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Agricultural Biotechnology Annual

Agricultural Biotechnology Annual Report

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Report Highlights:
In Nicaragua, imports of Genetically Engineered crops (GE) are limited to the use of animal feed since the Nicaraguan Commission of Risk Analysis of Living Modified Crops (CONARGEM) has not yet approved the use of GE crops for human consumption and/or cultivation. GE corn and soybean meal are the top imported products. The lack of an operational legal framework is a big limitation to promote the adoption of new biotechnologies.

Section I. Executive Summary:
Nicaragua is a signatory of the Cartagena protocol on biosafety and requires notification for imports of Genetically Engineered crops (GE) and a risk analysis for biotech events.
Imports of GE crops are limited to the use of animal feed since the Nicaraguan Commission of Risk Analysis of Living Modified Crops (CONARGEM) has not yet approved the use of GE crops for human consumption and/or cultivation. GE corn and soybean meal are the top import products. In 2014,

Nicaraguan imports of these two products reached over 229, 021 MT with a total value of $80 million. Importers and/or exporters cannot request approvals for new GE events since Nicaragua's biotech law, Law 705, lacks implementing regulations. This is a big limitation to the adoption of new biotechnologies in Nicaragua. Some of the best prospects in the mid-term can be the approval of new GE corn and soybean events for animal feed. However, the approval of new GE events will depend to a great extent on whether the implementing regulations of Law 705 are officially passed.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

PRODUCT DEVELOPMENT: Nicaragua has not developed any GE crops.

COMMERCIAL PRODUCTION: There is no commercial production of GE crops in Nicaragua.

EXPORTS: There is no commercial production of GE crops in Nicaragua and Nicaragua does not export GE crops to the United States or other countries.

IMPORTS: Nicaragua imports genetically engineered (GE) corn and GE soybean meal for the animal feed industry. In 2014, Nicaraguan imports of yellow corn from the United States reached over 154,472 metric tons (MT) with a total value of US $40.7 million. Soybean meal imports reached over 79,549 MT with a total value of US $39.6 million. Imports of other biotechnology products from countries other than the United States are limited or non-existent.

FOOD AID RECIPIENT COUNTRIES: Nicaragua continues to be a large food aid recipient due to its limited capacity to supply food for human and animal consumption. At present, the imports of GE crops for human consumption are not allowed since the Nicaraguan Commission of Risk Analysis of Living Modified Organisms (CONARGEM) has only approved the use of GE crops for animal feed purposes. Non-GE crops and some GE processed food products, such as textured soy protein, soybean flour and refined vegetable oil are accepted for use in food assistance programs.

PART B. POLICY:

REGULATORY FRAMEWORK: The two Nicaraguan institutions responsible for regulating GE plants and animals are the new Institute of Agricultural Health and Protection (IPSA), recently created by the Government of Nicaragua, and the Ministry of Natural Resources and Environment (MARENA). Additionally, there are two commissions, the National Commission on Bio-safety (CONABIO) and the Commission of Risk Analysis of Living Modified Crops (CONARGEM), that serve as advisory bodies for the Government of Nicaragua (GON) on issues related to biosafety of GE crops and animals.

Nicaragua became a party to the Cartagena protocol in 2003. The same year, the GON began requiring notifications for imports of GE crops and a risk analysis for biotech events. However, no commission to perform risk analysis was formed until July 23, 2004, when CONARGEM was formed to be the GON's advisory body on biosafety of GE crops and Animals.

On April 13, 2010, the GON published Law 705 on the prevention of risks arising from organisms derived from new technologies through molecular biotechnology. This law supersedes chapter XVI of Law 291 (basic law on animal and plant health ("%USERNAME%": Are these the proper titles of the laws?)) and establishes a complete comprehensive science based framework for the use of Genetically Engineered Organisms in confined use, research, release into the environment, commercialization (exports and imports), reproduction, multiplication, evaluation of field production, transportation, transit, bio-medication, conservation, and other uses. To date, Law 705 has not been operational because it lacks the procedural norms for its implementation. This creates a big limitation to the Nicaraguan Biotechnology legal framework, as regulations cannot be implemented. Please refer to the following link to see Law 705.

