Call for technical data on the permitted food additives phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452)

Published: 5 July 2023

Deadline: 5 March 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.

EFSA's scientific opinion on the re-evaluation of phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives

The EFSA Panel on Food Additives and Flavourings (FAF) provided on 12 June 2019 a scientific opinion re-evaluating the safety of phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) when used as food additives[3].

The Panel considered that adequate exposure and toxicity data were available. The Panel considered phosphates to be of low acute oral toxicity and there is no concern with respect to genotoxicity and carcinogenicity. No effects were reported in developmental toxicity studies. The Panel derived a group acceptable daily intake (ADI) for phosphates expressed as phosphorus of 40 mg/kg body weight (bw) per day and concluded that this ADI is protective for healthy adults because it is below the doses at

[1] OJ L 354, 31.12.2008, p. 16.
[2] OJ L 80, 26.3.2010, p. 19.
[3] EFSA Journal 2019;17(6):5674 (https://www.efsa.europa.eu/en/efsajournal/pub/5674)

which clinically relevant adverse effects were reported in short-term and long-term studies in humans. However, this ADI does not apply to humans with moderate to severe reduction in renal function. Ten per cent of the general population might have chronic kidney disease with reduced renal function and they may not tolerate the amount of P per day which is at the level of ADI.

Exposure to phosphates from the whole diet was estimated using mainly analytical data. The values ranged from 251 mg P/person per day in infants to 1,625 mg P/person per day for adults, and the high exposure (95th percentile) from 331 mg P/person per day in infants to 2,728 mg P/person per day for adults. The Panel noted that in the estimated exposure scenario based on analytical data exposure estimates exceeded the proposed ADI for infants, toddlers and other children at the mean level, and for infants, toddlers, children and adolescents at the 95th percentile. The Panel also noted that phosphates exposure from food supplements exceeds the proposed ADI. The Panel concluded that the available data did not give rise to safety concerns in infants below 16 weeks of age consuming formula and food for medical purposes.

The Panel indicated that appropriate analytical methods must be developed and validated to recognised international protocols so that they are fit for purpose with respect to expected phosphate concentration ranges. There should also be clear distinction between methods for total phosphate and methods for identifying and quantifying separate phosphate types, i.e. methods must be robust, and the units used for reporting phosphate content should be standardised. The Panel highlighted the need for development of analytical methods since those currently available for total phosphate and phosphate speciation do not cover the entire range of foodstuffs permitted to contain phosphate additives.

The Panel recommended that:

- The European Commission considers setting numerical Maximum Permitted Level for phosphates as food additives in food supplements.
- The European Commission considers revising the current limits for toxic elements (Pb, Cd, As and Hg) in the EU specifications for phosphates (E 338–341, E 343, E 450–452) in order to ensure that phosphates (E 338–341, E 343, E 450–452) as a food additive will not be a significant source of exposure to those toxic elements in food.
- The European Commission considers revising the current limit for aluminium in the EU specifications for the use of calcium phosphate (E 341).
- The European Commission to consider revising the current EU specifications for calcium dihydrogen phosphate (E 341(i)), calcium hydrogen phosphate (E 341(ii)), tricalcium phosphate (E 341(iii)), dimagnesium phosphate (E 343(ii)) and calcium dihydrogen diphosphate (E 450(vii)) to include characterisation of particle size distribution using appropriate statistical descriptors (e.g. range, median, quartiles) as well as the percentage (in number and by mass) of particles in the nanoscale (with at least one dimension < 100 nm) present in calcium dihydrogen phosphate (E 341(i)), calcium hydrogen phosphate (E 341(ii)), tricalcium phosphate (E 341(iii)), dimagnesium phosphate (E 343(ii)) and calcium dihydrogen diphosphate (E 450(vii)) used as a food additive. The measuring methodology applied should comply with the EFSA Guidance document (EFSA Scientific Committee, 2018).
- The development of analytical methods for the determination of phosphate additives in the range of foods and beverages permitted to contain them should be considered.
- The EFSA Scientific Committee reviews current approaches to the setting of health-based guidance values for regulated substances which are also nutrients to assess if a coherent harmonised strategy for such risk assessments should be devised.

