Abstract

Food packaging and food contact materials are essential elements in the effort to provide consumers worldwide with safe and nutritious food. But packaging manufacturers must be prepared to deal with a diverse global regulatory landscape, as well as customer procurement requirements based on voluntary standards. This white paper summarises the principle regulatory requirements for food packaging and food contact materials in major jurisdictions around the world.
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**Introduction**

In today’s modern society, consumers have been responsible for significant changes in the way in which food is prepared and consumed. With less time available for daily tasks, more and more consumers are finding refrigerated and other prepared foods a convenient alternative to home-cooked meals. Further, a 2009 report by the Neilsen Company reveals that 44% of global consumers dine out between one and three times a week. [1]

Access to safe and nutritious food has always been of paramount importance to consumers around the world. But changes in patterns of food preparation and consumption increase the general importance of food safety, and highlight the critical role that food packaging and food contact materials play in overall efforts to provide consumers with safe and nutritious food. Indeed, advances in modern food packaging materials have provided food producers and retailers with packaging options that generally preserve the safety and quality of food products, regardless of how they are distributed.

Because of their important role in food safety, food packaging and food contact materials are subject to regulations in most major markets, including the U.S., the European Union (EU), China and Japan. These regulations are designed to ensure that packaging and contact materials adequately protect food against microorganisms, pests and other forms of contamination, but also that packaging materials that come in direct contact with food are not themselves a source of harmful contaminants.

This white paper provides a general overview of the principle regulatory requirements for food packaging and food contact materials in major jurisdictions around the world. The paper is intended for food packaging manufacturers and food producers, as well as food retailers and regulators.
What are food packaging and contact materials, and how do they impact food safety?

The U.S. Food and Drug Administration (FDA) defines food contact substances as “any substance intended for use as a component of materials uses in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food.” [2] As this definition makes clear, food packaging and food contact materials are used in every stage of the food production and distribution process.

Aside from their essential role in production and distribution, food packaging and food contact materials also help to preserve essential food characteristics, such as the form, shape or texture of a food product. Packaging and contact materials also help to prolong or preserve a product’s freshness, thereby extending its shelf life. And packaging and contact materials provide a barrier to pests and contaminants.

Food packaging and food contact materials come in a variety of forms. Packaging can include bottles, cans, jars, cartons and bags, as well as wrapping materials. Food contact materials can also include food plating and utensils, and appliances whose surfaces come in contact with food products (for example, a toaster or coffee maker). Packaging and contact materials can be made of paper, plastic, petroleum-based substances, engineered products and recycled materials. Packaging materials based on agricultural ingredients like plant fibers, sugars and starches are increasingly available, and are also popular with food producers and consumers alike since they are environmentally-preferable to conventional packaging materials and use less energy to manufacture.

Food packaging and food contact materials usually contain additives, such as colorants and chemicals. In many cases, prolonged contact between food and packaging or contact materials can result in the transfer of these additives from the packaging or contact material to a food product. Food packaging materials may also contain monomers, which are single organic molecules that have failed to bond with other molecules during the material production process or that have been produced as a result of material decomposition.

In addition, recycled materials used in food packaging are often exposed to chemicals and other agents during the recycling process. The safety profile of some of these agents is not well understood, and may be harmful in the amounts required for material reprocessing. Finally, food packaging and contact materials can also come in contact with potentially harmful substances during the production process or in storage, thereby cross-contaminating any enclosed food.

Food packaging and contact material regulations and standards

Regulations and requirements regarding food packaging and food contact materials are generally intended to preserve the physical, chemical and sanitary integrity of food products. However, in practice, regulations and standards intended to achieve this goal take a variety of different approaches.

In the EU and the so-called Mercosur (Mercado Comun del Sur) countries in South America, regulators maintain mandatory “positive lists” of materials and substances that can be used in food packaging. In some individual countries, mandatory positive lists are supplemented by voluntary standards.
that include expanded positive lists of acceptable materials. In other jurisdictions, including Mexico and South Africa, food packaging and food contact material safety is generally addressed through mandatory product safety requirements.

Other requirements and voluntary standards may be applicable to food packaging and food contact materials that include certain polymers, additives or colorants, or which include recycled materials. In addition to specific material requirements, jurisdictions may impose further constraints on the use of food packaging and food contact materials. These constraints can include formal material registration programs, or required toxicology assessments of new materials prior to registration and use.

The following sections of this paper provide additional details regarding food packaging and contact material regulations and standards applicable in specific jurisdictions.

