Update: Food Packaging Regulations in Latin America

This article is reprinted from Food Packaging Bulletin Issue 7 (2018) with the permission of the publisher Research Information.

We previously provided an overview of MERCOSUR’s (Mercado Común Del Sur or the “Common Market of the South”) food-contact regulations in 2014.[1] This article presents an updated review of the regulatory scheme governing the use of food-contact materials in MERCOSUR member countries in light of significant new developments.

I. Background

MERCOSUR, the largest trading bloc in South America, was established by the Treaty of Asuncion del Paraguay on March 26, 1991 to promote free trade among member countries. The countries of MERCOSUR comprise the fifth largest economy in the world and the combined population of its member countries exceeds 295 million.[2] MERCOSUR’s full members are Brazil, Argentina, Paraguay, and Uruguay. Venezuela became a formal MERCOSUR member in July 2012, but the country has since been suspended indefinitely for its failure to meet key provisions of MERCOSUR legislation.[3] Bolivia, which was approved to become a full member in July 2015, is now in the process of implementing an accession protocol, i.e., working towards adopting provisions in its domestic law to “accede” to the trade bloc.[4] Associate members of MERCOSUR include Chile, Colombia, Ecuador, Peru, Suriname, and Guyana.

The Common Market Group (GMC), the executive body of MERCOSUR, approves the recommendations of working subgroups, including those of the Packaging Group, which is responsible for reviewing and updating food-contact legislation. Approved recommendations are known as GMC Resolutions and are referred to as GMC Res. No. XX/YY where XX is the resolution number and YY are the last two digits of the year the resolution was adopted. MERCOSUR member states are required by the Protocol of Ouro Preto to transpose the GMC resolutions into national legislation and are bound by the MERCOSUR resolutions once the legislation is officially incorporated into national law.

Notably, MERCOSUR Packaging Group delegates have suggested informally that updates to their food contact resolutions should occur every five years, although the timeline for the amendment process has stretched to far longer periods (e.g., some eleven years for the modifications to the additives resolution, discussed below, last adopted in 2007 and currently in the last stages of amendment). The long delays in clearing new compounds under the current system presents significant challenges to industry in this increasingly global economy, as the pace for clearances in other jurisdictions, such as the European Union (EU) and United States, is much more rapid.

II. Regulation of Food-Contact Materials in MERCOSUR

Full members of MERCOSUR have largely harmonized their legislation with respect to the regulation of food packaging materials in these countries. Similar to the EU, MERCOSUR member states must comply with a general
safety standard and applicable positive lists (i.e., any substance not listed on an applicable positive list may not be used). In addition, with the exception of Brazil, finished food packages must be registered with MERCOSUR member states prior to sale in those countries. Brazil does not impose any registration requirements unless the finished food packaging product contains recycled materials.

The general safety standard, GMC Res. No. 03/92 (“General Criteria for packaging and articles to come into contact with foodstuffs: terminology, general criteria, and classification of materials”), requires all food-contact materials to: (1) be manufactured in accordance with good manufacturing practices (GMPs); (2) be of suitable purity; (3) not transfer any harmful or toxic compounds from the packaging to the food; and (4) not cause an unacceptable change in food composition, taste, or odor. The resolution defines food packaging and equipment broadly, and encompasses any article used during the processing, storage, marketing, and consumption of food (e.g., plastics/regenerated cellulose, elastomers and rubbers, paper and paperboard, ceramics, glass, metals and alloys, wood including cork, textiles, paraffin waxes and microcrystalline waxes). However, GMC Res. No. 03/92 does not apply to materials such as fruit coatings or natural sausage casings, which form a unit with the food and are consumed with the food. The resolution also imposes overall migration limits (OMLs) that apply to the food packaging material. GMC Res. No. 32/99 specifies the test methods that should be used to determine overall migration values. Notably, and much like the EU, MERCOSUR’s general standards for food-contact materials apply to housewares (e.g., disposable cups, plates, utensils, and other articles used to serve or dispense food for fairly immediate consumption), as well as equipment used with food, other than for drinking water.

MERCOSUR has issued GMC resolutions for the following categories of food-contact materials: plastics; metals and lubricants for metal surfaces; glass and ceramic; cellulose (paper, paperboard, cardboard); regenerated cellulose; elastomers; adhesives; and paraffins. While substances that are used on the exterior of cans are not yet regulated under MERCOSUR, as a can substrate is considered to be a true functional barrier to any migration from that exterior coating, polymeric coatings intended for use on the interior of cans must comply with MERCOSUR resolutions pertaining to food-contact plastics (i.e., GMC Res. No. 02/12 and GMC Res. No. 32/07, discussed below). Furthermore, polymeric coatings on paper and other substrates also must comply with MERCOSUR GMC Res. No. 02/12 and GMC Res. No. 32/07. We focus our discussion below on MERCOSUR’s treatment of plastics and paper, in particular.

