Call for data for the re-evaluation of malic acid and malates (E 296; E 350-352) as food additives

CONTENTS

RE-EVALUATION OF MALIC ACID AND MALATES (E 296; E 350-352), AS FOOD ADDITIVES

Under the programme for the re-evaluation of food additives set in Regulation (EU) No 257/2010

CALL FOR DATA NEEDED TO COMPLETE THE RE-EVALUATION OF THE SAFETY IN USE AS FOOD ADDITIVES

BACKGROUND

According to Regulation (EC) No 1333/2008[1], food additives that were permitted for use in the European Union before 20 January 2009 need to be re-evaluated by the European Food Safety Authority (EFSA). The programme for this re-evaluation is defined by Regulation (EU) No 257/2010[2]. This programme should have been completed by the end of December 2020; however, this deadline could not be achieved, and a number of food additives remain to be re-evaluated.

Among the food additives that remain to be re-evaluated in accordance with the above regulations, EFSA is interested in collecting any documented information that could support the re-evaluation of malic acid and malates (E 296; E 350-352).

In order to ensure an effective re-evaluation, it is important that EFSA retrieves from the interested parties all the relevant data for the re-evaluation of the selected food additives.

Therefore, in accordance with article 6(3) of the Regulation (EU) No 257/2010, EFSA launches a public call for data, in order to acquire documented information (published and/or unpublished) on malic acid and malates (E 296; E 350-352).

The submission of the requested information is without prejudice to the final opinion of the FAF Panel.

[1] OJ L 354, 31.12.2008, p. 16–33. ELI: http://data.europa.eu/eli/reg/2008/1333/oj
[2] OJ L 80, 26.3.2010, p. 19–27. ELI: http://data.europa.eu/eli/reg/2010/257/oj

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institutions, academia) and/or other stakeholders, the opportunity to submit documented information (published and/or unpublished) relevant to the re-evaluation of the following food additives:

TABLE 1. List of the food additives included in this call for data

NAME	E NUMBER	CHEMICAL NAME(S)	EFSA-Q-NUMBER
MALIC ACID	E 296	hydroxybutanedioic acid; hydroxysuccinic acid	2011-00598
SODIUM MALATE	E 350(i)	Disodium DL-malate; disodium salt of hydroxybutanedioic acid	2011-00631
SODIUM HYDROGEN MALATE	E 350(ii)	Monosodium DL-malate; monosodium 2-DL-hydroxy succinate	2011-00632
POTASSIUM MALATE	E 351	Dipotassium DL-malate; dipotassium salt of hydroxybutanedioic acid	2011-00633
CALCIUM MALATE	E 352(i)	Calcium DL-malate; calcium-α-hydroxysuccinate; calcium salt of hydroxybutanedioic acid	2011-00634
CALCIUM HYDROGEN MALATE	E 352(ii)	Monocalcium DL-malate; monocalcium 2-DL-hydroxysuccinate	2011-00635

These food additives were already included in a previous 'Call for data on miscellaneous food additives' published by EFSA in 2010[3]

No data were submitted for these food additives in response to the earlier calls for data.

DEADLINE FOR SUBMISSION OF INTEREST VIA EU SURVEY

Interested parties and stakeholders should express their interest to submit data via EU Survey tool by **28/07/2024.**
EU Survey Malic acid and malates

DEADLINE FOR SUBMISSION OF DATA

Interested parties and stakeholders should provide by **31/12/2024** the information described below.
In accordance with Article 6(4) of the Regulation (EU) No 257/2010[2] the information not submitted within the final deadline will only exceptionally be considered and EFSA can finalise its opinions on the basis of the information already provided.

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

[3] Call for scientific data on miscellaneous food additives permitted in the EU and belonging to several functional classes. (Published: 9 June 2010).

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.

PREVIOUS RELEVANT EVALUATIONS

Malate occurs in all living organisms as an intermediate in the citric acid cycle. It occurs in relatively high amounts in many fruits and vegetables. Malic acid has two stereoisomeric forms (L- and D enantiomers), although only the L-isomer exists naturally.

Malic acid, sodium malate, potassium malate, and calcium malate, (E 296; E 350(i), E 351, E 352(i)) have previously been evaluated by the Scientific Committee for Food (SCF) in 1991[4] when a group ADI (Acceptable Daily Intake) "not specified" was established.

The SCF report stated the following:

> "*in evaluating the acceptance of malate emphasis is placed on the well-established metabolic pathway of this anion and the daily consumption of malate-containing food. The malate anion also occurs in D(+) and L(-) forms. The available evidence shows that D(+)-malate is metabolised without difficulty and there is no clear evidence for a need to distinguish between the enantiomers when malate is used in food".*

Previously, the Joint FAO/WHO Expert Committee on Food Additives (JECFA,1980)[5] had also considered that both enantiomers of malic acid are readily metabolised by laboratory animals and humans, and that there was no reason to distinguish between *L*-malic acid (JEFCA No: 619) and *DL*-malic acid when considering their use in foods. The group ADI "not specified", initially established at the 13th JECFA meeting in 1969, was therefore confirmed.

L-Malic acid is also an authorised food flavouring in the EU, identified as FL-No 08.017. It has been previously evaluated by EFSA in FGE.10 Rev3 (EFSA CEF, 2012)[6].

Calcium malate is a source of calcium permitted for use in the EU in food supplements and in food for special medical purposes and total diet replacement for weight control. It was evaluated by the former EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) in 2006 (EFSA AFC, 2006)[7].

In 2014, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) evaluated the safety of malic acid or a mixture of its sodium and calcium salts when used as technological additives for all animal species and concluded that their use does not pose a risk to all animal species and the environment (EFSA FEEDAP, 2014)[8]. The 2014 FEEDAP opinion reported earlier considerations of the European Medicines Agency Committee for Veterinary Medicinal Products (CVMP) that concluded that there was no reason to suggest that D-malic acid or the DL racemate should be regarded differently from the naturally occurring *L*-form.

[4] SCF, 1991; 25th report. Available at: https://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_25.pdf
[5] JECFA, 1980; 23rd report. Available at: https://iris.who.int/bitstream/handle/10665/41403/WHO_TRS_648.pdf?sequence=1
[6] EFSA CEF Panel, 2012. Available at: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2012.2563
[7] EFSA AFC Panel, 2006. Available at: https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2006.391a
[8] EFSA FEEDAP Panel, 2014. Available at: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3563

Consequently, for malic acid (all enantiomeric forms) and its mono-and di-basic salts with sodium, potassium, and calcium, the CVMP concluded that there was no need to set maximum residue levels (MRLs) to limit consumer exposure via residues in foods derived from treated animals (EMEA, 1997)[9].

More recently, the EFSA CEP Panel Opinion on substances used in plastic materials and articles intended to come into contact with food (EFSA CEP, 2020)[10] classifies malic acid as a low priority substance.

PRELIMINARY APPROACH FOR THE RE-EVALUATION

The FAF Panel considers that the safety of the food additives malic acid, sodium malate, sodium hydrogen malate, potassium malate, calcium malate, and calcium hydrogen malate (E 296; E 350-352) can be assessed in a joint scientific opinion, given that all these substances share a common metabolic fate.

EFSA has been made aware of a possible ambiguity in the identity and characterisation of the food additive malic acid (E 296) with respect to the melting range indicated in the current EU specifications. Information on the **enantiomeric forms** of the substances used as food additives, accompanied by relevant analytical data to support their identification are sought in order to formulate recommendations for possible revisions of the current specifications (**Information/data sought n.1**)

In order for the FAF Panel to confirm that the **conventional risk assessment** is adequate to re-evaluate the safety in use of these already permitted food additives, and that an additional assessment related to the presence of particles at the nanoscale is not needed, information is required for confirming that (a) the material does not contain a fraction of small particles, or (b) a fraction of small particles is present but properly covered by the conventional risk assessment (see **Information/data sought n.2**).

Up-to-date information on the manufacturing process and specifications will be used to assess the potential **presence of toxicologically relevant impurities** (see **Information/data sought n.3**).

An adequate estimation of the **total dietary exposure** will be the starting point for the safety assessment and to this end, not only the reported use levels will be considered, but also the analytical data submitted to EFSA and the information on natural occurrence (see **Information/data sought n.4**).