Overall purpose of this call for data

To give the opportunity to business operators to submit the technical data needed to address issues identified by EFSA in the re-evaluation of the safety of phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives.

Information required for the food additives phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452)

With reference to the conclusions and recommendations in the Scientific Opinion on the re-evaluation of phosphates, information is sought on:

1. Safety evaluation strategy and corresponding testing strategy

In August 2021, EFSA published a *Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles* (EFSA SC Guidance on particle-TR).[4] This Guidance establishes information requirements for conventional materials which do not meet the definition of engineered nanomaterial set out in the Novel Food Regulation (EU) 2015/2283. The EFSA SC Guidance on particle-TR is applicable since its publication in August 2021, and outlines appraisal routes (e.g. solubility/dissolution rate; particle size distribution; appropriateness of safety studies) to confirm that an assessment of the fraction of small particles including nanoparticles is not needed.

Based on the available information in the existing EU specifications regarding solubility in water, some of these food additives (namely: E 338, E 339 (i, ii, iii), E 340 (i, ii, iii), E 450 (i, ii, iii, v), E 451 (i, ii) and E 452 (i soluble polyphosphate)) are soluble in water and therefore conventional risk assessment is considered applicable to the food additives listed above.

The food additives E 341 (i, ii, iii), E 343 (i, ii), E 450 (vi, vii, ix) and E 452 (i insoluble polyphosphate, ii, iii, iv)) are instead slightly or sparingly soluble in water. In order to confirm that conventional risk assessment is also adequate to re-evaluate the safety of these food additives and that an additional assessment related to the presence of particles at the nanoscale is not needed, information demonstrating that E 341 (i, ii, iii), E 343 (i, ii), E 450 (vi, vii, ix) and E 452 (i insoluble polyphosphate, ii, iii, iv)) meet at least one of the Decision criteria listed in Table 1 of the EFSA SC Guidance on particle-TR is requested.

Interested parties and/or business operators are kindly invited to provide scientific evidence, supported by data, confirming that the food additives E 341 (i, ii, iii), E 343 (i, ii), E 450 (vi, vii, ix) and E 452 (i insoluble polyphosphate, ii, iii, iv)) meet at least one of the Decision criteria listed in Table 1 of the EFSA SC Guidance on particle-TR. Nevertheless, interested parties and/or business operators may submit information on more than one appraisal route.

The outcome of this exercise will indicate the guidance document to be used for the risk assessment of the food additives E 341 (i, ii, iii), E 343 (i, ii), E 450 (vi, vii, ix) and E 452 (i insoluble polyphosphate, ii, iii, iv)), i.e. whether data submitted according to the current EFSA Guidance for submission for food additive evaluations[5]**Error! Bookmark not defined.** will be sufficient or whether these should be complemented with the considerations outlined in the EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health.[6]

2. Technical data for the revision of the specifications for phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452)

[4] https://www.efsa.europa.eu/en/efsajournal/pub/6769
[5] EFSA Journal 2012;10(7):2760 (https://www.efsa.europa.eu/en/efsajournal/pub/2760)
[6] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5327

