



## INFOCARD ELANBiz

### Sanitary Registration of Food and Beverages in Peru<sup>1</sup>

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**The purpose of this infocard is to provide details on the main requisites for the registration of commercialized food and beverages in Peru**

This infocard describes the conditions in force for obtaining the documents proving **sanitary registration for both domestic and imported products**. This is useful for European companies that wish to export or invest in Peru. The following questions address what the sanitary registry is and how it works.<sup>2</sup>

#### What is the Sanitary Registration of Food and Beverages for Human Consumption?

It is a document that **authorizes a natural or legal person to manufacture, package, import and market** products for human consumption in Peru. It is a certificate which confirms that food and/or beverages are harmless<sup>3</sup>.

The sanitary registration is regulated by the Ministry of Health<sup>4</sup> through the General Directorate for Environmental Health (DIGESA).<sup>5</sup> DIGESA regulates the technical, regulatory, environmental and health oversight and control aspects of food for human consumption (produced locally or abroad). The exceptions to DIGESA's mandate are: food made from industrialized fisheries and aquacultures (the responsibility of SANIPES)<sup>6</sup>. Primary food processing products such as fruits and vegetables (under the National Agricultural Health Service - SENASA ([www.senasa.gob.pe](http://www.senasa.gob.pe))) and products with health properties (under the General Directorate for Medicines, Supplies and Drugs – DIGEMID [www.digemid.minsa.gob.pe](http://www.digemid.minsa.gob.pe)).

DIGESA's Sanitary Registration and Health Certification Division assesses compliance with standards and requirements for the grant of the Certificate of Health Registration for Industrialized Foods and

<sup>1</sup> The information contained in this infocard is of a general nature. For more detailed information and commercial promotion events, as well as possible business contacts, please contact the Commercial Offices of the Member States and the bilateral Chambers in Lima.

<sup>2</sup> For dairy, check the specific infocard on Dairy Products.

<sup>3</sup> Art. 103 of the Rules of Procedure regarding the Vigilance and Sanitary Control of Food and Beverages, passed by Supreme Decree N 007-98-SA.

<sup>4</sup> [www.minsa.gob.pe](http://www.minsa.gob.pe)

<sup>5</sup> [www.digesa.minsa.gob.pe](http://www.digesa.minsa.gob.pe)

<sup>6</sup> [www.sanipes.gob.pe](http://www.sanipes.gob.pe)



Beverages (domestic or imported). It also produces a unique coding system, subject to health surveillance and control.<sup>7</sup>

## Which Products are Subject to Registration?

The products which require Sanitary Registration by DIGESA are:

PRODUCT	IN CHARGE OF DIGESA Sanitary Registry	EXAMPLES
Primary food processing products for human consumption	<b>NO</b>	- Fruits and vegetables - Eggs - Meat
Industrialized products for human consumption	<b>YES</b>	- Oil - Wine - Cookies - Beverages in general
Products with health properties	<b>NO</b>	- Herb products - Nutritional supplements - Medicine
Fish or aquaculture products	<b>NO</b>	- Fish and seafood - Fish flour

## What is the Procedure for the Sanitary Registration?

The **importer** must apply for the sanitary registration of products for import. Previously, importers had to register with the **Single Taxpayer Registry (RUC)**, a registry in charge of the Tax Administration.<sup>8</sup>

The process of sanitary registration is carried out entirely online using the Web Platform "[Single Window for Foreign Trade \(VUCE\)](#)"<sup>9</sup>. To start the process, the importer must have a Single Foreign Trade Application (SUCE) number<sup>10</sup>. Otherwise, the procedure must be carried out with the corresponding receipt from the bank.

According to Article 105° of the Rules of Procedure for Oversight and Sanitary Control of Foods and Beverages [Supreme Decree N° 007-98 – SA](#) duly amended by [Supreme Decree N° 004-2014-SA](#) (hereinafter the "**Rules of Procedure**") the requisites for applying for sanitary registration are:<sup>11</sup>

<sup>7</sup> DIGESA is not in charge of the registration of nutritional supplements and/or dietary products in the Sanitary Registry. That is within DIGEMID's mandate (Supreme Decree N° 016-2011-SA)

<sup>8</sup> All people who carry out economic activities in Peru are subject to taxation whether domiciled or not and must register with the Single Taxpayer Registry (RUC); including importers. See National Superintendence of Customs and Tax Administration – SUNAT: <http://www.sunat.gob.pe/>

<sup>9</sup> Single Window for Foreign Trade. Website through which procedures related to foreign trade and sanitary registration are carried out, among others [www.vuce.gob.pe](http://www.vuce.gob.pe).

<sup>10</sup> Source: Article 105 of Supreme Decree N° 007-98-SA.

