

Parma, 18 MAY 2018  
Ref. BU/JR/ec (2018) –OC-19337554

Dr Michael Warhurst  
Executive Director, CHEM Trust  
[Michael.warhurst@chemtrust.org](mailto:Michael.warhurst@chemtrust.org)

By email only

**Subject: Your letter on the assessment of chemicals in food contact materials and grouping of bisphenols.**

Dear Dr. Warhurst,

Thank you for your letter dated 27 March 2018 where you refer to the publication of your report on the properties and regulation of bisphenol groups of chemicals.

As you may be aware, EFSA's role in the food safety system extends solely to providing scientific advice that serves to inform regulatory decisions about food safety that are taken by risk managers in the EU (European Commission, Member States and European Parliament). As such, EFSA has no role in taking decisions on labelling, authorisations, or restrictions. The vast majority of EFSA's work is carried out in response to requests for scientific advice with specific terms of reference, as set by the risk managers mentioned above.

With regards to BPS, which is on the authorised list for use in plastic food contact materials, EFSA has had some preliminary discussions with the European Commission on this substance and it is currently under assessment by the European Chemicals Agency (ECHA). For BPF and BPAF as alternatives to BPA which you also mention in your report, please note that neither substance has been authorised in the EU for use in plastic food contact materials. Only chemicals that have undergone a positive assessment can be on the Union List of substances that are permitted for use in the manufacture of plastic food contact materials.

With regards to BPA, EFSA's 2015 scientific opinion concluded that there is no concern for consumers from dietary exposure to BPA and low concern for exposure to all sources. EFSA set a reduced tolerable daily intake (TDI), pending new US studies designed to address uncertainties about possible reproductive, developmental, immune system and other effects.

EFSA is currently working on a mandate received from the European Commission in which it was asked to re-evaluate the safety of BPA for consumers and to re-assess the temporary TDI for BPA. This work will be performed according to a pre-defined protocol<sup>1</sup> setting *a priori* the criteria for the inclusion of new studies and the appraisal of toxicological evidence. The final version of the protocol was the result

---

<sup>1</sup> EFSA (European Food Safety Authority), Gundert-Remy U, Bodin J, Bosetti C, FitzGerald RE, Hanberg A, Hass U, Hooijmans C, Rooney AA, Rousselle C, van Loveren H, Wölfle D, Barlzone F, Croera C, Putzu C and Castoldi AF, 2017. Bisphenol A (BPA) hazard assessment protocol. EFSA supporting publication 2017:EN-1354. 76pp. doi:10.2903/sp.efsa.2017.EN-135. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2017.EN-1354>

of a public consultation and a stakeholder workshop held in Brussels on 14 September 2017. These two public engagement initiatives gave all interested parties the opportunity to contribute at an early stage to EFSA's ongoing work on BPA and led to a substantial revision of the draft protocol.

In its new opinion, EFSA will review studies published since 2012 (the cut-off for EFSA's 2015 opinion) including studies reviewed by ECHA's Member State Committee, but also the extensive National Toxicology Program studies in the US. These studies will cover the possible health effects highlighted in EFSA's previous opinion. EFSA also continues to liaise closely with ECHA on BPA, following the latter's recent identification of BPA as a Substance of Very High Concern in relation to its endocrine disrupting properties.

We welcome your reference in the report to EFSA's ongoing work on cumulative risk assessment, which is being piloted in the area of pesticides. EFSA agrees with you about the importance of assessing the mixture effect of chemicals and continues to devote considerable effort to developing this complex area of regulatory science. A draft guidance on mixtures and a draft statement on the genotoxicity assessment of chemical mixtures are set to be endorsed for public consultation by EFSA's Scientific Committee towards the end of May 2018. Your comments on these draft documents would be very much welcome.

Finally, you may be interested to know EFSA's Scientific Conference this year, which takes place in Parma from 18-21 September 2018, will include a session with experts from the CLARITY-BPA Programme and a first public discussion about the data from the whole research programme.

Thank you again for your interest in EFSA's work on food contact materials. I have asked my colleague Ms Claudia Roncancio Peña, Head of the Food Ingredients & Packaging Unit at EFSA, to make herself available to you should you have any further queries or require any further assistance. Please feel free to contact her directly at [Claudia.RONCANCIOPENA@efsa.europa.eu](mailto:Claudia.RONCANCIOPENA@efsa.europa.eu)

Yours sincerely,



Bernhard Url

cc: Claudia Roncancio Peña, Head of Food Ingredients & Packaging Unit  
James Ramsay, Head of Engagement and Cooperation Unit a.i.