A. Plastics

MERCOSUR has adopted GMC Res. No. 56/92 (“General provisions for plastic containers and equipment in contact with food”), which includes an OML of 50 mg/kg food in (1) plastic packaging or equipment with a capacity above or equal to 250 mL, (2) plastic packaging where it is not possible to estimate the surface area in contact with food, and (3) plastic packaging having sealing elements or a small area. The overall migration limit is 8 mg/dm² of surface area of the plastic in contact with food for packaging and equipment with a capacity below 250 mL. The resolution also sets forth specific migration limits (SMLs) for certain heavy metals that might be present. Unless specifically authorized elsewhere, recycled plastics are prohibited under GMC Res. No. 56/92.

Two separate GMC resolutions identify those substances that may be used in the manufacture of food-contact plastics: GMC Res. No. 02/12 (“Positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic packaging and equipment that come into contact with food”) and GMC Res. No. 32/07
("Positive list of additives for plastic materials intended for the manufacture of packages and equipment in contact with food"). These positive lists are based on clearances in the EU’s Plastics Regulation (Commission Regulation (EU) No 10/2011, as amended) and, to a lesser extent, the U.S. Food and Drug Administration’s food additive regulations.

GMC Res. No. 02/12 identifies monomers, polymers, and other starting substances that may be used in the manufacture of food-contact plastics. The resolution also describes limitations that apply to the listed substance, such as those pertaining to use, composition, and specific migration. In addition, GMC Res. No. 02/12 provides a list of products obtained by bacterial fermentation that may be used in food-contact plastics. Notably, and as discussed above, GMC Res. No. 02/12 applies to polymeric coatings directly in contact with food, even if the polymeric coating is applied to other material substrates (e.g., metal, film, and paper and paperboard). Brazil has proposed adding new substances to GMC Res. No. 02/12, as well as reducing the SML for bisphenol A (BPA).[5]

GMC Res. No. 32/07 lists those additives that may be used in the manufacture of food-contact plastics. These include substances that are added to plastic to obtain a desired effect (e.g., antioxidants, foaming agents, lubricants, and plasticizers) and substances that are used to produce an appropriate polymerization medium (e.g., surfactants, pH buffering agents, and solvents). It excludes impurities, intermediates, and aids to polymerization (e.g., catalysts, initiators, accelerators). The resolution also sets limits on use level, composition, and specific migration.

MERCOSUR has been in the process of revising GMC Res. No. 32/07 for some years, modelling the revisions much more closely on the EU’s Plastics Resolution No. 10/2011. The final draft of the revised GMC Res. No. 32/07, designated by the National Coordinators as Res. No. 05/18[6] (“MERCOSUR Technical Regulation on the positive list of additives for the preparation of plastic materials and polymeric coating in contact with foodstuffs”), was elevated to the National Coordinators during the MERCOSUR SGT No. 3 meeting at the end of August. Res. No. 05/18 applies to additives intentionally added to a formulation to achieve a particular physical or chemical effect during manufacture or in the final material, as well as adjuvants used in the production of polymers, including those used in polymeric coatings in direct contact with food. The positive list in Res. No. 05/18 would not apply to “polymerization aids,” non-intentionally added substances (NIAS), including impurities, intermediate reaction products, and breakdown products. The draft resolution includes SMLs and usage restrictions for an updated list of permitted additives, in addition to defining calculation methods for assessing compliance with SMLs. As of the issuance of the draft resolution, solvents are excluded from the scope of the draft resolution, provided they: (1) have a boiling point less than 150°C; (2) are not mutagenic, carcinogenic, or reproductive toxicants (CMRs); and (3) do not migrate at levels greater than 0.01 mg/kg. The draft resolution was notified to the World Trade Organization on September 9, 2018.[7]

B. Paper

As mentioned above, GMC Res. No. 02/12 lays out requirements that are applicable to polymeric coatings on paper and paperboard. MERCOSUR has also adopted three updated resolutions on paper and paperboard: GMC Res. No. 40/15 (“Technical regulations on cellulosic materials, containers, and equipment intended to contact food”), GMC Res. No. 41/15 (“Technical regulations on cellulosic materials for hot cooking and filtration”), and GMC Res. No. 42/15 (“Technical regulations on materials, containers, and cellulose equipment intended to be in contact with food during cooking or heating in oven”). Argentina,[8] Brazil,[9] and Uruguay[10] have transposed these
resolutions into national legislation as of the date of this article.

GMC Res. No. 40/15 is the general MERCOSUR regulation on paper and establishes a positive list of additives used in paper and paperboard, including recycled fibers. It does not apply to paper used for filtration, infusion, cooking, or microwave applications. The resolution identifies certain restrictions on use, migration limits (total migration limit is 8 mg/dm$^2$), and composition. According to the meeting minutes of the Food Commission from the August 27-31, 2018 SGT No. 3 meeting, Brazil has proposed inclusion of new substances in this resolution.[11]

GMC Res. No. 41/15 establishes a positive list for cellulosic materials used to filter aqueous foods. The resolution also sets limits on the nitrogen content of total residue from hot water extraction of paper.