<sup>11</sup> See <http://www.digesa.minsa.gob.pe/expedientes/detalles.aspx?id=28>



- **Name or company name, address and Single Taxpayer Registry (RUC) number** of the natural or legal person applying for registration.
- **Name that reflects the true nature of the product<sup>12</sup>, comercial name or brand** of the product applying for sanitary registration.<sup>13</sup>
- **Name or company name, address and country of manufacturer** if it applies.
- **Address of the manufacturing plant** if it applies.
- **Results of physicochemical and microbiological analyses** of the finished product; processed and issued by a laboratory accredited by the [National Institute of Quality - INACAL](#) or another accrediting body of a foreign country with international recognition, party to the Mutual Recognition Arrangement of [ILAC \(International Laboratory Accreditation Cooperation\)](#) or the IAAC (Inter American Accreditation Cooperation).<sup>14</sup>
- **List of ingredients and quantitative composition of additives** identifying the latter by their generic name and international numerical reference (GSFA Code).
- Preservation and storage conditions.
- **Data on the packaging used** considering type, material and presentation.
- **Shelf-life of the product** under normal preservation and storage conditions.
- **Production lot identification system** (for traceability and decoding purposes).
- **Directoral Resolution Number for Technical Validation Certificate of the HACCP Plan** or General Principles of Hygiene, correspondingly.
- **Labeling Draft** as established by Article 117° “Content of the labels” of the “Rules of Procedure concerning the Oversight and Sanitary Control of Food and Beverages”, passed by Supreme Decree N° 007-98-SA. According to the above article, the content of the labels must adhere to the provisions of the Peruvian Metrological Norm for the Labelling of Packaged Products and contain at the very least the following information:
  - a) Name of the product
  - b) List of ingredients and additives used in the manufacture of the product
  - c) Name and address of the manufacture
  - d) Name, company name and address of the importer, which may be added in a separate label

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<sup>12</sup> Codez Stan N° 01-1985 and Law N° 29571.

<sup>13</sup> The composition of the product must be considered, as well as the CODEZ STAN 1-1985

<sup>14</sup> Concerning food with special regimes, they must submit the results of the bromatological analysis. Food for special regimes is listed under Article 6.2, section IX of the NTS N° 071-MINSA/DIGESA-V.01. [“Norma sanitaria que establece los criterios microbiológicos de calidad sanitaria e inocuidad para los alimentos y bebidas de consumo humano”](#)



- e) Sanitary Registration Number
  - f) Date of expiry; when the Codex Alimentarius deems it necessary for the product or when Peruvian sanitary law is applicable
  - g) Batch code or key
  - h) Special conditions for preservation, if applicable.
- **Certificate of Free Commercialization and/or Certificate of Use** issued by the competent authority of the country of the manufacturer (original and copy) when the food or beverage is imported. This certifies that the product is freely marketed in its country of origin and that it is manufactured in a plant that complies with the Rules of Procedure.

The sanitary registration is done **according to product or group of products and manufacturer**; only one product or group of products can be registered per file.<sup>15</sup> For purposes of definition, products with the **same qualitative composition of basic ingredients** and which share the **same food additives** are considered to belong to a group of products. Thus, each flavored product in a group must have its own registration. Additionally, concerning foods and beverages subject to special regimes, their nutritional properties must be listed.

## How do you Renew, Update or Amend the Sanitary Registration?

The sanitary registration has a validity of **five years** from the date of issuance. The registration may be renewed through the [VUCE](#) by an application submitted by the beneficiary of the registration between sixty and seven business days before its expiry date. Registrations whose renewal isn't initiated seven days to expiry will expire automatically once the period covered by the previous registration is over. Any request submitted after the aforementioned deadline shall be treated as an application for a new sanitary registration.

The re-registration with the sanitary registry is subject to the same conditions, requisites and deadlines for the initial registry. The validity of such re-registration shall be counted from the date of expiry of the registration whose renewal is requested. If there are samples of the product still on the market yet the registration expired without the beneficiary having applied for a renewal, they shall have to be recalled by the beneficiary within ninety calendar days. If there is no compliance with the above, the products will be confiscated and the public will be informed that the product lacks registration.

In accordance with Article 109 of Supreme Decree N° 007-98-SA, the beneficiary must request the update and amendment of the sanitary registry in the event that the product or group of products, in the registry, undergo any modifications or change affecting the information, data and conditions under which the registry was issued. This update or amendment must be communicated in writing to DIGESA at least seven business days before it becomes effective. Importers must communicate such updates

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<sup>15</sup> Art. 104 of the Rules of Procedure for Oversight and Sanitary Control of Food and Beverages, passed by Supreme Decree N° 007-98-SA



or amendments before the import process, attaching documents which support or evidence such changes.

