PRACTICAL MANUAL FOR IMPORTING AND EXPORTING PROCESSED FOODS











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First edition 2022

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September, 2022

TABLE OF CONTENTS

ACRONYMS PRESENTATION

11 GENERAL INFORMATION ON PROCESSED FOOD MONITORING

- 1.1 Processed food health monitoring
- 1.2 DIGESA as the authority for food health monitoring
- 1.3 Why are processed foods considered restricted merchandise?
- 1.4 How is authorized the selling of processed foods?

PROCESSED FOOD IMPORTING

- 2.1 Previous licenses and procedures for processed food importing
- 2.2 Processed food importing stages

PROCESSED FOOD EXPORTING

- 3.1 Previous procedures for processed food exporting
- 3.2 Processed food exporting stages

4 DIGESA PROCEDURES RELATED TO FOREIGN TRADE – TUPA 30 TO 35

- 4.1 Health Registration (TUPA 30)
- 4.2 Changes to the Food Health Registration (TUPA 31)
- 4.3 Imported Product Health Registration Certificate (TUPA 32)
- 4.4 Free Sale Certificate (CLV) for human consumption of foods manufactured and/or prepared in the country (TUPA 33)
- 4.5 Official Health Certificate for exporting human consumption goods (TUPA 34)
- 4.6 Official Technical Validation of the HACCP Plan (TUPA 35)

REFERENCES

ACRONYMS

MRA	Mutual Recognition Agreements
GMP	Good Manufacturing Practices
CIF	Cost, Insurance, and Freight
CLV	Free Sale Certificate
CODEX	Codex Alimentarius
CSOE	Official Health Certificate for Exporting Human Consumption Foods
DAM	Customs Merchandise Declaration
DIGESA	General Directorate of Environmental Health and Food Safety
FBD	Foodborne diseases
FAO	Food and Agriculture Organization of the United Nations
FDA	The United States Food and Drug Administration
FEMA	Flavor and Extract Manufacturers Association
FOB	Free on Board
НАССР	Hazard Analysis Critical Control Points
IAAC	Inter-American Accreditation Cooperation
ILAC	International Laboratory Accreditation Cooperation
VAT	Value Added Tax
IPM	Municipal Promotion Tax
MINCETUR	Ministry of Foreign Trade and Tourism
MINSA	Ministry of Health
NTP	Peruvian Technical Standard
OWHO	World Health Organization
PGH	General Principles of Hygiene
PHS	Hygiene and Health Program
RUC	Single Taxpayer Number
SANIPES	National Organization of Fishing Health
SENASA	National Service of Agricultural Health
SUCE	Single Foreign Trade Application
SUNAT	National Superintendence of Customs and Tax Administration
TFO	Trade Facilitation Office (TFO) Canada
TUPA	Uniformed Administrative Procedure Text
UIT	Tax Unit
VUCE	Single Window for Foreign Trade

5

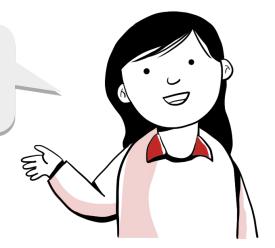
PRESENTATION

The Global Alliance for Trade Facilitation project, executed by the Trade Facilitation Office (TFO) Canada, promotes the improvement of transparency and predictability practices at the General Directorate Environmental Health (DIGESA), a technical-regulatory body of the Ministry of Health, regarding the issuance of licenses related to processed food importing and exporting. The project includes three components. One of them consists of preparing didactic instruments that facilitate understanding of procedures and services in charge of DIGESA.

In this sense, said component has prepared the *Practical Manual for Importing* and *Exporting Processed Foods* to didactically explain the requirements, conditions, and procedures related to exporting and importing processed foods so that companies can easily get health authorizations to manufacture, commercialize, import, and export processed foods.

This manual describes the fundamentals of processed food monitoring simply through 4 sections: the first covers the general aspects of monitoring, competent authorities, and required authorizations; the second and third contains those applicable controls to importing and exporting processed foods; the fourth describes aspects to consider for dealing with each of the procedures related to import and export activities.

If you have any questions on this subject, you can consult the **DIGESA** website of the **Ministry of Health**: www.digesa.minsa.gob.pe



GENERAL INFORMATION ON PROCESSED FOOD MONITORING

1

This section provides general information on how to monitor processed food quality and safety for importing and exporting.

1.1 Processed food sanitary controls

When discussing sanitary food control, we refer to the governmental monitoring of food production and trade as part of the consumer's health protection policy. The likelihood of foodborne diseases (FBD) is a factor that can put consumer's health at risk, since a single case can spread to several people and even get an entire population sick. This situation may impact domestic trade and food exports.

Consequently, any food for human consumption must meet hygiene and sanitary standards that guarantee their safety; that is, that does not cause harm to people who ingest them.

I only want to sell safe products!

That's what you must do! That's the best practice to avoid adverse results on the consumer's health.





Given the growing innovation in food manufacturing and its cross-bordertrade potential, a set of international standards, compiled in the *Codex Alimentarius*, has been approved; thus, setting theguidelines and practices to ensure food safety and quality.



VOCABULARY

Safety: According to the Food Safety Law (approved by Legislative Decree 1062), safety is the guarantee that food will not harm the consumers when it is prepared and/or consumed according to its intended use.

