

Minutes | 26 November 2025

## 35th meeting of the BfR Commission for Consumer Products

---

The BfR Commission for Consumer Products (BeKo) advises the German Federal Institute for Risk Assessment (BfR) as an honorary and independent expert body on issues relating to health risk assessment for Consumer Products made of plastics and other materials, on the development of recommendations and on the BfR's work on EU directives and Council of Europe resolutions.

With its scientific expertise, the Commission advises the BfR and can assist the Institute as a network of experts in the event of a crisis. The Commission consists of 18 members appointed for a four-year term (2022-2025) through an open tender and application procedure. They distinguish themselves through scientific expertise in their respective field. The members of the Commission are obliged to preserve confidentiality towards third parties and to fulfil their duties impartially. Any conflicts of interest regarding individual agenda items (TOPs) discussed in the meeting are subject to transparent queries and disclosure.

The meeting minutes below reflect the scientific opinion of the BfR Commission. The Commission recommendations are entirely advisory in nature. The Commission itself does not issue any decisions or expert opinions and is not authorized to issue instructions to the BfR (and vice versa) nor involved in its risk assessments.

### Preliminary remark

The 35th meeting of the BfR Commission for Consumer Products was held as a hybrid event.

### Agenda Item 1 Welcome and assumption of the agenda

The chair, Professor Dr Thomas Simat, welcomes those present. The commission is declared to have a quorum. The agenda is approved.

At the end of the term of office, the BfR thanked all members for their advice and bid farewell to the departing members.

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

## Agenda Item 2 Declaration of conflicts of interest

The Chair asked whether there were any conflicts of interest relating to individual agenda items or specific topics. The members stated that there were no conflicts of interest.

## Agenda Item 3 EFSA: *Literature review on micro- and nanoplastic release from food contact materials during their use*

The European Food Safety Authority (EFSA) recently published an overview and assessment of existing scientific literature on the possible release of microplastics from food contact materials<sup>1</sup>. One of the authors and a member of the BeKo presents the work and its main conclusions.

The speaker first gives an overview of selected scientific articles on microplastics (MP) from food contact materials.<sup>2</sup> In addition to the multitude of different measurement principles, particular attention is paid to challenges and "pitfalls" in sample preparation and interpretation of measurement results. For example, one publication incorrectly included soluble substances that had dissolved from the sample during the migration test when heated and later precipitated as particles during cooling. These substances were identified as conventional polymer additives that could not be attributed to the polymer of the food contact material itself.<sup>3</sup> The additives have undergone toxicological assessment and do not pose a health risk at the amounts released. Another example of incorrect MP findings was found in a publication on the investigation of MP from plastic tea bags. The BfR has already published an opinion on this.<sup>4</sup> In a further investigation of PET water bottles for MP concentration in water, polyethylene particles were found in almost all samples tested, indicating contamination from the environment or production rather than migration/abrasion from the PET bottle itself.<sup>5</sup>

With regard to exposure to MP from food contact materials, the speaker reports that there is currently little good data available for a reliable exposure assessment. It seems certain that the release of MP particles from plastic food contact materials during use occurs mainly through abrasive processes such as scratching, cutting or breaking, and not through contact with food itself. The actual amounts of particles released are much lower than the figures published in many (flawed) publications. These may be several orders of magnitude too high. In future, investigations into the release of MPs from food contact materials should be carried out according to a validated standard protocol, for which defined reference MPs are required. New approaches are needed to determine nanoparticle concentrations below 1 mm in diameter, as previous approaches are not applicable or only applicable to a limited extent.

<sup>1</sup> EFSA, 2025: Literature review on micro- and nanoplastic release from food contact materials during their use <https://doi.org/10.2903/sp.efsa.2025.EN-9733>

<sup>2</sup> N. P. Ivleva, 2021, "Chemical Analysis of Microplastics and Nanoplastics: Challenges, Advanced Methods, and Perspectives". *Chemical Reviews*, 121, 11886–11936.

<sup>3</sup> M. N. Gerhard, et al., 2022, "Can the presence of additives result in false positive errors for microplastics in infant feeding bottles?" *Food Additives & Contaminants: Part A*, 39(1), 185–197

<sup>4</sup> <https://www.bfr.bund.de/mitteilung/bfr-assessment-of-study-on-teabags-and-microplastics/>

<sup>5</sup> O. Hagelskjær et al., 2025, "Majority of potable water microplastics are smaller than the 20 µm EU methodology limit for consumable water quality." *PLoS Water* 4.1: e0000250

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

## **Agenda Item 4 Report on the 25th meeting of the KTW expert committee of the Federal Environment Agency (UBA) on 24/25 June 2025**

The UBA reports:

### **4.1 European activities on drinking water contact materials**

Now that the legal acts (implementing acts and delegated acts, IA and DA) on materials and substances in contact with drinking water have been published within the framework of the EU Drinking Water Directive (EU DWD)<sup>6</sup>, they will come into force on 31 December 2026.

The UBA has published information on the transition from national to European binding requirements<sup>7</sup>.

Products in contact with drinking water for which a correct confirmation of conformity (certificates or self-declarations by the manufacturer) has been issued by 31 December 2026 on the basis of the UBA assessment criteria and/or other national regulatory documents must only be certified in accordance with the European procedure from 31 December 2032 onwards. If these products are not yet certified according to the European procedure during the transition period, the national requirements for these products will continue to apply. However, this transitional arrangement does not apply to products manufactured on site. Products manufactured on construction sites must be certified according to EU procedures from 31 December 2026. All products in contact with drinking water will be subject to mandatory certification from 31 December 2026. Structures such as drinking water tanks can only obtain a single certificate.

In the value-added process, component certificates can be used for cement-bound materials and intermediate product certificates for organic materials – usually organic coatings – in order to minimize the testing and evaluation effort required to issue individual certificates for structures. The UBA will draw up a document on the certification process.

Furthermore, problems arise with the positive list, as the national assessments for the European positive list only contain raw materials that have been assessed in a Member State by 2021. Current assessments that were and will be carried out in the Member States between 2021 and 2026 can no longer be included in the European positive list. Manufacturers must therefore apply to the ECHA for a reassessment of their starting materials.

### **Accreditation and notification**

Over the past few months, DAkkS, UBA and the Federal Ministry of Health have discussed details of the future accreditation of certification bodies in accordance with EU-DWD and the resulting steps for their auditing. A joint checklist of criteria to be reviewed has been drawn up, which includes both the requirements of the relevant legal acts on the EU DWD and the specifications of the standards to be applied in accreditation procedures (EN 17065 and others).

<sup>6</sup> Official Journal L series daily view - EUR-Lex (europa.eu)

<sup>7</sup> <https://www.umweltbundesamt.de/dokument/uba-information-hygienische-anforderungen-an>

A corresponding provision in the Infection Protection Act is still formally necessary for the designation of the UBA as the notifying authority. The UBA does not plan to require an independent second assessment of bodies wishing to be notified as a prerequisite for notification. However, in the event of complaints or irregularities, the UBA will reserve the right to carry out its own inspections of the certification bodies.

The DAkKS is about to be informed about the accreditation program, which has now been completed and complies with the legal acts of the EU DWD, so that certification bodies will soon be able to submit applications for accreditation. The corresponding audits are scheduled for the period between the end of 2025 and the beginning of 2026 and, assuming they are successful, should result in the granting of accreditation by mid-2026. The UBA cannot notify the relevant body until 1 January 2027. Taking into account compliance with the two-week objection period to be observed from the date of notification to the European Commission, the notified bodies will then be able to issue EU certificates for successfully completed product certifications from mid-January onwards. Orders can be accepted and all necessary tests and assessments carried out immediately, as all details of the certification requirements comply with the provisions of the published EU DWD legal acts.

#### **4.2 National activities relating to materials in contact with drinking water<sup>8</sup>**

With regard to national regulations on materials in contact with drinking water, the 6th amendment to the KTW assessment basis and the metal assessment basis and the 4th amendment to the enamel assessment basis have been published. The silicone transition recommendation and the information on cement-bound materials have been updated. The modelling guideline was published in the Federal Health Gazette and on the UBA website after completion of the notification procedure.

##### **Further topics**

A working group is currently developing a recommendation for the assessment of ion exchange resins. This will be based on the regulatory documents of the legal acts already published. Ion exchange resins are tested in accordance with the European standard DIN EN 12873-3.

### **Agenda Item 5 Report by the Federal Ministry of Food, Agriculture and Rural Affairs (BMLEH) on national and European legislative procedures and the work of the Council of Europe**

The BMLEH reports:

#### **5.1 EU regulations**

##### **5.1.1 Revision of food contact material law**

The sustainability study has been completed. The final report has yet to be published. The aim of the study was to develop possible measures for sustainability in FCM law. The EU Commission would like to use the results of the study to develop a strategy by the end of

<sup>8</sup> <https://www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen/bewertungsgrundlagen-leitlinien#einfuehrung>

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

2026. The focus will be on pillars A (including finished food contact materials, information sharing) and B (including prioritization of substances).

