop them for commercial purposes. Nicaragua is a large food aid recipient due to its limited capacity to supply food for human and animal consumption. Yellow corn for animal feed is the only biotechnology crop imported from the United States. Imports of other biotechnology products from other countries are limited or non-existent.

## SECTION III BIOTECHNOLOGY POLICY

Nicaragua is signatory of the Cartagena Protocol and is in the process of implementing its provisions. As part of the process, the GON has begun to require notifications of imports of living modified organisms (LMO) and risk analyses for such imports.

An executive decree to require risk analyses on genetically modified organisms (GMOs) has been in effect since August 13, 2003 but the commission to perform risk analysis had not been formed. This decree was published in the *La Gaceta* 152. On July 23, 2004, the CONARGEN was named and sworn into office by President Bolaños. The Chief Director of the General Direction for Animal and Plant Health Protection (DGPSA) of the Ministry of Agriculture and Forestry (MAGFOR), serves as president of the eight-member commission. Other members include officials from the Nicaraguan Institute for Agricultural Technology, the Ministry of Environment and Natural Resources, the Ministry of Health, the Ministry of Industry Development and Commerce, the National Autonomous University of Nicaragua in León, the National Agrarian University, and the Central American University in Managua. Members of the CONARGEN are proposed by the different Ministries and Institutions and approved by the President. The CONARGEN is attached to MAGFOR through DGPSA, which also provides administrative support.

With the creation of the CONARGEN, the legal framework for the import, use and handling of GMOs outlined by Law 291, Basic Law of Animal Safety and Plant Health, as amended by Decree 59-2003, has entered into force. Importers of a biotechnology product are required to request a risk analysis of the event prior to importation. The CONARGEN does not have the technical capability to test if a product is transgenic or not, but it is responsible for reviewing the pertinent information presented by importers for the risk analysis. Based on this information, the CONARGEN recommends or denies the import of a GMO. The Minister of Agriculture and Forestry makes the final decision to allow or deny the import of a GMO. At present, yellow corn for animal feed (events approved in the United States) is the only biotech commodity that has been subjected to risk analyses, which are still ongoing.

The petitioner is required to submit the following information to the CONARGEN for biotechnology products for confined use, development of field tests, crop evaluations, seed multiplication, production or importation for the first time for direct consumption, and/or transformation.

### 1. General Information

- 1.1 Name, home address, telephone number of the company's legal representative or requesting institution.
- 1.2 Scientific and common names and any other designations used to identify recipient and vector agents involved in the production of each GMO.

1.3 Name, address and phone number of the person (s) who produced/processed or provided the GMO.

## **2. Requirements for transportation and/or importation of GMOs**

2.1 Description of the packing used to transport the GMO.

2.2 Quantitative description of the GMO to be transported, proposed transportation and/or importation schedule.

2.3 Transportation route of the GMO, including a description of the country of origin, port of entry, proposed intermediate and final destinations.

2.4 Description of the procedures and biosafety measures to prevent the escape and propagation of the GMO.

Note: If the GMO is not imported or transported within Nicaragua, the requirements listed above will not apply.

## **3. Specific Information regarding the GMO**

3.1 Objective and purpose for importing the GMO.

3.2 Characteristics of the organism from which the GMO derives.

3.3 Pertinent biological, physiological, genetic and environmental characteristics of the recipient organism including:

3.3.1 Name and identity of the organism.

3.3.2 Pathogenic, toxic and allergenic action.

3.3.3 Natural habitat and origin source and/or diversity of the organism, its distribution and function in the environment.

3.3.4 Mechanisms used by the organism to survive, multiply and spread in the environment.

3.3.5 Transfer channels of genetic material to other organisms. Products of plant origin should include the following information: lifecycle with special emphasis on auto crossbreeding, pollination, habitat, wild species and their distribution, mechanisms and frequency of auto crossbreeding with members of the same specie.

