Call for data for the re-evaluation of technical hexane used as an extraction solvent in the production of food and food ingredients

EFSA-Q-2025-00358

Via Carlo Magno 1A
43126 Parma – ITALY
+39 0521 036 111
www.efsa.europa.eu

EFSA-Q-number: EFSA-Q-2025-00358
Published:22/06/2025
Deadline for submission of data:23/10/2025

BACKGROUND

'Hexane' (henceforth called 'technical hexane') is an authorised solvent used in the extraction of food and food ingredients, defined as a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64 °C and 70 °C, for which conditions of use are specified in Part II and III of Annex I to Directive 2009/32/EC.

In its 2024 report[1], EFSA concluded that there is a need for a re-evaluation of the safety of the use of technical hexane as an extraction solvent in the production of food and food ingredients. Based on the conclusion of the report, the European Commission asked EFSA to carry out the re-evaluation (mandate received on 23 May 2025), which will be addressed by the EFSA Food Contact Materials (FCM) Panel.

To ensure an effective re-evaluation of the safety of technical hexane, it is important that EFSA retrieves relevant data. Therefore, EFSA launches a public call for data in order to acquire documented information (published, unpublished or newly generated). EFSA will then consider the relevance of the information provided for the risk assessment. The submission of the requested information is without prejudice to the final opinion of the FCM Panel.

OVERALL OBJECTIVE

The purpose of this call for data is to collect documented information (published, unpublished or newly generated) relevant to the re-evaluation of technical hexane used as an extraction solvent in the production of food and food ingredients, from interested parties (e.g., food business operators, national food authorities, research institutions, academia) and/or other stakeholders.

PREVIOUS RELEVANT EVALUATIONS

Technical hexane is currently authorised as an extraction solvent of food and food ingredients by Directive 2009/32/EC with maximum residue limits (MRLs) specified for various food categories.

Its safety was evaluated by the Scientific Committee on Food (SCF), with the last evaluation

[1] Technical Report on the need for re-evaluation of the safety of hexane used as an extraction solvent in the production of foodstuffs and food ingredients (EFSA, 2024). https://www.efsa.europa.eu/en/supporting/pub/en-9001

performed in 1996 (SCF, 1996[2]). The SCF derived a no-observed-effect-level (NOEL) of 23 mg/kg body weight (bw) for *n*-hexane (which was considered as the most relevant component of technical hexane). Based on an estimated exposure of the consumer to technical hexane residues of 0.1 mg/kg bw per day, it concluded that a margin of exposure of around 200 would exist between the exposure and the NOEL and, hence, that the use of technical hexane as an extraction solvent was acceptable.

In 2024, EFSA published a technical report on the need for the re-evaluation of the safety of the use of technical hexane as an extraction solvent in the production of food and food ingredients and concluded that additional information on the identity, impurities and use of the solvent, on the actual occurrence in food and on toxicological data is needed to perform the re-evaluation.

DATA SOUGHT

EFSA kindly invites interested parties to submit information as outlined below for each specific objective.

- EFSA considers that the **identity, specifications and the current application** of technical hexane should be better specified. Information on the manufacturing process, solvent extraction process and current applications will be used to assess the potential presence of toxicologically relevant impurities (section 1).

- An estimation of the **total dietary exposure** is also needed. In its 2024 report, EFSA based its exposure scenario on regulatory limits, i.e. not on actual occurrence data of technical hexane residues in food and food ingredients. To perform a refined exposure assessment, comprehensive information on the actual uses of technical hexane and representative occurrence data in food and food ingredients should be collected (section 2).

- EFSA considers that the available **toxicological data** need to be (re)evaluated in order to conclude on the safety of technical hexane use and the appropriateness of its currently authorised MRLs (section 3).

Stakeholders/business operators that wish to submit relevant information should consult the **EFSA report** on the need for re-evaluation of technical hexane and the EFSA **Guidance for submission for food additive evaluations** (EFSA ANS Panel, 2012[3]) for the preparation of the data submission. The guidance is currently being updated, with its publication expected in late 2025.