### **5.1.2 Regulation (EU) 2022/1616 (plastic recycling)**

To date, 127 PET authorization decisions have been voted on in the Standing Committee. A total of around 300 authorization decisions are to be voted on. Some assessments are more time-consuming because they are more than 15 years old and the recycling companies concerned can no longer be contacted due to various circumstances. Entries in the online register are checked and incorrect entries are corrected or deleted. The regulation amending the Recycling Regulation was published in the Official Journal of the EU on 13 November 2025. Among other things, incorrect references in the regulation were corrected.

### **5.1.3 Regulation (EU) No 2025/351 (amending Regulations (EU) No 10/2011, (EU) No 2022/1616, (EC) No 2023/2006 and (EC) No 282/2008)**

Six new substances that have undergone a positive assessment by EFSA have been taken up. The amending regulation was voted on by the Standing Committee on 19 September 2025. The Commission plans to take up further substances that have undergone a positive assessment by EFSA via an amending regulation. Amending regulations are currently being prepared for the adjustment of styrene and mineral oil. For total MOAH, a limit of quantification (LOQ) of 0.5 mg/kg is to be set for food simulants A, B, C, D1 and E, and 2 mg/kg for food simulant D2. These amendments are to be made in separate amending regulations.

The transition periods for the use of wood and wood fibers as well as salicylic acid have been extended by one year. The corresponding Regulation (EU) 2025/2240 was published in the Official Journal of the EU on 6 November 2025.

The EU Commission is withdrawing the general guidance on Regulation (EU) No 10/2011 and the guidance on information in the supply chain without replacement.

### **5.1.4 Regulation (EU) 2024/3190 (Regulation prohibiting the intentional use of bisphenol A and other bisphenols in materials and articles intended to come into contact with food)**

There was a correction to the Regulation, which was voted on by the Standing Committee on 19 September 2025. There were no changes to the content, only corrections. The European Commission has now published a comprehensive FAQ document on Regulation (EU) No 2024/3190.<sup>9</sup> Further discussions are needed on the monitoring of bisphenol A and other bisphenols.

## **5.2 Germany**

### *Regulation amending the Consumer Products Regulation and the Cosmetics Regulation*

The Federal Council will deal with the above-mentioned regulation on 19 December 2025. The announcement is to be made by 1 January 2026 if possible. In addition to the inclusion of further assessed substances in Annex 14, the transition period for the use of non-assessed

<sup>9</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52025XC06721>

substances is to be extended by one year until the end of 2026. This is to enable manufacturers to submit further dossiers for substances still required for printing inks in contact with food and to allow the BfR to carry out an assessment.

An FAQ document on the notification requirement has been published on the BMLEH website. The notification requirement was introduced by the Twenty-Second Ordinance Amending the Consumer Products Ordinance, which came into force on 1 July 2024. The FAQ document was jointly developed by the BMLEH, the BVL and the German federal states ("Laender") to clarify frequently asked questions.

### **5.3 Council of Europe**

The technical guideline on cork was published on 4 September 2025.<sup>10</sup> Old specifications have been updated.

The technical guideline for enamels is currently being developed. The document is to be based on the SRLs of the technical guideline for metals and alloys. In addition, enamel-specific release conditions are to be developed.

A BeKo member asks when novel recycling technologies will be assessed by EFSA. According to the BMLEH, the assessment is planned to begin in the near future.

## **Agenda Item 6 Latest news on toys**

The BfR reports:

### **6.1 Revision of the EU Toy Safety Directive**

A BfR employee reports on the current status of the ongoing revision of EU Directive 2009/48/EC on the safety of toys (*Toy Safety Directive*, TSD), which will then be directly applicable in all EU Member States as an EU Regulation (*Toy Safety Regulation*, TSR). According to the report, the trilogue negotiations between the European Parliament, the Council of the European Union and the European Commission were concluded on 10 April 2025 and a political agreement was reached. In June, the European Parliament's Committee on the *Internal Market and Consumer Protection* (IMCO) and the Committee of *Permanent Representatives* (COREPER) approved the final text. On 25 November, the draft regulation was adopted by the European Parliament. This means that the TSR can be expected to be published in the Official Journal of the EU before the end of 2025. The TSR will enter into force 20 days after publication and will then grant a transition period of 4.5 years during which the old TSD will remain in force.

### **6.2 Current discussions on amendments to the EU Toy Safety Directive**

The discussion on the intake of exemptions for the use of cobalt (category 1B carcinogen (has a high probability of being carcinogenic to humans), Category 2 mutagen (may cause heritable germ cell mutations in humans), Category 1B reproductive toxic substance (has a probability of being toxic to reproduction in humans)) in Annex A to Annex II of the TSD was already discussed at the 31st and 33rd meetings of the BfR Commission for Consumer

<sup>10</sup> <https://www.edqm.eu/en/-/cork-materials-and-articles-for-contact-with-food-new-edqm-technical-guide-available>

Products<sup>11,12</sup> ; The latest draft of the amending directive contains exemptions for (i) toys and toy components made of stainless steel in which cobalt has a prevalence (as an accompanying element) of the nickel used in stainless steel alloys, for (ii) toy components that conduct electricity, and for (iii) NdFeB magnets ("neodymium magnets") in toys, as long as they cannot be swallowed or inhaled.

The decision of the European Court of Justice of 1 August 2025, which confirmed the ruling of the European Court of Justice of November 2022, invalidates the harmonized classification of titanium dioxide with certain particle sizes as a Category 2 carcinogen. This renders obsolete the discussions already underway on the inclusion of exemptions for titanium dioxide in Annex A to Annex II TSD (see 33rd meeting). However, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) stated in its opinion<sup>13</sup> that certain scenarios involving the inhalation of "ultrafine" (nanoscale) titanium dioxide during the use of toys were not safe and also pointed out uncertainties in the risk assessment of possible oral intake of titanium dioxide during the use of toys. Discussions are currently underway at EU level as to whether the SCHEER opinion should be followed up with regulatory action and, if so, whether limit values for titanium dioxide in toys should be set.

Furthermore, the EU Commission has recently proposed a number of amendments to the TSD that have already been agreed for the TSR. These include, among other things, the alignment of the requirements for contact allergenic fragrances with the latest requirements of the EU Cosmetics Regulation (EC) No. 1223/2009, a reduction in the threshold values for traces of prohibited fragrances and the declaration of fragrances subject to labelling requirements from 100 to 10 mg/kg, a reduction in the migration limit for bisphenol A (BPA) to 0.005 mg/L, and a reduction in the emission limit for formaldehyde to 0.062 mg/m<sup>3</sup>.

### 6.3 Current developments in standardization

In the domain of the European EN 71 series of standards relating to the chemical and microbiological safety of toys, all standards and amendments to standards have now been adopted (see also 31st and 33rd meetings). The publications have already been released or are expected shortly. With regard to EN 71-3, the "dewaxing step" in sample preparation has been deleted and a clarification for mixed samples has been added. Furthermore, the technical specification CEN/TS 18217 on the migration of "elements" from plastics has been taken up. In EN 71-4, the specifications for potassium permanganate (a category 2 reproductive substance) were amended and a method for testing child-resistant fastenings was reintroduced after it had been deleted in an interim version. In EN 71-5, "sets for making play slime" were taken up as a new toy category and requirements for them were specified. In standard EN 71-7, "booster substances" (substances that are not preservatives themselves but enhance the effect of preservatives) have been listed as possible components in finger paints, the list of preservatives has been partially revised, the list of colourants has been updated and the normative reference for pH value determination has

<sup>11</sup> <https://www.bfr.bund.de/cm/343/31-sitzung-der-bfr-kommission-fuer-bedarfsgegenstaende.pdf>

<sup>12</sup> [https://www.bfr.bund.de/assets/01\\_Ver%C3%B6ffentlichungen/Protokolle/33-sitzung-der-bfr-kommission-fuer-bedarfsgegenstaende.pdf](https://www.bfr.bund.de/assets/01_Ver%C3%B6ffentlichungen/Protokolle/33-sitzung-der-bfr-kommission-fuer-bedarfsgegenstaende.pdf)

<sup>13</sup> SCHEER (Scientific Committee on Health, Environmental and Emerging Risks), Opinion on the safety of titanium dioxide in toys with regard to a possible derogation from its prohibition, 9 June 2023, corrigendum 6 October 2023, [https://health.ec.europa.eu/publications/scheer-scientific-opinion-safety-titanium-dioxide-toys-0\\_en](https://health.ec.europa.eu/publications/scheer-scientific-opinion-safety-titanium-dioxide-toys-0_en)

been changed. EN 71-9 has been withdrawn. Parts 10, 11 and 12 have not undergone any changes. The changes in EN 71-13 also concern the reintroduction of a method for testing child-resistant closures. The new parts 15-19 of the standard specify methods for testing some of the limit values in TSD, Annex II, Appendix C (formamide, organophosphorus flame retardants, isothiazolinones, phenol and BPA). The new standard EN 71-20 specifies microbiological requirements for aqueous toy materials. In the opinion of the BfR, the maximum authorized values specified in this standard for the *total aerobic microbial count* (TAMC), *total yeast and mould count* (TYMC) and bile-tolerant Gram-negative bacteria are too high.

