Required Report: Required - Public Distribution **Date:** December 05,2020

Report Number: NU2020-0012

Report Name: Agricultural Biotechnology Annual

Country: Nicaragua

Post: Managua

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

In Nicaragua, imports of genetically engineered crops (GE) are limited to use as animal feed. The Nicaraguan Commission of Risk Analysis of Living Modified Crops (CONARGEM) has not approved the use of GE crops for human consumption and/or cultivation. GE corn and processed grains, such as soybean meal, are the top U.S. imported products. The lack of implementing regulations to the biotechnology law continues to be a major limitation to the adoption of new biotechnologies. Discussions between the private sector and the Government of Nicaragua to complete the legal framework continue to be on hold due to the ongoing political crisis.

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 biotechnology 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 imported products. In 2019, Nicaraguan imports of these two products reached over 402,563 metric tons (MT) with a total value of $ 100 million. The United States is the top supplier followed by Brazil and Argentina. All imports of GE grains rely on discretionary import permits issued by the government of Nicaragua. Importers and/or exporters cannot request approval for new GE events since Nicaragua's biotech law, Law 705, lacks implementing regulations. This is a major limitation to the adoption of new biotechnologies in Nicaragua.

Since April 2018, Nicaragua has been immersed in a social political crisis and the private sector has stopped any discussions with the Government regarding the biotech legal framework. Some of the best prospects in the mid-term are the approval of GE corn and soybean events for cultivation and animal feed. However, the approval of GE events will depend, to a great extent, on whether the implementing regulations of Law 705 are passed.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

PRODUCT DEVELOPMENT: Nicaragua has not developed any genetically engineered (GE) crops.

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

EXPORTS: Nicaragua does not export GE crops to the United States or other countries.

IMPORTS: Nicaragua imports GE corn and soybean meal for the animal feed industry. In 2019, Nicaraguan imports of yellow corn from the United States reached 279,084 metric tons with a total value of $58.6 million. Soybean meal imports reached 123,479 MT in volume with a total value of $42.2 million. Imports of other biotechnology products from countries other than the United States are limited.

FOOD AID: Nicaragua continues to be a large food aid recipient due to its limited capacity to supply food for human and animal consumption. At present, 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 such crops for animal feed. Non-GE crops and some GE processed food products - such as textured soy protein, soybean flour and refined vegetable oils - are accepted for use in food assistance programs.

TRADE BARRIERS: U.S. GE corn and soybean meal have been entering the Nicaraguan market without major problems for a long time. The 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 request and make final determinations. Another drawback is that 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. The private sector relies on import permits from the Government of Nicaragua for the importation of GE grains

PART B: POLICY

REGULATORY FRAMEWORK: The two Nicaraguan institutions responsible for regulating GE plants and animals are the Institute of Agricultural Health and Protection (IPSA) 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. Subsequently, the GON began requiring notifications for imports of GE crops and risk analyses for biotech events. In 2004, CONARGEM was formed as 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 the basic law of Animal and Plant health (Law 291) and establishes a complete comprehensive science-based framework for the use of GE 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 is not operational because it lacks the procedural norms for implementation. This creates a major 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 competent authority for the implementation of the Nicaraguan biotechnology law (Law 705) 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 risk analyses 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 to formulate, implement and monitor agricultural policies (including biotechnology policies) that can have a positive economic, social and environmental impact and improve the livelihoods of small, medium and large farmers.

