Call for scientific and technical data on the permitted food additives oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452)

Published: 20 03 2024

Deadline for step 1 (Registration of the contact details of business operators interested in submitting data): 17 05 2024

Deadline for step 2 (Confirmation of data submission, deadlines and milestones): 20 09 2024

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].

In most cases, EFSA confirms the safety of the 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.

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.

EFSA's Scientific Opinion on the re-evaluation of oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), starch sodium octenyl succinate (E 1450), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452) as food additives

The EFSA Panel on Food Additives and Nutrient sources added to Food (ANS) delivered on 5 October 2017 a scientific opinion re-evaluating the safety of 12 modified starches (E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422, E 1440, E 1442, E 1450, E 1451 and E 1452) when used as food additives[3]. These modified starches were previously evaluated by the Scientific Committee on Food (SCF), which allocated to them an acceptable daily intake (ADI) 'not specified'.

In humans, modified starches are not absorbed intact but significantly hydrolysed by intestinal enzymes and then fermented by the intestinal microbiota. Using the read-across approach, the Panel considered that adequate data on short- and long-term toxicity and carcinogenicity, and reproductive toxicity are available. Based on in silico analyses, modified starches are considered not to be of genotoxic concern. No treatment-related effects relevant for human risk assessment were observed in rats fed very high levels of modified starches (up to 31,000 mg/kg body weight (bw) per day). Modified starches (e.g. E 1450) were well tolerated in humans up to a single dose of 25,000 mg/person. Following the conceptual framework for the risk assessment of certain food additives, the Panel concluded that there is no safety concern for the use of modified starches as food additives at the reported uses and use levels for the general population and that there is no need for a numerical ADI.

The combined exposure to E 1404–E 1451 at the 95th percentile of the refined (brand-loyal) exposure assessment scenario for the general population was up to 3,053 mg/kg bw per day. Exposure to E 1452 for food supplement consumers only at the 95th percentile was up to 22.1 mg/kg bw per day. Due to the discrepancies observed between the data reported from industry and the Mintel database, where modified starches (E 1404–E 1451) are labelled in more products than in food categories for which data were reported from industry, the Panel recommended collection of data on use and use levels of modified starches (E 1404–E 1451) in order to perform a more realistic exposure assessment. In addition, confirmation on the actual use of starch aluminium octenyl succinate (E 1452) in vitamin preparations (for encapsulation purposes) for food supplements should be sought.

Concerning the use of E 1450 in 'dietary foods for special medical purposes and special formulae for infants' (food category 13.1.5.1) and of E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422, E 1450 and E 1451 in food belonging to food category 13.1.5.2 (Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC), the Panel concluded, that the available data do not allow for an adequate assessment of their safety for infants and young children consuming these foods at the presently authorised maximum use levels of 20.000 or 50.000 mg/kg, respectively.

The assessment of the use of E 1450 in food categories 13.1.5.1 and 13.1.5.2 was addressed in the 2020 opinion on the re-evaluation of starch sodium octenyl succinate (E 1450) as a food additive in foods for infants below 16 weeks of age and the follow-up of its re-evaluation as a food additive for uses in foods for all population groups[4].

In addition, EFSA made some recommendations to be considered for possible revision of the EU specifications of these food additives.

Overall purpose of this call for data

[3] EFSA Journal 2017;15(10):4911 (https://www.efsa.europa.eu/en/efsajournal/pub/4911)
[4] EFSA Journal 2020;18(8):5874 (https://www.efsa.europa.eu/en/efsajournal/pub/5874)

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 oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452) as food additives.

It should be noted that this call for data does not cover toxicological data or data concerning the specifications for starch sodium octenyl succinate (E 1450), since those data were already requested in the call for data issued by EFSA for the assessment of the safety of the use of E 1450 in food for infants below 16 weeks of age, and which also dealt with uses of E 1450 for all population groups[5].

