Plastic and polymeric food contact materials

Take advantages from your supply chain management to navigate a complex global regulatory landscape

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Overview

This whitepaper discusses the difficulties companies may face when placing plastic and polymeric food contact materials into a global marketplace, strategies which companies can use to help ensure compliance and the role UL can play in applying these strategies for compliance purposes. International and local regulations can change and each customer's situation is different. This information should be considered to be an overview and not intended as specific advice.

Introduction

The articles we use to package, store, hold, prepare and cook our food are widely manufactured with plastics or polymeric materials. These products include storage containers, kitchenware and appliances. Because of the possibility that substances used to manufacture these products may migrate to the food we consume, governments have enforced strict health and safety regulations that cover food contact materials. These regulations are complex and not globally harmonized. They are not offered a la carte; rather, they are crucial for manufacturers, retailers and brands to consider and comply with during the entire life of the product. Noncompliant products can result in recalls that can be costly, not only monetarily, but also to brand reputation.

How can companies make sure their products meet safety and quality regulations across the global marketplace?

One important step is for companies to look at compliance from a new perspective. Waiting until final product testing can be too late for most companies to change the recipe. Focusing on compliance in the initial product concept phase can help food contact manufacturers avoid regulatory tangles before they arise.

Often, noncompliance derives from issues within the supply chain. Supply chains can be large and complex, made up of hundreds of suppliers across the world. Companies must maintain robust communication throughout the supply chain to make sure suppliers know about regulations in destination markets. If they fail in requesting appropriate documentation through the supply chain, the product is likely to fail in the testing phase.

A complex regulatory landscape

Understanding regulation in the destination market is not always easy.

The European Union, for example, has a complex regulatory landscape with many countries requiring different national standards. Commission Regulation (EC) No 1935/2004 provides a harmonized legal EU framework but sets out only the general principles for safety and inertness for all food contact materials.

The U.S. Food and Drug Administration (FDA) regulates the U.S. market, but individual states may have specific regulations as well.

China's National Food Safety Standards specify requirements on food contact materials and articles, but these are not the same as the European or U.S. regulations.

The use of plastics, specifically, in food contact materials comes under increased scrutiny and more complicated regulations across global markets. Plastics and polymers are extremely important to modern life, but some have proven to have adverse effects on human health, including endocrine-disrupting chemicals that disturb many different hormones. Regulation aims to set Specific Migration Limits (SML), quantifying the maximum allowed quantity of a specific substance that can migrate from a food contact material into the food itself. Toxicological studies helped derive the safety limits.

China's National Food Safety Standards GB 4806.6-2016 and GB 4806.7-2016 govern the use of plastics and polymers in food contact materials. In the EU, Regulation (EU) No 10/2011 guides Specific Migration Limit (SML), Overall Migration Limit (OML), migrated heavy metals and polyaromatic amines. In the U.S., regulatory status of plastic food contact materials is governed by the FDA under the Food Drug and Cosmetic Act (FD&C Act) and Title 21 Code of Federal Regulations (21 CFR) 170-199 as well as prior sanctioned materials, Threshold of Regulations (TOR), Generally Recognized as Safe (GRAS) and Food Contact Notifications.

The lack of a unified standard makes it more challenging to deliver products that fit the bill in every scenario. It's worth delving more deeply into the specific requirements for three major world markets. Regulations are regularly amended so the information presented here is accurate as of the publication date of this paper but should not be considered an exhaustive list.

United States

In the U.S., the overall regulatory status of food contact materials is governed by the FDA[1] under the FD&C Act and 21 CFR 170-199. Each individual substance in the formulation of a food contact article must be evaluated for its regulatory compliance to determine the regulatory status of the final item. A food contact material is regulatory compliant only if all substances in the formulation are approved for food contact use and required testing meets the regulations listed below.

The FDA website defines a food contact substance as "a substance intended for use as a component of materials used in the manufacturing, packaging, transporting, cooking or holding food." It classifies food contact substances that migrate into food as indirect food additives. If a functional barrier prevents a substance from migrating into the food, it is not considered an indirect food additive and is not required to have FDA approval. The overall status of the each individual substance that is expected to migrate to food because of its intended use is covered by one of the categories listed below, all listed on the FDA website. This overview should be considered a tool. It is current as of the publication date of this paper but may not reflect all recent revisions:

- **A regulation listed in 21 CFR 170-199**[2]

  The requirement for premarket approval in section 409 of the FD&C Act in 1958 resulted in the development of a petition process by which a company could request approval of a food additive for an intended use. The approval resulted in a regulation listed in 21 CFR. Components of a food packaging material used in compliance with a regulation in 21 CFR 174-179 need no further FDA review. Most of the regulated indirect food additives can be found in Center for Food Safety and Applied Nutrition's "Indirect Additive" Database.

