Safeguard Your Meals with Food-grade Product Testing Services

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Precisely Right.

Our services

Food contact materials and articles are designated to come into contact with food. Their regulatory compliance requirements and testing approaches may thus differ from those of other products. Generally, food contact materials and articles follow the compliance assessment principles listed below.

- Raw material composition based on positive lists indicated in the different regulations
- Final product testing
- Performance testing according to label claims

TÜV Rheinland offers comprehensive testing services for all types of food contact materials and articles, in accordance with the requirements of importing countries or any additional brand requirements. The following are examples of common food contact compliance tests:

- Food-grade testing at a glance
  - Sensorial examination to determine any transfer of taste or smell into foodstuffs
  - Overall and specific migration onto different materials
  - Release of heavy metals from certain materials
  - Volatile organic compounds from rubber and silicone materials
  - Metal composition
  - Extraction tests according to FDA legislation
  - Leachable heavy metals from glass and ceramic ware
  - Further materials and testing parameters based on specific legislation

TÜV Rheinland food-grade product compliance services

- Key services
  - Tailor-made testing programmes for international brands
  - Technical support
  - Extensive scope of food contact services for all kinds of materials
  - Technical advice on failed test results
  - Seminars and training programmes
  - Regular news updates on product regulations

EU Regulation (EC) No 1935/2004

In the European Union, materials and articles that come into contact with food are regulated by Regulation (EC) No 1935/2004, the scope and requirements of which are as follows.

- Scope

  Materials and articles in their finished state that
  - are intended to come into contact with food; or
  - are already in contact with food and are intended for that purpose; or
  - can reasonably be expected to be brought into contact with food or to transfer its constituents to food under normal or foreseeable conditions of use.

- To comply with the requirements of Regulation (EC) No 1935/2004, specific substances or groups of materials must also comply with the requirements of the following EU regulations and directives
  - (EU) No.10/2011: for plastic materials and articles
  - 84/500/EEC: for ceramic articles
  - 93/11/EEC: for N-nitrosamines and N-nitrosatable substances from rubber teats and soothers
  - 78/142/EEC for vinyl chloride monomer-containing materials
  - 1895/2005/EC: for certain epoxy derivatives

- Requirements

  Materials and articles must be manufactured in compliance with good manufacturing practices, and under normal or foreseeable conditions of use must not transfer their constituents to food in quantities that could
  - endanger human health; or
  - bring about an unacceptable change in the composition of the food; or
  - bring about a deterioration in the organoleptic characteristics thereof.

  (BADGE, BFDGE, NOGE)

- For unregulated materials not covered by the foregoing EU regulations or directives, there are recommendations in the form of policy statements (guidelines). The following are examples.
  - Coatings policy statement
  - Glass policy statement
  - Paper and board policy statement
  - Rubber policy statement
  - Silicone policy statement
  - Metal policy statement

These policy statements established by committees of experts in the European Council are not legal requirements, but can be seen as representing the current state of the art under which materials and substances that come into contact with food can meet the requirements of regulation (EC) No 1935/2004.

EU food-grade legislation

EU Regulation (EC) No 1935/2004 provides general provisions with which all food contact materials and articles must comply

To prove compliance with the general provisions, specific measures are in place for certain materials or substances

EU specific measures are in place for certain materials or individual substances

For materials that do not have specific EU legislation in place,

Council of Europe policy statements may indicate state-of-the-art requirements that prove general compliance with the provisions of (EC) No 1935/2004

The most common types of food-grade product materials testing for EU market

Type	Description	Examples
Migration test: overall migration	This test checks the overall inertness of food contact materials. It simulates the actual use of a product by selecting suitable food simulants and appropriate time and temperature conditions. After conditioning, the food simulant is evaporated to check the total weight of residue migrating from the food contact material. This weight is compared against the limit set by the regulation.	Global migration into: - 3% acetic acid - Ethanol in different concentrations - Iso-octane - Rectified olive oil - Poly(2,6-diphenyl-pphenylene oxide) (Tenax)
Migration test: specific migration	This test checks any possible migration of the material's monomers or additives into the foodstuffs. The test principle is the same as that for the overall migration test, but after conditioning the food simulant is taken for analysis of individual chemical substances or groups thereof. Specific limits for each substance apply.	Examples of specific migration tests: - Acrylonitrile - Nitrosamines - Formaldehyde - Melamine - Bisphenol A - Caprolactam
Total content test: residual substances	This test checks for the total remaining content of intentionally added substances or contaminations. The sample is completely digested or totally extracted for determination of a particular substance or group of substances.	Examples of total content tests: - Heavy metals - VOC - Isocyanates - PCP - Vinyl Chloride

