

Market Access

for
Diet Jelly – Products
Exempt from
Registration
ANVISA



October, 2010

This project was developed by the US Agricultural Trade Office (ATO) of the USDA/Foreign Agricultural Service in Sao Paulo, Brazil, in collaboration with private consultants, importers and customs agents. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies and procedures were 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.

Project Objective





The present project aims to catalogue all administrative procedures and legal requirements to export food products to Brazil, including:

- The identification of legal and administrative requirements involved in each step from door-to-door export process to Brazil.
- Costs estimates related to the fulfillment of each request.
- Possible delays related to each request/step in the food trading business with Brazil.
- Identification of legislation or regulations establishing each requirement.
- Highlight of existing differences in procedures/time/cost between the legal (theoretical) and practical course of actions throughout the import process.

- **Meat of bovine animals, frozen, boneless** (Chapter 02)
- **Fish** (Chapter 03)
- **Dairy products** (Chapter 04)
- **Fruit & Vegetables (Fresh/Dried)** (Chapter 08)
- **Sugar** (Chapter 17)
- **Candies** (Chapter 17)
- **Candies sugar-free** (Chapter 17)
- **Chewing gum** (Chapter 17)
- **Syrups** (Chapter 17)
- **Chocolate** (Chapter 18)
- **Cookies & Crackers** (Chapter 19)
- **Ready-to-eat cereals** (Chapter 19)
- **Pastry cook products** (Chapter 19)
- **Bread, pastry, cake products** (Chapter 19)
- **Snacks** (Chapter 20)
- **Diet jam** (Chapter 20)
- **Broths & Soups** (Chapter 21)
- **Condiments & Seasonings** (Chapter 21)
- **Tea** (Chapter 21)
- **Ketchup** (Chapter 21)
- **Mustard sauce** (Chapter 21)
- **Food preparations** (Chapter 21)
- **Sauces** (Chapter 21)
- **Non alcoholic beverages** (Chapter 21)
- **Whiskey** (Chapter 22)
- **Wine** (Chapter 22)

Food & Beverage Regulators

The Ministry of Agriculture, Livestock and Food Supply (MAPA) and the National Agency of Sanitary Surveillance (ANVISA) are the primary government regulators of agricultural products. Their jurisdiction follows:

MAPA	ANVISA
<p>Consumer-oriented products</p> <p>Food:</p> <ul style="list-style-type: none"> ▪ animal origin products (red meats and by-product, poultry meat and by-products, fish, seafood products, dairy products and eggs) ▪ Plant origin products (fruits and by-products, vegetables and by-products) <p>Beverages: alcoholic and non alcoholic (excluding those under ANVISA's authority).</p>	<p>Consumer-oriented products</p> <p>Food:</p> <ul style="list-style-type: none"> ▪ all processed products (except those under MAPA's authority) <p>Beverages: mineral water, flavored waters, energy drinks, hydroelectrolitic beverages and soy beverages</p>
<p>Intermediate products Wheat, flour, planting seeds, etc</p>	<p>Intermediate products Sugar, sweeteners, additives, colorants, etc</p>
<p>Pet food, feeds and fodders</p>	
<p>Ministério da Agricultura, Pecuária e Abastecimento</p>  <p>UM PAÍS DE TODOS GOVERNO FEDERAL</p>	 <p>ANVISA Agência Nacional de Vigilância Sanitária</p>

- Data based on a survey and research conducted in conjunction with third party to capture standard import procedures for food products.
- Companies surveyed are distributors/retailers, domestically owned of limited liability. Companies are small-medium size (except for Pao de Acucar Group, 2nd largest retailer), located in the main urban areas. In such structure a third party (broker) conducts the clearance process.
- Government agencies considered are those involved in whichever stage of the import process for food products, including policy makers
- The study includes all necessary documents, permits, licenses, authorizations and notifications required by Brazilian authorities. Documents filed simultaneously are counted separately.
- Procedures are considered only when interface with a third party (government or non-government) is made necessary. Each procedure is separated by its nature.
- Time is calculated in calendar days. The calculation is made from the moment it is initiated and lasts until it is completed. Procedures are not counted in parallel.
- Costs measure fees, taxes, tariffs, services of third parties to complete the clearance process. Cost estimate does not include import tariffs or taxes applied by the Brazilian authorities to trade goods.

Import process steps



PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

1. Formula Study

2. Label Development

3. Exporter's pro forma

4. Issuance of an Import License (LI)

Legislation

- Decree 55.871, March 26, 1965 (Approves maximum thresholds of inorganic contaminants – Table II)
- SVS/MS Edict 29, January 13, 1998 (Technical Regulation regarding Special Purpose Foods)
- SVS/MS Edict 685, August 27, 1998 (General principles for the establishment of Maximum Thresholds of Chemical Contaminants in Food)
- ANVS/MS Resolution 386, August 05, 1999 (Technical Regulation on additives used according to the Good Manufacturing Practices), and its amendments (RDC/ANVISA Resolutions 234, August 19, 2002, and 43, March 01, 2005)
- RDC/ANVISA Resolution 12, January 02, 2001 (Approves the Technical Regulation on microbiological standards for foods)
- RDC/ANVISA Resolution 272, September 22, 2005 (Approves the Technical Regulation for vegetable products, fruit products and eatable mushrooms)
- RDC/ANVISA Resolution 65, October 04, 2007 (Addresses the use of food additives in jellies), and its amendments (RDC/ANVISA Resolution 28, May 26, 2009)
- RDC/ANVISA Resolution 18, March 24, 2008 (Approves edulcorants permitted for use in foods and beverages)
- RDC/ANVISA Resolution 19, May 06, 2010 (Requirement that manufacturers and importers of foods and beverages inform the phenylalanine contents of products to ANVISA)

Timeframe

Legal/Theory: Not established
In practice: 2 days

Cost

Legal/Theory: Not established
In practice: R\$0 (importer) to R\$1,000.00 (consultant)

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

1. Formula Study

2. Label Development

3. Exporter's pro forma

4. Issuance of an Import License (LI)

Procedure

Legal/Theory: All foods must fit into one of ANVISA's pre-defined food categories, through specific resolutions which determine the technical regulations/Quality and Identity Standards (PIQ) for each of the categories. The PIQs define each of the ANVISA food categories, and determine, as well, specific quality and labeling criteria.

