



European Food Safety Authority

EXECUTIVE DIRECTOR

Parma, **13 APR 2012**  
Ref. CGL/PB/AF/AFC/emf(2012) - out-6497365

Paola Testori Goggi  
Director General  
European Commission  
Directorate General  
Health and Consumers  
Rue de la Loi, 200  
1049 Bruxelles  
Belgium

**Re: New EFSA mandate for a scientific opinion on BPA**

Dear Mrs Testori Goggi,

*Dear Paola,*

During its plenary meeting in February 2012, the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) discussed on the need to perform a new full re-evaluation of the human risks associated with exposure to BPA through the diet, also taking into consideration the contribution of non dietary sources to the overall exposure to BPA. I am pleased to inform you that EFSA accepted this self mandate to the CEF Panel on 29 March 2012. The mandate is attached to this letter, and is also available through the link below<sup>1</sup>.

The mandate foresees a full risk assessment of BPA and, in order to support this opinion, two new working groups have been set up to focus, respectively, on the hazard characterisation of BPA and on exposure to BPA. Experts from several Member state agencies, among others ANSES, BfR, RIVM and UBA, will join these workings groups.

The most recent exposure assessment of BPA was published in January 2007 by the former Panel on additives, flavourings, processing aids and materials in contact with food (AFC). A revised exposure assessment is now considered essential as several measures have been put in place in recent years to reduce BPA levels in food contact materials (especially in baby bottles). Furthermore, the contribution of non dietary sources to the overall exposure to BPA has not been considered by EFSA in its previous opinions. For the exposure assessment a call for data on occurrence of BPA in food and on migration of BPA from food contact materials is currently in preparation and will shortly be published on the EFSA website. This call is addressed to Member

<sup>1</sup><http://registerofquestions.efsa.europa.eu/roqFrontend/?wicket:interface=:3:::>

States, food producers, packaging converters and other stakeholders. EFSA will also launch a contract to collect and screen the scientific literature (2006-2012) concerning BPA occurrence in food- and non-food sources, as well as BPA migration data from food contact materials.

With respect to BPA toxicology, the CEF Panel had expressed in its statement<sup>2</sup> of 24 November 2011 the need for a review of new toxicity data. EFSA's risk assessment will also take into account findings from ongoing research in the United States and from the ANSES' risk assessment report, which are expected to become available later in 2012.

In light of the complexity of the issue and the expected amount of data, the CEF Panel has proposed to deliver its scientific advice by May 2013.

Yours sincerely,



Catherine Geslain-Lancéelle

Cc :



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<sup>2</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/2475.htm>



European Food Safety Authority

EXECUTIVE DIRECTOR

Parma, 29 MAR 2012  
Ref: CGL/AE/ml (2012) - out: 6471635

[REDACTED]

**Subject: Mandate proposed to EFSA by the CEF Panel for a self-tasking opinion on the risk assessment of dietary Bisphenol A (BPA)**

Dear [REDACTED]

On 5 March 2012, you sent me a letter in which you requested my agreement that the CEF Panel prepares a self-tasking safety assessment of bisphenol A: "Scientific Opinion on the risks to public health related to the presence of bisphenol A in foodstuffs".

After consultation with the Mandates Review Committee, I recognise the need for EFSA to undertake a full re-evaluation of the safety of bisphenol A, based on all the most recent experimental evidence, and I formally agree with the proposed mandate (see annex). Regarding the timeframe, in view of the workload of the CEF Panel and after consultation of the FIP Unit, I consider appropriate to have this work finalised by the end of May 2013.

Yours sincerely,

[REDACTED]

Catherine Geslain-Lanéelle

Annex: Background and Terms of Reference

Cc: [REDACTED]

## Background

Bisphenol A (BPA) is used as a monomer in the manufacture of polycarbonates and epoxy resins and as an additive in plastics. Polycarbonates are used in food contact materials such as reusable beverage bottles, infant feeding bottles, tableware (plates and mugs) and storage containers. Epoxy resins are used in protective linings for food and beverage cans and vats.

EFSA issued scientific opinions on BPA in 2007, 2008 and in 2010.

In its opinion of 2007, EFSA performed a risk characterization for BPA, including a dietary exposure assessment and a hazard characterization. In this opinion, EFSA established a tolerable daily intake (TDI) for BPA of 0.05 milligram per kilogram (mg/kg) body weight based on the no adverse effect level of 5 mg/kg body weight in multi-generation rodent studies.

A new opinion on the toxicokinetics of Bisphenol was adopted by EFSA in 2008. Here, EFSA reaffirmed the TDI established in 2007, concluding that age-dependent toxicokinetics differences of BPA in animals and humans would have no implication for the assessment of BPA previously carried out by EFSA.

In 2010, the CEF Panel performed a new hazard characterization of BPA, based on a comprehensive evaluation of recent toxicity data. The Panel concluded that no new scientific evidence would call for a revision of the current TDI. However, it emphasized some uncertainties concerning some BPA-related effects of possible toxicological relevance, in particular biochemical changes in brain, immunomodulatory effects and enhanced susceptibility to breast tumours emerging from studies on developing animals. Given certain methodological shortcomings in the studies showing these effects, the Panel concluded that the relevance of these findings for human health could not be assessed, but that it would reconsider its opinion should any new relevant data become available. A Panel member expressed a minority opinion based on those uncertainties.

In 2011, EFSA has been asked to provide scientific advice in relation to possible divergences between the conclusions of the EFSA Scientific Opinion on BPA of September 2010 and those in the reports on BPA published in September 2011 by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES). On 1 December 2011 EFSA published a Panel statement on Bisphenol A in which the information in the ANSES report was considered not to change the views that the Panel expressed in 2010. However, concerning additional data in recent literature, the Panel stated that it would need further time to review more in depth the new studies. The Panel also underlined that there are ongoing low dose studies at NCTR/FDA and at NTP/NIEHS which aim to resolve, at least in part, the current uncertainties regarding the potential health effects of BPA.

EFSA is aware that ANSES (and possibly other organisations) will finalize their risk assessment report of BPA (including exposure assessment from the diet as well as from other routes) by the end of 2012.

EFSA also notes that its latest exposure assessment to BPA through dietary sources dates back to 2006, and thus considers it necessary to update such estimates in the light of the data since then available. The relevance of a dietary exposure assessment versus a more general exposure assessment via various routes of exposure should be explored. Also, in line with the 2011 conclusions of the CEF Panel, it is advisable for EFSA to undertake a full re-evaluation of the safety of BPA, based on all the most recent experimental evidence.

### **Terms of reference**

In accordance with Article 29 (1) of Regulation (EC) No 178/2002, the European Food Safety Authority asks its scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) to provide by May 2013 a scientific opinion on the risks for public health related to the presence of bisphenol A in foodstuffs.

In particular, the opinion should:

- evaluate the toxicity of BPA for humans, including for specific (vulnerable) groups of the population (e.g. pregnant women, infants and children, etc.) and considering all relevant toxicological information available;
- carry out an exposure assessment on the basis of the occurrence data available in the public domain and other occurrence data that may be available, and quantify as far as possible not only dietary exposure but also exposure from non-dietary sources;
- consider specifically the exposure situation for the supposedly most vulnerable groups of the population (e.g. pregnant women, infants and children, etc.) and take into account, if available, biomonitoring data when assessing the exposure and compare the results with the calculated exposure;
- characterize the human health risks taking into account specific groups of the population.