



TÜV Rheinland Electrical Food-grade Product Testing Service

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 **TÜVRheinland®**
Precisely Right.



Challenges

Electrical appliances for food production should ensure the safety of the final food. Due to the large amount of food contact parts in electrical appliances, it is hard for the compliance of the whole product. To guarantee the safety of food contact, Declaration of Compliance (DoC) and other information should be collected carefully to make sure each part were manufactured with good manufacturing practice (GMP). In addition, the document format and requirement from different appliances make the compliance harder.

The compliance and safety of electrical appliance intended for food contact are throughout the life cycle. It started from picking the raw materials and components which fulfill the requirement, to make sure the implementation of GMP within the supply chain in manufacturing, and perform verification tests on products according to various FCM regulations.

Product distribution laws and regulations must be realized, while monitoring the compliance status of DoC and the safety with interaction of the intended contact food and condition. Even the products' post-life cycle waste treatment shall be considered to guarantee the sustainability of raw materials and products.

Our services

▪ Regulatory Service

- Build a regulatory framework and alert system
- Product regulatory assessment
- Provide a technical platform for new legislation with Local authorities, Consumers' association and Industry Association

▪ Declaration of Compliance(DOC) management: Cover the whole supply chain from raw material to final product

▪ Proof Product certification – Safe for food, Tested for harmful substances

▪ Compliance assessment

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

▪ Product testing

- Content and migration test of substances
- NIAS testing service and risk assessment
- Material composition and screening
- Microbiology testing
- Sensory examination



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.

Our FCM Testing Capabilities

According to the food contact materials legislation all around the world, the global food contact materials safety requirement can be mainly concluded as 3 regions: Aisa, Europe, North & South America.

EUROPE

- European Union
- Belgium
- Croatia
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Italy
- Norway
- Poland
- Portugal
- Spain
- Sweden
- Swiss
- Luxembourg
- Netherlands

AISA

- China
- China - Taiwan
- India
- Indonesia
- Malaysia
- Singapore
- Thailand
- Vietnam
- Turkey

MIDDLE EAST

- Saudi Arabia
- UAE

NORTH & SOUTH AMERICA

- Argentina
- Brazil
- Colombia
- Mercosur
- United States



China GB

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 4806.2-2015 Nipple
- GB 4806.3-2016 Enamel
- GB 4806.4-2016 Ceramic
- GB 4806.5-2016 Glass
- GB 4806.6-2016 Plastic Resins
- GB 4806.7-2016 Plastic Materials and Articles
- GB 4806.8-2022 Paper and Paperboard Materials and Articles
- GB 4806.9-2016 Metal Materials and Articles
- GB 4806.10-2016 Paint and Coating
- GB 4806.11-2016 Rubber Materials and Articles
- GB 4806.12-2022 Bamboo and Wood Materials and Articles

Taiwan, China

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.

Japan

In Japan, 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.

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

▪ Requirement

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.

▪ 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.

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

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

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

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



- 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

The DGCCRF ("Direction générale de la concurrence, de la consommation et de la répression des fraudes") 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 5 Août 2020 on rubber elastomers

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.

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.

Italian DM

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 recognized as safe by the FDA, which conducts a material verification check sufficient to prove compliance with the provisions.

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 paper board	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 harmonized 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.



NIAS Testing Service

Ensure safety and quality of plastic material in contact with food

For plastic food contact materials going to EU market, substances that are used for manufacturing the food contact material must be taken from the Union list in Annex I of EU regulation no. 10/2011. Only those substances are allowed to be added intentionally to the formulation as monomers, additives or production aids. Most of the compliance checks now will target directly for the release of these intentionally added substances, as manufacturers or distributors are sure they are used in the manufacturing processes.