3.4 Description of the donor organism; recipient and vector organism, including pathogenic, toxic and allergenic characteristics; country and location where the GMO was collected, developed or produced; and the legal condition of the GMO in the country of origin.

3.5 Description of the actual or anticipated modification granted by the genetic material, incorporated in the GMO (attach maps of this genetic construction). Explain how this genetic modification differs from the unmodified organism. The following elements should be compared to the organism from which the GMO originated:

3.5.1 Pathogenic, toxic and allergenic action for humans and other organisms.

3.5.2 Survival capacity, persistence, competitiveness and transmission into the environment or other pertinent interactions.

3.5.3 Transfer capacity of genetic material and potential transmission channels.

- 3.5.4 Methods for detecting the organism in the environment and the transfer of the donated nucleic acid.
- 3.5.5 Characterization of the product or products from the inserted gene (s), and as they originate, stability of the genetic modification.
- 3.5.6 Detailed description of the molecular biology of the donor-recipient-vector system that sustains the origin of the GMO.
- 3.5.7 Evaluation of the potential impact on the agricultural environment that could result from releasing the GMO.
- 3.5.8 Detailed proposed experimental design for releasing the GMO into the environment and production system.
- 3.5.9 Total quantity of the GMO to be released and to be used for each experiment, if more than one experiment is to be established. Present a calendar indicating the agricultural practices and proposed experiments.
- 3.5.10 Present a map showing the geographic location of the experiment considering the following:
- i) When many genetic constructions are being tested in different sites, indicate which constructions are to be tested at which site.
  - ii) When several experiments are applied in the same site, indicate the specific location for each experiment.
  - iii) Describe the former use of the surrounding land and actual location of experiments. For GMOs of plant origin, include a list and description of wild and domestic species genetically related to the GMO that could become recipient of transgenic pollen.
  - iv) Specify dimensions and experimental area (excluding edges and rows of non-GMO material), description of places for GMO distribution such as greenhouses, laboratories, and growing chambers.
  - v) Specify procedures and biosafety measures to prevent contamination, escape and propagation of the GMO.
  - vi) Detailed description of the proposed method for final propagation of the GMO at the end of the experiment including final disposal and cleaning of other materials that were in close proximity with the GMO during the experiment.

#### **4. Additional Specific Information for Confined Use**

- 4.1 Number and volume of the organisms to be used.
- 4.2 Size of the operation.
- 4.3 Proposed confinement measures including the verification of their functioning.
- 4.4 Training and supervision of staff performing assigned duties.
- 4.5 Waste disposal control plans.
- 4.6 Unforeseen accident/event control plans.
5. Information for releasing the GMO into the environment.

Certification extended by the exporter's country of origin, authorizing the release of the GMO into the environment must be presented to the Chief Director of DGPSA for subsequent risk analysis.

USDA and MAGFOR have negotiated an agreement related to Article 24 of the Cartagena Protocol on the transboundary movement of LMO for food, feed or for processing. This agreement entered into force on February 18, 2005. The arrangement articulates a practical definition for LMO- and non-LMO shipments for purposes of applying the "may contain" documentation requirement, and recognizes that non-LMO shipments must be defined in a contract as having 95 percent or greater non-LMO content.

Currently, the CONARGEN is conducting a risk analysis for all genetic events authorized by the United States for yellow corn for purposes of processing and for animal feed only. Risk analyses for human food use were not requested. The GON is permitting the import of U.S. yellow corn pending completion of the risk analyses.

Importers have not asked the CONARGEN to develop risk analysis for any other genetically modified crops besides yellow corn. Legislation allows for field-testing of biotechnology crops after the required risk analysis, but field trials of a biotech crop have never been conducted. Coexistence between biotechnology and non-biotechnology crops has not been reported.

