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Report Highlights:

Despite being passed in 2010, Nicaraguan biotechnology legislation lacks implementing regulations that would open additional opportunities for farmers and food processors to integrate new technologies into their operations. However, Nicaraguan companies continue to regularly import genetically engineered feed grains and oilseed products to support the growing livestock sector.

EXECUTIVE SUMMARY

Nicaragua is a signatory to the Cartagena Protocol on Biosafety and requires notification for imports of genetically engineered (GE) crops and a risk analysis for biotechnology events. Since the National Commission for Risk Analysis of Living Modified Organisms (CONARGEM) has not yet approved GE crops for human consumption and/or cultivation, utilization is limited to animal feed and importation is regulated by government-issued, shipment-specific import permits.

Corn and soybean meal represent the highest volume imported GE products, with the United States supplying more than 95 percent of total imports in 2021. Imports of U.S. corn exceeded $140 million in 2021, and imports of U.S. soybean meal were $75 million. U.S. shipments of both corn and soybean meal reached record high volumes in 2021, up 24 and 36 percent respectively. Brazil and Argentina are residual suppliers of corn and soybean meal.

Without implementing regulations to bring Nicaragua's comprehensive biotechnology framework into effect, research, development, and cultivation of biotech plants, animals, and microbes cannot occur. However, even without an operational trade policy framework, Nicaraguan importation of GE products is relatively stable and predictable, due to sustained demand for livestock feed and ingredients.

Additional information on Agricultural Biotechnology in Nicaragua can be found in the 2022 Food and Agricultural Import Regulations and Standards Country Report.

Contents

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

PRODUCT DEVELOPMENT
Nicaragua has not developed 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 to other countries.

IMPORTS
The Nicaraguan livestock industry relies upon imported GE corn, GE soybeans and soybean meal. Imports of GE products from countries other than the United States are limited.

FOOD AID
Nicaragua is a food aid recipient due to its limited capacity to supply food for human and animal consumption. U.S. food aid to Nicaragua has included non-GE crops and some food products processed from GE crops, such as textured soy protein, soybean flour, and refined vegetable oils. The National Commission for Risk Analysis of Living Modified Organisms (CONARGEM) has only approved GE crops for animal feed.

TRADE BARRIERS
Though dependent upon annual or semi-annual import permit issuances, U.S. GE corn, GE soybean and soybean meal have generally not faced barriers or disruptions to trade, despite the absence of a Nicaraguan regulatory framework for products of genetic engineering or innovative biotechnologies.

PART B: POLICY

REGULATORY FRAMEWORK

Terminology used in Nicaraguan legal instruments referring to agricultural biotechnology:

Legal Term (in Spanish)	**Legal Term** (in English)	**Laws / Regulations Containing Term**	**Legal Definition** (in English)
Organismo Vivo Modificado (OVM)	Living Modified Organism (LMO)	• Law No. 705	Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Legal Term (in Spanish)	**Legal Term** (in English)	**Laws / Regulations Containing Term**	**Legal Definition** (in English)
Biotecnologia Molecular	Molecular Biology	• Law No. 705	The application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

The two Nicaraguan institutions responsible for regulating GE plants and animals are the Institute of Agricultural Protection and Health (IPSA) and the Ministry of Environment and Natural Resources (MARENA). Two commissions – the National Biosafety Commission (CONABIO) and CONARGEM – serve as advisory bodies to the Government of Nicaragua (GON) on issues related to 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 GE crops and animals on biosafety.

On April 13, 2010, the GON published The Prevention of Risks Arising from Organisms Derived from New Technologies through Molecular Biotechnology Law (better known as Law 705). This law supersedes chapter XVI of the Basic Law of Animal and Plant Health (Law 291) and establishes a comprehensive, science-based GE organism framework for 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 implementing regulations, and without regulations virtually all aspects of plant biotechnology research, development, and cultivation are effectively prohibited. The text of Law 705 can be found here (Spanish only).

