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Print

Bisphenol A: EFSA consults on assessment of risks to human health

EFSA is launching a public consultation on its draft assessment of the human health risks posed by exposure to bisphenol A (BPA). The Authority has undertaken a comprehensive review of scientific literature and previous risk assessments from expert bodies on BPA. All stakeholders and interested parties are invited to comment on the document through an online public consultation that runs until 13 March 2014. EFSA particularly welcomes input from national risk assessment bodies that have previously evaluated BPA. As part of its commitment to openness and engagement, EFSA will also hold a meeting with stakeholders to discuss feedback received from the consultation.

BPA is a chemical compound used in food contact materials such as packaging and other consumer products. In March 2012, EFSA's Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) decided to undertake a full re-evaluation of the human risks associated with exposure to BPA through both dietary and non-dietary sources such as thermal paper and dust. To ensure EFSA had access to the most recent studies, the Authority liaised closely with European and national bodies engaged in BPA evaluations as well as with other scientific experts on studies currently in progress.

EFSA reviewed over 450 studies relating to potential health hazards associated with BPA and identified likely adverse effects on the liver and kidney and effects on the mammary gland as being linked to exposure to the chemical. It therefore recommends that the current tolerable daily intake (TDI) be lowered. The Authority also noted that uncertainties remained over a number of other health hazards considered as less likely. As a result the proposed TDI should be set on a temporary basis pending the outcome of research from the US National Toxicology Program (NTP) which will address many of these current uncertainties about the potential health effects of BPA. However, EFSA concludes that BPA poses a low health risk to consumers as exposure to the chemical is well-below the temporary TDI.

EFSA said that much of the science underpinning these conclusions is still developing and this draft opinion therefore contains a number of uncertainties. The CEF Panel will

complete an assessment of these uncertainties in the final version of the opinion due to be published later in 2014.

Iona Pratt, Chair of EFSA's Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), said: "The risk assessment of BPA has been hugely complex. EFSA concludes there is an estimated safe level of exposure to BPA – known as the TDI – but has reduced this and set it on a temporary basis because of continuing uncertainties over the risks posed by the chemical. Our experts have identified health hazards associated with exposure to BPA. However, we say the risk to human health is low because consumer exposure to BPA is below the temporary TDI (t-TDI). While we have analysed the best available evidence using state-of-science methods, we recognise that understanding in these areas is constantly advancing. Therefore our conclusions are as definitive as they can be in light of current data."

- Public consultation on the draft opinion on bisphenol A (BPA) – Assessment of human health risks

Main findings of draft opinion on the toxicity of BPA

- EFSA concludes that exposure to BPA is likely to adversely affect the kidney and liver, as well as causing effects on the mammary gland.
- The opinion additionally considers the possible effects of BPA on the reproductive, nervous, immune, metabolic and cardiovascular systems, as well as in the development of cancer. While an association between BPA and these other effects is not considered likely at present, EFSA concludes they may be of potential concern for human health and they add to the overall uncertainty about the risks of the substance.
- EFSA's experts recommend that the tolerable daily intake (TDI) for BPA be lowered from its current level of 50 µg/kg bw/ day (or 0.05 mg/kg/bw/day) to 5 µg/kg bw/day (0.005 mg/kg/bw/day) and be set on a temporary basis.
- EFSA says the health risk for all population groups is low – including for fetuses, infants, young children and adults. This is because the highest estimates for combined oral and non-oral exposure to BPA are 3-5 times lower than the proposed t-TDI, depending on the age group. For all population groups, oral exposure on its own is more than 5-fold below the proposed t-TDI.
- The CEF Panel has used a three-step methodology to derive the proposed t-TDI:
    - Health hazards that previous scientific studies and reviews have suggested as being associated with BPA exposure were evaluated by applying a weight of evidence approach. These were effects on the reproductive, neurological, metabolic, immune and cardiovascular systems, as well as genotoxic and **c**arcinogenic effects, mammary gland changes and general toxic effects.EFSA concludes there is sufficient evidence to support a likely association between BPA exposure and general toxic effects - specifically effects on the kidney and liver – as well as between BPA exposure and changes in the mammary gland.

- A statistical method known as the benchmark dose approach was used to estimate the level at which BPA causes a small but measurable effect on the kidney, liver and mammary gland in animals. Findings on the kidney in mice were used as a basis for the t-TDI as they were considered to be critical effects occurring reliably at the lowest benchmark dose.
- EFSA also assessed new research results that provide greater insight into the way BPA behaves in the bodies of animals compared to humans. Based on this comparison, EFSA was able to convert the dose level at which BPA causes an effect in mice into an equivalent oral dose for humans. This allowed EFSA to use real data in deriving the t-TDI instead of standard default values - conservative estimates used in the absence of real data - that were used in previous assessments of BPA.

- FAQ on bisphenol A

Notes to editors

Bisphenol A is used as a monomer in the manufacture of polycarbonate plastic found in such items as reusable drinking bottles, storage containers and in the epoxy lining of some food and drink cans.

Tolerable Daily Intake (TDI) – the estimated quantity of a chemical substance that can be ingested daily over a lifetime without posing a significant risk to health. Exposure to such substances may not be avoidable as some are found in foods as a result of transfer from food contact materials. TDIs are expressed by body weight, usually in milligrams or micrograms (of the substance) per kilogram of body weight, and per day in the case of repeated exposure. 1 milligram (mg) = 1,000 micrograms (µg).

EFSA has taken a two-step approach to the scientific opinion on BPA. A draft exposure assessment was developed in July 2013. The Authority is now delivering a draft review on the possible toxicity and human health risks from exposure to the substance.

Contacts

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