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## **Dominican Republic**

### **Food and Agricultural Import Regulations and Standards - Narrative**

#### **FAIRS Country Report**

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**Report Highlights:**

This report summarizes the key technical and import requirements for food and agricultural products imposed by the Government of the Dominican Republic. Major changes include (1) the enforcement of the sanitary registration requirement for all food products produced domestically and imported, especially for dairy products and wine; (2) a requirement that labels for prepackaged foods be in the Spanish language and placed at origin; and (3) a Certificate of No Objection be issued by the Ministry of Health before alcoholic beverages can be imported into the Dominican Republic. The report describes the relevant policies and processes which U.S. exporters must navigate in order to successfully export their product to the Dominican Republic.

**Note:** This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service at the U.S. Embassy/Santo Domingo, Dominican Republic for exporters of U.S. agricultural products. While great care was taken in the preparation of this report, the information provided may not be completely accurate due to either changes in policies since its preparation, or because clear and consistent information about these policies was not available at the time of publication. It is highly recommended that U.S. exporters verify the relevant import requirements with their foreign customers, who normally have the most updated information on local requirements and can research such matters with local authorities, prior to exportation. **FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY’S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.**

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**Section I. General Food Laws**

In the Dominican Republic (DR), there are at least 19 food safety and sanitation standard regulations composed of laws, norms, and presidential decrees and documents. The key documents include two major laws, two Presidential Decrees, one regulation, and a Presidential Document, as follows:

- 1) General Law No. 358-02 dated September 9, 2005 for the Protection of Consumer or User Rights (ProConsumidor);
- 2) General Health Law No. 42-01 dated March 8, 2001;
- 3) Presidential Decree No. 1139 dated July 28, 1975 approving the DR Sanitary Regulation for Milk and Dairy Products;
- 4) General Regulation (Presidential Decree) No. 528-01 dated May 14, 2001 for Risk Control in Food and Beverages;
- 5) General Labeling Standard for Pre-packaged Products (RTD 53/NORDOM 53, 4<sup>th</sup> revision)

- dated November 27, 2014 (published in 2015);
- 6) Presidential Document dated July 12, 2016 on the enforcement of the Sanitary Registration and labeling requirement at origin (see a complete list in Attachment 1).

Additional information on each of these documents is provided below and in Attachment 1.

In addition to these documents, the importation and commercialization of foods, beverages and agricultural products and by-products is largely regulated by DR-CAFTA, the Codex Alimentarius (CODEX), and the World Trade Organization (WTO).

**DR-CAFTA.** The DR-CAFTA was duly ratified by the Dominican Congress via Resolution No. 375-05, dated September 6, 2005, and promulgated by the Dominican Executive Branch on September 9, 2005. In addition to its provisions, Law No. 424-06 was enacted to adapt Dominican Laws to the requirements already established by DR-CAFTA and ensure the application of the latter treaty in the country. Nevertheless, the agreement was effective in the DR on March 1, 2007.

**Codex Alimentarius (CODEX).** In order to implement the provisions contained in the Codex Alimentarius, the Dominican Executive Branch promulgated Presidential Decrees 170-01 and 1352-04, which respectively created and ratified the National Committee on the Codex Alimentarius ("*Comité Nacional del Codex Alimentarius (CONCA)*").

Article 127 of the Dominican General Health Law No. 42-01 establishes that production, manufacturing, storage, importation, commercialization, transportation, and manipulation are subject to the guidelines indicated in said law, the NORDOMS and the Codex Alimentarius.

Moreover, Article 24, paragraph II, of Presidential Decree 528-01 incorporates the Codex Alimentarius as part of the guidelines that pre-packaged foods and beverages need to follow to achieve regulatory compliance in the DR. The aforementioned article indicates, "*All foods covered by this Regulation and any other formulations and preparations that can be developed must comply with the food standards developed by the Codex Alimentarius, adopted or approved by its auxiliary technical committees thereof, and approved by the General Directorate of Standards and Quality Systems (DIGENOR) [today, INDOCAL]*".

**World Trade Organization (WTO).** The DR has been a member of the WTO since March 9, 1995 and a Member of GATT since May 19, 1950. The DR's membership in the WTO was duly approved by Dominican Congress through Resolution 2-95. Since then, the Dominican Republic has committed itself to comply with the standards and procedures that regulate multilateral commerce.

Furthermore, within the Framework of the 1994 GATT, the DR presented a Technical Rectification of List XXIII of Tariff Concessions for 8 agricultural products considered sensitive to the economy, adopted by Congress through Resolution 92-99.

## **Section II. Food Additive Regulations**

The Ministry of Health and Social Welfare (MOH) controls the health risks associated with the inappropriate use of additives or toxins, as well as the presence of disease-causing organisms. The MOH defines the procedure for the application, issuance, and renewal of the necessary approvals, as well as establishing the conditions for permit cancellation. The Presidential Decree No. 528-01 (Regulation 528-01) dated May 14, 2001 in its articles 1, 11, and 247 establishes the MOH's scope regarding additives. For example, it will control the health risks generated by the inadequate use of contaminating additives or toxins and by the presence of organisms that cause diseases (Art. 1), as well as additives to improve the color, aroma, and conservation of food (Art. 11). The total percentage of additives must be declared, as well as the use for those that are specifically required

(Art. 247). (See the MOH/DIGEMAPS contact information below in Appendix I).

Additionally, the General Labeling Standard for Pre-packaged Products (RTD 53/NORDOM 53, 4<sup>th</sup> revision) dated November 27, 2014 (published in 2015) specifies the following on Section 5.2.4 for processing aids and processing of food additives: Any food additive that, because it has been used in the raw materials or other food ingredients, and is transferred to this food in a significant quantity or quantity sufficient to perform a technological function, will be included in the list of ingredients. However, food additives transferred to food in quantities lower than those necessary to achieve a technological function and processing aids, shall be exempt from the declaration requirement in the list of ingredients. This exemption does not apply to the specifically required food additives and processing aids mentioned above.

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

Presidential Decree No. 244-10, dated April 27, 2010, establishes the Technical Regulations regarding the Maximum Residue Levels (MRLs) in the Dominican Republic. This regulation identifies the MRLs of pesticides and their metabolites for different fruits, vegetables and related crops for human and animal consumption. (See the MoAg contact information below in Appendix I).

#### **Irradiated Foods**

The specific regulation on irradiated foods is found in the General Labeling Standard for Pre-packaged Products (RTD 53/NORDOM 53, 4<sup>th</sup> revision) dated November 27, 2014 (published in 2015). Section 6.2 says that the label of any food that has been treated with ionizing radiation must carry a written statement indicating the treatment near the name of the food. The use of the international symbol indicative that the food has been irradiated is optional and should be placed near the name of the product. When an irradiated product is used as an ingredient in another food, this circumstance must be declared in the list of ingredients. Also, when a product consisting of a single ingredient is prepared with irradiated raw material, the product label must contain a statement indicating the treatment.

### **Section IV. Packaging and Container Requirements**

Packaging, as well as labeling, must comply with the format established in the norm General Labeling Standard for Pre-packaged Products (RTD 53/NORDOM 53, 4<sup>th</sup> revision) dated November 27, 2014 (published in 2015) regarding the Labeling for Pre-Packaged Foods.

Additionally, for products of plant origin, the General Requirements for Importation require that the ship's holds and/or vans/containers be clean and disinfected before placing the merchandise or shipment inside. The merchandise or shipment will also be subject to phytosanitary inspection upon arrival in the Dominican port. Also, some products or by-products will require phytosanitary treatment and must come free of pests and/or soil. Packages made of wood must comply with NIMF No. 15-Revision 2009. (Contact information for the National Committee for the Application of Sanitary and Phytosanitary Measures (CNMSF) is provided below in Appendix I).

Additionally, the Ministry of Public Health and Social Welfare (MOH), through the General Directorate of Drugs, Food and Sanitary Products (DIGEMAPS) has a form called "List of Requirements for No Objection of Importation of Raw Materials of Dairy Products" [DIGEMAPS-AL-LI-011, version 002, dated Mayo 19, 2017]. This form requests details about the type of import, whether it is containerized or loose cargo, and the number of containers. (Contact information for the MOH/DIGEMAPS is provided below in Appendix I).

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

Labeling must comply with the format established in the Norma Dominicana (NORDOM), General Labeling Standard for Pre-packaged Products (RTD 53/NORDOM 53, 4<sup>th</sup> revision), dated November 27, 2014 (published in 2015) regarding the Labeling for Pre-Packaged Foods.

Dominican legislation requires the following information on the product's packaging materials: *name of the product, list of ingredients; net weight; manufacturer's and importer's name and address; the importer's industrial registry number (granted by PROINDU.S.TRIA); marketing authorization number (granted by the Ministry of Public Health and Social Welfare); country of origin; batch identification number; manufacturing date; expiration date; instructions for conservation of the product; and instructions for use.* The text must be in the Spanish language and it must be legible and intelligible for consumers, in accordance with Article 38 of Law 358-05 for the Protection of Consumers and Users' Rights. No further specifications are set forth by law regarding text size.

