“MERCOSUR and other Latin American FCMs regulations”

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Presentation at the:
FRENCH DIRECTORATE FOR COMPETITION POLICY, CONSUMERS AFFAIRS AND FRAUD CONTROL OFFICE OF SAFETY AND ALERT NETWORK (DGCCRF)
Paris, France, June 24, 2011

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Colombia: Sara Torres (Ministry of the Social Protection)

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Paraguay: Alba Costa (INTN – National Institute of Technology and Standardization)

(*) Members of the Iberoamerican CYTED Program food packaging projects.
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- Country blocks in Latin America.
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MERCOSUR (MERCADO COMUN DEL SUR)  
MERCOSUL (MERCADO COMUM DO SUL)  
COMMOM MARKET OF THE SOUTH

- CREATED BY THE TREATY OF ASUNCION DEL PARAGUAY  
(MARCH 26, 1991)
- CONSOLIDATED BY THE TREATY OF OURO PRETO – BRAZIL (DECEMBER 17, 1994)

PACKAGING GROUP
FOOD COMMISSION

TECHNICAL SUBGROUP 3 (SGT 3) – “TECHNICAL REGULATIONS AND EVALUATION OF CONFORMITY”

GMC (Grupo Mercado Común) – COMMON MARKET GROUP

Argentina  
Brazil  
Paraguay  
Uruguay
THE HARMONISATION OF NATIONAL REGULATIONS

STANDARDIZATION – TBT REMOVAL

Recommendations

EU

GERMANY

USA

REFERENCE REGULATIONS AND RECOMMENDATIONS FOR THE HARMONISATION PROCESS IN MERCOSUR.
PROPOSALS OF REGULATIONS

FOOD COMMISSION

GMC – COMMON MARKET GROUP

SANCTIONS REGULATIONS

TRANSPOSITION OF REGULATIONS INTO NATIONAL LEGISLATIONS

MERCOSUR RESOLUTIONS IN FORCE

(Adapted from M. Padula and A. Ariosti (IATA, 2002) and G. Kopper and A. Ariosti (Academic Press, 2009; ELSEVIER, 2010)).

<table>
<thead>
<tr>
<th>MATERIAL</th>
<th>SUBJECT</th>
<th>GMC RESOLUTION Nº</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>Framework Resolution: general requisites for FCMs</td>
<td>3/92</td>
</tr>
<tr>
<td></td>
<td>General requisites for positive lists up-dating</td>
<td>31/99</td>
</tr>
<tr>
<td></td>
<td>Reference analytical methodology for the control of FCMs</td>
<td>32/99</td>
</tr>
</tbody>
</table>

Nomenclature: GMC Resolutions are referred to by the designation XX/YY, where XX is the GMC Resolution number and YY are the two last digits of the year of sanction.

### Plastic FCMs

<table>
<thead>
<tr>
<th>New!!</th>
<th>2010</th>
<th>Revised 2010</th>
<th>Public consultation finished</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General requisites</strong></td>
<td></td>
<td></td>
<td>56/92</td>
</tr>
<tr>
<td><strong>Positive list of resins and polymers</strong></td>
<td></td>
<td></td>
<td>24/04 (to be repealed)</td>
</tr>
<tr>
<td>Positive list of additives</td>
<td></td>
<td></td>
<td>32/07</td>
</tr>
<tr>
<td><strong>Migration methods</strong></td>
<td></td>
<td></td>
<td>32/10</td>
</tr>
<tr>
<td><strong>Colorants and pigments</strong></td>
<td></td>
<td></td>
<td>15/10</td>
</tr>
<tr>
<td>Method for the determination of residual vinyl chloride monomer content in PVC</td>
<td></td>
<td></td>
<td>47/93, 13/97 (to be repealed)</td>
</tr>
<tr>
<td>Method for the determination of residual styrene monomer content in polystyrene</td>
<td></td>
<td></td>
<td>86/93, 14/97 (to be repealed)</td>
</tr>
<tr>
<td>Method for the determination of specific migration of mono- and diethylene glycol</td>
<td></td>
<td></td>
<td>11/95, 15/97 (REPEALED)</td>
</tr>
<tr>
<td>Fluorinated polyethylene</td>
<td></td>
<td></td>
<td>56/98</td>
</tr>
<tr>
<td>Polymeric and resinous coatings for foods</td>
<td></td>
<td></td>
<td>55/99</td>
</tr>
<tr>
<td>Refillable PET packages for carbonated non-alcoholic beverages</td>
<td></td>
<td></td>
<td>16/93</td>
</tr>
<tr>
<td>Multilayer PET packages, with central layer containing recycled material, for carbonated non-alcoholic beverages</td>
<td></td>
<td></td>
<td>25/99</td>
</tr>
<tr>
<td>Recycled PET for food packages (multilayer and monolayer packages)</td>
<td></td>
<td></td>
<td>30/07</td>
</tr>
</tbody>
</table>