A. European Union

In the EU, requirements applicable to food packaging and food contact materials are detailed in Framework Regulation (EC) No. 1935/2004, [3] which establishes minimum requirements applicable to most types of food contact materials. These requirements mandate that all food contact materials:

<table>
<thead>
<tr>
<th>THESE REQUIREMENTS MANDATE THAT ALL FOOD CONTACT MATERIALS:</th>
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<tbody>
<tr>
<td>▪ Are safe</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>▪ Do not transfer components or chemicals to food so as to endanger human health, change food composition or adversely affect food taste or odor</td>
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<tr>
<td></td>
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<tr>
<td>▪ Are produced consistent with good manufacturing practices, consistent with the requirements of Regulation (EC) No. 2023/2006</td>
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<td></td>
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<tr>
<td>▪ Are traceable through the production chain</td>
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<td></td>
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<tr>
<td>▪ Bear the EU’s “glass-and-fork” symbol or otherwise labeled to signify compliance with the requirements</td>
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</tbody>
</table>

Under Regulation 1935/2004, food contact materials must be authorised by the European Food Safety Authority (EFSA) prior to being placed on the market. Food contact materials that have been authorised are listed in a publically-available online database maintained by the EFSA. [4]

Food packaging and food contact materials are also subject to the EU’s Plastics Regulation (EU) No. 10/2011, [5] which addresses the use of all plastic materials intended to come in contact with food. Importantly, Regulation 10/2011 establishes an overall migration limit (OML) for plastic products that come in contact with food, as well as specific migration limits (SMLs) and residual quantity in material (QM) limits for certain substances. Compliance with these limits is verified through a testing scheme described in the Regulation. Consistent with the requirements of Regulation 1935/2004, plastic food packaging and food contact materials are also subject to review and authorisation by the EFSA prior to being placed on the market.
B. United States

In the U.S., regulations affecting food packaging and food contact materials are dictated by U.S. FDA regulatory requirements affecting each individual substance used in a given food packaging or food contact material. The FDA recommends the following approach to determine the regulations that apply to individual food contact material substances, and the path to achieve compliance with its regulations:

Consult 21 CFR (Code of Federal Regulations) 174-179 to determine if a substance used in a food contact material is a regulated indirect additive. Regulated additives can include adhesives and components of coatings, paper and paperboard components, polymers and irradiation used in the production process and handling of food.

Consult 21 CFR 182-186 to determine if a substance used in a food contact material is listed as “generally recognised as safe” (GRAS).

Consult 21 CFR 181 to determine if a substance used in a food contact material is listed as “prior sanctioned.”

Consult the FDA’s listing of Threshold of Regulation Exemptions to determine if a substance falls below the threshold of regulation and is therefore exempt.

Consult the FDA’s listing of Food Contact Substance (FCS) Notifications to determine if the FDA has previously been notified about a separate use of a given substance.

If a manufacturer determines that a specific food contact material substance is not covered by any of the above regulations or listings, a manufacturer can either:

1. Submit a Threshold of Regulation Exemption request;
2. Satisfy the criteria necessary to GRAS status; or
3. Submit an FCS Notification.\(^6\)

The FDA’s FCS Notification route is generally the preferred method for obtaining agency clearance for previously unused food contact substances. The FDA is required to complete its review of FCS Notification requests in not more than 120 days, significantly shorter than the period required for previous food additive petition processes. An FCS Notification is also proprietary to the manufacturer who has requested it, and is not applicable to the same substance produced by a different manufacturer.
Food packaging and food contact materials produced or used in China are regulated under the China Food Safety Law issued in 2009, which prohibits the importation, purchase or use of any food product that does not comply with the applicable Chinese food safety standards (formerly referenced as Guobiao (GB) or national standards). There are estimated to be more than 130 Chinese food safety standards applicable to food packaging and food contact materials, including standards that address food contact additives, specific food contact products, and specific food contact material groups, such as paper, metal or ceramic.

One of the most important food safety standards is GB 9685, Hygienic Standard for Use of Additives in Food Containers and Packaging Materials. The standard includes a positive list of more than 1500 approved additives, as well as SML and QM limits. A recently updated edition of the standard also includes a negative list of food additives that are prohibited.

The process for obtaining approval for the use of new food contact material additives is detailed in China’s Management Rules for the Administrative Approval of New Varieties of Food-Related Products. Manufacturers seeking approval for new additives must be able to demonstrate that proposed substance has a clear scope of use, will not alter the structure, color or flavor of the food it contains, and will not adversely affect human health under reasonably foreseeable uses. Testing is required to validate toxicology claims. [7]

In addition to compliance with applicable food safety standards, manufacturers based in China that produce food packaging materials made of plastic or paper must hold a quality safety (QS) certificate issued by China’s General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

The process for obtaining approval for the use of new food contact material additives is detailed in China’s Management Rules for the Administrative Approval of New Varieties of Food-Related Products.
D. Japan

Unlike some other industrialised countries, Japan does not require premarket review or approval of food contact materials prior to their use. Instead, food packaging and food contact materials are expected to meet the general provisions of Japan’s Food Sanitation Law, which prohibits the sale of food packaging and food contact materials containing substances that could be harmful to human health. Enforcement is achieved through random inspections and testing of products, along with penalties for non-compliance.