For alcoholic beverages, an additional disclaimer must be included with the following warning: "*El consumo de alcohol perjudica la salud*" (the consumption of alcohol damages the user's health), according to General Health Law No. 42-01.

The U.S. exporter should forward a sample of the package to the importer to facilitate label development. For products whose label is not in the Spanish language, an adhesive sticker which contains all of the required information can be used on the original label. However, Presidential Document dated July 12, 2016 now requires that food products have a Sanitary Registration and are labeled at origin.

On October 3, 2017, the MOH notified the WTO TBT Committee (G/TBT/N/DOM/224) the new Food Health Regulations (Reglamento Sanitario de Alimentos), which establishes the objectives, scope, general requirements and principles of food hygiene, food health authorizations, sanitary registration, cancellation of registration, health certifications, food importation, exportation and donation, sale of street foods, packaging and labeling, advertising, enrichment, fortification and food property claims, food supplements, food classification, food preservation, monitoring, alerts, traceability, violations, and penalties.

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

All required standards are covered in the General Regulation (Presidential Decree) No. 528-01 dated May 14, 2001 for Risk Control in Food and Beverages. This is going to be replaced by the new Food Health Regulations (Reglamento Sanitario de Alimentos) submitted to the WTO TBT Committee on October 3, 2017 (G/TBT/N/DOM/224 dated October 3, 2017), as well as in the General Labeling Standard for Pre-packaged Products (RTD 53/NORDOM 53, 4<sup>th</sup> revision) dated November 27, 2014 (published in 2015).

## **Section VII. Facility and Product Registration Requirements**

It is recommended that U.S. exporters develop direct dialogue with potential Dominican importers for several reasons: (i) they will be best equipped to discuss key topics such as product feasibility in the market, prices and distribution; (ii) regarding marketing authorization approvals, Dominican law provides that the product label must contain the name and address of the local importer who is responsible, along with the manufacturer, for the quality and purity of the product in question to the local authorities; (iii) the Phytosanitary and Zoo-sanitary Guidance Letters and permits must also contain the name and address of the local importer; and (iv) in order to benefit from tariff quota allocations, these can only be requested by an individual or legal entity residing in the Dominican Republic (local importer).

Nonetheless, a U.S. exporter can also establish a branch in the Dominican Republic or incorporate a Dominican company and directly import the goods. Once this process has been carried out, the U.S. exporter can obtain the corresponding marketing authorization approval, the Phytosanitary or Zoo-sanitary Guidance Letters, and permits.

The import process into the Dominican Republic may be divided into three major phases: **Pre-export, Pre-arrival** and **Import Clearance**, depending on the product category. To fulfill the local requirements, the importer must work alongside the exporter, particularly in the initial phase, when the documents for shipment are prepared. Most companies use registered customs agents, upon arrival of the goods (third phase), to comply with clearance formalities, although this may also be done directly by the importer.

<b>PRE-EXPORT</b>
Trademark Registration Certificate, granted by the National Office of Industrial Property of the Dominican Republic (ONAPI), when applicable
Technical Form (only applicable for first imports, when same supplier is used by the local distributor)
Marketing Authorization Approval/ Phytosanitary or Zoo-sanitary Guidance Letters and Permits
Certificate of Origin
Product Labeling in compliance with NORDOM 53
Pro-forma invoice
Appointing Customs Agents
<b>PRE-ARRIVAL</b>
Bill of Lading or Airway Bill
Import Declaration
<b>IMPORT CLEARANCE</b>
Payment of Import Taxes
Inspection request to the quarantine office at the port of entry
Quarantine controls (when applicable)
Submission of copy of the Marketing Authorization Approval/ original Phytosanitary or Zoo-sanitary Guidance Letter
Submission of Phytosanitary or Zoo-sanitary permit issued by the Department of Agriculture and Livestock Promotion
Submission of the original invoice
Customs' Valuation
Product release

Governed by: Articles 2 and 16 of Law No. 4990 regarding Plant Protection, and Article 1 of

**Import Procedure Phases**

***Prior to Shipment (Pre-Export)***

**Process for obtaining a trademark registration before the National Office of Industrial Property (ONAPI). (See Section X. Copyright and/or Trademark Laws for detailed information).**

Process for obtaining Marketing Authorization Approval before the Ministry of Public Health and Social Welfare:

The marketing authorization application must contain the following information and be accompanied by a set of documents:

- (i) Application- one original version and one hard copy of the letter addressed to the Minister of Health and Social Welfare, requesting the marketing authorization approval of the product and indicating the following information: *name and address of the applicant; name of the product; type of product and trademark; name or company name of the manufacturer; location and address of the manufacturer; qualitative and quantitative product formulas; list of ingredients; description of the product's manufacturing process; and characteristics of the product's container or package.*
- (ii) Accompanied by- three original samples of the product, in the same presentation (package or container) in which it will be sold in the market (in case of liquids, each sample must contain a minimum of 250 milliliters; in case of solids, each sample must contain a minimum of 250 grams); copy of the trademark registration certificate granted by the National Office of Industrial Property; copy of the importer's Industrial Registry Certificate granted by the Development Center and Industrial Competitiveness (PROINDU.S.TRIA); Free-Sale Certificate issued by the exporting country, duly legalized under the Hague Convention ("Apostille"); copy of the importer's Mercantile Registry Certificate; copy of the importer's sanitary license (granted by the Ministry of Public Health and Social Welfare); and, authorization granted in favor of the legal representative of the product in the country, duly legalized under the Hague Convention ("Apostille").
- (iii) Other- Labeling must comply with the format established in the norm NORDOM 53 (3<sup>rd</sup> Revision), regarding the Labeling for Pre-Packaged Foods.

**Note:** Beginning to be implemented by January 1, 2017 but delayed starting for April 1, 2017, all food products produced domestically and imported must have the current sanitary registration as well as the inclusion of a product label in the Spanish language that must be placed at origin. Enforcement of the regulation for pre-packaged foods will initially focus on dairy products and wine, but the Dominican Government has indicated it will later extend enforcement to other products.

- (iv) Registration Process: The application process begins with the filing of the application. Afterwards, the samples provided along with the application are sent by the Ministry of Public Health and Social Welfare to the National Laboratory "Dr. Defilló" or to another authorized laboratory by the Ministry, to run a health analysis on the product. Once the analysis and the application are approved, the Ministry issues a Marketing Authorization Certificate with a registration number. The authorization must be renewed every five (5) years, and can be done for indefinite periods.

Generally, this application is carried out by the legal representative/local distributor of the product in the country, but can also be done by the manufacturer. Note that for such purposes, the foreign

manufacturer has to appoint a local distributor before the application is submitted to the MOH, as explained below.

- (i) Timeframe: The process for obtaining marketing authorization approval may take approximately three (3) months (in general terms, given that there is no timeframe established by law).
- (ii) Fees: The official fees involved in obtaining a marketing authorization approval amount to a total of **RD\$4,000.00 Dominican Pesos**, roughly equivalent to \$83.00. This payment must be separate from others. A certified check must be made in the name of "Dirección General de Salud Ambiental" for a sum of **RD\$1,600.00 Dominican Pesos**, roughly equivalent to \$33.00. Finally, another certified check must be made in the name of "Ministerio de Salud Pública y Asistencia Social" for the sum of **RD\$2,400.00 Dominican Pesos**, roughly equivalent to \$50.00. These expenses do not include attorney's fees.

**Note:** All ingredients contained in pre-packaged food and beverage items should meet the requirements specified in Presidential Decree (or Regulation) No. 528-01, regarding the Rules for the Control of Risks in Food and Beverages.

### **Tariff Quotas and Concessions Processes in the Dominican Republic**

Currently, they are two different and separate processes to request tariff quotas in the Dominican Republic: (i) allocation of Tariff Quotas granted to the United States of America, under DR-CAFTA; and (ii) Tariff Quota Allocations process for products listed in the Technical Rectification of List XXIII made by the Dominican Republic before the World Trade Organization (WTO) (regulated agricultural products).

#### Tariff Quota Allocations under DR-CAFTA

Any individual or legal entity, residing in the DR, may request the allocation of tariff quotas, with the exception of industry associations or nongovernmental organizations, of the tariff concessions granted to the United States.

- (i) Tariff Quota Application: Interested parties must submit a written application to the Office of Agricultural Trade Agreements ("OTCA") of the Ministry of Agriculture, to participate in the allocation process of tariff quotas. The OTCA is responsible for the administration of tariff quotas under the DR-CAFTA.

