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GAIN Report

Global Agricultural Information Network

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Market Access Brief for Chewing Gum

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Market Development Reports

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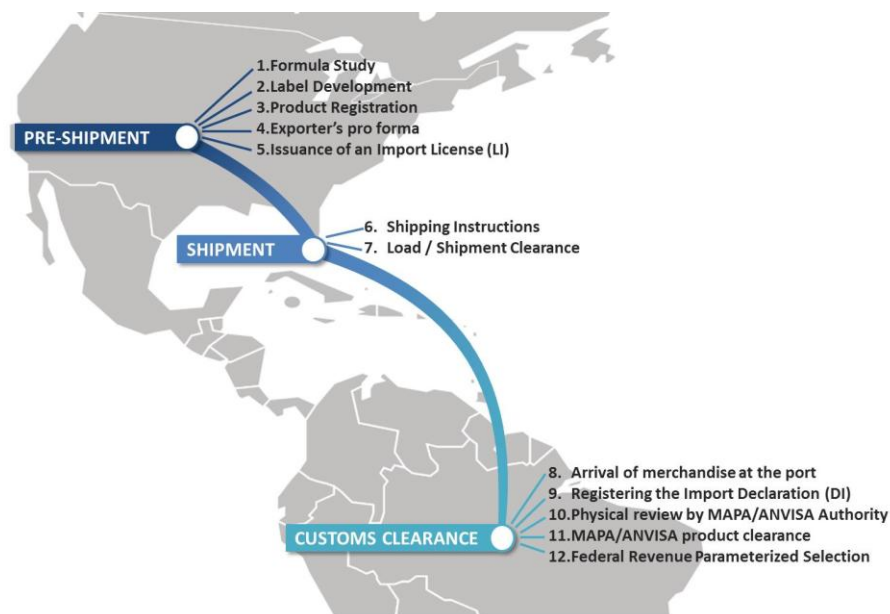
Report Highlights:

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 Chewing Gum into Brazil

Level of complexity of importing chewing gum into Brazil: Low



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 chewing gums must comply with Brazilian legislation. It is recommended to perform a compliance study to determine if the chewing gum 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*)
 - CNNPA Resolution n° 3 of June 03, 1976
 - RDC Resolution n° 265 of September 22, 2005

- b) Food Additives

- RDC Resolution n° 387 of August 05, 1999
- RDC Resolution n° 45 of November 03, 2010
- RDC Resolution n° 46 of November 03, 2010
- RDC Resolution n° 18 of March 24, 2008 (sweeteners)

c) Food Safety

- Contaminants
 - .Decree n° 55,871 of March 26, 1965
 - .SNVS/MS Ordinance n° 11 of May 15, 1987
 - .SVS Ordinance n° 685 of August 27, 1998
 - .RDC Resolution n° 42 of August 29, 2013
- Microbiology
 - .RDC/ANVISA Resolution n° 12 of January 02, 2001
- Mycotoxins
 - .RDC Resolution n° 7 of February 18, 2011
 - .RDC Resolution n° 59 of December 26, 2013
 - .RDC Resolution n° 138 of February 08, 2017
- Foreign Matter
 - .RDC Resolution n° 14 of March 28, 2014
- Pesticide Residues
 - .RE Resolution n° 165 of August 29, 2003

2) Product Registration

The regular chewing gum, without sugar or diet, is exempt from registration. The importer should regularize the product with ANVISA as soon as it arrives in Brazil, according to the provisions of ANVISA Resolutions n° 22 and 23 of March 15, 2000, and RDC Resolution n° 27 of August 06, 2010. See item 12.

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 n° 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
- Nutrition Information mandatory information that must be according to RDC Resolutions n° 359, 360/03 and n° 163/06. The Nutrition Facts should follow one of the ANVISA approved formats and provide mandatory information about:
 - .energetic value
 - .carbohydrate
 - .protein
 - .total fat
 - .saturated fat
 - .trans fat
 - .dietary fiber
 - .sodium.

Following is one of the approved formats for a nutrition facts table:

NUTRITION FACTS		
Serving... g or ... ml (household measure)		
Quantity per serving		% VD (*)
Energetic valuekcal =....kJ	
Carbohydrate	g	
Protein	g	
total fat,	g	
saturated fat,	g	
<i>Trans</i> fats	g	**
dietary fiber, and	g	
Sodium	mg	

* % Daily Values based on a 2,000-kcal or 8,400-kJ diet. Your daily values can be higher or lower, depending on your energy needs.

** Daily Value not established.

The Nutrition Facts must provide information per serving of the food, indicating its corresponding Household Measure. A serving is the average amount of food that should be consumed by healthy persons, with age above 36 months, at each consumption occasion, to allow a healthy diet. The term

Household Measure is the measure equivalent to the serving of food, obtained by using a utensil that is commonly employed by the consumer to measure food (for example, glass, cup, tablespoon and others). The RDC Resolution n° 359/03 determines the servings of each food and their corresponding household measures.

