

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: 3/14/2014

GAIN Report Number:

Nicaragua

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

Approved By:

Prepared By:

Jimmy Bolaños

Report Highlights:

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

Section I. Food Laws:

As in most Central American Countries, Nicaragua's agricultural import regulations are shared between the Ministry of Agriculture and Forestry (MAGFOR) and the Ministry of Health (MINSA). MAGFOR is responsible for the inspection of agricultural products at the boarders and the registration of animal feeds, agrochemicals and seeds, while MINSA regulates processed food registration.

There are two basic laws that authorize these ministries to supervise food imports: Basic law of Animal and Plant Health (Law No. 291), whose main objective is to prevent the propagation of pests and diseases, and the General Health Law (Law No. 423), which covers all aspects related to human health, including food safety aspects of processed food imports. MAGFOR's General Division of Animal and Plant Health Protection (DGPSA) is the entity responsible of implementing law 291 while MINSA implements law 423.

Besides the main regulations mentioned above, there are series of mandatory and voluntary technical norms developed by the Ministry of Trade of Nicaragua (MIFIC) along with other Ministries and industries (also known as *Normas Tecnicas Obligatorias Nicaraguenses* (NTON) or *Normas Tecnicas Nicaragueneses*). These technical norms are developed by the Metrology Department of the Ministry of Trade of Nicaragua (MIFIC) according to the different demands from the industry that seek to improve productive processes, products and national services. A complete list of these <u>regulations</u> is available online.

Finally, at the regional level, Nicaragua is a member of 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.

Among the new Central American regulations that have been adopted by Nicaragua are the Technical Regulation on Food Additives (RTCA. 67.04.54:10), Technical Regulation on General Labeling of Prepackaged Food Products (RTCA 67.01.07.10), Technical Regulation on nutritional labeling of prepackaged food products for human consumption older than 3 years (RTCA 67.04.48:08), and Technical Regulation on registration requirements for fertilizers (RTCA 65: 05:54:09). More information about these regulations will be discussed below.

A key aspect to understand import logistics in Nicaragua is that that every importer must have an import permit from MAGFOR and MINSA prior to the importation of any shipment and the agricultural products imported (processed food, agrochemicals, seeds and feedstuff) must be registered at MINSA or MAGFOR. The import requirements are usually met by the importer. Therefore, a good communication between the exporter and importer is a key for success.

Another important point is that the process of registering a product in Nicaragua can take up to three months due to the limited capacity of the Ministries of Agriculture and Health. This is a limitation that inhibits the continuous imports of new products to the Nicaraguan market.

Some of the key points exporters should follow before exporting to Nicaragua are: 1) Make sure the food products are registered at the Ministry of Health or MAGFOR prior to the exportation, 2) have the

importer request a permit to MINSA or MAGFOR for the importation, and 3) make sure to present a copy of the commercial invoice, sanitary certificate and certificate of origin at the border. <u>Import requirements of animal and plant products and sub-products</u> are available online.

Section II. Labeling Requirements:

Nicaragua signed two Central American Technical Regulations: General Labeling of Prepackaged Food Products (RTCA 67. 01.07.10) and Nutritional Labeling of Prepackaged Food Products for Human Consumption for the Population Older than 3 Years (RTCA 67.04.48:08) that cover all aspects related to labeling requirements.

According to the Central American Technical Regulation on General Labeling of Prepackaged Food Products (RTCA 67.01.07.10), that entered into effect 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 below must appear on the product label in Spanish, except when indicated otherwise by a national standard or by the Codex Alimentarius. Stick-on labels are allowed.

- Product name.
- Net content and drained weight in international system units.
- Artificial color and flavors (if any).
- Ministry of Health registration number
- Ingredients listed in decreasing order, by weight.
- Importer's name and address.
- Lot number and expiration date.
- Country of origin.
- Preservation and use instructions.

Nicaragua, as part of the Central American Customs Union, also signed the Central American Technical Regulation on "Nutritional Labeling of Prepackaged Food Products for Human Consumption for the Population Older than 3 Years". This regulation will become operational in January 2014 and 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 the Central American Region. Please see samples below.

