

Call for collection of data on phthalates, structurally similar substances and replacement substances migrating from or occurring in food contact materials (Plasticisers_FCM_2023)

Background

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002, EFSA received from the European Commission a mandate (M-2020-0183) with the request to conduct preparatory work for the re-evaluation of phthalates, structurally similar substances and replacement substances that are potentially used as plasticisers in food contact materials (FCMs). This mandate included a request to consider migration data in the context of the dietary exposure assessment. To this end, in 2022, EFSA conducted a data collection to gather results generated in experimental studies on FCMs before their actual use (e.g. tests on migration of plasticisers from FCMs using food/food simulants, or tests on concentration of plasticisers in FCMs¹). This data collection will continue in 2023.

Submission of data

National food authorities, research institutions, academia, food business operators and other stakeholders are invited to submit data on migration or occurrence of plasticisers (phthalates, structurally similar substances and replacement substances) in FCMs. A list of substances identified as potential plasticisers (EFSA CEP Panel, 2022²), and therefore considered within this call for data, is available at <https://doi.org/10.5281/zenodo.6519824> (both Tables 1 and 2 in Annex I). Some examples of relevant groups of substances potentially used as plasticisers are:

- Phthalates
- Terephthalates
- Citrates
- Benzoates

Stakeholders are invited to express to EFSA their interest in submitting migration or concentration data by contacting data.collection@efsa.europa.eu, preferably by the 30th of June 2023.

How to submit data

Data must be submitted electronically in Extensible Markup Language (XML) format to the EFSA Data Collection Framework (DCF) <https://dcf.efsa.europa.eu/dcf-war/dc>. User credentials are required to access the DCF web interface, please contact data.collection@efsa.europa.eu to obtain the credentials.

¹ Concentration of plasticising agents in or migration from FCM are intended to be established through testing under controlled laboratory conditions of contact with food simulants (or exceptionally with food itself) before the actual use of the FCM.

² EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré C, Barat Baviera JM, Bolognesi C, Chesson A, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Lampi E, Mengelers M, Mortensen A, Rivière G, Steffensen I-L, Tlustos C, Van Loveren H, Vernis L, Zorn H, Ahrens B, Fabjan E, Nicolas R, Polci L, Baert K, Volk K and Castle L, 2022. Scientific Opinion on the identification and prioritisation for risk assessment of phthalates, structurally similar substances and replacement substances potentially used as plasticisers in materials and articles intended to come into contact with food. EFSA Journal 2022;20(5):7231, 26 pp. <https://doi.org/10.2903/j.efsa.2022.7231>

The xml files must be structured with the ad-hoc data model specifically defined for this data collection, using the associated EFSA controlled terminologies (also called catalogues):

- A guidance document describing the data model, an excel reporting tool, instructions on data reporting and a list of substances to consider for reporting are available at <https://doi.org/10.5281/zenodo.6519824>. In case data are compiled manually using the EFSA tool, the XML file must be generated for direct submission to the DCF.
- The complete list of terms that are to be used to report the data to EFSA are contained in Catalogues. The annual major release of the catalogues (31/01/2023) can be downloaded from <https://doi.org/10.5281/zenodo.779880>. EFSA catalogues are available in the Catalogue browser. **Guidance on the installation and use of the EFSA Catalogue browser can be found at <http://www.efsa.europa.eu/en/supporting/pub/en-1726>**

The DCF will be open for the reporting of data in the context of the call for 'Plasticisers_FCM_2023', from **5 May 2023 to 31 August 2023**.

The communication below is not applicable to Member State competent authorities.

Please note that all confidentiality requests within the frame of this call for data, must be submitted separately via email to EFSA to confidentialityrequestassessment@efsa.europa.eu. The ground or legal basis for the confidentiality request and the justification must be provided as well as the name of the field/(s) for which a confidentiality request is made. **Failure to submit the requested information will prevent EFSA from assessing the confidentiality request. As a consequence, all information submitted to EFSA will be made available to the public by EFSA in accordance with the provisions of Article 38(1).**

Nonetheless, in case EFSA receives a new mandate for which data collected via this call will be used as a basis for EFSA's outputs, data providers will be notified at least 3 months before the publication of the EFSA outputs about the new requirements to submit their confidentiality requests **via the Portalino** (available [here](#)). Information on how to submit confidentiality requests and how to use this tool is available online <https://www.efsa.europa.eu/en/about/transparency> and [here](#). Whenever a confidentiality request is submitted, a non-confidential version and a confidential version of information claimed confidential must be submitted together with each confidentiality request. You are also required to box or earmark information claimed confidential in the confidential version of the information you share with EFSA. **Finally, please note that confidentiality requests must be submitted or EFSA is required to proactively publish all information, documents and data already submitted without delay, pursuant to Article 38(1)(c) / 38(1)(d) of the GFL and Article 6(1) of EFSA's Practical Arrangements of transparency and confidentiality.**

Contact details

Please address any technical enquiries regarding the reporting of data to data.collection@efsa.europa.eu