In Practice: A product's Formula Study consists of analyzing the complete composition of the product, including the additives used, and their respective quantities, in order to tell whether it fulfills its PIQ, aside from verifying whether all ingredients and additives are allowed for the product category in Brazil, as well as whether it obeys maximum established limits, depending on the case.

Number of Documents

- **1**
- 1. Quantitative product formula

Process Initiator

Exporter, importer or consultant.

Inquiries

ANVISA/General Coordination for Special Products (CGPESP)

ANVISA SIA, Trecho 5, Área Especial 57, Bloco D, 2º Andar

71205-050 Brasília, DF

Phone: (55-61) 3462-5329

E-mail: gpesp@anvisa.org.br

Home Page: www.anvisa.gov.br

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

1. Formula Study

2. Label Development

3. Exporter's pro forma

4. Issuance of an Import License (LI)

Legislation

- Executive Order 986, October 21, 1969 (Approves basic standards on foods)
- Decree 72.718, August 29, 1973 (Approves general standards on irradiation)
- INMETRO Edict 091, April 20, 1989 (Quantitative indication in jellies)
- SVS/MS Edict 27, January 13, 1998 (Technical Regulation regarding Additional Nutritional Information)
- SVS/MS Edict 29, January 13, 1998 (Technical Regulation regarding Special Purpose Foods)
- RDC/ANVISA Resolution 21, January 26, 2001 (Approves Regulation on food irradiation)
- INMETRO Decree 157, August 19, 2002 (Technical regulation on metrology)
- RDC/ANVISA Resolution 259, September 20, 2002 (Technical Regulation on Packaged Food Labeling), and its amendments (RDC/ANVISA Resolution 123, may 13, 2004)
- RDC/ANVISA Resolution 340, December 13, 2002 (Approves Regulation on the declaration of tartrazine in the list of ingredients)
- PL 10.674, May 16, 2003 (Requires commercial food products to indicate the presence of gluten)
- RDC/ANVISA Resolution 359, December 23, 2003 (Technical Regulation of Packaged Food Portions for Nutritional Labeling Purposes)
- RDC/ANVISA Resolution 360, December 23, 2003 (Technical Regulation on Nutritional Labeling of Packaged Foods, turning the nutritional labeling mandatory), and its updates/ additions (RDC/ANVISA Resolution 163, August 17, 2006)
- ANVISA Technical Report 26, June 14, 2007 (Regulates the labeling of foods added with scents)

Timeframe

Legal/Theory: Not established

In practice: 2 days

Cost

Legal/Theory: Not established

In practice: R\$0 (importer) to R\$1,000 (consultant)

Procedure

Legal/Theory: There are some items required to appear on product front or side labels in Brazil, depending on the product:

1. Items required on the front panel:
 - Technical name, according to ANVISA classification (RDC/ANVISA Resolution 259/02), in letters of the same color and size (SVS/MS Edict 29/98);
 - Brand (RDC/ANVISA Resolution 259/02);
 - Information on scents / colorants used;
 - Quantitative Indication (INMETRO Edict 157/02), and the minimum height of letters and numbers must follow the provisions of INMETRO Edict 157/02, as follows:

Net Content (g or ml)	Minimum height of algorithms (mm)
Less than or equal to 50	2.0
Greater than 50 and less than or equal to 200	3.0
Greater than 200 and less than or equal to 1000	4.0
Greater than 1000	6.0

The letters used for writing unit-of-measure symbols must have a minimum height of 2/3 (two-thirds) of the height of the numbers.

For imported products, if the original packaging gives no indication of quantity on the main panel, or if such indication is in dimensions or units which do not agree with those established in INMETRO Edict 157/02, an authorization may be requested from INMETRO to allow the quantity statement elsewhere than on the front panel, through the use of a tag. However, in such cases, the size of the letters used must be, at a minimum, two times greater than those established.



Procedure

2. Items required on the side panels:

- List of ingredients (RDC/ANVISA Resolution 259/02);
- The expression "Contains Gluten," or "Does Not Contain Gluten," clearly visible, depending on the case (PL 10.674/03);
- Nutritional Information (RDC/ANVISA Resolution 359 and 360/03):

The Nutritional Information is mandatory information that must be in agreement with RDC/ANVISA Resolutions 359 and 360/03, that is, it must follow the model it has defined.

According to said Resolution, the Nutritional Information table must provide the following information:

- ✓Energy Value
- ✓Carbohydrates
- ✓Protein
- ✓Total fat
- ✓Saturated fat
- ✓Trans fats
- ✓Fiber
- ✓Sodium

Below is one of the approved samples of nutritional table:

NUTRITIONAL INFORMATION		
Portion of... grams (Household Measure)		
Quantity per portion		% Daily Requirement (DA) *
Energy Value	Kcal = kJ	%
Carbohydrates	g	%
Protein	g	%
Total fat	g	%
Saturated fat	g	%
Trans fats	g	**
Fiber	g	%
Sodium	Mg	%

* % Daily requirements with reference to the basis in a 2,000 kcal, or 8,400 kJ diet. One's daily amounts may be greater or less than these amounts, depending on one's energy needs. ** Daily requirement not established

Procedure

The Nutritional Information table must be prepared per food portion, and the portion must have its respective home-cooking measurements.