#### **SECTION IV MARKETING ISSUES**

On June 21 2004, environmentalist and consumer advocacy organizations submitted a bill to the National Assembly to regulate the use of biotechnology products. These groups argue that GMO regulations are very important to protect consumers from mass distribution of biotechnology products. This bill proposes the creation of institutions that would oversee GMO distribution with civil society participation. These regulations would prevent potential risks to human health, protect biodiversity and enforce environmental security. Prospects for passage of this legislation are uncertain.

At present there is no labeling regulation for food or feed containing GMOs. Therefore, threshold labeling percentages for both intended and adventitious presence of GMOs have not been established. There is no law or regulation governing the use of labeling terms such as "biotech-free," "non-biotech," or "non-GMO."

#### **SECTION V CAPACITY BUILDING AND OUTREACH**

In May 2005, a State Department sponsored a speaker from the University of California, who addressed the risks attributed to GMOs and effectively advocated a science-based approach to GMO regulation during a three-day program in Managua and León. In his presentations to government officials, researchers, faculty and students from the major universities in Nicaragua, audiences were largely receptive. Several GMO-skeptics expressed concern about the future of Nicaragua's organic products export-market niches should GMOs be widely grown in the country. The speaker addressed the critics' concern, underlining the need for a rational approach to GMO regulation that addressed risks on a case-by-case basis and steered away from prejudicial, over-arching restrictions that would prevent developing countries from taking advantage of GMOs proven benefits. The speaker noted that a rational, science-based approach to GMOs need not undermine organic production, which deserves a protective regulatory framework whenever economically significant. In this regard, he noted that organic coffee farmers in Nicaragua, for example, would not be affected by the planting of genetically modified corn or soy seeds by other farmers.

In 2005/2006, qualifying members of the CONARGEN will be considered for Norman E. Borlaug research fellowships. Fellows will pursue short-term (approximately 6-12 week) training programs, to be conducted at either an international agricultural research center of the Consultative Group for International Agricultural Research, or any one of a variety of institutions including U.S. land grant universities, private sector organizations, and U.S. government agencies.

In 2002 a USAID-funded project on seed improvement (PROMESA) was completed. It included a component to support development of an agricultural biotechnology regulatory framework through dissemination of information on biotechnology plant products to encourage the adoption of regulatory policies based on scientific and economic criteria; establishment of an Agricultural Biosafety Commission; and approval of field testing of at least one plant biotechnology product. The press component, which

aimed to increase public understanding of agricultural biotechnology, generated newspaper articles and broadcast media coverage. Similarly, technicians, policy makers, universities and farmer organizations received information through seminars, workshops and a twice-monthly bulletin.

Prior to the PROMESA's implementation, the GON had adequate technical expertise but inadequate definition of regulatory procedures. PROMESA helped the MAGFOR design a science-based regulatory framework.

The Nicaraguan population has limited understanding of biotechnology products. Generally, consumers associate biotechnology exclusively to GMOs. The limited information flow to consumers is channeled through environmentalist and consumer advocacy organizations that oppose the use and commercialization of biotechnology products. In particular, these groups have taken a vocal stand against imports of biotechnology corn. The lack of information reduces the level of acceptance of biotechnology products among consumers and could become a limiting factor in the market. Up until now, surveys on the overall perception of biotechnology products have been conducted among decision makers, university students and professionals.

### **Country Needs**

Members of the CONARGEN are well educated in different agricultural fields and are inclined to base their decisions on factual scientific data. However, they lack the proper infrastructure to conduct detailed risk analysis. The CONARGEN has expressed interest in developing a laboratory and office space that would help to develop their work.

U.S. companies that produce biotechnology products, including planting seed varieties that would be suitable for Nicaraguan conditions, may wish to consider working with a local representative to initiate regulatory review of new-to-market product(s) and at the appropriate time to start marketing the product to agricultural and livestock producers and to processors. U.S. exporters should take into the account the need to educate Nicaraguan users and consumers as part of their marketing strategy.

Areas where Nicaraguan government officials and academics would be interested in training and research include: tissue culture, identification of disease resistant genes, biopesticides, and products for the pharmaceutical industry.