Completion of the DR-CAFTA Tariff Quota Allocation Application Form is required along with the following documents:

- In case of Individuals: *copy of identification card; copy of the National Taxpayer Registry as an individual; description of individual's economic activity; certification issued by the General Director of Customs, which guarantees the import history of the goods requested; information on physical infrastructure (i.e., copy of deed or lease, including additional photos of physical space); current safety certificate or health permit, issued by the General Directorate of Drugs, Foods and Sanitary Products (DIGEMAPS) of the Ministry of Public Health and Social Welfare, certifying the safety conditions for handling the goods requested; and, designated address, phone, mobile and fax for notifications.*
- In case of Legal Entities: *copy of national taxpayer registry; copy of the Mercantile Registry Certificate issued by the competent Chamber of Commerce and Production; certification issued by the General Director of Customs, guaranteeing the import history of the goods requested; copy of the last General Assembly of Shareholders, duly registered by the competent Chamber of Commerce and Production; designation of the representative of the company as its legal representative, duly notarized and legalized by the Attorney General of the Dominican Republic; copy of the identity card of the legal*

*representative of the company; information on infrastructure, (i.e., copy of deed or lease, including additional photos of physical space); current safety certificate or health permit, issued by the General Directorate of Drugs, Foods and Sanitary Products (DIGEMAPS), of the Ministry of Public Health and Social Welfare), certifying the safety conditions for handling the goods requested; and, designated address, phone, mobile and fax for notifications.*

**(ii) Allocation Process:** The Commission (composed by the Minister of Agriculture, the Minister of Industry and Commerce, and the General Director of Customs) publishes a tariff rate quota announcement in at least one national newspaper and on the websites of the Ministry of Agriculture ([www.agricultura.gob.do](http://www.agricultura.gob.do)) and the Office of Agricultural Trade Agreements ([www.otcasea.gob.do](http://www.otcasea.gob.do)) for the next calendar year, no later than October 1 of each year. The deadline for submitting Tariff Quota applications is 15 business days after the tariff rate quota announcement.

The allocation of the volumes of tariff quotas is based on: historical record of the total imports of agricultural goods carried out by the interested party during the past three consecutive calendar years, preceding the calendar year in which the tariff quota is available; the quantities requested by the interested parties, provided they are commercially viable; and, the quantities available for traditional Importers and new importers, in the corresponding calendar year. The tariff quotas shall be allocated as follows: (a) 80 percent to traditional importers and (b) 20 percent to new importers.

The allocation shall be granted and published in a national newspaper by the Commission by January 1 of each year. The importer must then obtain a Phytosanitary Guidance Letter (prepared by the Department of Plant Protection) or a Zoo-sanitary Guidance Letter (prepared by the Department of Animal Health of the General Directorate of Livestock). The corresponding Guidance Letter is then delivered to the Department of Agriculture and Livestock Promotion along with the commercial or pro forma invoice for issuance of the permit.

**Tariff Quota Allocations process for regulated agricultural products and by-products of plant and animal origin, protected by the Technical Rectification of List XXIII made by the Dominican Republic before the World Trade Organization.**

Under the provisions of Article XXVIII of the General Agreement on Tariffs and Trade (GATT) of 1994, the Dominican Republic made a Technical Rectification of its List XXIII of Tariff Concessions for eight (8) agricultural products. In particular: garlic, rice, sugar, chicken meat, onions, beans, powdered milk, and corn.

Below, the Assigned Quotas to the Products of the Technical Rectification, as established in Presidential Decree No. 569-12:

<b>Products of the Technical Rectification</b>				
<b>Products</b>	<b>Headings and Subheadings</b>	<b>Volume (Metric Tons)</b>	<b>Basic Tariff %</b>	<b>Non-Quota Tariff %</b>
Rice	10.06	17,810	20	99
Garlic	0703.20	4,500	25	99
Sugar: Refined /	17.01	30,000	20 / 14	85

Brown				
Chicken Meat	0207.10, 0207.21 and 0207.41	11,500	25	99
Onion	0703.10	3,750	25	97
Beans	0713.31, 0713.32 and 0713.33	18,000	25	89
Milk	0402.10, 0402.21 and 0402.29	32,000	20	56
Corn	10.05	1,091,000	Does Not Apply	Does Not Apply

The Commission for Agricultural Imports publishes an Annual Calendar for the Import of Tariff Quotas for the above products. These products are placed for public auction organized by the Exchange Agribusiness of the Dominican Republic (BARD, per its Spanish acronym). The Commission and the BARD publish, in a national newspaper, the calendar for the import of the tariff quotas and organize the public auction on the set date. After those products have been awarded, the BARD issues an auction certification to be used before the General Directorate of Customs, for the import clearance. In accordance with Article 6, Paragraph VII, of Presidential Decree 505-99 (modified by Presidential Decree 569-12), additional quantities can be placed for auction in a calendar year.

Likewise, after the tariff quotas have been assigned, the importer must obtain a Phytosanitary Guidance Letter, prepared by the Department of Plant Protection or a Zoo-sanitary Guidance Letter, prepared by the Department of Animal Health of the General Directorate of Livestock. This process is done through inter-agency cooperation. In other words, the importer does not have to go through the process of obtaining the Phytosanitary nor the Zoo-sanitary Guidance Letters. The Guidance Letters are then delivered to the Department of Agriculture and Livestock Promotion along with the commercial or pro forma invoice, for issuance of the authorization. Depending on the product and if it is pre-packaged, when applicable, the importer must obtain a marketing authorization approval.

**Process for obtaining Phytosanitary and Zoo-sanitary Guidance Letters before the Ministry of Agriculture:**

**Fresh Fruits and Vegetables/Processed Vegetables/Tree Nuts**

- (i) Application: The application is made through a form ("Formulario de Solicitud Guía de No Objeción Fitosanitaria"), which must be completed and filed before the Department of Plant Protection, with the following information: name of the importer; address; telephone and fax numbers; goods to be imported; quantity; unit of measurement; port of origin; port of departure; port of entry; use; and transportation. In addition, a written request must be addressed to the Division of Plant Quarantine accompanied by the invoice or pro-forma invoice, certificate of origin, and Phytosanitary or Zoo-sanitary Certificate issued by the exporting country.
- (ii) Fees: The fees involved in obtaining a Guidance Letter from the Department of Plant Health (Phytosanitary Guidance Letter) are **RD\$200.00 Dominican Pesos**, roughly equivalent to \$4.00. After this phase is completed, the Department of Promotion for Agriculture and Livestock will then issue the Phytosanitary permit for a cost of **RD\$2,000.00 Dominican Pesos**, roughly equivalent to \$41.00.

**For Animals products and by-products**

- (i) Application is made through a written letter (one original and three hard copies) filed before the General Directorate of Livestock, indicating the following information: name of the importer; address; telephone and fax numbers; goods to be imported; quantity; unit of

measurement; country of origin and country of export, port of origin; port of departure; port of entry; use; transportation; value of the goods, and animal species from which the product is made. This application must be accompanied by the commercial invoice or pro forma invoice.

- (ii) Once the shipment arrives to the Dominican Republic, it shall be accompanied by the original International Sanitary Certificate (in Spanish) and the original Certificate of Origin.
- (iii) Accompanied by: The U.S. exporter must work with the local importer in order to obtain the Phytosanitary and Zoo-sanitary Guidance Letters and Permits, since the application must be accompanied by copies of the following documents: invoice or pro forma invoice, certificate of origin, and Phytosanitary or Zoo-sanitary certificate issued by the exporting country.
- (iv) Registration Process: Prior to loading any shipment, the local importer must request in writing, a permit for the importation of the goods. If there are Phytosanitary or Zoo-sanitary requirements, a Phytosanitary or Zoo-sanitary Guidance Letter is issued with the requirements for importation by the Department of Plant Protection or the General Directorate of Livestock, respectively. (If there are no requirements, the request is sent to the Unit of Pest Risk Analysis. The Unit of Pest Risk Analysis will issue its recommendation. After the Guidance Letter is issued, the Department of Agricultural and Livestock Promotion will issue the permit).
- (v) Timeframe: The Phytosanitary and Zoo-sanitary Guidance Letters may take up to two to three days, so long as only negligible risk is involved in the importation of the goods in question. The permit issued by the Department of Agricultural and Livestock Promotion may take an additional two to three days as well.
- (vi) Fees: The fees involved in obtaining a Guidance Letter from the Department of Animal Health (Zoo-sanitary Guidance Letter) amount to **RD\$2,000.00 Dominican Pesos**, roughly equivalent to \$41.00. After this phase is completed, the Department of Promotion for Agriculture and Livestock will then issue the Zoo-sanitary permit for a cost of **RD\$3,000.00 Dominican Pesos**, roughly equivalent to \$62.00, for poultry products, and **RD\$5,000.00 Dominican Pesos**, roughly equivalent to \$103.00, for pork products.

### **Labeling (See Section V. Labeling Requirements for detailed information)**

#### **Invoice or Pro Forma Invoice**

Before shipment, an invoice or pro forma invoice must be sent to the Dominican importer since this document is used for obtaining the Guidance Letters and permits from the Ministry of Agriculture and initiates the import clearance process. Upon arrival of the goods, the importer must have received the original invoice since it will be used to clear the goods and for payment of tariffs, duties, and taxes.

