As the largest trading bloc in South America, MERCOSUR (Mercado Común Del Sur or the “Common Market of the South”) has been the subject of growing commercial interest for companies that produce food-contact materials. An essential component of entering the MERCOSUR market is understanding the regulatory scheme that governs the use of food-contact materials in the region. As discussed in greater detail below, the regulation of food-contact materials has been largely harmonized in those countries that enjoy full membership in MERCOSUR. These members include the founding members of the MERCOSUR agreement (Brazil, Argentina, Paraguay, and Uruguay), along with Venezuela, which became a formal MERCOSUR member in July of 2012. Associate members of the trading pact include Bolivia, Chili, Colombia, Ecuador, Peru, Suriname, and Guyana.

This article will present an overview of MERCOSUR’s food-contact regulations, followed by a discussion of how the regulations are implemented by its individual member countries.

**MERCOSUR Food Packaging Regulations**

MERCOSUR was established by the Treaty of Asuncion del Paraguay on March 26, 1991 for the purpose of promoting free trade among member countries. The Common Market Group (GMC), the executive body of MERCOSUR, approves recommendations of working subgroups (including the Packaging Group responsible for review of food-contact legislation) as GMC Resolutions. Member countries are required to transpose the GMC Resolutions into national legislation, but are not bound by MERCOSUR legislation until adopted under national law.

The MERCOSUR nations use a positive list approach to regulate food-contact materials. In other cases, if an individual substance is not listed on an applicable resolution covering a harmonized food-contact sector, the compound may not be used. In addition, with the exception of Brazil, finished food packages must be registered with MERCOSUR’s Member States prior to sale in those countries. With respect to Brazil, the country does not impose any registration requirements, unless the finished food packaging contains recycled materials. (See below for further details on the specific requirements that apply in Brazil.)

A general safety standard applies to all food-contact materials, as set out in GMC Resolution No. 3/92, “General Criteria for packaging and articles to come into contact with foodstuffs: terminology, general criteria, and classification of materials.” GMC Resolution No. 3/92 requires that all food-contact materials: 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 also imposes overall migration limits that apply to the finished food packaging material. A separate regulation, GMC Resolution No. 32/99, specifies the test methods that should be used to determine overall...
migration values. MERCOSUR’s general standards for food-contact materials apply to housewares (i.e., 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.

To date, MERCOSUR has issued GMC resolutions applicable to the following specific 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. With regard to substances used in interior can coatings, MERCOSUR has not promulgated a separate resolution for these compounds. However, polymeric coatings intended for use on the interior of cans must comply with MERCOSUR resolutions pertaining to food-contact plastics (GMC Resolution No. 02/12 and GMC Resolution No. 32/07, discussed below).

In terms of food-contact plastics, two separate resolutions set out positive lists of substances that may be used in the manufacture of food-contact plastics. These positive lists are based on clearances in the European Union’s (EU) Plastics Regulation (Commission Regulation (EU) No 10/2011, as amended, and, to a lesser extent, the U.S. Food and Drug Administration’s (FDA) food additive regulations. Specifically, GMC Resolution 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”) sets out a list of monomers, polymers, and other starting substances that may be used to produce food-contact plastics, along with information on limitations that apply to the substance in terms of use, composition, and specific migration. In addition, the resolution provides a list of products obtained by bacterial fermentation that may be used in food-contact plastics.

In addition to the positive list of monomers, polymers, and other starting materials, MERCOSUR has promulgated a separate regulation on additives intended for use in food-contact plastics. Specifically, GMC Resolution No. 32/07 (“Positive List of Additives for Plastic Materials Intended for the Manufacture of Packages and Equipment in Contact with Foods”) sets out a positive list of additives that may be used in the production of food-contact plastics. The positive list includes substances that are added to plastic to obtain a desired effect (e.g., antioxidants, foaming agents, lubricants, and plasticizers), together with substances that are used to produce an appropriate polymerization medium (e.g., surfactants, pH-regulating agents, and solvents). Limits on use level, composition, and specific migration also are included in the legislation. The MERCOSUR packaging review group currently is in the process of revising the resolution, and an updated version of the legislation is expected in the near future.

With regard to obtaining a clearance for a new food-contact substance that is subject of harmonized MERCOSUR legislation, petitions must be submitted to either the Argentina National Food Commission (CONAL) or the Brazil National Agency of Sanitary Surveillance (ANVISA). Once CONAL or ANVISA deem a petition to be acceptable, the submission is forwarded to MERCOSUR. One prerequisite to submission of the petition is that the substance must be subject of an existing food-contact clearance in the U.S. or the EU. There currently is no specified regulatory timeframe specified for review of food-contact submissions, although it is not unusual for it to take one to two years to obtain a new positive listing for a substance in the relevant MERCOSUR legislation. Further time is then needed to transpose the amended legislation into the national law of the individual Member States of MERCOSUR.
We summarize below information on the authoritative bodies and requirements applicable to marketing food-contact materials in the individual Member States of MERCOSUR.

