Call for data relevant to the safety assessment of heat-treated chia seeds (Salvia hispanica L.) in the framework of Regulation 2283/2015

**EFSA-Q-number:** EFSA-Q-2019-00667

**Published:** 25/10/2019

**Deadline for registering interest for submission:** 25/11/2019

**Deadline for submission of data:** 25/02/2020

**Background**

The first authorisation for placing on the Union market of chia seeds (Salvia hispanica L.) as a novel food to be used in bread products was granted by European Commission (EC) Decision 2009/827/EC\(^1\) following the European Food Safety Authority’s Opinion (EFSA NDA Panel, 2009\(^2\)). Subsequent authorisations for extension of use of chia seeds pursuant to Article 4 of Regulation (EC) No 258/97\(^3\) were based on risk assessments carried out by the Member States national authorities. This lead to further authorisations of chia seeds in the following food categories: bread products, baked products, breakfast cereals, fruit, nut and seed mixes, fruit juice and fruit/vegetable blend beverages, pre-packaged chia seed as such, fruit spreads, yoghurt, sterilised ready to eat meals based on cereal grains, pseudo-cereals and/or pulses.

Those requests for extensions of use which were submitted but not assessed prior to 1 January 2018 were forwarded by the EC to EFSA in accordance with the Article 35(1) of Regulation (EU) 2015/2283\(^4\).

On 16 July 2018\(^5\), the EC requested EFSA to carry out an overall safety assessment for chia seeds in view of updating the 2009 EFSA NDA Panel opinion to ensure that the currently authorised uses, and the requested extensions of use, comply with the requirements of Article 7 of Regulation (EU) 2015/2283.

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When carrying out the risk assessment, EFSA identified one study on wheat-based biscuits (Mesias et al., 2016\textsuperscript{6}) which reported that partial replacement of wheat flour by chia flour as dough ingredient (10\%, 15\% and 20\% chia flour, respectively) and baking at 190\(^\circ\)C resulted in increased formation of the process contaminant acrylamide compared to the control. EFSA considered that baking normally implies heat treatment above 120\(^\circ\)C, temperatures at which acrylamide may be formed. EFSA noted that also other extended uses may include heat treatment during processing or cooking procedures at temperatures which may result in the formation of process contaminants such as acrylamide. In the absence of information that addresses such possible formation of acrylamide in the applications submitted, the safety of such proposed uses could not be evaluated in the scientific opinion (EFSA NDA Panel, 2019\textsuperscript{7}) published on 17 April 2019. That safety assessment covered only the use of chia seeds in foods which are usually not subject to thermal processing or cooking procedures.

In order to complete the safety assessment of chia seeds, the EC submitted an additional request\textsuperscript{8} to EFSA for a scientific opinion on the safety of chia seeds in foods subject to thermal processing which may result in the formation of processing contaminants.

**Overall objective**

The purpose of this call is to collect data relevant to the evaluation of the safety of heat-treated chia seeds.

**Information sought**

EFSA kindly invites all interested parties (governments, interested organisations, business operators, universities and research institutions) to submit analytical data (published, unpublished or newly generated) concerning heat-treated chia seeds in relation to:

- the formation of acrylamide, furan and alkylfurans in foods with added chia seeds which are subject to heat-treatment above 120\(^\circ\)C (during processing and/or cooking),
- the levels of free asparagine in the whole or ground chia seeds (including chia flour).

Ideally, the data submitted to this call should include also information on:

- the used chia product, e.g. chia flour, ground or whole chia seeds,
- whether all experiments were conducted with only one batch or different batches,
- the source (e.g. origins/geographical location),
- other ingredients used,
- the weight/type of the produced product,
- percentage of chia product in the final product
- heating conditions (temperature, time, the type of cooking).

\textsuperscript{6} Mesias M, Holgado F, Martínez-Ruiz G and Morales FJ, 2016. Risk/benefit considerations of a new formulation of wheat-based biscuit supplemented with different amounts of chia flour. LWT - Food Science and Technology, 73, 528–535


Deadlines for registering interest and submission of data

Interested parties should provide by the deadline of 25/02/2020 the information described above. To assist our planning for assessment purpose, within one month from the publication of this call, please communicate in writing by email 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, together with the detailed instructions on how to submit the data, 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 (25/02/2020).

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, affiliation, e-mail address and telephone number) to the other parties that have expressed an interest to provide the requested information. If you do not wish to make your 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 Regulation (EU) No 2015/2283, 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. Therefore, business operators 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.

A decision is taken by EFSA on each confidentiality request submitted by concerned individuals. Confidential status may be granted to information the disclosure of which might significantly harm the competitive position of business operators or other interested parties. Interested business operators or other interested parties will be informed by EFSA about which information or data will be granted confidential treatment, and on the legal remedies available thereto should a decision rejecting their confidentiality requests be taken.

Submission of information

Interested parties should submit by e-mail to EFSA (nda_callfordata@efsa.europa.eu) the information and the supporting documents listed below in electronic form (searchable files, including PDFs).
Alternatively, the information can be provided to EFSA using data storage devices such as memory sticks, CD-ROMs, DVDs, etc.

In both cases, the following supporting documents should be considered:

**Mandatory**

- cover letter stating:
  - The reference to the specific call for data (EFSA-Q-2019-00667)
  - The contact details\(^{10}\) (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 legal representative of the submitter that they hold all the necessary rights to grant permission to EFSA to use and, where appropriate, to disclose, the submitted information, data, document, paper or study for the purposes 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;

**Optional**

- separate folders with any relevant confidentiality request related to the submitted information or data. Information or data for which a confidentiality request is submitted should be kept to a minimum, and shall be supported by verifiable evidence composed of precise and factual information or, ideally, documents proving that the disclosure of the information would result in concrete harm to the commercial or economic interest of the concerned individual, or would undermine the protection of privacy and the integrity of the concerned individual;

- the consent that EFSA may share the submitted data or information with the European Commission/Member States national authorities dealing with novel foods applications;

- the explicit and written decision of the data owner to donate the information or data to EFSA. By donating to EFSA the submitted information or data, the concerned operator or interested party waives any right on the relevant information or data.

**Contact details for submission of information/data**

It is recommended that submissions are sent electronically to the following e-mail address: 

**nda_callfordata@efsaeuropa.eu**

Please use the same e-mail address for enquiries and further clarifications.

Alternatively, submissions on data storage devices (e.g. CD, DVD, memory stick, etc.) may be sent to the following address:

**European Food Safety Authority**

Nutrition Unit
Via Carlo Magno 1/a
I-43126 Parma
Italy

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\(^{10}\) The interested parties shall notify EFSA of any change in the contact details by sending an e-mail to 

**nda_callfordata@efsaeuropa.eu**