Future standardization work will include the adaptation of existing standards to the TSR and the development of a standard for generic sample preparation for toys (both concentrations and release methods) to support the conformity assessment of a product with the generic hazard-based prohibition of presence and the exemption for traces that are technically unavoidable under good manufacturing practice (GMP), provided that the toy remains safe.

## **Agenda Item 7 Report on the 9th meeting of the Leather and Textiles Committee on 4 November 2025**

The BfR reports:

### **7.1 Migration of dyes from textiles**

As at the 7th<sup>14</sup> and 8th<sup>15</sup> meetings of the Committee, a report is given on the project to obtain current data on the release (migration) of dyes from clothing textiles. In addition to cotton samples coloured with only one dye ("defined dyeing"), market samples with a high cotton content from four retailers were also examined. The challenge with market samples is that they are usually coloured with dye mixtures of unknown composition in order to achieve a desired colour shade, and therefore dye release can only be estimated with a high degree of uncertainty. The level of dye migration determined or estimated by UV/VIS measurements with basic sweat simulant in the defined-dyed cotton samples is comparable to that in the market samples and is low in most samples. However, individual samples stood out due to higher migration. Additional colour fastness tests showed that the samples with the highest migration values also had poor colour fastness values.

### **7.2 Current issues in the leather domain**

According to industry reports, the leather industry has been migrating from Europe, and thus also from Germany, to Asia and America for several years. This trend is expected to continue in the coming years, with an increasing number of companies in the leather industry in Germany closing down. The reasons for this are complex and include, among other things, the many legal requirements for the leather industry in the EU and the increasing use of collagen, the main protein that makes up leather, in other industries.

<sup>14</sup> <https://www.bfr.bund.de/cm/343/7-sitzung-des-ausschusses-textilien-und-leder-der-bfr-kommission-bedarfsgegenstaende.pdf>

<sup>15</sup> <https://www.bfr.bund.de/cm/343/8-sitzung-des-ausschusses-textilien-und-leder-der-bfr-kommission-fuer-bedarfsgegenstaende.pdf>

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

There are also reports of alternatives to leather. In addition to some high-quality leather alternatives, there are also materials that are advertised as "natural" but sometimes contain high amounts of plastic and/or have unfavorable properties, such as low durability.

In addition, leather is to be officially recognized as a bio-based material in accordance with CEN/TC 411 standards by the end of 2025.

### **7.3 The Ecodesign Regulation**

Regulation (EU) 2024/1781<sup>16</sup> (*Ecodesign for Sustainable Products Regulation*, ESPR) came into force in 2024 and aims to make products more environmentally friendly, recyclable and energy efficient. Delegated acts specify product-specific requirements, e.g. for durability, reusability and reparability, as well as for the proportion of recycled content, energy efficiency and environmental impact. The requirements can apply to all phases of the product life cycle and vary depending on the product group. The products are to be supplemented by a digital product passport containing further information, e.g. on the supply chain or recycling. As textiles, among other product groups, have been given the highest priority, the requirements are to be defined within the next few years.

### **7.4 Current findings on textiles and leather products**

Several state monitoring agencies and a testing institute report on their findings in textiles and leather products from previous years. Not only were exceedances of limit values for regulated chemicals reported, but also violations of the Textile Labelling Regulation (EU) 1007/2011<sup>17</sup>. In general, the rejection rates are in the low single-digit percentage range, but can be significantly higher, especially in the case of targeted campaigns such as those at Christmas markets or risk-based sampling.

### **7.5 Standardization projects of the Committees**

This section reports on standardization projects relevant to textiles and leather products at national, European and international level.

### **7.6 Skin sensitizers in textiles**

The presentation will feature an evaluation of data from the Information Network of Dermatological Clinics (IVDK) for the period from 2000 to 2019, which shows no evidence of an increase in the proportion of dermatitis patients with suspected textile intolerance. The results of patch tests (epicutaneous tests) performed on patients with suspected contact allergy to textile dyes in IVDK clinics between 2007 and 2014 are also discussed. The relevance of positive reactions must be critically questioned, as the dyes tested are hardly used anymore for dyeing clothing textiles and there is a high degree of cross reactivity between the test substances Disperse Orange 3 and p-phenylenediamine (PPD). Positive reactions to PPD can also be caused by current or historical sensitization from oxidative hair dyes and henna tattoos. Patients with a positive reaction to samples of their own textiles, which were suspected to be the cause of the skin condition, rarely reacted to the dyes

<sup>16</sup> <https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:02024R1781-20240628>

<sup>17</sup> <https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:02011R1007-20180215>

tested. Overall, the link between allergic contact dermatitis and dyes or chemicals in clothing textiles can rarely be clearly detected.

### **7.7 Bisphenols, per- and polyfluoroalkyl substances and thermodesorption**

New measurement data on bisphenols in textiles and leather products are presented, which were also discussed at the 7th and 8th committee meetings<sup>14,15</sup>.

For classification purposes, these measured values were compared with the proposed limit values from the restriction proposal on bisphenols, which has been withdrawn for revision. It became apparent that there would be insufficient compliance with the proposed concentration and migration limit values in many cases.

A new method for analyzing per- and polyfluoroalkyl substances (PFAS) in products and mixtures is presented. Unlike the previous method (extraction with methanol), alkaline hydrolysis (DIN EN 17681-1:2025) detects not only free PFAS but also ester-bound PFAS, resulting in significantly higher values than with the extraction method.

Thermodesorption is an analytical method that can be used to measure volatile, thermally stable substances. The technology is expensive to purchase, but the operating costs are lower than with previous methods. The small sample quantity required can be an advantage, but can also lead to false negative results. Furthermore, the desorption rate is unknown; the comparability of the measurement results across different laboratories would also have to be demonstrated if the method were to be taken up for routine screening.

### **Agenda Item 8 Latest news from monitoring**

Swiss monitoring has reported the migration of plasticizers from PVC films into sliced cheese. The analysis is complex, as a separate method must be used for epoxidized soybean oil (ESBO), polyadipates and the other plasticizers. Simulation cannot be used to adequately test the films, as the fat reduction factor for cheese pieces is too high at 3, and the true migration is underestimated. For cheese pieces wrapped in PVC films, the migration guidelines/limit values may be reached and exceeded. Twenty samples from Switzerland and 30 from Italy were examined. As Swiss companies have been encouraged in the past not to sell cheese pieces in PVC film<sup>18</sup>, the samples were difficult to find. In cheese speciality shops where PVC film is still used, the cheese is often repackaged for sale and not sold in PVC film. For this reason, only one non-compliant sample (out of 20) was found in Switzerland. In Italy, however, pieces of cheese are still frequently wrapped in PVC film and sold, which is why 7 (out of 30) samples were non-compliant there.

In addition, there are reports of migration of primary aromatic amines from polyamide kitchen utensils. Even after more than a decade with limit values in the Plastics Regulation (EU) No. 10/2011, 4 out of 14 relevant samples were still found to exceed the maximum migration values. Discussions were also held with the companies about the migration conditions and the surface-to-volume ratio. In general, it was found that test reports were incomplete and did not contain sufficient information on the test conditions.

<sup>18</sup> Information sheet: PVC films and cheese <https://www.zh.ch/content/dam/zhweb/bilder-dokumente/themen/gesundheit/gebrauchsgegenst%C3%A4nde/MD-00105.pdf>

An employee from the German monitoring authority reports on new legal requirements regarding SML exceedances under Regulation (EU) No. 10/2011. One new feature is that a specific performance criterion must be applied when conducting an assessment of an SML exceedance, whereby a unilateral assessment is made using an extended standard measurement uncertainty. The regulation enables a clear assessment of the measurement value at which non-compliance with the SML occurs. The speaker reports that there are no clear rules on the criteria according to which a measurement value is to be assessed as compliant. Several examples show that, after applying the specific performance criterion, measured values above a limit value do not necessarily lead to non-compliance, thus creating uncertainty with regard to the conformity assessment. From a monitoring perspective, conformity can only be determined if the measured value does not exceed the SML with certainty.

In addition, the speaker states that Regulation (EU) No 10/2011 does not clearly specify whether this rule also applies to substances for which no migration is authorized and a limit of detection (LOD) is specified. From a monitoring perspective, no expanded measurement uncertainty or standard measurement uncertainty should be included for substances whose migration must not be detectable. Similar questions arise with regard to the application of the specific performance criterion when testing the total migration value.