1. IDENTITY, SPECIFICATIONS AND APPLICATION

COMPOSITION, IMPURITIES AND SPECIFICATIONS

Directive 2009/32/EC defines technical hexane as 'a commercial product consisting essentially of acyclic saturated hydrocarbons containing six carbon atoms and distilling between 64°C and 70°C', with *n*-hexane as main constituent. Its composition in terms of the identity and fraction of

[2] SCF (Scientific Committee for Food), 1996. Reports of the Scientific Committee for Food. 35th series. Hexane used as an extraction solvent. Opinion expressed on 17 June 1994. Available online: https://food.ec.europa.eu/document/download/ff57e43e-a6ef-49dc-a79f-d4b74da7f0d9_en?filename=sci-com_scf_reports_35.pdf

[3] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). Guidance for submission for food additive evaluations. EFSA Journal. 2012 Jul;10(7):2760.

components and potential impurities is not directly specified. In fact, the composition largely depends on factors such as the mineral oil source and the manufacturing process (which includes distillation). Information on the composition of technical hexane is scarce, but typical components other than *n*-hexane are reported to be hydrocarbons with a boiling point around that of n-hexane, i.e. 2-methyl-pentane, 3-methyl-pentane and heptane, as well as some minor components such as 2,4-dimethylpentane, cyclopentane, cyclohexane and methyl-cyclopentane (US EPA, 2005). JECFA (2006) mentioned potential impurities in 'food grade' technical hexane, i.e. PAH, benzene and lead. Mineral oil hydrocarbons (MOH) levels in 'fresh' technical hexane were reported in recently published articles (see EFSA's 2024 report). As the legislation does not set specifications for impurities, various grades of technical hexane for food extraction are available on the market, with their specifications depending on the supplier.

In order to carry out the safety assessment, additional information following the EFSA Guidance for submission for food additive evaluations and the EFSA report on technical hexane is sought from the business operators and other interested parties. In particular:

- Description of the **processes used to produce technical hexane**, including the description and goal of key steps involved (for example to remove impurities).
- **Analytical data** on the **composition** of technical hexane, including typical levels and expected range of *n*-hexane and of all the other components that may be part of the technical hexane mixture.
- Information **on impurities of potential toxicological relevance** (i.e. identity[4] and analytical data on their levels in technical hexane), together with specifications of technical hexane used in the extraction of food and food ingredients.
- Methods for analysis of technical hexane in food.

Compositional data are sought for each relevant step of the extraction process, i.e. for "fresh" technical hexane and for that recycled during the extraction process, supported by the description of the method(s) used, certificates of analysis and relevant raw and validation data. The analytical data provided should adequately cover the between-batches variability (see the EFSA Guidance for submission for food additive evaluations) and be representative of the technical hexane currently placed in the EU market.

APPLICATION OF TECHNICAL HEXANE AS AN EXTRACTION SOLVENT FOR THE PRODUCTION FOOD AND FOOD INGREDIENTS

The 2024 EFSA report considered that the extraction process may propagate the impurities of technical hexane to the extracted food, depending on their intrinsic physicochemical properties, the type of extraction process and the extent of recycling of the solvent within the process. These considerations were based on typical extraction processes for vegetable oils (i.e. only one of the authorised applications) and did not consider the actual presence of impurities in the extracted foods.

Therefore, to conclude on the safety, information on the identity and levels of impurities in technical hexane (section 1) should be completed with information on the processes of solvent extraction. In particular, the following information is sought:

- Information on the **actual applications** of technical hexane as an extraction solvent (i.e. for which food/food ingredient it is currently used; what is the fraction of that food/food ingredient that is extracted with technical hexane).
- Description of the various types of **food extraction processes** using technical hexane as an extraction solvent. The description should include a comprehensive description of how

[4] For impurities consisting of various chemical classes of different toxicological potential such as MOH, the information provided should identify the various classes.

the food is extracted and how the solvent is separated from the food and recycled/recovered/purified/replenished. In particular, information is sought on the amounts of solvent that are used per amount of extracted food and the fraction of "fresh" solvent that is added to replenish losses.
- Information on the potential **refinement steps** that are applied to purify the solvent and the extracted food before, during and after the process.
- information on the **potential propagation of impurities** throughout the extraction process.
- Information on the fate of technical hexane components during the processing of food, i.e. if degradation/reaction products are expected to be generated.

