

Food safety: Standards and requirements for food contact materials

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Food safety is a central aspect of consumer protection. To ensure that food meets the highest standards, different regulations and guidelines exist in different countries. These standards are particularly important for products that come into direct contact with food. At national, EU and international levels, materials that come into direct contact with food must therefore meet strict legal requirements to ensure consumer health and safety.

Recommendations of the German Federal Institute for Risk Assessment (BfR)

The recommendations of the German Federal Institute for Risk Assessment (BfR) represent the latest scientific and technological knowledge. As such, they serve as an important and broadly recognized benchmark for assessing whether an article that comes into contact with food meets legal requirements.

The key principle is that materials and commodities must be manufactured in such a way that ensures only safe levels of substances are transferred to food, not posing a health risk to consumers under expected conditions of use. This specifically means:

Materials that come into contact with food should be designed to transfer as few substances as possible to the food. If any migration occurs, it must be at such minimal levels that:

- consumer health is not at risk
- there is no unacceptable change in the composition of the food
- there is no deterioration in the food's smell and taste

Distributors of commodities that come into contact with food are responsible for complying with these standards. They must ensure that their products meet legal specifications and do not pose health hazards to consumers.

Categorization of commodities from natural and synthetic rubber

Most commodities made from natural and synthetic rubber intended for food contact, typically do not come into full-surface contact with food for long periods of time. Rather, only a part of their surface make contact for short periods of time.

Unlike the FDA, which focuses primarily on the characteristics of the food in contact, the BfR (German Federal Institute for Risk Assessment) classifies commodities made from natural and synthetic rubber that come into contact with food into four groups. This categorization is based on the different conditions of use that occur in practice:

- **Category 1 (long-term contact)**
This category includes commodities that come into contact with food for longer than 24 hours up to several months when used as intended.
- **Category 2 (medium contact time)**
This category includes commodities that come into contact with the food for a maximum of 24 hours when used as intended.
- **Category 3 (short-term contact)**
This category includes consumer articles that come into contact with the food for a maximum of 10 minutes during intended use.
- **Category 4 (insignificant contact)**
This category includes commodities which, when used as intended, are only used under such

conditions that no transfer to the food is to be expected.

Alongside to different requirements for allowed raw materials, different migration limits are set for the finished product in each category.

Category 4 is generally exempt as the extremely short contact time does not require specific migration requirements.

Food and Drug Administration (FDA)

Rubber molded parts play a crucial role in sensitive applications, especially in the food sector, where they can directly affect human health.

The **Food and Drug Administration (FDA)** is a U.S. agency tasked with the regulation of food, pharmaceuticals, medical devices and cosmetics, ensuring that these products are safe for public health.

FDA compliance refers to adherence to FDA regulations and standards. It is especially important for rubber molded parts in contact with food, as it ensures that the materials and products used meet the FDA's stringent requirements.

Distinguishing between fatty and aqueous foods

The FDA considers the specific application when evaluating compliance. An important aspect is the distinction between fatty and aqueous foods:

- **Fatty foods**
Foods with a high fat content, such as oils, butter, cheese and chocolate, require that rubber molded parts in contact with fatty foods meet specific

requirements. These standards are necessary to prevent unwanted migration of substances.

- **Aqueous foods**
This includes foods with a high water content, such as soups, juices and fruit. In this area, specific regulations apply to rubber molded parts to ensure food safety and quality.

Manufacturers in the food industry have specific requirements for rubber molded components and the materials used. Compliance with FDA regulations is particularly important and its relevance extends beyond the United States.

FDA regulations for molded rubber parts in contact with food

Food safety control and assurance is an important area of concern. Rubber articles intended for food contact must meet the requirements of paragraph 177.2600, which applies to both U.S.-made and imported goods.

Although the FDA's main jurisdiction is the United States, its regulations and standards are recognized worldwide. Manufacturers of rubber molded parts and articles for the food industry, designed for repeated food contact, must ensure that their products comply with FDA regulations.

