

Frequently Asked Questions and Answers concerning the BfR Recommendations on Food Contact Materials

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Materials which come into contact with foods may not release substances into foods which involve a health risk for consumers. Examples of such materials are plastics, paper, cardboard or rubber.

The Federal Institute for Risk Assessment provides the database “Recommendations on Food Contact Materials” on its website. The goal of the BfR Recommendations is to define the conditions under which no migration of substances with a health risk occurs from the contact materials to the foods.

Given the large number of enquiries concerning the database, BfR has compiled the following questions and answers on the BfR recommendations:

What are consumer articles?

The term “consumer articles” is defined in § 2 of the German Foods, Consumer Articles and Feeds Act (LFGB). It includes consumer products such as toys and garments, but also materials which come into contact with foods.

What are food contact materials and articles?

During production, transport, storage, consumption etc, foods come into contact with articles which can be made of many different materials. These include packaging of plastics, paper or cardboard, crockery and cups made of plastics, saucepans and frying pan with polymer coatings as well as tanks and pipes consisting of plastics or metal, or metal in food processing plants.

From a consumer health protection perspective these materials may not release harmful substances into foods; the same applies to substances which impair the smell or taste of the foods.

What are the BfR Recommendations on Food Contact Materials?

The BfR Recommendations on Food Contact Materials are to ensure that materials do not release substances into foods which could cause a health risk for consumers.

The recommendations are based on lists of substances which BfR or its predecessor organisations have assessed since 1952. The substances on this list are, when used for the mentioned purpose, in compliance with the mentioned restrictions can be considered as non-hazardous for health in accordance with the current state of science and technology.

Every recommendation refers to a specific material, for instance silicone or paper. Originally the recommendations dealt primarily with substances for the production of plastics with food contact. Therefore, the term “Plastics Recommendations” was used for a long time. This area is, however, now increasingly regulated on a European level.

The BfR recommendations reflect the current state of science and technology for the conditions under which consumer products made of high polymer materials meet the requirements of § 31.1 of the German Foods, Consumer Articles and Feed Act (LFGB) and Article 3.1 of Regulation (EC) 1935/2004 on Materials and Articles Intended to Come into Contact with Food as to their safety for human health.

What materials are taken into account in the BfR Recommendations?

BfR publishes recommendations on high polymers, such as plastics, silicones, natural and synthetic rubber as well as papers, cartons and cardboards. This applies to areas which are not yet regulated by statutory provisions. Furthermore, the Institute makes recommendations which refer to the intended use of the materials. This includes recommendations on artificial sausage skins, plastic dispersions for the coating of articles for food contact or temperature resistant coatings for cooking, frying and baking equipment.

The further development of statutory provisions is taken into account by corresponding updates of the recommendations. For plastics, for which harmonised regulations are already available on an EU level, the BfR Recommendations are restricted to components of catalytic systems (catalysts and initiators) and polymerisation auxiliaries, which have not yet been taken into account by the EU provisions or have not yet been finally considered.

What legal status do the BfR Recommendations have?

The BfR Recommendations on Food Contact Materials are no legal norms. However, they reflect the current state of science and technology for the conditions under which consumer products of high polymer materials meet the requirements of § 31.1 of the Food, Consumer Articles and Feed Act (LFGB) and Article 3.1.a of Regulation (EC) 1935/2004 in terms of their non-hazardousness for human health. Consequently, food contact materials and articles must be produced in accordance with good manufacturing practice so that under normal or foreseeable conditions of use no ingredients are released into foods in amounts which could endanger human health.

How can I apply for the inclusion of a substance into the BfR Recommendations?

In order to include a new substance into the BfR Recommendations on Food Contact Materials, an application must be made to BfR. The latter has to formally correspond to the "Note for Guidance" of the European Food Safety Authority (<http://www.efsa.europa.eu/en/efsajournal/doc/21r.pdf>). Furthermore, the applicants are requested to complete a substance overview defined by BfR and submit it together with the application documents.

The applications must be submitted by 1 December of the previous year and / or by 1 July so that BfR can process the documents. The Consumer Articles Committee of BfR can then discuss the applications in its April and November meetings. The documents must be submitted in duplicate. Furthermore, two CDs with the complete data must be submitted in a searchable format, eg as a Word or PDF document. If the application includes data which according to the applicant should be treated confidentially, another CD without the confidential data is required on top.

Further information can be found on the internet page "Database BfR Recommendations on Food Contact Materials":

http://www.bfr.bund.de/en/database_bfr_recommendations_on_food_contact_materials__formerly__plastics_recommendations__-1711.html

How can I access the database of the BfR Recommendations on Food Contact Materials and what do I have to observe?

BfR makes the "Database BfR Recommendations on Food Contact Materials" available free of charge on the following internet page: <https://bfr.ble.de/kse/faces/DBEmpfehlung.jsp>

Any commercial use of the Recommendations is not permitted without the consent of BfR.

