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Required Report - public distribution

Date: 12/26/2017

GAIN Report Number: DR1715

Dominican Republic

Food and Agricultural Import Regulations and Standards - Certification

FAIRS Export Certificate Report

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Report Highlights:

This report describes the major export certificates required by the Government of the Dominican Republic (DR) for imports of food and agricultural products. Major changes in 2017 include (1) the DR's enforcement of the sanitary registration requirement to 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 to be issued by the Ministry of Health before alcoholic beverages can be imported into the DR.

Executive Summary & Disclaimer

In 2017, the Dominican Republic (DR) continued issuing several updates of the Presidential Document mandate to apply the sanitary registration and labeling requirements for Normas Dominicanas (NORDOM) 53, a local regulation for labeling prepackaged food products produced domestically and imported. This Mandate was dated July 12, 2016 and ordered to be implemented by January 1, 2017, but the implementation was delayed until April 1, 2017. The Presidential Document requires that all food products produced domestically and imported have a current sanitary registration and that the product label provides this registration number, is in the Spanish language, and is 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, effective August 1, 2017.

On October 3, 2017 the MSP submitted the new Food Health Regulations to the WTO's Technical Barriers to Trade (TBT) committee (G/TBT/N/DOM/224). This document establishes the objectives, scope, general requirements, and general 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 labelling, advertising, enrichment, fortification and food property claims, food supplements, food property claims, food classification, food preservation, monitoring, alerts, traceability, violations and penalties. For more details, please see Post's 2017 FAIRS narrative report, DR1714.

Additionally, on July 25, 2017, the MSP issued Resolutions 11 and 12. Resolution 11 states that the MSP will develop the procedures, processes and requirements necessary for the sanitary notification procedure and automatic renewal within a period of 60 days. Resolution 12 states that the MSP will develop the processes and requirements necessary for a simplified sanitary registration process for food and beverages from specified countries with a strong food safety system (including the United States) within a period of 60 days. However, at the time of publication, these clarifications have not been published.

This report was prepared by the USDA Foreign Agriculture Service's Office of Agriculture Affairs in Santo Domingo, Dominican Republic for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate because policies may have changed since its preparation, or clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. 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.

Section I: List of all Export Certificates Required by the Dominican Republic and the Products they cover

The Dominican Republic has several documentation requirements for prepackaged imported food and agricultural products. Requirements include those relating to quality, quarantine, origin, and import control and can vary between products and product categories. Products may also have to meet other criteria, such as packaging requirements, treatment options, and labeling requirements.

Following a major internal restructuring within the DR's Ministry of Public Health and Social Welfare (MSP), some import measures have been modified and implemented with little prior notice. In addition, coordination challenges with the Ministry of Agriculture have led to delays at the port. Therefore, in this changing regulatory environment, it is vital for U.S. exporters to work closely with Dominican importers to ensure that documentation requirements are met before shipping. Failure to do so could result in delays in products entering the country or rejections at the border.

Export Certification Requirement Examples

The following provides a sample of products and certification requirements. Please note that not all sample copies of attestations are available as they differ for each product and are subject to change.

Table A: List of All Export Certificates Required by the Government of the Dominican Republic for Sections I, II and III

No.	Section I	Section II			Section III
	Product (s)	Title of Certificate	Purpose	Requesting Ministry	Attestation Required on Certificate
1	Vegetable Origin	U.S. phytosanitary certificate	Phytosanitary Certificate	Min. of Agric.	Phytosanitary conditions required to allow the entry and mobilization of plants, products and by-products into the DR. Import permit and certification of free sale also required.
2	Pets	U.S. sanitary certificate	Sanitary Certificate	Min. of Agric.	Adherence to a protocol that is designed by country and species, including laboratory testing. With the exception of dogs and cats, all live animals, birds, and animal trophies, need prior permission from the General Livestock Department to enter the Dominican Republic. Import permit also required.
3	Veterinary Products	U.S. sanitary certificate	Sanitary Certificate	Min. of Agric.	Sanitary conditions required to allow the entry and mobilization of the product. Import permit and certification of free sale also required.