Japan’s Food Sanitation Law also authorises the Japanese Ministry of Health, Labour, and Welfare (MHLW) to develop specifications for food packaging and food contact materials. These specifications include general specifications that apply to all food packaging and packaging materials, material-specific specifications, and application-specific specifications.

In addition to MHLW specifications, food contact material manufacturers must also be prepared to comply with voluntary industry standards and requirements promulgated by various Japanese trade organisations. The most important and influential trade organisations include the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA), the Japan Hygienic PVC Association (JHPA) and the Japan Paper Association (JPA). Frequently, Japanese food producers will require evidence of compliance with various standards produced by these and other trade organisations as a procurement condition.

Unlike some other industrialised countries, Japan does not require premarket review or approval of food contact materials prior to their use. Instead, food packaging and food contact materials are expected to meet the general provisions of Japan’s Food Sanitation Law.

E. Korea

South Korea follows a framework similar to Japan through the imposition of general food safety requirements and the prohibition of food contact materials that contain substances potentially harmful to human health.

South Korea follows a framework similar to Japan through the imposition of general food safety requirements and the prohibition of food contact materials that contain substances potentially harmful to human health. Also, like Japan, South Korea’s Ministry of Food and Drug Safety (MFDS) is responsible for the development of regulations and standards related to food packaging and food contact materials. In early 2013, the MFDS published revised standards for food packaging, Korea Standards and Specifications for Utensils, Containers and Packaging for Food Products. The new standards address specifications for individual materials, general test methods, and manufacturing and usage specifications.
The consortium of South American countries known as Mercosur includes Argentina, Brazil, Paraguay, Uruguay and Venezuela (Bolivia’s membership request is currently being ratified by legislatures in current Mercosur member states). Food packaging and food contact materials are subject to the requirements of GMC (Grupo Mercado Comun, or Common Market Group) Resolution No. 3/92, which stipulates general safety criteria for food packaging and food contact materials. An additional 37 separate resolutions address specific safety requirements for various types of packaging materials. Food contact material substances that have already been reviewed and approved in the U.S. or the EU are generally approved for use in Mercosur countries. Other requests for additions of new substances to a positive list are submitted for review to government food authorities in either Brazil or Argentina.
Summary and conclusion

Food packaging and food contact materials are an important element in the overall effort to provide consumers worldwide with safe and nutritious food. However, packaging manufacturers must be prepared to deal with a complex global regulatory landscape, in which individual jurisdictions have adopted different regulatory frameworks for the review and approval of food packaging and food contact materials. The approval process can be further complicated by customer procurement requirements based on voluntary standards promulgated by industry and trade groups, as well as by the specific substances used in packaging materials.

Manufacturers seeking worldwide acceptance for their food packaging products and materials will benefit from a thorough understanding of all of the substances used in their products and materials, and a detailed analysis of the regulations and standards applicable to those substances. This information can lead to the development of a comprehensive regulatory approval strategy that can eliminate duplicate product review and testing activities and result in a more efficient and cost-effective product approval process.

Through its comprehensive analysis, certification, auditing and inspection services, TÜV SÜD can assist manufacturers in navigating and complying with food packaging and food contact materials regulations and standards worldwide. With over 17,000 employees, TÜV SÜD operates worldwide at more than 800 locations. As partners in our customers’ processes, our specialist teams ensure that technology, systems, and know-how strengthen our customers’ global competitiveness.
GLOSSARY OF ACRONYMYS

AGSIO – administration of quality supervision, inspection and quarantine
CFR – code of federal regulations
EFSA – european food safety authority
EU – european union
FDA – food and drug administration
FCS – food contact substance
GB – guobiao
GMC – grupo mercado comun
GRAS – generally recognized as safe
JHOSPA – japan hygienic olefin and styrene plastics association
JHPA – japan hygienic pvc association
JIPA – japan paper association
MFDS – ministry of food and drug safety
MHLW – ministry of health, labor, and welfare
OML – overall migration limit
QM – quantity in material
OS – quality safety
SML – specific migration limit

FOOTNOTES

[8] An English translation of Japan’s Food Sanitation Law is available through the Japanese Law Translation Database System, maintained by the Japan External Trade Organisation (JETRO). http://www.japaneselawtranslation.go.jp/law/detail/1?i=18co-01&ay=%E9%A3%89%E5%93%81%E6%A1%88%E7%8E%8B%E6%93%89&page=7 (last accessed on October 4, 2013)

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