1. Technical data required

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452) as food additives by EFSA, information is sought on:

1.1 Information related to the specifications for oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452):

- Analytical data on current levels of lead, mercury, cadmium, arsenic and manganese in commercial samples of the food additives.
    - The results of the individual samples (including sample ID and sampling date) as well as summary statistics (mean, P50, P95, range) are requested. The results should adequately cover the between-batches variability and should be representative of the food additives currently placed on the EU market. The analyses should be performed with appropriate analytical methods applying state of the art techniques. Specific data on the methods of analysis used should be provided. These include, but are not limited to, the principle of the method, the scope of the method (i.e. the range of sample types that the method is used for), the concentration units used to express the analytical result(s), validation parameters of the method (in particular limit of detection (LOD) and quantification (LOQ)). For impurities for which limits are included in the current specifications (i.e. lead, mercury, and arsenic), business operators are requested to submit the analytical results obtained in the context of Article 17(1)[6] of Regulation (EC) No 178/2002[7] during the last 5 years. Submission of results from a shorter timespan should be justified.
- To provide a proposed limit for lead, mercury, cadmium, arsenic and manganese based on the analytical results and its lowest technologically achievable level in the food additive.

[5] https://www.efsa.europa.eu/en/consultations/call/180718-4

[6] Article 17(1) of Regulation (EC) No 178/2002: Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

[7] OJ L 031 1.2.2002, p. 1

- Data demonstrating the absence of *Salmonella* spp. and *Escherichia coli* as well as data on the total aerobic microbial count (TAMC) and total combined yeast and mould count (TYMC). To provide proposed limits for microbiological parameters based on the microbiological results and its lowest technologically achievable level in the food additive.
- Analytical data on current levels of sulphur dioxide in commercial samples of the food additives. Business operators are requested to submit the analytical results obtained in the context of Article 17(1)[8] of Regulation (EC) No 178/2002[9] during the last 5 years. The results of the individual samples (including sample ID and sampling date) as well as summary statistics (mean, P50, P95, range) are requested. The results should adequately cover the between-batches variability and should be representative of the food additives currently placed on the EU market. Submission of results from a shorter timespan should be justified. The analyses should be performed with appropriate analytical methods applying state of the art techniques. Specific data on the methods of analysis used should be provided. These include, but are not limited to, the principle of the method, the scope of the method (i.e. the range of sample types that the method is used for), the concentration units used to express the analytical result(s), validation parameters of the method (in particular limit of detection (LOD) and (LOQ)).
- To provide a proposed limit for sulphur dioxide based on the analytical results and its lowest technologically achievable level in the food additive.
- Data on the actual percentage of:
    - ✓ Carboxyl groups in E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422, E1440, E 1442, E 1451;
    - ✓ Acetyl groups in E 1414, E 1420, E 1422, E 1451;
    - ✓ Adipate groups in E 1422;
    - ✓ Hydroxypropyl groups in E 1440, E 1442;
    - ✓ Octenylsuccinyl groups in E 1452.
- Analytical data on current levels of:
    - ✓ octenylsuccinic acid residue in commercial samples of E 1452;
    - ✓ residual phosphate in commercial samples of E 1410, E 1412, E 1413, E 1414, E 1442;
    - ✓ vinyl acetate in commercial samples of E 1414, E 1420;
    - ✓ propylene chlorohydrin in commercial samples of E 1440, E 1442;
    - ✓ aluminium in commercial samples of E 1452.

  Business operators are requested to submit the analytical results obtained in the context of Article 17(1)[10] of Regulation (EC) No 178/2002[11] during the last 5 years. The results of the individual samples (including sample ID and sampling date) as well as summary statistics (mean, P50, P95, range) are requested. The results should adequately cover the between-batches variability and should be representative of the food additives currently placed on the EU market. Submission of results from a shorter timespan should be justified. The analyses

[8] Article 17(1) of Regulation (EC) No 178/2002: Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

[9] OJ L 031 1.2.2002, p. 1

[10] Article 17(1) of Regulation (EC) No 178/2002: Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

[11] OJ L 031 1.2.2002, p. 1

should be performed with appropriate analytical methods applying state of the art techniques. Specific data on the methods of analysis used should be provided. These include, but are not limited to, the principle of the method, the scope of the method (i.e. the range of sample types that the method is used for), the concentration units used to express the analytical result(s), validation parameters of the method (in particular limit of detection (LOD) and (LOQ)).