The Codex Alimentarius is a set of standards, guidelines, and codes of practice approved by the Codex Alimentarius Commission (CAC). This Commission is the core element of the Joint FAO/WHO Food Standards Program and was established by the Food and Agriculture Organization of the United Nations. (FAO¹) and the World Health Organization (WHO), to protect consumer health and promote fair practices in the food trade.

 $^{^{1}}$ Food and Agriculture Organization of the United Nations.



FOR MORE INFORMATION

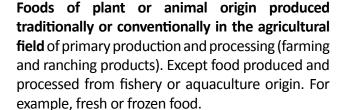
please visit: https://www.fao.org/fao-who-codexalimentarius/es/

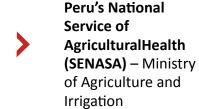
In Peru, food safety controls are conducted by three technical-regulatory agencies, depending on the type of food, as described below:

FOOD TYPE

REGULATORY AUTHORITY













Water-extracted species, intended for human or animal consumption, or as raw material for industry (fishery origin food) and fishery products, born and raised under control or caught during the juvenile phase and kept in captivity until reaching commercial sizes, and put into the market as food products (food from aquaculture).

National
Organization of
Fishing Health
(SANIPES) - Ministry
of Production







Industrial foods (also called processed foods or manufactured foods). These are foods and beverages transformed from raw materials of plant, animal, or mineral origin(or a combination of them) using physical, chemical, or biological procedures (or a combination of these) and contain additives to obtain food for human consumption.

of Environmental
Health and Food Safety
(DIGESA) - Ministry of
Health



VOCABULARY

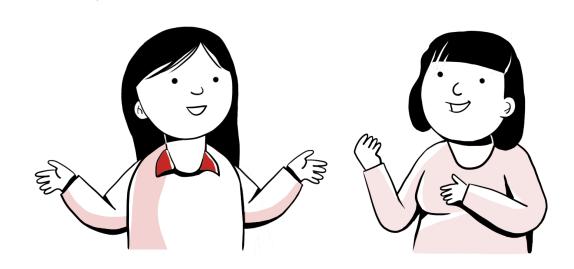
Primary production: The stages of the food chain up to, for example, harvesting, slaughtering, hunting, milking, including fishing.

Primary processing: It is the phase of the food chain applied to the primary production of food not subject to transformation. This phase includes dividing, splitting, selecting, slicing, boning, mincing, peeling or skin, shreding, cutting, cleaning, defatting, husking, grinding, chilling, freezing, quick freezing or thawing.

Did you know that additives are substances other than raw materials that are added to foods and beverages to improve their conservation conditions and preserve their nutritional values, safety, freshness, flavor, texture or appearance?

Yes, controlling authorities allow the use of the additives included in the list of additives allowed by the Codex Alimentarius and the FDA.

Does it also control the use of additives?



In the case of flavorings, only those previously accepted by the Food and Drug Administration of the United States of America, the European Union, and the Flavor and Extract Manufacturers Association, also of the United States of America are allowed.



FOR MORE INFORMATION

Please visit:

https://www.fda.gov/ | https://www.femaflavor.org

1.2 DIGESA as the Food Safety Control Authority

DIGESA is the technical-regulatory agency of the Ministry of Health in charge of regulating and monitoring the safety of processed foods for human consumption, excluding fishery and aquaculture food.

DIGESA controls the facilities that manufacture and fractionate foods, as well as processed food itself. For this reason, companies are in the obligation to comply with sanitary standards that ensure the product safety they want to commercialize

Also, after obtaining the authorization, DIGESA will continue to exercise its control over your products through health surveillances or inspection activities

How should I verify my product's safety?

You can do it by complying with the procedures that DIGESA requires before authorizing its import, manufacture, and sale.

Also, after obtaining the authorization, DIGESA will continue to exercise its control over your products through health surveillances or inspection activities.



Four types of authorizations granted by DIGESA:

	LICENSE TYPE	LICENSE NAME
1	Autorization for MSEs that produce high-risk processed foods	Codex Alimentarius General Principles of Food Hygiene Certificate (TUPA MINSA 53)
2	License for the production of high- risk processed foods and/or when it is required to get the CSOE	HACCP Plan Official Technical Validation Certificate (TUPA MINSA 35)
3	License for the production or importation and commercialization of processed foods	Human Consumption Food Health Registration (TUPA MINSA 30)
4	License to import processed foods that have an active sanitary registration from a third party	Imported Product Health Registration Certificate (TUPA MINSA 32)

The fourth section in this manual provides specific information on these licenses.



VOCABULARY

Uniformed Administrative Procedure Text (TUPA): Synthesized document that provides relevant information for the company regarding all administrative procedures and services exclusively provided by public administration entities. Likewise, the textoffers to stakeholders complementary information such as: service locations, schedules, means of payment, contact information or notices. The authorities can only demand performance of procedures, presentation of requirements or payment of fees that are previously incorporated into the entity's TUPA. The TUPA cannot create procedures or requirements, only synthesize existing ones.