#### **Appointing Customs Agents**

Most companies use authorized customs agents for handling the import clearance, although the importer can carry it out directly. The customs agent is responsible along with the consignee for managing the way in which the import procedures are carried out. The customs agent must be licensed to operate as such by the Ministry of Finance and endorsed by the General Directorate of Customs.

#### ***During Shipment (Pre-Arrival)***

##### **Shipping Instructions**

Shipping instructions advise all the details of the cargo and exporter's requirements for its physical movement. It contains the information related to the sale and the merchandise's conditions upon embarkation, such as the quantity of product, form of payment, transport temperature, packaging, and pallet used.

In the DR, depending on the product in question, several conditions must be met:

- The ship's containers must be cleaned and disinfected before placing the products for

shipping.

- Imported fruits and vegetables must be free of plague or symptoms of diseases, and must not have soil, sawdust or foreign matter, with the exception of mosses previously disinfected, for its packaging.
- All wood packaging must comply with the International Standard for Phytosanitary Measures (ISPM) No. 15, to reduce the risk of introduction and spread of forest pests and diseases.
- Fruits and vegetables should not be packaged or covered in jute bags.
- Fresh fruits must arrive in refrigerated containers, with temperatures between 0°C (32°F) and 2.20°C (36°F) per Resolution 84/96 of the Ministry of Agriculture.

### **Import Declaration**

The importer must prepare the Import Declaration through the Automated System for Customs Management (SIGA, per its Spanish acronym). Nonetheless, only companies can present the Import Declaration through the SIGA. Individuals must file directly before the General Directorate of Customs.

The process for importation is initiated when the shipping company presents the import cargo manifest. The Import Declaration is presented electronically through the SIGA and the following information must be provided: *goods to be imported, quantity, description, value, tariff code, weight, and must contain attached scanned copies of the documents related to the importation.*

The following documentation must be scanned and uploaded to the SIGA: commercial invoice, bill of lading or airway bill, marketing authorization certificate, Phytosanitary or Zoo-sanitary Guidance Letters and permits, certificate of origin, custom agent's ID card, auction certificate issued by the BARD (for products included in the Technical Rectification), among other documents. The governmental authority reserves the right to require additional documentation. These will be required in original upon arrival of the goods along with the bill of lading or the airway bill.

To declare the goods through SIGA, the Single Customs Declaration Form (DUA, per its Spanish acronym) must be completed. Both the importer and the customs agent have the authorization in a Token previously supplied by the General Directorate of Customs (DGA, per its Spanish acronym). The Token is an electronic device able to access the DGA's database for the details related to the import declaration in question.

Importers have ten days, counting from the date of arrival of the goods to present the Import Declaration. Failure to do so will result in sanctions for late declaration.

### **Product Arrival (Import Clearance)**

After the import declaration process has been carried out, the consignee can request the physical inspection, under the governmental authority's discretion, of the goods through the SIGA. This is done along with the customs inspectors and the supplementary control staff, which may include personnel from the Ministry of Agriculture, through the Divisions of Plant and Animal Protection, and the Ministry of Public Health and Social Welfare, among other competent authorities.

Depending on the products in question, an inspection is made by the inspector of the quarantine office of the port of entry whom will verify the documentation and perform a physical inspection of the shipment in order to search for possible plagues and to take samples for its remittance to the diagnostics laboratory. (If the pest is common, the goods could be released with a treatment, depending on the level of infestation. If the pest is of quarantine concern, the goods may be returned to its place of origin, confiscated or incinerated.)

Once the physical inspection has been verified with the declaration and the original documents

(which had been previously scanned), the file is revised by the Technical Department for verification of the tariff codes, value, commercial agreement, technical rectification, safeguard measurements, and tariff quota allocations, among others. Once the file has been approved and closed, payment can be made and the goods may be cleared.

In September 2017, the Ministry of Agriculture started to implement the Customs Authority's electronic system, One Stop Shop of External Trade (or VUCE in Spanish) to digitize their agricultural imports authorizations process. The system is currently being used for a handful of commodities, including apples, grapes, citrus, vegetables, and meats. Once fully implemented, the system is expected to increase transparency for traders, who will be able to view the status of their approvals and reasons for any rejections.

### **Payment of Import Duties and Taxes of Goods**

The GATT Agreement, 1994, mandates that the customs value must be based as far as possible in the price actually paid or payable, generally indicated in the commercial invoice for the goods being valued. This price is called transaction value and is the primary basis for determining the customs value. If this did not exist, or if the price paid or payable could not be accepted as the basis for valuation, this Agreement provides five other procedures on the faculty of the importer to request reversal of the application of the method for valuation.

To liquidate the goods, it is necessary to take into account several aspects:

- The proper tariff code must be assigned.
- According to the Tax Code of Dominican Republic, Law No. 146-00 and its amendments, the calculation of tax settlement is obtained by subtracting the tariff quota percentage from the CIF value, this amount is called Tariff; afterwards, both quantities (CIF + Tariff) are added, the 18 percent ITBIS tax is applied to its sum. The ITBIS is also collected by Customs for encumbered goods.
- In addition, Selective Tax on Consumption may be applied to certain products, such as alcohol.

Payment can be made physically through a certified check or administration check. Payment of duties and taxes must be made out to "Colector de Aduanas" and tariffs for customs services must be made out to "Dirección General de Aduanas." All payments can be paid in any of the local customs offices. However, the person carrying out the payment must be certified as such by the importer.

Payment can also be made electronically, through the e-banking pages of the following local banks: Banco Popular Dominicano, Citibank, BHD-León and Nova Scotia (Scotiabank). An access pin, administered by the commercial bank, must be obtained.

In case of disputes, parties may refer themselves to the administrative tribunals of the DR, may recur to arbitration, or may appeal to the Dispute Settlement Body of the WTO.

### **Standard Documents**

On average, U.S. Exporters and local importers will deal with 16 different documents generated during the import process.

1. Trademark Certificate;
2. Free-Sale Certificate;
3. Manufacturing process diagram;
4. Qualitative and quantitative formulas;
5. Authorizations granted to the local importer or third parties;

6. Product Label;
7. Certificate of Origin;
8. International Health Certificate;
9. Phytosanitary or Zoo-sanitary Certificate issued by the exporting country;
10. Phytosanitary or Zoo-sanitary Guidance Letters issued by the Ministry of Agriculture;
11. Phytosanitary or Zoo-sanitary Permits issued by the Ministry of Agriculture;
12. Commercial Invoice or Pro Forma;
13. Import Declaration;
14. Bill of Lading or Airway Bill;
15. Marketing Authorization Approval\*; and
16. Petition for sanitary inspection (for quarantine purposes) and clearance;

\* **Note:** Beginning to be implemented by January 1, 2017 but delayed starting for April 1, 2017 all food products produced domestically and imported must have the current sanitary registration (or Marketing Authorization Approval) as well as the inclusion of a product label in the Spanish language that must be placed at origin. Additionally, on July 11, 2017 the Ministry of Public Health and Social Welfare (MSP) instructed the General Customs Director (DGA) to require a Certificate of No Objection to import alcoholic beverages into the DR. Enforcement of the regulation for pre-packaged foods will initially focus on dairy products and wine, but the Dominican Government has indicated it will later extend enforcement to other products.

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

All required certifications and testing requirements are covered in the General Regulation (Presidential Decree) No. 528-01 dated May 14, 2001 for Risk Control in Food and Beverages. This is going to be replaced by the new Food Health Regulations (Reglamento Sanitario de Alimentos) submitted to the WTO TBT Committee on October 3, 2017 (G/TBT/N/DOM/224 dated October 3, 2017), as well as in the General Labeling Standard for Pre-packaged Products (RTD 53/NORDOM 53, 4<sup>th</sup> revision) dated November 27, 2014 (published in 2015).

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

As a first step, U.S. exporters must determine what type of import license is required for the product in question in order to ensure its access into the Dominican market. In the DR, there are two ministries in charge of regulate the importation of all foods and pre-packaged products into the country: a) Ministry of Agriculture (MoAg); and b) Ministry of Public Health and Social Welfare (MOH) through the General Directorate of Drugs, Food and Sanitary Products (DIGEMAPS).

#### **Marketing Authorization Approval**

The Marketing Authorization Approval or health permit (identified in Spanish as "*registro sanitario*") is a permit issued by the **Ministry of Public Health and Social Welfare** (MOH), through the General Directorate of Drugs, Food and Sanitary Products (DIGEMAPS), for all imported pre-packaged food and beverage products. It serves as a mechanism for the government authorities to guarantee that pre-packaged products and by-products manufactured in or imported to the DR meet the minimum sanitary standards and are safe for human consumption, in accordance to Dominican the General Health Law, No. 42-01 (Articles 109 and 129), Presidential Decree No. 528-01 (Articles 5, 6, 7, 8 and 367) and NORDOM 53.