No.	Section I	Section II			Section III
	Product (s)	Title of Certificate	Purpose	Requesting Ministry	Attestation Required on Certificate
4	Fishery Products	U.S. sanitary certificate	Sanitary certificate	Min. of Agric.	<ul style="list-style-type: none"> - Number of the Marketing License - Type, net quantity in kilograms and FOB cost according to the final invoice of the product(s) - The country where the product comes from - Airport or pier where it will enter - Container Number and Seal. - Commercial invoice (NOT PROFORMA) - Certificate of Origin of competent authority - Bill of Lading - Copy of the current marketing license <p>These items must be sent in a Letter of Request to the Dominican Council for Fisheries and Aquaculture (COD OPESCA).</p> <ul style="list-style-type: none"> - Certificate of No Objection for Import of Fishery Products also required.
5	Live Animals	U.S. zoosanitary certificate	Sanitary certificate	Min. of Agric.	Freedom from Food and Mouth Disease, Contagious Bovine Pleuropneumonia, and Rift Valley fever, among other requirements. With the exception of dogs and cats, all live animals, birds, and animal trophies, need prior permission from the General Livestock Department, to enter the Dominican Republic.
6	Animal Products	U.S. sanitary certificate	Health Requirement/Import Permit	Min. of Agric.	Sanitary conditions required to allow the entry and mobilization of animal products into the DR. Import permit and certification of free sale also required.
7	Food and Beverages	U.S. sanitary certificate	Sanitary Certificate	Min. of Health	Sanitary conditions and regulations related to the production, handling, import, export, packaging, storage, distribution, transport and sale of food for human consumption. Certification of free sale and sanitary registration also required.
8	Dairy Products	U.S. sanitary certificate	Sanitary Certificate	Min. of Health	Sanitary conditions for dairy products. Import permit and certification of free sale also required.

Note: Links to guidance documents describing the specific requirements for each product type are provided in Appendix 1.

Section II: Purpose of Specific Export Certificate

To import agricultural goods into the DR, the importer must supply a different set of documents depending upon the category of the product being imported. The documents are listed above by category, including vegetable origin products, animal products, and food and beverages. A full list of such categories requirements is provided in the matrix above and specific web page links are included in Appendix I.

Section III: Specific Attestation Required on Export Certificate

An original export certificate must accompany each export bill of lading (BOL) at the time of entry into the Dominican Republic. Export declarations provided by suppliers or manufacturers must comply with the sanitary requirements and conditions to allow the entry and mobilization of animals and animal products, plants, products, and by-products into the country, which were determined by risk analysis. A full list of the requirements for each category is provided in Table A above and specific web page links are included in Appendix I.

Section IV: Government Certificate Legal Entry Requirements

Apart from quarantine and phytosanitary requirement regulations, imported products may also have to meet other requirements as summarized in the table below. For additional information, review Post's 2017 FAIRS narrative report, DR1714.

Table B: Government Certificate Legal Entry Requirements

	Product (s)	Title of Certificate	Does the original certificate need to accompany the product at the time of entry?	How long is the certificate valid? Can certificate be applied to multiple shipments?	Will the country accept a Suppliers or Manufacturer's Export Declaration as proof of compliance?	Will the foreign country accept a U.S. State issued export certificate?	Will the country derogate export certificates? Which certificates? How do you apply?
1	Vegetable Origin	Importation of Products & By-products of Vegetable Origin	Yes	5 years, but are valid only once to facilitate one shipment entry	Yes, this is required in addition to the DR required certificates listed in Table A	Yes, this is required in addition to the DR required certificates listed in Table A	Yes, the country may derogate a certificate that does not comply with the requirements in a case by case procedure
2	Vegetable Origin	Process to Import Vegetable Products	Yes	"	"	"	"
3	Vegetable Origin	Vegetable Quarantine	Yes	"	"	"	"
4	Vegetable Origin	General Requirements for the Importation of Vegetable Origin Products	Yes	"	"	"	"
5	Pets	Sanitary Requirements for the entry of Pets to the Dominican Republic	Yes	"	"	"	"
6	Products & Veterinary Establishments	Registration of Products & Veterinary Establishments	Yes	"	"	"	"
7	Fishery Products	Certificate of No Objection for Import of Fishery Products	Yes	"	"	"	"
8	Live Animals	Zoo sanitary Certificate for an animal	Yes	"	"	"	"
9	Animal Products	Zoo sanitary Certificate for an animal product	Yes	"	"	"	"
10	Food and Beverages	Food Health Regulation	Yes	"	"	"	"