- To provide a proposed limit based on the analytical results and its lowest technologically achievable level in the food additive for the following impurities:
    - ✓ octenylsuccinic acid residue in commercial samples of E 1452;
    - ✓ residual phosphate in commercial samples of E 1410, E 1412, E 1413, E 1414, E 1442;
    - ✓ vinyl acetate in commercial samples of E 1414, E 1420;
    - ✓ propylene chlorohydrin in commercial samples of E 1440, E 1442;
    - ✓ aluminium in commercial samples of E 1452.

1.2 Data on uses/use levels of the food additives oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), and acetylated oxidised starch (E 1451) in accordance with Annex II, Part E of Regulation (EC) No 1333/2008

It was noted that for the re-evaluation, no use levels were provided to EFSA for several authorised uses in food category 13.1. According to Appendix A of the 2017 EFSA opinion on modified starches[12], use levels were provided/missing for the following uses:

Current authorisations in FC 13.1.3:

E-number	Name	Maximum level (mg/l or mg/kg as appropriate)	Restrictions/exceptions	
E 1404	Oxidized starch	50 000	only processed cereal-based foods and baby foods	No use level provided
E 1410	Monostarch phosphate	50 000	only processed cereal-based foods and baby foods	No use level provided
E 1412	Distarch phosphate	50 000	only processed cereal-based foods and baby foods	No use level provided
E 1413	Phosphated distarch phosphate	50 000	only processed cereal-based foods and baby foods	No use level provided
E 1414	Acetylated distarch phosphate	50 000	only processed cereal-based foods and baby foods	No use level provided
E 1420	Acetylated starch	50 000	only processed cereal-based foods and baby foods	No use level provided
E 1422	Acetylated distarch adipate	50 000	only processed cereal-based foods and baby foods	Use level provided

[12] EFSA Journal 2017;15(10):4911 (https://www.efsa.europa.eu/en/efsajournal/pub/4911)

E 1451	Acetylated oxidised starch	50 000	only processed cereal-based foods and baby foods	No use level provided

Current authorisations in FC 13.1.4:

E-number	Name	Maximum level (mg/l or mg/kg as appropriate)	
E 1404	Oxidized starch	50 000	No use level provided
E 1410	Monostarch phosphate	50 000	No use level provided
E 1412	Distarch phosphate	50 000	No use level provided
E 1413	Phosphated distarch phosphate	50 000	No use level provided
E 1414	Acetylated distarch phosphate	50 000	No use level provided
E 1420	Acetylated starch	50 000	No use level provided
E 1422	Acetylated distarch adipate	50 000	No use level provided

Current authorisations in FC 13.1.5.2:

E-number	Name	Maximum level (mg/l or mg/kg as appropriate)	
E 1404	Oxidized starch	50 000	No use level provided
E 1410	Monostarch phosphate	50 000	No use level provided
E 1412	Distarch phosphate	50 000	No use level provided
E 1413	Phosphated distarch phosphate	50 000	No use level provided
E 1414	Acetylated distarch phosphate	50 000	No use level provided
E 1420	Acetylated starch	50 000	No use level provided
E 1422	Acetylated distarch adipate	50 000	Use level provided
E 1451	Acetylated oxidised starch	50 000	No use level provided

Considering that for the use of E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422 and E 1451 in food belonging to food category 13.1.5.2 (Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC), EFSA concluded that the available data do not allow for an adequate assessment of their safety and that consequently toxicological data are requested (see point 2 of this call), the Commission also request data on the use of these food additives.

