



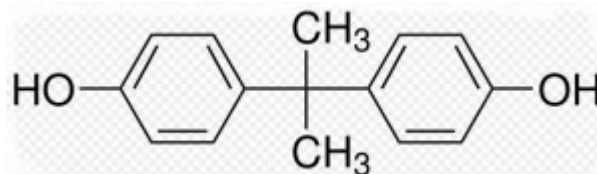
Introduction to the process of bisphenol A risk assessment by EFSA

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**Follow-up meeting on the public consultations on bisphenol A
23 April 2014, Bruxelles**

Bisphenol A (BPA): legislation

BPA is authorised in the European Union as monomer or other starting substance for the manufacture of plastic food contact materials with a specific migration limit of 0,6 mg/kg food. BPA shall not be used to manufacture polycarbonate infant feeding bottles or as additive in plastic food contact materials and articles (Commission Regulation (EU) No 10/2011)



BPA: previous evaluations and current re-evaluation by EFSA

- Many evaluations by ...
 - national authorities (France, Denmark, Sweden, Belgium, Germany, etc)
 - SCF (2002)
 - EFSA (**2006**, 2008, 2010, 2011)
 - European Chemical Bureau (EU-RAR, 2002; 2008)
 - EU-JRC (2010)
 - FAO-WHO (2010)
 - Food Standard Australia New Zealand (FSANZ, 2010)
 - Health Canada (2008)
 - Japanese AIST (2005, 2011)
 - U.S. FDA (2008, 2010, 2013)
 - U.S. NTP –CERHR (2008)

- 2012: EFSA's CEF Panel decided to undertake a full re-evaluation of the human risks associated with exposure to BPA through the diet, and contribution of non-dietary sources to the overall exposure to BPA ("self-tasking")



Preparation of the re-evaluation of BPA: Transparency and openness

- Continuous monitoring of scientific publications on BPA via two outsourcing projects and considerations of submitted literature. Draft opinion considers literature from 2006 onwards for occurrence/exposure and from 2010 onwards for hazard identification/characterisation until Dec 2012)
- Call for data July 2012
 - EFSA invited Member States, research institutions, academia, food business operators (e.g. food packaging manufacturers and food industries) and other stakeholders to submit analytical data on
 - i) occurrence of BPA in food and beverages intended for human consumption,
 - ii) BPA migration from food contact materials, and
 - iii) occurrence of BPA in food contact materials



Preparation of the re-evaluation of BPA: Transparency and openness

- Creation of two working groups (WG) 'BPA exposure and BPA toxicology' by CEF Panel (April/May 2012) due to the high amount of scientific literature/data
 - WG BPA exposure: 9 external experts/panel members in the areas of biomonitoring, exposure, migration and 1 hearing expert
 - WG BPA toxicology: 17 external experts/panel members in the area of metabolism, general toxicity, carcinogenicity, reproductive and developmental toxicity, neurotoxicity, immunotoxicity, pathology, human epidemiology, BMD modelling, genotoxicity and exposure assessment (since May 2013) and 14 hearing experts.
 - Task: to prepare a draft opinion on the risks to public health related to the presence of BPA in foodstuff
- Draft exposure (part 1) and health risks (part 2) of the BPA opinion prepared by these two CEF WGs were many times discussed during CEF Panel plenary meetings

Preparation of the re-evaluation of BPA: Transparency and openness

Two step approach:

- Endorsement of draft opinion exposure assessment part by CEF Panel on 4 July 2013 and web-based public consultation between 25 July - 15 September 2013
- Endorsement of draft opinion on hazard and risk assessment part by CEF Panel on 12 December 2013 and web-based public consultation between 17 Jan – 13 March 2014



Today's follow up meeting of the public consultation: Transparency and openness

Objective:

EFSA wants to ensure that all scientific views and information received during the two public consultation processes on exposure and health risks are fully understood and considered by the CEF Panel in order to feed into the final version of the opinion on “the risks to public health related to the presence of bisphenol A in foodstuffs” before its adoption



Next steps: Finalisation of BPA opinion

- Discussions on the outcome of public consultation exposure assessment part considered by WG BPA exposure and recently during the 46th CEF Panel meeting
- Discussions on the outcome of the public consultation hazard and risk assessment part started by WG BPA toxicology
- Comments received during public consultations and today's follow-up meeting will be considered by the CEF Panel during its plenary meetings
- Report on the outcome of the public consultations will be published in Dec 2014
- Adoption and publication of BPA opinion expected in Dec 2014