

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

**Date:** 12/6/2017 **GAIN Report Number:** 

# Nicaragua

Food and Agricultural Import Regulations and Standards - Narrative

No major changes on Nicaragua's Food Import Regulations

**Approved By:** 

**Prepared By:** 

Jimmy Bolaños

#### **Report Highlights:**

This report lists the main Nicaraguan food laws, technical regulations and import requirements.

#### **Section I. General Food Laws**

Nicaragua's food import regulations are shared between the Nicaraguan Institute of Agricultural Protection and Health (IPSA) and the Nicaraguan Ministry of Health (MINSA). IPSA is responsible for the inspection of agricultural products, including fresh produce, grains, processed foods, animal feeds, agrochemicals and seeds at the borders while MINSA regulates processed food products registration.

A general requirement of Nicaragua's import regulations is that the importer must have an import permit prior to the importation of any shipment. Processed foods also require a sanitary register number from the Ministry of Health (MINSA) and/or the Nicaraguan Institute of Agricultural Protection and Health (IPSA). Good communication between the exporter and importer is essential for a successful commercial relationship.

There are two basic laws that authorize these ministries to supervise food imports: Basic Law of Animal and Plant Health (Law 291, 1998) whose main objective is to prevent the propagation of pests and diseases, and the General Health Law (Law 423, 2002) which covers all aspects related to human health, including food safety aspects of processed food imports.

Nicaragua is a member of the Central American Integration System (SICA) that intends to harmonize food safety and import regulations. Under SICA, Nicaragua has adopted several Central American Technical Regulations, also known as RTCAs, related to import procedures and food safety. A complete list of these <u>Technical Regulations</u> is available at the SICA online <u>library</u>.

Additionally, Nicaragua has a series of internal mandatory and voluntary technical norms (known as NTON) that regulate plants, animals, food products, agrochemicals and other products. Theses technical norms are developed by the Nicaraguan Ministry of Trade (MIFIC) in coordination with the private sector and other Ministries. A complete list of these regulations is available at the Nicaraguan Ministry of Trade Website..

The most relevant food regulations approved in the last two years by Nicaragua are the Central American Regulation for Organic products, <u>RTCA 67.06.74.16</u> and a <u>Comprehensive Guide</u> for the implementation of the Central American Regulation on the Labeling of Prepackaged Foods, RTCA. 67.01.07.10. The Central American regulation for organic products only allows the imports of organic products that have an organic certificate from the exporting country's competent authority or designated agency. This comprehensive guide provides a number of examples of prepackaged food labels and includes a number of frequently asked questions.

Even though this report provides a list of the key food import regulations, in Nicaragua it is highly recommended that U.S. exporters verify the full set of import requirements with importers before any goods are shipped. The reason is that import procedures might be subject to change.

MINSA regulates food and beverage additives through the Central American Technical Regulation, RTCA 67.04.54:10. The RTCA 67.04.54:10, establishes food additives and the maximum levels permitted according to their function and type of food. Any substance used as an ingredient is exempt from this regulation. The technical standards of this regulation were adopted from Codex's general regulation on food additives (Codex Stan 192-1995 (Rev. 6-2005). Other sources are JECFA, FEMA and the FAO Food and Nutrition Paper on specifications for food additives. The food additives approved list with its maximum permissible levels can be found in the Central American Technical Regulation RTCA.67.04.54:10.

#### **Section III. Pesticides and Other Contaminants**

IPSA is the agency that tests for pesticides and other contaminants on fresh produce, grains, raw meats and dairy products. Nicaragua has adopted the Codex Maximum Residue Limits for pesticides and Extraneous Maximum Residue limits since it doesn't have any regulation on this matter. However, the tests are required for Nicaraguan export products such as meat, seafood, peanuts but not for imports.

In Nicaragua all pesticides must comply with regulation <u>Law 274, 1998</u> and the <u>obligatory technical</u> <u>norm (NTON-02-010-02)</u> on environmental standards for the classification and labeling of pesticides that establishes the general criteria for the eco-toxicological classification, as well as for the selection of signs and symbols and phrases of danger that must appear on the label of pesticides and toxic substances.

### Section IV. Packaging and Container Requirements

Nicaragua does not have any general law on packaging and container requirements. Food service and warehouse type importers sell their products in larger size containers. Most retailers sell their products in sizes that are more convenient for consumers in terms of price and contents.