FOR MORE INFORMATION

Visit http://aplicativos.digesa.minsa.gob.pe/NormativaBuscador?ga=2.175492907.806112068.1660670848-666412454.1656954783

1.3 Why processed foods are deemed as restricted merchandise?

The monitoring of processed food imports and exports aims to reduce the risks of diseases, to guarantee the consumer's health, and generate trust in consumption. Thus, processed foods are considered restricted goods and require an authorization to enter and leave the country.



VOCABULARY

Restricted products: goods that require authorization by legal mandate from one or more public entities for its entry, transit, or exit from the national territory.

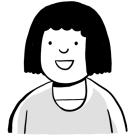
1.4 How is authorized the selling of processed foods?

Licenses to manufacture and sell food are obtained through administrative procedures approved by public entities. The requirements and deadlines for license issuance are specified in these procedures. Consequently, the procedures are incorporated into the Administrative Procedure Uniformed Texts (TUPA) and published on the entity's web portal.



The application to commercialize restricted goods is made to DIGESA, through the Single Window for Foreign Trade (VUCE). If the procedure is not in the VUCE, it is directly requested from DIGESA.

The information you need to start an administrative procedure is in the TUPA of the Ministry of Health.





The requirements demanded in each administrative procedure are organized **here**, as well as the term that each procedure lasts and the amount of the fee to be paid, among other aspects.

http://www.digesa.minsa.gob.pe/expedientes/tupas.aspx

PROCESSED FOOD IMPORTING

2

This section will provide you the guidelines as to the authorizations and procedures to start importing processed foods, as well as the stages involved in the importing process.

It is important to know the products you want to import and its characteristics such as:

- > Product features
- > Elaboration process
- Suppliers
- > Supply chain
- Conditions of packaging
- Preparation of the merchandise for its transportation, commercialization, customs procedure, etc.

Importation is a procedure carried out by Customs. When imports are goods intended to be consumed in the country is called "importation for consumption". Since processed foods are restricted goods, they require a pre-market authorization before entering the country. This authorization can be the Sanitary Registry or the Imported Product Sanitary Registry Certificate. If the product is processed and of animal origin, it is required the Export Certificate from the country of origin and the SENASA Inspection Report.

As an importer, it is crucial for you to know the tariff subheading of the product you wish to import and if it requires a Sanitary Registration. It is suggested to consult with DIGESA, experts, or customs agents with experience in importing processed foods.

For example, according to the current version of the Peruvian Customs Tariff (2022), fresh or chilled whole trout are classified under the tariff subheading 0302.11.00.00.



You can consult the Customs Tariff of Peru here:

https://www.sunat.gob.pe/orientacionaduanera/aranceles/2022/arancel-ad-2022.pdf

To find out if a product is a restricted merchandise, and therefore requires health registration, our legislation allows of the requesting of advance resolutions. However, this procedure is in its implementation stage. Meanwhile, to find out if the products are restricted, you can file a query at the DIGESA reception desk.

Keep in mind that customs legislation requires the intervention of an authorized customs agent to carry out import procedures at customs when the merchandise exceeds 2,000.00 USD of FOB value.





VOCABULARY

Tariff subheading: Standard numerical code assigned by the customs authority to each type of product subject to international trade, taking into account its physical, chemical, and technical characteristics, among others.

Advance resolutions: are binding opinions issued by Customs at user request, on specific details related to the goodsregarding their classification and origin, in preparation for their import or export.

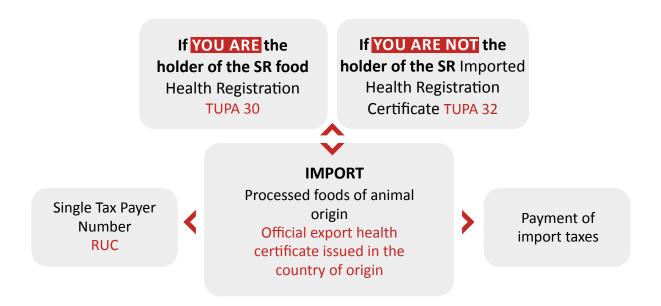
FOB: Acronym for Free On Board. Term used to agree in an international merchandise sale that the price refers to merchandise placed on board of the ship, with all expenses, duties, taxes and risks borne by the seller until the moment the merchandise has passed the ship's border, freight excluded.

CIF: Acronym for Cost, Insurance and Freight. This term is used for an international merchandise sale and refers to the price with freight paid and insurance covered

2.1 Previous authorizations and procedures for importing processed food

As observed, for the importation of processed foods, it is necessary that the importer has obtained the required authorizations.

The following is a summary table of licenses and procedures required to start importing processed foods:





Health Registration Certificate for Imported Products

Products manufactured abroad and imported must have a Health Registration -when the imported product is authorized for the first time- or an Imported Product Health Registration Certificate -when a product was previously registered by another person-.

One of the requirements to get the Health Registration is to have a Free Sale Certificate (CLV) issued by the authority in the country of origin.



FOR MORE INFORMATION

On the list of competent authorities to issue Free Sale Certificates visit: http://www.digesa.minsa.gob.pe/Orientacion/CLV/Autoridades-Competentes-CLV.pdf



Processed foods with portions of animal origin

If the processed food you wish to import is of animal origin, you must submit the Official Safety Certificate for Exports from the country of origin that certifies that the product complies with the safety and animal health requirements established by the competent authorities. This document will be checked during the physical inspection executed by SENASA at the points of entry.

