Date: 6/13/2019
GAIN Report Number: BR19019

Brazil

Post: Sao Paulo ATO

Market Access Brief for Infant Formulas

Report Categories:
Market Development Reports

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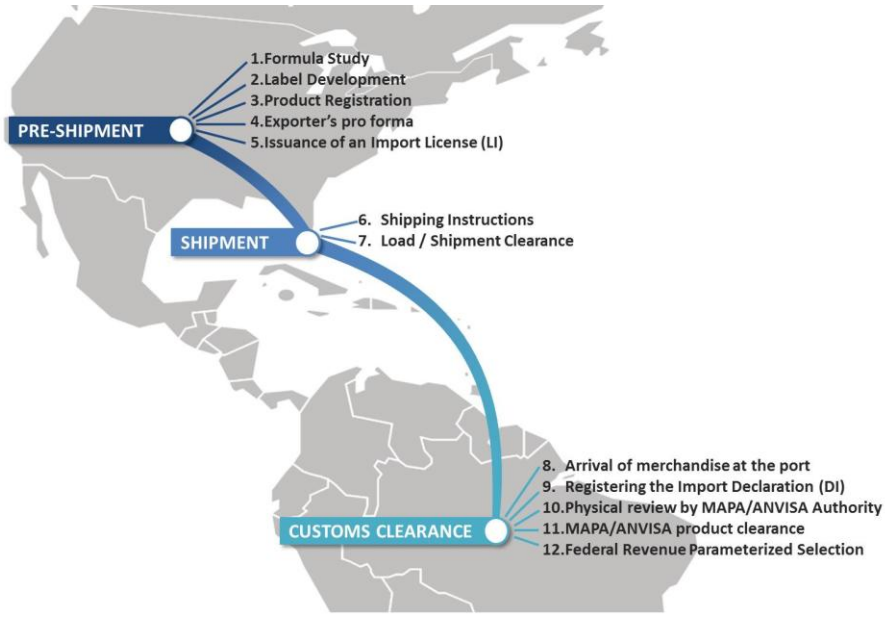
Report Highlights:
U.S. exporters often reach out to our office with questions about market access and Brazil's import regulations, finding legislation confusing and not transparent. To bring a bit more clarity, ATO Sao Paulo prepared a series of Market Access Briefs by product category. These briefs are intended to serve as a guide for each step of the export process from formula study and label development to shipping and final customs clearance. ATO Sao Paulo also assigned a complexity level for each product category. The information contained in each brief was developed in concert with private consultants, importers, and customs agents.

DISCLAIMER: This report was developed by the U.S. Agricultural Trade Office (ATO), 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 the study, 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 is not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their Brazilian 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 RULE AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

I. Import Procedures for Infant Formulas into Brazil

Level of complexity of importing Infant Formulas into Brazil: High



1) Formula Study

Under the Brazilian legislation, regulators must maintain "positive" lists of ingredients approved for consumption. In addition, all food or beverage ingredients must meet government specifications and tolerance levels. The "Technical Regulation" provides the "Identity and Quality Standard" (PIQ) for any given product. This means that only specifically authorized products (including additives, colorings, preservatives, etc.) are allowed to enter the market. All imported Infant Formulas must comply with Brazilian legislation. It is recommended to perform a compliance study to determine if the Infant Formula is in accordance to Technical Regulations (RT), limits of additives and food safety criteria. In case of non-compliance, the product must be adjusted to the requirements of the legislation.
Legislation:

a) Technical Regulations (*Food Standard)*
   - RDC Resolution nº 42 of September 19, 2011;
   - RDC Resolution nº 45 of September 25, 2014,
   - RDC Resolution nº 43 of September 19, 2011;
   - RDC Resolution nº 46 of September 25, 2014,
   - RDC Resolution nº 44 of September 19, 2011;

- RDC Resolution nº 47 of September 25, 2014, and
- RDC Resolution nº 45 of September 19, 2011;
- RDC Resolution nº 48 of September 25, 2014.

b) Food Additives
- RDC Resolution nº 46 of September 19, 2011;
- RDC Resolution nº 49 of September 25, 2014.

c) *Food Safety*
- Contaminants
  .Decree nº 55,871 of March 26, 1965
  .SNVS/MS Ordinance nº 11 of May 15, 1987
  .SVS Ordinance nº 685 of August 27, 1998
  .RDC Resolution nº 42 of August 29, 2013
- Microbiology
  .RDC/ANVISA Resolution nº 12 of January 02, 2001
- Mycotoxins
  .RDC Resolution nº 7 of February 18, 2011
  .RDC Resolution nº 59 of December 26, 2013
  .RDC Resolution nº 138 of February 08, 2017
- Foreign Matter
  .RDC Resolution nº 14 of March 28, 2014
- Pesticide Residues
  .RE Resolution nº 165 of August 29, 2003, and updates