	Product (s)	Title of Certificate	Does the original certificate need to accompany the product at the time of entry?	How long is the certificate valid? Can certificate be applied to multiple shipments?	Will the country accept a Suppliers or Manufacturer's Export Declaration as proof of compliance?	Will the foreign country accept a U.S. State issued export certificate?	Will the country derogate export certificates? Which certificates? How do you apply?
1 1	Food and Beverages	Sanitary Registration Notification Procedure & Automatic Renewal	Yes	**	**	**	**
1 2	Food and Beverages	Simplified Sanitary Registration of Food & Beverages	Yes	**	**	**	**
1 3	Food and Beverages	Free Sale Certificate	Yes	**	**	**	**
1 4	Food and Beverages	On-line Registered Products Certification	Yes	**	**	**	**
1 5	Dairy Products*	Sanitary Registration of Imported Pre-packaged Dairy Products	Yes	**	**	**	**

* The Government of the DR is in the process of issuing updated specific regulations for dairy products. The timeline is currently unknown.

Section V: Other Certification/Accreditation Requirements

• Prepackaged Products/Dairy/Alcoholic Beverages

On July 12, 2016, the Dominican government issued a statement announcing the enforcement of NORDOM 53, a local regulation for labeling prepackaged foods. Beginning April 1, 2017, all food products imported and produced domestically must have a current *Sanitary Registration*. In addition, the label on prepackaged products must be in the Spanish language and applied *at the point of origin* instead of in the destination country as is the usual practice. As stated in the government document, enforcement of the regulation is currently focused on dairy products and alcoholic beverages, but it is expected to be extended to other products.

These requirements are not new, but rather a reinforced application of laws and regulations that have been in place since 2001. On October 3, 2017 the Ministry of Public Health and Social Welfare (MSP) submitted the new Food Health Regulations to the WTO's Technical Barriers to Trade (TBT) committee (G/TBT/N/DOM/224). This document establishes the objectives, scope, general requirements, and general 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 labelling, advertising, enrichment, fortification and food property claims, food supplements, food property claims, food classification, food preservation, monitoring, alerts, traceability, violations, and penalties.

Additionally, on July 25, 2017, the MSP issued Resolutions 11 and 12. Resolution 11 states that the MSP will develop the procedures, processes and requirements necessary for the sanitary

notification procedure and automatic renewal within a period of 60 days. Resolution 12 states that the MSP will develop the processes and requirements necessary for a simplified sanitary registration process for food and beverages from specific countries, including the United States, within a period of 60 days. However, at the time of publication, these clarifications have not been published.

The Government of the DR is also in the process of issuing updated specific regulations for dairy products. The timeline is currently unknown.

Appendix I

Please, see below the certificates list along with the web page link where you can find them. Please note that many of the links below are only provided in the Spanish language.

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

Address: (Dirección): Km. 6 1/2 Autopista Duarte, Los Jardines del Norte, Santo Domingo, D.N., República Dominicana.

b) Process to Import Vegetable Products/National Committee for the Application of Sanitary and Phytosanitary Measures (CNMSF)

<http://www.cnmsf.gob.do/default.aspx?tabid=161>

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

c) Vegetable Quarantine/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

d) 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/RequisitoFitosanitariodeImportacion%3%B3n/tabid/147/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

e) Sanitary Requirements for the entry of Pets to the Dominican Republic/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
Service Hours: Lunes a Viernes de 8:00 a.m. - 3:00 p.m.*

- f) Division of Registration of Products and Veterinary Establishments/ General Directorate of Livestock (DIGEGA)
<http://www.ganaderia.gob.do/index.php/sobre-nosotros/departamentos/item/división-de-registro-de-productos-y-establecimientos-veterinarios>

Contact Information:

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

- g) 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/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

- b) Sanitary Registration Notification Procedure and Automatic Renewal/Ministry of Public Health/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

- c) Simplified Sanitary Registration of Food and Beverages/Ministry of Public Health/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

- d) Free Sale Certificate/Ministry of Public Health/General Directorate of Medicines, Food and Health Products (DIGEMAPS)
http://digemaps.msp.gob.do/digemaps/clv/requisitos_clv.php

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

- e) Registered Products Certification/Ministry of Public Health/General Directorate of Medicines, Food and Health Products (DIGEMAPS)
http://digemaps.msp.gob.do/digemaps/certificaciones/requisitos_certificaciones.php

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

- f) Sanitary Registration of Imported Pre-packaged Dairy Products Renewal/Ministry of Public Health/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

3. United States Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS)

a) Live Animals

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oi/sa_by_country/sa_d/ct_animal_dom_republic


b) Animal Products

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/iregs-for-animal-product-exports/sa_international_regulations/sa_by_country/sa_d/ct_product_dominican_republic