Legislations:

a) *General Rules*

- Decree n° 55,871 of March 26, 1965
- Law Decree n° 986 of October 21, 1969
- RDC Resolution n° 259 of September 20, 2002
- RDC Resolution n° 123 of May 13, 2004

b) *Net weight declaration*

- INMETRO Ordinance n° 157 of August 19, 2002
- INMETRO Ordinance n° 73 of May 19, 1999

c) *Nutritional labeling*

- RDC Resolution n° 359 and n° 360 of December 23, 2003
- RDC Resolution n° 163 of August 17, 2006.

d) *Warnings*

- Aspartame, Polyalcohols
.SVS/MS Ordinance n° 29 of January 13, 1998
- Tartrazine
.RDC Resolution n° 340 of December 13, 2002
- Gluten
.Law n° 10,674 of May 16, 2003
- GMO
.Decree n° 4,680 of April 24, 2003
.CC/PR/MJ/MS/MAPA Joint Normative Instruction n° 01 of April 1, 2004
.MJ Ordinance n° 2,658 of December 22, 2003
- Allergens
.RDC Resolution n° 26 of July 02, 2015
- Lactose
.Law n° 13,305 of July 04, 2016
.RDC Resolution n° 136 of February 08, 2017
- Irradiation
.Decree n° 72,718 of August 29, 1973
.RDC Resolution n° 21 of January 26, 2001

e) *Nutritional Claims*

- RDC Resolution n° 54 of November 12, 2012
- RDC Resolution n° 03 of February 04, 2013

f) *Food for Special Dietary Uses*

- SVS/MS Ordinance n° 29 of January 13, 1998, and

- RDC Resolution n° 135 of February 08, 2017.

() Except for nutritional claims and claims allowed for Foods for Special Dietary Uses, all information is mandatory, when applicable, and should be included in product labeling.*

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 n° 81 of May 05, 2008
- SECEX/MDIC Ordinance n° 23 of July 14, 2011
- RDC Resolution n° 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 ANVISA 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 Lading (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 n° 81 of May 05, 2008,
- Decree n° 6,759 of February 05, 2009, and
- RDC Resolution n° 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 n° 797 of December 20, 2007
- RFB Normative Instruction n° 800 of December 27, 2007, and n° 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 n° 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 n° 680 of October 02, 2006
- SRF Normative Instruction n° 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 n° 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 n° 9,782 of January 26, 1999,

- RDC Resolution n° 222 of December 28, 2006, as amended,
- RDC Resolution n° 81 of May 05, 2008,
- MF/MS Interministerial Ordinance n° 45 of January 27, 2017, and
- RDC Resolution n° 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 n° 55/06:

Legislation:

- RDC Resolution n° 81 of May 05, 2008
- Decree n° 6,759 of February 05, 2009

11) How to regularize the product?

a) Exemption of registration

The exporter files the Communication of Product Import (CIP) with the Health Department of the City of the location of the warehouse, for the regularization and commercialization of the products under the responsibility of ANVISA that do not require registration. CIP is one of the documents provided to the Sanitary Authority to release the merchandise. Therefore, it is filed before the arrival of merchandise, or even on the date of arrival, but not earlier than ten (10) days before the arrival.

The CIP is filled out by the importer, signed by the Legal Representative of the company, and is accompanied by a copy of the Operating License of the warehouse and registered in two (02) copies.

The CIP contains the following information:

- importer data (corporate name, complete address, CNPJ, telephone and e-mail address),
- warehouse data (legal name, complete address, CNPJ, telephone and e-mail address),
- date of product import,
- date of product commercialization start,
- category of food, according to RDC Resolution n° 27 of August 06, 2010,
- the technical name of the product,
- brand,
- package material,
- expiration,
- commercial perspective (local, state, national or export),
- name of the manufacturer, and
- origin country.

After registration of product CIP, within a maximum period of thirty (30) days after the date when product commercialization started, the Request of Control Analysis (SAC) should be registered with that Local Health Department. The Control Analysis is an instrument available to the Sanitary Surveillance to check if the product is according to Brazilian legislation and information contained in product CIP.

The following information is required to fill out the SAC:

- category of food, according to RDC Resolution n° 27 of August 06, 2010,
- the technical name of the product,
- 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 product formula, three (03) copies of the product label or tag in Portuguese, and one (01) copy of CIP Protocol.

The interested importer prepares the CIP and 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 with the registration of CIP and SAC.

b) Phenylalanine content

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

Legislation:

- ANVS/MS Resolution n° 22 and 23 of March 15, 2000
- RDC Resolution n° 27 of August 06, 201
- RDC Resolution n° 19 of May 06, 2010