Declaration of Compliance

According to Regulation (EC) No 1935/2004 , materials and articles intended to come into contact with food also need a declaration of compliance (DoC) from the manufacturer or distributor in the supply chain. The DoC is needed when specific measures exist, and it should contain information about product usage and a statement from the responsible party that the product complies with all applicable rules. Upon request, TÜV Rheinland can assist in preparing a DoC to be signed by the manufacturer or importer of the goods. To issue such a declaration, a test report with results supporting the product's compliance with (EC) No 1935/2004 and its related legislation is necessary.

German LFGB

In Germany, food contact materials and articles are regulated by the German Food, Commodity and Feed Law (LFGB).

To prove compliance with the regulation, the legal specifications of the following ordinance must also be followed.

- Commodity Regulation, Restriction of Chemical Ordinance

When materials are not covered by the regulation

The recommendations of the Federal Institute for Risk Assessment (BfR) governing materials intended to come into contact with food (Formerly "Plastic Recommendation") must be followed.

The LFGB regulates food, feed, cosmetics and consumer products such as toys, textiles and food contact materials. LFGB Section 31 is specifically dedicated to food contact materials and is linked to European Regulation (EC) No 1935/2004.

Requirements of food contact materials

Section 30 Bans to protect health

This section prohibits the manufacture, marketing and treatment of commodities that come into contact with foodstuffs and human skin or mucus membranes and endanger human health through the transmission of toxic substances or impurities.

Section 31 Transfer of substances of food

This section prohibits the use or placing on the market of materials and articles intended to come into contact with food that do not fulfil the food contact requirements stated in Article 3, Section 1 of European Regulation (EC) No 1935/2004.

Section 33 Rules to protect against deception

This section prohibits the placing on the market of materials and articles intended to come into contact with food if the labelling, advertising and presentation of those materials and articles mislead consumers.

Specific measures of certain food contact materials or individual substances can be found within the German Commodity ordinance and the recommendations of the German BfR (Federal Institute for Risk Assessment).

BfR recommendations for food contact materials

For materials that are not covered by EU legislation, the BfR's recommendations for food contact materials act as the state-of-the-art requirements for proving compliance with the general provisions of Regulation (EC) No 1935/2004 and the LFGB.

The BfR recommendations focus on polymeric materials, but also consider other materials:

- Polymers (PP, PE, ABS, SAN, Nylon, etc.)
- Temperature-resistant coatings (Part LI. "Temperature Resistant Polymer Coating Systems for Frying, Cooking and Baking Utensils")
- Paper and paperboard material (Part XXXVI. "Paper and Paperboard for Food Contact")
- Silicones (Part XV. "Silicones")
- Natural and synthetic rubber (Part XXI "Natural and Synthetic Rubber")

French DGCCRF and Italian Presidential Decree of 1982

French market

The DGCCRF (“Direction générale de la concurrence, de la consommation et de la répression des frauds”) is a French authority responsible for fair trade and consumer safety that also covers food safety, including food contact materials and articles.

General provisions concerning the safety of food contact materials and articles are taken under the French Decree 2007-766, which represents the national version of EU Regulation (EC) No 1935/2004.

Specific measures for certain food contact materials or individual substances can be found within several Arrêtés, such as:
- Arrêté du 13 Janvier 1976 on stainless steel
- Arrêté du 27 Août 1987 on aluminium
- Arrêté du 25 Novembre 1992 on silicone elastomers
- Arrêté du 9 Novembre 1994 on rubber elastomers

French ban on Bisphenol A

France placed a total ban on all Bisphenol A (BPA)-containing food packaging, containers and utensils at the beginning of 2015. BPA can be used in the manufacturing of epoxy coating, which is commonly found in tin cans and polycarbonate plastic (PC) materials. As a comparison, according to current harmonised EU legislation, BPA use is only prohibited in the manufacturing of PC infant feeding bottles while other European countries might restrict its use in the manufacturing of certain baby and childcare food care articles.

This creates a controversial situation within the European member states and affected industries. TÜV Rheinland is closely following the latest developments to keep you up to date with any changing provisions.