IPSA

The Institute of Agricultural Protection and Health (IPSA) is the competent authority for Nicaraguan biotechnology law (Law 705) implementation in the fields of agriculture, forestry, and aquaculture. In 2014, IPSA superseded the former Directorate General of Agricultural Protection and Health (DGPSA), which was responsible for risk analysis of GE traits. Though the absence of implementing regulations prevents IPSA from performing risk analysis of or approving new GE traits, import permits for U.S. GE

corn and soybean meal continue to be issued. More information about IPSA regulatory authorities is available here and on its official website here (Spanish only).

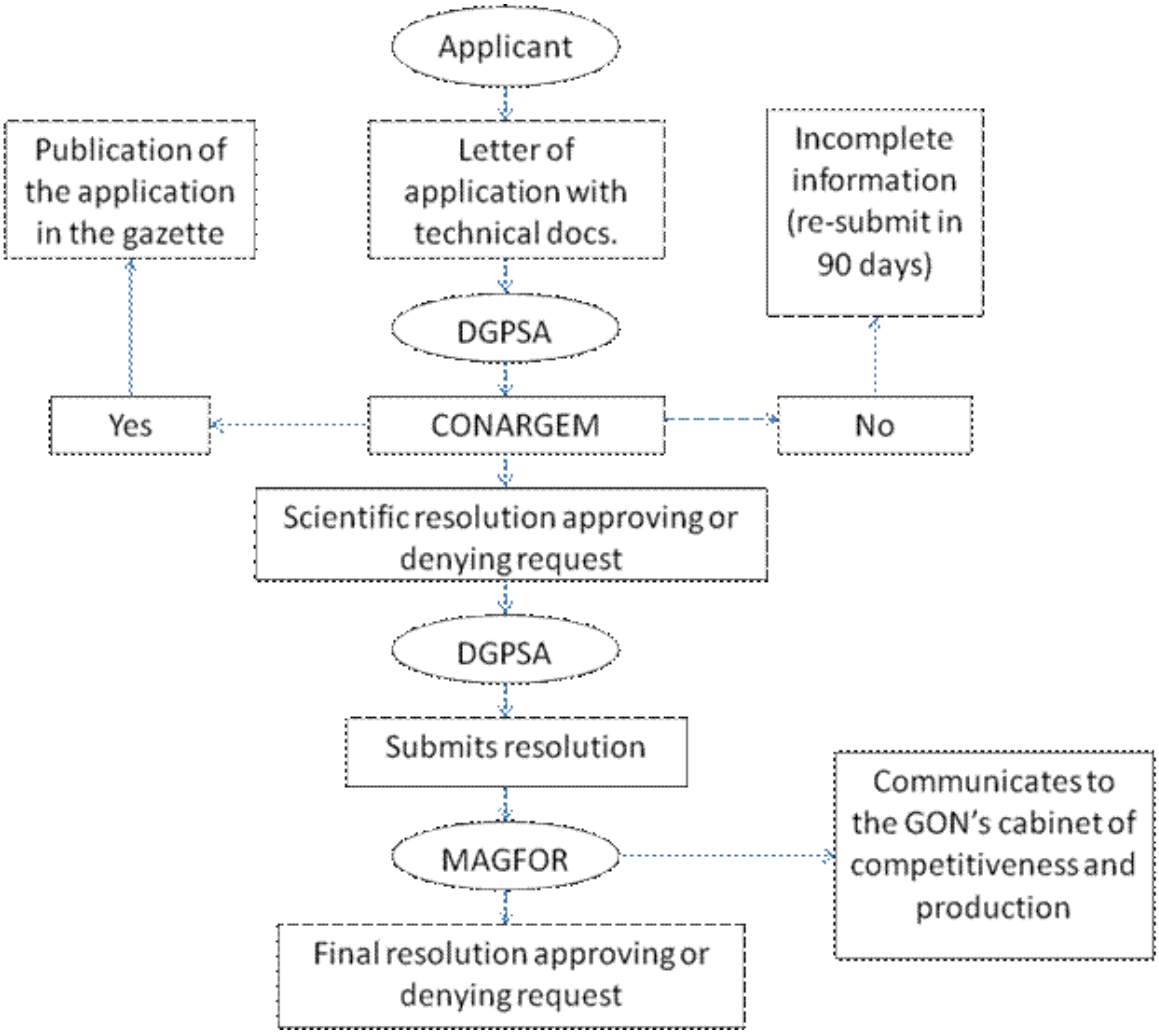
MAG
The Ministry of Agriculture (MAG) formulates, implements, and monitors agricultural policies (including biotechnology policies) that can have a positive economic, social, and environmental impact and improve the livelihoods of small-, medium-, and large-scale farmers.