Portion is the average amount of food which must be consumed by a healthy person above 36 months of age, at each sitting, with the aim of promoting a healthy diet.

Household Measure, a measurement, equivalent to a portion of food, is employed, employing utensils commonly used by the consumer for food measurement (Ex: cup, tablespoon, teaspoon, etc).

The portions and their respective home-cooking measurements are determined for each type of food by RDC/ANVISA Resolution 359/03.

- Country of Origin (RDC/ANVISA Resolution 259/02);
- Manufacturer's data (name and complete address) (RDC/ANVISA Resolution 259/02);
- Importer's data (corporate name, complete address, and corporate ID number - CNPJ) (RDC/ANVISA Resolution 259/02);
- Expiration Date (RDC/ANVISA Resolution 259/02);
- Lot. The lot may be replaced with the manufacturing date, when stated, or expiration date (RDC/ANVISA Resolution 259/02);
- Storage care (RDC/ANVISA Resolution 259/02);
- Use and/or preparation instructions, if necessary (RDC/ANVISA Resolution 259/02);
- Specific warning sentences, defined by the Technical Regulation, if necessary (SVS/MS Edict No. 29/98).

In the case of a product whose label is not in the Portuguese language, an adhesive sticker can be used, on the original label, containing all the required information in Portuguese. The aforementioned sticker may be applied at either at the product's origin or destination, but must always be applied prior to its commercialization (RDC/ANVISA Resolution 259/02).

In practice: Same as the Legal/Theory procedure.



PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

1. Formula Study

2. Label Development

3. Exporter's pro forma

4. Issuance of an Import License (LI)

Number of documents

- 3
- 1. Quantitative product formula
- 2. Certificate of Nutritional Information containing: carbohydrates, protein, total fats, saturated fats, trans fats, dietary fiber and sodium in 100g
- 3. Original product label

Process Initiator

Exporter, importer or consultant.

Inquiries

ANVISA/General Coordination for Special Products (CGPESP)

ANVISA SIA, Trecho 5, Área Especial 57, Bloco D, 2º Andar

71205-050 Brasília, DF

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E-mail: gpesp@anvisa.org.br

Home Page: www.anvisa.gov.br

MDIC/National Institute of Metrology, Standardization, and Industrial Quality (INMETRO)

Avenida Nossa Senhora das Graças, 50

25250-020, Duque de Caxias, RJ

Phone: (55-21) 2679-9001

E-mail: dimep@inmetro.gov.br

Home Page: www.inmetro.gov.br

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

1. Formula Study

2. Label Development

3. Exporter's pro forma

4. Issuance of an Import License (LI)

Legislation

- Not established

Timeframe

Legal/Theory: Not established

In Practice: 1 day (after closing the sale, and depending on the exporter)

Cost

Legal/Theory: No cost

In Practice: No cost

Procedure

Legal/Theory: Not established

In Practice: Once the sale of the merchandise is closed between the exporter and the importer, the import operation starts. The development of a pro forma invoice will be necessary in order for this to occur. The pro forma invoice is a standard document used in the international trade sector, on which all the information related to the sale, and details of the acquired merchandise (product data, form of payment, method of transport, etc) are included.

Number of documents

- **1**
- 1. Pro forma Invoice

Process initiator

Exporter and importer.

Inquiries

N/A

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

1. Formula Study

2. Label Development

3. Exporter's pro forma

4. Issuance of an Import License (LI)

Legislation

- MAPA Normative Instruction 36, November 10, 2006 (Approves the International Agricultural Inspection Procedural Manual), and its amendments (MAPA Normative Instructions No. 24, of June 16, 2009, No. 36 of September 29, 2009, No. 37 of September 29, 2009, No. 39 of September 29, 2009, No. 45 of October 29, 2009, No. 49 of November 04, 2009, and No. 8 of March 08, 2010)
- RDC/ANVISA Resolution 81, May 05, 2008 (Technical Regulation of Sanitary Surveillance of Imported Goods)
- SECEX/MDIC Edict 10, May 24, 2010 (Consolidates the procedures applicable to foreign trade operations), and its amendments (SECEX Edicts 11, June 22, 2010, and 13, June 29, 2010)

Timeframe

Legal/Theory: up to 60 days (with the possibility of passing that period for reasons beyond the control of the Brazilian government's pertinent agency).

In practice: 6 days

Cost

Legal/Theory: No cost

In Practice: No cost

Procedure

Legal/Theory: Once the importer accepts the pro forma invoice, it must check with Integrated Foreign Trade System (SISCOMEX), using the NCM code (equivalent to the HS code) of the product to be imported, along with whether an import license is needed.

The Import License (LI) is a document issued electronically, through SISCOMEX, by the importer, which is approved by ANVISA, and which authorizes the import of the product in question. The LI is a document demanded for customs clearance.

The issuance of the LI may be done after the merchandise is shipped, through SISCOMEX, but before it arrives in Brazil. This procedure can be done by the importer or by a licensed person, previously authorized to run the SISCOMEX system in the importer's name.

In practice: Same as the Legal/Theory procedure.