The speaker also reports that, during investigations of melamine articles from China, products were found that appeared to have been coated with a so-called PDAP coating, which significantly reduces the migration of melamine and formaldehyde. However, the composition of the coating has not yet been analytically determined. The members of the Commission are also not yet aware of such a polymer coating. It is assumed that it is polydiallyl phthalate.

## **Agenda Item 9 Presentation by the *Federation of the European Cookware, Cutlery & Houseware Industries (FEC): "Holistic risk analysis of various frying pan alternatives"***

A representative of the FEC, Mr Gerfin, presents the advantages and disadvantages of different types of frying pans: Polytetrafluoroethylene (PTFE)-coated pans with an Aluminum base (typically black-coloured non-stick pans), ceramic-coated pans with an aluminum base, uncoated stainless steel pans and uncoated cast iron pans.

The coated pans have an aluminum base, which has significantly better thermal conductivity and heat capacity than iron and stainless steel. Coatings are applied to the aluminum base to achieve a non-stick coating and to replace aluminum with food. When considering the operating temperatures of frying pans, the smoke and flash points of cooking fats and oils must be taken into account, as use above these temperatures is not to be expected. Depending on the fat, these are between 170 and 250 °C or 220 and 280 °C. Heating coated pans above these temperatures is not recommended, as both the silicone oils contained in the ceramic coating and the PTFE decompose at temperatures above 350 °C. Water-based foods do not typically exceed 100 °C, and fats begin to smoke before reaching their decomposition temperature (see above). Therefore, unless a coated pan is heated when empty, the consumer is warned by sensory events. With PTFE-coated pans, there is a possibility that particles may be released from the coating. However, these are chemically inert and usually too large to be taken up by the body. There is no reason to assume that they pose a hazard to consumers (see

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

also the BfR FAQ on cookware with PTFE non-stick coating<sup>19</sup> ). Although ceramic-coated pans do not contain any fluorinated substances, tests show that their non-stick properties deteriorate much more quickly.

The advantages of uncoated iron and stainless steel pans are that no coating can be destroyed, which means they have a long service life, but their non-stick properties are correspondingly low. This usually requires the use of more cooking fat and skilled handling of the pan. In the case of iron pans, acidic foods can also lead to high migration of elements.

Other pan alternatives were mentioned but not considered in detail. The market shows a high number of new developments.

## **Agenda Item 10 Reports from the National Reference Laboratory for Substances Intended to Come into Contact with Food and the National Reference Laboratory for Process Contaminants for the MOSH/MOAH substance group in food**

The BfR reports:

A restructuring has been carried out within the BfR. As part of this, the National Reference Laboratories for Substances Intended to Come into Contact with Food (NRL-FCM) and the NRL for Process Contaminants, substance group MOSH/MOAH in food (NRL PC MOH) have been transferred to the newly established unit "Reference Laboratory for Food and Feed Analysis" in the unit "Food Contact Materials" since 1 July 2025.

The NRL FCM successfully participated in the EURL FCM's interlaboratory comparison tests for the determination of PFAS and various bisphenols. In cooperation with TÜV Rheinland, a method evaluation study was conducted for a § 64 method for the determination of chloropropanols in cold water extracts (DIN EN 645) from paper, cardboard and fiberboard using GC-MS. The NRL PC MOH successfully participated in the EURL's interlaboratory comparison study for the determination of MOH in olive oil for process contaminants.

The NRL-FCM is currently working on various research projects, including the evaluation of suitable milk simulants for the migration of substances from elastomers and the evaluation of suitable food simulants for the release of elements from enamel.

The NRL PC MOH was actively involved in the preparation of the EURL Guideline on GCxGC analysis for mineral oils, which has now been published.<sup>20</sup>

<sup>19</sup>

[https://www.bfr.bund.de/assets/01\\_Ver%C3%B6ffentlichungen/Ausgew%C3%A4hlte\\_Fragen\\_und\\_Antworten\\_zu\\_Geschirr\\_mit\\_Antihafbeschichtung\\_aus\\_PTFE\\_f%C3%BCr\\_das\\_Braten\\_Kochen\\_und\\_Backen.pdf](https://www.bfr.bund.de/assets/01_Ver%C3%B6ffentlichungen/Ausgew%C3%A4hlte_Fragen_und_Antworten_zu_Geschirr_mit_Antihafbeschichtung_aus_PTFE_f%C3%BCr_das_Braten_Kochen_und_Backen.pdf)

<sup>20</sup> <https://orbit.dtu.dk/en/publications/analysis-of-mosh-and-moah-in-food-by-gcgc-guidance-on-analysis-in/>

## **Agenda Item 11 Current or intended adjustments to the BfR recommendations**

### **11.1 New preliminary remark in the BfR recommendation XXXVI, XXXVI/1, XXXVI/2 and XXXVI/3 on genotoxic carcinogens such as certain cationization reagents and primary aromatic amines**

Genotoxic carcinogens must not be detectable in the finished product; in most cases, a limit of detection (LOD) of 2 mg/kg food/food simulant applies. Benchmark dose modelling of carcinogenicity studies of selected primary aromatic amines has shown that the current limit of detection (LOD) (2 mg/kg food) results in a MOE of just over 10,000. If the MOE is 10,000 or higher, EFSA sees no reason for risk management measures in its guidance on the MOE approach. Taking into account co-exposure to several of the substances mentioned and population groups with higher consumption per kilogram of body weight per day, such as children, the MOE may be less than 10,000. The BfR therefore aims to gradually lower the limits of detection for these substances as far as technically and analytically possible. This is stated in a new preliminary remark.

The new preliminary remark should read as follows:

"For some genotoxic carcinogens that may occur, for example, as reaction and degradation products or impurities in the manufacture of food contact materials in accordance with this recommendation and for which a transfer to food should not be detectable, specific limits of detection (LODs) are specified in this recommendation (e.g. certain primary aromatic amines or 1,3-dichloropropanol). A measurement uncertainty is not applicable. The specified limits of detection correspond to the current technical standard. They are regularly reviewed to ensure they are up to date and, if possible, further reduced. The aim is that no transfer of genotoxic carcinogenic substances above 0.15 µg/kg food is detectable."

The preliminary remark was also presented at the meeting of the Paper Committee on 17 September 2025. The committee pointed out that cross contamination by primary aromatic amines cannot be ruled out in certain technical processes. The BfR emphasizes that, from a toxicological point of view, the transfer of genotoxic carcinogenic substances above 0.15 mg/kg of food should be avoided as far as possible. The reduction of the limits of detection for individual listed genotoxic carcinogenic substances is an ongoing process and is carried out when a limit of detection below 2 mg/kg food/food simulant is technically achievable. If a new LOD cannot be met due to the manufacturing process, the BfR may carry out a substance-specific assessment based on existing carcinogenicity studies. If the margin of exposure (MOE) is sufficiently high, the BfR may set the transition in accordance with the ALARA (*As Low As Reasonably Achievable*) principle to a technically feasible value for the BfR recommendation.

### **11.2 Notes on the amendment to the Annex to the BfR recommendation XXXVI of 1 October 2025**

The BfR reports on the amendments to the Annex to Recommendation XXXVI and the associated enquiries to the BfR.

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

The annex to the BfR recommendation XXXVI specifies, among other things, which recovered fibers are recommended for the manufacture of paper, cardboard and paperboard in contact with food. Several amendments to this annex came into force on 1 October 2025. Upon request, new types of paper and sources of paper were taken up in the annex, albeit with restrictions. The previous footnote listing excluded types of paper/collections was moved to the main text, and the names of waste collections that are not to be used were updated.

It became clear from the enquiries received by the BfR that the previous restrictions in the former footnote were sometimes interpreted differently in practice. Therefore, additional information was provided on the intention and purpose of the annex, on definitions of the relevant waste collections and, in particular, on the use of paper type 5.03 (beverage cartons).

The overriding objective of the Annex to Recommendation XXXVI on recycled fibers is and remains to use only suitable fiber sources for the production of FCM paper so that the food contact materials produced from it do not pose a health risk to consumers. Paper collections and grades with a high degree of contamination are still considered unsuitable. These include, in particular, paper type 5.01 ("mixed waste paper" according to DIN EN 643), regardless of its origin, as well as paper, cardboard and paperboard of any type originating from household waste or household-like commercial waste, mixed packaging waste or commercial waste. The definitions used by the BfR for the collections mentioned are explained below in German and English to facilitate the interpretation of this recommendation:

**Haushaltsabfälle:** auch „Hausmüll“: gemischter Abfall, der von den Haushalten gesammelt wird und nicht recycelt werden kann. In Deutschland: schwarze Tonne. Alles, was nicht recycelt werden kann, gehört in die schwarze Tonne, z. B. Dinge, die nicht in die gelbe Tonne/Sack (siehe Beschreibung unten), den Glascontainer, die blaue Papiertonne oder die Biotonne gehören.