- Analytical data on current levels of lead, mercury, cadmium and arsenic in commercial samples of the food additives phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338, E 339 (i, ii, iii), E 340 (i, ii, iii), E 341 (i, ii, iii), E 343 (i, ii), E 450 (i, ii, iii, v, vi, vii, ix), E 451 (i, ii) and E 452 (i, ii, iii, iv)). Business operators are requested to submit the analytical results obtained in the context of Article 17(1)[7] of Regulation (EC) No 178/2002[8] during the last 5 years for the specific salts (i.e. the roman number should be specified). 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 of the method (in particular limit of detection (LOD) and (LOQ).
- The lowest technologically achievable level for lead, mercury, cadmium and arsenic in order to adequately propose maximum limits in the specifications.
- Analytical data on current levels of aluminum in commercial samples of the food additive calcium phosphate (E 341 (i, ii, iii)). Business operators are requested to submit the analytical results obtained in the context of Article 17(1) of Regulation (EC) No 178/2002 during the last 5 years for the specific salts (i.e. the roman number should be specified). 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 of the method (in particular limit of detection (LOD) and (LOQ).
- The lowest technologically achievable level for aluminium in the food additive calcium phosphate (E 341) in order to adequately propose a maximum limit in the specifications.

3. Analytical method: the development of analytical methods for the determination of the different phosphate additives in the range of foods and beverages permitted to contain them.

Appropriate analytical methods must be developed and validated to recognised international protocols so that they are fit for purpose with respect to expected phosphate concentration ranges and the foodstuffs permitted to contain phosphate additives. There should also be clear distinction between methods for total phosphate and methods for identifying and quantifying separate phosphate types; methods must be robust, and the units used for reporting phosphate content should be standardised.

4. Data on uses/use levels of the food additives phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452)

[7] 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.

[8] OJ L 031 1.2.2002, p. 1

Since EFSA has established a numerical Acceptable Daily Intake (ADI) for the food additives phosphoric acid–phosphates – di-, tri- and polyphosphates (E 338–341, E 343, E 450–452), numerical maximum use levels should be defined for all their permitted uses. Therefore, all current authorisations at *quantum satis* should be revised. In addition, it was noted that no use levels were provided under the re-evaluation to EFSA for several authorised uses. Food business operators are invited to submit use levels for these uses.

Uses in accordance with Annex II, Part E of Regulation (EC) No 1333/2008

According to Annex II (Part E) of Regulation (EC) No 1333/2008, phosphates (E 338–341, E 343, E 450–452) are authorised at *quantum satis* in the following food categories (FC):

- FC 5.3 Chewing gum;
- FC 17.1 Food supplements supplied in a solid form, excluding food supplements for infants and young children;
- FC 17.2 Food supplements supplied in a liquid form, excluding food supplements for infants and young children.

According to Annex II (Part E) of Regulation (EC) No 1333/2008, calcium phosphates (E 341) is authorised at *quantum satis* in the following FC:

- FC 11.4.2 Table-top sweeteners in powder form;

According to Appendix F of the 2019 EFSA opinion on phosphates, no use levels were provided for the following uses:

Food category code	Food category name	Restrictions/exceptions
01.7.6	Cheese products (excluding products falling in category 16)	Only unripened products
01.8	Dairy analogues, including beverage whiteners	Only processed cheese analogues
07.1	Bread and rolls	Only pizza dough (frozen or chilled) and 'tortilla'
07.2	Fine bakery wares	
09.2	Processed fish and fishery products including molluscs and crustaceans	Only salted fish of the Gadidae family that have been pre-salted by injecting and/or brine salting with an at least 18% salt solution and often followed by dry salting
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	Only processed cereal based foods and baby foods, only for pH adjustment
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	Only in fruit-based desserts
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC	Only biscuits and rusks
13.1.5.1	Dietary foods for infants for special medical purposes and special formulae for infants	

13.1.5.2	Dietary foods for babies and young children for special medical purposed as defined in Directive 1999/21/EC	Only biscuits and rusks
13.4	Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009	
14.2.3	Cider and perry	
14.2.4	Fruit wine and made wine	
14.2.5	Mead	
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	Except: whisky, whiskey
14.2.7	Aromatised wine-based products as defined by Regulation (EEC) No 1601/91	
14.2.7.1	Aromatised wines	
14.2.7.2	Aromatised wine-based drinks	
14.2.7.3	Aromatised wine-product cocktails	
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	
15.2	Processed nuts	
16.	Desserts excluding products covered in categories 1, 3 and 4	Only dry powdered dessert mixes E

Food business operators are requested to provide:

- ✓ data on actual normal/typical use levels and maximum use levels for these food categories/uses, as well as any other information relevant to perform a refined exposure assessment. 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 foodstuffs belonging to a food category or only certain foodstuffs (to potentially allow the definition of appropriate restrictions/exceptions of use in Annex II, Part E of Regulation (EC) No 1333/2008).
- ✓ the specific food additive for which the use level is provided.