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

1. Formula Study

2. Label Development

3. Exporter's pro forma

4. Issuance of an Import License (LI)

Number of documents

- 1
- 1. LI

Process initiator

Importer or licensed representative (customs agent)

Inquiries

ANVISA/General Coordination for Special Products (CGPESP)

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MF/Secretariat of Foreign Trade (SECEX)

Esplanada dos Ministérios, Bloco J, Sala 814

70053-900, Brasília, DF

Phone: (55-61) 2109-7080

E-mail: decex.coord@desenvolvimento.gov.br

Home Page: <http://www2.desenvolvimento.gov.br/sitio/secex/secex/>

5. Embarkation Instructions

6. Bill of Lading/Transport

Legislation

- MAPA Normative Instruction 36, November 10, 2006 (Approves the International Agricultural Inspection Procedural Manual), and its amendments (MAPA Normative Instructions No. 24, of June 16, 2009, No. 36 of September 29, 2009, No. 37 of September 29, 2009, No. 39 of September 29, 2009, No. 45 of October 29, 2009, No. 49 of November 04, 2009, and No. 8 of March 08, 2010)
- RDC/ANVISA Resolution 81, May 05, 2008 (Technical Regulation of Sanitary Surveillance of Imported Goods)
- Decree 6.759, February 05, 2009 (Regulates the management of customs activities, and the inspection, control and taxation of foreign trade operations), and its amendments (Decree 7.213, June 15, 2010)

Timeframe

Legal/Theory: Not established
In practice: 1 day

Cost

Legal/Theory: No cost
In practice: No cost

Procedure

Legal/Theory: In order to embark merchandise, the importer must provide the exporter with the Embarkation Instructions which consist of a document containing all the information pertinent to the transaction and the embarkation condition of the merchandise, such as the quantity of product, form of payment, shipping temperature, packaging, use of pallet(s) etc.

One point that should be noted is the pallet material used in shipping. Pallets of untreated wood, arriving in Brazil, must be inspected by the Ministry of Agriculture inspector to check for the presence of pests, aside from coming together with the phytosanitary certificate with additional declaration on the treatment applied, or the treatment certificate stamped by the National Organization for Phytosanitary Control (ONPF) of the exporting country.

The phytosanitary certificate with additional declaration on the applied treatment, or the certificate of treatment, stamped by the ONPF of the exporting country, will not be demanded for wooden pallets that come marked with the international stamp approved by the Food and Agriculture Organization (FAO), International Phytosanitary Measure Norm (NIMF 15). Nonetheless, the NIMF 15 marking does not free the pallet from being inspected by the Ministry of Agriculture.

Inspection is done macroscopically, and the entire pallet must be checked. If any pests are found, the pallet must undergo the proper treatment (fumigation) or be destroyed, in which case a Memorandum of Occurrence is issued. Pallets made of different materials (cardboard, fiber, plastic, etc) and those made of processed or industrialized wood are exempt from these demands.

5. Embarkation Instructions

6. Bill of Lading/Transport

Procedure

In the embarkation instruction must also contain all the documents that the exporter must send to the importer for clearance of the product:

1. Commercial invoice, an invoice, which, according to Article 557 of Decree 6.759/09, must contain the following information:

- Exporter's and importer's complete name and address;
- Specification of merchandise in Portuguese or in an official language of the General Agreement on Tariffs and Trade, or, if in another language, accompanied by a translation in the Portuguese language, subject to acceptance by the customs authority, containing proper and commercial denominations, with indication of the elements indispensable for the product's perfect identification;
- Brand, number, and, if available, reference number of the packages;
- Quantity and type of packages;
- Gross weight of shipment, meaning that of the merchandise with all its containers, packages and other wrapping;
- Net weight, meaning the weight of the merchandise without any wrapping;
- Country of origin, meaning that country where the merchandise was produced or where its last substantial transformation took place;
- Acquisition country, meaning that country where the merchandise was acquired to be exported to Brazil, whether or not the country of origin or of its inputs;
- Transit country, meaning that country where the merchandise was located at the moment of its acquisition;
- Unit and total prices of each type of merchandise, and the amount and nature of reductions and discounts given to the importer, if any;
- Freight and other costs connected with the merchandise specified on the invoice;
- Payment terms and currency;
- Terms of condition of sale (INCOTERM).

2. Bill of Lading or AWB;

3. Certificate of Analysis;

4. Packing list;

5. Copy of Certificate of Origin issued by the Chamber of Commerce.

In practice: Same as the Legal/Theory process

5. Embarkation Instructions

6. Bill of Lading/Transport

Number of documents

- **1**
1. Embarkation instruction



Process initiator

Exporter, importer and shipping company



Inquiries

N/A



5. Embarkation Instructions

6. Bill of Lading/Transport

Legislation	<ul style="list-style-type: none"> ▪ Not established
Timeframe	<p>Legal/Theory: Not established</p> <p>Practice: 2 days</p>
Cost	<p>Legal/Theory: Not established</p> <p>In practice: No cost</p>
Procedure	<p>Legal/Theory: Not established</p> <p>In practice: The exporter sends the Shipping Instructions containing all the information necessary for issuance of the cargo manifest (maritime BL, air AWB, rail RWB or highway CRT) to the shipper. This is the proof of loading, issued by the shipping company, and containing the entire description of shipping.</p>
Number of documents	<ul style="list-style-type: none"> ▪ 0
Process initiator	Exporter and shipping company
Inquiries	N/A

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Arrival of the merchandise at the port

8. DI Registration at SISCOMEX

9. Physical review by ANVISA's Inspector

10. Product Clearance by ANVISA

11. Federal Revenue Parameterized Selection

12. CIP and SAC Preparation

Legislation

- RFB/MT Normative Instruction 797, December 20, 2007 (Addresses the provision of information necessary for customs control of shipments, cargos and units of cargo, and of the collection of the Freight Surcharge for Merchant Marine Renovation)
- RFB Normative Instruction 800, December 27, 2007 (Addresses computerized customs control of the movement of shipments, cargos and units of cargo in customs ports)

Timeframe

Legal/Theory: Not established
In practice: 2 days

Cost

Legal/Theory: Not established
In practice: from R\$10.00/metric tone to R\$400.00/container, depending on the type of shipping and the shipper

Procedure

Legal/Theory: Once the merchandise arrives in port, the cargo should be sent to a customs terminal (storage) pre-designated by the importer. Otherwise, it will be sent to a terminal with which the transport company has an agreement. Once the merchandise is duly positioned in the terminal, the presence of the cargo must be confirmed, which consists of informing the conditions of its receipt to SISCOMEX. With no presence of cargo, it is not possible to execute the registration of the Import Declaration (DI) on SISCOMEX.
In practice: the same as the Legal/Theory procedure.