  - General Indirect Food Additives (21 CFR 174[3])
  - Adhesives and Components of Coatings (21 CFR 175[4])
  - Paper and Paperboard Components (21 CFR 176[5])
  - Polymers (21 CFR 177[6])
  - Adjuvants, Production Aids, and Sanitizers (21 CFR 178[7])
  - Irradiation in the Production, Processing and Handling of Food (21 CFR 179[8])

- **Generally Recognized as Safe (GRAS), including but not limited to GRAS regulations found in 21 CFR 182, 184 and 186 or GRAS notice**

  Not all substances which are GRAS are listed in FDA's regulations. FDA has instituted a procedure whereby someone may inform FDA of their own GRAS determination. A list of these GRAS notices, with FDA's response letter to the notifier, is also available on the FDA website under "Summary of all GRAS Notices[9].

  - Substances GRAS in food (21 CFR 182[10])
  - Substances affirmed as GRAS in food (21 CFR 1841[11])
  - Substances affirmed as GRAS for use in food packaging (21 CFR 186[12])

- **Prior Sanction letter**[13]

  Prior Sanctioned substances are those substances whose use in contact with food is the subject of a letter issued by FDA or USDA before 1958 offering no objection to a specific use of a specific substance.

- **Threshold of Regulation (TOR) exemption request**[14]

  A substance used in a food contact article may be exempted by FDA from the need of a Food Contact Notification (FCN) or a petition (regulation) as a food additive if the use in question has been shown to result in a very low concentration (0.5 ppb). For details see, "Submitting Requests Under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles."

- **Effective Food Contact Substance Notification (FCN)**[15]

  In 1997, the FDA amended the Food, Drug and Cosmetic Act to streamline the way which the FDA conducted approvals. The new procedures established a notification process for food contact substances. This process is intended to replace the petition process as the primary means for authorizing new food contact substances. However, it is the FDA's decision as to when the petition process is more appropriate for evaluating data to provide an adequate assurance of safety. The listing of effective food contact substance notifications, the regulation, guidance documents[16] and additional information regarding the notification program are listed on the Food Contact Substance web page. However, you should be aware that FCNs are proprietary and users must be able to trace the substance they use back to the manufacturer for which the notification is effective.

  In accordance with Section 409(h)(2)(C) of the Federal Food, Drug and Cosmetic Act and FCN is specific to the manufacturer that applies for the approval of the food contact substance and the conditions of used identified in the notification. It is not an approval for a similar or identical substance produced or prepared by a manufacturer other than the manufacturer identified in the notification. FCNs are proprietary to the manufacturer for which the notification has been approved, therefore, the food contact substance must be obtained from the manufacturer noted on the FCN.

The FDA has stated, "It is the responsibility of the manufacturer of a Food Contact Substance (FCS) to ensure that food contact materials comply with the specifications and limitations in all applicable authorizations. When reviewing your composite formulations to determine compliance, consider each authorization to be composed of three parts: the identity of the substance, specifications including purity or physical properties and limitations on the conditions of use."

China

In China, food container and packaging materials are regulated under the Food Safety Law of the People's Republic of China. This law prohibits the import, use or purchase of food-related products, including food packaging materials, that do not comply with the applicable Chinese Food Safety Standards promulgated by the National Health Commission (NHC). In November 2016, the NHC published a list of 53 mandatory national standards (FCM GB standards) for food contact materials and articles.

With the release of these new standards, a new scheme of Chinese FCM GB standards were established. This new scheme includes four major sections: General Standards, Product Standards, Test Methods and General Hygiene Requirement. These regulations are current as of the publication of this paper. This overview may be considered a tool but may not contain all recent revisions.

General standards

- GB 4806.1-2016 National Food Safety Standard — General Safety Requirements for Food Contact Materials and Articles defined the definition of food contact materials in China. It specifies the basic requirements, restrictions, compliance, test methods, traceability, product information requirements, declaration of compliance and the Good Manufacturing Practice (GMP) on food contact materials and articles (FCMs). It sets out the framework which apply to all kinds of food contact materials and articles in China.
- GB 9685-2016 National Food Safety Standard — Standards for Uses of Additives in Food Containers and Packaging Material, sets out a positive list of additives that can be used to produce various food contact materials and articles including their use scope and restrictions. If the additives to be used in these kinds materials and articles are not explicitly listed, it must be approved by the NHC first before they can be used to produce certain types of food contact materials and articles in China.

