Call for scientific and technical data on the permitted food additive gold (E 175)

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Deadline for step 1 (Registration of the contact details of business operators interested in submitting data): 10 April 2018

Deadline for step 2 (Confirmation of data submission, deadlines and milestones): 6 September 2018

Background

According to Article 32 of Regulation (EC) No 1333/2008[1], food additives permitted in the EU before 20 January 2009 should be subject to a new risk assessment by the European Food Safety Authority (EFSA). The programme for the re-evaluation of these permitted food additives has been set up by Commission Regulation (EU) No 257/2010[2].

So far EFSA has not identified a major safety concern (such as a proven carcinogenic or genotoxic activity) for any of the re-evaluated food additives. In fact, in most cases EFSA confirms the safety of those food additives at their currently reported uses and use levels. However, for some additives EFSA has identified issues that require a follow-up. Additional specific data is needed to address those issues.

The additives whose safety re-evaluation by EFSA was hindered by limited data availability, but which are not expected to pose an immediate food safety concern, are not going to be immediately removed from the Union list of permitted additives, or their uses and/or use levels revised. Instead, business operators are requested to indicate to the Commission their interest in the continuity of approval of the additive(s) under re-evaluation and in providing, by a certain deadline, the data needed by EFSA to complete its risk assessment. In general, new toxicological studies will be needed to generate these missing data.

Once EFSA has assessed the new data, the current authorisation of the additive(s) may be revised, if needed.

If business operators do not provide the requested data (by the predefined deadline) the present authorisation will be revised based on EFSA's current scientific opinion and the additive(s) may be removed from the Union list of permitted additives. The same applies if the new data submitted is not sufficient for EFSA to conclude the risk assessment, since there will be no successive requests for additional data.

Food additives for which EFSA has identified concerns in terms of exposure or specifications will be subject to the same follow-up approach, but EFSA's assessment of the new data may not always be needed.

The Commission will undertake that the time assigned for addressing issues identified by EFSA is as short as possible and dependent on the time needed to generate and assess the required new data.

EFSA's Scientific Opinion on the re-evaluation of gold (E 175) as a food additive

The EFSA's Panel on Food Additives and Nutrient Sources added to Food (ANS) delivered a scientific opinion re-evaluating the safety of gold (E 175) when used as a food additive[3].

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.
[3] https://www.efsa.europa.eu/en/efsajournal/pub/4362

Gold (E 175) was previously evaluated by the Scientific Committee on Food (SCF) in 1975. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has not reviewed gold due to lack of data. None of the Committees established an acceptable daily intake (ADI).

The Panel noted the limited data on absorption, distribution, metabolism and excretion (ADME) of elemental gold and the absence of toxicological data on gold used as a food additive (E 175) and considered the data to be too limited to perform a risk assessment for E 175.

Elemental gold has a very low solubility and thus the systemic availability and effects are expected to be low. In contact with tissues ionic gold can be released from elemental gold and a high local concentration of gold can be reached at the site of contact.

The Panel noted that no data on subchronic, chronic toxicity and genotoxicity of elemental gold were available. The Panel concluded that, despite the absence of toxicity data, but taking into account the low solubility of elemental gold, systemic availability and thus systemic effects of elemental gold would not be expected.

The Panel recommended that the specifications for gold (E 175) should include the mean particle size and particle size distribution (± SD), as well as the percentage (in number) of particles in the nanoscale (with at least one dimension below 100 nm), present in the powder form of gold (E 175). The methodology applied should comply with the EFSA Guidance document.

Exposure estimates of gold (E 175) reached up to 1.32 µg/kg body weight (bw)/day in the maximum level exposure assessment scenario and up to 0.33 µg/kg bw/day in the refined, non-brand-loyal, exposure scenario.

Overall purpose of this call for data

To give the opportunity to business operators to submit the scientific and technical data needed to address issues identified by EFSA in the re-evaluation of the safety of gold (E 175) as a food additive.

Scientific and technical data required

The data required to address the various issues identified by EFSA in the re-evaluation of the safety of gold (E 175) as a food additive are the following:

- **Data on particle size and particle size distribution for E 175:** Because of their potential importance in toxicokinetics and toxicological effects, particle size and particle size distribution should be included in the EU specifications for the food additive gold (E 175) in Commission Regulation (EU) No 231/2012[4]. Detailed and comprehensive proposed specifications for the characterisation of the fraction of nanoparticles present in the food additive gold (E 175) should be submitted. Information on particle size and particle size distribution for the food additive gold (E 175) supported by analytical data, in line with the draft "EFSA guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health"[5], is requested. This should allow the establishment of parameters in the EU specifications for gold (E 175) that fully characterise the material used as a food additive;

[4] OJ L 83, 22.3.2012, p. 1.
[5] https://www.efsa.europa.eu/en/consultations/call/180112

- **Toxicological data for E 175:** A toxicological database should be generated with the food additive gold (E 175) (characterised as referred above), and in line with the tiered approach described in the EFSA's current guidance for submission for food additive evaluations (EFSA ANS Panel, 2012) [6].