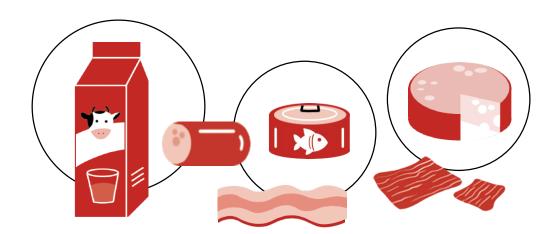


FOR MORE INFORMATION

On Export Health Certificate (CSOE) specimens per country of origin visit: http://www.digesa.minsa.gob.pe/Orientacion/Modelos_Certificados_ Importacion.asp



Examples of animal origin processed foods: Bacon, hams, sausages; pickled, dried, smoked, canned meat; pork/poultry fats; concentrated milk and cream; cheeses; fresh poultry egg yolks, etc.





FOR MORE INFORMATION

On Convention 004-2016-MINAGRI-DM and its annex that provides a list of processed foods with their subheadings, please go to:

http://www.digesa.minsa.gob.pe/convenios/CONVENIO_0004_2016 MINAGRI_DM.pdf



Single Tax Payer Number

If you are interested in importing foods into the national territory for its use or consumption, you need to establish a formal company. You must have a Single Taxpayer Number (RUC). Additionally, the importer must be domiciled in Peru, except in cases of simplified declarations.

Exceptionally, if you as importer do not hold a RUC, you can import using your National Identity Document, immigration card, passport or safe conduct, only in the case of:

- Occasional imports (up to 3 per year) whose FOB value per operation does not exceed one thousand US dollars (USD 1,000.00).
- A single annual import for an FOB value between one thousand (USD 1,000.00) and three thousand (USD 3,000.00).





Payment of import-related taxes²

You must make the following payments to import processed foods:

Duties or Ad-Valorem	0%, 6% and 11% on the CIF value, according to the tariff subheading of the product you are going to import.
Value Added Tax (VAT, IGV in Peru) & Municipal Promotion Tax (IPM)	18%
VAT / IGV perception Advance payment scheme	3.5%, 10% if there are irregularities in your RUC or 5% if you import used goods.



Remember that import duties are expressed in dollars of the United States of America.

² Superintendence Resolution 210-2004/SUNAT Article 3.

2.2 Importing stages for processed foods

Once you obtained the corresponding authorizations, registrations and/or certifications, you will be ready tocontinue with the customs import processed foods:



First stage: Forward the merchandise to a customs regime³



Once the merchandise arrives, there is a maximum period of 15 calendar days, counted from the day after the end of the unloading, to submit to the import regime for consumption. Importers forward goods through customs agents.

If the goods are not imported within the timeframe, they are deemed abandoned by losing ownership over the goods.



Second stage: Provide a number for the Customs Merchandise Declaration (DAM) of imports for consumption

Customs forwarding of the goods requires providing a number to a DAM. You must have the following documents:



- > Invoice, bill of sale, operator's document or other proof that represents the transfer of goods to a customer domiciled abroad, as applicable; or affidavit of value and description of the merchandise when there is no sale.
- > Transport Document: Bill of lading, waybill or air waybill or land waybill, depending on the means of transport to be used.
- Transportation Insurance, in case of insured merchandise.

For processed foods, you must have the certificate previously mentioned in 2.1 as follows:

- > Health Registration or Imported Product Health Registration Certificate.
- If the processed food to be imported is of animal origin, you must present the Official Health Certificate for Exports from the country of origin and comply with the health and animal health requirements established by the competent authorities.

Customs Regime is the legal destination that customs users declare for goods subject to customs control at the time of arrival, departure or transit. Each regime determines the benefits and legal obligations to be fulfilled by the declarant. The main customs regimes are Import for Consumption, Definitive Export, Temporary Admission for Re-export in the same condition, Warehousing, Transit and others



Third stage: Complete the importing procedure



Importing must be completed no later than 30 calendar days following the date the numbering of the DAM (deferred clearance) or 30 calendar days after the date of unloading completion (anticipated clearance), as appropriate.

Pay close attention because, in case the term expires, the importer can lose ownership of the goods due to legal abandonment and passes to the State.





VOCABULARY

Advance customs clearance: It is the customs clearance modality that allows numbering the import declaration before the arrival of the transport vehicle to our country.

Differed customs clearance: It is the customs clearance modality in which the import declaration is numbered when the transport vehicle is already in our country.

PROCESSED FOOD EXPORTING

3

In this section you will learn about the services provided by DIGESA for exporting processed foods, as well as the stages involved in the export process. As an exporter you must know the requirements on quality, packaging, labeling and health requirements demanded from the country of destination of the merchandise.

Final exporting⁴ of processed foods is not affected by the payment of any tax. However, as an exporter you will assume some operating expenses: port expenses, expenses in storage terminals, shipping agent expenses, consolidator or cargo agent, and customs agent expenses; which will depend on each particular operation and each company providing the service.

If the merchandise you are going to export exceeds USD 5,000.00 of FOB value, you must hire a customs brokernt to carry out the export procedure.