2) Product Registration (SISCOLE Compliance)

Yes, the registration of infant formulas is mandatory. The importer should regularize the product with ANVISA as soon as it arrives in Brazil, according to the provisions of ANVISA Resolutions nº 22 and 23 of March 15, 2000, and RDC Resolution nº 27 of August 06, 2010.

a) Registration of Company

The importing company, the representative of the manufacturer in Brazil, or the subsidiary company registers with ANVISA Website. The importer makes the electronic registration through an electronic form provided by ANVISA and filled with basic company´s information.

b) Registration Fee

The application for registration requires the payment of a fee, which value depends on the size of the company. The annual revenue stated in the Income Tax Return determines the size of the company. Such evidence is provided at the time of company´s registration.

Company´s Classification	**Annual Revenue**	**Registration Fee**
Group I – large	Above R$ 50.000.000,00 (fifty million BRL)	R$ 10.637,40

Group II – large	Equal to or lower than R$ 50.000.000,00 (fifty million BRL) and higher than R$ 20.000.000,00 (twenty million BRL).	R$ 9.041,79
Group III average	Equal to or lower than R$ 20.000.000,00 (twenty million BRL) and higher than R$ 6.000.000,00 (six million BRL).	R$ 7.446,18
Group IV – average	Equal to or lower than R$ 6.000.000,00 (six million BRL).	R$ 4.254,96
Small	Equal to or lower than R$ 1.200.000,00 (one million, two hundred thousand BRL) and higher than R$ 244.000,00 (two hundred and forty-four thousand BRL).	R$ 1.063,74
Microenterprise	Equal to or lower than R$ 244.000,00 (two hundred and forty-four thousand BRL).	R$ 531,87

c) Before commercializing or importing any product that is subject to registration with ANVISA, it is necessary to submit the product for the evaluation and approval by ANVISA. This procedure is called Registration of Product, and it is complete with the publication of the enrollment in the Federal Official Gazette (DOU).

The registration of product consists of preparing a process to be filed with ANVISA, in Brasília. Following documents are required:

- Cover Sheet
- Petition Form 1, which must be filled out with following information:
  . the corporate name of registration applicant,
  . number of registration of the applicant with ANVISA (leave this blank if this is the first process),
  . code and description of the food category, according to RDC/ANVISA Resolution nº 27/10,
  . the technical name of the product, and
  . quantitative composition of the product.
- Petition Form 2, signed by the legal representative and technician of registration applicant, which requires the following information:
  . the corporate name, city, state, and country of manufacturer,
  . number of registration of register applicant (leave this blank if this is the first process),
  . the expiry date of the product,
  . the technical name of the product,
  . brand, and
  . package material that is in contact with the food.
- Original evidence of the payment of ANVISA fee in any bank.
- Label wording.
- Certificate of analysis, as required.
- Registration form of company, if this is the first process.
- Operating license of the warehouse.

The ANVISA offices in Brasília register the process, according to the submission requirements. As of June 27, 2017, the processes are submitted only in electronic media, as provided for in RDC Resolution

nº 86 of June 27, 2016. Once the process is under study by GPESP/ANVISA technicians in Brasília, and if necessary, they may require more information about a certain subject, or some change. The period for compliance with the requirements is 120 consecutive days. At the end of the process analysis, the number of product registration is published in the Federal Official Gazette (DOU).

Legislation:

- Law nº 9,782 of January 26, 1999,
- ANVS Resolution nº 22 and 23 of March 15, 2000,
- RDC Resolution nº 222 of December 28, 2006,
- RDC Resolution nº 76 of October 23, 2008,
- RDC Resolution nº 65 of December 21, 2009,
- RDC Resolution nº 27 of August 6, 2010,
- RDC Resolution nº 25 of June 16, 2011,
- RDC Resolution nº 17 of March 22, 2012,
- RDC Resolution nº 50 of November 06, 2013,
- RDC Resolution nº 28 of July 03, 2015,
- RDC Resolution nº 86 of June 27, 2016,
- ANVISA Normative Instruction nº 08 of June 27, 2016, and
- MF/MS Interministerial Ordinance nº 45 of January 27, 2017.

3) Label Development

If the label of a product is not in Portuguese, it is possible to place an adhesive label containing all mandatory information in Portuguese over the original label. This label can be placed at origin or in Brazil, but always before its commercialization.

In general, the label and tag must contain the following information:

a) *Mandatory items in Front Panel*

- Technical name, as defined in the specific Technical Regulations
- Brand
- Information about alcohol content
- Weight/volume indication – note the minimum height for figures and letters, according to the following table

Net content (g or ml)	Minimum height of letters (mm)
Lower than or equal to 50	2.0
Higher than 50 and lower than or equal to 200	3.0
Higher than 200 and lower than or equal to 1,000	4.0
Higher than 1,000	6.0

When the original package of the product does not show any indication of quantity in the main panel or shows dimensions or units in disagreement with those determined in the INMETRO Ordinance nº 157/02, such information should be inserted on the label before the product goes to the final consumer.

b) *Other Mandatory items*

- List of Ingredients
- Warnings (allergens, gluten, alcohol consumption and others)

- Origin Country
- Manufacturer data (name and complete address)
- Importer data (corporate name, complete address and CNPJ)
- Number of importer registration
- Expiration date
- Lot. Manufacturing date or expiration date can replace the lot
- Conservation care
- Instructions for use and preparation, as applicable
- Other information required by the specific Technical Regulations

Legislation:

a) General Rules
   - Decree nº 55,871 of March 1965,
   - Law Decree nº 986 of October 21, 1969,
   - INMETRO Ordinance nº 2,051 of November 08, 2001,
   - RDC/ANVISA Resolution nº 222 of August 05, 2002,
   - RDC Resolution nº 259 of September 20, 2002; RDC Resolution nº 123 of May 13, 2004,
   - Law nº 11,265 of January 03, 2006; Law nº 11,474, of May 15, 2007,
   - RDC Resolution nº 43 of September 19, 2011; RDC Resolution nº 46 of September 25, 2014,
   - RDC Resolution nº 44 of September 19, 2011; RDC Resolution nº 47 of September 25, 2014, and
   - RDC Resolution nº 45 of September 19, 2011; RDC Resolution nº 48 of September 25, 2014.

b) Net weight declaration
   - INMETRO Ordinance nº 157 of August 19, 2002.

c) Nutritional labeling
   - RDC Resolution nº 360 of December 23, 2003.

d) Warnings
   - Gluten – Law nº 10,674 of May 16, 2003,
   - Allergens - RDC Resolution nº 26 of July 02, 2015, and
   - Lactose – Law nº 13,305 of July 04, 2016; RDC Resolution nº 136 of February 08, 2017.

4) Exporter's Pro Forma

The import operation begins after the commercialization of merchandise is agreed upon by the exporter and importer. For importation, a Pro-Forma Invoice must be created, a standard document used in international commerce, containing all information about the negotiation and details of purchased merchandise (product data, payment terms, transport mode and other data).

5) Issuance of an import License (LI)

After accepting the Pro Forma Invoice, the importer must get an Import License (LI). The LI is one document issued electronically through the Integrated Foreign Trade System (SISCOMEX) by the importer and approved by ANVISA. The LI is required to clear the product. The LI can be requested after the shipping of merchandise but it needs to be issued before the product arrival. The importer or a

person previously authorized to operate the SISCOMEX on behalf of the importer performs this procedure.

Legislation:

- RDC Resolution nº 81 of May 05, 2008,
- SECEX/MDIC Ordinance nº 23 of July 14, 2011, as amended, and
- RDC Resolution nº 74 of May 02, 2016.

6) Shipping Instructions

Before shipping, the importer has to provide the exporter with Shipping Instructions, consisting of information about the negotiation and terms of merchandise shipping, such as quantity of product, payment terms, the temperature of transportation, packaging, pallet, etc. ***Special note on pallets.*** Before shipping goods to Brazil, exporters should be aware of wood pallets and wood packaging regulations. Pallets must be in compliance with International Standards for Phytosanitary Measures N° 15 **(**ISPM 15) and have the International Plant Protection Convention (IPPC) stamp. For countries that have not adopted the ISPM 15 standards, the phytosanitary certificate may be substituted for the IPPC stamp, with an additional declaration on treatment records or the certificate of treatment stamped by the National Plant Protection Organization (NPPO). Wood pallets, both treated and untreated, are always inspected by MAPA. Inspectors will check for the presence of pests and may or may not release the cargo. Costs related to phytosanitary treatment or returning pallets/cargo to the country of origin will be the exporter/importers' responsibility. The pallets made with different materials (cardboard, fibers, plastics, and others) and those made with industrialized or processed wood are exempt from these requirements.