### Metallic FCMs

<table>
<thead>
<tr>
<th>Glass and ceramic FCMs</th>
<th>General requisites</th>
<th>46/06</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cellulose based FCMs</strong> (paper, paperboard and cardboard)</td>
<td>General requisites (to be repealed along with the following four Resolutions)</td>
<td>19/94, 35/97, 20/00</td>
</tr>
<tr>
<td>Positive list of components</td>
<td></td>
<td>56/97</td>
</tr>
<tr>
<td>Global migration method</td>
<td></td>
<td>12/95</td>
</tr>
<tr>
<td>Papers for hot filtration and cooking</td>
<td></td>
<td>47/98</td>
</tr>
<tr>
<td>Papers for cooking in oven (new)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recycled cellulose fibers</td>
<td></td>
<td>52/99</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Regenerated cellulose FCMs</th>
<th>Films</th>
<th>55/97</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casings</td>
<td></td>
<td>68/00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Elastomeric FCMs</th>
<th>General requisites</th>
<th>54/97</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive list of components</td>
<td></td>
<td>28/99</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adhesives</th>
<th>General requisites</th>
<th>27/99</th>
</tr>
</thead>
</table>

| Paraffins for food contact | General requisites | 67/00 |
FCMs must comply with the sanitary requirements established in these Resolutions.

The main requirements are:
- inclusion of components in positive lists
- compliance with the overall migration limit(s)
- compliance with the specific migration limit(s) (SML)
- compliance with concentration limit(s) in FCMs (QM)
- avoid undesirable changes of food sensory properties
- specific requisites on pigments and colorants
- general prohibition of plastics reuse (with exceptions).

Most FCMs (e.g.: final package) need a pre-market approval/registration established by Resolution GMC 3/92 (item 3.4) and specific FCMs Resolutions.

The Member States Sanitary Authorities issue approvals/registrations of FCMs.

The manufacturer of a FCM must obtain its approval/registration (e.g.: items 10 and 11, Resolution GMC 56/92 for plastics).

The final FCM user (e.g.: food manufacturer) must buy and use only approved/registered FCMs (e.g.: item 12, Resolution GMC 56/92 for plastics).
PETITIONS OF INCLUSIONS OF NEW FOOD CONTACT SUBSTANCES IN THE MERCOSUR POSITIVE LISTS:

➢ ARGENTINA:

SUBMIT PETITION TO THE CONAL (NATIONAL FOOD COMMISSION) – BUENOS AIRES

➢ BRAZIL:

SUBMIT PETITION TO THE ANVISA (NATIONAL AGENCY OF SANITARY SURVEILLANCE) – BRASILIA

MERCOSUR Strategic Association of Industrial Technology Institutes

To this Association belong the following Institutes, which work in collaborative projects dealing with food packaging, standardization and regulatory issues in MERCOSUR:

• INTI (National Institute of Industrial Technology) - Argentina
• INMETRO (National Institute of Metrology, Standardization and Industrial Quality) - Brazil
• INT (National Institute of Technology) - Brazil
• INTN (National Institute of Technology and Standardization) - Paraguay
• LATU (Uruguay Technological Laboratory) - Uruguay
CYTED (IBEROAMERICAN PROGRAM “SCIENCE AND TECHNOLOGY FOR DEVELOPMENT”) PROJECT XI.7

“IMPACT OF MIGRATION OF COMPONENTS AND RESIDUES FROM PACKAGING IN THE QUALITY AND SAFETY OF PACKAGED FOODSTUFFS AND ITS INFLUENCE IN TRADE” 1997-2001

International Coordinator: Dr. Ramón Catalá (IATA-Valencia, Spain).

“Migration of components and residues from packaging in contact with foodstuffs”. Ramón Catalá and Rafael Gavara, Eds. Institute of Agrochemistry and Food Technology, Valencia, Spain, 2002.
FOOD AND FCMs LEGISLATION IN ARGENTINA


Chapter IV: Utensils, containers, packages, wrappings, devices and accessories in contact with foodstuffs.

1960: the Argentine Dr. Carlos Grau, a pioneer in advocating harmonization of food regulations, was the main responsible for writing the LATIN AMERICAN FOOD CODE, that reproduces the ARGENTINE FEDERAL FOOD REGULATION (1953).

It includes specific requirements for FCMs as in Chapter IV. A revised version was published in 1964.

It was the basis for several Latin American countries Food Codes, and for harmonization in the region.

It is an update of the ARGENTINE FEDERAL FOOD REGULATION (1953).

It maintains Chapter IV, into which the FCMs MERCOSUR Resolutions are transposed at present.


There are several Sanitary Authorities that approve/register FCMs, according to the Argentine Food Code – Chapter IV, that incorporates the MERCOSUR Resolutions:

• National Level:
  ➢ INAL (FOOD NATIONAL INSTITUTE)
  ➢ SENASA (NATIONAL SERVICE OF FOOD HEALTH AND QUALITY)
  ➢ INV (NATIONAL INSTITUTE OF VITIVINICULTURE)

• Provincial Level:
  Official Laboratories of the City of Buenos Aires, of the Province of Buenos Aires, of the Province of Córdoba, of the Province of Mendoza, of the Province of Santa Fe, etc.