The MOH also controls the health risks associated with the inappropriate use of additives or toxins, as well as the presence of disease-causing organisms and defines the procedure for the application, issuance, and renewal of marketing authorization approvals. As well, it establishes the conditions for permit cancellation.

The following pre-packaged products require marketing authorization approval in the Dominican Republic: “cheese, yogurt, breakfast cereal, tree nuts, wine and beer, prepared foods, condiments, sauces, and snack foods”.

### **Phytosanitary and Zoo-sanitary Permits**

Oversight of fresh fruits and vegetables, processed vegetables, animal products and by-products, tree nuts, and dairy products is primarily the responsibility of the **Ministry of Agriculture (MoAg)**, through the Department of Plant Protection, the Department of Animal Health of the General Directorate of Livestock, and the Department of Agricultural and Livestock Promotion.

This government body supervises the health risks associated to the diseases of plants and animals as well as their products and by-products. It is also entitled to grant the corresponding permits for the import of certain goods.

“Fresh fruits and vegetables, processed vegetables, and tree nuts”, require a Phytosanitary Guidance Letter, whereas “poultry, pork, and dairy products” require a Zoo-sanitary Guidance Letter. There is not a specific document listing which products need to comply with these requirements. Current regulation provides that all products with vegetable, animal and agricultural origins must have these permits to be legally imported and distributed in the Dominican Republic. Depending on the type of product, either the Department of Plant Protection or the Department of Animal Health of the General Directorate of Livestock will issue a Guidance Letter to the importer with the requirements for the importation. After the Guidance Letter is issued, the Department of Agricultural and Livestock Promotion will issue the permit.

It is recommended that U.S. exporters develop direct dialogue with potential Dominican importers for several reasons: (i) they will be best equipped to discuss key topics such as product feasibility in the market, prices and distribution; (ii) regarding marketing authorization approvals, Dominican law provides that the product label must contain the name and address of the local importer who is responsible, along with the manufacturer, for the quality and purity of the product in question to the local authorities; (iii) the Phytosanitary and Zoo-sanitary Guidance Letters and permits must contain as well, the name and address of the local importer; and (iv) in order to benefit from tariff quota allocations, these can only be requested by an individual or legal entity residing in the Dominican Republic (local importer).

Nonetheless, a U.S. exporter can also establish a branch in the DR or incorporate a Dominican company and directly import the goods. Once this process has been carried out, the U.S. exporter can obtain the corresponding marketing authorization approval, the Phytosanitary or Zoo-sanitary Guidance Letters, and permits.

## **Section X. Copyright and/or Trademark Laws**

### **Process for obtaining a trademark registration before the National Office of Industrial Property (ONAPI)**

The trademark application must contain the following information and be accompanied by a set of documents:

- (iii) Application: one (1) original version and one (1) hard copy of the letter addressed to the Director of the Department of Distinctive Signs, requesting the registration of the trademark in question and indicating the following information: *applicant's name and address; mercantile registry number and national taxpayer number (in case of a Dominican applicant); goods and/or services to be protected pursuant to the International Nice Classification of Goods and Services; and printed versions of the trademark's design (when applicable).*

- (iv) **Registration Process:** The application process begins with the filing of the trademark application. If the mark is approved in the substantive evaluation stage by the National Office of Industrial Property (ONAPI, per its Spanish acronym), publication fees must be paid. Afterwards, the trademark is published in the Official Gazette of the ONAPI. As from this date, third parties have a 45-day period in order to file for opposition against the application (since the Dominican Republic complies with the pre-grant opposition system). If no third party contests the application within this period, the registration certificate is issued which is renewable every ten years. This process is generally carried out by the holder of the trademark or by the distributor if the latter has a Power of Attorney for these matters.
- (v) **Timeframe:** The trademark registration process takes approximately three to four months.
- (vi) **Fees:** The official fees involved in obtaining a trademark registration will depend if the trademark in question is a word or design application and on the amount of classes that may be requested. A word application under one international class amounts to **RD\$5,735.00 Dominican Pesos**, roughly equivalent to \$120.00. These expenses do not include attorney's fees.

## APPENDIX I

### Government Regulatory Key Agency Contacts

#### 1. **Ministry of Agriculture**

- a) Importation of Products & By-products of Vegetable Origin

<http://www.agricultura.gob.do/index.php/servicios/item/392-informacion-sobre-procedimientos-para-la-importacion-de-productos-y-subproductos-de-origen-vegetal>

Contact Information:

Plant Health Department Services (Sanidad Vegetal)  
Tel.: 809-547-3888 Ext. 4101; Email: [servicios@agricultura.gob.do](mailto:servicios@agricultura.gob.do)  
Address: Km. 6 1/2 Autopista Duarte, Los Jardines del Norte, Santo Domingo, D.N., República Dominicana.

- b) Process to Import Vegetable Products; Vegetable Quarantine; General Requirements for the Importation of Vegetable Origin Products/National Committee for the Application of Sanitary and Phytosanitary Measures (CNMSF)

<http://www.cnmsf.gob.do/Generalidades/CuarentenaVegetal/tabid/145/Default.aspx>

Contact Information:

CNMSF  
Address: Km 6 ½, Autopista Duarte, Urb. Jardines del Norte, P.O. Box: CP 10602. Santo Domingo, Distrito Nacional. Tel: (809) 227-6188 / (809) 227-3164.  
Email: [rd.cnmsf.snni@gmail.com](mailto:rd.cnmsf.snni@gmail.com)

- c) Sanitary Requirements for the entry of Pets to the Dominican Republic; Registration of Products and Veterinary Establishments /General Directorate of Livestock (DIGEGA)

<http://www.ganaderia.gob.do/index.php/servicios/dir-sanidad-animal/requisitos-para-ingreso-de-mascotas-a-rd>

Contact Information:

*Address: Autopista 30 de Mayo, Ciudad Ganadera, Santo Domingo,  
D.N. Teléfono: 809-535-9689; Email: [digeqa@ganaderia.gob.do](mailto:digeqa@ganaderia.gob.do)  
Service Hours: Lunes a Viernes de 8:00 a.m. - 3:00 p.m.*

- d)** Certificates of No Objection for Import of Fishery Products/Dominican Council for Fisheries and Aquaculture (CODOPESCA)

<http://www.codopesca.gob.do/2013-05-18-04-20-9/certificados-de-no-objecion-para-importacion-de-productos-pesqueros>

Contact Information:

CODOPESCA - Consejo Dominicano de Pesca y Acuicultura

*Address: Autopista Duarte, km. 6 1/2, Edif. Agricultura, Jardines del Norte, Santo Domingo República Dominicana. Tel: 809-547-3888; Fax: 809-547-3284; Web page: <http://www.codopesca.gob.do>*

## **2. Ministry of Health**

- a)** Food Health Regulations/Ministry of Public Health; Sanitary Registration Notification Procedure and Automatic Renewal; Simplified Sanitary Registration of Food and Beverages; Free Sale Certificate; Registered Products Certification; Sanitary Registration of Imported Pre-packaged Dairy Products Renewal/General Directorate of Medicines, Food and Health Products (DIGEMAPS)

<http://www.sespas.gov.do/ventanilla>

Contact Information:

Ministerio de Salud Pública y Asistencia Social

Av. Dr. Héctor Homero Hernández esq. Av. Tiradentes, Ensanche La Fe; Santo Domingo, D.N. 10514

Tel: 809-541-3121; Email: [infoministeriodesalud@gob.do](mailto:infoministeriodesalud@gob.do)

## **3. Ministry of Industry and Commerce and Mypimes**

Contact Information

- a)** 7mo. Piso, Edificio de Oficinas Gubernamentales Juan Pablo Duarte (Edificio JPD)

Av. México Esq. Leopoldo Navarro, Gascue

Santo Domingo, D.N., República Dominicana

Apartado Postal: 9876

Teléfono: (809) 685-5171 Ext.: 642 / Fax: (809) 686-1973

[info@mic.gob.do](mailto:info@mic.gob.do)

- b)** Av. 27 de Febrero Núm. 209, Ensanche Naco

Santo Domingo, D.N., República Dominicana

Apartado Postal: 10121

Teléfono: (809) 567-7192 / Fax: (809) 381-8076

<https://www.mic.gob.do/>

## **4. National Institute for the Protection of Consumer Rights (PRO CONSUMIDOR)**

Contact Information

Av. Charles Sumner #33, Los Prados

Santo Domingo, D.N., República Dominicana

Tel.:809-472-2731

[info@proconsumidor.gob.do](mailto:info@proconsumidor.gob.do); <http://proconsumidor.gob.do/>

