EFSA updates advice on bisphenol A

News Story
30 September 2010

Following a detailed and comprehensive review of recent scientific literature and studies on the toxicity of bisphenol A at low doses, scientists on the European Food Safety Authority's (EFSA) CEF[1] Panel conclude they could not identify any new evidence which would lead them to revise the current Tolerable Daily Intake[2] for BPA of 0.05 mg/kg body weight[3] set by EFSA in its 2006 opinion and re-confirmed in its 2008 opinion[4]. The Panel also state that the data currently available do not provide convincing evidence of neurobehavioural toxicity of BPA.

One Panel member expressed a minority opinion[5], saying some recent studies point to uncertainties regarding adverse health effects below the level used to determine the current TDI. Although the Panel member agrees with the rest of the Panel's general view that these studies could not be used to establish a lower TDI, the expert recommends that the current TDI should become a temporary TDI.

The CEF Panel members acknowledge that some recent studies report adverse effects on animals exposed to BPA during development at doses well below those used to determine the current TDI. These studies show biochemical changes in the central nervous system, effects on the immune system and enhanced susceptibility to breast cancer. However, these studies have many shortcomings. At present the relevance of these findings for human health cannot be assessed, though should any new relevant data become available in the future[6], the Panel will reconsider this opinion.

The latest work carried out by EFSA scientists followed a request from the European Commission to: a) carry out a review of recent scientific literature on the toxicity of BPA to assess whether the TDI should be updated; b) assess a new study on possible neurodevelopmental effects (i.e. possible effects to the brain and central nervous system) of BPA in rats, known as the Stump study; and c) advise on the risk assessment by Denmark's DTU Food Institute.

Detailed notes to editors

Bisphenol A is used in the manufacture of polycarbonate plastic found in such items as reusable drinking bottles, infant feeding bottles and storage containers, and in the lining of some food and drinks cans. Due to the possible association of BPA with negative health effects, the endocrine active substance has been the subject of considerable attention worldwide.

EFSA has held consultations in recent months with experts from across Europe and scientific discussions with several international risk assessment authorities, such as the U.S. Food and Drug Administration (FDA), Health Canada and the the World Health Organisation (WHO) on the subject of BPA, including the design of scientific studies on BPA, toxicological aspects and the strengths and weaknesses of certain studies. EFSA will also contribute to an expert consultation organised by the WHO and the Food and Agriculture Organisation (FAO) in November on the safety of BPA.

EFSA is monitoring ongoing publications on BPA and is aware of studies being carried out and planned worldwide. Furthermore, some Panel members are involved in EFSA's ongoing work to monitor trends and developments in the assessment of health risks of endocrine active substances.

In its review of available scientific literature, the Panel notes that some human epidemiological studies suggest associations between exposure to BPA and coronary heart disease and reproductive disorders but the design of these studies does not allow one to conclude whether BPA is the cause of these health effects.

The Panel says the study by Stump on rats demonstrates that BPA has no effects on brain tissue, motor activity or auditory startle response. The Stump study authors claim that their study also shows BPA has no effects on learning and memory. The Danish risk assessment on BPA[7] said that while the Stump study did not provide any clear evidence of BPA having harmful effects on the types of behaviour investigated in the study, it did give rise to uncertainty over the effects on learning ability, which was found in some rats at low doses.

The Panel identified possible shortcomings in the analysis of the Stump study data during further review in summer 2010 and called on EFSA's Assessment and Methodology Unit (AMU)[8] to conduct a statistical re-analysis of the learning and memory behaviour data from these rat tests. This re-analysis found a very high variation in results[9] and therefore the Panel considers the study to be inconclusive with respect to learning and memory and of limited value for the risk assessment of BPA. In addition, the Panel says that based on its literature review it does not consider the currently available data as convincing evidence that BPA has any adverse effects on aspects of behaviour, such as learning and memory.

Scientific Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A

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[1] CEF = the Panel for food contact materials, enzymes, flavourings and processing aids

[2] The TDI is an estimate of the amount of a substance, expressed on a body weight basis, that can be ingested over a lifetime without appreciable risk.
[3] TDI based on no adverse effect level (NOAEL) of 5 mg/kg bw/day from a multi-generation reproductive toxicity study in rats, where the critical effects were changes in body and organ weights in adult and offspring rats and liver effects in adult mice. A 100-fold safety factor was applied to take account of intraspecies/ interspecies differences.
[4] Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to 2,2-BIS(4-HYDROXYPHENYL)PROPANE and Toxicokinetics of Bisphenol A - Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC)
[5] EFSA considers it important that scientists are able to express an opinion which diverges from an adopted opinion, that is called a minority opinion. Among the top criteria for the selection of experts are not only their scientific expertise and proven scientific excellence in one, or preferably several, of the fields in EFSA's remit, but also their independence. Selection of experts
[6] EFSA has set up a system whereby new studies on BPA are continuously monitored by the Authority.
[7] The conclusion of the DTU Food Institute is based on three main arguments: a degree of uncertainty with regard to effects on learning ability as in Stump study; doubts on normal dose-response for BPA; some effects which have not been considered, namely certain aspects of learning and memory.
[8] To find out more about AMU's work, please follow this link.
[9] The Panel noted that the data suffered from so-called censoring in the data generated by the maze swimming tests by rats. The test was aimed at detecting how many errors the rats made in swimming through the maze (called the Biel maze) to escape in a 3-minute limit set by the Stump study authors. If the rats did not escape, they were taken out of the maze and recorded as if they had exited in the maximum three minutes (so-called censoring). If they had been given more than 3 minutes, they might have made more errors but this was not taken into account in the original analysis provided by the Stump study, so the design and the analysis of the results from the test were limited. The re-analysis of AMU takes into account this censoring.