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**SÃO PAULO STATE GOVERNMENT**  
Secretariat of Agriculture and Food Supply

**Overview of food packaging regulations in Brazil and other South American countries**

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BRAZIL




**Brazil**

- ✓ Food contact material regulations are published by the Brazilian Health Regulatory Agency (ANVISA) which belongs to the Ministry of Health
- ✓ MERCOSUR'S Common Market Group (GMC) Resolutions are incorporated by ANVISA in the form of Ordinances and Resolutions
- ✓ The GMC Resolutions are published by ANVISA according to the type of material (plastic, glass, cellulose, elastomers, regenerated cellulose, waxes) and the identification numbers of the corresponding regulations are different

*For instance, the GMC resolution on General criteria and material classification, which is GMC N. 03/92, was published by ANVISA as Resolution RDC N. 91 from May 11, 2001*

<http://portal.anvisa.gov.br/room/233861967127/86006ea18e-4f86a45c-4a13f9d311d>




**Brazil**

**Plastic Materials**

MERCOSUR Resolution	Subject	Corresponding Brazilian Regulation
GMC N. 03/92	General provisions	Resolution RDC N. 91/2001
GMC N. 56/92	General provisions for plastic materials	General Provisions of Resolution N. 105/1999
GMC N. 32/07	Positive List of Additives (Under review)	Resolution RDC* N. 17/2008
GMC N. 02/12	Positive List of Monomers and Polymers	Resolution RDC N. 56/2012


\* RDC: Collegiate Directorate Resolution



**Brazil**

**Plastic Materials**

MERCOSUR Resolution	Subject	Corresponding Brazilian Regulation
GMC N. 30/07	Post-consumer recycled PET (PCR-PET)	Resolution RDC N. 20/2008
GMC N. 25/99	Multilayer PET with recycled layer	Ordinance N. 987/1998
GMC N. 16/93	Returnable PET packages for non-alcoholic carbonated beverages	Annex IX of Resolution N. 105/1999
GMC N. 15/10	Colorants for plastic materials	Resolution RDC N. 52/2010
GMC N. 32/10	Overall and Specific Migration – Test conditions	Resolution RDC N. 51/2010



**Brazil**

**Plastic Materials**

MERCOSUR Resolution	Subject	Corresponding Brazilian Regulation
-	General criteria for fixed equipment supply, storage and distribution of drinking water	Annex VII of Resolution N. 105/1999
GMC N. 56/98	Fluorinated polyethylene	Annex VIII of Resolution N. 105/1999

Resolution N. 105/1999 has General Provisions and 14 Annexes, but many of them have been revoked, with just General provisions and the Annexes VII, VIII and IX remaining.

Resolution RDC N. 41/2011  
Prohibition of the use of bisphenol A (BPA) in baby bottles



**Brazil**

**Plastic Materials - Overview**

In Brazil, to demonstrate the compliance of plastic materials, the following resolutions must be followed:

- Resolution N. 105/1999
- Resolution N. 17/2008
- Resolution N. 51/2010
- Resolution N. 52/2010 (if there is colorant)
- Resolution N. 56/2012

➔ Specific requirements for materials with recycled PET

**Brazil**

**Other Materials and Regulations**

- Adhesives
- Elastomers
- Waxes and Paraffins
- Regenerated Cellulose Film
- Regenerated Cellulose Casings
- Metallic materials
- Glass material
- Cellulosic material

**Brazil**

MERCOSUR's efforts to amend the Additives Resolution, GMC Res. No. 32/07 (Brazil – Resolution N. 17/2008)

Brazil: Public Consultation N° 599 was published on January 22, 2019 concerning the positive list of additives and the closing meeting is scheduled to June 14, 2019.

<http://portal.anvisa.gov.br/consultas-publicas/visualizar/389760>

**Brazil**

MERCOSUR's efforts to amend the Additives Resolution, GMC Res. No. 32/07

The update also includes the following requirements:

- Specific migration limits (group restriction): **Al (1mg/kg)**; Ba (1 mg/kg); Co (0,05 mg/kg), Cu (5 mg/kg), Fe (48 mg/kg), Li (0,6 mg/kg); Mn (0,6 mg/kg); Ni (0,02 mg/kg); **Zn (5 mg/kg)**.
- Primary Aromatic Amines (PAAs): not detected (detection limit= 0,01mg/kg)
- Fat consumption reduction factor (FRF): lipophilic substance according to Table 1
- Determination of the specific migration by approximation

**Brazil**

MERCOSUR's efforts to amend the Additives Resolution, GMC Res. No. 32/07 - Technical Regulation on Positive List of Additives for **Plastic Materials**, Packaging and Equipment in contact with Food.

**BUT:** 3.2. Polymeric Coatings

They can only be prepared with the substances included on the positive lists of **polymers and additives for plastic materials in contact with foods** and comply with restrictions of use, limits of composition and specific migrations established in the Resolutions.

[Resolution GMC 46/06 – Metallic materials](#)

2.1. The adhesives can only be prepared with one or more substances mentioned on the "Positive List of Polymers and Resins for Plastic Packaging and Equipment in contact with Food", on the "**Positive List of Additives for Plastic Materials and Equipment in contact with Food**", on the "Positive List for Cellulosic Materials and Equipment in contact with Food" and on the "Positive List for Elastomeric Materials and Equipment in contact with Foods", approved in corresponding legislation.