Number of documents

- 0

Process initiator

Importer of licensed person (customs agent), shipping company warehouse or customs warehouse.

Inquiries

N/A

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Arrival of the merchandise at the port

8. DI Registration at SISCOMEX

9. Physical review by ANVISA's Inspector

10. Product Clearance by ANVISA

11. Federal Revenue Parameterized Selection

12. CIP and SAC Preparation

Legislation

- SRF Normative Instruction 680, October 2, 2006 (Disciplines import customs clearance)
- SRF Normative Instruction 702, December 28, 2006 (Amends SRF Normative Instruction 680, October 2, 2006)

Timeframe

Legal/Theory: Not established
In practice: 1 day

Cost

Legal/Theory: The cost to register a DI, according to Normative Instruction 702/06 is R\$30.00 per DI. But the cost for each addition of merchandise varies according to the number of additions.

Number of Additions	Amount per Addition (R\$)
Up to the 2 nd addition	10.00
3 rd to 5 th addition	8.00
6 th to 10 th addition	6.00
11 th to 20 th addition	4.00
21 st to 50 th addition	2.00
From the 51 st addition	1.00

In practice:

Rate cost: R\$30.00 + amount pertaining to the number of additions to the DI (same as the Legal/Theory procedure).

Procedure

Legal/Theory: After release of the LI by ANVISA, the importer or licensed customs agent must register the import declaration (DI) with SISCOMEX.

PRE-EMBARKATION

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11. Federal Revenue Parameterized Selection

12. CIP and SAC Preparation

Procedure

The DI is a document which will contain all the information on the import:

- Importer data;
- Cargo data;
- Data on the bonded warehouse;
- Merchandise data;
- Negotiated payment terms;
- Federal taxes: Import Tax (II), Industrialized Products Tax (IPI), Social Integration Program (PIS), Obligatory Contribution to Social Security Financing (COFINS) and antidumping rights when applicable. Federal taxes are automatically debited from the importer's account or from that of the customs agent;
- State tax: Merchandise Circulation Tax (ICMS). The ICMS is collected through the State Collection Guide (GAE), payable at any bank in Brazil. Original proof of payment must be sent to the Federal Revenue;
- Complementary information, depending on the case (for example, authorized customs agent);
- Negotiated currency parity tax (exchange rate) determined by the Central Bank;
- Detailed description of the merchandise, according to the LI and the commercial invoice.

In practice: Same as the Legal/Theory procedure

Number of documents

- 0

Process initiator

Importer or licensed person (customs agent)

Inquiries

MF/Secretariat of Federal Revenue (SRF)

Esplanadas dos Ministérios - Bloco P

70048-900 Brasilia, DF

Phone: (55-61) 3412-2000/3000

Home Page: www.receita.fazenda.gov.br

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Arrival of the merchandise at the port

8. DI Registration at SISCOMEX

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Inquiries

MF/Secretariat of Foreign Trade (SECEX)

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PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Arrival of the merchandise at the port

8. DI Registration at SISCOMEX

9. Physical review by ANVISA's Inspector

10. Product Clearance by ANVISA

11. Federal Revenue Parameterized Selection

12. CIP and SAC Preparation

Legislation

- RDC/ANVISA Resolution 222, December 28, 2006 (Procedures of electronic petition and collection within the scope of the National Agency of Sanitary Surveillance – ANVISA), and its amendments (RDC/ANVISA Resolutions 76, October 23, 2008, and 65, December 21, 2009)
- RDC/ANVISA Resolution 81, May 05, 2008 (Technical Regulation of Sanitary Surveillance of Imported Goods)

Timeframe

Legal/Theory: Not established
In practice: 2 days

Cost

Legal/Theory: The tax varies according to the number of items imported and the size of the company.

Imported Merchandise	Tax per Size of Firm (R\$)					
	Group I	Group II	Group III	Group IV	Small Company	Micro-company
Up to ten items: goods, products, ingredients or inputs	100	85	70	40	10	5
11 to 20 items: goods, products, ingredients or inputs	200	70	140	80	20	10
21 to 30 items: goods, products, ingredients or inputs	300	255	210	120	30	15
31 to 50 items: goods, products, ingredients or inputs	1,000	850	700	400	100	50
51 to 100 items: goods, products, ingredients or inputs	2,000	1,700	1,400	800	200	100

In practice: Same as the Legal/Theory procedure

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Arrival of the merchandise at the port

8. DI Registration at SISCOMEX

9. Physical review by ANVISA's Inspector

10. Product Clearance by ANVISA

11. Federal Revenue Parameterized Selection

12. CIP and SAC Preparation

Procedure

Legal/Theory: Once the LI has been issued through SISCOMEX, A Petition for Sanitary Inspection and Clearance must be entered, through the ANVISA site. Once the petition is entered, a National Collection Guide (GRU) is generated, which is a federal tax on the import of products within the competence of ANVISA.

Access to the petition and collection system will be contingent on the importer's prior registration at the ANVISA electronic address, and on the personal password, secret and non-transferrable, through the internet.

Registration is done electronically, by the importer, by filling out the electronic form, made available by ANVISA, which contains basic company information.

