Call for use level and/or analytical data for the exposure assessment of lycopene – EFSA-Q-2023-00639

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Deadline:
30 September 2024 - 23:59 (CET)

Submission deadline: 30 September 2024

1 Background

On 28 March 2023, the European Food Safety Authority (EFSA) adopted a scientific opinion on "Safety of yellow/orange tomato extract as a Novel food pursuant to Regulation (EU) 2015/2283". In its opinion, EFSA concluded that the safety of the novel food has not been established under the proposed conditions of use. In that opinion, EFSA indicated that the estimated intakes of the novel food would lead to an exceedance of the ADI when considering natural occurrence and exposure to lycopene when used as a food additive.

The above-mentioned opinion refers to a number of EFSA assessments (EFSA AFC Panel 2008, EFSA NDA Panel, 2008a; 2008b; 2008c, EFSA ANS Panel 2017) concerning lycopene exposure when used as a novel food or a food additive. It is concluded from those assessments that the overall exposure to lycopene when all possible sources are taken into account, namely from background diet, novel food and food additive use, may exceed the established ADI.

In addition, EFSA ANS Panel, in its 2017 opinion, acknowledged the uncertainties in the dietary exposure estimates, which could result in an overestimation of the exposure to lycopene (E 160d) as a food additive in European countries and therefore concluded that a refined exposure estimate would be recommended focusing on food categories contributing the most to its estimates in order to decrease uncertainties in its current estimates.

In light of the above, in accordance with Article 31 of Regulation (EC) 178/2002, the European Commission requested EFSA to provide scientific and technical assistance as regards the exposure assessment of lycopene.

In particular, EFSA was requested to carry out an exposure assessment of lycopene taking into account the combined intakes of lycopene from background diet, from its use as a food additive in accordance with Annex II of Regulation (EC) No 1333/2008, and when used as novel food in the context of Regulation (EU) 2015/2283. In doing so, EFSA should take into account data

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on the intake of lycopene from these three sources. To this end, EFSA should collect data via literature search and call for data.
In order to ensure a reliable exposure assessment, it is important that EFSA retrieves from interested parties all relevant data.

Therefore, in accordance EFSA launches a public call for data in order to acquire documented information (published and/or unpublished) on lycopene.

2 Overall objective

The purpose of this call for data is to offer interested parties (e.g., food business operators, national food authorities, research institutions, academia) and/or other stakeholders, the opportunity to submit documented information (published and/or unpublished) relevant to the intake assessment of lycopene from the background diet, use of lycopene as a food additive (E 160d) or as novel food. For this purpose, use level and analytical data are aimed to be collected, using different submission procedures that are explained in detail below.

3 Submission of use level data

Interested business operators and/or parties (individual food manufacturers and food manufacturer associations) are invited to submit data on use levels in foods and beverages for human consumption for lycopene as a food additive (E 160d) or as a novel food. In order to streamline the data collection exercise, food manufacturers are invited to liaise with the relevant food manufacturer associations for the data submission. In particular, data providers shall ensure that the same data are not sent several times to EFSA (e.g., by both the food manufacturer and also by the association to which the food manufacturer belongs to).

If an interested party has information that lycopene as food additive or as novel food is not used for one or several food categories, this information is highly relevant for EFSA. Such information will be cross-checked with information sent by all interested parties.

Data providers should be aware that EFSA may need to contact them once the initial submission is received. The aim is to clarify foods not well characterised/identified or to check any possible mistakes (e.g., on maximum permitted levels or MPLs) or not plausible data (e.g,. on reported levels, proposed dilution factors). Replies to these requests are strongly encouraged as EFSA reserves the right to discard these data if feedback is not received.

Data submission of use levels of lycopene (E 160d) as food additive in food and beverages intended for human consumption should be reported in the MS Excel template AddUseLevTemplate.xlsm, while use levels of lycopene as novel food should be reported in the MS Excel template NovelFoodUseLevTemplate.xlsm.

The format of the templates is structured in accordance with the Guidance on Standard Sample Description [1] (SSD Guidance) and includes features that support manual data entry.

To submit use level data on any of the two legal frameworks please download the zip file 'Use_data_submission_lycopene.zip', which also contains a technical guidance on the use of

the reporting template ('Guidance on using addUseLevTemplate and NovelFoodUseLevTemplate.pdf'). Please follow the instructions described in the first work sheet of the templates, and more extensively within the technical guidance for the correct use of the reporting format to avoid compromising its functionalities.