[Resolution GMC 27/99 - Adhesives](#)

**Brazil**

**Legislation updates**

Brazil procedures to request the inclusion of substances in the positive lists or the development of a new regulation (new technologies) or a regulation update:

- ✓ A formal request (a petition) must be made to ANVISA by companies or industry associations
- ✓ It must be addressed to ANVISA
- ✓ The petitioner must have an office or a representative office in Brazil

**PLASTIC MATERIALS**

If there is no harmonized regulation in MERCOSUR, ANVISA will evaluate the request and may include the subject in its Regulatory Agenda in accordance with the priority established by ANVISA

if there is a harmonized regulation in MERCOSUR, it should follow the MERCOSUR procedures

**Brazil**

**Good Manufacturing Practices (GMP)**

Public Consultation N. 42, May 13, 2015 (**is ready to be published**)

**Good Manufacturing Practices** for manufacturers of packaging and equipment intended to come into contact with food

- ✓ The requirements are similar to those described in the standards used for certification (mainly PAS 223:2011 and BRC IoP)

## Brazil

### Registration and Imported products

#### ✓ Resolution N. 23 of March 15, 2000

Guide on basic procedures for registration and exemption from registration of products related to food

#### ✓ Resolution N. 22 of March 15, 2000

Technical Regulation on procedures for registration and exemption from registration of imported products related to food

#### ✓ Resolution RDC N. 27 of August 06, 2010

This regulation updates food and packaging exempted from registration and those with mandatory registration



## Brazil

### Resolutions N. 22/2000, N. 23/2000 and RDC N. 27/2010

#### Main Points:

- ✓ Packaging and materials for food contact are **exempted from mandatory registration** (except those made of recycled materials)

The **recycled materials** have **mandatory registration**  
In Brazil, only these materials are allowed: **PCR-PET** and **Cellulosic**



## Brazil

### Resolution N. 22 and N. 23 of March 15th, 2000

Packaging and materials for food contact are exempted from obligatory registration (except for recycled packages)



However:

- Packaging and food industries must comply with the published technical regulations
- Sanitary Inspection is required (Operation License)
- Good Manufacture Practices must be implemented in compliance with legislation
- HACCP must be implemented
- Companies must inform the beginning of the manufacture of the product to the Sanitary Authority



## Brazil

### Resolution No 22 for imported products

Exporting to Brazil

The same steps, procedures and technical requirements for the packages produced nationally must be observed by the local representative in Brazil and/or importer.

- Sanitary or Operation License of the warehouse
- The importation of products must be informed to the Authority through a specific form
- Good manufacturing / storage products must be implemented
- Compliance with the Brazilian technical regulations in force



## Brazil

MERCOSUR and Brazil have no specific regulation for these topics

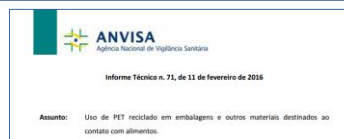
- ✓ **Nanomaterials:** it is recommended to send specific petitions to ANVISA
- ✓ **Printing inks:** it is recommended to follow the requirements of Swiss Legislation or EUPIA guide
- ✓ **Active and Intelligent packaging**
- **Biopolymers (PLA, PHB...)**

Other Issues

- ✓ They should be in compliance with plastic regulations for food contact materials
- ✓ They should be listed on the Positive Lists (Resolution RDC N. 58/2012 and Resolution RDC N. 17/2008)






## Brazil




Technical information regarding recycled PET for food contact

The document aims to guide the National Sanitary Surveillance System (SNVS) department and the productive sector regarding the legislation in force on the use of PET-PCR in packaging intended for food contact and procedures for regularization of resin, articles and packaging obtained from this type of material.



**Brazil**



Agência Nacional de Vigilância Sanitária  
ANVISA

? PERGUNTAS & RESPOSTAS

Materiais em contato com alimentos


GERÊNCIA-GERAL DE ALIMENTOS  
Gerência de Avaliação de Risco e Eficácia de Alimentos

7ª edição  
Brasília, 19 de agosto de 2017

Questions and Answers

Food contact material

The document is currently unavailable  
It is being updated







**Brazil**



To contact ANVISA:  
<http://portal.anvisa.gov.br/contato>

CANAL DE ATENDIMENTO

SERVIÇOS

1. **SEM CUSTO** 0800 6 782

2. **Serviço de Informação ao Cidadão (SIC)**

3. **Dúvidas**

4. **Formulário eletrônico**

5. **Solicitação sobre Atendimento ao Público**

**Horário de atendimento**  
 Segunda a sexta, das 7h00 às 18h00 (exceto feriados).

**Para que serve?**  
 Para se obter informações mais rápidas sobre a atuação da Anvisa e sobre os serviços oferecidos pela Agência.

**Prazo de resposta**  
 Os documentos serão processados dentro do prazo de 15 dias úteis, exceto nos casos de atendimento prioritário. Caso contrário, o prazo é de até 30 dias úteis.





Secretariat of Agriculture and Food Supply