Also, the Shipping Instruction must contain all documents to be submitted by the exporter to the importer:

- Certificate of Analysis and Certificate of Origin, issued by a laboratory or an entity of the country of origin contained in the list available on MAPA Website.

- A commercial invoice containing following information:
  - complete name and address of exporter
  - full name and address of the importer
  - specification of merchandise, in Portuguese or the official language of the General Agreement on Tariffs and Trade, or in another language, accompanied by a translation into Portuguese, at the discretion of customs authority, containing own and commercial denominations, with an indication of the elements that are indispensable for their perfect identification
  - mark, numbers and reference number of volumes, if any
  - quantity and type of volumes
  - gross weight of volumes, in other words, the burden of merchandise with all its containers, packages and other wrappers
  - net weight, i.e., the weight of the merchandise free of every wrapping
  - origin country, the country where the production of merchandise or the last substantial transformation occurred
  - acquisition country, the country of acquisition of the merchandise for exportation to Brazil, independently of the origin country of merchandise or inputs
  - source country, the country where the merchandise was at the time of acquisition

. unit and the total price of each type of merchandise and the amount and nature of decreases and discounts granted to the importer, if any
. freight and other expenses referring to the merchandise specified in the invoice
. payment terms and currency
. term and condition of sale (INCOTERM)

- Packing List (declaration with details of imported products).

- Bill of Lading
  The exporter submits the Shipping Instructions to the shipping company, containing the necessary information for the issuance of the bill of lading (Air Waybill (AWB), Railway Bill (RWB) or Road Bill (CMR) or Marine Bill of Landing (B/L). The bill of lading is the proof of shipping that is issued by the shipping company and contains all the details of transportation.

Legislation:
- RDC Resolution nº 81 of May 05, 2008,
- Decree nº 6,759 of February 05, 2009, and
- RDC Resolution nº 74 of May 02, 2016.

7) Arrival of the Merchandise at the Port

When the merchandise arrives at the port, the cargo proceeds to the Bonded Warehouse (warehouse) pre-designated by the importer. Otherwise, the cargo goes to the terminal with which the shipping company has an agreement. After the proper placement of the merchandise, the terminal confirms and generates a "Cargo Manifest", in other words, the terminal informs the conditions of cargo receipt on the SISCOMEX. The registration of the Import Declaration (DI) in the SISCOMEX is not possible without the cargo manifest.
Legislation:
- RFB/MT Normative Instruction nº 797 of December 20, 2007, and
- RFB Normative Instruction nº 800 of December 27, 2007, and nº 1,473 of June 02, 2014.

8) Registering the Import Declaration (DI)

After the clearance of LI by ANVISA, the importer or authorized customs agent registers the Import Declaration (DI) with the SISCOMEX. The DI is a document containing all information about the importation.

- Importer data
- Cargo data
- Bonded warehouse data
- Merchandise data
- Negotiated payment terms
- Federal taxes (Import Tax (II), Industrialized Products Tax (IPI), Social Integration Tax (PIS), and Social Contribution Tax (COFINS) and antidumping rights, as applicable); federal taxes are automatically debited from importer or customs agent account
- State taxes – State Value Added Tax (ICMS); the ICMS is collected using the Form of State Collection (GAE), which is payable at any bank branch in Brazil. The Federal Revenue Service should receive the original payment evidence.

- Additional information, as the case may be (for example, authorized customs agent)
- The exchange rate of the negotiation currency, as determined by the Brazilian Central Bank
- A detailed description of merchandise, according to the LI and the commercial invoice

The cost for registration of a DI, according to SRF Normative Instruction nº 1,158/11 is of R$ 185,00 per DI, plus the cost of each merchandise added, which varies according to the number of additions. Cost of fee = R$185,00 + value referring to the number of additions of DI.

Number of Additions	Value per Addition (R$)
Up to 2nd addition	29,50
From 3rd to 5th addition	23,60
From 6th to 10th addition	17,70
From 11th to 20th addition	11,80
From 21st to 50th addition	5,90
As of the 51st addition	2,95

Legislation:

- SRF Normative Instruction nº 680 of October 02, 2006, and
- SRF Normative Instruction nº 1,158 of May 24, 2014.