Once registered on the ANVISA site, the importer or contracted customs agent can request an Electronic Petition of Sanitary Inspection and Clearance on the site itself, on which he will provide information about the imported merchandise, amount or number of imported merchandise and the cargo manifest.

Upon finishing the electronic petition, the National Collection Guide tax (GRU) will be generated in the name of the interested party, and payment can be made through a direct electronic debit on a bank account, or at any bank.

The amount of the tax varies according to the number of items imported and the size of the company.

After payment of the tax, the ANVISA inspector will physically inspect the product, gathering samples for analysis. According to RDC/ANVISA Resolution 81, 05.05.08, this procedure is required only for products subject to LI.

In practice: Same as the Legal/Theory procedure

Number of documents

- **7**
- 1. Petition for Sanitary Inspection and Clearance, from ANVISA with its respective GRU paid
- 2. Commercial invoice
- 3. Bill of Lading or AWB
- 4. Certificate of Analysis, issued by lot or shipment, and issued by the manufacturer or producer
- 5. Packing list
- 6. Import license (LI)
- 7. Operational license of the warehouse where the product will be stored

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Arrival of the merchandise at the port

8. DI Registration at SISCOMEX

9. Physical review by ANVISA's Inspector

10. Product Clearance by ANVISA

11. Federal Revenue Parameterized Selection

12. CIP and SAC Preparation

Process initiator

Importer or licensed representative (customs agent)

Inquiries

ANVISA office located at the merchandise point of entry into Brazil.

MF/Secretariat of Federal Revenue (SRF)

Esplanadas dos Ministérios - Bloco P

70048-900 Brasilia, DF

Phone: (55-61) 3412-2000/3000

Home Page: www.receita.fazenda.gov.br

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Arrival of the merchandise at the port

8. DI Registration at SISCOMEX

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10. Product Clearance by ANVISA

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12. CIP and SAC Preparation

Legislation

▪ RDC/ANVISA Resolution 81, May 05, 2008 (Technical Regulation of Sanitary Surveillance of Imported Goods)

Timeframe

Legal/Theory: Not established
In practice: immediately upon physical inspection

Cost

Legal/Theory: No cost
In practice: No cost

Procedure

Legal/Theory: Once the LI is approved by ANVISA, the imported product is cleared by that agency, and must follow the clearance process demanded by the Federal Revenue.
In practice: Same as the Legal/Theory procedure.

Number of documents

▪ 0

Process initiator

Importer or licensed representative (customs agent).

Inquiries

ANVISA office located at the merchandise point of entry into Brazil.

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Arrival of the merchandise at the port

8. DI Registration at SISCOMEX

9. Physical review by ANVISA's Inspector

10. Product Clearance by ANVISA

11. Federal Revenue Parameterized Selection

12. CIP and SAC Preparation

Legislation

- RDC/ANVISA Resolution 81, May 05, 2008 (Technical Regulation of Sanitary Surveillance of Imported Goods)
- Decree 6.759, February 05, 2009 (Regulates the management of customs activities, and the inspection, control and taxation of foreign trade operations), and its amendments (Decree 7.213, June 15, 2010)

Timeframe

Legal/Theory:

- a) Green Channel: around 1 day, upon parameterization;
- b) Yellow Channel: approximately 2 days, upon parameterization;
- c) Red Channel: around 4 days, upon parameterization;
- d) Gray Channel: time for release of merchandise varies, possibly taking more than 60 days, upon parameterization.

In practice: Same as the Legal/Theory procedure.

Cost

Legal/Theory: No cost

In practice: No cost

Procedure

Legal/Theory: Upon registration of the DI, the process goes into Federal Revenue parameterization with SISCOMEX. This is an internal process, of the system itself, for channel selection:

- a) Green Channel: dispenses with the examination of documents and inspection of the merchandise, taking about 1 day for the release of the merchandise;
- b) Yellow Channel: only an examination of documents is necessary, taking approximately 2 days for the release of the merchandise;
- c) Red Channel: aside from document review, the merchandise must be physically inspected, a process that takes around 4 days for the release of the product;
- d) Gray Channel: this is the channel for the application of special customs control, in which it becomes necessary to request new documents due to inconsistencies declared in the Pro forma, IL, bill of lading and DI. For this procedure, the time needed for release of the merchandise is undefined.

In practice: Same as the Legal/Theory procedure.

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

8. DI Registration at SISCOMEX

9. Physical review by ANVISA's Inspector

10. Product Clearance by ANVISA

11. Federal Revenue Parameterized Selection

12. CIP and SAC Preparation

Number of documents

- **9**
 1. Petition for Sanitary Inspection and Clearance, from ANVISA with its respective GRU paid
 2. Commercial invoice
 3. Bill of Lading or AWB
 4. Certificate of Analysis, issued by lot or shipment, by the manufacturer or producer
 5. Packing list
 6. Import license (LI)
 7. Import declaration (DI)
 8. ICMS collected guide
 9. Operational license of the warehouse where the product will be stored

Process initiator

Importer or licensed representative (customs agent)

Inquiries

MF/Secretariat of Federal Revenue (SRF)

Esplanadas dos Ministérios - Bloco P
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PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Goods Arrival at Port

8. DI Registration at SISCOMEX

9. Physical Check by ANVISA's Inspector

10. Product Clearance by ANVISA

11. Federal Revenue Parameterized Selection

12. CIP and SAC Preparation

Legislation

- ANVS/MS Resolution 22, March 15, 2000 (Addresses the Basic Procedures for Registration and Dismissal of the Requirement to Register Imported Products Relevant to the Food Segment)
- ANVS/MS Resolution 23, March 15, 2000 (Addresses the Manual of Basic Procedures for Registration and Dismissal of the Requirement to Register Imported Products Relevant to the Food Segment), and its amendments (RDC/ANVISA Resolution 27, August 06, 2010)
- RDC/ANVISA Resolution 27, August 06, 2010 (Approves the categories of Foods and Packaging that are exempted from and required to make Registration)