Should you need any support in filling in the reporting format, please contact data.collection@efsa.europa.eu

Interested business operators and/or parties should submit the information/data in electronic format **exclusively via the tool Submission Builder "Portalino"** (available here).

Submission of data in any other form (email, third party e-submission platforms, etc) will not be accepted.

Information on how to use Portalino and submit confidentiality requests are available online here. This user guide provides information about the submission of food-chain dossiers and datasets via Portalino. As such it should be read together with the User Guide on Confidentiality and with any administrative and scientific documents relevant for the submission, if applicable

Interested business operators and/or interested parties should submit the following information to EFSA **via Portalino**, clearly stating:

- **in the Subject of the submission: Call for data for the exposure assessment of lycopene - EFSA-Q-2023-00639.**
- The contact details (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;
- If claiming confidentiality for one or more sections of the documents/data submitted, two separate versions (**confidential** and **non-confidential**) of the submitted information/data must be submitted, as indicated here. Each section claimed confidential must be accompanied by a confidentiality request in Portalino. You are also required to box or earmark each information/passage claimed confidential in the confidential version of the information you share with EFSA.

Please note that confidentiality requests must be submitted if information should be kept confidential since EFSA is required to proactively publish all information, documents and data it receives 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. In case EFSA receives a new mandate for which data collected via this call will be used as a basis for EFSA's outputs, EFSA will also apply these rules of transparency: data providers will be notified about the requirement to submit their confidentiality requests via the Portalino at least 3 months before the planned publication date of the output.

EFSA retains the possibility to use the data for the safety assessment of the same or other substance under the same or other legal or regulatory frameworks.

Please note that EFSA may, where legally possible, use or re-use relevant data for the evaluation of the same or another substance under the same or a different legal or regulatory framework from the one mentioned above.

[1] European Food Safety Authority; Standard sample description for food and feed. EFSA Journal 2010;8(1):1457 [54 pp.]. http://www.efsa.europa.eu/en/efsajournal/doc/1457.pdf

4 Deadlines for submission of use level data and disclosure of contact details

Interested parties and stakeholders should provide by **30/09/2024** the information described below.

In accordance with Article 6(4) of the Regulation (EU) No 257/2010 the information not submitted within the final deadline will only exceptionally be considered and EFSA can finalise its opinions on the basis of information provided within the deadline.

5 Submission of analytical data / results

Food manufacturers, national food authorities, research institutions, academia, food business operators and other stakeholders are invited to submit analytical (occurrence) data on lycopene as a food additive (E 160d), from natural presence or as a novel food. The type of data will be reported using the eval.Info.conclusion data element, linked to the CONCLUS catalogue: "natural occurrence" if lycopene is naturally present in the matrix and "nutrient" if lycopene is used as novel food. For data on lycopene as food additive, this data element can be used to indicate presence data.

Lycopene is included in the priority list of substances in the annual call for food additive occurrence data in food and beverages intended for human consumption. Additional information is provided in the published call: https://www.efsa.europa.eu/en/call/open-call-food-additive-occurrence-data-food-and-beverages-intended-human-consumption-2

Analytical data/results are not accepted if submitted through Portalino. Please be aware to follow the instructions of the call.

In order to receive access to the DCF web interface please contact: data.collection@efsa.europa.eu

6 Confidentiality

According to Article 39 of Regulation (EC) No 178/2002, EFSA shall not divulge to third parties confidential information received for which confidential treatment has been requested and justified, except for information which must be made public if circumstances require so, in order to protect public health. It follows that confidential treatment may be given by EFSA to

disclosure the information of which might significantly harm the competitive position of business operators or other interested parties.

Therefore, business operators and/or the interested parties should indicate which information they wish to be treated as confidential and provide verifiable justification supporting such request.

7 Correspondence

Please address any **administrative enquiries** (e.g. links, deadline inquires etc) to RAL@efsa.europa.eu.

Should you require **assistance when filling in the Excel file for analytical data/use levels** or have specific questions on how to send the data, please contact data.collection@efsa.europa.eu.

8 Documents

Use_data_submission_lycopene.zip including the following files:

- MS Excel® AddUseLevTemplate.xlsm
- MS Excel® NovelFoodUseLevTemplate.xlsm
- Guidance on using AddUseLevTemplate and NovelFoodUseLevTemplate.pdf
- Annex Food Category Description
- Annex Food Category Description Novel Foods.xlsx

9 Related topic(s)

Food additives Food ingredients and packaging Novel Food Nutrition