Sample of Current Labels:

Name of the Product	
Ingredients: xxxxxxxxxx	
XXXXXXXXXX XXXXXXXXXX	Use instructions:
XXXXXXXXXX XXXXXXXXXX	Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
XXXXXXXXXXX XXXXXXXXXX	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	xxxxxxxxxxxxxxxxx
Imported by: xxxxx Address: xx	xxx Sanitary Registry #: xxxxx Telephone: xxxxx
Country of Origin :xxxxx	•
Lot number and expiration date	9.

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 (KI)	
Total Fat (g)	
Saturated Fat (g)	
Carbohydrates (g)	
Sodium (mg)	
Total Protein (g)	

MINSA will be responsible for supervising and implement technical regulation RTCA 67.01.60:10. 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 additives through the Central American Technical Regulation, RTCA 67.04.54:10 on additives for food and beverage. 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 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. More information on this matter may be found here.

Section V. Pesticides and Other Contaminants:

Nicaragua has a basic law for Pesticides <u>and Agrochemicals (law 724)</u>. This law authorizes MAGFOR to regulate every aspect related to the trading and processing of pesticides and chemicals. Besides law 724, 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>

According to these laws:

- All importers of agrochemicals need to get a permit from the General Direction for Animal and Plant Health Protection (DGPSA) before selling any product.
- All Agrochemical products need to be registered at DGPSA prior to any importation.
- Exporters must have a legal representative in Nicaragua. This is because suppliers need to be registered at DGPSA.
- Have a permit of the warehouse or store where the agrochemicals are going to be stored.

To register a synthetic pesticide the importer needs to:

- Request the approval to import a sample for product registration purposes. This is done at DGPSA
- 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)
- The results from the different Ministries need to be published on the official gazette
- Submit labels and other information relevant to product description to DGPSA
- Importer gets product registration
- Importer pays a fee annually to revalidate the permit

The process of registering a product can take up to the three months and cost about U\$ 750. For specific information about each step see this link.

For microbiological pesticides, the importer needs to 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 RTCA 65.05.61:11.

Section VI. Other Regulations and Requirements:

For Genetically Engineered Crops (GE):

Nicaragua has a regulation for the prevention of risks arising from Living Modified Organisms through molecular biotechnology (<u>Law 705</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 rules for its implementation. At the moment, GM 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> about the requirements for the registration of fertilizers. This technical regulation will enter into effect in January 2014. The main objective of this regulation is to establish the list of requirements to register fertilizers.

Among the requirements to import fertilizer are:

- Importer must be registered at DGPSA prior to the importation
- The exporter must have a legal representative living in Nicaragua
- Fertilizers must be registered at DGPSA

The process of registering a fertilizer involves:

- Request product registration. Importers need to fill in format "Solicitud para Fertilizantes y Enmiendas".
- Present 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 certificate of origin and a letter from competent
 government authority explaining the reasons why the product has not been registered and
 confirming that the manufacturer is authorized to produce and trade fertilizers.
- Present 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 and solid mass and mass and volume for liquids.

- Present an original certificate of analysis of the fertilizer, provided by the manufacturer or formulator, indicating the nutrients and corresponding percentages mas/solid mass and wolume for liquids.
- Statement of the presence or absence of heavy metals (Cadmium, chromium, arsenic, mercury and lead) expressing the maximum concentration in parts per million (ppm)
- 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 present a product safety fact sheet.

Section VII. Other Specific Standards:

There are no other specific standards.

Section VIII. Copyright and/or Trademark Laws:

Several general principles are important for effective management of intellectual property rights in Nicaragua. First, it is important to have an overall strategy to protect intellectual property. Second, intellectual property is protected differently in Nicaragua than in the United States. Third, 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. No "international copyright" exists that will automatically protect an author's writings throughout the entire world. Protection against unauthorized use in a particular country depends, basically, on the national laws of that country. Most countries do, however, offer copyright protection to foreign works under certain conditions, and these conditions have been greatly simplified by international copyright treaties and conventions.