EXPORTING FCMs TO ARGENTINA:

- THE FCM MUST COMPLY WITH THE ARGENTINE FOOD CODE – CHAPTER IV, WHICH INCORPORATES THE MERCOSUR RESOLUTIONS.
- THE FCM MANUFACTURER MUST HAVE A LEGAL REPRESENTATIVE IN ARGENTINA.
- EU AND/OR US-FDA FCMs CLEARANCES FACILITATE THE PROCEDURE, BUT COMPLIANCE WITH THE ARGENTINE FOOD CODE REGULATIONS IS OBLIGATORY.
- IMPORTED FCMs MUST BE APPROVED/REGISTERED (ACCORDING TO ITEM 3.4 OF MERCOSUR RESOLUTION 3/92) BY THE CORRESPONDING SANITARY AUTHORITY AND INAL.

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) in the European Union - 1

• Regulation (EC) 1907/2006 and amendments.
• Creation of ECHA (European Chemicals Agency), located in Helsinki, Finland.
• Plastics polymers are exempted from registration.
• All substances present in articles and intended to be released must be registered (if > 1 ton/year)
• Substances of very high concern present in articles have to be notified (if > 1 ton/year and concentration > 0.1% (w/w) in article) (e.g.: certain phthalates in plastics articles) before 1st June 2011.
REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) in the European Union – 2

• Possible globalization of REACH to Canada, Japan and USA.
• Greater interest in plastics recycling.
• Non-viability of exported articles to the EU that do not comply with the REACH Regulation.
• Exporters to the EU must have an Only Representative (OR) in the EU.

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) in the European Union – 3

• The Argentine Chamber of the Chemical and Petrochemical Industry (CIQYP) signed an agreement with REACHLaw in 2008. This Finnish company can act as OR of Argentine exporters and as consultant in technical and regulatory issues related to REACH.
• In November 2010, the Argentine Ministry of Industry issued Resolution 178/2010, establishing that the OAA (Argentine Accreditation Organism) shall control the laboratories performing toxicological and eco-toxicological tests of chemical substances according to GLPs developed by the OECD (Organization for Economic Cooperation and Development).
FCMs REGULATIONS IMPLEMENTATION

➢ The Sanitary Authority in Brazil is ANVISA (National Agency of Sanitary Surveillance)

www.anvisa.gov.br

➢ Discrepancy with MERCOSUR Regulation:
FCMs (except those manufactured with recycled materials) are exempted from the premarket approval/registration (ANVISA Resolutions 22 and 23 (2000) and Secretary of Agriculture Instruction 49 (2006)).

➢ Nevertheless, FCMs must comply with the Brazilian “Portarias” (Ministerial Decrees) and the ANVISA Resolutions that adopt the MERCOSUR Resolutions.

➢ CETEA-ITAL and the INSTITUTO ADOLFO LUTZ (São Paulo) perform FCMs sanitary evaluations.

➢ A proposal of regulation on FCMs GMPs is under a process of public consultation since 2009 (Public Consultation 79/2009).
EXPORTING FCMs TO BRAZIL:

- THE FCMs MUST COMPLY WITH THE BRAZILIAN LEGISLATION THAT INCORPORATES THE MERCOSUR RESOLUTIONS.
- THE FCM MANUFACTURER MUST HAVE A LEGAL REPRESENTATIVE IN BRAZIL.
- IMPORTED FCMs ARE EXEMPTED FROM THE PREMARKET APPROVAL/REGISTRATION (ANVISA Resolution 22 (2000) and Secretary of Agriculture Instruction 49 (2006)) (except those manufactured with recycled materials).
- THE IMPORTATION OF THE FCMs MUST BE INFORMED TO THE SANITARY AUTHORITY.
The MERCOSUR GMC Resolutions on FCMs are adopted by Decrees of the Ministry of Public Health and Social Welfare.

The Agency responsible for the application of Legislation on food and FCMs is:

- INAN (NATIONAL INSTITUTE OF FOOD AND NUTRITION) (Ministry of Public Health and Social Welfare)
  www.inan.gov.py

The official technical Agency responsible for the control of FCMs is:

- INTN (NATIONAL INSTITUTE OF TECHNOLOGY, STANDARDIZATION AND METROLOGY).

INTN performs FCMs sanitary evaluations.
www.intn.gov.py

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COOPERATION INTN - INTI - JICA

During 2005 and 2006 personnel from INTN, was trained by INTI professionals on FCMs sanitary and technological issues and control tests, at their facilities in Asunción and at INTI (Buenos Aires), in the framework of a collaborative Project JICA (Japan International Cooperation Agency) - INTN (Paraguay) - INTI (Argentina).

 jap.png

ji.png
The MERCOSUR Technical Secretariat has its headquarters in Montevideo, the capital of the country.

The MERCOSUR GMC Resolutions on FCMs are incorporated into the Uruguayan Food National Regulation by Decrees of the Ministry of Public Health.

The Ministry of Public Health is in charge of the obligatory registration of food products and FCMs. [www.msp.gub.uy](http://www.msp.gub.uy)

LATU (Uruguay Technological Laboratory) (Montevideo) performs FCMs sanitary evaluations, participates in the MERCOSUR Packaging Group, and belongs to the MERCOSUR Strategic Association of Industrial Technology Institutes.

