Call for technical and toxicological data on the substances "N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine (FCM No 19) and "N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine hydrochlorides (FCM No 20) for their use in plastic materials and articles intended to come into contact with food, including in food for infants

EFSA-Q-number: EFSA-Q-2019-00763

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Deadline for registering interest: 20/01/2020

Deadline for submission of data: 20/04/2020

Updated deadline: 30/06/2022

Background as provided in the mandate[1]

The chemically and structurally similar substances N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine (FCM no 19), and N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine hydrochlorides (FCM No 20) are currently authorised as additives for the manufacture of plastic food contact materials (FCM), and are listed in Annex I of Regulation (EU) No 10/2011[2], with a Group Specific Migration Limit (SML (T)) of 1.2 mg/kg food and additional restrictions.

A business operator notified EC scientific evidence on FCM 20 that indicates this substance may cause previously unknown adverse effects to health in an OECD 414 developmental toxicity study that was conducted as part of additional testing required under REACH.
Given the potential concerns regarding these two substances based on the new evidence submitted by the business operator and the t-TDI on which the present SML is based, the Commission requested EFSA to review and, if necessary, to update the initial assessments made by the SCF and EFSA, as provided for in Article 12(3) of Regulation (EC) No 1935/2004[3]. The European Commission asked EFSA to evaluate whether their authorisations are still in accordance with the requirements of this Regulation.

The European Commission asked EFSA to make use of all the available information on the safety of the substances from the dossier supporting the original application, the data submitted to EFSA in 2006, 2014 and any additional information that may be available to the applicant and to other users. To address this request, EFSA has requested the applicant to submit all the above-mentioned available data and information.

[1] EC Mandate, 2018; Ref. Ares (2018)6424827 - 13/12/2018; http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?3
[2] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1.
[3] Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4-17.

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With this call for data, EFSA aims to collect data that may be available to business operators and other interested parties on the safety of the substances in relation to their use to manufacture plastic food contact materials. This should ensure that the most complete data package will be used by EFSA for the elaboration of its opinion.

The request has been registered under the references EFSA-Q-2019-00763. Please use that reference for further communication with EFSA concerning this evaluation.

Overall objective

The purpose of this call for data is to offer interested parties the opportunity to submit documented information (published, unpublished or newly generated) relevant to the characterisation and the safety of the substances "N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine (FCM No 19) and "N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine hydrochlorides (FCM No 20) for their use in plastic materials and articles intended to come into contact with food, including in food for infants.

Information sought

EFSA invites business operators and other interested parties (governments, interested organisations, universities, research institutions, companies) to submit available information on the characterisation and the safety of the substances "N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine (FCM No 19) and "N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine hydrochlorides (FCM No 20), in relation to:

- **specification of the substances, if any;**
- **description of the manufacturing process(es), purity of the substances and impurities related to the manufacturing process(es) including the manufacturing process(s);**
- **physical and chemical properties of the substances;**
- **uses of the substances including uses in plastic articles expected to be in contact with food for infant;**
- **migration of the substances, their impurities and any related reaction and degradation products;**
- **residual content of the substances in the plastic food contact articles;**
- **potential toxicity, including its potential to accumulate in human;**
- **as well as any other data relevant for the safety assessment.**

Data submitted should follow the recommendation of the EFSA Note for Guidance[4] (providing the details in the corresponding section), with the exception of the non-applicability in this case of the tiered approach for data requirement. In other words, all the data relevant to the toxicological potential of the substances should be submitted and should not be limited to the minimum data requirement triggered by the estimated exposure/migration level as per the EFSA Note for Guidance
The information shall be documented and supported, as far as possible, by raw data and technical/scientific reports.

[4] Note for Guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials; https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.21r

Deadline for submission of data and disclosure of contact details

Business operators and other interested parties should provide earlier or at the latest by 30/06/2022 the information described below.
To assist our planning for assessment purpose, within one month from the publication of this call, please communicate in writing by email 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 via e-mail and by updating the current call.
Information not submitted within the final deadline will only exceptionally be considered, and EFSA can decide to finalise its opinion solely on the basis of the information provided within the final deadline (30/06/2021).
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 and address of your organisation/business, e-mail address and telephone number) to the other parties that has expressed an interest to provide the requested information. If you do not wish to make these contact details available, clearly indicate it in your first communication.

Confidentiality

In order to comply with its requirements for transparency as outlined in Article 38 of Regulation (EC) No 178/2002 and in article 20 of Regulation (EU) No 1935/2004, EFSA has to disclose in its published scientific opinions data received/available which are considered essential for the scientific assessment, as well as background information supporting the scientific reasoning. However, 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, or whenever its conclusions highlight foreseeable adverse health effects. Furthermore, EFSA is subject to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents[5].
Therefore, business operators and/or interested parties submitting relevant datasets in response to this call are requested to proactively and clearly identify, as part of their submission, all parts or bits of information/data they consider as deserving confidential treatment. For each item for which a request for confidential treatment is submitted, the concerned individual has to provide verifiable justification supporting each request by indicating the reasons and circumstances proving why the disclosure of these elements would cause them financial harm. Note that the information described in article 20(2) of the Regulation (EU) No 1935/2004 cannot be confidential.
In application of Article 20(3) of Regulation (EU) 1935/2004, following a proposal from EFSA, the Commission will decide after consulting the interested business operator and/or the other interested parties, which information should be kept confidential. The full opinion will be published in accordance with Article 10(6) of Regulation (EC) No 1935/2004 once the decision on confidentiality will be received from the European Commission.

[5] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43–48.

Submission of information

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

- **cover letter that should contain:**
  - **Reference to the specific call and the specific EFSA question number indicated (EFSA-Q-2019-00763);**
  - **Reference to the substances concerned and their FCM number;**
  - **The contact details[6] (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;**
- statement 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 better 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.
- separate folders with the confidential and with the non-confidential parts.
- **the consent that EFSA may share the submitted data or information with the European Commission/Member States national authorities dealing food contact materials safety;**

Correspondence

Please send all electronic correspondence, including enquiries to: fip@efsa.europa.eu
Submissions should be sent to the following address:

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

Following the emergency restrictions on movement imposed by EU governments due to the COVID-19 outbreak, a Decision by EFSA's Executive Director has been recently signed concerning the electronic submission of applications for regulated products during COVID-19 outbreak.

With this decision, exceptionally and during the emergency period due to the Corona virus outbreak - EFSA will allow companies and institutions (applicants, the European Commission, EU Member States) to share documentation with the Authority through their chosen internet-based software. This Decision applies to the submission of technical dossiers, update of technical dossiers and responses to requests for missing or additional information during the life-cycle of the application (see related news[7]) These measures will remain in place until further notice.

[6] 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).
[7] https://www.efsa.europa.eu/en/news/e-submission-regulated-product-applications-through-internet-based-software