Keep in mind that customs legislation requires the intervention of an authorized customs agent to carry out export customs procedures when the merchandise to be exported exceeds USD 5,000.00 of FOB value.

If it is a lesser value, then it is not mandatory, only optional.





To send food to another country, you do not require health authorization from DIGESA. However, you must have a Single Taxpayer Number (RUC) and any previous certificates the country of destination may require.



Exceptionally do not have a RUC, you can import using your National Identity Document, immigration card, passport or safe-conduct, only in the case of:

- Occasional exports (up to 3 per year) whose FOB value per operation does not exceed one thousand US dollars (USD 1,000.00).
- ➤ A single annual export for an FOB value between one thousand (USD 1,000.00) and three thousand (USD 3,000.00)



Besides you do not require a specific authorization from DIGESA to carry out the export as such. You can even be exempted from the requirement of a Sanitary Registry if your product is manufactured only for export purposes. However, if the country of destination requires any of the documents mentioned later in this manual, as an exporter you have the option to request them from DIGESA.

⁴ Final exporting is the technical name for the customs regime pertaining to the departure of goods abroad for use or consumption outside the country.

3.1 Procedures previous to the exportation of processed food exporting

If the country of destination requires an export certificate to verify product safety, exporters must get the Official Health Certificate (CSOE) for Exporting Food for Human Consumption (TUPA 34).

http://www.digesa.minsa.gob.pe/expedientes/detalles.aspx?id=32

To get this certificate, you must have the HACCP Plan Validation Certificate (TUPA 35) that includes the production lines and product to be exported.

http://www.digesa.minsa.gob.pe/expedientes/detalles.aspx?id=34

In addition, depending on the request of the exporter, you need a Free Sale Certificate (CLV) of food for Human Consumption manufactured and/or processed in the country can be issued. (TUPA 33⁵), as long as the exporter already has the Health Registration for the product to be exported.

http://www.digesa.minsa.gob.pe/expedientes/detalles.aspx?id=31



Before exporting, find out about the benefits for promoting exports (refund of VAT via Balance in Favor of Exporters and Drawback).

Likewise, we recommend you to review the Trade Agreements signed between Peru and other countries so that you can take advantage of tariff preferences agreed with the country of destination. (www.acuerdoscomerciales.gob.pe).

To access these tariff preferences as an exporter you must demonstrate that your product originates from Peru. To do this, you'll need to get a Certificate of Origin before certifying entities delegated by the Ministry of Foreign Trade and Tourism Single Window for Foreign Trade VUCE, (Mincetur), which will be granted provided that you fulfill the requirements to that end.

⁵ For more information about these three certificates, check section 4.

3.2 Processed food exporting stages

Once you have obtained the certificates or records that are required in the country of destination to verify the safety of the product, you can continue the procedures at Customs to export processed foods:



First stage: Enter the merchandise in a Temporary Warehouse



The customs agent must enter the merchandise to a temporary warehouse in the primary customs zone⁶.



It is possible to ship directly from the premises of the person who exports, provided that the corresponding authorization process has been carries out at Customs.



Second stage: Provide a number to the Customs Merchandise Declaration (DAM) for Final Exporting



Customs forwarding of the goods requires providing a number to a DAM. To do so you must have the following documents:

- Invoice, bill of sale, operator's document, or other proof that represents the transfer of goods to a client domiciled abroad, or an affidavit of value and description of the merchandise when there is no sale.
- > Transport document: Bill of lading, waybill or air waybill or land waybill, depending on the means of transport to be used.
- > Other documents according to the kind of clearance, if applicable.



Third stage: Shipping of the merchandise



The goods must be shipped within 30 calendar days from the day following the date when the declaration is provided a number with. Otherwise, the customs declaration is canceled and the export is disallowed.

⁶ Place where merchandise pending authorization for transfer to the port by the customs authority is entered and temporarily stored.



Fourth stage: Complete the exporting procedure

The customs agent must regularize the export within 30 calendar days, following the date of the end of shipping. This will allow access to the tax or customs benefits applicable to the export, such as Balance in Favor of the Exporter and Drawback.



Before shipping the product abroad, coordinate with your client in the country of destination to determine if any authorization issued by the competent Peruvian authorities is necessary.

I will do so. In addition, I will ask if other requirements such as packing, labeling, etc, are to be fulfilled.







VOCABULARY

Drawback: This is the customs regime that allows obtaining refunding of a percentage of the FOB Export value of the goods, as a total or partial reimbursement of the customs duties that have been levied on the import of inputs that are incorporated or consumed when producing the exported goods. The Drawback rate has been 3% since 2019.

4 DIGESA PROCEDURES RELATED TO FOREIGN TRADE - TUPA 30 TO 35

This section presents the procedures related to foreign trade that are carried out at DIGESA.