[www.latu.org.uy](http://www.latu.org.uy)
In an attempt to establish standardized sanitary requirements and to eliminate hurdles to commerce, a network of scientific organizations has launched the **GLOBAL HARMONIZATION INITIATIVE** to facilitate harmonization of food safety regulations. The objective is to discuss, globally, the scientific issues that buttress the decisions made by individual governments and international regulatory bodies in order to achieve global scientific consensus on such issues. **President:** Dr. Huub Lelieveld (The Netherlands)

More information: [www.globalharmonization.net](http://www.globalharmonization.net)

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**Academic Press –**
**Elsevier –** UK, 2009 and USA, 2010.

Christine Boisrobert, Sangsuk Oh, Aleksandra Stjepanovic and Huub Lelieveld, Editors.

**Chapter 14: “Food Packaging Legislation: Sanitary Aspects”.**

Authors: Gisela Kopper (US-FDA Regional Office, San José de Costa Rica; University of Costa Rica) and Alejandro Ariosti (INTI-Plastics Center; University of Buenos Aires).
## COMPARISON OF FCMs LEGISLATIONS.

<table>
<thead>
<tr>
<th>Subject</th>
<th>US-FDA</th>
<th>EU</th>
<th>MERCOSUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level</td>
<td>National</td>
<td>Supranational (27 Member States)</td>
<td>Supranational (4 Member States)</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Subject of FCMs</th>
<th>US-FDA</th>
<th>EU</th>
<th>MERCOSUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal status</td>
<td>Drinking water supply equipment is excluded from the Regulation.</td>
<td>Drinking water supply equipment is excluded from the Regulation.</td>
<td>Drinking water supply equipment is excluded from the Regulation.</td>
</tr>
<tr>
<td></td>
<td>FCMs are considered as indirect food additives.</td>
<td>Houseware and utensils are not excluded.</td>
<td>Houseware and utensils are not excluded.</td>
</tr>
<tr>
<td></td>
<td>Houseware and utensils are excluded.</td>
<td>Houseware and utensils are not excluded.</td>
<td>Houseware and utensils are not excluded.</td>
</tr>
<tr>
<td>Subject</td>
<td>US-FDA</td>
<td>EU</td>
<td>MERCOSUR</td>
</tr>
<tr>
<td>---------</td>
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<td>----------</td>
</tr>
<tr>
<td>Type of Legislation</td>
<td>Federal Law (Title 21-CFR)</td>
<td>Directives (must be transposed into the National Legislations). Regulations (direct application without transposition).</td>
<td>Resolutions (must be transposed into the National Legislations).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subject</th>
<th>US-FDA</th>
<th>EU</th>
<th>MERCOSUR</th>
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<tbody>
<tr>
<td>Subject</td>
<td>US-FDA</td>
<td>EU</td>
<td>MERCOSUR</td>
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<tr>
<td>----------------------------------</td>
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<td>----------</td>
</tr>
<tr>
<td>Main regulated FCMs</td>
<td>Plastics, Paper and board, Elastomers</td>
<td>Plastics, Elastomers, Ceramics, Regenerated cellulose (films)</td>
<td>Plastics, Paper and board, Elastomers, Metals, Glass, Ceramics, Regenerated cellulose (films and casings)</td>
</tr>
<tr>
<td>Regulated FCMs logo or label</td>
<td>---</td>
<td>Obligatory and standardized logo or obligatory label (with exceptions).</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td>---</td>
<td>Voluntary label on recycled plastic FCMs. (ISO 14091/eq.)</td>
<td>Obligatory label on refillable and recycled PET packages.</td>
</tr>
<tr>
<td>Subject</td>
<td>US-FDA</td>
<td>EU</td>
<td>MERCOSUR</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>-------------------------------</td>
<td>---------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Legal obligation for the FCMs producer</td>
<td>Compliance with the Legislation.</td>
<td>Obligatory Declaration of Compliance with the Legislation.</td>
<td>Compliance with the Legislation.</td>
</tr>
<tr>
<td></td>
<td>➢ Case by case obligatory approval system for recycled, and active and intelligent FCMs.</td>
<td>➢ Case by case obligatory approval system for FCMs that comply with the Legislation (partially applied in Brazil).</td>
<td></td>
</tr>
<tr>
<td>Positive lists</td>
<td>General use positive lists, non proprietary (under the Petition-Regulation system).</td>
<td>General use positive lists, non proprietary.</td>
<td>General use positive lists, non proprietary.</td>
</tr>
<tr>
<td></td>
<td>➢ Case by case positive list (FCNs list), proprietary (under the FCN system).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject</td>
<td>US-FDA</td>
<td>EU</td>
<td>MERCOSUR</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>-------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Plastics positive list</td>
<td>- Polymers</td>
<td>- Monomers and other starting substances (fully harmonized).</td>
<td>- Polymers (fully harmonized).</td>
</tr>
<tr>
<td></td>
<td>- QM (e.g.: styrene)</td>
<td>- SML (based on toxicological risk assessment data (TDI))</td>
<td>- SML (=LME) (*)</td>
</tr>
<tr>
<td></td>
<td>- Several purity criteria and specifications of use (based on exposure risk assessment, CF, IT, EDI, CEDI, ADI).</td>
<td>- QM</td>
<td>- QM (=LC) (*)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Very few purity criteria and specifications of use.</td>
<td>- Purity criteria and specifications of use transposed from EU and US-FDA FCMs Legislations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Migration of lipophilic substances: FRF, D2RF, TRF correction factors (with exceptions) (Regulation (EC) 10/2011)</td>
<td>(*) in Spanish and Portuguese</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subject</th>
<th>US-FDA</th>
<th>EU</th>
<th>MERCOSUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall migration limits (plastics)</td>
<td>0.5 mg/in² (=7.75 mg/dm²)</td>
<td>10 mg/dm²</td>
<td>8 mg/dm²</td>
</tr>
<tr>
<td></td>
<td>50 mg/kg</td>
<td>60 mg/kg (for infants and children FCMs)</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td></td>
<td>(supposing 10 g food / in² FCM surface area contact)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Threshold of regulation (TOR)</td>
<td>0.5 µg/kg (dietary base)</td>
<td>Not established</td>
<td>0.5 µg/kg (dietary base), only in the case of postconsumer decontaminated recycled PET (Resolution GMC 30/07)</td>
</tr>
<tr>
<td>Subject</td>
<td>US-FDA</td>
<td>EU</td>
<td>MERCOSUR</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>---------------------------------</td>
<td>-----------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Non-toxicological concern migration limit(s)</td>
<td>Derived from the TOR, different values for different plastics.</td>
<td>10 µg/kg</td>
<td>Derived from the TOR, and accepted only in the case of decontaminated recycled PET (= 10 µg/kg).</td>
</tr>
<tr>
<td>Functional barrier concept</td>
<td>Adopted</td>
<td>Adopted</td>
<td>Adopted for multilayer PCR PET bottles</td>
</tr>
<tr>
<td>Active and intelligent materials</td>
<td>Regulated (See FCNs list)</td>
<td>- Regulation (EC)1935/2004. - Regulation (EC) 450/2009</td>
<td>Non regulated</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subject</th>
<th>US-FDA</th>
<th>EU</th>
<th>MERCOSUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Assessment Authority</td>
<td>US-FDA</td>
<td>EFSA</td>
<td>Food Commission-SGT 3</td>
</tr>
<tr>
<td>Risk Management Authority</td>
<td>US-FDA</td>
<td>EU Commission EU Council of Ministers EU Parliament</td>
<td>GMC (Common Market Group)</td>
</tr>
</tbody>
</table>
NOTES ON MIGRATION TESTS - 1