As already mentioned above, EFSA's "Guidance for submission for food additive evaluations" provides a description of the data requirements for the evaluation of the safety of a food additive and therefore it will be useful to clarify the nature of the data requested. Also EFSA's scientific report on "Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products"[7] could be useful.

Procedure of the call for data

Step 1: Registration of the contact details of business operators interested in submitting data

Business operators are requested to communicate to the Commission **by 10 April 2018** whether they are interested that gold (E 175) remains permitted in the EU and therefore whether they are interested in providing the new data required. This communication should include full contact details of the business operator (name of business operator, name of contact person, postal address, telephone number and email address), as well as a clear indication of which of the requested data (including the food additive concerned) the business operator would be interested in providing. This communication should be submitted to the email address Sante-E2-Additives@ec.europa.eu.

Once the deadline for step 1 has elapsed, the Commission will make publicly available (on DG SANTE's website on food additives[8]) the list of business operators having expressed interest in submitting the data required. This aims at facilitating interactions among business operators and a possible coordinated action in the generation and submission of data.

Communication of interest to submit data would be considered as permission for the Commission to include the details of the party concerned in a list to be published online. In case a party objects to the online publication of its contact details, this should be mentioned on the first communication to the Commission.

Step 2: Confirmation of data submission, deadlines and milestones

Business operators are requested to confirm **by 6 September 2018** their intention to submit the new data required and to provide a list of the data they intend to submit, a timeline for submission of those data as well as a justification for that timeline. When appropriate, the timeline should be in line with EFSA's Scientific Report on "Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products". Business operators are also requested to provide a list of intermediate milestones of the data generation and when they will be achieved. This communication should be sent to the email address Sante-E2-Additives@ec.europa.eu.

The Commission will acknowledge receipt of this confirmation of data submission and will confirm the proposed timetable for data submission as well as the defined milestones and their time scheduling. Business operators will be requested to keep the Commission informed of the timely achievement of these milestones.

[6] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2760.pdf
[7] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3553.pdf
[8] http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm

After completion of this step (step 2), the data to be submitted and both deadlines and milestones will be published on the DG SANTE's website[9].

Submission of the required data

Business operators are requested to submit the above-indicated data by the agreed deadline in one paper and two electronic copies (standard physical medium such as CD, DVD or USB flash drive). Common electronic formats should be used (e.g. MS Office, Adobe Acrobat Reader) allowing content copying and printing (no content copy protection). The text of the files should be searchable using the search facilities of standard software packages. The submission should include a cover letter stating clearly in the subject line the food additive(s) to which it refers.

All data shall be submitted by registered post to the following contact address:

Bruno Gautrais, Head of Unit E2
European Commission
Directorate-General for Health and Food Safety
Directorate E – Food and feed safety, Innovation
Unit E2 – Food Processing Technologies and Novel Foods
B-1049 Brussels

Once the new data are received, they will be submitted to EFSA for evaluation and preparation of a scientific opinion, if appropriate.

Confidential data

Business operators have the right to request a confidential treatment of certain information. They shall indicate which data they wish to be treated as confidential and give verifiable justification for each part for which a confidential treatment is required following the provisions on confidentiality as laid down in Article 12 of Regulation (EC) No 1331/2008[10]. Furthermore, the business operator shall provide the Commission with two paper and electronic versions of the dossier, namely the complete dossier and a second version of the complete dossier without confidential information.

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

In line with Union policy objectives on animal welfare and testing on vertebrates, EFSA aims to avoid the duplication of testing on vertebrates, and to achieve an optimal use of the relevant financial and human resources by the private sector. Therefore, in anticipation of cases where EFSA may be interested in using or reusing relevant information or data (i.e. technical, toxicological data) for the evaluation of the same substance under a different legal or regulatory framework from the one mentioned above, or for the evaluation of another substance under the same or different legal framework as above, please indicate explicitly in writing, whether by participating in the voluntary submission of relevant data or information, you also give EFSA the permission to use and/or reuse these data for other EFSA safety assessments, and/or for a data sharing exercise with third parties or other international bodies.

[9] http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation/index_en.htm
[10] OJ L 354, 31.12.2008, p. 1.