



Update on the regulatory situation for food contact materials in Brazil and other South American countries

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BRAZIL

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Packaging Technology Center

Cellulosic Packaging
Transport and Distribution

Plastic Packaging

Metal Packaging
Glass Packaging

Packaging & Environment

(www.cetea.ital.sp.gov.br)



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AGRICULTURA E ABASTECIMENTO



GOVERNO DO ESTADO DE
SÃO PAULO
RESPEITO POR VOCÊ

Agenda

- Update on Brazilian Regulations
- Specific Issues of MERCOSUR:
Paraguay and Uruguay
- Non-MERCOSUR Countries:
Chile, Peru, Venezuela, Ecuador, Bolivia
- Conclusion



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BRAZIL:

Area: 8,515,692 km²

States: 27

Population: 190,755, 799 inhabitants
(08/01/2010)

(Source: IBGE – Census 2010)



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Brazil

Food Packaging Materials Resolution have been published by the National Agency of Sanitary Surveillance (ANVISA) - Ministry of Health, according to the type of packaging material, plastics, metal, glass, cellulose, elastomers, regenerated cellulose.

General criteria

The GMC Resolution on general criteria and material classification was published as Resolution RDC N. 91 of May 11, 2001

(www.anvisa.gov.br/alimentos/legis/especifica/embalagens.htm)




Brazil

Plastic materials

The GMC Resolutions on plastic materials were consolidated into Resolution N. 105 of May 19, 1999 and published on May 20, 1999 in the Diário Oficial da União - DOU.

➡ Annexes:
I, III, IV, V, VI, X, XIII and XIV were repealed.





Brazil

Resolution 105/99 – Annexes repealed

- Annex I – Foods and food simulants classification
- Annex III – Positive List of additives
- Annex IV – Colorants and pigments
- Annex V – Total migration
- Annex VI – Total migration with simulant olive oil
- Annex X – Aromatic amines (pigments and colorants)
- Annex XIII – Specific migration of MEG and DEG (SML methodology)
- Annex XIV – Specific migration of terephthalic acid (SML methodology)



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Brazil

Plastic materials

- ✓ The Positive List of Additives was updated by Resolution RDC N.17 of March 17, 2008
- ✓ Colorants and pigments including aromatic amines were updated by Resolution N.52 of November 30, 2010
- ✓ The total and specific migration procedures and foods and food simulants classification were updated by Resolution N. 51 of November 30, 2010.



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Brazil

Resolution 105/99 – Annexes in force

Annex II – Positive List of monomers and polymers

Annex XI – Determination of styrene (LC)

Annex XII – Determination of vinyl chloride (LC)

Annex VII – General criteria for fixed equipment supply, storage and distribution of drinking water

Annex VIII – Fluorinated polyethylene

Annex IX – Returnable PET packages for non-alcoholic carbonated beverages



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Brazil

Plastic materials

✓ The Resolution on multilayer PET was published as Decree N.987 of December 8, 1998

✓ The Resolution on Post-consumer Recycled PET was published as Resolution RDC N.20 of March 26, 2008



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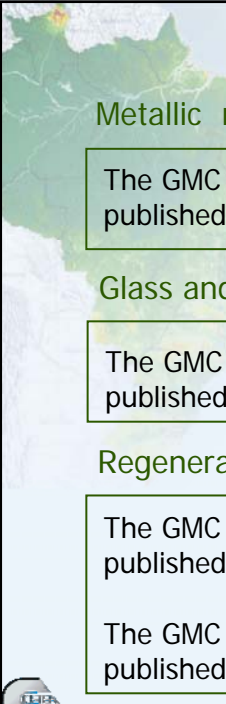
Brazil

Cellulosic Materials

The GMC Resolutions on cellulosic materials were consolidated into Decree N. 177 of March 8, 1999

The Resolution on Recycled Cellulosic Materials was published as Resolution RDC N.129 of May 10, 2002

The Resolution on Cellulosic Materials - inclusion of pentachlorophenol was published as Resolution RDC N.130 of May 10, 2002



Brazil

Metallic materials

The GMC Resolution on metallic materials was published as Resolution RDC N. 20 of March 22, 2007



Glass and ceramics

The GMC Resolution on glass and ceramics was published as Decree N. 27 of March 13, 1996

Regenerated cellulose

The GMC Resolution on regenerated cellulose film was published as Resolution RDC N. 217 of August 1, 2002

The GMC Resolution on regenerated cellulose casing was published as Resolution RDC N. 218 of August 1, 2002





Brazil

Elastomeric materials

The GMC Resolutions on elastomeric materials were consolidated as Resolution RDC N. 123 of June 19, 2001

Food-contact paraffins

The GMC Resolution on paraffins was published as Resolution RDC N. 122 of June 19, 2001

Adhesives


The GMC Resolution on adhesives was published as an Annex of Resolution RDC N. 91 of May 11, 2001

Film-forming – food coating

The GMC Resolution on film-forming preparations intended for food coating was published as Resolution RDC N. 124 of June 19, 2001



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Brazil

New polymers, monomers or additives

A petition to ANVISA is necessary in order to include the substance on the Positive Lists of MERCOSUR.

The petition must be addressed to ANVISA and the petitioner should have an office or a representative office (agency) in Brazil.

New packaging technologies

The process must be evaluated by ANVISA. A petition is also necessary. Legal representative in Brazil is required



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Brazil

➡ Obligatory Registration is not required

➡ Good Manufacturing Practices



Brazil

Registration

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

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

Nevertheless:

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



Exporting to Brazil

Resolution No 22 *for imported products*

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 practices must be implemented
- Compliance with the Brazilian technical regulations in force




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Resolutions N. 22/2000 and 23/2000 –
Responsibilities and necessity or not of registration

Ongoing update!



Public Consultation N.95 of December 21, 2009



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Brazil

Public Consultation N.95 of December 21, 2009

Technical Regulation regarding procedures for Sanitary Registration and Notification of products exempt from registration

- Keeps the same principle and structure of Resolutions 22 and 23/2000 with more details of the requirements and procedures
- Applies to Brazilian and imported products



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Brazil

Resolution RDC N. 27 of August 6, 2010 updates the food and packaging categories exempt or not from obligatory registration

Annex I: Foods and packaging exempt from obligatory registration (Packaging)

Annex II: Foods and packaging with obligatory registration (New packaging technology (Recycled packaging))



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Brazil

Resolution RDC N. 27 of August 6, 2010 updates the food and packaging categories exempt or not from obligatory registration

Annex III: Documents required for registration and other administrative procedures relating to registration

Annex IV: Company Registration Form

Annex V: Application Form 1 - FP1 (product)

Annex VI: Application Form 2 – FP2 (presentation)

Annex VII, VIII and IX: Instructions for completing FP1 and FP2



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Brazil

Good Manufacturing Practices (GMP) / HACCP

A Resolution related to GMP is to be applied for food packaging producers.

ANVISA is also enhancing the Sanitary Inspection and Control Activities of packaging producers



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Public Consultation N. 79, November 18, 2009

Guide on Good Manufacturing Practices and Sanitary Inspection for manufacturers of packaging and equipment intended to come into contact with food

- Harmonization of the action of Sanitary Inspection on packaging and equipment manufacturers
- Development of an Instrument of Verification of Good Manufacturing Practices



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Brazil

Public Consultation N. 79, November 18, 2009

Guide on Good Manufacturing Practices and Sanitary Inspection for manufacturers of packaging and equipment intended to come into contact with food

- Annex I – Technical Regulation on GMP and Sanitary Inspection
- Appendix I - Checklist of GMPs for manufacturers of packaging and equipment intended to come into contact with food



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Annex I – Technical Regulation on GMP and Sanitary Inspection

- Production Plant
 - Location
 - Physical Facilities
 - Sanitary Facilities
- Integrated Pest Management
- Sanitation of Facilities and Equipment
- Health & Personal Care
- Waste Management








Brazil

Annex I – Technical Regulation on GMP and Sanitary Inspection

- Production
 - Raw materials
 - Manufacture
 - Finished product control
 - Storage and transport of finished product
- Records
 - Records of Hygiene and Sanitation Quality System
 - Manual of Good Manufacturing Practices
 - Standard Operating Procedures - POP
 - Records of manufacturing operations

