Call for data for the Scientific Opinion on the evaluation of the safety in use of plant preparations containing hydroxycitric acid

NIF Unit

CONTENTS

Call ***3***

Background **3**

Overall objective **3**

Specific objectives **3**

data sought and data submission format **4**

Deadlines for submission of data and disclosure of contact details **5**

Confidentiality **5**

Submission of information/DATA **6**

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. 6

Correspondence **7**

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EFSA-Q-number: EFSA-Q-2022-00805
Published: 05/07/2023
Deadline for registering interest: 07/08/2023
Deadline for submission of data: 12/01/2024

CALL

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 on the safety of hydroxycitric acid (HCA) in foods including preparations such as food supplements.

In order to ensure a comprehensive assessment, EFSA launches a public call for all potentially relevant available data (published, unpublished or newly generated data) from interested parties. 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. 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institutions, academia) and/or other stakeholders, the opportunity to submit documented information (published and/or unpublished) relevant to the re-evaluation of HCA from all sources in foods including preparations such as food supplements.

SPECIFIC OBJECTIVES

- **Specific Objective 1: occurrence data**

EFSA is looking for analytical data on the content of **HCA** in plant preparations and food, including food supplements.

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

EFSA is looking for use levels recommended by manufacturers for food supplements containing HCA

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

EFSA is looking for biological and toxicological data to support the assessment of a causal relationship between dietary exposure to HCA as single substance and/or in plant preparations and the a priori identified adverse effects, including data on absorption, digestion, absorption and metabolism for HCA and within the food matrix.

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 at the bottom of the webpage. 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 dietary 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.

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 (botanical preparation and its components)

EFSA is seeking data to answer the following assessment sub-questions:

Table 1: Assessment sub-questions and identified potential adverse effects

Number	Sub-question	Identified potential adverse effects
1	What is the absorption, distribution, metabolism and excretion (ADME) of HCA?	• Body weight loss resulting from a toxic mode of action of HCA • Glucose homeostasis (e.g. hypoglycaemia) • Cardiovascular system (e.g. hypotension)
2	a. Is there a causal relationship between HCA as single substance and identified potential adverse effect?	

	b. Is there a causal relationship between intake of plant preparations and food containing HCA and the identified potential adverse effect?	• Reproductive system (e.g. reproductive impairment, developmental impairment, malformations, embryonic and foetal death) • Liver (e.g. liver fibrosis/cirrhosis/necrosis/hepatitis) • Pancreas (e.g. pancreatitis) • Gastrointestinal (e.g. gastrointestinal disorders) • Nervous system (e.g. serotonin syndrome, spontaneous clonus, inducible clonus and diaphoresis, tremor and hyperreflexia) • Other (e.g. organ weights)
3	What are the potential mode(s) of action for the relationships found between preparations containing HCA as a single substance and identified potential adverse effects?	
4	What is the dose-response relationship between intake of plant preparations containing HCA or HCA as purified substance and risk of identified potential adverse effects?	

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, 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.

In order 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. It follows that 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 HCA-EFSA-Q-2022-00805 (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.

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.