

Navigating compliance for plastic and polymeric food contact materials

Effectively manage your supply chain while
navigating a complex global regulatory landscape



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Overview

This e-book outlines the challenges companies face when bringing plastic and polymeric food contact materials (FCM) to global markets. It also highlights practical strategies for demonstrating compliance and how UL Solutions can support companies in implementing these strategies effectively.

International and local regulations are subject to change, and each customer's situation may vary. This information is intended as a general overview and should not be relied upon as specific advice.



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Introduction

Most of the packaging, storage, holding, preparation and cooking articles we use for food are made from plastics or polymeric materials. These products include storage containers, kitchenware and appliances. Because substances used to manufacture these products may migrate to the food we consume, government agencies have enforced strict health and safety regulations that cover food contact materials.

These regulations are complex and not globally harmonized. They are not optional; manufacturers, retailers and brands must consider them throughout the entire product life cycle. Noncompliant products can result in recalls, which may be costly in terms of both revenue and brand reputation.

How can companies confirm that their products meet relevant safety and quality regulations across global markets?

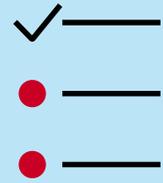


One important step is for companies to approach compliance from a new perspective

Waiting until final product testing can be too late to adjust the material formulation. Prioritizing compliance in the initial product concept phase can help food contact manufacturers avoid regulatory pitfalls. Noncompliance often stems from issues within the supply chain. Supply chains can be large and complex, made up of hundreds of suppliers around the world.

To manage compliance risks, companies must maintain clear communication throughout the supply chain. Suppliers need to understand regulations that apply in the product's destination market. If appropriate documentation is not requested and collected, the product may fail testing requirements.





A complex regulatory landscape

Understanding regulations in the destination market is not always straightforward.

In the European Union (EU), the regulatory landscape is multifaceted. While many national standards apply, Commission Regulation (EC) No 1935/2004 provides a harmonized legal EU framework for food contact materials. However, it only sets general principles for safety and inertness, leaving detailed requirements to additional directives or national measures.

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

China's National Food Safety Standards outline requirements for food contact materials and articles, but these differ from European and U.S. regulations.

The use of plastics in food contact materials is under growing scrutiny, with increasingly complex regulations across global markets. Plastics and polymers are extremely important to modern life, but some may adversely affect human health, including endocrine-disrupting chemicals that interfere with many different hormones. Regulations aim to set specific migration limits (SML), which quantify the maximum limit of a specific substance that can migrate from a food contact material into the food itself.



Toxicological studies play a crucial role in establishing 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 covers SML, overall migration limit (OML), migrated heavy metals and polyaromatic amines. In the U.S., the 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. Additional categories include Prior Sanction, Threshold of Regulation (TOR) exemption, Generally Recognized as Safe (GRAS) designation and Food Contact Notification (FCN).

The lack of a unified standard makes it more challenging to deliver products that meet requirements in every region. It is important to understand the specific regulations for each major world market. Because regulations are regularly updated, this information is accurate as of the publication date of this e-book 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 FDA¹ under the FD&C Act and 21 CFR 170-199.² Each substance used in a food contact article must be individually evaluated to determine the compliance of the final item. A food contact material is considered compliant only if all substances in its formulation are approved for food contact use and required testing meets applicable regulations.

The FDA 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.”³ Substances that migrate into food are classified 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 may not require FDA approval.

Each substance expected to migrate to food due to its intended use must comply with one of the categories listed on the FDA website.

This overview is intended as a tool and reflects information available as of the publication date of this e-book. It may not reflect all recent revisions.

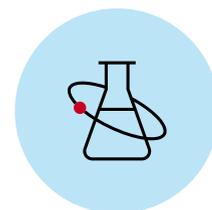


A regulation listed in 21 CFR 170-199

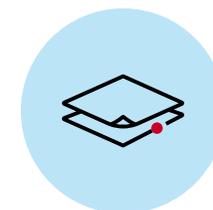
In 1958, the FD&C Act required premarket approval for food additives. This led to the development of a petition process, allowing companies to request approval for specific uses of food additives. Approved uses are listed as regulations in 21 CFR. Components of a food packaging material that comply with a regulation in 21 CFR 174-179 do not require further FDA review.⁴



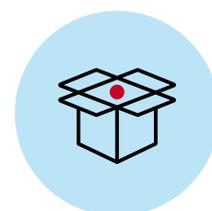
Most regulated indirect food additives can be found in the Center for Food Safety and Applied Nutrition's Indirect Additive Database. This includes:



General indirect food additives (21 CFR 174)⁵



Adhesives and components of coatings (21 CFR 175)⁶



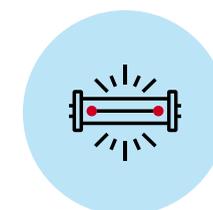
Paper and paperboard components (21 CFR 176)⁷



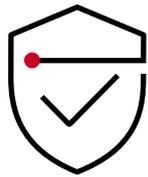
Polymers (21 CFR 177)⁸



Adjuvants, production aids and sanitizers (21 CFR 178)⁹



Irradiation in the production, processing and handling of food (21 CFR 179)¹⁰



Generally Recognized as Safe (GRAS)

GRAS substances include, but are not limited to, those submitted through a GRAS notice. Not all GRAS substances are listed in the FDA's regulations. The FDA has established a procedure that allows companies to inform the FDA of their own GRAS determinations.

A list of GRAS notices¹¹ and the FDA's response letters to notifiers is available on the FDA website under "Summary of all GRAS Notices" and it refers to:

- Substances GRAS in food (21 CFR 182)¹²
- Substances affirmed as GRAS in food (21 CFR 1841)¹³
- Substances affirmed as GRAS for use in food packaging (21 CFR 186)¹⁴

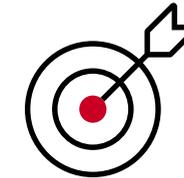
Prior sanction letter

Prior-sanctioned substances are those substances that received a letter issued by the FDA or USDA before 1958 offering no objection to a specific use of a specific substance in a food contact material.¹⁵



Threshold of Regulation (TOR) exemption request

The FDA may exempt a substance used in a food contact article from the need for an FCN or a petition (regulation) as a food additive if its use results in a very low concentration (0.5 parts per billion). For details, see "Submitting Requests Under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles."¹⁶



Effective FCNs

In 1997, the FDA amended the FD&C Act to streamline its approval process.¹⁷ The new procedures established a notification process for food contact substances, designed to replace the petition process as the primary means for authorizing new food contact substances. However, the FDA may still require the petition process when it determines that additional data is necessary to provide an adequate assurance of safety.

The Food Contact Substance web page provides a list of effective FCNs, regulations, guidance documents¹⁸ and additional information regarding the notification program. Note that FCNs are proprietary. Users must be able to trace the food contact substance back to the manufacturer named in the approval notification.

Under Section 409(h)(2)(C) of the Federal FD&C Act, an FCN is applied only to the specific manufacturer that submitted it and only under the conditions of use identified in the notification. The authorization does not extend to similar or identical substances produced or prepared by other manufacturers.

The FDA states:

“

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.”¹⁹

In March 2024, the FDA amended the FCN regulation to include how and when the agency may determine that an FCN is no longer effective. These updates can be found in 21 CFR 170.105. Prior to this ruling, the FDA could only determine an FCN ineffective based on safety concerns. Under 21 CFR 170.105, an FCN may be declared no longer effective if:



Data or other information available to the FDA, including data not submitted by the manufacturer or supplier, demonstrate that the intended use of a food contact substance is no longer safe.



The manufacturer or supplier specified in the FCN has ceased or intends to cease producing, supplying or using a food contact substance for the approved use.



The intended use is already authorized by a food additive regulation.



The intended use is already covered by a Threshold of Regulation exemption.





China

In China, food containers 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 issued 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 was established.²⁰

This new scheme includes four major sections:

- General standards
- Product standards
- Test methods
- General hygiene requirements

These regulations are current as of the publication of this e-book. This overview may be considered a tool, but it may not contain all recent revisions.

General standards²¹

GB 4806.1-2016 — National Food Safety Standard — The General Safety Requirements for Food Contact Materials and Articles in China

This standard specifies the basic requirements, restrictions, compliance protocols, test methods, traceability, product information requirements, declaration of compliance and the good manufacturing practice (GMP) for FCMs. It establishes the framework that applies to all kinds of FCMs in China.

GB 9685-2016 — National Food Safety Standard — The Standards for Uses of Additives in Food Containers and Packaging Material

This standard provides a list of additives that can be used to produce various food contact materials and articles, including their use scope and restrictions. If a specific additive is not explicitly listed, it must be approved by the National Health Commission (NHC) before it can be used to produce certain types of FCMs in China.

Product standards

This new series of product standards replaces many older hygiene standards for materials and articles. The revised standards include requirements for composition, physical and chemical indicators, specific test conditions and labeling:

GB 4806.2-2015	National Food Safety Standard — Nipples
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 4806.7-2023	National Food Safety Standard — Food Contact Plastic Materials and Articles
GB 4806.8-2022	National Food Safety Standard — Food Contact Paper and Paperboard Materials and Articles
GB 4806.9-2023	National Food Safety Standard — Food Contact Metal Materials and Articles
GB 4806.10-2016	National Food Safety Standard — Food Contact Coatings
GB 4806.11-2023	National Food Safety Standard — Food Contact Rubber Materials and Articles
GB 4806.12-2022	National Food Safety Standard — Food Contact Bamboo and Wood Materials and Articles
GB 4806.13-2023	National Food Safety Standard — Food Contact Composite Materials and Articles
GB 4806.14-2023	National Food Safety Standard — Food Contact Printing Inks
GB 4806.15-2024	National Food Safety Standard — Adhesives for Food Contact Materials and Products
GB 14934-2016	National Food Safety Standard — Disinfection Tableware



Test methods

After the implementation of the new scheme, food contact material compliance in China has become more comprehensive and systematic. Understanding these requirements is essential for demonstrating compliance with the new Chinese FCM regulations, including:



GB 31604.1-2023 and GB 5009.156-2016 – The basic standards for selecting test conditions and conducting pre-treatment of test specimens



GB 31604.2-2016-GB 31604.9-2016 – Detection methods for different test indicators required by product standards, such as the determination of overall migration and potassium permanganate consumption



GB 31604.10-2016-GB 31604.63-2025 – Outline test methods for various substances that may have SML or quantity maximum (QM) restrictions under GB 9685 or GB 4806 standards



General hygiene requirements for manufacturing

GB 31603:2015 — National Food Safety Standard — The General Health Code for Production of Food-Contact Materials and Products.

This standard sets baseline requirements for the entire manufacturing process for various food contact materials and articles. Manufacturers should establish a detailed workflow to demonstrate compliance. This standard can act as GMP for food contact materials.

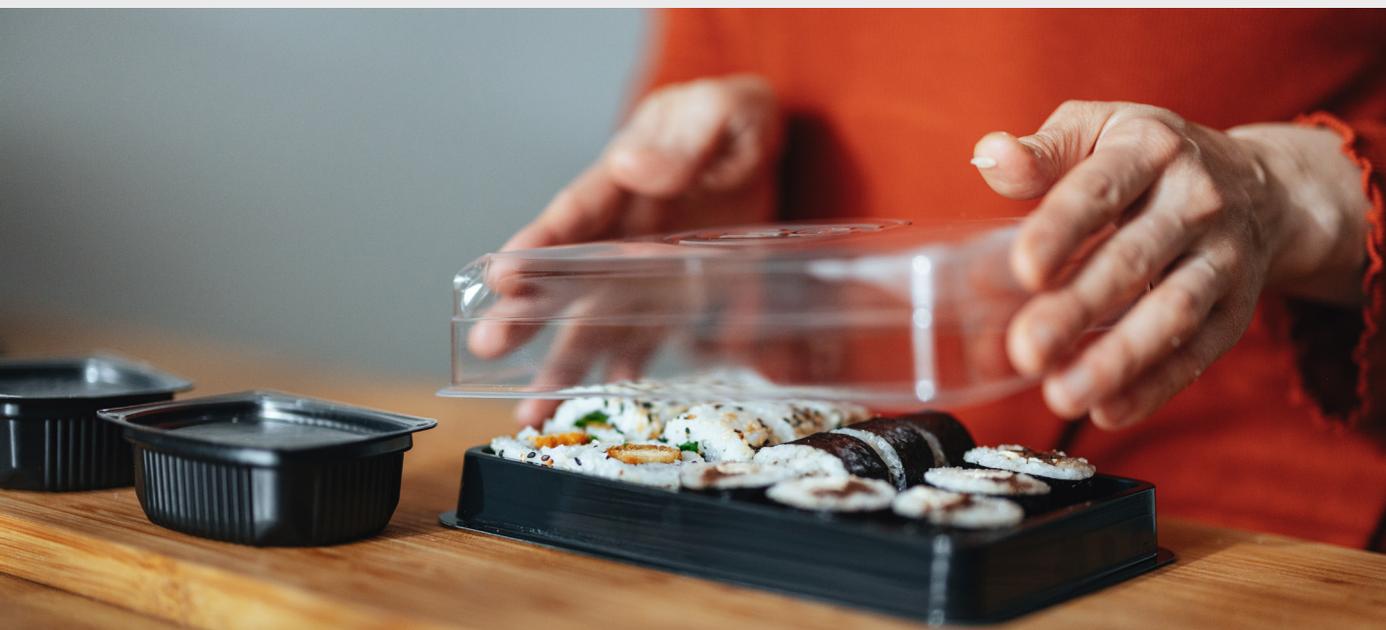


Japan

Japan's Food Sanitation Act (FSA) was amended in June 2020 to introduce a positive list (PL) system for synthetic resins. This approach is conceptually similar to EU 10/2011 but has its own lists, limits and testing methods. Currently, the mandatory PL applies only to plastics, but a long-standing set of Japan Food Sanitation Law (JFSL) test specifications still applies to all FCMs.

Manufacturers and importers must

- Prove every intentionally added substance is included on Japan's PL or otherwise exempt
- Keep a Japanese-language technical file
- Submit an import notification with supporting test reports — preferably from an approved foreign laboratory (AFL) — for each shipment



Legal framework

Regulation	Scope and key points
Food Sanitation Act (Act No. 233/1947, last amended 2020) ²²	Art. 16 “Utensils and containers/packaging must not be injurious to human health.” Art. 16-2 recordkeeping by the importer (≥3 years)
Ministry of Health, Labour and Welfare of Japan (MHLW) Notification No. 196/2020 ²³	<ul style="list-style-type: none"> • Positive List table for synthetic resins • Defines categories (General, I-VIII) and SML

Compliance conclusion – Japan

PL screening is mandatory. Every intentionally added substance in a plastic or other synthetic resin food contact article must appear on the current MHLW Positive List (Notification No. 196/2020) and be used within the stated category, concentration and specific migration limit.

- It is illegal to sell any product that contains even one nonlisted additive (and exceeds the 0.01 mg cm² NIAS threshold) on the market.

Finished-product testing to JFSL methods is also mandatory.

- Quarantine stations at the port of entry rely on the test limits and procedures set out in the JFSL specs for plastics.
- Importers must attach a current JFSL test report to each import notification; without it, customs may sample and test the shipment themselves, which can delay clearance.

Laboratory acceptance is restricted to MHLW-approved facilities.

- MHLW recognizes only reports issued by domestic quarantine laboratories or by an AFL that appears on its official roster.
- As of the April 2025 list, the following UL Solutions sites are AFL-listed and can perform full JFSL tests:
 - UL Solutions in Hong Kong (HK20008)
 - UL Solutions in Italy (IT20001)



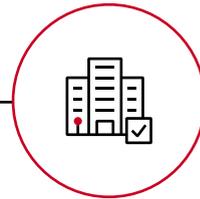
European Union (EU)

In the EU, all materials and articles intended to come into contact with food must meet the general criteria imposed by the Framework Regulation 1935/2004²⁴, establishing that there is sufficient inertia in every phase of contact between FMCs and food and any type of negative influence on the quality, nutritional and organoleptic properties of the food is avoided. In addition, all food contact materials must be manufactured according to GMP, as regulated by Regulation (EC) 2023/2006.

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

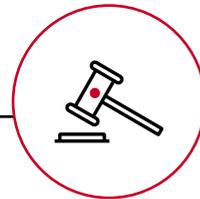
These materials must not:

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



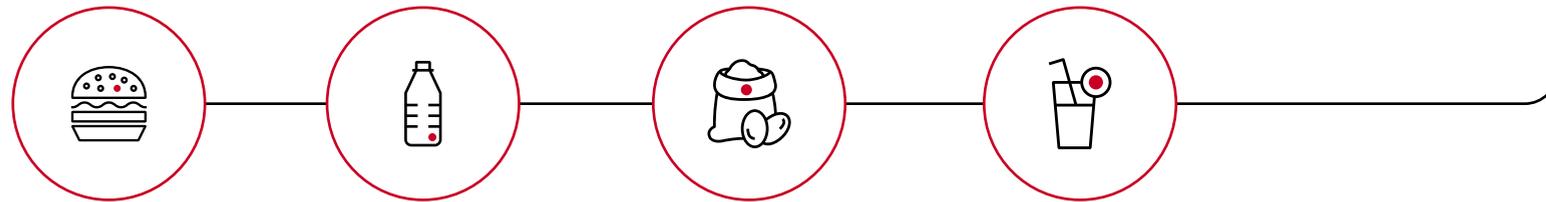
The framework also establishes:

- Special rules for active and intelligent materials (they are, by design, not inert)
- Powers to enact additional EU measures for specific materials (e.g., plastics)
- The procedure to perform safety assessments of substances used to manufacture FCMs, involving the European Food Safety Authority (EFSA)²⁵
- Rules on labeling, including an indication for use (e.g., coffee maker, wine bottle, soup spoon) or by reproducing the appropriate symbol. For more information, please refer to the following document on symbols for labeling food contact materials.²⁶
- Rules for compliance documentation and traceability



Commission Regulation (EC) No 2023/2006²⁷ requires that manufacturing processes are well controlled. This includes:

- Premises suited to food contact production and staff trained on critical stages
- Documented quality assurance and quality control systems maintained at the premises
- Selection of suitable starting materials that support safety and inertness of the final articles



GMP apply to all stages in the manufacturing chain of FCMs, although the production of starting materials is covered by separate legislation.

As part of the CAST Project²⁸ (Contatto Alimentare Sicurezza e Tecnologia, which translates to Food Contact Safety and Technology), general and specific GMP guidelines were developed for the application of Regulation No. 2023/2006/CE for materials and articles intended to come into contact with food. The guidelines are structured in sections for general and specific applications, including chains of aluminum, paper and boards, flexible packaging, plastics, coated and uncoated metals and alloys, wood, cork, and glass.

The most comprehensive, specific EU measure is the Commission Regulation (EU) No 10/2011,²⁹ 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 compliance.

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

A key mechanism for the safety of plastic materials is the use of migration limits, which 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. These are established by the European Food Safety Authority (EFSA) based on the toxicity data of each specific substance. To confirm the overall quality of the plastic, the migration to food of all substances together may not exceed the overall migration limit of 60 mg/kg for food, or 10 mg/dm² of the contact material.

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

To demonstrate the safety, quality and compliance of plastic materials, adequate data on the composition of intermediate materials must be communicated throughout 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 that records the reasoning behind the safety of a plastic food contact material and must be made available to enforcement authorities upon request. This documentation also supports the manufacturer's responsibility under GMP (Commission Regulation (EC) No 2023/2006).³⁰

The information required in the DoC is outlined in a standard format in Annex IV of Regulation (EU) No 10/2011 to help facilitate the exchange of relevant information. It is crucial to understand that a plastic food contact material is considered 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). In the United States, recalls are handled by the Consumer Product Safety Commission (CPSC). Both RASFF and CPSC quickly notify consumers and manufacturers to help minimize potential harm. Strong management is critical to building trust and delivering safer, compliant food contact products to your target market.

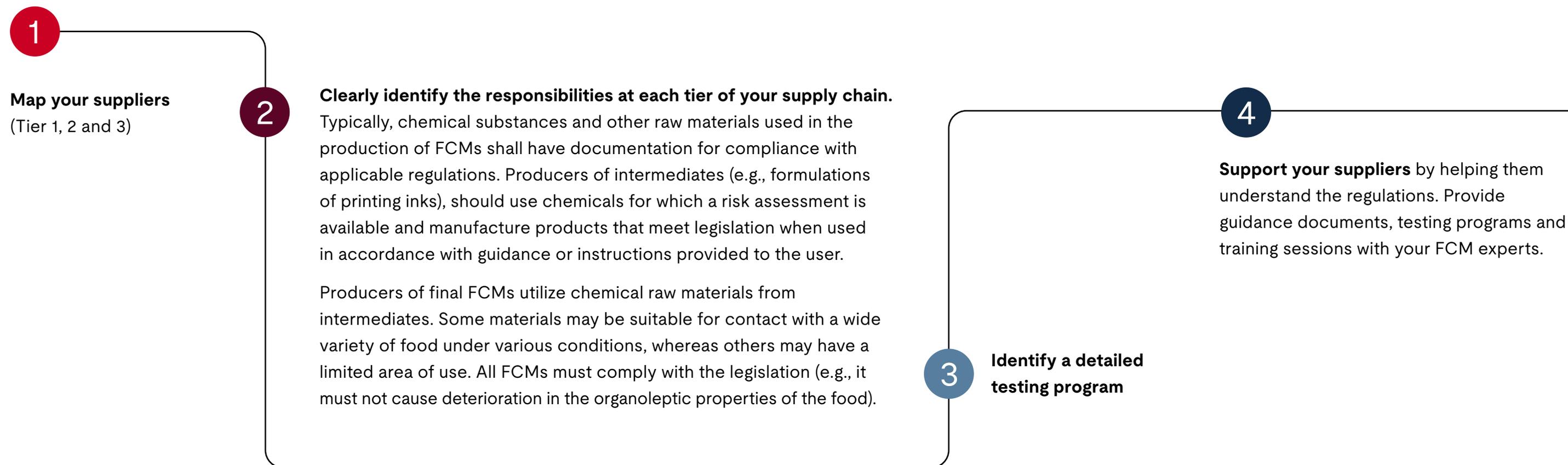
This includes mechanisms to continually monitor production. Because of the potential impact on human health and safety, food contact materials require extensive documentation. Without appropriate technical files, bills of materials or chemical lists, product testing may be incomplete. This can delay market entry or increase the risk that an unsafe food contact product will reach consumers.

Enlisting a trusted independent third party like UL Solutions can help companies take a data-driven approach to navigate compliance with regulatory requirements for exporting food contact materials to their target markets. Our global regulatory research team can help companies identify requirements for specific markets and guide requests to suppliers for specific documentation. We offer customized testing, inspection, audit and training programs for brands and retailers to address needs during all stages of the supply chain, from product development to getting items onto shelves efficiently.



Tips to demonstrate compliance

If you are a manufacturer of a food contact product, or if you are responsible for placing a product on the market, keep the following key steps in mind when approaching compliance:



Tips to demonstrate compliance

If you are a manufacturer of a food contact product, or if you are responsible for placing a product on the market, keep the following key steps in mind when approaching compliance:

5

Give suppliers clear instructions related to the product you intend to manufacture, including the destination market. Confirm that suppliers understand the type of documents you require to support compliance.

6

Commit to a competent review of all the documents you receive from your suppliers

7

Organize audits and inspections of supplier facilities to confirm the compliance, safety and quality obligations are being met (e.g., GMP where expected, astatically correct, sharp points and edges).

8

Make sure you refer to the most current legislation, taking into account any transitional periods that may apply, such as Commission Regulation (EU) 2024/3190 of 19 December 2024 on the Use of Bisphenol A (BPA) and Other Bisphenols and Bisphenol Derivatives with Harmonised Classification for Specific Hazardous Properties in Certain Materials and Articles Intended to Come into Contact with Food.³¹



How can UL Solutions help you demonstrate your products are compliant with the destination country's regulations?

There are complex regulations and standards to help support the safety and quality of plastic and polymeric food contact materials worldwide. These regulations are not harmonized and continue to change. Noncompliant products can put a company and its brand reputation at risk for recalls.

UL Solutions can help identify requirements, guide documentation requests, review PLs against your formulation, and perform testing, audits and inspections. Through testing and training, UL Solutions supports manufacturers in demonstrating compliance with regulations and standards to bring safer and higher-quality food contact materials to market.

We work with customers to establish comprehensive testing programs that assess compliance with applicable food contact standards. When scientific expertise, objective authority and market access matter, working with UL Solutions experts can help you navigate the road ahead.

Contact us at RCP@UL.com to connect with a UL Solutions representative.

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