**haushaltsähnliche Gewerbeabfälle:** gemischte Abfälle, die z. B. aus Industrieanlagen, öffentlichen Mülltonnen oder gewerblichen Einrichtungen wie Cafés, Büros usw. stammen und einen ähnlichen Inhalt wie Haushaltsabfälle haben. In Deutschland wird dieser Abfall wie Haushaltsabfall behandelt.

**gemischte Verpackungsabfälle:** Laut Bundesministerium für Umwelt, Klimaschutz, Naturschutz und nukleare Sicherheit: Die Gelbe Tonne oder der Gelbe Sack dient der Sammlung von sogenannten Leichtverpackungen. Dazu gehören Verpackungen aus Kunststoff, Metall, Verbundstoffen und Naturmaterialien. Beispiele sind u. a. Plastikbecher, Wurst- und Käseverpackungen, Konservendosen, Getränkekartons, Plastiktüten. Verpackungen aus Glas oder Papier/Pappe/Karton gehören nicht in die Gelbe Tonne oder den Gelben Sack, sondern müssen getrennt gesammelt und dem Recycling zugeführt werden.

**gewerbliche Abfälle:** Der Begriff, auch „Industrieabfälle“ genannt, bezeichnet gemischte Abfälle, die z. B. aus Industrieanlagen oder Gewerbebetrieben gesammelt werden. Dieser Abfall ist nicht mit dem Hausmüll vergleichbar, sondern oft spezifisch für bestimmte Branchen. Beispiele für Gewerbeabfälle sind Produktionsabfälle (z. B.

Metallspäne, Holzreste, Kunststoffreste), Verpackungen aus dem Versand, Chemikalien oder Öle aus Werkstätten, Bau- oder Baustellenabfälle. Diese Abfälle enthalten in der Regel größere Mengen an industriell genutzten Materialien und damit auch potentiell gefährliche Stoffe. In Deutschland regelt die Gewerbeabfallverordnung (GewAbfV), wie Gewerbeabfälle getrennt, verwertet und beseitigt werden müssen. Im Gegensatz zu diesen gemischten gewerblichen Abfällen, sind die selektiv gesammelten Produktionsabfälle aus der Papierproduktion (Papierabschnitte etc.) bei den „gewerblichen Abfällen“ nicht mitgemeint.

*English version of the definitions:*

**Household waste:** In Germany: The black bin. This refers to the mixed waste that is collected by households. Everything that cannot be recycled is collected in the black bin, such as items that should not be placed in the yellow bin or yellow bag (see description below), the glass container, the blue paper bin, or the organic waste bin.

**household similar commercial waste:** Or other term “household similar industrial waste” is a mixed waste that is collected e.g., from industrial facilities, public trashcans or commercial facilities such as cafes, offices etc. and has a similar content as the household waste. In Germany, this waste is treated as household waste.

**mixed packaging waste:** In Germany this is often called “yellow bin or yellow bag”. According to the German Federal Ministry for Environment, Nature Conservation and Nuclear Safety the definition is: The yellow bin or yellow bag is used to collect so-called lightweight packaging. This includes packaging made of plastic, metal, composite materials, and natural materials. Examples include e. g. plastic cups, sausage and cheese packaging, tin cans, beverage cartons, plastic bags. Glass or paper/cardboard/cardboard packaging does not belong in the yellow bin or yellow bag; it should be collected separately and sent for recycling.

**commercial waste:** Or other term “industrial waste” is a mixed waste that is collected e.g., from industrial facilities or commercial facilities. This waste is not comparable to household waste, but is often specific to certain industries or professions. Examples for commercial waste are production waste (e.g., metal shavings, wood scraps, plastic scraps), packaging from shipping, chemicals or oils from workshops, construction waste or construction site waste. This type of waste usually contains larger quantities of industrially used materials and therefore hazardous substances. In Germany, the Commercial Waste Ordinance (GewAbfV) regulates how commercial waste must be separated, recycled, and disposed of. In contrast to the mixed commercial waste mentioned here, selectively collected production waste from paper production (paper scraps, etc.) is not included in the category “commercial waste.”

Recommendation XXXVI recommends fibers from selective, clearly defined collection streams for the production of FCM papers: these include, in particular, waste paper from traditional selective paper collection (“blue bin”) and other selective paper collections such as production waste and offcuts directly from paper production. As part of the latest revision, exceptions to the exclusion of use for certain paper types (types 5.01, 5.02, 5.03,

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

5.14) have also been introduced, but only for certain limited uses (e.g. indirect contact only, with maximum quantities, etc.). The exact wording can be found in the annex to the recommendation.

Type 5.03 (beverage cartons) is typically disposed of as mixed packaging waste and is therefore not recommended for unrestricted use in the manufacture of FCM paper. As described above, grade 5.03 should only be used without restriction if it comes from selective waste paper collection (so-called misplaced waste) or if it is selectively collected unused production residues or cuttings (*pre-consumer waste*).

With reference to the BeKo protocol of the 23rd meeting (2019), it is clarified that the BfR does not issue any "exemptions" and that the text of the currently valid version of the BfR recommendation applies. This also applies to the use of paper grade 5.03 (DIN EN 643) in the BfR recommendation XXXVI.

The BfR continuously updates the BfR recommendations to reflect the current state of science and technology. In order to create a reliable basis for risk assessment decisions, the BfR asks the industry to provide data on the use of different paper types and collection streams for paper production and use, as well as data on the resulting paper quality in terms of chemical and microbiological contamination.

### **11.3 New BfR Recommendation XXI/3 and amendment of BfR Recommendations XXI, XXI/1 and XXI/2**

The development of Recommendation XXI/3 has been announced since the publication of the general revision of Recommendation XXI (July 2020). The development has been completed and publication is expected in March 2026.

Recommendation XXI/3 applies to consumer goods made of thermoplastic elastomer vulcanizates (TPV). With the publication of Recommendation XXI/3, the following paragraph will be deleted from Recommendation XXI/1: "The aforementioned rubbers can be used alone or in combination. The aforementioned rubbers can also be used in combination with copolymers of ethylene, propylene, butylene, vinyl esters and unsaturated aliphatic acids, as well as their salts and esters, provided they comply with sections A and B of the currently applicable version of Recommendation XXXV. Nitrile rubber may also be used in combination with polyvinyl chloride homopolymer, provided that it complies with the currently applicable version of Recommendation II. In both cases, the rubber content must be vast. Products manufactured in this way shall be regulated in Recommendation XXI/3 in future." Part B of Recommendation XXXV is deleted and replaced by a reference to Recommendation XXI/3.

Furthermore, references in Recommendations XXI and XXI/1 are amended or supplemented. The titles of Recommendations XXI/1 and XXI/2 are amended to read: "...based on natural and synthetic rubber..." instead of "...made of natural and synthetic rubber..." as previously.

### **11.4 Cross-material re-evaluation of peroxides**

The BfR presents the project for the cross-material re-evaluation of peroxides listed as cross-linking agents in the BfR recommendation:

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

Numerous peroxides are listed in the BfR recommendations on materials for food contact, but in the vast majority of cases the assessment is no longer up to date. In a first step, the focus is on peroxides used as cross-linking agents, as the amounts used are generally higher than for initiators and catalysts. The peroxides listed below are used as cross-linking agents for various materials:

CAS #	Name
94-36-0	Benzoyl peroxide
80-43	Dicumyl peroxide
3457-61-2	tert-butyl cumyl peroxide
78-63-7	2,5-Dimethyl-2,5-di(tert-butylperoxy)hexane
895-85-2	Di-(4-methylbenzoyl)peroxide
2167-23	2,2-Bis-(tert-butylperoxy)butane
110-05-4	Di-tert-butyl peroxide
2212-81-9	1,3-Bis(tert-butylperoxyisopropyl)benzene
1068-27-5	2,5-Dimethyl-2,5-di-tert-butylperoxy-hexin-3
25155-25-3	Bis(tert-butylperoxyisopropyl)benzene
105-74-8	Lauroyl peroxide
614-45-9	tert-Butyl perbenzoate

It therefore seems sensible to aim for a simultaneous assessment of the substances for uses in different materials. This is a new approach, and it is to be expected that a single applicant will not be able to provide all the necessary data. The BfR asks manufacturers and users of peroxides to submit information and analytical data with the aim of answering the following questions:

- Which peroxides are still in use and which are not?
- What impurities are present?
- What degradation products are formed?
- Are these the same for all relevant materials/applications? What factors play a role?
- What amounts of peroxides and degradation or reaction products are present in the various materials?
- In what amounts do peroxides and degradation or reaction products migrate from the various materials into food (simulants)?

Each stakeholder should contribute the data available to them. The BfR is acting as the coordinating body in this assessment project. The aim is to compile a data set from information provided by various companies that is sufficient for a risk assessment.

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

The data received will be treated as confidential by the BfR; companies will receive feedback individually. Meetings of all contributing stakeholders will be held at fixed times. Progress and missing data will then be announced at these meetings. These meetings will only be open to stakeholders who have submitted data themselves.