Food business operators are requested to provide for all uses of E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422 and E 1451 authorised in food category 13.1 in accordance with Annex II, Part E of Regulation (EC) No 1333/2008 and for which no use level data were provided under the re-evaluation:

- data on normal and maximum use levels of E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422, and E 1451, indicating whether these additives are used individually or in combination in each food category. When used in combination (as a group) the use level provided should be applicable to the group (and not to each member of the group). A numerical maximum level needs to be provided (the *quantum satis* principle should not be applied for these food additives). For dried and/or concentrated foods which need to be reconstituted, the level

provided shall apply to the food as reconstituted according to the instructions on the label taking into account the minimum dilution factor;

- information on whether the reported use and use levels concern all different types of foodstuffs belonging to a food category or only certain types (to allow for further refinement of the exposure assessment).
- confirmation as to whether the food additives are not used in food categories in which they are permitted in accordance with Annex II, Part E of Regulation (EC) No 1333/2008.

Data on use levels of E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422, and E 1451 authorised in food category 13.1 in accordance with Annex II, Part E of Regulation (EC) No 1333/2008 and for which no use level data were provided under the re-evaluation should be reported using the template developed for this purpose (MS Excel® file "Data on use of E 1404-1451 in accordance with Annex II, Part E.xls"), following the instructions provided in the template. This template is available on the re-evaluation webpage under this specific call for data.

If no use data are provided for the food additives listed above (E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422 and E 1451) authorised in food category 13.1, it will be considered that there is no interest that the use of the specific food additive remains authorised in that food category. Consequently, the authorisation for the use of the specific food additive (E 1404, 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422, E 1440, and E 1451) in that food category will be withdrawn.

Therefore, if an interested party has information that modified starches (E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422, and E 1451) are not used in a food subcategory belonging to food category 13.1, this information should also be provided. Such information will be cross-checked with information sent by all interested parties replying to the call.

1.3 Data on uses/use levels of the food additive acetylated starch (E 1420) and acetylated oxidised starch (E 1451) in accordance with Annex III, Part 5, Section B of Regulation (EC) No 1333/2008

In accordance with Annex III, Part 5, Section B, acetylated starch (E 1420) and acetylated oxidised starch (E 1451) are authorised as food additive in nutrient preparations to be used in processed cereal based foods and baby foods for infants and young children as defined by Directive 2006/125/EC, under the condition that the maximum level in foods mentioned in point 13.1.3 of Part E of Annex II is not exceeded.

The European Commission seeks confirmation on the actual use of acetylated starch (E 1420) and acetylated oxidised starch (E 1451) as a food additive in nutrient preparations. Therefore, data on actual use of E 1420 and E 1451 in accordance with Annex III, Part 5, Section B of Regulation (EC) No 1333/2008 (actual normal and maximum use levels) should be reported using the template developed for this purpose (MS Excel® file "Data on use of E 1420 and 1451 in accordance with Annex III Part 5 Section B.xls"). This template is available on the re-evaluation webpage under this specific call for data.

If no data are provided for the currently authorised use of E 1420 and E 1451 in accordance with Annex III, Part 5, Section B, it will be considered that there is no interest that that use remains authorised. Consequently, that authorisation will be withdrawn.

Therefore, if an interested party has information that E 1420 and E 1451 is not used in accordance with Annex III, Part 5, Section B, this information should also be provided. Such information will be cross-checked with information sent by all interested parties replying to the call.

2. Toxicological data required for oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E

1422) and acetylated oxidised starch (E 1451) for the uses in food category 13.1.5.2 'Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC'.

Data to support the quantitative read across between E 1450, and E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422 and E 1451 (see 2017 and 2020 EFSA opinions[13,14]) to assess the potential health effects of E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422 and E 1451 when used in food for infants and young children under food category 13.1.5.2. This may include available data from clinical studies on the potential health effects of E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422 and E 1451 when used in foods belonging to food category 13.1.5.2. In case these data are not available, observational clinical data on the safety of use in quantitative terms should be provided.

Post-marketing surveillance data and available published and unpublished case reports should be provided in addition.