Product standards

- GB 4806.3-2016: National Food Safety Standard - Enamel articles
- GB 4806.4-2016: National Food Safety Standard - Ceramic articles
- GB 4806.5-2016: National Food Safety Standard - Glass articles
- GB 4806.6-2016: National Food Safety Standard - Food contact plastic resins
- GB 4806.7-2016: National Food Safety Standard - Food contact plastic materials and articles
- GB 4806.8-2016: National Food Safety Standard - Food contact paper, paperboard and paper articles
- GB 4806.9-2016: National Food Safety Standard - Food contact metal materials and articles
- GB 4806.10-2016: National Food Safety Standard - Food contact coatings
- GB 4806.11-2016: National Food Safety Standard - Food contact rubber materials and articles
- GB 14934-2016: National Food Safety Standard - Disinfection tableware

This series of new product standards combined and superseded many old hygiene standards for materials and articles. In those revised standards, there are requirements for composition, physical and chemical indicators, specific test conditions, and labeling.

Test methods

- GB 31604.1-2016 and GB 5009.156-2016 are the basic standards on how test conditions should be selected and how to conduct pre-treatment for test specimen.
- GB 31604.2-2016 – GB 31604.9-2016 are detection methods for different test indicators required in product standards, such as the determination of overall migration, potassium permanganate consumption, among other things.
- GB 31604.10-2016 – GB 31604.49-2016 are test methods for various substances that may have SML or QM restrictions in GB 9685 or GB 4806 standards.

Food contact material compliance in China is now more comprehensive and systematic after the implementation of new scheme. It is essential to understand all the requirements to ensure compliance with the new Chinese FCM regulation.

General hygiene requirement for manufacturing

- GB 31603:2015 – National Food Safety Standard - General Health Code for Production of Food-contacted Materials and Products, sets basic requirements for the entire manufacturing process for various food contact materials and articles. Manufacturers should establish detailed workflow to ensure compliance. It can act as Good Manufacturing Practice (GMP) for food contact materials.

European Union

In the European Union, all materials and articles intended to come in contact with food have to respect the general criteria imposed by the Framework Regulation 1935/2004. The goal is to ensure that in every phase of contact between food contact materials (FMCs) and food, sufficient inertia is ensured and any type of negative influence on the quality, nutritional and organoleptic properties of the food is avoided. In addition, all food contact materials should be manufactured according to Good Manufacturing Practice as regulated by Regulation (EC) 2023/2006.

Commission Regulation (EC) No 1935/2004[17] provides a harmonized legal EU framework. It sets out the general principles of safety and inertness for all FCMs.

The principles set out in Regulation (EC) No 1935/2004 require that materials do not:

- Release their constituents into food at levels harmful to human health
- Change food composition, taste and odor in an unacceptable way

Moreover, the framework provides:

- Special rules on active and intelligent materials (they are by their design not inert)
- Powers to enact additional EU measures for specific materials, e.g., for plastics
- The procedure to perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority[18]
- Rules on labeling including an indication for use, e.g., coffee maker, wine bottle, or a soup spoon or by reproducing the appropriate symbol. For more information, please refer to the following document on Symbols for labeling food contact materials.[19]
- Rules for compliance documentation and traceability

Commission Regulation (EC) No 2023/2006[20] ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation:

- Premises fit for purpose and staff awareness of critical production stages
- Documented quality assurance and quality control systems maintained at the premises, and
- Selection of suitable starting materials for the manufacturing process with a view to the safety and inertness of the final articles

Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

In the frame of the CAST Project[21] (Food Contact Safety and Technology) general and specific guidelines for the application of the Regulation No. 2023/2006/CE on Good Manufacturing Practice in the supply chain of materials and articles intended to come into contact with food were developed. The guidelines are structured in a section for general application and in a section for specific applications, in particular the chains of aluminum, paper and boards, flexible packaging, plastics, coated and uncoated metals and alloys, wood, cork, glass.

The most comprehensive specific EU measure is Commission Regulation (EU) No 10/2011[22] on plastic materials and articles. It sets out rules on the composition of plastic FCMs and establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs. The Regulation also specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles.

Regulations are regularly amended. The consolidated version should be considered as a tool for your convenience but may not contain all the most recent amendments:

Consolidated version of Commission Regulation (EU) No 10/2011

An important mechanism to ensure the safety of plastic materials is the use of migration limits. These limits specify the maximum amount of substances allowed to migrate to food. For the substances on the Union List the Regulation sets out Specific Migration Limits (SML). These are established by European Food Safety Authority (EFSA) on the basis of toxicity data of each specific substance. To ensure the overall quality of the plastic, the overall migration to a food of all substances together may not exceed the Overall Migration Limit (OML) of 60 mg/kg food, or 10 mg/dm2 of the contact material.