- The present MERCOSUR overall (OM) and specific (SM) migration tests conditions follow the EU Directives previous to Regulation (EC) 10/2011.

- With respect to Regulation (EC) 10/2011:
  - The OM and SM testing of FCMs not yet in contact with food procedures suit the pre-market approval system established in MERCOSUR.
  - OM 2 test would be the most used in MERCOSUR.
  - Fatty food simulants: the fatty food Simulants D used in MERCOSUR are iso-octane and EtOH 95% v/v in distilled water; the substitute Simulant D’ in MERCOSUR is EU Simulant D2. No problem to use Simulant D1. But several food categories need to be tested with Simulant D2 (Reg. (EC) 10/2011).

NOTES ON MIGRATION TESTS - 2

- No migration is required in MERCOSUR for dry foods without surface oil or fat. Simulant E must be used for dry foods in the EU.

- MERCOSUR adopted SMLs for migrating substances according to Directive 2002/72/EC and amendments. According to Regulation (EC) 10/2011, if a substance has no established SML in the positive list, a generic SML of 60 mg/kg shall apply.

- This can be solved for non-volatile migrants, using the OM value. Note that the OM limit in MERCOSUR is 50 mg/kg.
NOTES ON MIGRATION TESTS - 3

- There are no requirements, yet, for primary aromatic amines (PAAs) total specific migration limit (SML(T)) in MERCOSUR. (Annex II to Regulation (EC) 10/2011).

- MERCOSUR has SML(T)s for elements in the plastics additives positive list (Resolution GMC 32/07), and Regulation (EC) 10/2011 has SMLs for elements in Annex II. The elements and the limits are the same, except for iron (Fe), which has no limit in MERCOSUR.

RESOLUTION GMC 30/07: POST-CONSUMER RECYCLED PET

➢ The decontamination technologies applied must:

• be validated through challenge tests performed by internationally well-known laboratories;

• have a no objection letter (NOL) from the US-FDA or an European Decision about their use;

• be approved and registered by the National Sanitary Authority, after the technical opinion of its Technical Reference Laboratory (e.g.: INTI in Argentina).

➢ The technologies can be based in physical, chemical or hybrid processes.

➢ The threshold of regulation (TOR), according to 21 CFR 170.39, is established.
Regulation 30/07 establishes requisites for:
- the producer of PCR-PET
- the recycler (manufacturer of PET packages or packages precursors (e.g.: parisons or sheets) containing PCR-PET)
- the final user (food manufacturer)

Quality assurance system required

GMPs required

Sensory analysis of PCR-PET required

Labelling of the final package must indicate:
- producer identification
- batch number or traceability codification
- the acronym: “PET-PCR” (post-consumer recycled PET in Spanish and Portuguese).