Timeframe

Legal/Theory: Not established
In practice: 1 day

Cost

Legal/Theory: from R\$500 to R\$1,000.00 (for execution of analyses)
In practice: from R\$500 to R\$1,000.00 (for execution of analyses) + R\$400.00 (consultant)

Procedure

Legal/Theory: In order to regularize and be able to market the products under ANVISA'S authority, exempt of registration, it is necessary to file, according to ANVS/MS Resolutions No. 22, 03.15.00, No. 23, 03.15.00, and No. 27, 08.06.10, within ten (10) days after their import, a Product Import Communication (*Comunicação de Importação de Produtos - CIP*), at the City Health Office where the warehouse is located.

CIP must be filed in two (02) counterparts, signed by the company's Legal Representative, with a copy of the warehouse's Running Permit.

For filling out the product's CIP, the following information is necessary:

- Importer's Data (Corporate Name, complete address, corporate ID number (CNPJ), telephone and email for contact);
- Warehouse Data (Corporate Name, complete address, corporate ID number (CNPJ), telephone and email for contact);
- Product Import Date;
- Product commercialization beginning date;
- Food category, as per RDC/ANVISA Resolution 27, 08.06.10;

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Goods Arrival at Port

8. DI Registration at
SISCOMEX

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ANVISA's Inspector

10. Product Clearance by
ANVISA

11. Federal Revenue
Parameterized Selection

12. CIP and SAC Preparation

Procedure

- Product's Technical Name;
- Brand;
- Packaging Material;
- Expiration Date;
- Commercial perspective (municipal, state, national or export);
- Manufacturer's Name;
- Country of Origin.

After filing the product's CIP, the Control Analysis Request (*Solicitação de Análise de Controle* - SAC) must be filed in the same City Health Office within thirty (30) days after starting to market the product. The Control Analysis is the instrument available to the Sanitary Surveillance to check if the product is, in fact, in agreement with the Brazilian laws and with what was informed in the product's CIP.

For filling out the product's SAC, the following information is necessary:

- Food category, as per RDC Resolution 27, 08.06.10;
- Product's Technical Name;
- Product's Brand;
- Warehouse Data, for collecting the sample (Corporate Name, complete address, corporate ID number (CNPJ), telephone and email for contact).

SAC must be filed in three (03) counterparts, signed by both the Legal Representative and the Technician in Charge of the company, with three (03) counterparts of the product's formula, three (03) counterparts of the product's label or tag in Portuguese, and one (01) copy of the CIP Filing Certificate.

The product's CIP and SAC must be made by the interested importer, who may hire or not a third party experienced in the subject to help, and there are no sanitary fees for this procedure.

Once CIP and SAC have been duly filed, then the legal sanitary procedures that the company must perform for marketing the product are completed.

In practice: Same as the Legal/Theory procedure.

PRE-EMBARKATION

EMBARKATION

CUSTOMS CLEARANCE

7. Goods Arrival at Port

8. DI Registration at
SISCOMEX

9. Physical Check by
ANVISA's Inspector

10. Product Clearance by
ANVISA

11. Federal Revenue
Parameterized Selection

12. CIP and SAC Preparation

Number of documents

- 4
- 1. Warehouse Running Permit
- 2. CIP
- 3. Product's label / tag
- 4. Control Analysis Application



Process initiator

Importer or consultant.



Inquiries

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Trade Example



Import Cost	R\$	%	Comments	
Ocean container				
PRODUCT: Diet Jelly			HC 2007.10.00	
FOB (Free on Board) Price in R\$	80,000.00	100%	% Import Tax (II) =	16%
Freight in R\$	7,000.00		%ICMS	18%
Maritime Insurance	1.600.00		%IPI	0%
CIF (Cost, Freight and Insurance) Price in R\$	88,600.00			
II (Import Tax)	12,404.00		% CIF	
IPI (Industrialized Products Tax)	0.00		% CIF + II	
SISCOMEX (Integrated Foreign Trade System) rate	40.00		Minimum amount	
Import License (LI)	165.00		3 LI, R\$55.00/ each	
ARFM (Merchant Marine surcharge)	1750.00		25% maritime freight	
Logistics Costs at the Port of Santos				
CODESP (Santos Port Authority), Catapazias (Customs Duty), ATP (Port Additional Tariff)	400.00			
SDAS (Broker's Syndicate)	584.00		2% CIF, maximum R\$584.00	
Storage	600.00		0.35% CIF, minimum R\$600.00	
Customs agent	760.00		documents, registry of the DI, handle the clearance process	
ANVISA	300.00		3 LI, R\$100.00/each	
Demurrage (container)	0.00			
Insurance at the port	0.00			
PIS (Social Integration Program)	1,666.57		Formula	1.65%
COFINS (Obligatory Contribution to Social Security Financing)	7,802.96		Formula	7.60%
ICMS (Value Added Tax)	24,259.07		%(CIF + II + PIS + COFINS + SISCOMEX)	
Clearance Cost	139,331.60	74%	x FOB	
Cost without ICMS	115,072.53	43%	x FOB	

NOTE: CUSTOMS AGENT COST IS EQUAL TO 1% OF THE VALUE OF THE MERCHANDISE (FOR THE ENTIRE PROCESS)

Legal Framework



Decree 55.871, March 26, 1965 (Approves maximum thresholds of inorganic contaminants – Table II)

Executive Order 986, October 21, 1969 (Approves basic standards on foods)

