



FCM

HCT-202409-07

German BfR releases new recommendations on food contact rubber materials

Recently, Germany's BfR released a new version of the rubber material recommendation. Although the recommendation is not legally binding, according to the RASFF violation notification, the provisions in the recommendation will be used by German officials as a basis for supervising the safety of food contact materials. Therefore, the requirements in the recommendation are widely adopted by the food contact material industry. The main updates to the recommendation are as follows:

XXI. Commodities based on natural and synthetic rubber

1. The version is updated to 01.09.2024, and the original version is 01.02.2023.
2. Explicitly delete the substances in Table 2 of XXI/1 and XXI/2 for which no assessment application has been submitted within 2 years as required.
3. Update Table 1: Evaluated starting materials, additives and production aids.

XXI/1. Commodities based on natural and synthetic rubber in contact with food

1. The version is updated to 01.09.2024, and the original version is 01.02.2023.
2. The scope of seals in Article 2.8 is updated from " caps, gaskets, stoppers and similar closures" to "caps, gaskets, stoppers and similar closures as well as membranes"; in addition, it is clarified that if the intended use of the seal is uncertain, the most unfavorable foreseeable surface area to volume ratio should be assumed, and if it cannot be estimated, the surface area to volume ratio is assumed to be 1 dm²/kg.
3. Article 3.2 adds instructions that rubber can be used alone or in combination.
4. Update Table 1: List of rubbers / latices and Table 2: Not conclusively evaluated raw materials, additives and processing aids.
5. Update the total migration limit of products in categories 1-3, including: the total migration limit of bottle caps, seals, bottle stoppers and similar closures and films is changed from "10 mg/dm²" to "60 mg/dm²". For disposable glove latex, the total migration limit is 30 mg/dm² when tested in 3% acetic





acid, of which the maximum organic content is 10 mg/dm².

6. The formaldehyde migration limit of products in categories 1-3 is changed from "3 mg/l" to "6 mg/kg".

Note: Category 1 refers to products that have a contact time with food of more than 24 hours to several months; Category 2 refers to products that have a contact time with food of up to 24 hours; Category 3 refers to products that have a contact time with food of up to 10 minutes.

XXI/2. Special consumer goods made of natural and synthetic rubber and of latices made of natural and synthetic rubber (formerly special category)

1. The version is updated to 01.09.2024, and the original version is 01.07.2021.

2. Updated Additives and manufacturing aids not conclusively evaluated.

3. The formaldehyde migration limit is changed from "3 mg/l" to "6 mg/kg".

HCT SOLUTION

In this update, special attention should be paid to the requirements for seals and the modification of formaldehyde migration limits. There is no transition period for the above updated requirements, so it is recommended that relevant companies complete the investigation and switching of materials as soon as possible to ensure that the products are legal and compliant.