The BfR will then issue a communication stating which analytical/toxicological data still needs to be submitted for assessment. With regard to the general requirements for analytical and toxicological data, the BfR refers to the guideline for the safety assessment of substances used in the manufacture of food contact materials.<sup>21,22</sup>

A period of three years is planned for the re-evaluation. One year after the start of the process, the collection of application and analysis data should be completed. After the second year, the collection of toxicological data should be completed, and the third year will be used for risk assessment. The BfR's recommendations will then be updated accordingly. All peroxides mentioned – regardless of whether they are used as cross-linking agents or initiators – are given a three-year deadline for assessment in the recommendations. Peroxides from the above list that have not been assessed are expected to be removed from the recommendations on 31 March 2029. Data can be submitted to the BfR with immediate effect. For further information, stakeholders should contact [fcfcm@bfr.bund.de](mailto:fcfcm@bfr.bund.de).

The BfR notes that other peroxides in the BfR recommendations are also to be re-evaluated. There are plans to publish a collective recommendation on catalysts and initiators. Stakeholders are advised to take up important peroxides that are not on the above list in this pilot project for cross-material assessment. Any extension of the list of peroxides for assessment would be announced on the BfR website and in the BeKo.

### **11.5 Deletion of dichlorobenzoyl peroxide from the BfR recommendation**

With the next revision of the recommendations (spring/summer 2026), the entry bis-(2,4-dichlorobenzoyl)peroxide (DCBP; CAS 133-14-2) will be deleted from Recommendation XV. The BfR has no data on the possible presence of polychlorinated biphenyls (PCBs) in silicones cross-linked with DCBP<sup>23</sup> for food contact. In order to prevent consumer exposure and possible environmental releases of PCBs, the BfR will no longer recommend the use of DCBP for the manufacture of food contact materials.

### **11.6 N,N-Bis(2-hydroxyethyl)alkyl-(C12-C18)amine in the BfR recommendation XIV**

EFSA has conducted a new assessment of the antistatic agent N,N-bis(2-hydroxyethyl)alkyl-(C12-C18)amine, which is also listed in the BfR recommendation XIV. Based on this EFSA opinion<sup>24</sup>, the BfR has reviewed its entry for this substance in the BfR recommendation XIV and will amend it accordingly in the next update of the BfR recommendations. A migration

<sup>21</sup> <https://www.bfr.bund.de/veroeffentlichung/leitlinie-fuer-die-sicherheitsbewertung-von-substanzen-zur-herstellung-von-lebensmittelbedarfsgegenstaenden/>

<sup>22</sup> <https://www.bfr.bund.de/cm/349/guideline-for-the-safety-assessment-of-substances-for-the-manufacture-of-food-contact-materials-and-articles.pdf>

<sup>23</sup> Perdi, A. and Jan, J (1994).; Formation of polychlorobiphenyls in silicone rubber; DOI: 10.1016/0045-6535(94)90187-2

<sup>24</sup> <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2025.9104>

guideline value of 5 mg/kg and the exclusion of contact with food for small children will be added. The updated entry will read as follows:

"N,N-bis(2-hydroxyethyl)alkyl-(C12-C18)amine, with a maximum application rate of 2 mg per dm<sup>2</sup> of surface area of finished coated articles made from vinylidene chloride copolymer dispersions. Articles treated with this antistatic agent must not come into contact with liquid foodstuffs. The transfer to food must not exceed 5 mg/kg. Not recommended for contact with foodstuffs for infants."

### 11.7 Adjustments in the BfR recommendation XXV of 1 July 2025

The BfR reports on the changes to Recommendation XXV, which deals with the use of waxes in the manufacture of impregnations, coatings and pressure-sensitive adhesives for food contact materials. The changes took effect on 1 July 2025.

Most of the changes are based on an *EFSA opinion* from 2023<sup>25</sup> on the re-evaluation of the substance with FCM No. 93 from Regulation (EU) No. 10/2011 ("low-viscosity waxes"). In line with the EFSA opinion, the BfR now recommends for the first time the use of low-viscosity wax with the physicochemical characteristics specified in the *EFSA opinion* for FCM 93 in finished products in contact with fats and oils and fatty foods, provided that migration does not exceed 5 mg/kg. For the general use of low-viscosity waxes, the composition was defined in Part A in accordance with the *EFSA opinion* and a migration guideline value of 5 mg/kg was added.

Another significant change concerns the headings of two sections. Part I. A has been renamed from "Hard paraffins of natural origin" to "Hard paraffins type 1: low-viscosity waxes"; Part I. C has been renamed from "Synthetic hard paraffins" to "Hard paraffins type 2: high-viscosity waxes". In addition, some outdated analytical methods have been updated, such as the determination of the solidification temperature.

## Agenda Item 12 Report on the meeting of the Toxicology Committee on 25 November 2025 (only topics not covered under another item on this agenda)

### 12.1 Applications within the scope of the BfR recommendations

#### 12.1.1 2-propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with 4-hydroxybutyl-2-propenoic acid ester, 2-[(1-oxohexadecyl)amino]ethyl 2-propenoic acid ester and 2-[(1-oxooctadecyl)amino]ethyl 2-propenoic acid ester, acetate (CAS: 2307185-12-0)

The polymer has been proposed for inclusion in the BfR recommendation XXXVI as a surface finishing and coating agent. Questions remain to be clarified regarding some NIAs in relation to their assessment using *read-across* and *in silico* tools, as well as possible further degradation products.

<sup>25</sup> <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.7761>

### 12.1.2 Shellac (CAS: 9000-59-3)

An application was submitted for "wax-free shellac produced by physical decolourisation" (CAS 9000-59-3) for the BfR recommendation XXXVI as a surface finishing and coating agent. The applicant refers to the EFSA's re-evaluation from 2024.<sup>26</sup> The BfR will ask questions regarding the technically necessary application rate and a better description of the use.

## 12.2 Applications within the framework of the UBA's KTW applications

The BfR supports the UBA in the hygienic assessment of substances in contact with drinking water (Drinking Water Ordinance).

### 12.2.1 N-cyclohexylbenzothiazole-2-sulfenamide (CBS) CAS 95-99-0

At the 29th and 33rd meetings of the Toxicology Committee, an application to the Federal Environment Agency for the use of CBA as an accelerator for the sulphur-based vulcanisation of elastomers was already discussed. As a genotoxic potential could not be ruled out, an  $MTC_{Tap}$  value of 0.1 µg/l was set for CBS and its degradation products benzothiazole (BT, CAS 95-16-9) and 2-benzothiazolone (BTon, CAS 934-34-9). The Federal Environment Agency has currently received an application to increase the migration guidelines for CBS and its degradation products BT and BTon to  $MTC_{Tap} = 2.5$  µg/l. In summary, it was found that CBS itself is not relevant for assessment due to rapid hydrolysis. The BfR and the committee members agree with the UBA's assessment that the data submitted for BT and BTon cannot rule out genotoxic potential. An increase in the  $MTC_{Tap}$  is not recommended.

## Agenda Item 13 Report on the meeting of the Paper Committee on 17 September 2025 (only topics not covered under another item on this agenda)

The BfR reports:

### 13.1 PFAS in paper

A representative of the Swiss Federal Office for Food Safety and Veterinary (BLV) presented the results of investigations into PFAS in food contact materials made from bagasse and other plant fibers. The extractants and migrants examined most frequently contained 6:2 fluorotelomer alcohol (FTOH). After basic hydrolysis, the values for 6:2 FTOH were orders of magnitude higher. This indicates the presence of fluoropolymers with ester-bound fluorotelomer alcohols. As the Danish guidance value for PFAS (20 mg organic fluorine/kg food contact material) was exceeded by up to 50 times, the speaker concluded that PFAS was intentionally used in the products examined.

In another presentation, a speaker from a German regional authority reported on the results of investigations into the intentional use of PFAS in paper. The values for the PFAS found were significantly lower for samples that underwent extraction without hydrolysis than for samples that underwent hydrolysis. Here, too, 6:2 FTOH was mainly found. In addition, 8:2

<sup>26</sup> <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2024.8897>

FTOH was found in microwave popcorn packaging containing PFAS and in packaging labelled as PFAS-free. With regard to total fluorine analysis, the speaker reported that one of the biggest challenges remains the differentiation between inorganic and organic fluorine.

Another committee member presented data on the release of FTOH from paper samples in a micro-emission chamber onto adsorbent tubes and subsequent analysis by TD-GC-MS. In nine of the 15 samples tested, the residual content of 6:2 FTOH was above 25 mg/kg paper, the future limit value from Regulation (EU) No. 2025/40 (PPWR). The FTOH-positive samples showed a low release of ester-bound FTOH in a subsequent rapid hydrolysis test. The speaker considers deliberate use for grease-proofing the papers examined to be unlikely due to the low concentrations. Due to the low recovery rate of the rapid hydrolysis method used, a reanalysis of the samples after complete hydrolysis is planned.