DIGESA PROCEDURES ⁷	WHAT IS IT ALL ABOUT
Food Health Registration (TUPA 30)	It allows to manufacture, import and commercialize processed foods. It is granted for each product or group of products, and each manufacturer.
Changes to the Food Health Registration (TUPA 31)	 You can request kinds of changes: Administrative data updates (For example, owner/manufacturer data such as company name, or any transfer that is not related to safety) Change of the health conditions declared on the product or products.
Imported Product Health Registration Certificate (TUPA 32)	You can request this document if you are not the holder of a Health Registration and you wish to import and sell foods or beverages already registered in favor of a third party.
Free Sale Certificate (CLV) for human consumption of foods manufactured and/or prepared in the country (TUPA 33)	 This is an official document issued at stakeholder request, which certifies that a specific food is for free sale in the country which manufactured and exports the product. You need to have a Health Registry before you get the CLV.
Official Health Certificate for Exporting (CSOE) human consumption foods (TUPA 34)	 This is an official document issued at stakeholder request, according to the type of product and particular specifications pointed out by the exporter, for each clearance or shipment lot and country of destination. You request it for the entrance of a product to the country of destination. You require the HACCP Plan Official Technical Validation Certificate before you get the CLV.
HACCP Plan Official Technical Validation (TUPA 35)	Hazard Analysis Critical Control Points (HACCP) is a system that, focusing on critical control points, allows to identify, assess and control hazards that are significant to guarantee food safety. The HACCP Plan is the document prepared by each company under the HACCP System principles. Its Official Technical Validation is the process by which the authority verifies that the HACCP Plan elements are effective, efficient and applied according to the establishment's specific conditions and situations.

⁷http://www.digesa.minsa.gob.pe/expedientes/tupas.aspx

4.1 Food Health Registration (TUPA 30)

It is an authorization to manufacture, import and sell processed foods, granted for each product or group of products and each manufacturer.

A group of products is a set of products made by the same manufacturer, which have the same qualitative composition of basic ingredients that identifies the group and share the same food additives.

Samples with no commercial value of processed foods and those that are donated by foreign entities for charitable purposes do not require Health Registration.

Please check the Sanitary Directive approved by Ministerial Resolution 865-2020 / MINSA to know if an industrially processed food qualifies as a "sample without commercial value."

https://www.gob.pe/institucion/minsa/normas-legales/1293820-865-2020-minsa

Product presentation must not use pharmaceutical dosage means (capsules, tablets, pills, etc.).

RATE	8,48% UIT
RELATED / INVOLVED SERVICES	 Laboratory (reference amounts: S/ 180 - S/ 500 each, depending on the type of product or that of the company itself) In the following link, you will find the list of laboratories accredited by the National Quality Institute (INACAL): https://www.inacal.gob.pe/acreditacion/categoria/directorio-organismos-acreditados Notary fees Apostilled foreign documents, according to country of origin (for example, CLV) Expenses for delays/demurrage
REQUIREMENTS	 \$1. Request via VUCE (Single Request for Foreign Trade - SUCE) containing: Applicant details (name or corporate name, address and RUC) Product name and brand Manufacturer data (name or business name, country of manufacturing establishment) List of ingredients and additives in decreasing order (from highest to lowest percentage) Conservation and storage conditions Data of the container used Shelf life Lot identification system Physical-chemical and microbiological certificate⁸ issued by the manufacturer's quality control laboratory, by a laboratory accredited by the National Quality Institute (INACAL) or another accrediting body that has signed a Mutual Recognition Agreement (MRA), of the International Laboratory Accreditation Cooperation - ILAC) or the International Laboratory Accreditation Cooperation - ILAC) or the Inter-American Accreditation Cooperation (IAAC).

⁸ https://www.gob.pe/institucion/minsa/normas-legales/247682-591-2008-minsa

To find the list of laboratories accredited by the National Institute of Quality (INACAL), please go to:

https://www.inacal.gob.pe/acreditacion/categoria/directorio-organismosacreditados

RM 591-2008 MINSA

https://www.gob.pe/institucion/minsa/normas-legales/247682-591-2008-minsa

GENERAL CODEX REGULATION ON POLLUTANTS AND TOXINS IN FOOD AND FEED

https://www.fao.org/fileadmin/user_upload/livestockgov/documents/ CXS_193s.pdf

Likewise, they must comply with all the Microbiological Requirements. Therefore, both reports and results must be attached, they should not be older than one year and must comply with other legal specifications in R.M. 591-2008/MINSA, D.S. 007-98-SA, and the Codex Alimentarius for standards and the FDA, as applicable.

If, due to its nature, the product does not correspond to microbiological testing in a national standard and only the physicochemical test must be submitted, the provisions of the Codex Alimentarius must be taken into account, in the Codex Official Standards Texts section or, as a reference, what is established in the Peruvian technical standards (NTP) regarding the product in question.

Certificate of bromatological testing issued by a laboratory accredited by INACAL or another accrediting body that signs the MRA of ILAC or IAAC, when applicable.

