

Re-evaluation of Bisphenol A by EFSA and BfR

TÜV Rheinland LGA Products - Information

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On April 19th, the European Food Safety Authority (EFSA) published the long-awaited [re-evaluation of BPA¹](#).

The provisional tolerable daily intake (TDI) of 4 µg bisphenol A (BPA) per kilogram body weight per day derived in 2015 was reduced by a factor of 20,000 to 0.2 ng/kg body weight per day.

The German Federal Institute for Risk Assessment (BfR) has looked closely at the EFSA derivations and has come to a significantly different and very conservative TDI value of 200 ng/kg body weight per day. This value is a factor of 20 lower than EFSA's previous provisional TDI value from 2015.

These different assessments are due to the fact that BfR does not use the endpoint defined as relevant by EFSA.

The study in mice, which is questionable in several respects (polycarbonate feed boxes, uncontrolled feeding, ...), showed a relative increase in Th17 cells.

This was not associated with adverse effects in the mice studied, the animals remained healthy.

The relevance of the results to human health is also questionable. There are only associations that such effects also occur in skin diseases such as neurodermatitis.

The BfR has identified the effect of BPA on male fertility as the most sensitive endpoint (estrogen-like effect, but with a significantly lower potential effect than estrogens) and bases its assessment on studies in rats in which a reduction in sperm count was observed.

There are several studies with effects ranging from about 100 µg/kg bw/day to 450,000 µg/kg bw/day where no effects were reported. In the [conservative approach of the BfR²](#) (German only), the studies reporting lower effects were taken into account.

The European Medicines Agency (EMA) also comes to a different conclusion. The controversial assessments lead to the unusual situation that "[reports on divergent views³](#)" have been published, in which the differences are presented.

¹ <https://www.efsa.europa.eu/en/efsajournal/pub/6857>

² <https://www.bfr.bund.de/cm/343/bisphenol-a-bfr-schlaegt-gesundheitsbasierten-richtwert-vor-fuer-eine-vollstaendige-risikobewertung-werden-aktuelle-expositionsdaten-benoeigt.pdf>

³ <https://www.ema.europa.eu/en/topics/topic/bisphenol>

POTENTIAL CONSEQUENCES

- The new TDI will result in BPA intakes being exceeded in all population groups, even though exposure is decreasing. This is likely to result in increased media coverage.
- The TDI values now under discussion are not limit values and are not initially relevant for the assessment of food contact articles.
- The current limit (SML for BPA) of 0.05 mg/kg test food will be maintained for the time being.
- The decision on a new limit value lies with the Commission. It will have to decide whether to follow the EFSA's assessment or that of the BfR/EMA. The debate is far from over.
- If the TDI is reduced by a factor of 20, as advocated by BfR, the limits of the most sensitive and already sophisticated methods (LC-MS/MS or Q-TOF) will be reached.
- The TDI proposed by EFSA indicates a limit that is not analytically achievable for these methods. Additional enrichment methods will be required, which will significantly increase effort, reagent/space requirements and errors.
- With the lowered limit in question, the continued use of BPA-based polymers (and possibly other bisphenols) in the coatings sector is more than questionable.
- EFSA's assessment of the current proposal to restrict bisphenols in the EU with a general limit of 10 mg/kg for almost all materials (with certain exceptions and transition periods) does not help the situation.

Also have a look at our previous customer information on bisphenols. We will be happy to send you a copy upon request.

Further information on current legal changes can also be found on our homepage at www.tuv.com or <https://www.tuv.com/regulations-and-standards/en/>.

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