European Food Safety Authority (EFSA)

Press Room

EFSA updates advice on bisphenol

23/07/2008

The European Food Safety Authority's AFC Panel[1] has issued a further scientific opinion on a specific aspect of the chemical bisphenol A (BPA), concerning its elimination from the body and how that relates to the risk assessment of BPA for humans. The aim was to take into account recent data and consider any implications for the existing EFSA advice on BPA set out in its 2006 opinion, which concluded that exposure to BPA is well below the Tolerable Daily Intake (TDI). People are exposed to BPA which may be present in food through its use in certain food contact materials such as baby bottles and cans.

The conclusions of the Panel are that after exposure to BPA the human body rapidly metabolises and eliminates the substance. This represents an important metabolic difference compared with rats. EFSA will continue to monitor closely scientific findings regarding BPA and any related health effects.

The AFC Panel, in its final session, took into account both the previous and the most recent information and data available on the way that BPA and related substances are handled in the human body. The Panel concluded that the exposure of the human foetus to BPA would be negligible because the mother rapidly metabolises and eliminates BPA from her body. The scientists also concluded that newborns are similarly able to metabolise and eliminate BPA at doses below 1 milligram per kilogram of body weight per day. This implies that newborns could effectively clear BPA at levels far in excess of the TDI of 0.05 mg/kg bw set by the Panel and therefore its 2006 risk assessment remains valid.

The Panel considered the significant differences between humans and rodents, such as the fact that people metabolise and excrete BPA far more quickly than rodents. This body of evidence further limits the relevance of low-dose effects of BPA reported in some rodent studies used for human risk assessment.

In its previous risk assessment, the Panel derived a TDI of 0.05 mg/kg body weight based on the no-observed-adverse-effect level (NOAEL) of 5 milligram/kg body weight/day for effects in rats and included an uncertainty factor of 100. In this latest assessment, the Panel concluded that this TDI provides a sufficient margin of safety for the protection of the consumer, including foetuses and newborns.

EFSA took note of the U.S. National Toxicology Program's draft brief on BPA and of the Canadian government's recent Draft Screening Assessment on BPA, which took into account findings from the low-dose studies, notably with respect to neurodevelopmental toxicity, though both pointed out that these studies were limited in rigour, consistency and biological plausibility.

EFSA also took into account the recent report published by one of the institutes of the European Commission's Joint Research Centre (EC, 2008)[2] which concluded that due to the low confidence in the reliability of the developmental neurotoxicity studies and the lack of consistency in the results of behavioural testing, no conclusions can be drawn from these studies. This opinion is very similar to that of EFSA in 2006.

EFSA is equally aware of the report of the Norwegian Scientific Committee for Food Safety, (VKM, 2008)[3], which concluded that the findings did not provide sufficient evidence for setting a robust lower NOAEL than the current NOAEL set by EFSA at 5 mg/kg body weight/day.

See the Opinion on Toxicokinetics of Bisphenol A of the former AFC Panel.

Full text of the 2006 opinion of the former AFC Panel.

Related links

Bisphenol-A on the U.S. Food and Drug Administration website

Chemical Substances in Batch 2 of the Challenge (Canada)

See also the "European Union Risk Assessment Report" and the "Report of the Norwegian Scientific Committee for Food Safety" (VKM, 2008).

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[1] The work of the AFC Panel is now shared between two new panels – the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) and the Panel on food additives and nutrient sources added to food (ANS)

[2] The European Risk Assessment Report is published by the Consumer Product Safety and Quality Unit, formerly known as the European Chemicals Bureau and is part of the Institute for Health and Consumer Protection, which is one of the institutes in the European Commission's Joint Research Centre (JRC).

[3] The Norwegian Scientific Committee for Food Safety, examined four studies on developmental neurotoxicity of BPA and its report recognises that the relevant studies suffer from major shortcomings. The report recommended that only a study conducted according to a Good Laboratory Practice (GLP) on developmental effects at low doses could eliminate uncertainty on these potential effects of BPA.