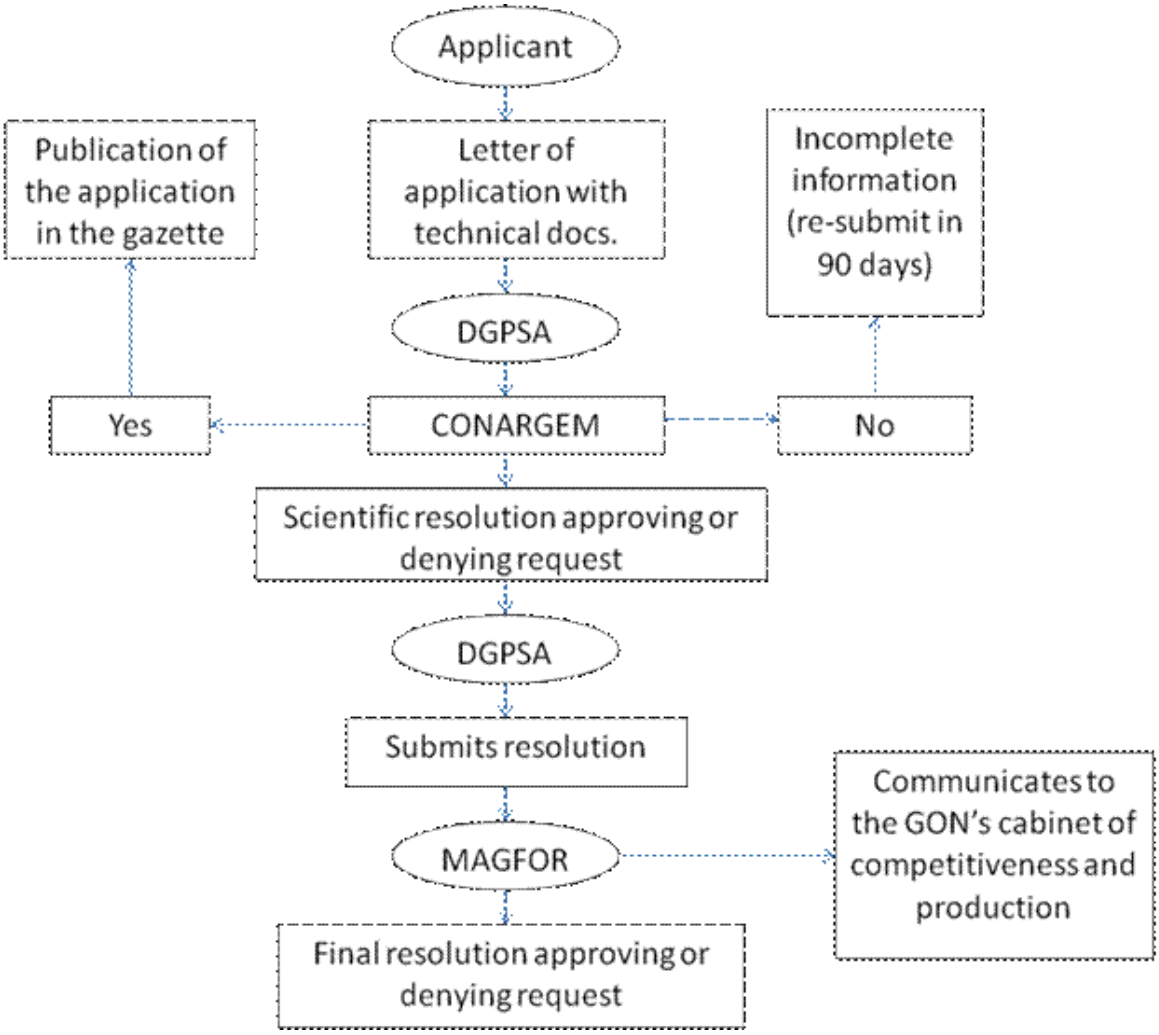
MARENA: The Ministry of Environment and Natural Resources (MARENA), through the General Direction of Biodiversity and Natural Resources, is the competent authority for the implementation of Law 705 on issues related to bioremediation, conservation, preservation and other uses related to biological diversity.

CONABIO: The National Commission on Bio-safety (CONABIO) has the main function of harmonizing and recommending policies related to the use and implementation of biosafety measures of GE crops. CONABIO also provides advice to the President of Nicaragua on issues related to biosafety. CONABIO consists of representatives from 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 biosafety to the Government of Nicaragua (GON), assigned to MAG and MARENA on a rotational basis. Every six months CONARGEM's presidency pro-tempore shifts between MAG and MARENA. CONARGEM's roles include reviewing requests related to the approval of new biotech events, proposing guidelines for the risk analyses of GE crops, developing procedural norms for operations, and assisting the GON to formulate policies and strategies related to biosafety. **Note**: CONABIO is best characterized as an advisory body to the President

while CONARGEM is the commission responsible for analyzing requests related to the approval of new biotech events.

THE APPROVAL PROCESS FOR NEW GE EVENTS: According to Law 705, the regulatory procedures for the approval of GE food, feed, processing and environmental releases are the same. Complete approval usually takes 270 days beginning the day after the competent authority receives completed applications.
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 risk analyses for GE crops) required for its implementation. Please refer to the flow chart below for more details.



Source: *Valoración de la situación actual de la bioseguridad en los aspectos normativos jurídicos y organizativos en Nicaragua. José René Orue, 2009*. **Note:** IPSA replaced the former General Direction of Animal and Plant Health Protection (DGPSA).

APPROVALS: Currently, there are no GE corn events legally approved in Nicaragua. The private sector relies on import permits from the Government of Nicaragua for the importation of GE grains. In 2005, the GON

announced Ministerial Resolution 034-2005 which approved the issuance of phytosanitary 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 and the GON are working together to finalize the implementing regulations of Law 705 and to update the aforementioned resolution.

STACKED OR PYRAMIDED 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 approved trait. Stack event approvals follow the same procedures of any GE crop described in article II and III of Law 705.

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

INNOVATIVE BIOTECHNOLOGIES: Nicaragua has not established any specific regulations for innovative biotechnologies, including, new genomic techniques, new breeding techniques, precision breeding, targeted mutagenesis, gene editing, among others. Law 705 regulates all organisms derived from biotechnologies.

COEXISTENCE: 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 of GE and non-GE crops will be considered on a case-by-case basis in accordance with the results of the risk analyses.

LABELING and TRACEBILITY: Nicaragua does not have a specific law for the labeling and traceability of GE crops. However, according to Law 705, GE exporters will need to comply with the provisions established in 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. http://www.pgrfa.org/gpa/nic/textos/leyes/leydesemillas.pdf

MONITORING AND TESTING: The Nicaraguan Agricultural Protection and Health (IPSA) requires the testing for GE traces on all imported grain shipments. The tests are conducted by the Central American University Biotechnology Lab. A main purpose of the lab tests is to identify if the imported commodities have GE positive traces. In the case of corn, IPSA has a specific protocol that ensures that corn seeds are not used for cultivation.