POST-CONSUMER RECYCLED PET (PCR-PET) IN SOUTH AMERICA:

MERCOSUR: Resolution GMC 30/07 (2007).

During 2008 it has been transposed into the National legislations of:

Argentina
Brazil
Uruguay

It has not yet been transposed into the Paraguayan legislation (as of May 2011).
POST-CONSUMER RECYCLED PET (PCR-PET) IN SOUTH AMERICA:

**BOLIVIA:** Standard 716002 of IBNORCA (Bolivian Institute of Standardization and Quality) (2009), in which the author collaborated, describes the requisites for PCR-PET, following the MERCOSUR Resolution GMC 30/07; the Bolivian Supreme Decree (Decreto Supremo) 0559 (2010) makes Standard 716002 obligatory (with exceptions).

**ECUADOR:** there is interest in PCR-PET validated technologies. An adequate regulatory framework must be developed (2011).

POST-CONSUMER RECYCLED PET (PCR-PET) IN SOUTH AMERICA (cont.):

**COLOMBIA:** the proposal of Regulation for Plastic and Elastomeric FCMs (Article 14, Paragraph 2), in which the author collaborated, establishes that the INVIMA can evaluate petitions for the authorization of validated technologies of post-consumer plastics decontamination and recycling (2010).

**PERU:** a proposal to modify the Supreme Decree 7/1998, in order to allow the use of validated technologies for the post-consumer plastics decontamination and recycling after their authorization by the sanitary authority, was submitted to the DIGESA (Environmental Health Directorate General) – Health Ministry (2010). As of May 2011, it is pending of official sanction.
POST-CONSUMER RECYCLED PET (PCR-PET) IN SOUTH AMERICA:

**CHILE**: there is interest in a project to regulate the use of PCR-PET for food applications.

At present, Article 129 of the Supreme Decree 977/1996 “Food Sanitary Regulation” establishes general restrictions to the reuse of packages intended to come into contact with foodstuffs.

During April 2011 a proposal of modification of the Supreme Decree was prepared by the author in collaboration with the industry, in order to allow the use of PCR-PET in the manufacture of food packages.

In May 2011 the proposal was submitted to the Health Ministry for its consideration.
The National Sanitary Code (Law 09/1979) and the Health Ministry Decree 3075/1997 set the general framework for food processing, packaging, handling and storage.

Decree 612/2000 establishes that food and beverages must be registered by the National Institute of Drugs and Food Surveillance (INVIMA), the technical agency of the Ministry of Social Protection.

www.invima.gov.co
www.minproteccionsocial.gov.co

The INVIMA performs also sanitary evaluations of FCMs and issues approvals.

Article 267 of the National Sanitary Code states that FCMs must comply with the requisites established by specific Regulations issued by the Health Ministry.

According to this mandate, the INVIMA and the Ministry of Social Protection are coordinating a program to issue several specific Regulations on FCMs.

This process, in which the author collaborated, has had financial support from the USAID - MIDAS Program (“Más Inversión para el Desarrollo Alternativo Sostenible” – “More inversion for a sustainable alternative development”). (2008-2009).

The recommendation to the Colombian Sanitary Authorities has been to develop National Regulations that take into account international references, such as the EU, MERCOSUR and US-FDA Legislations. (Harmonization – Mutual recognition)
The objective is to avoid divergent emerging Regulations.

Present situation (May 2011):

The following regulations were subjected to a public national and international consultation process during 2010-2011, and are pending of official sanction during this year:

- Technical Regulation on FCMs (Framework Regulation);
- Four specific Technical Regulations on: Plastic and Elastomeric FCMs; Metallic FCMs; Glass and Ceramic FCMs; and Cellulosic FCMs.

TECHNICAL STANDARDS

The ICONTEC (Colombian Institute of Technical Standards) ([www.icontec.org.co](http://www.icontec.org.co)) coordinates the certification of products and issues the Colombian Technical Standards (NTC). There are two voluntary standards of sanitary interest:

- NTC 5022 Plastics materials and articles for contact with food and beverages – Determination of the overall migration. (Based on the EU methodology).
- NTC 5023 Plastics materials and articles for contact with food and beverages. (Positive lists, GMPs, purity criteria and SMLs, methodology) (Based on the EU and the US-FDA regulations).
SITUATION IN MEXICO

➢ The Federal Commission for the Protection from Sanitary Risks, COFEPRIS (www.cofepris.gob.mx), is the official agency appointed by the Ministry of Health to perform food, additives and packaging risk assessment and management.

➢ The Framework Legislation for FCMs is the “Regulation on Sanitary Control of Products and Services” (1999):
  Title 2, Article 17: establishes the FCMs general sanitary requirements.
  Title 23, Article 207: defines FCMs as indirect food additives.
  Title 24. Packages and products packaging sanitary requirements. (Articles 209 to 214).
  Article 210: establishes that the classification of different packaging materials and their physical, chemical and toxicological characteristics shall be defined in specific Standards.
Article 212: establishes that if it can be proved that the final package is safe, then, reused, recycled and non-specified-by-Standards materials can be used in its manufacture.

Article 214: bans the reuse of food and beverages packages in which drugs, hygiene products, pesticides, fertilizers or toxic or dangerous substances have been previously packaged.