Brazil

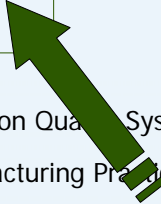
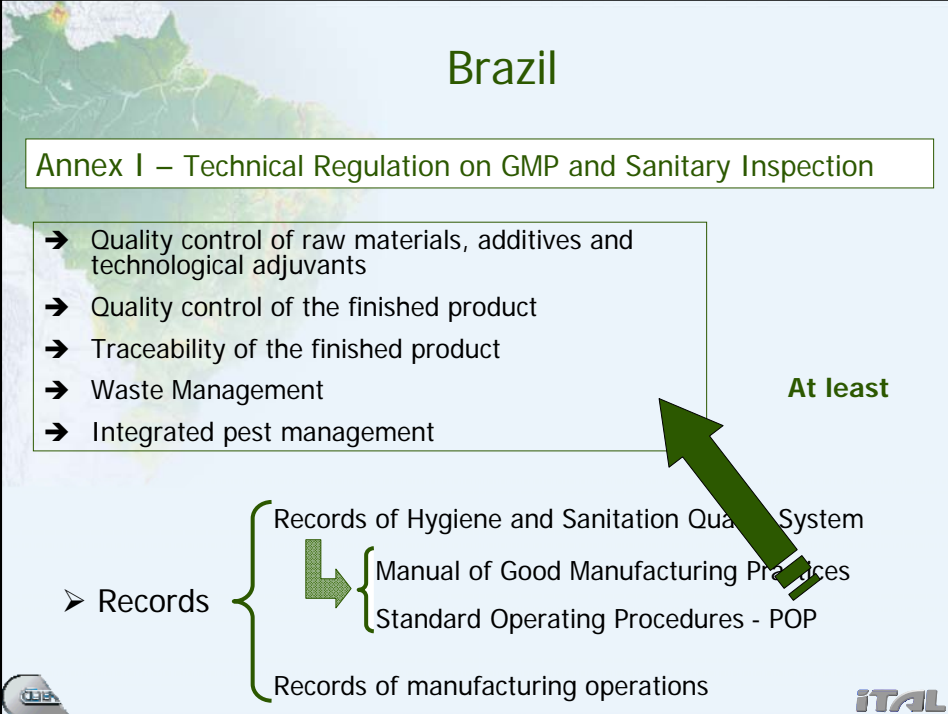


Annex I – Technical Regulation on GMP and Sanitary Inspection

- Quality control of raw materials, additives and technological adjuvants
- Quality control of the finished product
- Traceability of the finished product
- Waste Management
- Integrated pest management

At least

➤ Records

- Records of Hygiene and Sanitation Quality System
- Manual of Good Manufacturing Practices
- Standard Operating Procedures - POP
- Records of manufacturing operations

Active and intelligent packaging





Mercosur/Brazil

Mercosur and Brazil have no specific legislation on active or intelligent packaging

Currently:

1. Released substances in compliance with Food Legislation

Specific Legislation on food additives and technological coadjuvants. *They are separated by function and food types, restrictions on use and maximum quantities allowed*

(<http://www.anvisa.gov.br/alimentos/legis/especifica/aditivos.htm>)



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Mercosur/Brazil

Mercosur and Brazil have no specific legislation on active or intelligent packaging

Currently:

2. Additives listed on Positive List of Additives for plastic materials

Resolution RDC N. 17 of March 17, 2008

Positive List of Additives

Four additives with silver are included in the last update

(http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2008/res0017_17_03_2008.html)



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Mercosur/Brazil

Mercosur and Brazil have no specific legislation on active or intelligent packaging

Although Brazil does not have a special requirement for active packaging, it is recommended to label the sachet, p.e. *"Do not eat"*. It is important for consumer information and safety.

The sachet material has to be approved if it will be in direct contact with food.