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 <u>local attorneys</u> 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 their self 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:

Process to Register Food Products at MINSA:

Processed food products are regulated by 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

competent government sanitary authorities. 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:

- Request for sanitary registry
- Updated copy of Nicaraguan sanitary registration
- Technical specifications of the product
- Certificate of free sale issued by a competent government authority
- Three samples of 500g from the same lot in its original package. For liquids three samples of one liter
- Cashier receipt for laboratory analysis
- Two labels of the product. If the label is not in Spanish an additional label with Spanish translation must be attached
- Cashier receipt for certification (500 Córdobas) approximately US \$24

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.

Process to register Agrochemicals at MAGFOR:

- Request the approval to import a sample for product registration purposes. This is done at DGPSA
- 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)
- The results from the different Ministries need to be published on the official gazette
- Submit labels and other information relevant to product description to DGPSA
- Importer gets product registration

• Importer pays a fee annually to revalidate the permit

For more information please refer to the Tramites Nicaragua website.

Plant Products and Sub-Products:

Plant Products and Sub-Products are regulated by the Plant Health Direction at DGPSA. This direction requires a SPS certificate, a certificate of chemical treatment (when applicable) to issue an import permit. Please refer to <u>technical norm 11 005-08</u> for additional information on import requirements applied to 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 General Direction for Animal and Plant Health Protection (DGPSA).
- Fill in "import request format" at DGPSA.
- Present a copy of the commercial invoice or letter of the donor in case it is a donation.
- Request the approval from the Department of seeds in case the imported products are seeds or vegetative materials.
- If it is a donation, request the approval of MAGFOR.
- Payment receipt from DGPSA once the import is authorized.
- MAGFOR reviews the applications and sends a letter stating either if it is approved or not. If it is not approved, MAGFOR should provide the technical reasons of their decision.

Veterinary products and animal feeds

- Exporter needs to have a legal representative in Nicaragua
- Importer needs to be registered at DGPSA
- Vet product or animal feed must be registered at DGPSA
- Fill in "import request format" at DGPSA. Attached to this request, the

Importer needs provide a copy of the commercial invoice, information of the supplier, certificate of origin and phyto-sanitary certificate.

• MAGFOR reviews the applications and sends a letter stating either that the request is approved or not. If it is not approved, MAGFOR should provide the technical reasons of their decision.

Animal Products and Sub-Products

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

Appendix I. Government Regulatory Agency Contacts:

Government Agencies:

Processed Food

Ricardo Orozco **Director of Food Department** Ministry of Health of Nicaragua Phone: 2289-4700 Ext. 1298 dra@minsa.gob.ni

Meyling Centeno Responsible of Product Registry Ministry of Health of Nicaragua Phone: 2289-4700 Ext. 1298

eta@minsa.gob.ni

MAGFOR's Quarantine Department

Reyna Martinez Quarantine Department, Animal Health Ministry of Agriculture and Forestry Phone: (505) 2278-0225 reyna.martinez@dgpsa.gob.ni

Marlene Vargas Quarantine Department, Plant Health marlene.vargas@dgpsa.gob.ni (505) 2278-4239

Seeds

Jorge Garcia Chief of the Seed Department Ministry of Agriculture and Forestry semillas@dgpsa.gob.ni

Phone: (505) 2772-0037

Agrochemicals

Rolando Garcia Chief of Product Registry/Agrochemicals Ministry of Agriculture and Forestry rgarcia@dgpsa.gob.ni

Phone: (505) 2278-3418 Ext. 151

Animals, Feed and Vet Products

Marvin Rodriguez Director Animal Health Department Ministry of Agriculture and Forestry Tel: (505) 2278 3417

devec@dgpsa.gob.ni

Appendix II. Other Import Specialist Contacts:

Jimmy Bolaños Agricultural Specialist U.S. Embassy, Managua, Nicaragua Carretera Sur, Km 5.5 Phone (505) 2252-7100 Ext.7621 jimmy.bolanos@fas.usda.gov

Claudia Giron Agricultural Assistant U.S Embassy, Managua, Nicaragua Carretera Sur, Km 5.5 Phone (505) 2252-7100 Ext. 7653 Claudia.giron@fas.usda.gov