

Draft new opinion on bisphenol A: Re-evaluation by the European Food Safety Authority open for public consultation

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Bisphenol A is a chemical compound used as a source substance for polycarbonate plastics and epoxy resins. The European Food Safety Authority (EFSA) has re-evaluated potential health risks associated with bisphenol A and made the outcome publicly available for comment on 15 December 2021.

<https://www.efsa.europa.eu/en/news/bisphenol-efsa-draft-opinion-proposes-lowering-tolerable-daily-intake>

EFSA's newly derived Tolerable Daily Intake (TDI) value for bisphenol A is 0.04 nanograms per kilogram of body weight per day. The TDI value indicates the amount of a substance that can be ingested daily over a lifetime without an identifiable health risk. The new value is about 100,000 times lower than the provisional (temporary) health-based guidance value previously given by EFSA. For people of all ages, intake of bisphenol A from food and other sources exceeds this new value - even though total intake in the population has been declining for years.

Since the publication of EFSA's temporary TDI in 2015, numerous new studies have been published. The background to the lowering of the TDI by EFSA is above all evidence from studies on mice that an intake of bisphenol A by the dams (the mother animals) during gestation and in the first period after birth can lead to changes in cell counts in the specific immune system of their progeny. To what extent these effects on the immune system are detrimental to the organism concerned (mouse) and whether the results can be transferred to humans is, in the opinion of the BfR, currently still an unresolved scientific question.

A causal relationship between bisphenol A intake and immunological effects in humans cannot be confirmed by studies in humans so far.

BfR will comment on EFSA's statement after a comprehensive review.

The risk assessment of bisphenol A has been the subject of scientific and public discussions worldwide for years. In January 2015, EFSA had published an opinion on the assessment of health risks from bisphenol A in food and identified the use of bisphenol A in food contact materials, such as polycarbonate containers and food cans with inner coatings made of synthetic resins, as an important source of entry. The TDI published in 2015 was considered temporary.

In July 2016, bisphenol A was classified as toxic to reproduction (category 1B "May impair fertility") according to the CLP Regulation and as a result was identified as a Substance of Very High Concern (SVHC) under the REACH Regulation in January 2017. The REACH Regulation is the European Chemicals Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals. In June 2017, the substance was re-identified as SVHC due to its properties as an endocrine disruptor for human health, and in 2018, it was identified as SVHC for being an endocrine disruptor for the environment. Endocrine disruptors are substances that can cause damage by acting similar to hormones.

According to a report published in October 2021, the CLARITY-BPA research program launched by the US Food and Drug Administration (FDA) concludes that the effects of long-term bisphenol A intake on the immune system of rats were moderate and not dose-dependent. The authors conclude that the observed BPA-mediated changes [...] are unlikely to alter immune competence in adult rats.

https://ntp.niehs.nih.gov/ntp/results/pubs/rr/reports/rr18_508.pdf

The use of bisphenol A in the manufacture of polycarbonate infant bottles was banned across the EU back in 2011. The ban was generally extended to polycarbonate drinking vessels and bottles for infants and young children in 2018. A limit for the transfer of bisphenol A into food was set for all other plastic food contact materials as well as for internal coatings made of epoxy resin for canned food on the basis of EFSA's TDI from 2015.

The use of bisphenol A in thermal papers (e.g. sales slips, parking tickets, parcel labels) in concentrations above 0.02% has been banned since 2020. In principle, this corresponds to a ban on use, as concentrations below 0.02% do not lead to the desired technical effect (colour developer).

Currently, several European countries, including Germany, are jointly preparing a draft that is intended to largely restrict the use of bisphenol A and other bisphenols. The draft is planned to be submitted to the expert committees of the European Chemicals Agency for review in 2022.

Further information is available on the BfR website

https://www.bfr.bund.de/en/a-z_index/bisphenol_a-129760.html

About BfR

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