## APPENDIX II

### Other Import Specialist Technical Contacts

#### World Trade Organization (WTO) Enquiry Points

Each member government is responsible for the notification procedures associated with agreements under the WTO. Issues in this report relate to the Sanitary, Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements. WTO obligations include notifying to the WTO any significant trade-related proposals that are not substantially the same as international standards, providing copies of the proposed regulation upon request, allowing time for comments, and also providing upon request copies of other relevant documents on existing regulations related to food and agriculture. Information on Dominican Republic's regulations, standards and certification procedures can also be obtained through the National Inquiry Point listed below:

#### **Ministerio de Salud Pública y Asistencia Social Departamento de Alimentos**

Ave. Dr. Héctor Homero Hernández, Esq. Av. Tiradentes, Ensanche La Fe; Santo Domingo, D.N., R.D. 10514; Tel: +1 809-541-3121

Email: [info@ministeriodesalud.gob.do](mailto:info@ministeriodesalud.gob.do); [rosariocabreart@gmail.com](mailto:rosariocabreart@gmail.com)

[https://members.wto.org/crnattachments/2017/TBT/DOM/17\\_4492\\_00\\_s.pdf](https://members.wto.org/crnattachments/2017/TBT/DOM/17_4492_00_s.pdf)

(for the latest notification)

## ATTACHMENT I

### **Legal Differences between Law, Presidential Decrees, Congressional Resolutions, Resolutions and NORDOMs** **Differences between Legal Norms in the Dominican Republic**

The main differences between legal norms in the Dominican Republic depend on four fundamental aspects: (i) the enacting body, (ii) the regulated content/aspects, (iii) the modification/derogation process, and (iv) their binding character.

In general terms, their hierarchical level is as follows: (1) Constitution; (2) Laws; (3) Presidential Decree; (4) Congressional Resolutions; (5) Resolutions; and (5) Standards and Norms.

- **Laws**. Laws are enacted by the Dominican Republic's Congress. Laws enacted to regulate matters set forth by Constitution and therefore, categorized as "organic" have a higher ranking than special or general laws. Laws can only be modified or derogated by another law enacted later in time and/or by the Constitution. A Law can also be derogated by a judgment issued by a Court with competence to decide the matter at hand.
- **Presidential Decrees**. Presidential Decrees are enacted by the Executive Branch of the Dominican Republic, the President. In many cases, such pieces are issued in a form of a regulation ("*Reglamento*") that will complement a Law, providing the specific aspects for its application; therefore, such regulations are subordinated to the Law. They can be derogated or modified by a subsequent Decree or by a Law.
- **Congressional Resolutions**. Congressional Resolutions are enacted by the Dominican Congress, but have an administrative character. The Congress is entitled to issue a Resolution to set forth a position in regards to a national or international matter. It does not constitute law itself. It can be modified and derogated by a Law, a Presidential Decree, or by another Congressional Resolution, issued later in time. Congressional Resolutions require

the approval of the Executive branch.

- **Resolutions.** Resolutions are enacted by the governmental body that is responsible for applying or overseeing a Law, Presidential Decree, or any other legal documents. It serves as a decision to a matter that has not been expressly regulated by law.
- **Standards and Norms.** Standards and Norms are, in addition, enacted by the competent governmental body, as authorized by Law, Presidential Decree, or Regulations. It provides, for common and repeated use, rules, guidelines, or characteristics for products or processes to be done before governmental authorities and between private persons or entities.
  - NORDOM's ("*Normas Dominicanas*"), in contrast, do not possess a binding character, in accordance to the Eleventh Transitional Provision of Law No. 166-12 dated July 12, 2012 (that creates the Dominican System for Quality ("*Sistema Dominicano para la Calidad*"), and are issued by the Dominican Institute for Quality ("*Instituto Dominicano para la Calidad*") (SIDOCAL), as documents to establish the quality parameters and specifications that products, services and processes would ideally require to meet. Nowadays, NORDOM 53 is the only Norm that possesses a binding character, in accordance to Presidential Decree 528-01.

## **ATTACHMENT II**

### **Revised Legal Framework**

1. Law 3489 dated February 14, 1953, on Customs.
2. Law 4030 dated January 12<sup>th</sup>, 1955, that Declares of Public Interest the Sanitary Defense of Cattle;
3. Law 4990 dated September 3<sup>rd</sup>, 1958, regarding Plant Protection;
4. Presidential Decree No. 1139 dated July 28, 1975 approving the DR Sanitary Regulation for Milk and Dairy Products;
5. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) Agreement dated January 1, 1995;
6. Resolution No. 84/96 dated September 17, 1996, given by the Ministry of Agriculture regarding Fresh Fruit;
7. Presidential Decree No. 505-99 dated November 24, 1997, regarding the Regulation for the Import of the Agricultural Products in the Technical Rectification of List XXIII of the Dominican Republic before the World Trade Organization (WTO);
8. Congressional Resolution No. 92-99 dated October 13, 1999, that approves the Technical Rectification of List XXIII of Tariff Concessions of the Dominican Republic before the World Trade Organization (WTO) and orders the Adjudication of said Tariff Concessions through Public Auction;
9. Law No. 146-00 dated December 27, 2000, regarding Tariff Reform;
10. General Health Law No. 42-01 dated March 8, 2001;
11. General Regulation (Presidential Decree) No. 528-01 dated May 14, 2001 for Risk Control in Food and Beverages;
12. General Law No. 358-02 dated September 9, 2005 for the Protection of Consumer or Users' Rights (ProConsumidor);
13. Resolution No. 024/2006 dated November 22, 2006, given by the Ministry of Agriculture, regarding the Phytosanitary Certificate;
14. Presidential Decree No. 705-10 that establishes the Regulations for the Assignment and Administration of the Tariff Quotas granted by the Dominican Republic under the DR-CAFTA;
15. Presidential Decree No. 244-10 dated April 27, 2010, which establishes the Technical Regulations regarding the Maximum Residue Levels of Pesticides in Fruits, Vegetables, and

related thereto;

16. Presidential Decree No. 569-12 dated September 11, 2012, regarding the Procedure for Allocation of Tariff Quotas for the Products in the Technical Rectification of List XXIII of the Dominican Republic before the World Trade Organization (WTO);
17. General Labeling Standard for Pre-packaged Products (RTD 53/NORDOM 53, 4<sup>th</sup> revision) dated November 27, 2014 (published in 2015);
18. Presidential Decree 82-15 dated April 6, 2015, which creates the General Directorate of Drugs, Food and Sanitary Products;
19. Presidential Document dated July 12, 2016 on the enforcement of the Sanitary Registration and labeling requirement at origin.

#### **Schedule A: Fresh Fruits and Vegetables/Processed Vegetables**

##### ***Phytosanitary requirements for the import of fresh fruit***

The application is made through a form ("Formulario de Solicitud Guía de No Objeción Fitosanitaria"), which must be completed and filed before the Department of Plant Protection, with the following information: name of the importer; address; telephone and fax numbers; goods to be imported; quantity; unit of measurement; port of origin; port of departure; port of entry; use; and transportation.

In this regard, the following documentation and conditions must be met:

1. An original Phytosanitary certificate must be obtained from the country of origin.
2. An original Certificate of Origin must also be obtained.
3. The goods must be shipped in refrigerated containers at a temperature of 32-36°F.
4. Fruits must meet 14-day quarantine.
5. Certification that the ship was sanitized and disinfected before the goods were loaded.
6. Certification that the goods have been produced and packaged in areas free of *Ceratitis Capitata* (Mediterranean Fruit Fly).
7. Authorization issued by the Department of Promotion for Agriculture and Livestock along with the original Phytosanitary Guidance Letter issued by the Department of Plant Protection must be presented to the inspector of quarantine control at the port of entry.
8. In order to obtain the Guidance Letter before the Department of Plant Protection, government fees amount to **RD\$200.00 Dominican Pesos**, roughly equivalent to \$4.00. After this phase is completed, the Department of Promotion for Agriculture and Livestock will then issue the Phytosanitary permit for a cost of **RD\$2,000.00 Dominican Pesos**, roughly equivalent to \$41.00. These expenses do not include legal fees.

##### ***Phytosanitary requirements for the import of fresh or processed vegetables***

The application is made through a form ("Formulario de Solicitud Guía de No Objeción Fitosanitaria"), which must be completed and filed before the Department of Plant Protection with the following information: name of the importer; address; telephone and fax numbers; goods to be imported; quantity; unit of measurement; port of origin; port of departure; port of entry; use; and transportation.

In this regard, the following documentation and conditions must be met:

1. Phytosanitary Certificate or Health Certificate issued by the authorities of the country of origin.
2. Certification that the ship was sanitized and disinfected before the goods were loaded.
3. If jute bags are used, these must be new.
4. The goods must be free of pests and soil.
5. The goods must be free of mites, whiteflies and aphids.
6. In case of wood packaging, it must comply with NIMF Resolution No. 15.
7. The goods will be inspected upon arrival into the Dominican territory and examined by the Phytosanitary Diagnostics Laboratory.