A product is considered to have changed nature in the following cases:

- When an ingredient or additive not initially declared in the registry is added to the product;
- When an ingredient initially declared in the registry is withdrawn;
- When an additive is replaced by another that does not have the same technological function, as established by the CODEX STAN 192: 1995 and its corresponding amendments.

## What are the Recommendations for Imported Products?

We recommend the following:

- Review the specific sanitary regulations currently in force according to the type of product imported i.e. the Salt Fortification Law, the Rules of Procedure for Water Quality for Human Consumption (Supreme Decree N° 031-2010-SA). The rules of procedure for Infant Foods (Supreme Decree N° 009-2006-SA), Bread, Biscuitry and Bakery Products (Technical Health Regulation N° 088-MINSA/DIGESA-Vo01) and Ministry Resolution N° 1020-2010/MINSA).
- All **documents issued abroad** must not be over **one year old** from the date of issuance. The documents must have a Spanish translation.
- Concerning the import of foods whose sanitary registration is ongoing, the application itself shall not be considered to be a granted sanitary registration. The importer must wait until their registration request has either been granted or denied.
- Check [DIGESA](#)'s website for a **list of competent authorities** who may issue the Certificate of Free Sale in the country of origin of the imported product. Where the competent authority cannot be identified in the DIGESA list, the applicant must submit a document issued by the competent authority in the country of origin in accordance with its laws.

## Other Relevant Provisions: Ad Warning Labelling (health octagons)

On 17 June 2019 the "[Manual of Advertisement Warnings](#)"<sup>16</sup> entered into force. The document establishes the obligation to include public warnings in the shape of an octagon on all processed foods whose content of sodium, sugar, saturated fats and trans fats exceeds the technical parameters for healthy processed foods.<sup>17</sup> This obligation applies to all natural and legal persons who market, import, provide and manufacture processed foods, as well as to whoever advertises such products.<sup>18</sup>

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<sup>16</sup> The Manual was approved within the framework of the provisions established in the [Law N° 30021, Law for the Promotion of Healthy Nutrition for Children and Adolescents](#), and its [Rules of Procedure, passed by Supreme Decree N° 017-2017-SA](#).

<sup>17</sup> The technical parameters are established in Article N° 4 of the Rules of Procedure of the Law, passed by Supreme Decree N° 017-2017-SA.

<sup>18</sup> Article 2 of the Law N° 30021.



As for the content of the octagon advertisement warnings, these must include the corresponding warning depending on whichever applies:

- **HIGH IN SODIUM:** Avoid its excessive consumption – Ministry of Health.
- **HIGH IN SUGAR:** Avoid its excessive consumption – Ministry of Health.
- **HIGH IN SATURATED FATS:** Avoid its excessive consumption – Ministry of Health.
- **CONTAINS TRANS FATS:** Avoid its consumption – Ministry of Health.

These ad warnings must be printed in the front label of the product.<sup>19</sup> Nevertheless, the use of adhesives to display the warnings will be allowed **until 17 June 2020** for big and medium companies<sup>20</sup> and **until 31 March 2022** for micro and small enterprises.<sup>21</sup> **After these deadlines, the advertisement warnings will have to be printed on the label.** The European Commission has formally requested the Peruvian government to allow the indefinite use of adhesives.

## Useful Links

- Codex Alimentarius:  
<http://www.digesa.minsa.gob.pe/Codex/que-es-el-codex.pdf>
- DIGEMID: General Directorate of Medicines, Consumables and Drugs:  
<http://www.digemid.minsa.gob.pe/>
- SENASA: National Service of Agrarian Health:  
<http://www.senasa.gob.pe/senasa/>
- DIGESA: General Directorate of Environmental Health:  
<http://www.digesa.minsa.gob.pe/>
- Sanitary Registry of Foods  
[http://www.digesa.minsa.gob.pe/Expedientes/Consulta\\_Registro\\_Sanitario.aspx](http://www.digesa.minsa.gob.pe/Expedientes/Consulta_Registro_Sanitario.aspx)
- Single Window for Foreign Trade (E): MANUALS – RESTRICTED MERCHANDISE:  
<https://www.vuce.gob.pe/documentacion.html>
- Sanitary Regulation that establishes the microbiological criteria of sanitary control and safety for foods and beverages destined for human consumption:  
<http://www.digesa.minsa.gob.pe/NormasLegales/Normas/RM591MINSANORMA.pdf>

**This infocard has been prepared by the experts of the EU MAT Peru Project, which provides updated information for the platform Elanbiz**

<sup>19</sup> Article 15 of the Rules of Procedure. Passed by [Supreme Decree N° 017-2017-SA](#).

<sup>20</sup> Sub-section 8.3 of the Eighth Complementary Provision of [Supreme Decree N° 015-2019-SA](#).

<sup>21</sup> Sub-section 8.5 of the Eighth Complementary Provision of [Supreme Decree N° 015-2019-SA](#).

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