MARENA
The Ministry of Environment and Natural Resources (MARENA), through its Directorate General 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 Biosafety Commission (CONABIO) is responsible for harmonizing and recommending policies related to the use and implementation of GE crop biosafety measures. CONABIO also advises the President of Nicaragua on issues related to biosafety. CONABIO consists of representatives from MAG, MARENA, Ministry of Trade, and the Ministry of Health as well as the Secretary of the Nicaraguan Council of Science and Technology, an independent plant scientist, and four independent academics with biosafety expertise.

CONARGEM
The National Commission for Risk Analysis of Living Modified Organisms (CONARGEM) is overseen by MAG and MARENA, with leadership rotating between the two ministries every six months. CONARGEM reviews new biotech event approval requests, proposes guidelines for GE crop risk analysis, develops procedural norms, and assists the GON in formulating biosafety policies and strategies. Note: CONABIO is best characterized as an advisory body to the President, while CONARGEM is the commission that would be responsible for analyzing requests related to the approval of new biotech events.

Approval Process for New GE Events
According to Law 705, the approval process of GE events for food, feed, processing, and environmental release should be the same. However, applicants cannot apply for approval of GE events at this time, because Law 705 lacks implementing regulations. Complete approval is expected to take 270 calendar days, beginning the day after the competent authority receives completed applications. 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 DGPSA in 2014. MAGFOR is the acronym for MAG's antecedent, the Ministry of Agriculture and Forestry.

APPROVALS / AUTHORIZATIONS

There are currently no GE events approved in Nicaragua, and all importation of GE products is facilitated by annual / semi-annual import permits from the Government of Nicaragua. The 2005 GON Ministerial Resolution 034-2005 approved the issuance of phytosanitary import 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 in effect as Law 705 superseded its regulatory authority. The private sector and the GON have been working together to finalize the implementing regulations of Law 705 and to update Ministerial Resolution 034-2005.

STACKED or PYRAMIDED EVENT APPROVALS / AUTHORIZATIONS

Law 705 does not distinguish between the approval process for plants that combine two or more approved traits (i.e., stacked or pyramid events) and plants that have just one approved trait. Stacked event approvals would follow the same procedures as any other GE crop under Law 705.

FIELD TESTING
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. Law 705 encompasses all organisms derived from biotechnologies, including those from new genomic techniques, new breeding techniques, precision breeding, targeted mutagenesis, and genome editing among others.

COEXISTENCE
As part of the risk assessment process for GE 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 according to 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, exporters of GE crops 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 Law 280 on Production and Trading of Seeds (Spanish only).

MONITORING AND TESTING
IPSA requires testing for trace levels of GE events for all imported grain shipments; tests are conducted by the Central American University Biotechnology Lab. For GE corn shipments, IPSA requires a specific protocol to ensure imported GE corn seeds are not used for cultivation.

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

ADDITIONAL REGULATORY REQUIREMENTS
Beyond those requirements specified in Law 705, FAS/Managua is not aware of any additional requirements.

INTELLECTUAL PROPERTY RIGHTS (IPR)
Nicaragua's Law 318 on Plant Variety Protection (Spanish only) 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.

CARTAGENA PROTOCOL RATIFICATION
Nicaragua ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity on August 28, 2002; related measures 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
None at this time.

PART C: MARKETING

PUBLIC / PRIVATE OPINIONS
Public awareness of GE technologies and products is 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 limited research.

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 environmental ambitions. 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 biotechnology professionals and improving awareness among Nicaraguan citizens.

Agricultural producers are generally interested in cultivating GE corn and soybean varieties, but cannot do so without implementing regulations under Law 705. While the private sector supports the use of GE seeds, there are nonprofit organizations opposed to GE technologies promoting initiatives to preserve and enhance native seeds.

MARKET ACCEPTANCE / STUDIES
Public awareness of GE technologies and products is limited. FAS/Managua is unaware of any Nicaragua-specific research or analysis of market acceptance of GE technologies and products.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

PRODUCT DEVELOPMENT
In the absence of implementing regulations, research into and development of GE animals or livestock clones are effectively prohibited.

