



Parma, 29 January 2007

Frequently Asked Questions Bisphenol A (BPA)

What is BPA?

Bisphenol A (BPA) is a chemical that is mainly used in combination with other chemicals to manufacture plastics and resins. It has been used in the manufacture of these materials for many years. BPA is also known by its proper chemical name, 2,2-bis(4-hydroxyphenyl) propane.

How does it get into our diet?

BPA is used in polycarbonate, a type of transparent, rigid plastic. Polycarbonate is used to make food containers, such as returnable beverage bottles, infant feeding (baby) bottles, tableware (plates and mugs) and storage containers.

Residues of BPA are also present in epoxy resins used to make protective coatings and linings for food and beverage cans and vats.

Small amounts of BPA can migrate from polycarbonate plastics or epoxy resin linings into foods and beverages. BPA can also migrate into foods if the plastic or resin is damaged or breaks down.

Is it legally permitted for use in food contact materials in the EU?

Yes. BPA is permitted for use in food contact materials in the European Union¹. It is also permitted for food contact use in other countries such as the USA and Japan.

Why is there concern about BPA?

BPA is one of a number of chemicals that may have the potential to interact with hormone systems in the body (a so-called 'endocrine disrupter'). It has been known since the 1930s that BPA can mimic the female sex hormone, oestrogen. The effects on fertility and reproduction and the endocrine (hormonal) system have been subject to much scientific debate, linked to reports of low-dose effects of BPA in rodents.

Why has EFSA carried out a new review of BPA?

Some 200 scientific papers have been published on BPA since the last review by the European Commission's Scientific Committee on Food in 2002. Therefore there was a need to review the data, including these new studies. The review has been carried

¹ BPA is permitted for use in food contact materials in the European Union under Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intending to come into contact with foodstuffs. Official Journal of the European Union L39/1-42 13.2.2003.

out by EFSA's Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC).

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

What has changed since BPA was last assessed for safety?

Further studies, including a recently published 2-generation study in mice, have provided the experts with additional data missing in the past. The Panel has reassessed the 2002 opinion based on more evidence of the significant differences between humans and rodents, as well as stronger scientific evidence that reduced the uncertainties around the level of risk that were considered in 2002.

What has the Panel concluded?

The Panel has concluded that the setting of a full rather than a temporary Tolerable Daily Intake (TDI) is now appropriate, following an extensive review of all available data. People's dietary exposure to BPA, including that of infants and children, is well below the new TDI.

Are there any particular concerns for infants and children?

In its evaluation the Panel gave special attention to infants and children as they belong to the groups with the highest potential dietary exposure to BPA relative to the body weight. The Panel's estimates of intake were based on conservative ('worst case') estimations. Potential intakes for infants and children are estimated to be well below the TDI.

How much can be consumed without harm?

A 3-month-old bottle-fed baby that weighs around 6 kg would need to consume more than 4 times the usual number of bottles of baby formula a *day* before it would reach the TDI.

GENERAL INFORMATION

What is a 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.

Why was the TDI temporary and is now a full TDI?

A temporary TDI is allocated if there are uncertainties in the data that may be resolved by further studies and it is known that significant new data will be available in the near future.

In the case of BPA, the Scientific Committee on Food (SCF) set a temporary TDI in 2002 by applying an additional uncertainty factor 5 times higher than the 100-fold factor that is usually used. This was done because of the then lack of complete data as regards reproduction and developmental studies. After the results of the new 2-generation study on mice became available in October 2006, together with other studies published over the last 4 years, the information gap was filled and the AFC Panel was able to establish a full TDI of 0.05 milligrams/kg body weight, using the usual 100-fold uncertainty factor.

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