Electronic Copy of Selected Export Certificates

Example: Free Sale Certificate/Ministry of Health

Effective since August 28, 2016

	DIRCCION GENERAL DE MEDICAMENTOS, ALIMENTOS Y PRODUCTOS SANITARIOS	Código	DIGESALAPS ES LE 090
		Versión	001
	Lista de Requisitos para Certificado de Libre Venta Línea	Fecha de actualización	28 de agosto 2016

Requisitos generales y administrativos

1. Tener el formulario digital con los datos requeridos
2. Tener Certificado de Buenas Prácticas de Manufactura vigente
3. Efectivo de pago

Interacciones para el uso del servicio

- El costo de pago debe estar emitido a favor del titular o representante del régimen ordinario
- No es imprescindible validar los datos del Certificado de Libre Venta al momento de realizar su solicitud, no obstante a la información del formulario de registro sanitario aprobado.
- Este trámite es solicitado exclusivamente por la web con pago de
- La solicitud debe ser realizada por el titular o representante del producto
- El solicitante debe poseer el formulario de solicitud firmado y sellado por la empresa, para enviar el certificado en la Ventanilla Única de Servicios
- Se recomienda un trámite CTU de productos con modificaciones al régimen en proceso
- No se emiten Certificados de Libre Venta a:
 - 1) Productos con riesgo de toxicidad de elevada, que en breve se encuentre en proceso de inscripción
 - 2) Productos o establecimientos con procesos sancionados en el Departamento de Vigilancia Sanitaria de esta dirección

Tiempo de respuesta: Sete (7) días

Example of Product Certification/Ministry of Health
Effective since November 07, 2016

	DIRECCION GENERAL DE MEDICAMENTOS, ALIMENTOS Y PRODUCTOS SANTARIOS	Código:	DIGEMAPS-RS-LI-0322
		Versión:	001
	Lista de Requisitos para Certificación de Productos en Línea	Fecha de revisión:	07 de noviembre 2016

Requisitos generales y administrativos

1. Tener el formulario digital con los datos requeridos.
2. Poder Certificado de Buenas Prácticas de Manufactura vigente.
3. Rembo de pago.

Instrucciones para el uso del servicio:

- El recibo de pago debe emitido por el MSP.
- Es imprescindible *validar los datos de la Certificación al momento de realizar su solicitud*, en relación a la(s) informada(s) de o los certificado(s) de registro sanitario aprobado.
- Este trámite es solicitado exclusivamente por la web gub.uy/gps/ps
- El solicitante debe presentar el formulario de solicitud firmado y sellado con el recibo de pago, para retirar el certificado en la Ventanilla Unidad de Servicios.
- Solo se aceptan 10 productos por certificación
- No se emiten Certificaciones a:
 - Productos con fechas de tres meses de vigencia, que no hayan suscritos su solicitud de renovación
 - Productos o establecimientos con procesos abiertos en el Departamento de Vigilancia Sanitaria, Inspección y Control de esta dirección.

Tiempo de respuesta: Cinco (5) días

Example of Renewal Application for Sanitary Registration of Pre-packaged Imported Dairy Products/Ministry of Health

Effective since July 27, 2016

	DIRECCION GENERAL DE MEDICAMENTOS, ALIMENTOS Y PRODUCTOS SANITARIOS	Código:	DIGEMAPS-RS-LI-081
	Requisitos de Solicitud de Renovación Registro Sanitario de Productos Lácteos Pre-envasados-Productos Importados	Versión:	001
		Fecha de Revisión	27 Julio 2016

Este formulario debe ser llenado de forma digital

Nombre comercial/Nombre del Producto: <small>(Tal como se encuentra etiquetado)</small>	
Categoría de producto: <input type="checkbox"/> Leche fluida <input type="checkbox"/> Fermentados <input type="checkbox"/> Queso <input type="checkbox"/> Crema <input type="checkbox"/> Leche en polvo <input type="checkbox"/> Otros (especifique) _____	
Nombre y dirección del solicitante del registro sanitario del producto:	
Nombre del fabricante del producto (Razón Social):	Dirección del Fabricante/ País de origen:
Acondicionador/Envasador del producto (Si aplica):	
Nombre del Representante legal	Cédula/ RNC del Representante legal
Correo electrónico /Teléfono del Representante legal:	Persona de contacto/ Número de teléfono/Correo electrónico:
Presentación(es) del producto a comercializar:	Presentado bajo la forma: <small>(corresponde al estado físico del producto)</small>
Envase(s) primario del producto: <small>(corresponde al envase que se encuentra en contacto directo con el producto)</small>	Características y/o especificación del o los envase (s) primario(s), debe especificar peso/volumen:
Observaciones del producto (opcional):	
Note: En caso de modificación de alguna información del producto con respecto a lo registrado deberá presentar los trámites correspondientes.	