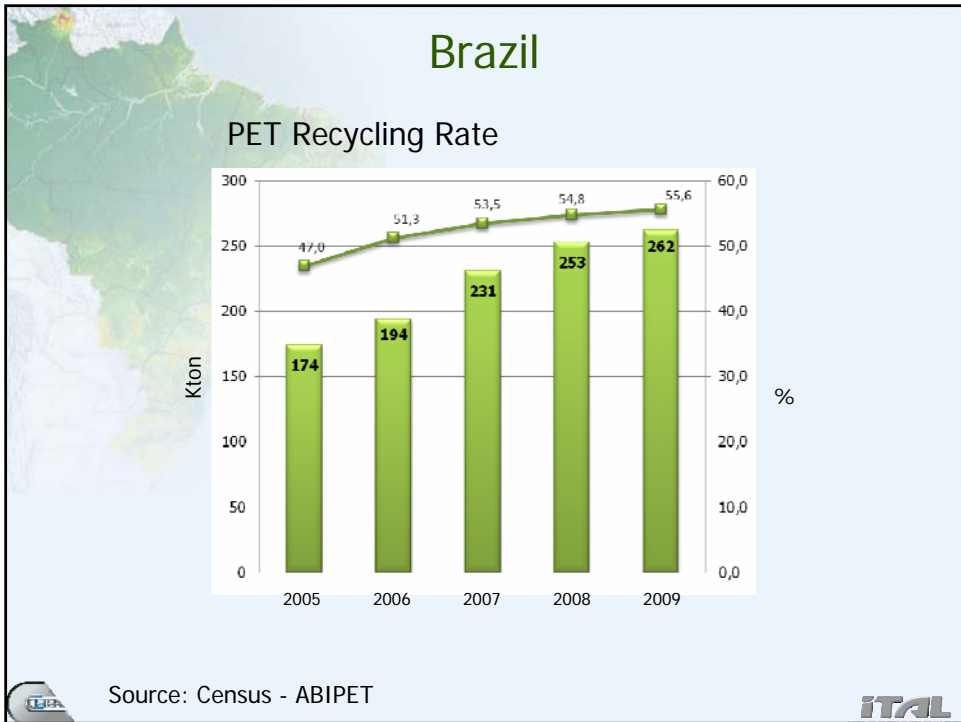
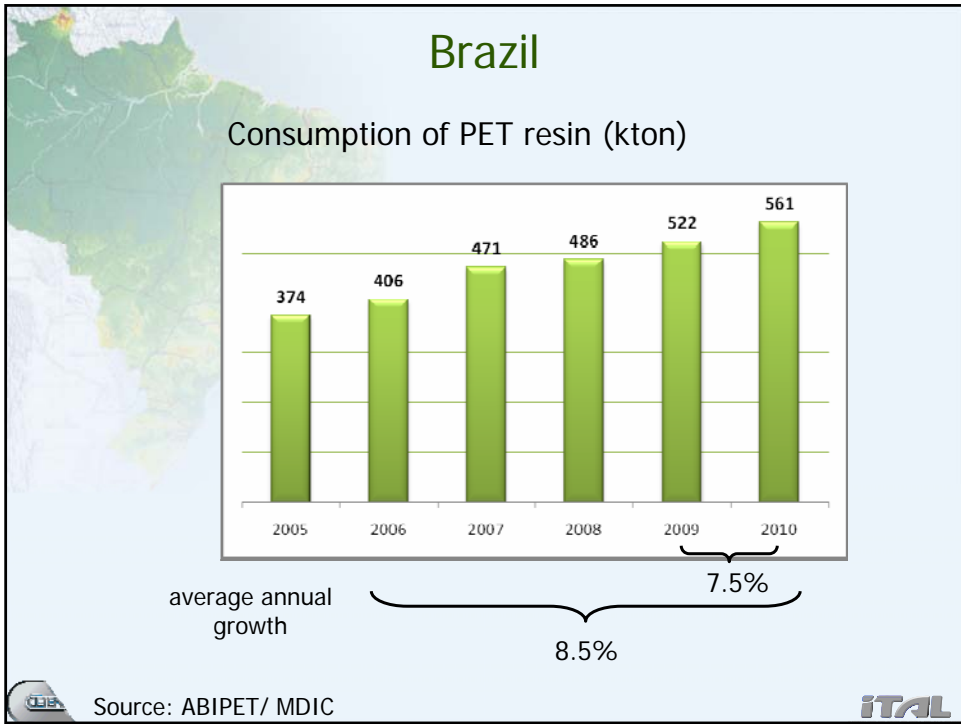