**Argentina:** The use of food-contact materials is governed by the Argentine Food Code (Código Alimentario Argentino – CAA). Food-contact materials are approved and registered by one of three national sanitary authorities. These entities are as follows:

- **The National Wine Institute (Instituto Nacional de Vitivinicultura - INV):** Responsible for materials used in wine packaging.
- **The National Service of Agricultural Food Health and Quality (Servicio Nacional de Sanidad y Calidad Agroalimentaria - SENASA):** Responsible for food-contact materials that are used by food companies registered by SENASA. These registered companies include those that process certain vegetables and meat and seafood products.
- **The National Food Institute (Instituto Nacional de Alimentos - INAL):** Responsible for imported food-contact materials and those food-contact materials used by food and beverage companies not registered with SENASA. INAL also has authority over packaging materials used by health supplement manufacturers.

In accord with MERCOSUR’s approval and registration requirements, all food-contact materials that are imported into Argentina must be approved and/or registered by the appropriate government entity.

**Brazil:** The National Agency of Sanitation Surveillance (ANVISA) has jurisdiction over food-contact materials in Brazil. An additional license must be granted by the Ministry of Agriculture, Livestock, and Food Supply (MAPA) for dairy packaging. Brazil adopted the MERCOSUR regulations governing food-contact materials on March 22, 1996. However, in 2000, Brazil exempted food-contact materials from MERCOSUR’s registration requirements, except for those food-contact materials manufactured with recycled materials.

While food-contact materials are exempt from MERCOSUR’s registration requirements, the materials must be in compliance with all applicable technical resolutions and any Brazilian legislation that incorporates the MERCOSUR resolutions. In addition, ANVISA must be notified when any food-contact materials are imported into Brazil.

**Paraguay:** The Ministry of Health of Paraguay published Decree 17056 on April 29, 1997, which adopted the food packaging standards promulgated by MERCOSUR as national law. As a result, any food packaging material marketed in Paraguay must comply with the MERCOSUR regulations described above. The National Institute of Food and Nutrition (INAN) is the Paraguayan agency responsible for enforcing food and 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 that pertain to food-contact materials.

Paraguay Ministerial Decree 6115/2011, adopted in February 2011, established the National Registry of Packages in Contact with Foodstuffs (Registro Nacional de Envases en contacto con alimentos – RNE). Under this decree, registration of food-contact materials is mandatory in Paraguay.

**Uruguay:** The MERCOSUR resolutions on food-contact materials were incorporated into the Uruguayan Food National Regulation in 1994. Registration of food-contact materials is required. Uruguay’s Ministry of Public Health is responsible for registration of food-contact materials (and food products). The Uruguay Technological Laboratory (LATU) performs...
assessments of food-contact materials.

Venezuela: Full membership in MERCOSUR was granted to Venezuela on July 31, 2012. From this date, Venezuela has four years to fully adopt MERCOSUR’s resolutions. Currently, food packaging materials are subject of Venezuela’s Food General Regulation (Reglamento General de Alimentos), Decree 525 (1959), and other standards, including Resolution 82 (2007), which sets out GMPs for food-contact materials. Venezuelan standards developed by the Fund for Standardization and Quality Certification (Fondo para la Normalizacion y Certificacion de Calidad – FONDONORMA), which replaced Venezuelan Commission for Industrial Standards (Comisión Venezolana de Normas Industriales – COVENIN), are still referenced as COVENIN standards. Currently, the COVENIN standards that relate to food packaging are those that speak to overall migration, heavy metals, and the use of isocyanate-based adhesives in food packaging.

Generally, packaging and container regulations are enforced by the National Autonomous Standardization, Quality, Metrology and Technical Regulations Service (Servicio Nacional de Estandarización, Calidad y Metrología – SENCAMER). This Service also is responsible for technical standardization, quality control, metrology, certification programs, and maintenance of the COVENIN norms.

Conclusion

Despite harmonization efforts, the regulatory framework of the individual Member States of MERCOSUR involves various government entities and registration and approval requirements. Given this regulatory landscape, and the growing economic momentum in the region, companies interested in entering the food-contact market in Latin America may be well-served by understanding not only the MERCOSUR system, but the legal requirements of the individual Member States as well.