http://legislacion.asamblea.gob.ni/SILEG/Gacetas.nsf/5eea6480fc3d3d90062576e300504635/23f47205d4aad71906257705006d686c?OpenDocument

IPSA

The Institute of Agricultural Health and Protection (IPSA) is the new competent authority for the implementation of the Nicaraguan biotechnology law (Law 705 on the Prevention of Risks arising from Living Modified Organisms through Molecular Biotechnology) in the fields of agriculture, forestry and aquaculture. IPSA is the legal entity that superseded the former General Direction of Animal and Plant Health Protection (DGPSA) which was responsible for conducting the risk analysis of new GE crops. For more information about IPSA please visit the following link:
http://legislacion.asamblea.gob.ni/normaweb.nsf/9e314815a08d4a6206257265005d21f9/8844f18c3ff68a0a06257cec0070c564?OpenDocument

MAG

The role of the Ministry of Agriculture and Livestock (MAG) is under review by the Government of Nicaragua due to the recent changes with IPSA. Note: In 2014, the Government of Nicaragua changed the name of the Nicaraguan Ministry of Agriculture from Ministry of Agriculture and Forestry (MAGFOR) to Ministry of Agriculture and Livestock (MAG).

MARENA

The Ministry of Environment and Natural Resources (MARENA) through the General Direction of Biodiversity and Natural resources is the competent authority for the implementation of Law 705 on issues related to bioremediation, conservation, preservation and other uses related to biological diversity.

CONABIO

The National Commission on Bio-safety (CONABIO) has the main objective of harmonizing and recommending policies related to the use and implementation of bio-safety measures of GE crops. CONABIO also provides advice to the President of Nicaragua on issues related to biosafety. CONABIO is formed by MAG, MARENA, Ministry of Trade, Ministry of Health, Secretary of the Nicaraguan

Council of Science and Technology, an independent plant scientist, and four independent academics with experience on biosafety.

CONARGEM

The Commission of Risk Analysis of Living Modified Organisms (CONARGEM) is the advisory body on bio-safety to the Government of Nicaragua (GON), assigned to MAG and MARENA on a rotational basis – Every six months CONARGEM's presidency pro-tempore changes between MAG and MARENA.