8. Authorization issued by the Department of Promotion for Agriculture and Livestock along with the original Phytosanitary Guidance Letter issued by the Department of Plant Protection must be presented to the inspector of quarantine control at the port of entry.
9. In order to obtain the Guidance Letter before the Department of Plant Protection, government fees amount to **RD\$200.00 Dominican Pesos**, roughly equivalent to \$4.00. After this phase is completed, the Department of Promotion for Agriculture and Livestock will then issue the Phytosanitary permit for a cost of **RD\$2,000.00 Dominican Pesos**, roughly equivalent to \$41.00. These expenses do not include legal fees.

### **Schedule B: Poultry and Pork**

The application is made through a written letter (one original and three hard copies) filed before the General Directorate of Livestock, indicating the following information: name of the importer; address; telephone and fax numbers; goods to be imported; quantity; unit of measurement; country of origin and country of export, port of origin; port of departure; port of entry; use; transportation; value of the goods, animal species with which the product is made. This application must be accompanied by the commercial invoice or pro forma invoice.

In addition, the following documentation and conditions must be met:

1. The products shall be covered by an International Health Certificate (in Spanish), issued by the Official Authority of Animal Health from the country of origin, stating compliance with the following requirements:
  - Poultry are born and raised in the exporting country;
  - The site of origin of the eggs remain under official animal health control;
  - The site is free of infectious or communicable diseases affecting the species;
  - The site of origin of the eggs is located within a 30km radius free of salmonella;
2. The animals, from which the animal products derive from, must be natives of the exporting country or must have remained in it for at least 90 days prior to slaughter and/or export.
3. The goods must contain the expiration date and must be good for consumption for at least six months.
4. Official certificate of Origin.
5. In the case of meat products, the exporting country must also certify that:
  - the meat comes from a slaughterhouse with address and approval number of a veterinarian, and if they are cut, with the same conditions;
  - The meat and packaging should bring a stamp certifying that they come from animals slaughtered in approved slaughterhouses and approved by the official veterinary authority;
  - Acknowledgment that the meat is fit for human consumption; and,
  - That the meat was cut in an accredited establishment under the inspection of the official veterinary organ;
  - When the authority considers it necessary, a veterinary commission, designated by the General Directorate of Livestock, will visit the country of exportation to recognize the epidemiological surveillance system and certify slaughterhouses and/or processing plants.
  - In order to obtain the Guidance Letter from the Department of Animal Health, government fees amount to **RD\$2,000.00 Dominican Pesos**, roughly equivalent to \$41.00 and from the Department of Agricultural and Livestock Promotion, government fees amount to **RD\$3,000.00**, roughly equivalent to \$63.00, for poultry products and **RD\$5,000.00**, roughly equivalent to \$105.00, for pork products. These expenses do not include attorney's fees.

### **Schedule C: Cheese, Yogurt, Breakfast Cereal, Tree Nuts, Wine and Beer, Prepared Foods, Condiments, Sauces, and Snack Foods**

## **Cheese & Yogurt**

In the DR, the importation of products and by-products considered as pre-packaged foods and beverages, including cheese and yogurt, are regulated by Presidential Decree No. 528-01, which approves the General Regulation for Foods and Beverages Risk Control in the Dominican Republic, dated May 14th, 2001.

The General Directorate of Drugs, Food and Sanitary Products or "DIGEMAPS" (before known as the Department for Foods and Beverages Risk Control) of the Ministry of Health and Social Welfare (*Dirección General de Medicamentos, Alimentos y Productos Sanitarios del Ministerio de Salud Pública y Asistencia Social*) is the official body in charge of authorizing the pre-packaged foods and beverages, including cheese and yogurt, that can be imported in the Dominican Republic. It establishes the requirements to request the marketing authorization (or health permit) (*registro sanitario*) for pre-packaged foods and beverages.

This marketing authorization (or health permit) (*registro sanitario*) is a pre-import requirement.

In general terms, the requirements to proceed with the importation of cheese and yogurt are the following:

- The exporter company from the United States should designate a local distributor or company who will serve as the legal representative of the product before the governmental authorities of the DR.
- The importer must first request before the Department of Foods and Beverages Risk Control, the marketing authorization (or health permit) (*registro sanitario*) application of the product. Such authorization usually takes around 3 months to be approved.
- In case it is the first time a manufacturing company of the product is going to present a marketing authorization (or health permit) application, authorities may require to proceed with an *in situ* inspection of the manufacturing plant, even if the plant is not located in the DR.
- Once the marketing authorization (or health permit, *registro sanitario*) application of the product is approved, the importer is able to request the importation of the product.
- When the shipment of product arrives to the country, the customs agents may, at their discretion, proceed to inspect the shipment/container. The marketing authorization (or health permit, *registro sanitario*) certificate of the product will be required by the customs agents to verify if the product has been authorized by the Ministry of Health.

### **Marketing authorization (or health permit; *registro sanitario*) Application Requirements**

The following documents must be submitted, along with the application to the Department of Foods and Beverages Risk Control, for the marketing authorization (or health permit, *registro sanitario*):

1. One original version and one copy of the letter addressed to the Minister of Health and Social Welfare requesting the marketing authorization (or health permit, *registro sanitario*) application of the product and indicating:
  - Name, Address and Phone Number of the Requester;
  - Name of the Product;
  - Type of Product and Commercial Name;
  - Name or Company Name of the Manufacturer;
  - Location and Address of the Manufacturer;
  - Characteristics of the Container and/or Package.
2. Two copies of the Mercantile Registry of the Importer;
3. Qualitative and Quantitative Formula of the product;

4. Three original samples of the product, with the same presentation in which it would be sold in the market for human consumption;
  - For solid products, at least 200 grams
  - For liquid products, at least 250 milliliters
5. Labeling Format in Accordance with NORDOM 53: Labeling for Pre-Packaged Foods;
6. Legalized Document (Power of Attorney) designating the legal representative of the product in the country.
7. Free Sale Certificate (FSC - "Certificado de Libre Venta"), duly legalized, when the product is imported;
8. Receipt issued by the Ministry of Public Health and Social Welfare. The official fees are **RD\$4,000.00**, roughly equivalent to \$84.00<sup>1</sup>.

### ***Pre-Export Requirements***

First, the U.S. Exporting Company should obtain a Free Sale Certificate of the product, issued by the Health Authority of the country of origin. This Certificate should certify that the manufacture, sell and consumption of the cheese and yogurt are freely allowed in the country of origin.

The U.S. exporter should designate a local distributor or company, who will serve as importer and legal representative of the products in the DR.

Cheese and yogurt must obtain a local marketing authorization (or health permit; *registro sanitario*), issued by the Ministry of Health and Social Welfare.

### **Zoo-sanitary Permit for Cheese and Yogurts**

In addition to the Marketing Authorization Approval, for cheese and yogurts (dairy products) a Zoo-sanitary Permit must be obtained before the Ministry of Agriculture given that these products derive from animal origin.

The application is made through a written letter (one original and three hard copies) filed before the General Directorate of Livestock, indicating the following information: name of the importer; address; telephone and fax numbers; goods to be imported; quantity; unit of measurement; country of origin and country of export, port of origin; port of departure; port of entry; use; transportation; value of the goods, animal species with which the product is made. This application must be accompanied by the commercial invoice or pro forma invoice.

In addition, the following documentation and conditions must be met:

1. The goods must be accompanied by an International Health Certificate (in the Spanish language), issued by the Official Authority of the country of origin. The certificate shall contain the name and address of the consignor and the consignee and the number and species of the products to be exported.
2. Technical form (in case of first imports).
3. Original Certificate of Origin.
4. The products and sub-products derived from the animals, should be native of the exporting country or should have remained in the same for at least 90 days prior to its sacrifice and/or export.
5. The products should indicate the expiration date and should not expire soon (for at least 6 months).

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<sup>1</sup> Other expenses are to be expected, especially if the interested party wished to accelerate the process by using an authorized private/alternate laboratory for sample analysis.

6. In order to obtain the Guidance Letter before the Department of Animal Health, government fees amount to **RD\$2,000.00 Dominican Pesos**, roughly equivalent to \$41.00, and before the Department of Agricultural and Livestock Promotion, government fees amount to **RD\$2,000.00 Dominican Pesos**, roughly equivalent to \$41.00. These expenses do not include attorney's fees.

### **Wine and Beer**

In the DR, the importation of products and by-products considered as pre-packaged foods and beverages, including wine and beer, are regulated by Presidential Decree No. 528-01 which approves the General Regulation for Foods and Beverages Risk Control in the Dominican Republic, dated May 14, 2001.

The General Directorate of Drugs, Food and Sanitary Products or "DIGEMAPS" (before known as the Department for Foods and Beverages Risk Control) of the Ministry of Health and Social Welfare (*Dirección General de Medicamentos, Alimentos y Productos Sanitarios del Ministerio de Salud Pública y Asistencia Social*) is the official body in charge of authorizing the pre-packaged foods and beverages, including wine and beer, that can be imported into the DR. It establishes the requirements to request the marketing authorization (or health permit, *registro sanitario*) for pre-packaged foods and beverages.