Code of Federal Regulation Title 21 (FDA 21 CFR 177.2600)

For manufacturers of rubber molded parts, the regulations outlined in CFR Title 21 – Food and Drugs, Section 177.2600 are crucial. This section regulates the use of rubber articles intended for "repeated use" and include paragraphs A through I.

Sections A to D of FDA 21 CFR 177.2600 list all allowable ingredients and their respective quantity limitations. Moreover, sections E and F apply to products in contact with non-dry foods.

Section E of FDA 21 CFR 177.2600 regulates finished rubber articles that come into contact with **aqueous foods**.

Section F of FDA 21 CFR 177.2600 regulates finished rubber articles that come into contact with **fatty foods**.

Both sections set specific requirements for migration and maximum extraction limits.

Ruber articles commonly used in the food industry

Gummiwerk KRAIBURG offers a wide range of compounds with different polymers for articles commonly used in the food industry, such as flat seals, O-rings, plugs and diaphragms in direct contact with food. These compounds meet the requirements of the FDA 21 CFR 177.2600 positive list.

The materials used should be resistant to all contact media involved in the application and capable of withstanding mechanical stress. In addition, it is often also necessary for these materials to be suitable for use over a wide temperature range.

3-A Sanitary

Cleaning guidelines are also set forth in the 3-A Sanitary Standards, which are developed by the hygiene organization 3-A Sanitary Standards, Inc. (3-A SSI) in the U.S. food industry. This organization is made up of experts, manufacturers and hygiene regulatory authorities. The 3-A Sanitary Standards have gained global recognition

and acceptance and are increasingly considered a legitimate standard demanded by end customers.

The 3-A Sanitary Standards and 3-A Accepted Practices provide sanitary guidelines for equipment and systems used in the manufacturing, processing and packaging of milk, dairy products and other perishable foods. These standards also outline specifications for materials used in the food industry that are subject to frequent cleaning cycles.

Material requirements and cleaning procedures

Materials must not only comply with FDA 177.2600 but also meet specific mechanical requirements and resist various substances, as tested on standard test specimens. This includes resistance to common cleaning agents and the temperatures experienced during sterilization. Furthermore, the requirements vary based on the maximum application temperatures during normal use and cleaning, as well as the maximum fat content of the food in contact:

- **Class I:** Application temperature up to 300 °F (149 °C)

For example: team valves in industrial steam systems
- **Class II:** Application temperature up to 250 °F (121 °C)

For example: seals in hot water heaters
- **Class III:** Application temperature up to 120 °F (49 °C)

For example: O-rings in refrigeration units

- **Class IV:** Application temperature up to 100 °F (38 °C)

For example: Refrigerator plugs

Many of our compounds meet the 3-A Sanitary Standards, including the sulfur-cured compounds from the KRAIBURG Pure series for drinking water applications. Depending on the polymer, even the highest requirement, Class I, is met.

Versatile polymers for food industry

EPDM

EPDM is well suited for dynamic applications and as a sealing material due to its good resistance to acids and alkalis. However, due to its low resistance to fats and oils, EPDM components are best used in scenarios involving contact with aqueous foods, such as in pump diaphragms or container seals.

NBR/HNBR

NBR and HNBR are characterized by their excellent dynamic properties and their exceptional resistance to fatty foods, including dairy products. Therefore, they are widely used in the food industry, particularly in components such as stators, seals and diaphragms in dosing pumps and valves.

HNBR is particularly favored in applications that require higher heat resistance, often due to increased operating temperatures. A common use for HNBR is in the seals of coffee machines.

NR

Natural rubber has excellent mechanical properties and high elasticity, making it possible to manufacture products with extremely low abrasion, particularly in the food industry.

Silicone (VMQ)

Due to its purity and very wide temperature range, silicone plays an important role in the food industry, which includes both cold and heat extremes. Common applications include hoses, bottle seals and baking molds.

Fluorelastomer (FKM)

Fluoroelastomer (FKM) is known for its exceptional heat resistance and excellent resistance to a wide range of solvents and chemicals. This makes FKM particularly suitable for demanding applications, whether static or dynamic. Common applications include seals, O-rings and food stators.