LOW LEVEL PRESENCE (LLP) POLICY: Nicaragua does not have a low-level presence policy.

ADDITIONAL REGULATORY 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

INTELLECTUAL PROPERTY RIGHTS (IPR): 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 new plant varieties either by natural means or genetic manipulation. Please click here for more information.

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, the International Plant Protection Convention, and the World Organization for Animal Health.

RELATED ISSUES: Not applicable.

PART C: MARKETING

PUBLIC/PRIVATE SECTOR OPINIONS: Public awareness of GE emerging technologies is still limited. There are only three laboratories in the country - 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 receiving approval from the Government to cultivate GE corn and soybean. The opposition to biotechnology comes mainly from some anti-biotechnology NGOs which are very active in Nicaragua and promote initiatives that aim to rescue, preserve and enhance native seeds, while refusing entry of GE planting seeds into the country.

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 Nicaraguan Council of Science and Technology (CONICYT) officially inaugurated the first Master's degree program in biotechnology with the objective of promoting excellence in scientific research and technological development, training biotech professionals and improving awareness among Nicaraguan citizens.

MARKET ACCEPTANCE/ STUDIES: Public awareness of biotechnology is still limited. Overall, the private sector supports the use of GE seeds. The opposition to approve the cultivation of GE seeds comes mainly from the Nicaraguan Government and some non-profit organizations that promote initiatives that aim to rescue, preserve and enhance native seeds. Post is not aware of any relevant country-specific studies on marketing of GE Plants and plant products.

STRATEGIES AND NEEDS: USDA will continue capacity building and outreach activities as appropriate.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

BIOTECHNOLOGY PRODUCT DEVELOPMENT: There are no GE animals or livestock clones 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.

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

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

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.

PART E: POLICY

REGULATORY FRAMEWORK: 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 law 705 pdf file:http://legislacion.asamblea.gob.ni/SILEG/Gacetas.nsf/5eea6480fc3d3

d90062576e300504635/23f47205d4aad71906257705006d686c? OpenDocument

APPROVALS: There are no GE Animals approved or registered in the country for use.

INNOVATIVE BIOTECHNOLOGIES: Nicaragua does not have any specific law related to innovative biotechnologies such as gene editing in animals.

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

ADDITIONAL REGULATORY REQUIREMENTS: There are no additional regulation requirements for animal biotechnology.

INTELLECTUAL PROPERTY RIGHTS (IPR): There are no IPR laws for GE or cloned animals.

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

RELATED ISSUES: Not applicable.

PART F: MARKETING

MARKET ACCEPTANCE: The information provided above regarding the acceptance of

plant biotechnology generally applies to animal biotechnology as well. Post expects the issue to be controversial if it becomes a public discussion topic.

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

MARKET ACCEPTANCE/STUDIES: Please refer to market acceptance for GE seeds.

CHAPTER 3: MICROBIOLOGICAL BIOTECHNOLOGY

PRODUCT DEVELOPMENT: There are no microbiological biotechnology products under development in Nicaragua at this time.

COMMERCIAL PRODUCTION: The only microbial biotech-derived food ingredients produced by Nicaragua are those traditionally used in the production of alcoholic beverages, dairy products, and processed products.

EXPORTS: Nicaragua exports alcoholic beverages, dairy products, and processed products which may contain microbial biotech-derived food ingredients.

IMPORTS: Nicaragua imports alcoholic beverages, dairy products, and processed products which may contain microbial biotech-derived food ingredients.

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.

PART H: POLICY

REGULATORY FRAMEWORK: The legal framework for microbial biotechnology is Nicaragua's law 705 on the prevention of risks arising from organisms derived from new technologies through molecular biotechnology. This law establishes a complete comprehensive science-based framework for the use of GE 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. Although the current regulation is very broad, it doesn't have any specific provisions for microbial biotechnology.

APPROVALS: Nicaragua has not yet approved any microbial agricultural biotechnology products.

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

MONITORING AND TESTING: Nicaragua does not monitor and/or test for any microbial agricultural biotechnology products.

ADDITIONAL REGULATORY REQUIREMENTS: There are no additional regulations for microbial agricultural products.

INTELLECTUAL PROPERTY RIGHTS (IPR): There are no IPR laws for microbial biotechnology products, GE seeds or animals.

Related Issues: Not applicable.

Part I: MARKETING

PUBLIC/PRIVATE OPINIONS: Microbial biotechnology is a new term for most of the key biotechnology stakeholders in Nicaragua. Post is not aware of any public/private opinions regarding microbial biotechnology.

MARKET ACCEPTANCE/STUDIES: The information provided above regarding the acceptance of plant biotechnology generally applies to microbiological biotechnology as well. Post expects the issue to be controversial if it becomes a public discussion topic.

Attachments:

No Attachments