2. ESTIMATION OF EXPOSURE

In the 2024 report, EFSA applied a conservative exposure assessment (called 'MRL scenario'), considering the MRLs set by Directive 2009/32/EC and consumption data from the EFSA Food Consumption database. It resulted in exposure estimates generally exceeding the estimate made by the SCF (i.e. 0.1 mg/kg bw per day for adult consumption), with exposure for children, toddlers and infants deviating to a greater extent than for other age groups. Under the MRL scenario, the maximum exposure at the 95th percentile for infants was estimated at 1.55 mg/kg bw per day. For infants below 16 weeks of age, it was up to 7.8 mg/kg bw per day.

The exposure assessment was based on regulatory limits and conservative assumptions on the applicable food categories. The report noted that "A refined exposure assessment may be performed only after the collection of information on (i) measured data on the composition of technical hexane used for extraction purposes, (ii) its range of application, (iii) knowledge on technical hexane residues in food and extracted food commodities, and (iv) the consumption of specific products.

The report did not consider residues of technical hexane in food of animal origin resulting from the preparation of feed or feed ingredients. As certain types of feed may contain hexane residues (Commission Regulation (EU) No 68/2013[5]), it is possible that technical hexane residues are carried over from feed to food. Certain components of technical hexane may be also naturally occurring in food. For such reasons, information on residue levels (item 2b) should be sought for any food and food ingredient (i.e. not only the categories for which technical hexane is authorised by Directive 2009/32/EC).

Based on the considerations above, to adequately estimate the exposure to technical hexane residues, individual food manufacturers and food manufacturer associations are invited to submit data on:

a. The **food** and **food ingredient categories** that may contain technical hexane due to its use as an extraction solvent in the preparation of food and food ingredients. This information should be submitted by using the file "Data_collection_technical hexane_EFSA-Q-2025-00358" attached to this call for data.

b. **Analytical data** of technical hexane residues **in food and beverages for human consumption**. Considering that technical hexane consists of various components, data should be submitted at least on residues of n-hexane. Please see the section "Data submission of analytical data on technical hexane residues in food" on how to submit such data.

[5] Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials. OJ L 29, 2013: p. 1-64. https://eur-lex.europa.eu/eli/reg/2013/68/oj/eng

3. TOXICOLOGICAL DATASET

The 2024 EFSA report concluded that the available information does not raise a concern for genotoxicity of technical hexane and *n*-hexane (i.e. its main component). However, according to the guidance on the genotoxicity assessment of chemical mixtures (EFSA Scientific Committee, 2019)[6], the genotoxicity of all the identified components needs to be addressed. The guidance foresees various evaluation routes, depending on the type of mixture and the available compositional data. Therefore, information should be sought on the genotoxicity potential of the other components of technical hexane following the EFSA guidance.

The EFSA report also considered that the toxicological information considered by the SCF is no longer sufficient to adequately conclude on the risk of technical hexane. As already reported in the SCF opinion (SCF, 1996)[7], *n*-hexane is absorbed after oral intake. Therefore, according to the EFSA Guidance for submission of data for food additive evaluations (EFSA ANS Panel, 2012), toxicity studies described in Tiers 1 and 2 are required. In general, these studies comprise (i) genotoxicity (in vitro and in vivo testing), (ii) toxicokinetics/absorption, distribution, metabolism and excretion (single dose), (iii) subchronic toxicity, (iv) chronic toxicity, (v) carcinogenicity and (vi) reproductive and developmental toxicity. Depending on the outcome of these studies, additional studies described in Tier 3 could be required.