What role does the BfR Consumer Articles Committee play in view of the Recommendations of BfR?

The BfR Consumer Articles Committee (BeKo), staffed with external experts, advises BfR on the assessment of applications for inclusion of substances into the BfR Database of Recommendations on Food Contact Materials. This is primarily done through the Committee Working Group "Toxicology" and the Working Group "Applications" of BeKo. The Committee and the two Working Groups meet twice a year.

Is BfR in charge of the authorisation of substances for the production of food contact materials?

BfR is not in charge of the authorisation of substances to produce food contact materials. The inclusion of a substance into the recommendations of BfR does not constitute any marketing authorisation from a legal point of view.

Which food contact materials are subject to authorisation procedures on the European level?

Regulation 1935/2004/EC provides for an application procedure for substances to produce food contact materials and articles which are authorised by the EU Commission after a positive assessment by the European Food Safety Authority (EFSA) and listed in the directories of the relevant EU Directives or Regulations.

The current state of regulations provides for such directories in the following cases:

a) Plastics:

Directive 2002/72/EC of 6 August 2002 relating to Plastic Materials and Articles Intended to Come into Contact with Foodstuffs.

b) Active and intelligent packaging:

Regulation (EC) 450/2009 of 29 May 2009 on Active and Intelligent Materials and Articles Intended to Come into Contact with Foodstuffs.

c) Regenerated cellulose films:

Directive 2007/42/EC of 29 June 2007 relating to Materials and Articles made of Regenerated Cellulose Film Intended to Come into Contact with Foodstuffs.

d) Processes for the recycling of plastics:

Regulation (EC) 282/2008 of 27 March 2008 on Recycled Plastics Materials and Articles Intended to Come into Contact with Foodstuffs and amending Regulation (EC) 2023/2006.

What institution is in charge of applications for authorisation of food contact materials?

The corresponding applications have to be submitted to the national contact points which are published under the following link:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/nat_contact_points_en.pdf

For Germany, the Federal Office of Consumer Protection and Food Safety (BVL) is the contact partner for these authorisation procedures. BVL transmits the applications to the European Food Safety Agency (EFSA).

Is BfR also in charge of materials which come into contact with drinking water?

Materials and articles which come into contact with drinking water (for instance plastic pipes) do not come under the sphere of responsibility of BfR, but are covered by the Federal Environmental Agency (UBA).

Does BfR answer questions on the legal assessment of consumer articles within the meaning of the Food, Consumer Articles and Feed Act (LFGB)?

BfR is not in charge of answering legal questions. The enforcement of the provisions of LFGB is the responsibility of the public authorities of the federal states.

BfR is merely available in case of questions relating to the interpretation of the BfR Recommendations on Food Contact Materials.

Does BfR monitor consumer articles which are on the German market?

The enforcement of provisions laid down in the Food, Consumer Articles and Feed Act (LFGB) is the responsibility of the public authorities of the federal states. The monitoring on site is normally carried out by the municipal regulatory agency which also inspects plants and takes samples. BfR is not the appropriate contact for questions relating to the monitoring of consumer articles.

Does BfR issue recommendations on materials which are appropriate for food contact?

As a matter of principle, all materials which comply with the applicable food law provisions are suitable for food contact. The non-hazardousness of the materials must be ensured by the producer or user. BfR does not have any information as to whether commercial materials meet the statutory requirements. Corresponding information can be provided by the manufacturer. If corresponding enquiries are made, the intended use conditions should be taken into account.

Does BfR test materials or consumer articles for companies or private persons?

As a matter of principle, BfR does not carry out any contract tests for companies or private individuals. Tests carried out by BfR exclusively serve the work of the National Reference Laboratory for Food Contact Materials, to support other public authorities or own scientific research.

Does BfR recommend test institutes?

BfR is often asked by manufacturers for contact data of test institutes, e.g. testing the legal compliance of food contact materials or for inclusion of substances into the BfR Recommendations in connection with a corresponding application. However, as a public authority BfR is not authorised to recommend test institutes.

Manufacturers may, however, contact the appropriate trade associations, which represent the individual materials or consumer articles. Chambers of Industry and Commerce may also provide information on test laboratories. Furthermore, the Expert Group of Self-employed Chemists within the German Chemical Society has a list of laboratories on its homepage.

With this information BfR does not make any assessment of the quality of the mentioned institutions.

Where do I find analytical methods to check the requirements for food contact materials?

Analytical methods conforming with the requirements for food contact materials can be found in the scientific literature and the following collections of procedures:

Official Collection of Test Procedures under § 64 LFGB, see:
<http://www.methodensammlung-bvl.de/>

Loose Leaf Collection of Carl Heymanns Verlag "Plastics in Food Trade", Volume 2 Examination of Plastics: <http://landingpages.wolterskluwer.de/de/html/content/365/Startseite/>

German Standards Institute (DIN), eg the standard series 1186 (Testing of the Global Migration of Plastics) and 13130 (Testing of the Specific Migration of Substances from Plastics).