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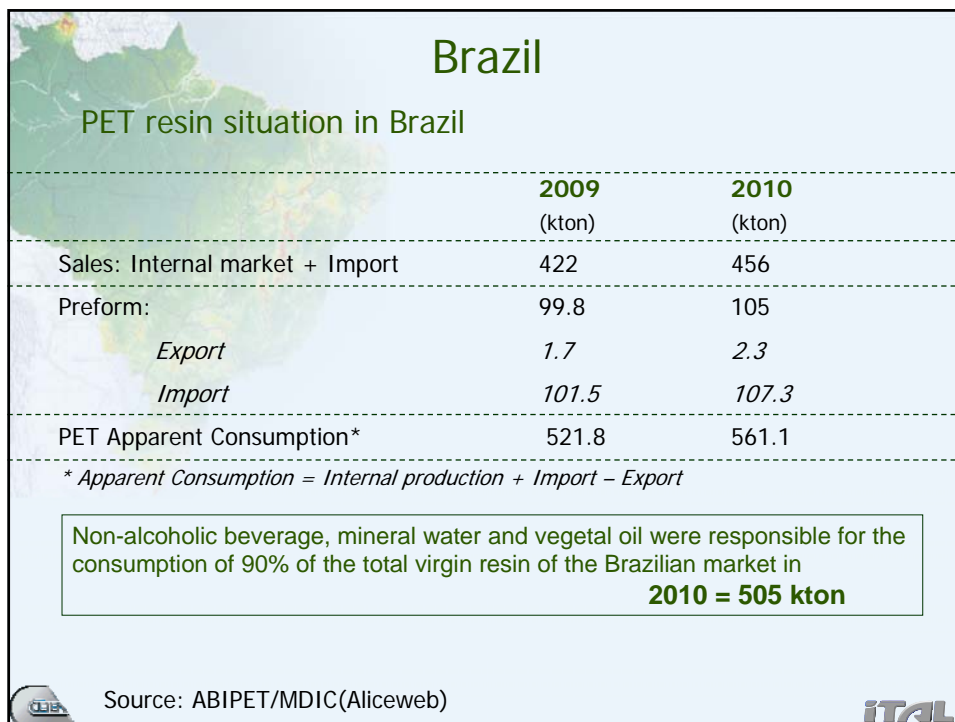