### **13.2 Latest news on bisphenol A (BPA) in paper**

A guest invited to attend this item on the committee meeting agenda presented results on BPA concentrations and migration studies from hygiene paper products, particularly kitchen towels. In internal studies conducted between 2014 and 2019, BPA concentrations ranged between 0.04 and 0.11 mg/L in cold water extract (CWE), which was in some cases above the guidance value for BPA at that time of 0.05 mg/kg food/food simulant. From 2019 onwards, a continuous decline in BPA concentrations and a slight increase in BPS concentrations were observed, with all extraction values remaining below 0.05 mg/L CWE. Bisphenols B and F were not detectable in the CW. In addition, results were presented on the transfer of bisphenols from bisphenol-containing kitchen towels to food (chips, puff pastry, cucumber) after different migration times (10 min - 24 h) and surface-volume ratios. In only one case was a transfer to the food determined (0.01 mg/kg cucumber); all other results were below the LOQ. When the study was repeated in 2025, no migration of BPA and BPS into the food cucumber (LOQ 0.004 mg/kg food) was detected.

Two committee members reported on a research project on BPA in recycled and fresh fiber paper, in which gas phase transfer from paper to the simulant MPPO (modified polyphenylene oxide) and to dry food (cornflakes) was investigated. The acetonitrile extract of virgin fiber papers showed a BPA concentration of less than 0.5 mg/kg paper. For recycled paper, a concentration of 1 mg/kg paper was detected in the acetonitrile extract. With 100% migration of BPA, the concentration in food for virgin fiber paper would be below the BfR TDI<sup>27</sup> for BPA of 12 mg/kg food, and for recycled paper it would be above the BfR TDI for BPA. For migration studies, virgin fiber paper and recycled paper were stored for 10 days at 40 °C in direct contact with MPPO and cornflakes, respectively. For all virgin fiber and recycled products tested (kitchen towels, (corrugated) cardboard), migration was well below the BfR TDI (12 mg/kg food). The speakers were unable to comment on compliance with the EFSA TDI (12 ng/kg food) due to the background contamination of the test objects and laboratory materials with BPA. However, it was at least possible to show that even at very low limits of quantification (LOQ), no significant transfer of BPA via the gas phase is measurable.

<sup>27</sup> [https://www.bfr.bund.de/cm/343/bisphenol-a-the-bfr-suggests-a-health-based-guidance-value-\(hbgv\)-for-a-complete-risk-assessment,-which-requires-current-exposure-data.pdf](https://www.bfr.bund.de/cm/343/bisphenol-a-the-bfr-suggests-a-health-based-guidance-value-(hbgv)-for-a-complete-risk-assessment,-which-requires-current-exposure-data.pdf)

At the committee meeting, experiences were exchanged on (realistic) test conditions for BPA in kitchen papers. The BfR currently considers cold or hot water extraction or a migration test in accordance with the JRC Guidance<sup>28</sup> to be reasonable test conditions. The application of a correction factor for the results of the cold water extract is being discussed at the committee meeting. This would be one way of sticking with the conventional cold water extract method and still obtaining a realistic BPA transfer to food. However, the BfR currently has no meaningful data available to determine such a factor. Stakeholders are asked to share any data they may have with the BfR. The BfR continues to refer to the test conditions for BPA in accordance with the specifications in the BfR recommendation XXXVI.

### **13.3 Work in the domain of standardization: Report on the work of CEN TC 172/WG 3**

Following amendments to the drafts, the water extract standards (EN 645 and EN 647) are now ready for voting. The reduced approach for kitchen rolls from the last draft has been removed. The chapter on calculating the results has been moved to the annex.

EN 16453 for the determination of phthalates in paper and cardboard extracts is up to date following the revision of the guidance values for the phthalates specified in the standard.

The draft standard for the determination of polycyclic aromatic hydrocarbons (PAHs) has been completed and was developed for 16 PAHs on the EPA list.

An assessment of the relevance of the EN 1230-1 sensor technology standard has shown that no revision is necessary.

Following the assessment of the current status of the sensory standard EN 1230-2, a revision is proposed. The revision will be discussed at the next meeting of the standards group.

The draft standard for optical brighteners has been revised with regard to specific analysis using HPLC for five analytes.

*Combustion ion chromatography* (CIC) is to be used to determine organic fluorine by differentiating between total fluorine and fluoride. No project is currently planned with regard to specific analysis for the investigation of PFAS. Regulatory requirements are awaited.

Specific analytical methods for bisphenols A, F and S are available for the development of a standard for the analysis of bisphenols. The target value will be based on regulatory requirements.

### **13.4 Miscellaneous**

#### **13.4.1 New application: paper coffee capsules**

The committee discussed which of the BfR recommendations for paper (XXXVI, XXXVI/1 or XXXVI/2) apply to paper coffee capsules. One committee member noted that capsules consisting mainly of cardboard could only be manufactured with substances listed in the BfR recommendation XXXVI, as the substances listed in the BfR recommendation XXXVI/1 could not provide the required functionality of the paper. The paper capsule does not act as a

<sup>28</sup> <https://publications.jrc.ec.europa.eu/repository/handle/JRC134290>

filter. However, there were also conflicting opinions in the committee regarding the filter effect of the capsule and the view that the product should be classified according to BfR Recommendation XXXVI/1 based on its use. There was agreement that conformity should be tested with the hot water extract. The committee asked the BfR to request further details on the technology from the manufacturers in order to discuss the issue further.

#### **13.4.2 Developers in thermal papers**

A committee member presented the results of investigations into the use of different developer substances in thermal papers. Bisphenol A is now only found in single-digit percentages of the samples examined. Since 2024, there has been an increase in the use of a non-phenolic urea-urethane polymer (CAS: 321860-75-7), which was found in up to 18% of the samples examined in 2025. In addition to bisphenol S, the urea-urethane derivative TSPH (N-(p-toluenesulfonyl)-N'-(3-(p-toluenesulfonyloxy)phenyl)urea), CAS: 232938-43-1) has been the most commonly used colour developer in recent years. Detailed data was presented at the 33rd meeting of the BeKo<sup>29</sup>. A non-phenolic colour developer was used in half of all samples examined. Due to the increased use of these developer substances, the speaker believes that non-phenolic developer substances should be given greater attention in future and subjected to a current risk assessment.

### **Agenda Item 14 Report on the meeting of the Rubber Committee on 16 September 2025**

The BfR reports:

The BfR reports that in the coming term of office, the "Rubber" Committee will be renamed the "Elastomers" Committee. Silicone elastomers will then also be discussed in this committee.

Further topics discussed at the meeting are listed under TOP 11.

### **Agenda Item 15 Current applications for intake into the BfR recommendation and report from the Applications Committee on 25 November 2025**

A BfR employee reports that a proposal was presented and discussed in the Proposals Committee:

"Ethene, homopolymer, oxidized, hydrolyzed, distillation residue from the manufacture of C16-C18 (CAS 25805-17-8) for the BfR recommendations XXXVI and XXXVI/1".

The application was discussed in the Applications Committee on 25 November. Additional analytical requirements have been imposed, relating to batch-to-batch variation in by-products and storage stability, among other things. The *read-across* to the distillation residues listed in the BfR recommendation XXXVI under points B.VI.19a and b results in a NOAEL of 300

<sup>29</sup> [https://www.bfr.bund.de/assets/01\\_Ver%C3%B6ffentlichungen/Protokolle/33-sitzung-der-bfr-kommission-fuer-bedarfsgegenstaende.pdf](https://www.bfr.bund.de/assets/01_Ver%C3%B6ffentlichungen/Protokolle/33-sitzung-der-bfr-kommission-fuer-bedarfsgegenstaende.pdf)

mg/kg body weight per day and the absence of genotoxicity. The Toxicology Committee has no additional toxicological requirements.

In addition, the committee discussed possible problems with the recycling of plastics that could occur in food contact materials. Two publications were specifically referred to here. The first was Mayrhofer et al.<sup>30</sup>, in which DNA-reactive mutagens were identified in many recycled polyethylene, polypropylene and polystyrene samples. The other was a publication by EuPIA (*European Printing Ink Association*)<sup>31</sup>, which describes the potential risks of printing inks in connection with higher temperatures for which the printing inks were not originally intended. Among the key points 1) to 5) listed on page 2, for example, is the degradation of nitrocellulose printing inks, which carries the hazard of nitrosamines forming at elevated temperatures, or the degradation of acrylic resins into smaller fractions. There is discussion and debate as to whether the associations and manufacturers concerned are aware of the potential problems and are monitoring them.