Decree 72.718, August 29, 1973 (Approves general standards on irradiation)

INMETRO Edict 091, April 20, 1989 (Quantitative indication in jellies)

SVS/MS Edict 27, January 13, 1998 (Approves the Technical Regulation regarding Additional Nutritional Information)

SVS/MS Edict 29, January 13, 1998 (Technical Regulation regarding Special Purpose Foods)

SVS/MS Edict 685, August 27, 1998 (General principles for the establishment of Maximum Thresholds of Chemical Contaminants in Food)

ANVS/MS Resolution 386, August 05, 1999 (Technical Regulation on additives used according to the Good Manufacturing Practices), and its amendments (RDC/ANVISA Resolutions 234, August 19, 2002, and 43, March 01, 2005)

ANVS/MS Resolution 22, March 15, 2000 (Addresses the Basic Procedures for Registration and Dismissal of the Requirement to Register Imported Products Relevant to the Food Segment)

ANVS/MS Resolution 23, March 15, 2000 (Addresses the Manual of Basic Procedures for Registration and Dismissal of the Requirement to Register Imported Products Relevant to the Food Segment), and its amendments (RDC/ANVISA Resolution 27, August 06, 2010)

RDC/ANVISA Resolution 12, January 02, 2001 (Approves the Technical Regulation on microbiological standards for foods)

RDC/ANVISA Resolution 21, January 26, 2001 (Approves Regulation on food irradiation)

INMETRO Decree 157, August 19, 2002 (Technical regulation on metrology)

RDC/ANVISA Resolution 259, September 20, 2002 (Technical Regulation on Packaged Food Labeling), and its amendments (RDC/ANVISA Resolution 123, May 13, 2004)

RDC/ANVISA Resolution 340, December 13, 2002 (Approves Regulation on the declaration of tartrazine in the list of ingredients)

PL 10.674, May 16, 2003 (Requires commercial food products to indicate the presence of gluten)

RDC/ANVISA Resolution 359, December 23, 2003 (Technical Regulation of Packaged Food Portions for Nutritional Labeling Purposes)

RDC/ANVISA Resolution 360, December 23, 2003 (Technical Regulation on Nutritional Labeling of Packaged Foods, turning the nutritional labeling mandatory), and its updates/ additions (RDC/ANVISA Resolution 163, August 17, 2006)

RDC/ANVISA Resolution 272, September 22, 2005 (Approves the Technical Regulation for vegetable products, fruit products and eatable mushrooms)

Normative Instruction 680, October 2, 2006 (Disciplines the customs clearance of imports)

MAPA Normative Instruction 36, November 10, 2006 (Approves the International Agricultural Inspection Procedural Manual), and its amendments (MAPA Normative Instructions No. 24, of June 16, 2009, No. 36 of September 29, 2009, No. 37 of September 29, 2009, No. 39 of September 29, 2009, No. 45 of October 29, 2009, No. 49 of November 04, 2009, and No. 8 of March 08, 2010)

RDC/ANVISA Resolution 222, December 28, 2006 (Procedures of electronic petition and collection within the scope of the National Agency of Sanitary Surveillance – ANVISA), and its amendments (RDC/ANVISA Resolutions 76, October 23, 2008, and 65, December 21, 2009)

SRF Normative Instruction 702, December 28, 2006 (Amends SRF Normative Instruction 680, October 2, 2006)

ANVISA Technical Report 26, June 14, 2007 (Regulates the labeling of foods added with scents)

RDC/ANVISA Resolution 65, October 04, 2007 (Addresses the use of food additives in jellies), and its amendments (RDC/ANVISA Resolution 28, May 26, 2009)

RFB/MT Normative Instruction 797, December 20, 2007 (Addresses the provision of information necessary for customs control of shipments, cargos and cargo units, and the collection of the Merchant Marine Renovation Surcharge)

RFB Normative Instruction 800, December 27, 2007 (Addresses computerized customs control of the movement of shipments, cargos and cargo units in customs ports)

RDC/ANVISA Resolution 18, March 24, 2008 (Approves edulcorants permitted for use in foods and beverages)

RDC/ANVISA Resolution 81, May 05, 2008 (Technical Regulation of Sanitary Surveillance of Imported Goods)

Decree 6.759, February 05, 2009 (Regulates the management of customs activities, and the inspection, control and taxation of foreign trade operations), and its amendments (Decree 7.213, June 15, 2010)

RDC/ANVISA Resolution 19, May 06, 2010 (Requirement that manufacturers and importers of foods and beverages inform the phenylalanine contents of products to ANVISA)

SECEX/MDIC Edict 10, May 24, 2010 (Consolidates the procedures applicable to foreign trade operations), and its amendments (SECEX Edicts 11, June 22, 2010, and 13, June 29, 2010)

RDC/ANVISA Resolution 27, August 06, 2010 (Approves the categories of Foods and Packaging that are exempted from and required to make Registration)

1. **Quantitative Product Formula**
2. **Certificate of Nutritional Information**
3. **Original Product Label**
4. **Pro Forma Invoice**
5. **Import License (LI)**
6. **Bill of Lading or AWB**
7. **Embarkation Instruction**
8. **Commercial invoice**
9. **Certificate of Analysis**
10. **Packing List**
11. **Petition for Sanitary Inspection and Clearance (ANVISA)**
12. **Operational license of the warehouse where the product will be stored**
13. **Import Declaration (DI)**
14. **ICMS guide collected**
15. **Certificate of Origin**
16. **Product Import Communication (CIP)**
17. **Request for Control Analysis (SAC)**
18. **Label or tag in Portuguese**

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Please do not hesitate to contact the offices below with questions or comments regarding this study or to request assistance.

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