### **Section V. Labeling Requirements**

There are two main Central American Technical regulations that have been adopted by Nicaragua that cover all aspects related to labeling requirements: the Technical regulation on General Labeling of Prepackaged Food Products (RTCA 67. 01.07.10) and the Technical regulation on the Labeling of Prepackaged Food Products for Human Consumption for the Population Older than Three Years (RTCA. 67.01.60:10). The main objective of these regulations is to establish the minimum labeling requirements for food products, including the labeling requirements for prepackaged food for the population over three years of age. On September 1, 2016, Central America Customs Union Countries (CACU) adopted a comprehensive guide to facilitate the implementation of the Central American Regulation on the Labeling of Prepackaged Foods, RTCA. 67.01.07.10. The comprehensive guide provides a number of examples of prepackaged food labels and includes a number of frequently asked questions. So far there are no regulations for the labeling of Genetically Modified Organisms. The complete guide can be found here.

According to the Central American Technical Regulation on General Labeling of Prepackaged Food Products (RTCA 67.01.07.10), implemented in July 2012, all imported food products must have labels

in Spanish. Despite this language requirement, other languages may be used as well, as long as the required information is also included in Spanish. The information that must appear on the label, except when indicated otherwise by a national standard or by the Codex *Alimentarius* includes: a) product name, b) net content and drained weight in international system units, c) artificial color and flavors (if any), d) MINSA registration number, e) ingredients listed in decreasing order by weight, f) importer's name and address, g) lot number and expiration date, h) country of origin, i) preservation and use instructions. The sticker-type label, in Spanish, is usually provided by the importer prior to retail sale.

The Central American Technical Regulation on Nutritional Labeling of Prepackaged Food Products (RTCA 67.04.48:08), implemented January 2014, requires listing nutrients such as total fat, saturated fat, carbohydrates, sodium, protein and energetic value in the label of prepackaged food. This regulation will apply to prepackaged food products that include nutritional value, nutritional and health declarations and that will be sold directly for human consumption in Central America. Donated and sample products are exempt of this regulation.

### Sample of Current Labels:

Name of the Product	
Ingredients: xxxxxxxxxxx	
XXXXXXXXXX XXXXXXXXXX	Use instructions:
XXXXXXXXXX XXXXXXXXXX	Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
XXXXXXXXXXX XXXXXXXXXX	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Imported by: xxxxx Address: xxxxx Sanitary Registry #: xxxxx Telephone: xxxxx Country of	
Origin :xxxxx	
Lot number and expiration date.	

### Sample of a Label with Nutritional Information:

Nutritional Information	
Portion SizeG or mL or Unity (g or mL)	
Portion per package	
Quantity per 100g or 100 ml or portion	
Energy (Kl)	
Total Fat (g)	
Saturated Fat (g)	
Carbohydrates (g)	
Sodium (mg)	
Total Protein (g)	

MINSA is responsible for supervising and implementing technical regulations RTCA 67.01.60:10 and RTCA 67.04.48:08. Please find more information on the labeling regulation via this hyperlink.

#### **Section VI. Other Specific Standards**

#### **Alcoholic Beverages**

Alcoholic beverages must comply with the Central American Regulation <u>RTCA.67.01.05:11</u> on the labeling requirements for alcoholic beverages. This regulation requires that alcoholic beverages should have a label, in Spanish, that indicates the name of the product, alcohol content, net content, ingredients list, name and address of the company, sanitary registry number, expiration date, lot tracking number with warning sign, which states that the excessive consumption of alcoholic beverages is harmful to health.

### **Diet Foods**

Diet foods, other than nutritional supplements or proteins without any therapeutic indication, are regulated by the General Division of Health Services of the Nicaraguan Ministry of Health (MINSA). The law that regulates diet foods is the general law of medicines and pharmacies (Law 292/). This law requires that all pharmaceutical products must be registered at MINSA prior to sale and can only be sold to legally authorized pharmacies in Nicaragua. For more information about this regulation, please refer to Nicaraguan Law of Medicines and Pharmacies.

#### **Vitamin Enriched Requirements:**

Nicaragua has approved several technical norms to fortify Sugar with Vitamin A ( NTON 03-028-99), Rice with Folic Acid, Cooper and other Micronutrients (03 091 11), Wheat Flour with Micronutrients such as Cooper, Vitamin B1, vitamin B2, Niacin and Folic Acid (RTCA. 67.01.15:07) and Salt with Iodine and Fluor (NTON 03 031-09). The technical norm for the fortification of rice has only been applied to rice donations targeting public schools. Refer to the hyperlinks of each regulation for more information.

### Section VII. Facility and Product Registration Requirements

Processed food facilities must be registered and approved by FDA, APHIS and/or FSIS and must send a written communication to the Nicaraguan Institute of Agricultural Protection and Health to express their interest in exporting to Nicaragua. IPSA's risk analysis division reviews the request and determines if the facility is suitable to export to Nicaragua. In cases when the facility is not officially registered and/or monitored by any of the U.S. agencies mentioned above and the food products are of high sanitary risk, then IPSA might request an inspection at origin that must be paid by the exporter. As of now, the inspections at origin have been targeted to seafood packing plants because of the high sanitary risks.