TECHNICAL STANDARDS


- The Federal Law on Metrology and Standardization, defines two types of standards:
  - NOM (Official Mexican Standards) (obligatory)
  - NMX (Mexican Standards) (voluntary)

- A catalog of NOM and NMX standards (in force and repealed) can be found at the Secretary of Economy – National Directorate of Standards site: www.economia.gob.mx

- In the field of FCMs, most of the standards have been issued during the 90´s.
At the present, the only NOM mandatory standard on sanitary issues in force is:


An example of NMX voluntary standard is:


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**MEXICO IN THE NAFTA**

- Article 756 of NAFTA recommends that Canada, Mexico and the USA “pursue equivalence of their respective sanitary and phytosanitary standards (SPS)”.
  
  → harmonize food production and products
  
  → national measures must not become technical barriers to trade (TBT)

- There is a NAFTA Committee on SPS, thus:
  
  → to facilitate the improvement of food safety and sanitary conditions
  
  → to promote the equivalence of SPS within the three NAFTA countries

- According to the Mexican Secretary of Economy the new Mexican standards issued will be based on the US-FDA regulations and the Codex Alimentarius recommendations.
SICA (Sistema de la Integración Centroamericana) (Central American Integration System)

**MEMBER STATES:**
- Belize
- Costa Rica
- El Salvador
- Guatemala
- Honduras
- Nicaragua
- Panama

**ASSOCIATE STATE:**
- Dominican Republic

**Secretariat:** Antiguo Cuscatlán
The Central American Integration System (SICA) was created by the Protocol of Tegucigalpa, Honduras, on 13th. December 1991, beginning its functions on 1st. February 1993.

www.sica.int

• Several Central American countries and the Dominican Republic do not have any specific regulations on FCMs, though their Health Laws and Health Codes establish some general requirements.

• No such requirements were identified for Nicaragua.

• Panama has general requirements and several specific requirements based on the Argentine Federal Food Regulation (1953) and the Latin American Food Code (1960).

Belize: Food and Drugs Act, chapter 291 (2000).


Dominican Republic: General Health Law 42 (2001), Article 111.

El Salvador: Health Code – Decree 955 (1988), Section 12, Article 88. The Ministry of Public Health and Social Assistance shall authorize and approve all the food, beverages and their raw materials, either of national production or imported. The imported articles must be authorized in the country of origin. The National Council of Science and Technology (CONACYT) has published standards on food packaging specifications and physical-mechanical tests.
SICA

Guatemala: Health Code – Decree 90 (1997), Article 137, Article 226 item 44, Article 231 item 5, Article 232 item 1. The Guatemalan Standards Commission (COGUANOR) has published standards on food packaging specifications and physical-mechanical tests for plastics, metallic and paperboard FCMs.

Honduras: Health Code – Decree 65 (1991), Article 79 (imported food, raw materials and FCMs), Article 84 (surfaces in contact with foods), Article 86 (forbids the reuse of containers if they are deteriorated; permits the reuse of containers if there is no risk of contamination), Article 239 (plastics FCMs can be imported if they comply with the requirements of the US-FDA or other country of origin regulations, up to the moment of the sanction of National regulations).

SICA

Nicaragua: no specific technical food regulation has been identified.

• Imported animal products and subproducts are controlled by the Ministry of Agriculture and Forestry (MAGFOR) (www.magfor.gob.ni)

• Imported processed food products are controlled by the Ministry of Health (MINSA) (www.minsa.gob.ni).

• Imported food products shall comply with Standards issued by the Ministries, the Codex Alimentarius recommendations or the Standards recognized by the international agreements signed by the Government (e.g. SICA Standards).
Panama: SICA

Decree 256 (1962) Registry and Control of Food and Beverages:

• Article 1 (scope).
• Article 49 A (FCMs shall comply with the requirements of the Codex Alimentarius).
• Article 53 (permitted and forbidden colorants for: glass; paper and paperboard; and external varnishes for metallic and wood containers).

• Articles 58 and Article 59 (general and specific requirements for FCMs) were adapted from the Argentine Federal Food Regulation – Decree 141/1953 and the Latin American Food Code (1960) (based on the former).

• In addition, several Articles mention general requirements for packages for different types of foods.

Panama: SICA


The last one, in Article 12, establishes that food packages shall comply with the requirements of the Codex Alimentarius, if no specific National regulation exists for a given product.
SICA

Resolution 176-2006 sanctioned by the Council of Ministers of Economic Integration (COMIECO) includes four Central American Technical Regulations (RTCA) (Reglamentos Técnicos Centroamericanos) (www.sica.int):

- **RTCA 67.01.30:06**: Processed foods. Procedure for granting a sanitary license to manufacturing plants and stores (“bodegas”).

- **RTCA 67.01.31.06**: Processed foods. Procedure for granting a sanitary registry and a sanitary inscription.

- **RTCA 67.01.32:06**: Requirements for the importation of processed foods for display and tasting at exhibitions.

- **RTCA 67.01.33:06**: Food and beverages processing industries. GMPs – General Principles.