In the case of products for special diets and infant foods, compliance with the specifications established in the following regulations must be accredited: Codex Alimentarius, Ministerial Resolution 451-2006/MINSA and DS 009-2006-SA.

https://www.gob.pe/institucion/minsa/normas-legales/251548-451-2006-minsa

https://www.gob.pe/institucion/minsa/normas-legales/251409-009-2006-sa

4 Labelling compliance affidavit according to Article 117 of Supreme Decree 007-98-SA.

http://www.digesa.minsa.gob.pe/Codex/D.S.007_98_SA.pdf

Certificate of Free Sale or Use issued by the competent authority of the country of origin or provenance, if it is an imported product. This certificate cannot be older than one year.

http://www.digesa.minsa.gob.pe/expedientes/detalles.aspx?id=31

DIGESA acknowledges CLVs issued by any of the authorities listed in: http://www.digesa.minsa.gob.pe/Orientacion/CLV/Autoridades-Competentes-CLV.pdf

REQUIREMENTS



EXAMPLE OF MICROBIOLOGICAL TEST FOR ANDEAN AND SWISS CHEESE

1.9 Quesos madurados (c majes, characato, saband amazónico, parmesano, otro	ía, dambo, go					
A canto microhiano	Categoria	Clase	n		Limite por	g
Agente microbiano	Calegoria	Clase	"	C	m	M
Coliformes	5	3	5	2	2 x 10 ²	10 ³
Staphylococcus aureus	8	3	5	1	10	10 ²
Listeria monocytogenes	10	2	5	0.	Ausencia /25 g	
Salmonella sp.	10	2	5	0	Ausencia /25 g	

For more information, please go to:

https://www.gob.pe/institucion/minsa/normas-legales/247682-591-2008-minsa http://www.digesa.minsa.gob.pe/orientacion/Infografia_tupa_29.pdf

EXAMPLE OF MICROBIOLOGICAL TEST FOR MARMALADE

XIV.6 Mermelada, jaleas y similares.						
Aporto migrahigno Catagorio Close a Limite por g					g	
Agente microbiano	Categoria	Clase	B.	·. :.	m	М
Mohos	3	3	. 5	1	10 ²	10 ³
Levaduras	3	3	5	1	10 ²	10 ³

To assign a correct name to your product, you can verify that its composition corresponds to a Codex standard. For example, to name your product as "jam" imust comply with the corresponding Codex standard. You can use the search engine or the Codex website

https://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/es/

In the Codex Texts, Official Standards, enter the word "jam" as a search criterion.

"3.2 Soluble Solids

The content of soluble solids for the finished products defined in Sections 3.1.2 (a) to (c), must be in all cases between 60 and 65% or higher. In the case of the finished product defined in Section 3.1.2 (d), the content of soluble solids must be between 40% - 65% or less".

This means that the content of soluble solids (°Brix) depends on the type of jam to be registered, and it is a test that must be submitted to get the health registration.

It must be taken into account that physicochemical criteria are only mandatory when the nature of the food must be demonstrated.

4.2 Changes to the Food Health Registration (TUPA 31)

Two kinds of changes can be requested:

- > Administrative data updates: data of the owner/manufacturer such as company name or any transfer that is not related to food safety.
- > Change in the health conditions declared on the products

It is inappropriate to change the product formulation, increase or decrease ingredients. Only supplies or ingredients that fulfill the same function or are of a similar family can be replaced (for example, potato starch for corn starch).

If an additive is changed, it must fulfill the same functions (for example, a colorant, emulsifier or preservative).

For the list of Codex additives (see Functional Classes), please go to:

https://www.fao.org/gsfaonline/reference/techfuncs.html?lang=es

If the establishment is changed, the new one must be in the same city or the same country

TERM	7 business days
RATE	1,39% UIT
RELATED / INVOLVED SERVICES	 Expenses related to the requested change. For example, the useful life study change (reference amounts: S/ 3,900 - S/ 4,000) Expenses for delays / new requests to be resolved faster.
	Application via VUCE (Single Application for Foreign Trade - SUCE) containing information on:
	 Updating the data of the Health Food Registration holder (transfer, change of company name and other changes in administrative data regarding the holder of the Health Registration).
	 Changes on the current conditions of the Food Health Registration Certificate was granted. https://www.vuce.gob.pe/
REQUIREMENTS	Affidavit of the update or changeTechnical support, when appropriate; for instance:
REQUIREMENTS	 Contract: In the case of transfer, merger and/or takeover, the duly legalized document that accredits the operation must be presented before submitting the application at the VUCE. Registration of the new legal representative in SUNAT: when the change regards the legal representative Useful life study: when the useful life time is changed to extend the life time, if it decreases it is not necessary.

4.3 Imported Product Health Registration Certificate (TUPA 32)

It is a document that can be requested if you are not the holder of a Health Registration and you wish to import and sell foods or beverages already registered by a third party.

It is necessary to periodically verify the validity of the health registration because if the holder cancels it, all the dependent certificates are automatically invalidated.

The same conditions that govern the holder's Health Registration on the date of its granting apply to the Imported Product Health Registration Certificate.

Any changes and/or new conditions of the original health registration have no effect for the granted Imported Product Registration Certificate.

TERM	5 business days
RATE	8,48% UIT
REQUIREMENTS	Application via VUCE (Single Application for Foreign Trade - SUCE) that records the current third party Health Registration.

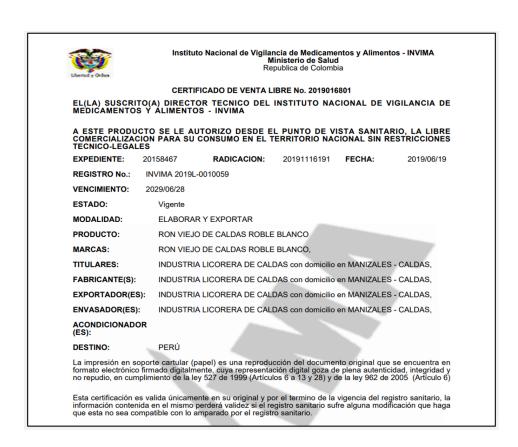
4.4 Free Sale Certificate (CLV) for human consumption of foods manufactured and/or prepared in the country (TUPA 33)

It is an official document issued, at stakeholder request, by the competent authority at the national level that certifies that food is for free sale in the country where it was manufactured and from where it is exported.