Data on use levels of phosphates (E 338–341, E 343, E 450–452) in the food categories listed above should be reported using the attached template developed for this purpose (MS Excel® file “Data on E 338-341 E 343 E 450-452 Annex II Reg 1333-2008.xls”), following the instructions provided in the template.

Data on E 338-341 E 343 E450-452 Annex

If no use data are provided for the food categories listed above, it will be considered that there is no interest that the use of phosphates (E 338–341, E 343, E 450–452) as food additives remains authorised in that food category. Consequently, the authorisation for the use of phosphates (E 338–341, E 343, E 450–452) in that food category will be withdrawn.

Therefore, if an interested party has information that phosphates (E 338–341, E 343, E 450–452) are not used in a food category, this information should also be provided. Such information will be cross-checked with information sent by all interested parties replying to the call.

Uses in accordance with Annex III, Part 1, 2, 3, 4 and Section A and B of Part 5 of Regulation (EC) No 1333/2008

Phosphates (E 338–341, E 343, E 450–452) are also authorised according to Annex III of Regulation (EC) No 1333/2008 as follows:

- Calcium phosphates (E 341) as carrier in all food additives at *quantum satis* (Annex III, Part 1).
- Phosphoric acid (E 338), Sodium phosphates (E 339), Potassium phosphates (E 340), Magnesium phosphates (E 343), Diphosphates (E 450) and Triphosphates (E 451) as food additives other than carriers in preparations of the colour E 163 anthocyanins with a maximum level in the preparations of 40,000 mg/kg singly or in combination (expressed as P_2O_5) (Annex III, Part 2).
- Calcium phosphates (E 341) as food additive other than carriers in:
    - in colour and emulsifier preparations with a maximum level in the preparations of 40,000 mg/kg (expressed as P_2O_5);
    - in polyol preparations with a maximum level in the preparation of 10,000 mg/kg (expressed as P_2O_5);
    - in E 412 guar gum preparations with a maximum level in the preparation of 10,000 mg/kg (expressed as P_2O_5) (Annex III, Part 2).
- Phosphoric acid (E 338) as a food additive in food enzymes with a maximum level in the enzymes preparation of 10,000 mg/kg (expressed as P_2O_5) and at *quantum satis* in the final products (food or beverages) (Annex III, Part 3).
- Sodium phosphates (E 339), Potassium phosphates (E 340), Calcium phosphates (E 341), Magnesium phosphates (E 343) as a food additive in food enzymes with a maximum level in the enzymes preparation of 50,000 mg/kg singly or in combination (expressed as P_2O_5) and at *quantum satis* in the final products (food or beverages). These food additives are also authorised to be used as carriers (Annex III, Part 3).
- Diphosphates (E 450), Triphosphates (E 451) and Polyphosphates (E 452) as a food additive in food enzymes with a maximum level in the enzymes preparation of 50,000 mg/kg singly or in combination (expressed as P_2O_5) and at *quantum satis* in the final products (food or beverages). These food additives are not authorised to be used as carriers (Annex III, Part 3).
- Phosphoric acid — phosphates — di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives including carriers in all food flavourings with a maximum level 40 000 mg/kg (singly or in combination expressed as P_2O_5) (Annex III, Part 4).
- Phosphoric acid — phosphates — di-, tri- and polyphosphates (E 338–341, E 343, E 450–452) as food additives in all nutrients except nutrients intended to be used in foodstuffs for infants and young children, with a maximum level of 40 000 mg/kg (expressed as P_2O_5) in the nutrient preparation (Annex III, Part 5, Section A).