9) Physical review by ANVISA Authority

a) Checking and release of cargo by ANVISA inspector

After the issuance of the LI through SISCOMEX, the exporter requests its approval by ANVISA. The ANVISA Website provides the necessary application for the Petition for Sanitary Inspection and Release. After filing this petition, the exporter pays a federal tax for the importation of products under the responsibility of ANVISA using the Federal Collection Form (GRU). The access to the electronic system of petitions and collection depends on a previous registration of importer through the Internet on ANVISA electronic address, and a personal, confidential, and non-transferable password. Once ANVISA approves the LI, the imported product is released by that Agency and goes through a clearance procedure required by the Federal Revenue Service.

b) Import Tax - ANVISA

The importer makes the electronic registration through an electronic form provided by ANVISA and filled with basic company´s information. Upon this registration on the ANVISA Website, the importer or customs agent requests the Electronic Petition for Sanitary Inspection and Release on the site, and provides information about the imported merchandise, the quantity of imported merchandise and the bill of lading.

When the electronic petition is complete, the Federal Collection Form (GRU) is generated for the payment by the interested party upon direct debit in a bank account, electronic means or at any bank branch. The amount of the fee varies according to the number of imported items and the size of the company. After the payment of this tax, the ANVISA inspector performs a physical checking of the

product, collecting a sample for analysis. According to RDC Resolution nº 81 of May 05, 2008, only the products subject to the LI require this procedure.

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

IMPORTED MERCHANDISE	VALUE OF FEE ACCORDING TO COMPANY SIZE (R$)					
	GROUP I	GROUP II	GROUP III	GROUP IV	SMALL COMPANY	MICRO COMPANY
Importation of a maximum of ten (10) items of goods, products, raw material or inputs.	177,92	151,23	124,54	71,168	17,79	8,90
Importation of eleven (11) to twenty (20) items of goods, products, raw material or inputs.	354,58	301,39	248,21	141,832	35,46	17,73
Importation of twenty-one (21) to thirty (30) items of goods, products, raw material or inputs.	531,87	452,09	372,31	212,748	53,19	26,59
Importation of thirty-one (31) to fifty (50) items of goods, products, raw material or inputs.	1.772,90	1.506,97	1.241,03	709,16	177,29	88,65
Importation of fifty-one (51) to one hundred (100) items of goods, products, raw material or inputs.	3.545,80	3.013,93	2.482,06	1.418,32	354,58	177,29

Legislation:

- Law nº 9,782 of January 26, 1999,
- RDC Resolution nº 222 of December 28, 2006, as amended,
- RDC Resolution nº 81 of May 05, 2008,
- MF/MS Interministerial Ordinance nº 45 of January 27, 2017, and
- RDC Resolution nº 74 of May 02, 2016.

10) Federal Revenue Parameterized Selection

After the registration of DI, the Federal Revenue Service performs the parameterization in the SISCOMEX. The system performs the parameterization, and selects one of following channels:

- Green Channel: exempts examination of documents and review of merchandise, and the release occurs in about one (01) day.
- Yellow Channel: only the review of records is required, and the release of merchandise takes place in about two (02) days.
- Red Channel: in addition to a review of documents, merchandise must be physically examined, and the release of the product takes place in about four (04) days.
- Gray Channel: this is a special customs control channel, and it may take more than 60 days after parameterization.

The parameterization process must conclude within the periods set forth, and after all correct documents for customs clearance are provided according to MAPA Normative Instruction nº 55/06:

Legislation:

- RDC Resolution nº 81 of May 05, 2008,
- Decree nº 6,759 of February 05, 2009

11) How to regularize the product?

In addition to ANVISA registration, it is necessary to file the Request of Control Analysis (SAC) to regularize and commercialize the product. This regularization is provided for in ANVS/MS Resolutions n° 22 and nº 23 of March 15, 2000, and is made with the Local Department of Health at importer´s location, within a maximum period of thirty (30) days after the beginning of product commercialization. The Control Analysis is an instrument available to the Sanitary Surveillance to check whether the product is according to the Brazilian legislation and information contained in registration process and label.

The following information is required to fill out the SAC:

- food category, according to RDC/ANVISA Resolution nº 27 of August 6, 2010,
- the technical name of the product,
- the product brand, and
- warehouse data for the collection of the sample (corporate name, complete address, CNPJ, name, telephone and e-mail address).

The SAC has three (03) copies, signed by the Legal Representative and the Responsible Technician of the company, accompanied by three (03) copies of approved Petition Forms 1 and 2, three (03) copies of approved label wording, and 1 copy of the publication of registration in the Federal Official Gazette.

The interested importer prepares the SAC, and a skilled third party may be hired to help. There are no sanitary fees for this procedure.
The legal sanitary procedures required from the company to commercialize the product finish when the SAC is duly registered.

The importers are required to inform ANVISA about the phenylalanine content of imported products.

Legislation:

- ANVS/MS Resolution nº 22 and 23 of March 15, 2000
- RDC Resolution nº 27 of August 6, 2010,
- RDC Resolution nº 19 of May 06, 2010.