	DIRECCION GENERAL DE MEDICAMENTOS, ALIMENTOS Y PRODUCTOS SANITARIOS	Código:	DIGEMAPS-RS-IJ-081
		Requisitos de Solicitud de Renovación Registro Sanitario de Productos Lácteos Pre-envasados-Productos Importados	Versión:
			Fecha de Revisión

Los expedientes deben ser presentados encuadrados en espiral por cada producto a registrar y, la documentación debe estar en el mismo orden que se encuentran los requerimientos a continuación:

Requisitos generales, administrativos y de calidad	Solicitante	
	Si	N/A
1. Copia del Certificado de Registro Mercantil del representante legal.		
a) Legible		
b) Vigente		
c) En caso de que sea una persona física anexar copia de cédula.		
2. Copia del certificado de registro sanitario con 3 meses de anticipación a la fecha de vencimiento.		
a) Legible		
3. Fórmula cualitativa y cuantitativa del producto en original y copia.		
a) Firmada por el personal responsable del fabricante o titular.		
4. Descripción de la elaboración del producto (línea de flujo).		
a) Incluye todos los pasos y procesos desde la elaboración del producto hasta obtener el producto final.		
5. Certificado de Venta Libre original expedido por la autoridad competente del país de origen.		
a) Vigente (Si no tiene fecha de vigencia se tomará como validez dos (2) años después de su emisión)		
b) Debe dar constancia explícita de que el producto cuyo registro se solicita es vendido y consumido legalmente con mismo nombre y fórmula en el país de su origen o elaboración.		
c) Debidamente apostillado o legalizado por el Ministerio de Relaciones Exteriores.		
d) Debe de declarar el fabricante del producto.		
e) En caso de que el nombre del producto declarado en el Certificado de Libre Venta sea diferente al declarado en el expediente, se deberá presentar declaración jurada emitida por el titular, debidamente legalizada indicando que se corresponde al mismo producto con cambio de nombre y con la misma composición.		
f) En caso de estar en un idioma diferente al español debe estar traducido por un intérprete judicial, la cual debe estar debidamente legalizada.		
6. En caso de maquila, fabricación de un producto para una empresa nacional, debe anexar:		
6.1 Certificado de exportación		

	DIRECCION GENERAL DE MEDICAMENTOS, ALIMENTOS Y PRODUCTOS SANITARIOS	Código:	DIGEMAPS-RS-LI-081
	Requisitos de Solicitud de Renovación Registro Sanitario de Productos Lácteos Pre-envasados-Productos Importados	Versión:	001
		Fecha de Revisión	27 Julio 2016

a) Incluye el nombre del o los producto (s) a fabricar.			
b) Vigente.			
c) Apostillado o legalizado por el Ministerio de Relaciones Exteriores.			
d) En caso de estar en un idioma diferente al español debe estar traducido por un intérprete judicial, la cual debe estar debidamente legalizada.			
Nota: El certificado de exportación (debe declarar el responsable de la fabricación del producto y el cumplimiento de las normativas sanitarias) puede ser sustituido por un documento equivalente emitido por la autoridad competente del país de origen.			
Nota: Si la relación fabricante titular se establece en el certificado de exportación no será necesario cumplir con el requisito 6.2			
6.2 Contrato de fabricación			
a) Incluye el nombre del o los producto (s) a fabricar.			
b) Vigente.			
c) Apostillado o legalizado por el Ministerio de Relaciones Exteriores.			
d) En caso de estar en un idioma diferente al español debe estar traducido por un intérprete judicial, la cual debe estar debidamente legalizada.			
7. Poder emitido por el titular del producto/Acuerdo de Distribución hacia el Representante legal en el país.			
a) Nombre del representante en el país.			
b) Vigente. (Si no tiene fecha de vigencia se tomará como validez dos (2) años después de su emisión).			
c) Apostillado o legalizado por el Ministerio de Relaciones Exteriores.			
d) En caso de estar en un idioma diferente al español debe estar traducido por un intérprete judicial, la cual debe estar debidamente legalizada.			
8. Formato de etiqueta, que cumpla con las directrices NORDOM 53:	Si	N/A	
a) Nombre del alimento.			
b) Marca registrada del producto.			
c) Lista de ingredientes del producto.			
d) Coadyuvantes de elaboración y transformación de aditivos alimentarios.			
e) Contenido neto/ peso escurrido del producto.			
f) Nombre y dirección del fabricante, envasador, distribuidor, importador o exportador del alimento.			
g) Acápite número de Registro Sanitario.			
h) País de Origen.			
i) Acápite de número identificación del lote de fabricación.			