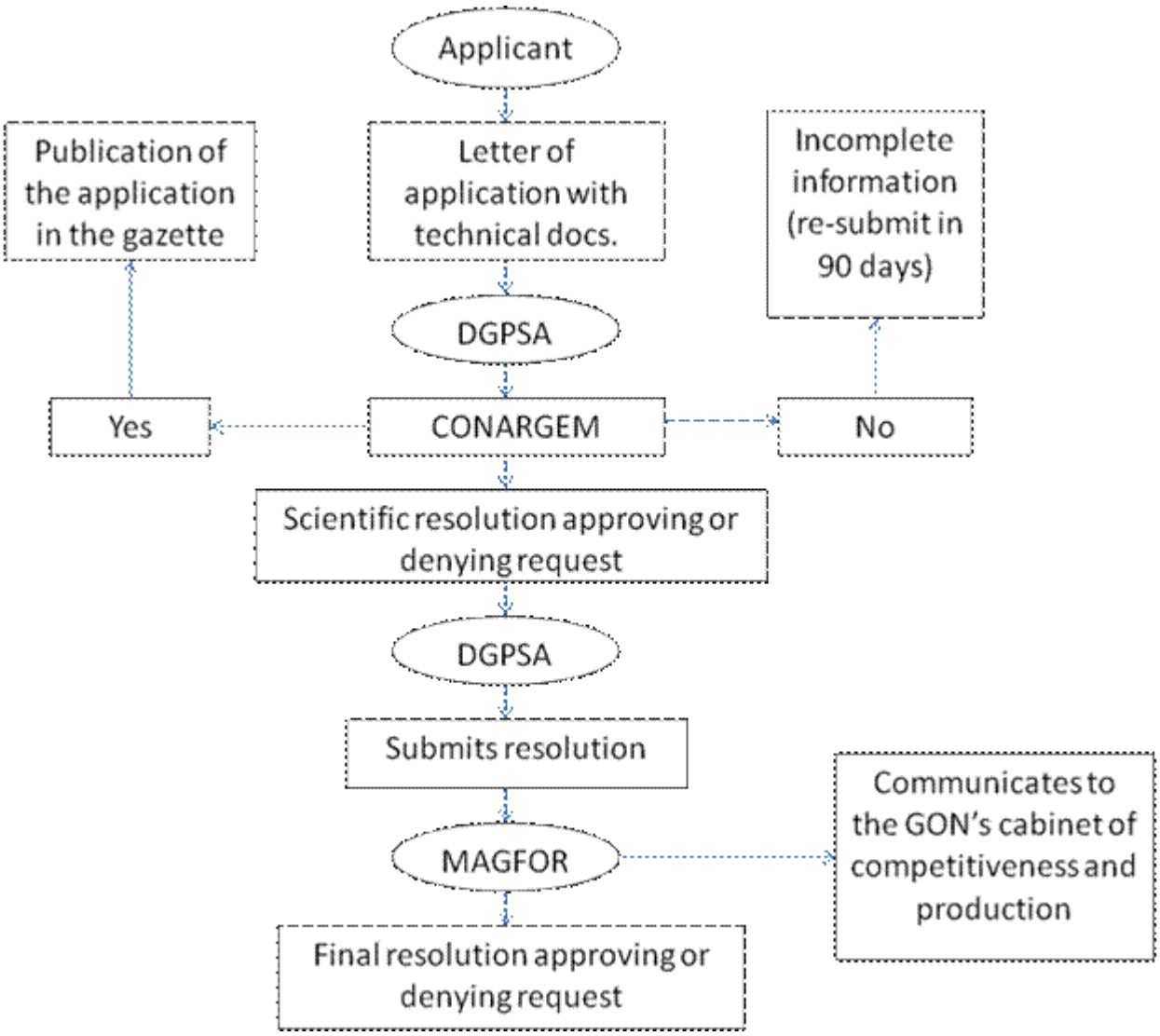
CONARGEM's roles include reviewing requests related to the approval of new biotech events, proposing guidelines for the risk analysis of GE crops, developing procedural norms for operation, and assisting the GON to formulate policies and strategies related to bio-safety.

Note: The main difference between CONABIO and CONARGEM is that CONABIO is more of an advisory body of the President and CONARGEM, is the commission responsible for analyzing requests related to the approval of new biotech events.

THE APPROVAL PROCESS OF NEW GE EVENTS:

According to Law 705, the regulatory treatment of the approval for GE food, feed, processing and environmental release is the same. Total approval is usually takes two hundred and seventy days beginning the day after the competent authority received the complete application.

Comment: At this time, importers and/or exporters cannot request the approval of new GE events since the Law 705, lacks the internal procedural norms (including the procedures to conduct a risk analysis for GE crops) required for its implementation. The flow chart below is subject to changes since the Government of Nicaragua created the New Institute of Agricultural Health and Protection (IPSA).



Source: *Valoración de la situación actual de la bioseguridad en los aspectos normativos jurídicos y organizativos en Nicaragua. José René Orue, 2009*.

APPROVALS: At the moment, there are no GE corn events legally approved. In 2005, the Government of Nicaragua approved Ministerial resolution 034-2005 which approved the phyto-sanitary permits for 15 GE corn events (676, 678, and 680, MS3, MS6, BT 176, BT11, CT 1507, MON 863, MON 810, T14, T25, DLL25, and GA21). However, this ministerial resolution is no longer current. The private sector is trying to have the GON renew and update the aforementioned resolution.

FIELD TESTING: Up to now, CONARGEM has not approved any GE crop for cultivation and therefore field testing is not allowed.

STACKED EVENT APPROVALS: Law 705 does not distinguish between the approval process for plants that combine two or more approved traits and plants that have just one. Stack event approvals follows the same procedures of any GE crop described in article II and III of Law 705.