The DGCCRF furthermore issued documents for food contact suitability on materials intended to come into contact with foodstuffs.The notice summarises the specific measures given by EU legislation and the national arrêtés, including provisions for materials not covered by the above, such as several pure, coated or plated metal materials, paper and paperboard, etc.

Italian market

The Decreto Presidente della Repubblica no. 777 del 23/8/1982 (amended by Decreto Legislativo no. 108 del 25/1/1992) transposes the general principles of (EC) No 1935/2004 into Italian national law. In terms of specific measures, the decree points for Decreto Ministero della Salute 21 marzo 1973 (DM 21/3/73) cover the following materials:
- Plastics
- Regenerated cellulose
- Rubber
- Paper and cardboard
- Glass
- Stainless steel

One general principle of Italian food contact legislation is the overall migration test, which is applied to almost all of the materials mentioned above. Another specific feature of Italian legislation is its colour migration test, which applies to all coloured polymeric materials including the plastic materials that fall under the scope of (EU) No 10/2011.

Italian legislation has also set a benchmark when it comes to stainless steel compliance testing, which consists of overall migration, specific release of chromium, nickel and manganese and a composition check against an approved list of stainless steel types.

There are also minor decrees available for materials not covered by the DM 21/3/73, such as Ministerial Decree no. 76 of 18/4/2007 for aluminium and Ministerial Decree 18/2/1984 for tin-plated cans.

Other EU national legislations

In addition to the general EU legislation and the abovementioned national legislations, we also provide compliance testing services for additional European national legislations, such as:

- Dutch “Regeling Verpakkingen en Gebruiksartikelen (Warenwet)“
- Swiss “Verordnung des EDI über Bedarfsgegenstände”
- Northern European legislation

We are constantly working to extend our service scope, so please don’t hesitate to ask about the availability of additional food contact legislations.

US FDA

In the US, food contact materials are regulated by the US Food and Drug Administration (FDA) and controlled by certain provisions. These materials fall under Title 21 of the Code of Federal Regulation (CFR) and are considered to be “indirect food additives”, as they might be reasonably expected to transfer their constituents into food.

Food contact materials are described in part 174-178 of Title 21 of the CFR:

- Part 174 – Indirect Food Additives General
- Part 175 – Adhesives and Components of Coatings
- Part 176 – Paper and Paperboard Components
- Part 177 – Polymers
- Part 178 – Adjuvants, Production Aids and Sanitizers

In general, the food contact materials must be proven safe by testing against the respective material chapter. However, some food contact materials are generally recognised as safe by the FDA, which conducts a material verification check sufficient to prove compliance with the provisions.

Our scope of FDA testing covers most food contact materials, including but not limited to:

Materials	Test Method/Specification
PP/PE	FDA 21 CFR part 177.1520
Silicone rubber	FDA 21 CFR part 177.2600
Polyamide (nylon)	FDA 21 CFR part 177.1500
Sealing gaskets	FDA 21 CFR part 177.1210
Polymeric coatings	FDA 21 CFR part 175.300
Paper and paperboard	FDA 21 CFR part 176.170
Ceramic	CPG 7117.06&7117.07 Sec. 545.400 (CPG 7117.06) & Sec. 545.450 (CPG 7117.07)
Stainless steel	GRAS evaluation

California Proposition 65

California Proposition 65 lists chemicals that are known to the State of California to cause cancer, birth defects or other reproductive harm. Californians might be exposed to these substances through the environment, homes, workplaces or any type of product. The proposition stands out from other provisions in that limits are defined by exposure. Furthermore, it can be enforced by both public institutions and private persons.

Food contact articles and materials are also covered by the proposition. Due to the nature of the provision, there are different ways and levels of ensuring compliance. If your product distribution covers this market, please approach us to find the most suitable solution for you.

South America – Mercosur

The South American trade union Mercosur shares a harmonised legislation on materials and articles expected to come into contact with foodstuffs. Mercosur currently consists of the following member states: Argentina, Bolivia, Brazil, Paraguay, Uruguay and Venezuela. The general principles and requirements for compliance are laid out in Resolution GMC 03/92.