Processed food products are regulated by the Nicaraguan Ministry of Health (MINSA) through the Direction of Food Control. The Direction of Food control has the following requirements to register food products:

• Request the sanitary registry number at MINSA and pay for the certification and laboratory

- analysis. (Importer must pay between \$80 and \$100).
- Pay for the laboratory analysis and certification at MINSA. Provide updated copy of sanitary registry number.
- Provide technical specifications of the product.
- Provide the certificate of free sale issued by a competent government authority.
- Provide three samples of 500 grams each from the same lot in its original package. For liquids, the importer must provide three samples of one liter.
- Provide two labels of the product. If the label is not in Spanish, the importer must provide a Spanish translation.
- Provide the cashier receipt for the certification.

Registration is valid for five years and can be renewed thirty days prior to expiration date by presenting all the requirements listed above. All documents presented in English must be translated into Spanish. Once MINSA registers a product, it will issue a certificate of free sale for mass distribution in Nicaragua. The registration process takes on average twenty-one days when all the required documents are presented. For additional information regulations on processed food products please visit MINSA'S Direction of Food Control website.

### **Section VIII. Other Certification and Testing Requirements**

Once a container arrives to the border, importers must present the following information to IPSA: Import permit, sanitary or phytosanitary certificate, certificate of origin and a copy of the commercial invoice. Additionally, the importer must present the bill of lading, packing list, and original invoice, declaration of invoice authenticity, import permit and certificate of origin to the Nicaraguan Customs Authority (DGA). It takes between three to five days for a container to be delivered at the importer's warehouse once it reaches the Nicaraguan border.

Regarding inspections at the border, the key legislation that establishes inspection procedures is COMIECO Ministerial Decree No. 338-2014 Sanitary and Phytosanitary Guidelines for the facilitation of trade in Central America. This Ministerial Decree classifies imported animal, plant and processed food products according to the sanitary and phytosanitary risk category they represent. If the imported product falls under the "A" category, the imported product must be inspected at the border because it is considered to be of high risk. If the imported product falls into the "B" (medium risk) or "C" (low risk) category, the imported products will be inspected randomly at the border by IPSA. For more information about this regulation please refer to the following link: <a href="http://visar.maga.gob.gt/visar/338-2014COMieco.pdf">http://visar.maga.gob.gt/visar/338-2014COMieco.pdf</a>.

### **Sample Products**

Import of processed foods for display and tasting purposes need to comply with the Central American Regulation RTCA. 67.01.05:11. This regulation applies to all processed food products that do not have a sanitary registry number and will be used for display and tasting purposes. Importers need to fill in

annex A of RTCA. 67.01.05:11 and provide a copy of the certificate of free sale. The imported products need to have a label that states that the products are not for sale. These products are not exempt for the regular sanitary and phytosanitary import procedures. For additional information please refer to <a href="RTCA.67.01.05:11"><u>RTCA.67.01.05:11</u></a>

### **Genetically Engineered Grains**

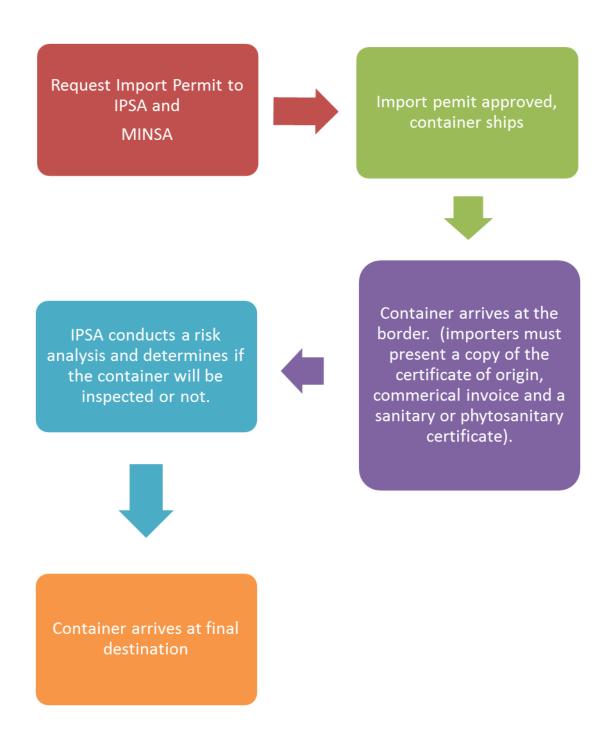
Nicaragua has a regulation for the prevention of risks arising from Living Modified Organisms through molecular biotechnology (<u>Law 705, 2010</u>). This regulation provides the guidelines to request the approval of new GE crops and other type biotechnological products. However, as of this date, this law lacks the internal rule for its implementation. GE corn is the only product being imported to Nicaragua. The private sector needs to requests an import permit to the Government of Nicaragua for every corn shipment. For more information about the current status of biotechnology in Nicaragua you can search here.