The regulation sets out detailed migration testing rules. Although migration testing in the food prevails, migration is usually tested using simulants. These simulants are representative for a food category, e.g. Acetic acid 3 % (w/v) is assigned for acidic foods. The migration testing is done under specific time/temperature conditions, representative for a certain food use and considers the worst foreseeable real food contact conditions.

To ensure the safety, quality and compliance of plastic materials, adequate data on the composition of (intermediate) materials has to be communicated via the manufacturing chain, up to but not including the retail stage. For this purpose, a Declaration of Compliance (DoC) needs to be provided. The DoC is based on supporting documentation which records the reasoning on the safety of a plastic food contact material, and which must be provided to enforcement Authorities on their request. The supporting documentation also provides an important link to the manufacturer's responsibility under GMP (Commission Regulation (EC) No 2023/2006).[23]

In order to allow the exchange of relevant information, the information to be included in the DoC is set out in a standard format in Annex IV of the Regulation (EU) No 10/2011. It is crucial to understand that plastic food contact material is compliant with the regulation only if all substances in the formulation are approved for the intended food contact use and all appropriate information is transmitted through the supply chain.

Developing a successful approach

When a particular food contact material is deemed unsafe, regulators react quickly to recall items. In Europe, the information is disseminated through the Rapid Alert System for Food and Feed (RASFF), an urgent notification system. In the United States, recalls are handled by the Consumer Product Safety Commission (CPSC). Both the RASFF and CPSC work with haste to notify consumers and manufacturers in order to minimize potential harm.

Strong management is crucial to create and nurture a trusted supply chain that can deliver safe, compliant food contact products to your target market. This includes mechanisms to continually monitor product production. Further, food contact materials require extensive documentation because of the sensitive nature of their potential effect on human health and safety. Without appropriate technical files, bills of materials or chemical lists, product testing will be incomplete. This may lengthen time to market or increase the possibility that an unsafe food contact product will reach consumers.

For many companies, enlisting a competent and independent third-party like UL can help deliver a recipe for success. Safety science expertise, independent objectivity and a data-driven approach can help guide your decision-making process and assist you in navigating the necessary compliance regulations for exporting food contact materials to your target markets.

The UL Global Regulatory Research team can help companies identify the different requirements for specific markets, guiding requests to suppliers for specific documentation. We support brands and retailers in creating customized testing, inspection, audit and training programs that address numerous needs during all stages of the supply chain, from developing a product to efficiently getting it onto shelves in target markets.

Tips to successfully approach compliance

If you are a manufacturer of a food contact product or you will be responsible for making the product available on the market you should keep in mind the following key steps to successfully approach compliance:

1. Map your suppliers (Tier 1, Tier 2, Tier 3)
2. Clearly identify the responsibilities of each tier of your supply chain. Typically, chemical substances and other raw materials produced and sold for the production of FCM shall have documentation for compliance with the requirements set in the applicable regulations. Producers of intermediates, e.g., formulations of printing inks, should use chemicals for which a risk assessment is available and produce products that will comply with the legislation when used in accordance with guidance or instructions of use given to the user. Producers of final FCM are producing the FCM from the chemical raw materials and/or from intermediates. Materials can be suitable for contact with a wide variety of food under many different conditions of use, while others can have a limited area of use. The FCM shall comply with the legislation, e.g., it must not cause deterioration in the organoleptic properties of the food
3. Identify a detailed testing program
4. Support your suppliers in the understanding of the regulations, provide guidance document(s), testing programs and propose training sessions with your food contact materials experts
5. Provide suppliers with clear instructions related to the product you wish to manufacture including the destination market. Verify that suppliers understand your expectations of the documents you require in support of compliance
6. Scrupulously commit to a competent review of all the documents you receive from your suppliers
7. Organize audits and inspections at suppliers' facility to ensure not only compliance, but also safety and quality obligations are being met (for example, GMP where expected, astatically correct, sharp points and edges)

Conclusion

There are complex regulations and standards to help ensure the safety and quality of plastic and polymeric food contact materials worldwide. These regulations are not harmonized and continue to change. Products that are non-compliant can put a company and their brand reputation at risk for recalls.

How can UL help you ensure your products are compliant to the destination country regulations?

UL can help identify requirements, guide in the request for documentation, review positive lists against the formulation, perform testing, audits and inspections. Through testing and training, UL supports manufacturers to comply with rigorous regulations and standards to bring safe and high-quality food contact materials to market. We work with customers to establish comprehensive written testing programs that provide the customer with a high degree of assurance that their products comply with the applicable food contact standards. The testing programs are designed based on relationships with suppliers, destination countries regulations, documentation review and the quantity, frequency and method of testing required. When scientific expertise, objective authority and market access matters, working with UL experts may help you navigate the road ahead.

For more information about UL's food contact materials services visit UL.com or contact us at QAInfo@ul.com.

Endnotes

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