

German Recommendation BfR 36 reviewed.

In absence of a harmonised EU measure, the German Recommendation BfR 36 is the main reference used on paper and board for food contact.

A new version was publicly released in June and the ECMA Food Safety Committee has been assessing the main changes in its meeting the 14/07.

<https://bfr.ble.de/kse/faces/resources/pdf/360.pdf>

<https://bfr.ble.de/kse/faces/resources/pdf/360-english.pdf>

For Bisphenol S, the same limit as for BPA has been introduced for the migration from recycled paper and board in contact with fatty or moist food. (0,05 mg/kg food)

The limit for aluminium stayed as it was at 1 mg/kg of food, but is now mainly applicable for moisty foods and not for fatty food anymore.

The limits for the phthalates were not adapted and the PFAS substances previously allowed are still included.

An important information to be aware of, is that BfR 36 is presented as an overall measure.

The final article should be checked for compliance with the BfR 36 too; Until now it was sufficient for carton makers to obtain a declaration from the board supplier on the compliance of the board with BfR 36. Now the carton maker has to perform further compliance work to check if the final article is fulfilling the included limits.

The assessment made is that If compliance certificates are obtained, not all chemicals need to be checked again, the main part will be covered but for certain categories of substances, there may be an issue, for instance the biocides. The same biocides present in the P&B substrate may also appear in the used inks.

German Ink Ordinance

Notified to the Commission back in July 2016, the German Ink Ordinance is now close to its final adoption.

The Ordinance has been forwarded for approval to the Bundesrat, the Federal Council in which the Länder are participating in the legislative process. The vote is expected on the 26/11.

Submitted text: <https://dserver.bundestag.de/brd/2021/0655-21.pdf>

In essence the Ordinance contains a positive list with all evaluated substances which can be used for manufacturing FCM inks and the limits to respect.

Other substances can also be used, if not in direct contact with food and not classified as CMR (carcinogenic, mutagenic, reprotoxic) and the migration is not detectable (0,01 mg/kg).

Compared to the previous versions, the final text contains also provisions regarding NIAS (Not Intentionally Added Substances) in analogy to the Plastics Regulation 10/2011.

This forwarding to the Bundesrat means, an agreement has been obtained among the federal ministries concerned, which so far could not be reached with the Federal Ministry of Economics.

In the compromise negotiations between the ministries, the included transitional period has been extended to 4 years for food contact materials.

It has also been agreed, the transition period may be adapted if the European Commission presents a legal regulation on printing inks or printed food contact materials.

One substance one assessment (OSOA)

A key concern within the industry associations in relation to the “Chemicals Strategy for Sustainability Towards a Toxic-Free Environment” (CSS) and the review of the Food Contact Materials legislation is an excessive or single focus on the hazardous characteristics of substances, under the authority of ECHA (European Chemicals Agency).

In a context of food safety, risk assessments are typically performed by EFSA (European Food Safety Agency) based on both, the hazard and the exposure to substances, with the well-known equation:

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$



The Packaging Joint Industry Taskforce developed a discussion paper on this concern, arguing in favour of a Tailored risk assessment for food contact materials and articles.

The PIJITF proposes a well-balanced approach where substances undergo first a “one substance - one hazard assessment” in which the hazard is defined by the intrinsic properties of the substance.

This should then be followed by a second step of an FCM specific risk assessment and management for food contact materials and articles, in which the risk resulting from oral exposure is assessed.

As the arguments may be useful in different discussions, the PIJITF paper - endorsed by ECMA - is available from the Members Only section of the ECMA website.

Interesting in this context is the online publication by leading staff members of the BfR.

“The EU chemicals strategy for sustainability questions regulatory toxicology as we know it : is it all rooted in sound scientific evidence ?”

<https://link.springer.com/article/10.1007/s00204-021-03091-3>

The article explains once more how the toxicity of substances is related to the exposure dose, argues in favour of a responsible use of the precautionary principle, questions the risks from exposure to mixtures of substances present at dose levels below their individual regulatory thresholds, confirms the concerns in relation to the endocrine disrupting chemicals and is well indicating how a move to a generic “ban” approach to wide classes of chemicals may be leading to inconsistencies and societal undesired consequences. (See FC update 29 09 21)

Mineral oils

All parties having introduced comments into the WTO notification process, obtained from the German authorities the same standard reply. There are no indications on the further political process.

For France, the publication of the Ministerial Decree which will provide more detail on the intended ban on mineral oils used in materials applied on the packaging, is still pending.

As previously covered the approach between Germany and France is entirely different. In essence the German measure is focussing on the protection against the migration of mineral oils from recycled paper and board, while the objective of the French ban is to avoid the presence of mineral oils in the paper and board material loop.

Food Contact Chemicals Database (FCCdb)

As reported in the Quarterly Update 2020 Q4, the Food Packaging Forum published a comprehensive database of food contact chemicals (FCC) and prioritized - using authoritative sources of hazard information - 608 FCCs for further assessment and substitution in FCMs/FCAs.

More background is provided in the detailed FC updates 22/12/20 and 29/09/21.

In relation to the prioritised substances ECMA has - late August - been writing to CEPI, EuPIA and FEICA, the European federations representing the paper and board, the ink and the adhesive manufacturers, to ask after the use and the performed risk assessment for the respectively 256, 377 and 147 substances which may - according to the FCCdb - be present in the materials our sector is using.

The first preliminary replies were discussed in the Food Safety Committee the 8/10.

GMP

As announced ECMA is now working on the development of specific guidance in relation to the second used certification scheme in the carton sector, “FSSC 22 000”.

The paragraphs for which specific guidance needs to be developed have been identified and were shared for comments in the FC network. (See update 29 09 21)