- > You need a Health Registration before you get the CLV.
- The CLV is issued per country of destination. Therefore, if the same food is exported to different countries, a CLV must be requested for each of them. http://www.digesa.minsa.gob.pe/Orientacion/CLV/Autoridades-Competentes-CLV.pdf

TERM	5 business days
RATE	1,54% UIT
REQUIREMENTS	Request via VUCE (Single Request for Foreign Trade - SUCE) that includes the current Health Registration.

EXAMPLE OF FREE SALE CERTIFICATE



4.5 Official Health Certificate for exporting Human Consumption Foods (CSOE) (TUPA 34)

- > It is an official document issued by the request of astakeholder, according to the type of product and particular specifications requested by the exporter, for each clearance or shipment lot and country of destination.
- It is requested so that a product can enter the country of destination.
- > The HACCP Plan's Official Technical Validation Certificate is required for its issuance http://www.digesa.minsa.gob.pe/expedientes/detalles.aspx?id=34
- > The company requestinga CSOE must have the current HACCP Plan's Official Technical Validation.
- > The products that will be included in the CSOE request must be included in the resolution of the HACCP Plan's Official Technical Validation.
- > The batches included in the CSOE request must have been manufactured within the validity of the HACCP Plan's Official Technical Validation.

The tests must indicate	the batches corresponding to the CSOE request.
TERM	2 business days
RATE	1,54% UIT
RELATED / INVOLVED SERVICES	 Inspections are unregulated services, their price depends on the market and it is referential. Storage for extra days of products without certification
REQUIREMENTS	 Request via VUCE (Single Request for Foreign Trade - SUCE) Health registration issued the day of production of the lot to be exported. It must include the production lines concerning the product to be exported. Report on the hygienic-health evaluation of the product to be shipped with regard to storage, container and packaging conditions, and testing report on selected samples taken from the respective shipment lot issued by the National Quality Institute (INACAL) or another accrediting institution of a foreign country that is a member of the MRA, the International Laboratory Accreditation Cooperation (ILAC) or the Inter-American Accreditation Cooperation (Inter American Accreditation). https://www.inacal.gob.pe/acreditacion/categoria/directorio-organismos-acreditados

4.6 Official Technical Validation of the HACCP Plan (TUPA 35)

The **HACCP Plan** is the document prepared by each company following the HACCP System principles. Its Official Technical Validation is the process by which the authority verifies that the elements of the HACCP Plan are effective, efficient, and applicable according to the establishment's specific conditions and situations.

http://www.digesa.minsa.gob.pe/NormasLegales/Normas/RM 449 2006.pdf

Before submitting the documents to DIGESA, it is recommended to conduct an internal audit of the facilities and documentation, to verify the compliance with all the requirements requested by the authority and reduce rejection risk. In this internal control, you can verify if you comply with the health standard for the Application of the HACCP System in the Manufacturing of Foods and Beverages.

When the HACCP Plan's Official Technical Validation is about to expire (after 2 years of its granting), the new validation must be requested at least 45 business days before the expiration of the previous resolution.

There must be an updated HACCP Plan that includes all the production lines and products that will be subject to the HACCP Plan's Technical Validation.

TERM	30 business days
RATE	21,42% UIT
RELATED / INVOLVED SERVICES	 > Time of the company's HACCP's responsible > Opportunity costs due to delay in inspection > Fixed costs without income flow to finance them, due to delay in the inspection > Lots not covered during the HACCP renewal procedure that cannot be exported.
REQUIREMENTS	 Request via VUCE (Single Request for Foreign Trade - SUCE) Manual of Good Handling Practices or Good Manufacturing Practices (GMP) and Hygiene and Sanitation Program (PHS) The latest version of the HACCP Plan for each product line

REFERENCES

Codex Alimentarius

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 https://www.leyes.congreso.gob.pe/Documentos/Leyes/28405.pdf
- Codex General Standard for Contaminants and Toxins in Food and Feed CODEX STAN 193-1995. 48 pages https://www.fao.org/fileadmin/user_upload/livestockgov/documents/CXS_193s.pdf
- Ministerial Resolution N.º 451-2006 that approves the Sanitary Standard for the manufacture of grain-based foods and others, destined for Social Food Programs. (2006) Official Gazette El Peruano. Laws. Lima, May 17, p. 318927-318928
 http://www.digesa.minsa.gob.pe/NormasLegales/Normas/RM_451_2006_modificacion.pdf
- Ministerial Resolution N.º 591-2008 that approves the Sanitary Standard that establishes the microbiological criteria of sanitary quality and safety for food and beverages for human consumption. (2008) Official Gazette El Peruano. Laws. Lima, August 29, p. 378827 https://www.gob.pe/institucion/minsa/normas-legales/247682-591-2008-minsa
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ATENCIÓN AL CIUDADANO

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