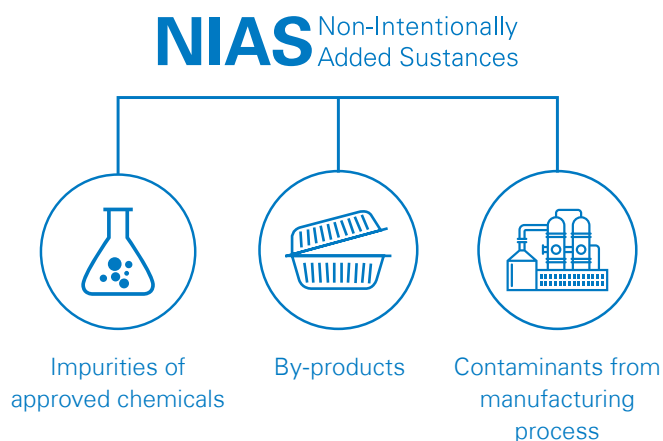
However, EU regulation no. 10/2011 also mentions another group of substances that are of particular interest. The “NIAS” (Non-Intentionally Added Substances) can also be found in plastic food contact materials even if they are not added directly. The EU regulation no. 10/2011 does not include comprehensive assessment of NIAS, but overall NIAS should be assessed to be sure that the plastic material is safe in contact with food, under the principles of article 3 of EC regulation 1935/2004.

IMPORTANCE OF NIAS

As testing techniques and requirements develop rapidly, authorities are also increasingly aware of advanced requirements such as NIAS testing. Hence, it is foreseeable that the assessment of NIAS will be extended to be a common requirement for product safety in consumer products with food contact and food production machines. It is therefore highly recommended to include NIAS assessment into your product compliance assessment to be well prepared for this upcoming trend.

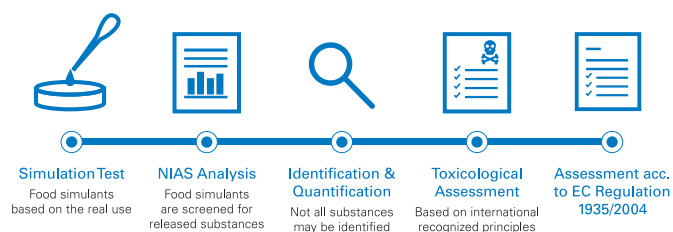
WHAT IS “NIAS”?

NIAS, as the name implies are substances that are not intentionally added into food contact materials, but are present. The reason can vary from substance to substance; some are impurities of the chemicals from the approved list (Union list of EU regulation no. 10/2011), some can be formed as by-products and some can be purely contaminants during manufacturing processes. The presence of these NIAS is often not expected, it can be any kind of chemical and can be dangerous if not assessed on the final food contact material.



WHAT IS TÜV RHEINLAND NIAS TESTING SERVICE ABOUT?

Our NIAS testing will help you to understand what kind of non-intentionally added substances can potentially migrate into food stuff from a food contact material. The test is carried out by simulation test with food simulants referring to EU regulation no. 10/2011, and then submitting the food simulants to NIAS analysis. The analysis technique scans all the released substances and identifies them at a very low detection level (10 parts per billion). A toxicological assessment (based on internationally recognized principles) will follow, which can tell whether these identified NIAS can potentially endanger human health. In case of an identified risk, that means the material cannot be guaranteed as safe and hence it can lead to the conclusion that the material is not suitable for food contact and violating the requirements under article 3 of EC regulation 1935/2004.



One thing to note is that no official standardized method is available for NIAS currently, and also not all found substances can be identified by any existing single laboratory technique. Therefore please contact your local TÜV Rheinland Group office contact to understand more about the NIAS testing. We will be happy to help and provide you the guidance to ensure a safer product in the market.



OUR SERVICES

As an accredited testing laboratory, we offer the following services:

- Design tailor-made testing programs for international buyers
- Provide strong technical support for customer enquiries
- Extensive scope of food contact testing for all materials
- Seminars and training

BENEFITS AT A GLANCE

NIAS tests carried out by TÜV Rheinland laboratories allows you to:

- Ensure food contact compliance with statutory and voluntary requirements
- Provide consumers with safe and tested products
- Boost confidence in the quality and safety of your products
- Document implementation of legal requirements with test reports

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