### **Section IX. Import Procedures:**

Every importer must be registered as a tax payer at the General Direction of Income and have a unique tax number known as RUC. The first step is to request an import permit to IPSA and/or MINSA. Processed foods also required a sanitary register number from the Ministry of Health (MINSA) and/or the Nicaraguan Institute of Agricultural Protection and Health (IPSA). Good communication between the exporter and importer is essential for a successful commercial relationship.

Once the container arrives to the border, importers must present the following information to IPSA: Import permit, sanitary or phytosanitary certificate, certificate of origin and a copy of the commercial invoice. Additionally, the importer must present the bill of lading, packing list, and original invoice, declaration of invoice authenticity, import permit and certificate of origin to the Nicaraguan Customs Authority (DGA). It takes between three to five days for a container to be delivered at the importer's warehouse once it reaches the Nicaraguan border. If the imported product falls under the "A" category according to COMIECO Resolution No. 338-2014, the imported product must be inspected at the border because it is considered to be of high risk. If the imported product falls into the "B" (medium risk) or "C" (low risk) category, the imported products will be inspected randomly at the border. Please refer to flow chart below.

Import Procedures Flow Chart for Processed Foods:



## Section X. Copyright and/or Trademark Laws

Intellectual property is protected differently in Nicaragua than in the United States. Rights must be

registered and enforced in Nicaragua under local laws. U.S. trademark and patent registrations will not protect a U.S. company in Nicaragua. Registration of patents and trademarks is on a first-in-time, first-in-right basis; consider applying for trademark and patent protection even before selling your products or services in the Nicaraguan market. It is vital that companies understand that intellectual property is primarily a private right and that the U.S. government generally cannot enforce rights for private individuals in Nicaragua. It is the responsibility of the rights' holders to register, protect, and enforce their rights where relevant, retaining their own counsel and advisors. Companies should seek advice from local attorneys or intellectual property consultants who are experts in Nicaraguan law.

While the U.S. government stands ready to assist, there is little we can do if the rights holders have not taken these fundamental steps necessary to securing and enforcing their intellectual property in a timely fashion. Moreover, in many countries, rights holders who delay asserting their rights on a mistaken belief that the U.S. government can provide a political resolution to a legal problem may find that their rights have been eroded or abrogated due to legal doctrines or unreasonable delay in prosecution. In no instance should U.S. government advice be seen as a substitute for the obligation of a rights holder to promptly pursue its case.

It is always advisable to conduct due diligence on potential partners. Negotiate from the position of your partner and give your partner clear incentives to honor the contract. A good partner is an important ally in protecting intellectual property rights. Consider carefully, however, whether to permit your partner to register your intellectual property rights on your behalf. Doing so may create a risk that your partner will list himself as the intellectual property owner and fail to transfer the rights should the partnership end. Projects and sales in Nicaragua require constant attention. Work with legal counsel familiar with Nicaraguan laws to create a solid contract that includes non-competition clauses, and confidentiality/non-disclosure provisions.

Small and medium-size companies should understand the importance of working together with trade associations and organizations to support efforts to protect intellectual property and stop counterfeiting. There are a number of these organizations, both Nicaragua- or U.S.-based. These include:

- The U.S. Chamber of Commerce and local American Chambers of Commerce
- National Association of Manufacturers (NAM)
- International Intellectual Property Alliance (IIPA)
- International Trademark Association (INTA)
- The Coalition Against Counterfeiting and Piracy
- International Anti-Counterfeiting Coalition (IACC)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Biotechnology Industry Organization (BIO)

# **Appendix I. Government Regulatory Agency Contacts:**

Government Agencies:

Ministry of Health's Food Regulations Division

Phone: (505) 289 4700, Ext. 217

Email: <u>eta@minsa.gob.ni</u> <u>alimento@minsa.gob.ni</u>

Institute of Agricultural Protection and Health's Food Safety Division

Phone: 22981330 / 22981331 / 22981349

Email: inocuidad@ipsa.gob.ni

# **Appendix II. Other Import Specialist Contacts:**

FAS Managua

agmanagua@fas.usda.gov