Post-consumer recycled
food-grade PET



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Brazil

RESOLUTION RDC N. 20/2008

The responsibility for the quality of the PCR-PET material is shared among:

Recycler	<ul style="list-style-type: none"> • Recycling Process • Plant authorization/Sanitary Authority Inspection • Quality control/Monitoring
Processor	<ul style="list-style-type: none"> • Sanitary Authority Inspection • Documentation and Traceability • Registration of the final package
Food Processor	<ul style="list-style-type: none"> • To use only packaging registered by the competent authority

Brazil

Recycler	<ul style="list-style-type: none"> • Recycling Process • Plant authorization/Sanitary Authority Inspection • Quality control/Monitoring
-----------------	--

Resolution RE N. 535 of February 18, 2009

CPR - Indústria E Comércio De Plásticos Ltda

PET PCR Food Grade

Other processes are under evaluation





Brazil

RESOLUTION RDC N. 20/2008

Labelling

The final package should contain:

- ✓ Identification of the manufacturer
- ✓ The lot number or code for traceability
- ✓ The expression "PET-PCR"



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Other Issues

Biopolymers - PHB, PLA, Starch, Green polyethylene...

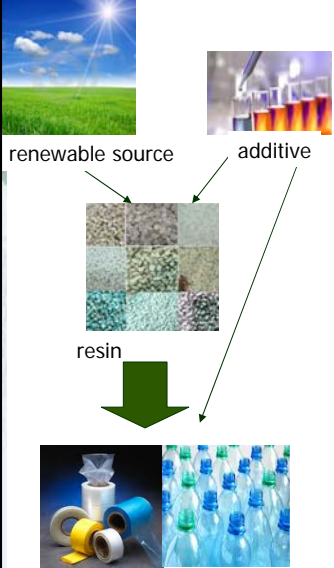
Nanomaterials and nanotechnology

Irradiation (inks, varnishes, lacquers...)- by product evaluation



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Brazil



renewable source



additive

resin

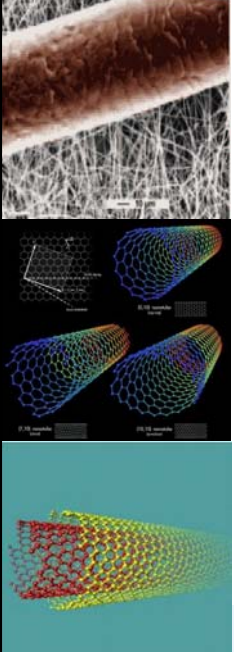
Brazil has great potential as a source of **biopolymers**.

But they have to comply with the requirements established by the Food Contact Legislation.

- ▶ The polymers and the additives must be listed on the Positive Lists and they have to comply with the restrictions.
- ▶ New polymers have to be evaluated to ensure they are safe to come into contact with foods.

Brazil



Mercosur and Brazil have no specific legislation on food contact **nanomaterials**

Packaging and equipment should not be a risk to human health.

Questions regarding the potential for migration, biological interactions, risk assessment, effective analytical techniques are not yet completely solved.

There are no materials with nanoparticles approved for food contact.




Paraguay

MERCOSUR GMC resolutions on food contact material have been incorporated into Paraguay legislation by the Paraguayan Ministry of Public Health and Social Welfare.

The Ministerial Decree N. 6115 of February 11, 2011, establishes the procedures for obligatory registration of packaging and materials for food contact in Paraguay.



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Paraguay

The government entity responsible for assuring correct application of food-related standards, rules and regulations and registration procedures in Paraguay is the National Institute of Food and Nutrition - INAN (Instituto Nacional de Alimentacion y Nutricion).

The National Institute of Technology, Standardization and Metrology (INTN) is also responsible for establishing the requirements for implementation of the registration procedures.



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Uruguay

MERCOSUR GMC Resolutions on food contact materials were incorporated into Uruguayan National Legislation by the Ministry of Public Health (MSP) by Decree N. 315/1994 of the Reglamento Bromatologico Nacional and updates.

The Obligatory Registration of food products and packaging in Uruguay is issued by the Ministry of Public Health.



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Non-Mercosur Countries

Chile, Bolivia, Ecuador, Peru and Venezuela have no specific regulation for food contact materials

General requirements are described in the Food and Beverage Regulation



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Chile

Decree n° 977/1996 - Sanitary Regulations for Foods - published by Ministry of Health
(Update on June 30th, 2000)

Establishes the sanitary conditions for production, importation, elaboration, packaging, storage, distribution and selling of foods

Some requirements for packaging for food products are included in articles 123, 125, 126 and 129

- Packaging must not contain any toxic substance and not transfer off flavor to the product.
- Limits for metal impurities for metallic packaging.
- Limits for residual monomers (styrene, vinyl chloride and acrylonitrile)

Chilean National Institute of Standardization (INN)
(www.inn.cl)

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Peru

General requirements are described in the Regulation for Food and Beverages - Ministerial Decree N. 007-98-AS of September 25th, 1998 (Articles 64, 118 and 119)

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Peru

INDECOPI (Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual), through Technical Committee for standardization - CTN 014 - Packaging. Flexible Plastic Packaging for Foods of the Technical and Commercial Regulations Commission, published since 2004 standards on packaging for food contact.

They include general provisions, foods and foods simulants classification, positive lists of monomers, polymers and additives (**similar to MERCOSUR and Brazilian legislation**) colorants and pigments, total migration determination, specific migration determination: terephthalic acid, nono and diethyleneglycol and determination of residual vinyl chloride, styrene, acrylonitrile monomers and isocyanates.



