Call for data relevant to the hazard assessment of Bisphenol A (BPA)

EFSA-Q-number: EFSA-Q-2018-00221

Published: 09/03/2018
Deadline for registering interest: 30/06/2018
Deadline for submission of data: 31/08/2018
Updated deadline: 15/10/2018

Background

Bisphenol A (BPA) is an authorised chemical substance to be used in the manufacture of food contact materials such as polycarbonate bottles and internal lining of cans. Its use has been restricted for some articles for infants (infant feeding bottles).

In its latest BPA risk assessment published in 2015, the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) reduced and set the Tolerable Daily Intake (TDI) for BPA on a temporary basis to account for uncertainties related to possible BPA effects at low doses on mammary gland, reproductive, neurological, immune and/or metabolic systems, thus committing to a re-evaluation of the TDI in light of the new data available. The extensive body of new literature that has been published on BPA from 2013 onwards and not previously appraised by EFSA will be evaluated following a pre-defined hazard assessment protocol available online (http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2017.EN-1354/epdf). This protocol states upfront and in detail the methods and/or the criteria that will be used in the planned BPA re-evaluation for data collection, study inclusion, evidence appraisal and integration and selection of data for hazard characterisation.

As stated in the BPA hazard assessment protocol and in order to ensure a thorough re-evaluation of BPA, it is important that EFSA retrieves all relevant data from interested parties willing to share their datasets with EFSA. Therefore EFSA is launching a public call for data in order to acquire documented information (published, unpublished or newly generated) to be used for the hazard assessment of BPA (including non-English studies translated into English).

The data sent to EFSA by means of this call will undergo the same screening for relevance and appraisal procedures foreseen for studies gathered through bibliographic searches, following the guidelines described in the BPA hazard assessment protocol.

Overall objective

The purpose of this call for data is to offer to interested parties and/or stakeholders the opportunity to submit human and animal hazard studies/data (published, unpublished or newly generated) relevant to the re-evaluation of BPA and its TDI.

Deadline for submission of data and disclosure of contact details

Interested parties and stakeholders should provide by the new updated deadline of **15/10/2018** the information described below.

From the publication of this call and until the 30/06/2018, please communicate in writing by e-mail to: fip@efsa.europa.eu, your availability to submit the requested information by the timeline specified above or any proposal for a new deadline providing justified reasons. Depending on the replies received the final deadline will be communicated to you through e-mail and by updating the current call.

Information not submitted within the final deadline will only exceptionally be considered and EFSA can finalise its opinions on the basis of the information already provided.

In order to facilitate the collaboration of all interested parties to provide the data needed, we are seeking your consent to disclose your personal data (name, e-mail address and telephone number) to the other parties that have expressed an interest to provide the requested information. If you do not wish to make your contact details available, clearly indicate it in your first communication.

Information sought

EFSA kindly invites business operators and other interested parties (governments, interested organisations, universities, research institutions, companies) to submit relevant data to assess the hazards related to the exposure to BPA and set a full TDI for this chemical, and in particular:

1. **Toxicological data derived from both animal and human studies.** In general, the effects considered relevant for the assessment could be included in the following health outcome categories: general toxicity (e.g. liver and kidney), reproductive, developmental, neurological, immune, cardiovascular, or metabolic toxicity, mammary gland effects or carcinogenicity, genotoxicity or any other toxicity

2. **Toxicokinetic data**

Confidentiality

According to Article 39 (1) of Regulation (EC) No 178/2002 EFSA may not divulge to third parties confidential information received for which confidential treatment has been requested, justified, and agreed, except for information which must be made public if circumstances so require, in order to protect public health, animal health or the environment.

Therefore, business operators or interested parties submitting relevant dataset in response to this call are requested to highlight as part of their submission all parts or bits of information or data they consider as deserving confidential treatment (i.e. no disclosure). Confidential treatment may be granted to information the disclosure of which might significantly harm the competitive position of business operators or other interested parties.

Interested business operator or other interested parties will be informed about which information or data will be granted confidential treatment.

Concerned business operators or interested parties may challenge decisions by an European Union (EU) institution, agency or body affecting their legal situation at the conditions set out under Article 263 of the Treaty on the Functioning of the European Union (TFEU), or file a complaint for alleged maladministration by an EU institution, agency or body under Article 228 of the TFEU.
**Submission of information**

Interested business operators and/or interested parties should submit the information to EFSA in electronic form (e.g. CD-rom, DVD, etc.) with a:

- (mandatory) cover letter that should contain:
  - Reference to the specific call and the specific EFSA question number indicated (EFSA-Q-2018-00221);
  - The contact details\(^1\) (name of contact person, name of company/organisation, e-mail address and telephone number) of the person responsible for the data submission and, if applicable, the list of interested business operators and/or interested parties represented and their contact details;

- (mandatory) statement of the legal representative of the submitter that they hold all the necessary rights to grant EFSA permission to use and, where appropriate, to disclose, the submitted information, data, document, paper or study for the purposes defined in this call. In case the submitter does not enjoy the necessary rights for these data or studies, they should share the contact details of the respective owner(s) of data and/or of the relevant intellectual property right, so that EFSA may seek their approval directly;

- (optional) separate folders with any relevant confidentiality claim they have on the submitted information or data. Information or data for which a confidentiality claim is submitted should be kept to a minimum, and shall be supported by verifiable evidence composed of precise and factual information or, ideally, documents proving that the disclosure of the information would result in concrete harm to the commercial or economic interest of the concerned individual, or would undermine the protection of privacy and the integrity of the concerned individual. Note that the information described in article 20(2) of the Regulation (EU) No 1935/2004\(^2\) cannot be confidential. Examples of information for which a confidentiality claim may be filed:
  - Method of manufacture or manufacturing process of the product in relation to which the claim is made;
  - Links between a producer or importer and the concerned individual;
  - Personal data, as defined by Regulation (EC) No 45/2001\(^3\);

- (optional) the consent that EFSA may share the data or information submitted with the European Chemicals Agency;

- (optional) the explicit and written decision of the data owner to donate the information or data to EFSA. By donating to EFSA the submitted information or data, the concerned operator or interested party waives any right on the relevant information or data.

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\(^1\) The interested parties shall notify EFSA of any change in the contact details by sending an e-mail to the FIP mailbox (fip@efsa.europa.eu)


Correspondence
Please send all electronic correspondence, including enquiries, to:

fip@efsa.europa.eu

Submissions of information/data should be sent to the following address:

European Food Safety Authority
FIP Unit
Via Carlo Magno 1/a
I-43126 Parma
Italy