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SICA

- Article 8 (item 8.3 – Packaging) of RTCA 67.01.33:06 on GMPs establishes:
  - A sanitary and clean storage of packages and containers.
  - Inspection before use in order to ensure that the packages and containers are in good state, clean and disinfected.
  - In the case of returnable packages and containers, these must be inspected and treated immediately before use.
The Caribbean Community (CARICOM) was created by the Treaty of Chaguaramas, Trinidad and Tobago, on 4th July 1973.

The CARICOM Single Market and Economy (CSME) was established by the Grand Anse (Grenada) Declaration (July 1989).

www.caricom.org
CARICOM MEMBER STATES
Antigua and Barbuda, The Bahamas, Barbados, Belize, Dominica, Grenada, Guyana (Secretariat: Georgetown), Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St. Vincent and the Grenadines, Suriname, Trinidad and Tobago.

CARICOM ASSOCIATE MEMBERS
Anguilla, Bermuda, British Virgin Islands, Cayman Islands, Turks and Caicos Islands.

CARICOM
➤ Agreement establishing the Caribbean Food Corporation (CFC) (1975, Georgetown, Guyana). Objective: created the CFC to deal with improving production, processing, packing, storage, transportation, distribution and marketing of food. The CFC was absorbed in 1999 by the Caribbean Agricultural Research and Development Institute (CARDI) (established in 1975; present headquarters: University of the West Indies, St. Augustine, Trinidad and Tobago).


➤ Caribbean Agricultural Health and Food Safety Agency (CAHFSA) (2010, Paramaribo, Suriname). Objective: to strengthen agricultural health and food safety and ensure the highest standards for trade in agricultural products.
The Revised Treaty of Chaguaramas (2001) calls for harmonized regimes in a number of areas, including consumer protection, regulation and labelling of food and drugs, sanitary and phytosanitary measures, standards and technical regulations, etc.

There are general requirements for food packages in some national regulations, e.g.:

- **Bahamas**: Food Act, chapter 236; besides, FCMs that comply with the US-FDA requirements are accepted.

- **Barbados**: Health Services (Food Hygiene) Regulations, chapter 44; Returnable containers Act, chapter 395A.

- **Belize**: Food and Drugs Act, chapter 291.

- **Guyana**: Food and Drugs Act, chapter 34.03: food must be adequately packaged and labelled, the Health Ministry can sanction regulations on packaging, and inspectors can take samples for analysis; Law Instituting Environmental Tax on Non-returnable Beverage Containers.

- **Jamaica**: Food and Drugs Act; Processed Food Act Regulations.

- **Trinidad and Tobago**: Food and Drugs Act, chapter 30:01.

- etc.
Agreement establishing the Free Trade Area between CARICOM and the Dominican Republic (Santo Domingo, Dominican Republic, 1998).

» Appendix VI to Annex I – Technical Barriers to Trade:

Article IX. Filling, labelling and packaging. The parties shall develop agreed standards. In the meantime, ISO Standards shall apply, and in the case of food additives, the Codex Alimentarius recommendations.

» Appendix VII to Annex I – Agreement on sanitary and phytosanitary measures:

Article II. Definitions. Contaminants from packaging. Packaging as food additive.
SITUATION IN CUBA

➢ There is no specific regulation for FCMs in Cuba.

➢ Two Obligatory Cuban Standards (NC) have been issued by the National Standardization Bureau (ONN):


➢ The Standardization Technical Committee 5 (CTN 5), created in 1996, is responsible for issuing standards on packaging.

www.nconline.cubaindustria.cu;
www.nc.cubaindustria.cu

➢ The Sanitary Authority that controls the application of the Obligatory Standards is the Institute of Nutrition and Food Hygiene.

www.inha.sld.cu

➢ There is no FCMs pre-market approval system at the present in the country.

➢ Approximately 70% or more of the FCMs used in the country are imported.
CONCLUSIONS 1

- In Latin America, FCMs sanitary requirements are included in official Regulations and voluntary or obligatory Standards, which means caring for public health and food quality.

- The regulatory situation in different countries is diverse, according to the realities of each one of them.

- Most countries in Latin America and the Caribbean are integrated into or associated to six politic-economic blocks (CAN, CARICOM, EU, MERCOSUR, NAFTA and SICA).

- MERCOSUR FCMs Resolutions appear to be the most advanced Regulations in Latin America and the Caribbean.
CONCLUSIONS 2

- There are countries that are working to approach their emerging Regulations to the EU, MERCOSUR and US-FDA Regulations, and/or approve FCMs that comply with these Regulations.

- Some countries do not have or have very incipient emerging Regulations.

- These countries use their own resources or those from International Programs and Cooperation Projects, to finance new developments in Regulations.

CONCLUSIONS 3

- In this process, it is important to proceed in order to avoid the sanction of divergent Regulations that could compromise public health and food quality and hinder international trade.

- Scientific exchange and training of technical personnel and regulatory officials, through Programs, Projects, Seminars, Symposia, Global Conferences, Strategic Associations, etc., are extremely important for the development of analytical and regulatory capabilities in Latin American countries.
THANK YOU VERY MUCH FOR YOUR KIND ATTENTION!!
MUCHAS GRACIAS POR SU ATENCION!!
YOUR QUESTIONS ARE WELCOMED!!

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