Based on this framework regulation, further specific measures for different materials are in place:

- Resolution GMC 56/92 and related resolutions on plastic materials
- Resolution GMC 46/06 on metal materials
- Resolution GMC 55/92 on ceramic and glass materials
- Resolution GMC 54/97 on elastomeric materials

The test principle of Mercosur resolutions is mainly following EU food contact legislation, but still contains elements specific only to the Mercosur provisions, e.g., colorants, metal and elastomer testing. TÜV Rheinland has full food contact compliance testing capabilities in line with Mercosur legislation.

Asian food contact legislations

Japan

Japan is one of the first countries in Asia to introduce provisions specific to food contact materials. Materials and articles in contact with food are regulated under the Japanese Food Sanitation Act, no. 233 (1947). Furthermore, materials are tested according to the Ministry of Health, Labour and Welfare (MHLW) Specifications and Standards for Food and Food Additives (MHLW Notice No. 370, 1959).

Japan's system requires that official test reports be issued exclusively by approved laboratories. TÜV Rheinland is one of these approved laboratories.

China

China issued a Food Safety Law in 2009, which regulates food contact materials. On April 24th, 2015, the 2009 Food Safety Law had been revised and came into effect on October 1st, 2015.

Provisions are set according to Chinese national standards – the GB ("guo biao") standards – each of which covers one specific material or product group.

- GB 9685-2016 Uses of Additives
- GB 4806.1-2016 General Safety Standard
- GB 4086.6-2016 Plastic Resins
- GB 4806.7-2016 Plastic Materials and Articles
- GB 4806.9-2016 Metal Materials and Articles

Taiwan

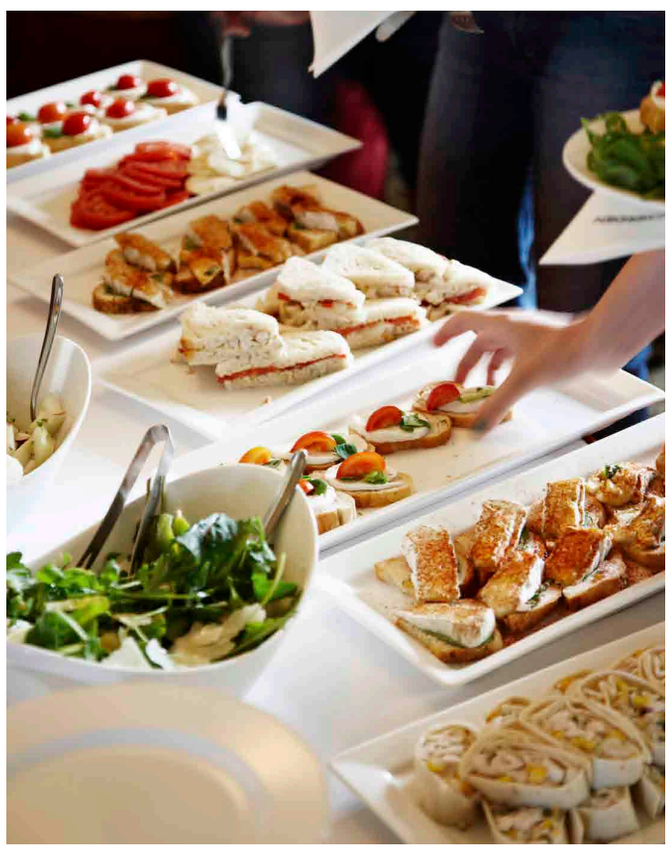
In Taiwan, food contact materials are regulated under the Taiwan Act Governing Food Sanitation. Test requirements and methods are described under the Taiwan Sanitation Standard for Food Utensils.

Thailand

In Thailand, food contact materials follow the general provisions of the Thailand Food Act, B.E. 2522 (1979).

Specific materials and products are regulated under certain notifications, such as:

- Notice of the Ministry of Public Health No.92 (B.E.2528) laying down limits for leachable heavy metals from ceramic and enamelled metal containers
- Notice of the Ministry of Public Health No. 295 B.E. 2548 (2005) on plastic materials
- Notice of the Ministry of Public Health No. 117 B.E. 2532 (1989) on feeding bottles



Principles of Asian food contact testing

The principles of Asian food contact materials testing are mainly based on total content testing of residual substances and extraction tests at set conditions. They mostly follow Japan as one of Asia's pioneering countries in the field of food contact legislation. Common examples of test parameters include:

- Total lead and cadmium
- Heavy metals as lead
- Consumption of potassium permanganate
- Evaporation residues
- Phthalates and migration of phthalates
- Other materials (subject to specific migration testing)

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