

European Food Safety Authority (EFSA)

Press Releases & News Stories

Press Release
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EFSA re-evaluates safety of bisphenol A and sets Tolerable Daily Intake

The European Food Safety Authority (EFSA) has today announced its opinion on dietary exposure to the chemical bisphenol A (BPA). People are exposed to BPA in food through its use in certain plastic and other materials that are used in products such as bottles and cans. EFSA's scientific AFC Panel^[1], has concluded that the setting of a full rather than a temporary Tolerable Daily Intake (TDI) is now appropriate, following an extensive review, including all available new data from the last five years. People's dietary exposure to BPA, including that of infants and children, is estimated to be well below the new TDI.

The re-evaluation of BPA focused on effects on reproduction and the endocrine (hormonal) system, about which there has been much scientific debate. Having considered both the pre-2002 and new studies available, the Panel concluded that the no-observed-adverse-effect level (NOAEL) of 5 milligram/kg body weight/day identified in the previous evaluation in 2002, remains valid. The Panel also concluded that reports of low-dose endocrine effects of BPA in rodents did not demonstrate such activity in ways that were robust or reproducible.

New studies have shown significant differences between humans and rodents, such as the fact that people metabolise and excrete BPA from their system far more quickly than rodents, further limiting the relevance of low-dose effects of BPA reported in some rodent studies for human risk assessment. Studies have also shown that mice are particularly sensitive to oestrogens. Given that BPA is a weak oestrogen, the absence of adverse effects at 5 milligram/kg body weight and below in a new robust study on mice and two generations of their offspring adds further confidence to the risk assessment.

The AFC considered the strength of the scientific evidence now available and the remaining uncertainties and included an uncertainty factor of 100 into its calculations to reach the TDI, which is common scientific practice. On this basis the Panel established a full TDI of 0.05 milligram/kg body weight. The previous temporary TDI, set in 2002, included an uncertainty factor of 500, but this has been reduced due to the substantial scientific evidence now available.

The full text of the opinion can be found at:

http://www.efsa.europa.eu/en/science/afc/afc_opinions/bisphenol_a.html

Notes for editors

- **What is BPA used for?**

BPA is used to manufacture polycarbonate, a rigid plastic used to make infant feeding bottles, plates, mugs, jugs, beakers, microwave oven ware and storage containers. Another common use is in the production of epoxy-phenolic resins which form internal protective linings for cans and metal lids and coatings for water storage tanks and wine vats. BPA can migrate in small amounts into foods and beverages stored in materials containing the substance.

- **Tolerable Daily Intake (TDI)**

The TDI is an estimate of the amount of a substance, expressed on a body weight basis that can be ingested daily over a lifetime without appreciable risk.

- **Assessments of BPA**

In 2002, the European Commission's Scientific Committee on Food (SCF) issued an opinion on BPA and set a temporary TDI of 0.01 milligram/kg body weight. Since 2002 nearly 200 further papers relevant to the safety of BPA have been published. The European Commission asked EFSA to re-assess the safety of BPA for use in food contact materials in the light of this important new information.

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[1] The AFC Panel: EFSA Panel on food additives, flavourings, processing aids and materials in contact with food