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Bolivia

Some general requirements are described in the Administrative Resolution N. 19 of March 12, 2004 Sanitary Requirements for the Manufacture, Storage, Shipping and Portioning of Foods and Beverages for Human Consumption (Article 44, Chapter VIII)

IBNORCA – Bolivian Institute for Standardization and Quality issued a series of standards covering packages for food contact (glass, metallic, paper and paperboard and plastic food containers).

(www.ibnorca.org)



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Bolivia

Decreto Supremo N° 0559 of June 23, 2010

Bolivian Standard – NB 716002

Post-consumer recycled food-grade polyethylene terephthalate (PET) (PET-PCR food-grade) in food-contact applications.

Sanitary Authority

SENASAG - Servicio Nacional de Sanidad Agropecuaria e Inocuidad Alimentaria.



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Ecuador

Some general requirements are described in the Food Regulation Executive Decree N. 4114 of July 22, 1988 (Title V, Chapter III – Filling and packaging, Articles 136 through 143)

INEN (Ecuadorian Institute of Standardization) is working on standards for food contact materials. Sixteen standards will be published this year (2011).

(www.inen.gov.ec)



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Venezuela

MERCOSUR Adhesion Protocol

Article 3 - Venezuela was to adopt the MERCOSUR norms gradually, in a period of four years from July 4, 2006.

Situation nowadays: Venezuela as a permanent member of MERCOSUR must still be ratified by Paraguay.



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Venezuela

Technical Regulation on Food (Ministerial Decree n° 525 of January, 12th, 1959) and Complementary Standards

Food packaging - national or imported - must be authorized by the competent authority of the Ministry of Health (Art. 18)

Requirements - Sanitary Authorization of Equipment, Materials, Additives and Packaging for Food Contact.

(articles 30 to 33 - Section 2 of Chapter II on Surveillance and Control of Foods, Complementary Standards)

Departamento de Control Higienico de Edificaciones, Equipos y Envases of the Dirección de Higiene de los Alimentos is responsible for the food packaging materials approval



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Venezuela

Resolution N. 082 of May 4, 2007 regarding Good Manufacturing Practices, Storage and Transportation of packaging and articles intended to be in contact with foods.

Venezuelan Standards - COVENIN

COVENIN Standards have been approved related to food safety and packaging materials for food contact.

- Total migration (plastic, cellulosic-based materials, sealants)
- Heavy metals in dyes, pigments, masterbatches and inks
- Residual vinyl chloride monomer
- Maximum extractable fraction in hexane
- Maximum soluble fraction in xylene
- Use of isocyanate-based adhesives

(www.fondonorma.gov.ve)

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Conclusions

MERCOSUR has specific food packaging legislation

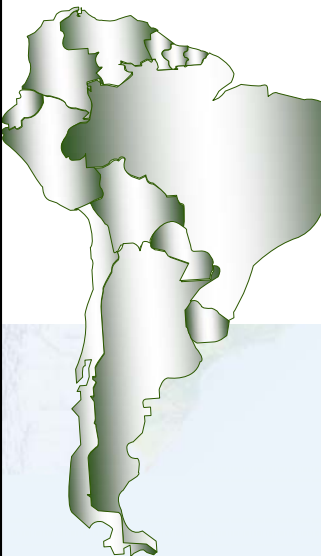
ARGENTINA, BRAZIL, PARAGUAY and URUGUAY have adopted the MERCOSUR Legislation

BRAZIL has some specific requirements regarding packaging registration process and good manufacturing practices



CHILE, BOLIVIA, ECUADOR, PERU and VENEZUELA have no specific food packaging legislation, only some requirements in the Regulations for Foods and Beverages

BOLIVIA, PERU, ECUADOR and VENEZUELA have standards related to food packaging materials

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Thank you for your attention!



A collage of various images representing Brazilian nature and urban development. The images include: a dense green forest with a winding path; a waterfall with a rainbow; a field of blue flowers; two colorful parrots; a large dam; a coastal town with a lighthouse; a tropical beach with palm trees; a toucan bird; a tiger; a modern city skyline; a stadium; and a large white dome structure.