- Tricalcium phosphate (E 341 (iii)) as food additives added in nutrients intended to be used in foodstuffs for infants and young children, with a maximum carry-over 150 mg/kg expressed as P_2O_5 and within the limit for calcium, phosphorus and calcium:phosphorus ratio as set in Directive 2006/141/EC in all nutrients in infant formulae and follow-on formulae as defined by Directive 2006/141/EC (Annex III, Part 5, Section B).
- Tricalcium phosphate (E 341 (iii)) as food additives added in nutrients intended to be used in foodstuffs for infants and young children, with a maximum level of 1 000 mg/kg expressed as P_2O_5 from all uses in final food mentioned in point 13.1.3 of Part E of Annex II is respected in all nutrients in processed cereal based foods and baby foods for infants and young children as defined by Directive 2006/125/EC (Annex III, Part 5, Section B).

For all the uses for which phosphates (E 338–341, E 343, E 450–452) are permitted in accordance with Annex III of Regulation (EC) No 1333/2008, food business operators are requested to provide:

- data on maximum use levels of Phosphates (E 338–341, E 343, E 450–452) in the preparation as well as in the final food (if applicable), expressed as P_2O_5, indicating which additive(s) is/are used. If Phosphates (E 338–341, E 343, E 450–452) are 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);
- information on whether the reported use concerns all preparations or only certain preparations (when appropriate).

Data on use levels of Phosphates (E 338–341, E 343, E 450–452) in accordance with Annex III of Regulation (EC) No 1333-2008 should be reported using the attached template developed for this purpose (MS Excel® file “Data on E 338-341 E 343 E 450-452 Annex III of Reg 1333-2008.xls”), following the instructions provided in the template.

Data on E 338-341 E 343 E 450-452 Annex

If no data are provided for a currently authorised use of Phosphates (E 338–341, E 343, E 450–452) as food additives in accordance with Annex III it will be considered that there is no interest that that use remains authorised. Consequently, that authorisation for the use will be withdrawn.

Therefore, if an interested party has information that Phosphates (E 338–341, E 343, E 450–452) are not used in accordance with Annex III this information should also be provided. Such information will be of course cross-checked with information sent by all interested parties replying to the call.

Procedure of the call for data

It should be noted that this call concerns only technical data. Therefore, the 2-step procedure used in previous calls for scientific and technical data is not followed. The 2-step procedure is considered to be more appropriate for calls for data requesting scientific data (e.g. toxicological data which require that new toxicological studies are performed). Therefore, the deadline of this call is the final deadline for submission of the requested technical data.

Business operators are requested to submit to the Commission by **5 March 2024** the above-requested data.

In order to streamline the data collection exercise, business operators are invited to liaise with the relevant food business operator associations for the data submission. In particular, data providers shall ensure that the same data are not sent several times to the European Commission (for example, they should not be sent by both the business operator and also by the association to which the business operator belongs to).

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"[9] 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 confidentiality requests complying with EFSA's Practical Arrangements concerning transparency and confidentiality[10], and in particular with Articles 9 and 10 thereof. Confidentiality requests may be submitted exclusively via the Portalino[11] to EFSA. The following information is available on the EFSA website:

- Information on how to submit confidentiality requests[12]
- Information on how to use this tool[13]

[9] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_guidance_circabc_data-sub.pdf
[10] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-transparency-and-confidentiality.pdf
[11] https://confportal.efsa.europa.eu/
[12] https://www.efsa.europa.eu/en/about/transparency
[13] https://www.efsa.europa.eu/sites/default/files/2021-05/portalino-quick-guide-business-users.pdf

- A user guide providing concrete tips on the submission of confidentiality requests[14].

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.

[14] https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf