FOOD CONTACT MATERIALS

Food contact materials (FCM) are materials and articles intended to come into contact with food. FCM products and materials include:

FCM have the potential to adversely alter the taste, odor and/or color of foods. There is also the risk that hazardous constituents such as heavy metals and additives may migrate into the food from the FCM, thereby endangering human health.

Legislation governing the safety of FCM is enforced around the world. In recent years, more rigorous restrictions have been promulgated, with stricter mechanisms being established by major trading nations to eliminate hidden dangers and strengthen the safety management of FCM.
GLOBAL FOOD CONTACT MATERIAL REGULATIONS SUMMARY

Most countries enforce some form of FCM safety regulation or standard. Differences in living standards and economic development, however, mean there is a great disparity in the comprehensiveness and severity of the legislation being enforced.

The following three regions have attracted the most attention.

<table>
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<tr>
<th>REGION</th>
<th>FOOD CONTACT MATERIAL REGULATION AND STANDARDS</th>
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<tbody>
<tr>
<td><strong>EUROPE</strong></td>
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</table>
| **EU** | Framework Regulation: (EC) No 1935/2004  
| **GERMANY** | Framework Regulation: LFGB Chapter 30 & 31  
BfR Technical Recommendation |
| **FRANCE** | French Décret n° 2007-766, Fiches materiaux organiques - matieres synthetiques,  
Fiches materiaux inorganiques, Fiches metaux alliage v2, Fiches materiaux organiques fibres vegetales, French Act 2012-1442, Note d’information 2012-93 DGCCRF |
| **ITALY** | Act No 283 of 30 April 1962, Presidential Decree No 777 of 23 August 1982,  
and DM 21/03/1973 etc. |
| **AMERICA** | |
| **USA** | 21CFR 174-189  
CPG Sec.545.400 & 545.450, CPG 7117.05 |
| **CALIFORNIA** | US Federal FCM Regulations; California Proposition 65 |
| **MERCOSUR** | Framework Regulation: GMC Res. No. 3/92  
Plastic: Mercosur GMC Res. No. 56/92, 32/10, 32/07, 02/12  
Rubber: Mercosur GMC Res. No. 54/97, 28/99  
Metal: Mercosur GMC Res. No. 46/06  
Ceramic: Mercosur GMC Res. No. 55/92  
Test Method: GMC Res. No. 66/99, 32/10 |
| **ASIA** | |
| **CHINA** | Food Safety Law of PRC  
General safety requirement: GB 4806.1-2016  
Additive standard: GB 9665-2016  
Standards of raw material & finished product: such as GB 4806.6-2016, GB 4806.7-2016,  
GB 4806.9-2016, GB 4806.11-2016, etc  
GMP: GB 31603-2015 |
| **JAPAN** | Japan Food Sanitation Law (No.233)  
MHLW Notice No.370 |
| **KOREA** | Korea Food Sanitation Law  
Standards and Specifications for Food Utensils, Containers and Packages |
FCM regulations have requirements relating to raw materials, production processes, and technical documentation (including testing and declaration of conformity) for finished products. It is important to select qualified materials, control the production environment and processes, and confirm the compliance of the finished product in accordance with related FCM regulations.

**KEY POINTS IN FCM COMPLIANCE**

**MATERIAL COMPLIANCE**
Most FCM regulations include a list of authorized monomers and additives, with some hazardous substances in the list having usage levels and migration limits.

Producers can decide the appropriate formula for raw materials based on these lists. Plastic materials with complex formulations and production processes have greater concern in market surveillance, especially PC, PVC, rubber, coatings etc.

**PRODUCTION PROCESS AND ENVIRONMENTAL COMPLIANCE**
FCM regulations commonly call for production in accordance to GMP (Good Manufacturing Practice). Qualifying products must conform to production process and environmental protection controls.

Special attention should be paid to preventing contamination under high temperature production process, such as rubber vulcanization and ceramic sintering, processes in which it is easy for contaminants to migrate.

**PRODUCT CONFORMITY CONFIRMATION**
Test reports and the finished product's declaration of conformity are usually included in the product's technical documentation, in case they are required by the buyer or a surveillance body. Testing finished products is dependent upon material classification and the actual use conditions. Material composition confirmation and use conditions are therefore important during testing.

European countries are also highly concerned with the organoleptic characteristics of the product. Failing a sensory test will always result in a product being recalled.

**SGS ONE-STOP SOLUTION THROUGH A PRODUCT’S LIFE CYCLE**

- **PRODUCT LIFE**
- **PRODUCT DESIGN AND DEVELOPMENT /RAW MATERIAL SELECTION**
- **SPECIFICATION OF PROCESS / PROCESS AND ENVIRONMENTAL CONTROL**
- **CONFIRMATION OF PRODUCT COMPLIANCE /TESTING AND DECLARATION**
- **INFORMATION THROUGH SUPPLY CHAIN**

**SGS ONE-STOP SOLUTIONS**

- **TRAINING SERVICE**
- **CONSULTING SERVICE**
- **MATERIAL / COMPONENT TESTING FINISHED PRODUCT TESTING**
- **RSTS DATABASE**
TRAINING SERVICE
SGS training courses let organizations gain a deeper understanding of FCM regulation requirements and help establish a management strategy.

CONSULTANCY SERVICE
Our consultancy service helps organizations identify high-risk processes and control points during manufacturing, analyze reasons for non-compliance, and helps reduce the risk of further non-conformities.

MATERIAL/COMPONENT TESTING
SGS provides a comprehensive testing service to confirm materials and components are compliant and ensures all FCM and product components conform to FCM regulatory requirements.

FINISHED PRODUCT TESTING
FCM testing of finished products is a tailored program relating to the actual use of the product. It helps organizations verify the compliance of finished products in a timely and cost-efficient way.

RESTRICTED SUBSTANCES TESTING SERVICE (RSTS) DATABASE
SGS’s Restricted Substance Testing Service (RSTS) database helps businesses manage and transfer their test reports. Additionally, it provides a convenient platform for enterprises to display their environmentally friendly products.

WHY SGS
SGS operates a dedicated team of experts in substance analysis, supply chain management and (eco-) toxicology, all backed by a global network of laboratories. From high quality testing to industry consultancy, SGS provides a convenient one-stop solution for operators in electrical and electronic supply chains.

ABOUT SGS
SGS is the world’s leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 89,000 employees, SGS operates a network of over 2,600 offices and laboratories around the world.

For more information, visit www.sgs.com/ee.

Blender. Tested.

WHEN YOU NEED TO BE SURE

SGS