A scoping literature search showed that there is recent information on potentially adverse effects of *n*-hexane and its metabolites, e.g. neurotoxicity, kidney, liver and lung toxicity, immunotoxicity, endocrine disrupting activity, male and female reproductive toxicity, capacity to cross the placental barrier and developmental toxicity. However, the relevance of this information was not appraised in the 2024 report. The search also showed that the studies with oral exposure available in literature may be limited. As a consequence, the re-evaluation may consider toxicological studies from any route of exposure.

Moreover, it is noted that technical hexane may be used to extract food or food ingredients that are used to prepare infant formula, for example vegetable oils, soy isolates or lipids[8]. Therefore, if such use is confirmed, specific toxicological data is requested to conclude on the safety of food used for infants below 16 weeks of age (EFSA Scientific Committee, 2017)[9].

Considering all the above, EFSA 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 technical hexane, n-hexane and the other components of technical hexane. In particular:

[6]Statement on the genotoxicity assessment of chemical mixtures. EFSA Journal 2019;17(1):5519, 11 pp. https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2019.5519

[7] SCF (Scientific Committee for Food), 1996. Reports of the Scientific Committee for Food. 35th series. Hexane used as an extraction solvent. Opinion expressed on 17 June 1994. Available online: https://food.ec.europa.eu/document/download/ff57e43e-a6ef-49dc-a79f-d4b74da7f0d9_en?filename=sci-com_scf_reports_35.pdf

[8] Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (Text with EEA relevance). OJ L 25, 2.2.2016, p. 1–29. https://eur-lex.europa.eu/eli/reg_del/2016/127/oj/eng

[9] Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age. EFSA Journal 2017;15(5):4849, 58 pp, https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4849

1. Toxicological data derived from both animal and human studies (via any route of exposure), as well as from in vitro studies, including MoA studies (in vitro and in vivo). In general, the effects considered relevant for the assessment could relate to the following health outcome categories: general toxicity (repeated dose, long-term toxicity studies, especially on lung, liver and kidney), reproductive and developmental toxicity (especially developmental toxicity of reproductive, neurological and immune system), neurotoxicity, immunotoxicity, endocrine disrupting effects, genotoxicity, carcinogenicity, or any other toxicity.

2. Toxicokinetic data and ADME studies.

DEADLINE FOR SUBMISSION OF DATA

Interested parties and stakeholders should submit by **23 October 2025** the information described below, except for occurrence data on residues in food, which should be submitted between **1st April 2025 – 30 June 2025** (ChemMon 2025) and between **1st April 2026 – 30 June 2026** (ChemMon 2026).

In order to facilitate the collaboration with all stakeholders that are submitting data, we are seeking the consent to disclose personal data (name, e-mail address and telephone number) to the other parties that have expressed the intention to provide information. In case stakeholders do not wish to make contact details available, they will have to clearly indicate it in their first communication to EFSA.

CONFIDENTIALITY

In order to comply with its requirements for proactive transparency, EFSA must, *inter alia,* make public the information on which its scientific outputs are based, as outlined in Article 38(1)(d) of Regulation (EC) No 178/2002, the "General Food Law" (GFL) and Article 6(1)(i) of EFSA's Practical Arrangements concerning transparency and confidentiality ("EFSA's Practical Arrangements"). Information/data received in the context of the present call are subject to the afore-mentioned proactive transparency requirements insofar as they will constitute information on which scientific outputs, including scientific opinions, are based.

However, in accordance with Articles 39-39e of the GFL confidential status may be awarded to information the disclosure of which might potentially harm the information owner to a significant degree. Provided that the conditions set out in Articles 39-39e and further detailed in EFSA's Practical Arrangements are satisfied, EFSA must not make public any information/data for which confidential treatment has been requested and duly justified pending its confidentiality assessment where urgent action is essential to protect human health, animal health or the environment.

SUBMISSION OF INFORMATION/DATA

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. The only exception is data requested under point 2b (analytical data of technical hexane residues in food, see next chapter).

Information on how to use Portalino and submit confidentiality requests are available online here. Information on how to use Portalino and submit confidentiality requests is available here. Information regarding confidentiality can be found in the User Guide on Confidentiality.
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 on technical hexane EFSA-Q-2025-00358**
- 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.