GMC Res. No. 42/15 applies to cellulosic materials used in contact with food during cooking or oven heating, as well as microwave applications, and includes a positive list of components. The resolution also identifies migration limits and conditions for extraction testing.

C. Obtaining Clearance for a New Food-Contact Substance in MERCOSUR

To obtain clearance of a new food-contact substance under harmonized MERCOSUR legislation, a company is required to submit a petition to either the Argentina National Food Commission (CONAL) or the Brazil National Agency of Sanitary Surveillance (ANVISA). The substance for which clearance is sought in MERCOSUR must already be the subject of an existing food-contact clearance in the U.S. or EU. Once CONAL or ANVISA has deemed a petition to be acceptable, it is forwarded to MERCOSUR’s Packaging Group for consideration and discussion. Currently, no regulatory timeframe is specified in which MERCOSUR must review food-contact petitions. Once incorporated into the MERCOSUR legislation, the amended legislation must be transposed into the national law of the individual MERCOSUR member states.

D. Member State Requirements

Each MERCOSUR member state has authoritative bodies and requirements that apply to food-contact materials marketed within the individual member state. We summarize this information below.

1. Argentina

Food-contact materials are governed by the Argentine Food Code and are approved and registered by one of three national sanitary authorities:

- **National Wine Institute** (INV) - Responsible for materials used in wine packaging.
- **National Service of Agricultural Food Health and Quality** (SENASA) - Responsible for food-contact materials that are used by food companies registered by SENASA, including companies that process certain vegetables, meat, and seafood products.
- **National Food Institute** (INAL) - Responsible for imported food-contact materials, food-contact materials
used by food and beverage companies not registered with SENASA, and packaging materials used by health supplement manufacturers.

All food-contact materials that are imported into Argentina must be approved and registered by the appropriate government entity, as listed above.

2. Bolivia

Bolivia was approved to become a full member of MERCOSUR in July 2015 and is in the process of integrating itself into the trade bloc. The Bolivian National Service of Livestock Health and Food Safety (SENASAG) is responsible for food safety in Bolivia. Administrative Resolution No. 019/2003 sets forth sanitary requirements for foods and beverages and requires that packaging materials for foods and beverages provide adequate protection to foods so that they do not become contaminated or damaged. Further, packaging materials must be non-toxic. The Bolivian Institute for Standardization and Quality (IBNORCA) has issued standards pertaining to food-contact materials.

3. Brazil

ANVISA governs food-contact materials in Brazil. Dairy packaging must obtain an additional license from the Ministry of Agriculture, Livestock, and Food Supply (MAPA). As mentioned above, Brazil exempted food-contact materials from MERCOSUR’s registration requirements, except those packages manufactured with post-recycled consumption food grade PET. Nevertheless, food-contact materials must comply with all MERCOSUR technical resolutions and any Brazilian legislation incorporating the MERCOSUR resolutions. ANVISA must also be notified when any food-contact materials are imported into Brazil.

4. Paraguay

Any food packaging material marketed in Paraguay must comply with the MERCOSUR regulations, as described above. The National Institute of Food and Nutrition (INAN) is the Paraguayan agency responsible for enforcing food-contact legislation. The National Institute of Technology, Standardization, and Metrology (INTN) has authority over the development, publication, and application of technical standards, including those pertaining to food-contact materials. Registration of food-contact materials is mandatory in Paraguay under the Paraguay Ministerial Decree 6115/2011, which established the National Registry of Packages in Contact with Foodstuffs.

5. Uruguay

MERCOSUR resolutions governing food-contact materials were incorporated into the Uruguayan Food National Regulation in 1994. Registration of food-contact materials is mandatory in Uruguay. The Ministry of Public Health is responsible for registering food-contact materials. The Uruguay Technological laboratory (LATU) performs assessments of food-contact materials.

III. Conclusion

Various government entities and registration and approval requirements make for a complex web when it comes to the regulation of food-contact materials in member countries belonging to the MERCOSUR bloc. Moreover, the
trade bloc is engaging in significant - albeit slow - developments in its regulation of certain food-contact materials, particularly with respect to the new paper resolutions and the draft resolution that is intended to revise the plastics additives legislation. These changes will take time to be transposed into the national legislation of each member country, though some countries have already transposed the paper regulations, as noted above. Given this regulatory landscape, companies interested in entering the food-contact market in MERCOSUR member countries may be well-served by understanding both the MERCOSUR system as well as the legal requirements of the bloc’s individual member states. * Several developments have occurred since this article was published. To read about them, see, Regulation of Food-Contact Materials in Latin America (Part 1).

* Catherine R. Nielsen and Mitzi Ng Clark are Partners in Keller and Heckman’s Washington, DC office. See www.khlaw.com.


[4] Id.


[6] Id.


[8] See Argentina Food Code - Chapter IV.

[9] See Brazil RDC Nos. 88, 89, and 90.