ADDITIONAL REQUIREMENTS: There are no additional requirements once the solicitation has been approved. For more information please refer to articles 17, 18, 19, 20, 21, 22, 23, 24 and 26 of Law 705.
http://legislacion.asamblea.gob.ni/SILEG/Gacetas.nsf/5eea6480fc3d3d90062576e300504635/23f47205d4aad71906257705006d686c?OpenDocument

CO-EXISTENCE: As part of the risk assessment process for new biotech events stipulated in Law 705, the competent authority, with the advice of the CONARGEM, may establish restricted areas for the release and use of living modified organisms. Therefore, policy measures related to the co-existence between GE and non GE crops will be considered case by case according to the results of the risk analysis.

LABELING: Nicaragua does not have a specific law for labeling on GE crops. However, according to Law 705, GE exporters will need to comply with the provisions established on the Cartagena Protocol on Biodiversity and international and regional agreements on this matter. For the specific case of labeling seeds, exporters will need to comply with Nicaraguan Law 280 on Production and Trading of Seeds which was approved on December 10, 1997 and published in the official Gazette on February 9, 1998. This regulation states that seed bags must have a label with information specifying its characteristics, genetic identification, germination, recommendations for management and conservation, quality and volume, etc. For more information please refer to the following link:
http://www.pgrfa.org/gpa/nic/textos/leyes/leydesemillas.pdf

TRADE BARRIERS: U.S. GE corn and soybean meal have been entering the Nicaraguan market without major problems. However, Nicaragua has a major limitation within the legal framework to regulate GE crops as explained above. The principal law that regulates GE crops and animals (Law 705) lacks the internal procedural norms for its implementation. This creates problems for importers who cannot request the approval of new GE crops because CONARGEM cannot evaluate the requests and make a decision. Another limitation is that the Ministerial Resolution (034-2005) that approves the imports of 15 GE corn events is no longer current and some previously approved events have been discontinued.

INTERLLECTUAL PROPERTY RIGHTS (IPRs): Nicaragua has a specific law (318) on Plant Variety Protection that establishes the standards to protect the rights of natural and legal persons that have created, discovered or developed a new plant variety either by natural means or genetic manipulation. Please refer to the link below for more information.
http://legislacion.asamblea.gob.ni/Normaweb.nsf/($All)/50E33B475568F720062570A100580157?OpenDocument

CARTAGENA PROTOCOL RATIFICATION: Nicaragua is signatory of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. It ratified the protocol on August 28, 2002 and entered into force in September 2003.

INTERNATIONAL TREATIES/FORA: Nicaragua is a member of several international

organizations, including Codex Alimentarius, OIE, COP-MOP and IPPC.

RELATED ISSUES: Not applicable.

MONITORING AND TESTING: MAGFOR requires the testing for GE traces on every imported grain shipment. The tests are made by the Central American University Biotechnology Lab. Part of the purpose of the tests is to identify if the imported commodities have GE positive traces. In the case of corn, MAGFOR has a specific protocol that involves the custody of containers to make sure that corn seeds are not used for cultivation.

LOW LEVEL PRESENCE POLICY: Nicaragua does not have a low level presence policy of GE crops.

PART C: MARKETING

MARKET ACCEPTANCE AND PUBLIC/PRIVATE SECTOR OPINIONS:
Public awareness of GE emerging technologies among Nicaraguans is still limited. There are only three laboratories nationwide – the Central American University, the National Autonomous University and the Polytechnic University - which perform GE testing and research.

The Nicaraguan market is new to the concept of GE technologies. However, the private sector is interested in increasing the number of approved biotech events for corn and, in the future, to have GE crops approved for cultivation. The opposition to biotechnology comes mainly from some anti-GE NGOs which are very active in Nicaragua and promote initiatives that aim to rescue, preserve and enhance native seeds, while refusing entry of GE seeds into the country.