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 17 May 2024 whether they are interested that E 1404, E 1410, E 1412, E 1413, E 1414, E 1420, E 1422 and/or E 1451 remain permitted in the EU for use as food additives in food for infants and young children under food category 13.1.5.2 and therefore whether they are interested in providing the new data required. This communication should include the contact details of the business operator (name of business operator and postal address), as well as a clear indication of which of the requested data the business operator would be interested in providing. In addition, the food additive has to be specified. 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) 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 in the first communication to the Commission.

If business operators do not reply to the step 1 of the call for 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.

Step 2: Confirmation of data submission, deadlines and milestones

Business operators are requested to confirm by 20 September 2024 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.

[13] EFSA Journal 2017;15(10):4911 (https://www.efsa.europa.eu/en/efsajournal/pub/4911)

[14] EFSA Journal 2020;18(8):5874 (https://www.efsa.europa.eu/en/efsajournal/pub/5874)

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.

According to Article 7c of Regulation (EU) No 257/2010 setting up a re-evaluation programme of approved food additives, interested business operators and other interested parties shall, without delay, notify EFSA of any study commissioned or carried out by them to support the re-evaluation of an approved food additive in accordance with Articles 4 to 7a of this Regulation. Laboratories and other testing facilities located in the Union shall also, without delay, notify EFSA of any study commissioned by business operators and other interested parties, carried out by such laboratories or other testing facilities to support the re-evaluation of an approved food additive in accordance with Articles 4 to 7a of this Regulation.

After completion of step 2, the data to be submitted, the deadlines and milestones will be published on the DG SANTE's website.

Any questions about this call for data should be sent to the email address SANTE-E2-Additives@ec.europa.eu.

Submission of the required data

Business operators are requested to submit the above-indicated data by the agreed deadline using the online platform CIRCABC. The "Guidance for online data submission on Food Improvement Agents via CIRCABC Sante-Cad-In Group"[15] provides practical information on how to use the CIRCABC platform for the online submissions.

Common electronic formats (e.g. MS Office®, Adobe Acrobat Reader®) allowing content copying and printing (no content copy protection) should be used for the files to be submitted. 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, and describing the data submitted. The cover letter should provide the contact details of the data submitter and should be addressed to:

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

This cover letter should also be sent separately to the functional mailbox SANTE-E2-Additives@ec.europa.eu.

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

Confidential data

According to article 8 of Regulation (EU) No 257/2010 setting up a re-evaluation programme of approved food additives, interested business operator or other interested party may submit a request to treat certain parts of the information or data submitted in accordance with this Regulation as confidential. Such requests shall be accompanied by verifiable justifications. You must submit

[15] https://food.ec.europa.eu/document/download/a545dc60-5993-4632-bf19-34bd34d1b355_en?filename=fs_food-improvement-agents_guidance_circabc_data-sub.pdf

confidentiality requests complying with EFSA's Practical Arrangements concerning transparency and confidentiality[16], and in particular with Articles 9 and 10 thereof. Confidentiality requests may be submitted exclusively via the Portalino[17] to EFSA. The following information is available on the EFSA website:

- Information on how to submit confidentiality requests[18]
- Information on how to use this tool[19]
- A user guide providing concrete tips on the submission of confidentiality requests[20].

Please note that whenever a confidentiality request is submitted, a non-confidential version and a confidential version of information claimed confidential must be submitted together with each confidentiality request. You are also required to box or earmark information claimed confidential in the confidential version of the information you submit. Please note that confidentiality requests must be submitted prior to the submission of the data via CIRCABC, and that if you do not submit the elements listed above within the given timeline, EFSA is required to proactively publish all information, documents and data already submitted without delay, pursuant to Article 38(1)(c) and (d) of the general food law and Article 6(1) of EFSA's Practical Arrangements of transparency and confidentiality.

The confidentiality requests shall be assessed in accordance with Article 12 of Regulation (EC) No 1331/2008, which shall apply *mutatis mutandis*.

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.

[16] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-transparency-and-confidentiality.pdf
[17] https://confportal.efsa.europa.eu/
[18] https://www.efsa.europa.eu/en/about/transparency
[19] https://www.efsa.europa.eu/sites/default/files/2021-05/portalino-quick-guide-business-users.pdf
[20] https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf