

Call for data for the evaluation of the safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C.Presl)

NIF Unit



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# CALL FOR DATA FOR THE EVALUATION OF THE SAFETY IN USE OF PREPARATIONS FROM THE FRUITS OF SWEET AND BITTER FENNEL (*FOENICULUM VULGARE* MILL. AND *FOENICULUM PIPERITUM* (UCRIA) C.PRESL)

EFSA-Q-number: EFSA-Q-2022-00804

Published: 04/07/2023

Deadline for registering interest: 04/08/2023

Deadline for submission of data: 12/01/2024

## BACKGROUND

In the context of Article 8(2) of Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of other substances to foods, the European Commission requested EFSA to assess the available information in relation to the safety in use of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C.Presl).

In order to ensure a comprehensive assessment, EFSA launches a public call for all potentially relevant data (published, unpublished or newly generated data) from interested. 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 NDA Panel.

## OVERALL OBJECTIVE

The purpose of this call for data is to offer interested parties (e.g. governments, 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institutions, academia) and/or other stakeholders the opportunity to submit documented information (published and/or unpublished) relevant to the safety evaluation of the safety in use of preparations from the fruits of sweet and bitter fennel.

## SPECIFIC OBJECTIVES

- **Specific Objective 1: occurrence data**

EFSA is looking for analytical data on the content of estragole, methyleugenol and safrole in foods (e.g. infusions, herbs, spices, compound foods) and food supplements.

- **Specific Objective 2: use levels for supplements**



EFSA is looking for use levels recommended by manufacturers for food supplements containing plant preparations that naturally contain estragole, methyleugenol and safrole.

- **Specific Objective 3: biological and toxicological data**

EFSA is looking for data on the absorption, digestion, absorption and metabolism (ADME) of estragole from fennel fruit preparations (i.e. when consumed in a food matrix) and whether ADME of estragole consumed in a food matrix is different to the ADME of estragole as pure substance.

EFSA is also looking for evidence for the extent to which the 1'-hydroxylation pathway is activated or sulphoconjugation of 1'-hydroxyestragole occurs at different levels of dietary exposure to estragole, as well as for the effect of the matrix (i.e. preparations from sweet and bitter fennel fruits) on the sulphoconjugation of 1'-hydroxyestragole, on DNA adduct formation and on the carcinogenicity of estragole.

## DATA SOUGHT AND DATA SUBMISSION FORMAT

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

### Specific objectives 1 and 2 (occurrence data and use levels for supplements)

To submit data in the context of specific Objectives 1 and 2, please fill in the Excel file downloadable on the EFSA webpage of this call. This Excel file contains a selection of different data fields to collect information considered as essential to assess the reliability of the data before being used for the exposure assessment. Dedicated data fields are also included for food supplements (dose forms, weight of the dose form, etc.) and tea/herbal infusions (e.g. preparation) to allow precise and accurate estimations of the dietary exposure.

Data providers are encouraged to provide the information on the use levels in the appropriate data field described in the above-mentioned Excel file. 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 [nda\\_callfordata@efsa.europa.eu](mailto:nda_callfordata@efsa.europa.eu).

### OTHER OPTION TO SUBMIT OCCURRENCE DATA

Please be informed that together with sending analytical data/use levels in the context of this call for data, it is also possible to submit analytical data as part of the 'EFSA Call for continuous collection of chemical contaminants occurrence data in food and feed'. These data must be submitted in electronic format (XML) to the EFSA Data Collection Framework (DCF) in SSD2 (Standard Sample Description version 2) format. You find all the details about this call [here](#) ([deadline 31 August 2023](#)).

### Specific objective 3 (biological and toxicological data)

EFSA is seeking data for the evaluation of the following questions :

1. Is the ADME of estragole consumed in a fennel food matrix different from the ADME of estragole as pure substance ?
2. To which extent is the 1'-hydroxylation pathway activated and to which extent does



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sulphoconjugation of 1'-hydroxyestragole occur at different levels of dietary exposure to estragole?

3. What is the effect of the matrix (i.e. preparations from sweet and bitter fennel fruits) on the sulphoconjugation of 1'-hydroxyestragole, on DNA adduct formation and on the carcinogenicity of estragole?

Examples of correct data formats:

- full study reports
- articles or reports under preparation (newly generated data)

Examples of incorrect data formats:

- abstracts
- posters

## DEADLINES FOR SUBMISSION OF DATA AND DISCLOSURE OF CONTACT DETAILS

Interested parties and stakeholders should provide by **12/01/2024** the information described below.

Within 4 weeks from the publication of this call, please communicate in writing by e-mail to: [nda\\_callfordata@efsa.europa.eu](mailto:nda_callfordata@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.

To facilitate the collaboration of all interested parties to provide the data needed, we are seeking your consent to disclose the name and address of your organisation/business 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

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 so require, in order to protect public health. As a result, confidential treatment may be given by EFSA to information the disclosure of which might significantly harm the competitive position of business operators or other interested parties.

## 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.

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 fennel-EFSA-Q-2022-00804" (the question number is indicated in the call for data on EFSA's website)**
- **in the Subject of the submission:** reference to the specific substance or process concerned within the call, when applicable.
- 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;
- Two separate versions (confidential and non-confidential) of the submitted information/data, 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.

## POSSIBILITY FOR EFSA 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 information or data (i.e. technical, toxicological 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.

## CORRESPONDENCE

Please address any **technical enquiries** to [RAL@efsa.europa.eu](mailto: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 [nda\\_callfordata@efsa.europa.eu](mailto:nda_callfordata@efsa.europa.eu).