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j) Fecha de duración mínima del producto (Acápites de fecha de caducidad).		
k) Instrucciones para la conservación.		
l) Instrucciones para su uso (si aplica).		
m) Etiquetado cuantitativo de los ingredientes (si aplica).		
n) Declaración de alimentos irradiados (si aplica).		
o) En español, en caso de estar en otro idioma, deberá emplearse etiqueta complementaria que contenga toda la información obligatoria en español.		
Nota: Si se trata de especias y de hierbas aromáticas, las unidades pequeñas en que la superficie más amplia sea inferior a 10 cm. podrán quedar exentas de los requisitos estipulados en las sub secciones 8 (e), 8 (j) al 8 (l).		
9. Para productos a ser analizados por el Laboratorio Nacional de Salud Pública Dr. Defilló.	Si	N/A
a) Tres (3) muestras del producto tal y como se va a vender en el mercado ¹ .		
* Cada muestra debe contener mínimo:		
Si es sólido 200 gr		
Si es líquido 250 ml.		
* Para productos Tetrapack, se deben depositar 4 muestras		
Si es sólido 200 gr		
Si es líquido 250 ml.		
* Para productos enlatados se debe depositar 4 muestras		
Si es sólido 200 gr		
Si es líquido 250 ml.		
b) Las muestras a depositar se corresponden a un mismo lote.		
c) Las muestras deben estar vigentes.		
¹ Las muestras a depositar pueden corresponder a cualquiera de las presentaciones del producto, pero del mismo lote. En el caso de que las muestras individuales tengan un peso o volumen menor al contenido mínimo, deberán presentar la cantidad de muestras necesarias para completar el mismo.		
d) Expediente analítico que incluya :		
Copia de la Formula cuali-cuantitativa del producto		
Copia de las Artes de Etiquetas presentadas para fines de evaluación		
Copia de la declaración jurada con el nombre a comercializar del producto (si aplica) ver punto 5 (e)		
10. Para productos a ser analizados por la Junta Agroempresarial Dominicana (JAD)/ Instituto de Investigación de Biotecnología e Industria (IIBI).	Si	N/A



DIRECCION GENERAL DE MEDICAMENTOS, ALIMENTOS Y PRODUCTOS SANITARIOS Requisitos de Solicitud de Renovación Registro Sanitario de Productos Lácteos Pre-envasados-Productos Importados	Código:	DIGEMAPS-RS-LI-081
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a) Comprobante original de la aceptación de muestras por parte de la JAD/IIBI. (No se aceptaran certificados de análisis emitidos previo al depósito del expediente)		
b) Una (1) muestra control, la misma se corresponde con el lote de la muestra depositada en el JAD/IIBI		
II. Recibo por valor de cuatro mil pesos (RD\$4,000.00), por cada producto a registrar mediante dos (2) cheques certificados a favor del Ministerio de Salud Pública, divididos de la siguiente forma, uno por valor de dos mil cuatrocientos pesos (RD\$2,400.00) y otro por mil seiscientos pesos (RD\$1,600.00).		

El solicitante del registro está obligado a entregar la documentación que establece los requisitos establecidos en la legislación vigente de acuerdo al tipo y categoría del producto y DECLARA que la información anteriormente descrita es verídica y coincide exactamente con la adjuntada.
 La DIGEMAPS puede cancelar el trámite si se comprueba incumplimiento o falta de veracidad en la información entregada.

Solicitante	Responsable	
	Firma	Fecha

Observaciones:

Ventana Única de Servicios	Supervisado por:	
	Firma	Fecha

Costo del servicio: RD\$ 4,000.00
 Tiempo de respuesta: 60 días hábiles

For further information, direct questions to:
Office of Agricultural Affairs (OAA)
Foreign Agricultural Services /US Department of Agriculture (FAS/USDA)
US Embassy Santo Domingo, Dominican Republic
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 Tel.: (809) 567-7775; Santo Domingo, D.N. 10605
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