When sharing information/data with EFSA, certain parts of the information/data may be requested to be treated as confidential provided that:

i. the information falls within the scope of the closed list of information items listed in the Annex to EFSA's Practical Arrangements and
ii. the confidentiality request is accompanied by a verifiable justification that demonstrates how the public disclosure of the information/data for which confidential status is requested would harm your interests to a significant degree.
iii. When claiming confidentiality for some of the information/data, both a non-confidential (public dissemination) and a confidential version of the information/data must be submitted as indicated here. A separate confidentiality request must be submitted for each document and for each legal ground under which information is claimed confidential. A precise description of the information/data claimed confidential must be provided to enable a clear identification and the information/data claimed confidential must be earmarked in the confidential version and redacted in the non-confidential version.

For submissions which do not contain any confidential information, only a non-confidential (public dissemination) version has to be uploaded to Portalino.

Please note that EFSA may, where legally possible, use or re-use relevant information or data (e.g., technical, toxicological data) for the assessment of the same or another substance/topic under the same or a different legal or regulatory framework from the one mentioned above.

DATA SUBMISSION OF ANALYTICAL DATA ON TECHNICAL HEXANE RESIDUES IN FOOD

HOW TO SUBMIT OCCURRENCE DATA

Data must be submitted in electronic format (XML) 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. For new accounts, to obtain the credentials please contact data.collection@efsa.europa.eu.

EFSA will only accept data in SSD2 (Standard Sample Description version 2) format and all occurrence data, received under the current contaminants data collection, need to be transmitted through the Data Collection Framework (**DCF**).

In case data are compiled manually, EFSA prepared a simplified tool, available at Zenodo, which supports new data providers with the preparation of datasets and consequently the preparation of XML file(s); the XML file(s) must be generated for direct submission to the DCF.

The tools for reporting chemicals are updated annually and are published each year, close to the opening of data collection. The data collection period for occurrence (analytical) data on technical hexane residues will be between **1st April 2025 – 30 June 2025** (ChemMon 2025) and between **1st April 2026 – 30 June 2026** (ChemMon 2026)**.**

Based on the **SSD2 model**, used in **Chemical Monitoring data collection,** there are specific reporting standards and a number of **mandatory elements** as minimum requirements for the successful transmission of data to EFSA and consequently the use of this data for future risk assessment and risk management measures.

Reporting elements, such as Sampling programme identification code (proId), Programme legal reference (progLegalRef), Sample taken identification code (sampId), Country of sampling (sampCountry), Coded description of the parameter(paramCode), are some of the **mandatory fields** which have to be reported for the data to be compliant with the SSD2 model. The full list of the mandatory elements can be found in Table 7, page 64, of the most recently updated Chemical monitoring reporting Guidance.

In case of an active participation in the preparation and transmission of occurrence data through DCF, it is advised to contact EFSAs IDATA Unit through the functional mailbox: data.collection@efsa.europa.eu, with the **request to create new DCF users** for Chemical Monitoring data collection.

SUPPORTING MATERIAL

Please find below some additional practical / background information regarding the Chemical Monitoring Data Collection (including the reporting of contaminants):

- short **video tutorial** describing how to send data to EFSA: https://www.youtube.com/watch?v=x4xPXDiWnpw
- Guidance for 2025 data collection: Chemical monitoring reporting Guidance; this document includes important information on the mandatory and optional data elements
- **ChemMon 2025** tools for reporting chemical to EFSA (supporting material in Zenodo, the tools and supporting materials are updated annually and are available in the beginning of April here: https://zenodo.org/doi/10.5281/zenodo.3714966.)
    - The Simplified tool, which is mainly used for the preparation of the datasets, is an excel-based template and can be further transformed into xml file and transmitted to EFSA platform, Data Collection Framework (DCF)

Considering that the data collection runs from April to June, it is kindly advised to go through the indicated material. Please let us know if any questions arise by sending an email to data.collection@efsa.europa.eu

CORRESPONDENCE

Please address any **enquiries** to RAL@efsa.europa.eu.
Please remember to indicate in the title of your email: **Call for data on hexane EFSA-Q-2025-00358**