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
In the absence of implementing regulations, risk assessment and importation of animals, livestock clones or products from these animals is effectively prohibited.

PART E: POLICY

REGULATORY FRAMEWORK
Law 705 provides MAG and MARENA with the legal authority to regulate animal biotechnology in Nicaragua. However, because implementing regulations have yet to be developed for Law 705, there is presently no pathway for approval of GE animals, livestock clones, or products from these animals.

For more information on Nicaragua's biotechnology regulatory framework and terminology, see Chapter 1, Part B.

APPROVALS / AUTHORIZATIONS
There are no GE animals, livestock clones, or products from these animals approved or registered in Nicaragua at this time.

INNOVATIVE BIOTECHNOLOGIES
Nicaragua has not established any specific regulations for innovative biotechnologies. Law 705 encompasses all organisms derived from biotechnologies, including those from genome editing in animals.

LABELING AND TRACEABILITY
Nicaragua has not developed regulations for labeling or traceability of products of animal biotechnology or cloning.

ADDITIONAL REGULATORY REQUIREMENTS
Nicaragua has not developed additional regulatory requirements for animal biotechnology.

INTELLECTUAL PROPERTY RIGHTS (IPR)
Nicaragua has not developed IPR laws for GE animals or for livestock clones.

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

RELATED ISSUES
None at this time.

PART F: MARKETING

PUBLIC / PRIVATE OPINIONS
Public awareness of GE animals, livestock clones, or products from these animals is limited. Though unaware of any research into public acceptance of animal biotechnology, FAS/Managua anticipates the subject could be controversial, based on broader cultural attitudes. Industry sources have expressed interest in eventual introduction of 'slick' varieties of popular beef and dairy breeds to improve cattle sector performance without sub-tropical cross-breeding. Industry sources did not anticipate public acceptance issues with consumers, who rely on price and quality as their primary decision-making factors.

MARKET ACCEPTANCE / STUDIES
Public awareness of GE technologies and products is limited. FAS/Managua is unaware of any Nicaragua-specific research or analysis of market acceptance of GE technologies and products.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

PRODUCT DEVELOPMENT
In the absence of implementing regulations, research into and development of microbial biotechnology are effectively prohibited.

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
There are neither official statistics nor estimates on exports of microbial biotechnology products. Nicaragua exports alcoholic beverages, dairy products, and processed products which may contain microbial biotech-derived food ingredients.

IMPORTS
There are neither official statistics nor estimates on imports of microbial biotechnology products. Nicaragua imports alcoholic beverages, dairy products, and processed products which may contain microbial biotech-derived food ingredients.

TRADE BARRIERS
In the absence of implementing regulations, risk assessment and importation of microbial biotechnology products is effectively prohibited.

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.

Law 705 provides MAG and MARENA with the legal authority to regulate microbial biotechnology in Nicaragua. 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 legislation is very broad, it doesn't have specific provisions for microbial biotechnology.

For more information on Nicaragua's biotechnology regulatory framework and terminology, see Chapter 1, Part B.

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

LABELING AND TRACEABILITY
Nicaragua has not developed regulations for labeling or traceability of products of microbial biotechnology.

MONITORING AND TESTING
Nicaragua does not monitor and/or test for presence of microbial biotech in imports or exports processed products.

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

INTELLECTUAL PROPERTY RIGHTS (IPR)
Nicaragua has not developed IPR laws for microbial biotechnology products.

RELATED ISSUES
None at this time.

PART I: MARKETING

PUBLIC / PRIVATE OPINIONS
Microbial biotechnology is a new term for most of the key biotechnology stakeholders in Nicaragua, let alone the general public. FAS/Managua is not aware of any public/private opinions regarding microbial biotechnology.

MARKET ACCEPTANCE / STUDIES
Though unaware of any research into public acceptance of microbial biotechnology, FAS/Managua anticipates the subject could be controversial, based on broader cultural attitudes. FAS/Managua is unaware of any Nicaragua-specific research or analysis of market acceptance of microbial biotechnology.

Attachments:

No Attachments