This marketing authorization (or health permit, *registro sanitario*) is a pre-import requirement.

In general terms, the requirements to proceed with the importation of wine and beer are the following:

- The exporter company from the United States should designate a local distributor or company who will serve as the legal representative of the product before the governmental authorities of the Dominican Republic.
- The importer must first request before the Department of Foods and Beverages Risk Control, the marketing authorization (or health permit, *registro sanitario*) application of the product. Such authorization usually takes around 3 months to be approved.
- Once the marketing authorization (or health permit, *registro sanitario*) application of the product is approved, the importer is able to request the importation of the product.
- When the shipment of product arrives to the country, the customs agents may, at their discretion, proceed to inspect the shipment/container with the products. The marketing authorization (or health permit, *registro sanitario*) certificate of the product will be required by the customs agents to verify if the product has been authorized by the Ministry of Health.

**Note:** On July 11, 2017, the Ministry of Public Health and Social Welfare (MSP) instructed the General Customs Director (DGA) to require a Certificate of No Objection to import alcoholic beverages into the DR. Enforcement of the regulation for pre-packaged foods will initially focus on dairy products and wine, but the Dominican Government has indicated it will later extend enforcement to other products.

### **Marketing authorization (or health permit; *registro sanitario*) Application Requirements**

The following documents shall be submitted along with the application before the Department of Foods and Beverages Risk Control, for the marketing authorization (or health permit, *registro sanitario*):

1. One original version and one copy of the letter addressed to the Minister of Health and Social Welfare requesting the marketing authorization (or health permit; *registro sanitario*) application of the product and indicating:
  - Name, Address and Phone Number of the Requester;

- Name of the Product;
  - Type of Product and Commercial Name;
  - Name or Company Name of the Manufacturer;
  - Location and Address of the Manufacturer;
  - Characteristics of the Container and/or Package.
2. Two copies of the Mercantile Registry of the Importer;
  3. Qualitative and Quantitative Formula of the product;
  4. Three original samples of the product, with the same presentation in which it can be sold in the market for human consumption;
    - For solid products, at least 200 grams
    - For liquid products, at least 250 milliliters
  5. Labeling Format in Accordance to NORDOM 53: Labeling for Pre-Packaged Foods;
  6. Legalized Document (Power of Attorney) designating the legal representative of the product in the country.
  7. Free Sale Certificate (FSC - "Certificado de Libre Venta"), duly legalized, when the product is imported;
  8. Receipt issued by the Ministry of Public Health and Social Welfare. The official fees are **RD\$4,000.00**, roughly equivalent to \$84.00<sup>2</sup>.

Specifically for alcoholic beverages, including wine and beer, the General Health Law No. 42-01, requires labels to declare the following disclaimer: "*El consumo excesivo de alcohol es perjudicial para la salud*" in Spanish ("The excessive consumption of alcohol carries health risks").

### ***Pre-Export Requirements***

In first place, the U.S. Exporting Company should obtain a Free Sale Certificate of the product, issued by the Health Authority of the country of origin. This Certificate should certify that the manufacture, sell and consumption of the wine and beer are freely allowed in the country of origin.

The U.S. exporter should designate a local distributor or company, who will serve as importer and legal representative of the products in the Dominican Republic.

Wine and Beer must obtain a local marketing authorization (or health permit, *registro sanitario*), issued by the Ministry of Health and Social Welfare.

### **Breakfast Cereal, Condiments and Sauces, Prepared Foods, Snack Foods, and Tree Nuts**

In the DR, the importation of products and by-products considered as pre-packaged foods and beverages, including breakfast cereal, condiments, sauces, prepared foods, snack foods and tree nuts, is regulated by Presidential Decree No. 528-01 which approves the General Regulation for Foods and Beverages Risk Control in the Dominican Republic, dated May 14th, 2001.

The General Directorate of Drugs, Food and Sanitary Products or "DIGEMAPS" (before known as the Department for Foods and Beverages Risk Control) of the Ministry of Health and Social Welfare (*Dirección General de Medicamentos, Alimentos y Productos Sanitarios del Ministerio de Salud Pública y Asistencia Social*) is the official body in charge of authorizing the pre-packaged foods and beverages, including breakfast cereal, condiments, sauces, prepared foods, snack foods and tree nuts, that can be imported into the DR. It establishes the requirements to request the marketing authorization (or health permit) (*registro sanitario*) for pre-packaged foods and beverages.

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<sup>2</sup> Other expenses are to be expected, especially if the interested party wished to accelerate the process by using an authorized private/alternate laboratory for sample analysis.

This marketing authorization (or health permit, *registro sanitario*) is a pre-import requirement.

In general terms, the requirements to proceed with the importation of breakfast cereal, condiments, sauces, prepared foods, snack foods and tree nuts are the following:

- The exporter company from the United States should designate a local distributor or company who will serve as the legal representative of the product before the governmental authorities of the Dominican Republic.
- The importer must first request before the Department of Foods and Beverages Risk Control, the marketing authorization (or health permit, *registro sanitario*) application of the product. Such authorization usually takes around 3 months to be approved.
- Once the marketing authorization (or health permit, *registro sanitario*) application of the product is approved, the importer is able to request the importation of the product.
- When the shipment of product arrives to the country, the customs agents may, at their discretion, proceed to inspect the shipment/container with the products. The marketing authorization (or health permit, *registro sanitario*) certificate of the product will be required by the customs agents to verify if the product has been authorized by the Ministry of Health.

#### **Marketing authorization (or health permit; *registro sanitario*) Application Requirements**

The following documents shall be submitted along with the application before the Department of Foods and Beverages Risk Control, for the marketing authorization (or health permit, *registro sanitario*):

1. One original version and one copy of the letter addressed to the Minister of Health and Social Welfare requesting the marketing authorization (or health permit, *registro sanitario*) application of the product and indicating:
  - Name, Address and Phone Number of the Requester;
  - Name of the Product;
  - Type of Product and Commercial Name;
  - Name or Company Name of the Manufacturer;
  - Location and Address of the Manufacturer;
  - Characteristics of the Container and/or Package.
2. Two copies of the Mercantile Registry of the Importer;
3. Qualitative and Quantitative Formula of the product;
4. Three original samples of the product, with the same presentation in which it be sold in the market for human consumption;
  - For solid products, at least 200 grams
  - For liquid products, at least 250 milliliters
5. Labeling Format in Accordance to NORDOM 53: Labeling for Pre-Packaged Foods;
6. Legalized Document (Power of Attorney) designating the legal representative of the product in the country.
7. Free Sale Certificate (FSC - "Certificado de Libre Venta"), duly legalized, when the product is imported;
8. Receipt issued by the Ministry of Public Health and Social Welfare. The official fees are **RD\$4,000.00**, roughly equivalent to \$84.00<sup>3</sup>.

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<sup>3</sup> Other expenses are to be expected, especially if the interested party wished to accelerate the process by using an authorized private/alternate laboratory for sample analysis.

### ***Pre-Export Requirements***

In first place, the U.S. Exporting Company should obtain a Free Sale Certificate of the product, issued by the Health Authority of the country of origin. This Certificate should certify that the manufacture, sale, and consumption of the breakfast cereal, condiments, sauces, prepared foods, snack foods and tree nuts is freely allowed in the country of origin.

The U.S. exporter should designate a local distributor or company, who will serve as importer and legal representative of the products in the DR.

Breakfast cereal, condiments, sauces, prepared foods, snack foods and tree nuts must obtain a local marketing authorization (or health permit, *registro sanitario*), issued by the Ministry of Health and Social Welfare.

### **Phytosanitary Permit for Tree Nuts**

Finally, regarding tree nuts, in addition to the Marketing Authorization Approval, a permit must be obtained before the Ministry of Agriculture given that these products derive from plant origin.

The application is made through a form ("Formulario de Solicitud Guía de No Objeción Fitosanitaria") which must be completed and filed before the Department of Plant Protection, with the following information: name of the importer; address; telephone and fax numbers; goods to be imported; quantity; unit of measurement; port of origin; port of departure; port of entry; use; and transportation.

In this regard, the following documentation and conditions must be met:

1. Original Phytosanitary or Health Certificate issued by the authorities of the exporting country.
2. Certification that the ship was sanitized and disinfected before the goods were loaded.
3. Jute bags should not be used for packaging.
4. The goods must be free of plagues and diseases.
5. The goods shall be inspected upon arrival to the Dominican territory and examined by the Phytosanitary Diagnostics Laboratory.
6. In order to obtain a Guidance Letter before the Department of Plant Health, the governmental fees amount to **RD\$200.00 Dominican Pesos**, roughly equivalent to \$4.00. After this phase is completed, the Department of Promotion for Agriculture and Livestock will then issue the Phytosanitary permit for a cost of **RD\$2,000.00 Dominican Pesos**, roughly equivalent to \$41.00. These expenses do not include attorney's fees.