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Nicaragua

# Food and Agricultural Import Regulations and Standards -Narrative

# **FAIRS Country Report**

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## **Report Highlights:**

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

#### Section I. Food Laws:

Nicaragua's agricultural 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 at the borders and the regulation of animal feeds, agrochemicals and seeds, while MINSA regulates processed food products. The general philosophy of Nicaragua's import regulations is that the importer must have an import permit prior to the importation of any shipment. Processed foods and agrochemicals 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.

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 <u>online</u>.

Nicaragua has also a series of 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 <u>regulations</u> is available online.

The most relevant regulations approved in 2016 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. The comprehensive guide provides a number of examples of prepackaged food labels and includes a number of frequently asked questions.

In addition to these two new regulations, this report provides a list of imported products and their risk category determined according to the COMIECO Resolution <u>No. 338-2014</u>. The risk category is used by the Nicaraguan Institute of Agricultural Protection and Health (IPSA) to determine whether a container should be inspected or not.

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 because import procedures might be subject to change.

#### Section II. 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 <u>here.</u>

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: xxxxxxxxxx  |   |
| *****  | Use instructions:                       |
| *****  | Xxxxxxxxxxxxxxxxxxxxxxx                 |
| *****  | ****                                    |
|  | *****                                   |
|  | *************************************** |
| 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 <u>labeling regulation</u> via this hyperlink.

#### Section III. Packaging and Container Regulations:

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 IV. Food Additives Regulations:

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 <u>RTCA.67.04.54:10</u>.

#### Section V. Pesticides and Other Contaminants:

Nicaragua has a basic law for Pesticides and Agrochemicals (Law 274, 1998). This law authorizes IPSA to regulate every aspect related to the trading and processing of pesticides and chemicals. Besides Law 274, Nicaragua has an <u>obligatory technical 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. In addition to this, in November 2012, Nicaragua signed a <u>Central American Technical Regulation on Requirements for Product Registry of microbiological pesticides (RTCA 65.05.61:11)</u>. The complete lists of all regulated and non-regulated approved chemicals are attached to this report.

According to these laws:

- All importers of agrochemicals are required to obtain a permit from IPSA before selling any product.
- All Agrochemicals need to be registered at IPSA prior to any importation.
- Exporters must have a legal representative in Nicaragua as all suppliers need to be registered with IPSA.
- Importers must have a permit for the warehouse or facility where the agrochemicals will be stored.

To register a synthetic pesticide an importer must:

- Request the approval to import a sample of the product for registration purposes at IPSA.
- Pay for a qualitative test analysis.
- Request a toxicological test at MINSA.
- Request an Eco-Toxicological test at the Ministry of Natural Resources and Forestry (MARENA).
- Have results from the different Ministries published in the official newspaper.
- Submit labels and other information relevant to product description to IPSA.
- Pay an annual fee to revalidate the permit after the initial registration is received.

#### Section VI. Other Regulations and Requirements:

#### 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 <u>Nicaraguan Law of Medicines and Pharmacies</u>.

#### Section VII. Other Specific Standards:

#### **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 <u>RTCA.</u> 67.01.05:11

#### Section VIII. 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)

#### Section IX. Import Procedures:

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, original invoice, declaration of invoice authenticity, import permit and certificate of origin to the Nicaraguan Customs Authority (DGA). Between three to five days is the approximate time it takes for a container to be delivered at the importer's warehouse, once it reaches the Nicaraguan border.

The Nicaraguan Institute of Agricultural Protection and Health (IPSA) is the agency responsible for the inspection of agricultural products 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. For more information about imported products and their risk category please refer to the following link: <u>http://visar.maga.gob.gt/visar/338-2014COMieco.pdf</u>.

Processed food products are regulated by the Nicaraguan Ministry of Health (MINSA) through the Direction of Food Control. The Direction of Food Control requires a certificate of free sale and a certificate of chemical analysis. To register food products, the petitioner must present a certificate of free sale issued in the country of origin by the competent sanitary authority. Food products must have a current sanitary registry in the country of origin. The Direction of Food control has the following requirements to register food products:

The importer must:

• 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.

#### Plant Products and Sub-Products:

Plant Products and Sub-Products are regulated by the Plant Health Direction at IPSA. This agency requires an SPS certificate, and certificate of chemical treatment, when applicable, to issue an import permit. Please refer to technical norm  $11\ 005\ 08$  for additional information on import requirements applied to the imports of plant products and plant sub-products.

#### Requirements to Obtain an Import Permit for Plant Products and Sub-Products:

- The importer needs to register on a yearly basis at the Nicaraguan Institute of Agricultural Protection and Health (IPSA)
- Fill in "import request format" at IPSA.
- Provide a copy of the commercial invoice. If it is a donation provide a copy of the donor.
- Request the approval from the seeds department at IPSA. If it is a donation, request the approval from IPSA.
- Provide a Payment receipt from IPSA once the import is authorized.
- IPSA reviews the application and sends a letter to the importer stating either the request was approved or not. If it is not approved, IPSA should provide the technical reasons justifying the decision.

#### Veterinary Products and Animal Feeds:

Exporters need to have a legal representative in Nicaragua:

- Importer needs to be registered at IPSA
- Vet product or animal feed must be registered at IPSA
- Fill in "import permit format" at IPSA. Attached to this request, the importer needs to provide a copy of the commercial invoice, information of the supplier, certificate of origin and the sanitary

certificate.

• IPSA reviews the application and sends a letter to the importer stating either the request was approved or not. If it is not approved, IPSA should provide the technical reasons justifying their decision.

#### Animal Products and Sub-Products

Animal products and sub-products are regulated by the Animal Health Direction at IPSA. This agency requires an SPS certificate to issue an import permit. Please refer to <u>APHIS' import and export matrix</u> for a list of plant or animal export protocols already negotiated between USDA and IPSA.

The process of registering a product can take up to three months and costs about \$750.

For microbiological pesticides, the importer must present a certificate of microbiological analysis and also provide basic information about potential side effects of the microorganisms, ability to colonize and cause damage, produce toxin as well as relevant metabolites. For additional information refer to <u>RTCA</u> <u>65.05.61:11</u>.

#### For Genetically Engineered Crops (GE)

Nicaragua has a regulation for the prevention of risks arising from Living Modified Organisms through molecular biotechnology (Law 705, 2010). 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. At the moment, GE corn is the only product being imported to Nicaragua. GE Corn is only used by the animal feed industry and cannot be used for cultivation.

## For Fertilizers

On July 05 2013, Nicaragua signed the Central American Technical Regulation <u>RTCA 65: 05:54:09</u> on the registration requirements for fertilizers. This technical regulation entered into effect in January 2014. The main objective of this regulation is to establish registration requirements for fertilizers.

#### Among the requirements are :

The importer must be registered at IPSA prior to the importation of any shipment.

- The exporter must have a legal representative living in Nicaragua.
- Fertilizers must be registered at IPSA.

The process of registering fertilizers involves:

- Requesting product registration. Importers are required to fill-out the *Solicitud para Fertilizantes y Enmiendas*.
- Providing an original certificate of free sale issued by the competent government sanitary authorities in the country of origin. When the product has not been registered in the country of

origin, the importer will need to present a certificate of origin and a letter from the competent government authority explaining the reasons why the product has not been registered and confirm that the manufacturer is authorized to produce and sell fertilizers.

- Providing an original certificate of qualitative and quantitative analysis, issued and signed by the manufacturer or formulator, indicating the nutrient composition, identifying the sources or compounds of the chemical formula, as well as inert ingredients, fillers and additives with corresponding percentages of mass, solid mass, and the volume for liquids, etc.
- Providing an original certificate of analysis of the fertilizer, provided by the manufacturer or formulator, indicating the nutrients and corresponding percentages mass/solid mass and the volume for liquids.
- Providing a statement of the presence or absence of heavy metals (cadmium, chromium, arsenic, mercury and lead) expressing their maximum concentration in parts per million (ppm).
- Providing a label of the product and safety indications of the product. This does not apply to fertilizers traded in bulk. For "bulk fertilizers," the importer should provide a product safety fact sheet.

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

#### Government Agencies:

Ministerio de Salud Dirección de Regulación de Alimentos Phone: (505) 289 4700, Ext. 217 Email: <u>eta@minsa.gob.ni</u> <u>alimento@minsa.gob.ni</u>

IPSA's (Quarantine Department, Seeds, Agrochemicals) PBX: 22981330 / 22981331 / 22981349 Email: <u>contacto@ipsa.gob.ni</u>

**Appendix II. Other Import Specialist Contacts:** FAS Managua agmanagua@fas.usda.gov