On the other hand, some Nicaraguan universities have started to include biotechnology in their curriculum, as they recognize the potential it has to contribute to food security, agricultural development and the environment. In 2013, the Vice President of Nicaragua, Omar Halleslevens, through the Nicaraguan Council of Science and Technology (CONICYT), and in conjunction with the National Council of Universities (CNU) officially inaugurated a master's degree program in biotechnology. He mentioned that some of the primary objectives of this master's degree are to promote excellence in scientific research and technological development, train professionals in biotechnology and improve the Nicaraguan citizens' knowledge in this field to be able to develop biotechnology in its different applications. These types of steps from the Government of Nicaragua (GON) will help to increase awareness of the importance of biotechnology in the future. For more information on this master's degree please refer to the following link:
http://www.conicyt.gob.ni/index.php/component/content/article/3-noticiasrapidas/277-biotec

MARKET STUDIES: Not applicable.

PART D: CAPACITY BUILDING AND OUTREACH

ACTIVITIES:

In October 2014, Embassy Managua supported the First National Agricultural Congress organized by the Union of Nicaraguan Agricultural Producers (UPANIC), which will now be organized on an annual basis. The theme for the Congress was biotechnology and productivity, with a special emphasis on Genetically Engineered Crops (GE). More than 300 participants from a variety of agricultural organizations attended, including farmers, regulators, business owners, researchers, NGOs, professors and government officials. The Congress facilitated a discussion space for interaction among farmers, experts and policy makers on the different applications of biotechnology, who rarely have an opportunity to discuss the technical issues surrounding biotechnology.

In May 2012, the United States Department of Agriculture (USDA) organized an international conference on Agriculture and Environment (CIAA), in Honduras. Ministers and Vice-Ministers of the Ministry of Agriculture and Forestry, from the eight member countries of the Central American Integration System (SICA), participated. As a concrete result of this conference, an Ad Hoc Technical Expert Group (AHTEG), comprised of regulators from SICA member countries, was formed. This group now intends to become a formal group of SICA, which can provide advice in biotechnology regulation, promotion of agriculture, and environmental conservation to the Central American region.

STRATEGIES AND NEEDS:

USDA will continue capacity building and outreach activities as appropriate.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE

BIOTECHNOLOGY PRODUCT DEVELOPMENT: There are no GE animals under development in Nicaragua at this time.

COMMERCIAL PRODUCTION: Nicaragua does not commercially produce any livestock clones or GE animals or products derived from animal biotechnologies.

BIOTECHNOLOGY EXPORTS: Nicaragua does not export any GE animals, livestock clones, or products from these animals at this time.

BIOTECHNOLOGY IMPORTS: Nicaragua has not imported GE animals or livestock clones or products from these animals.

PART F: POLICY

REGULATION: Law 705 (The Prevention of Risks Arising from Organisms Derived from New Technologies through Molecular Biotechnology) provides MAG and MARENA with the legal authority to regulate animal biotechnology in Nicaragua. The following is the link to the text of the law: http://legislacion.asamblea.gob.ni/SILEG/Gacetas.nsf/5eea6480fc3d3d90062576e300504635/23f47205d4aad71906257705006d686c?OpenDocument

LABELING AND TRACEABILITY: Labeling regulations have not been developed for products of animal biotechnology in Nicaragua.

TRADE BARRIERS: The principal law that regulates GE crops and animals (law 705) lacks the internal procedural norms for its implementation. Please refer to the section of trade barriers on the plant biotechnology chapter.

INTELECTUAL PROPERTY RIGHTS (IPR): There is no IPR law for GE animals.

INTERNATIONAL TREATIES/FORA: Nicaragua participates in the World Organization for Animal Health (OIE), although Post is not aware of specific interventions by Nicaraguan officials on the subject of animal biotechnology.

PART G: MARKETING

MARKET ACCEPTANCE: The information provided above on the subject of acceptance of plant biotechnology generally applies to animal biotechnology. Post would expect the issue to be controversial if and when it becomes a public discussion topic.

PUBLIC/PRIVATE OPINIONS: Please see the section on plant biotechnology.

MARKET STUDIES: Not applicable.

PART H: CAPACITY BUILDING AND OUTREACH

AC TIVITIES: No activities have been developed by Post over the last years specifically on animal biotechnology.

STRATEGIES AND NEEDS: Please see plant biotechnology section on this subject.