## **Agenda Item 16 Completed applications for the BfR recommendations and dossiers for Annex 14 of the Consumer Goods Ordinance with consultation in the BfR Commission**

The BfR reports:

### **16.1 Pentaerythritol, ethoxylated, ester with acrylic acid (PPTTA, CAS No. 51728-26-8)**

The dossier on the intake of PPTTA into Annex 14 of the German and Annex 10 of the Swiss Consumer Goods Regulations was already discussed at the 32nd meeting of the Toxicology Committee. PPTTA was considered non-genotoxic and the migrations of the numerous NIAS were considered toxicologically acceptable. At that time, analytical data were still pending, but these have since been satisfactorily provided. The BfR has recommended to the BMLEH that PPTTA be taken up in Annex 14 of the Consumer Goods Ordinance for indirect food contact with an SMG = 0.05 mg/kg.

### **16.2 Copolymer of ethyl acrylate, N-vinylformamide and sodium acrylate, hydrolysed (CAS No. 2244974-30-7)**

"Copolymer of ethyl acrylate, N-vinylformamide and sodium acrylate, hydrolyzed" is taken up in the BfR recommendation XXXVI as a retention agent with a maximum use level of 0.2%.

### **16.3 Copolymer of dimethylaminoethyl acrylate, acrylamide and acrylic acid, modified with less than 2% sodium methallylsulfonate and less than 2% N,N'-methylenebis(acrylamide)**

"Copolymer of dimethylaminoethyl acrylate, acrylamide and acrylic acid, modified with less than 2% sodium methallylsulfonate and less than 2% N,N'-methylenebisacrylamide" is taken

<sup>30</sup> <https://www.mdpi.com/2313-4321/8/6/87>

<sup>31</sup> [https://www.eupia.org/wp-content/uploads/2022/09/2016-02-24\\_EuPIA\\_Info\\_Note\\_Inks\\_and\\_Coatings\\_for\\_High\\_Temperature\\_Applications.pdf](https://www.eupia.org/wp-content/uploads/2022/09/2016-02-24_EuPIA_Info_Note_Inks_and_Coatings_for_High_Temperature_Applications.pdf)

up in the BfR recommendation XXXVI with a maximum use level of 0.5%. There will also be a footnote: "N,N'-methylenebisacrylamide must not be detectable in food (simulants) (limit of detection (LOD) 0.002 mg/kg)". It will be included in the database without a CAS number.

## **Agenda Item 17 Completed applications for the BfR recommendations and dossiers for Annex 14 of the Consumer Goods Ordinance without consultation in the BfR Commission**

### **17.1 Hydrocarbons, C11-C13, isoalkanes, <2 % aromatics (CAS 246538-78-3)**

A dossier on the intake of "hydrocarbons, C11-C13, isoalkanes, <2% aromatics" in Annex 14 of the German and Annex 10 of the Swiss Consumer Ordinance was assessed without consultation with the BeKo. Genotoxic potential was ruled out by negative Ames and micronucleus tests. For the further assessment of the substance mixture, the NOAEL = 236 mg/kg bw/d identified by EFSA in its opinion on MOSH from 2023 was used. Based on the target SMG = 12 ppm, the safety margin of 1200 considered acceptable by EFSA would be achieved or exceeded. However, as the NOAEL is based on a subchronic study and the data requirements for SMG > 5 ppm were therefore not met, the BfR recommended to the BMLEH that "hydrocarbons, C11-C13, isoalkanes, <2 % aromatics" be included in Annex 14 of the Consumer Ordinance as a solvent with an SMG = 5 mg/kg.

### **17.2 Calcined kaolin (CAS No. 92701-41-1)**

Here, the existing entry "aluminum silicates" under Table 1, Fillers in Recommendation XXI is extended to include CAS No. 92701-41-1 for calcined kaolin.

### **17.3 Aluminum hydroxide as a reaction product of trimethylaluminum and water**

"Aluminum hydroxide as a reaction product of trimethylaluminum and water" is taken up in Recommendation XXXVI as a surface finishing and coating agent. The entry is subject to the restriction "maximum layer thickness 8 nm".

## **Agenda Item 18 Miscellaneous**

### **18.1 Food contact materials containing gluten:**

The German Coeliac Society has drawn the BfR's attention to the fact that food contact materials containing gluten could pose a health risk to people with coeliac disease or gluten intolerance, especially if the materials are not labelled accordingly. A publication with selected research results on the transfer of gluten into food simulants<sup>32</sup> was attached to the request. As part of its early risk detection activities, the BfR would like to draw attention to the issue in general and to the possible transfer of gluten from food contact materials. In most cases, these are materials advertised as biodegradable, but there is a lack of reliable data. For example, the data from Mossburger and Scherf (2024) did not clearly indicate whether these were "genuine" food contact materials, i.e. those that are not suitable for

<sup>32</sup> <https://link.springer.com/article/10.1007/s00217-024-04570-4>

consumption. If food contact materials are labelled as edible, they are not covered by food contact material law, but by food law. There is already mandatory labelling for gluten as an allergen, and the relevant articles are usually easy for people with coeliac disease or gluten intolerance to recognize as unsuitable for them.

Nevertheless, the members of the BeKo agree that the issue should receive more attention. In particular, it is pointed out that in the catering sector, food contact materials that may contain gluten, such as plates or jam bowls made of wheat bran or composite materials, are given directly to consumers with food intended for consumption. In this case, it is difficult for the people affected to see or find out whether the food contact material could possibly contain gluten. The members are asked whether data is available on the transfer of gluten from food contact materials that may contain gluten to food or simulants. A member of the BeKo refers to older studies conducted by his own institute, in which no transfer of gluten into food could be observed. It is concluded that more data or data on currently available food contact materials that may contain gluten are needed and that these should be sent to the BfR.

### **18.2 Note on the annex to the EFSA guideline on the risk assessment of substances in food for children under 16 weeks of age**

The BfR refers to EFSA's current approach to the risk assessment of substances in foods for infants (<16 weeks) in the domains of food additives, pesticides, contaminants and food contact materials.<sup>33</sup> According to EFSA, the study parameters from a 90-day study, as required for substances with a migration between 50 and 5000 µg/kg of food, are not sufficient for assessing the risk to infants with increased food intake, a developing immune system and metabolism, and critical periods for certain effects. Additional data requirements will be imposed in future for substances used in food contact materials that come into contact with food for infants under 16 weeks of age. After converting the lower limit for Tier II (50 µg/kg food) to the lower body weight of infants and the higher food consumption per kg of body weight, data on Kinetics and possible effects on the development of newborns will therefore be required in future for the above-mentioned substances with a migration of more than 3 µg/kg food. A corresponding flow chart can be found in the EFSA opinion. If a substance is taken up by the body via the gastrointestinal tract, an *Extended One-Generation Reproductive Toxicity Study* (EOGRTS) or equivalent studies must be submitted. The EFSA points out that there is scientific rationale for deviating from this procedure.

This means that an EOGRTS is normally required for substances submitted for use in the manufacture of food contact materials and for all occurrences of NIAS (*non-intentionally added substances*) with a migration of more than 3 mg/kg food. Currently, there is no material – whether plastic, silicone, paper, etc. – for which the necessary studies are available for all substances migrating above 3 µg/kg food. A risk assessment could therefore not currently be carried out according to these standards. In addition to the high costs and number of animals (approx. 700 animals per study), the BfR considers the significance of an EOGRTS to be limited due to high doses and often ambiguous results in the development

<sup>33</sup> <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2017.4849>;  
[https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2017.4849&file=efs24849-sup-0001-Annex\\_A\\_FCM+Assessment\\_ForInfants\\_Belo\\_16w.pdf](https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2017.4849&file=efs24849-sup-0001-Annex_A_FCM+Assessment_ForInfants_Belo_16w.pdf)

and immunotoxicity cohorts, particularly in the concentration ranges relevant to food contact substances. As in the past, the BfR will examine the necessity of an EOGRTS for each individual case in its dossier assessment and will only request the study if it considers the rationale for doing so scientifically justified and necessary.

### **18.3 News from the BfR**

The BfR informs the BeKo about the restructuring of the institute. The management of the BeKo is now located in Department 8, "Food and Feed Safety in the Food Chain". In addition, current opinions by the BfR in the domain of food safety are briefly presented, including the opinion on metal objects in food contact<sup>34</sup>

The chair thanks all members for their participation and closes the meeting. The next meetings are expected to take place on the following dates:

Meeting of the Toxicology Committee of the BeKo	28 April 2026
Meeting of the BeKo Applications Committee	28 April 2026
36th meeting of the BeKo	29 April 2026

<sup>34</sup> <https://www.bfr.bund.de/opinion/kuechenutensilien-aus-metall-gehen-substanzen-ins-essen-ueber/>

*Contributions by Commission members identified by name reflect the opinion of the respective author and not the opinion of the German Federal Institute for Risk Assessment.*

---

## Contact

Office of the Commission for Consumer Products:  
friederike.kuehne@bfr.bund.de

Unit for the Safety of Food Contact Materials:  
fcm@bfr.bund.de

Further information on the commission system at the BfR:  
BfR-kommissionen@bfr.bund.de  
[bfr.bund.de/de/bfr\\_kommissionen-311.html](https://www.bfr.bund.de/de/bfr_kommissionen-311.html)