[9] EMEA CVMP, 1997. Available at: https://www.ema.europa.eu/en/documents/mrl-report/malic-acid-summary-report-committee-veterinary-medicinal-products_en.pdf
[10] EFSA CEP Panel, 2020. Available at: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.6124

INFORMATION/DATA SOUGHT

EFSA kindly invites business operators and other interested parties (governments, interested organisations, universities, research institutions, companies) to submit the following information.

1. IDENTITY AND CHARACTERISATION OF THE FOOD ADDITIVE

EFSA has been made aware by the European Commission about an issue related to the melting range for malic acid (E 296) currently reported in the applicable specifications in Regulation (EU) No 231/2012[11], as follows:

	E 296
	Malic acid
Einecs	230-022-8, 210-514-9, 202-601-5
Chemical name	hydroxybutanedioic acid; hydroxysuccinic acid
Melting range	127-132 °C

The EINECS numbers listed in the current EU specifications allow for the use of both the L-Malic and the racemic mixture of DL-Malic acid. However, according to information in the public domain, the melting point of L-malic acid falls in a range not included in the one currently indicated for the food additive E 296, which seems to have been established for the racemic mixture of DL-Malic acid.

In the case of the other food additives included in this call, the existing EU specifications do not contain any EINECS number and always refer to the DL-forms of the salt. No information on the melting range is indicated in the EU specifications.

Interested parties and/or business operators are kindly invited to i) clarify which stereoisomers are used as food additives E 296, E350-352; ii) provide scientific evidence, supported by data, to allow a revision of the existing specifications with respect to the melting range parameter of E 296, clarifying to which stereoisomer the information is referred to.

2. CONFIRMATION OF ADEQUACY OF CONVENTIONAL RISK ASSESSMENT

In August 2021, EFSA has 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)[12]. This Guidance specifies the information requirements for conventional materials that do not meet the definition of engineered nanomaterial set out in the Novel Food Regulation (EU) 2015/2283[13], and outlines appraisal routes (e.g., solubility) to confirm that an assessment of the fraction of small particles including nanoparticles is not needed.

For malic acid (E 296) and malates (E350(ii), E 351, and E 352(ii)), based on the available information from the literature, their reported solubility in water is higher than the threshold value of 33.3 g/L, indicated as a decision criterion for this appraisal route in the EFSA SC Guidance on particle-TR. For sodium malate (E 350(i)), based on the available information in

[11] OJ L 83, 22.3.2012, p. 1-295. http://data.europa.eu/eli/reg/2012/231/oj
[12] EFSA SC, 2021. Available at: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6769
[13] OJ L 327, 11.12.2015, p. 1–22. http://data.europa.eu/eli/reg/2015/327/oj

the existing EU specifications, its solubility is reported as 'freely soluble in water', thus substantially higher than the threshold value of 33.3 g/L. Therefore, the conventional risk assessment is considered applicable to E 296, E350(i), E350(ii), E 351, and E 352(ii).

The information presented in the current EU specifications for **calcium malate (E 352(i))**, indicates that this food additive is 'slightly soluble in water'. This implies that its solubility is likely to be below the threshold value of 33.3 g/L reported in the EFSA SC Guidance on particle-TR. Therefore, in order to confirm that the conventional risk assessment is also adequate to re-evaluate the safety of calcium malate (E 352(i)) and that an additional assessment related to the presence of particles at the nanoscale is not needed, information is requested demonstrating that calcium malate (E 352(i)) meets at least one of the Decision criteria listed in Table 1 of the EFSA SC Guidance on particle-TR[12].

Interested parties and/or business operators are kindly invited to provide scientific evidence, supported by data, e.g., confirming that the food additives calcium malate (E 352(i)) meets at least one of the Decision criteria listed in Table 1 of the ,EFSA SC Guidance on particle-TR[12].

Nevertheless, interested parties and/or business operators may submit information on more than one appraisal route.

3. POTENTIAL PRESENCE OF TOXICOLOGICALLY RELEVANT IMPURITIES

3.1. INFORMATION ON MANUFACTURING PROCESS AND RELATED SPECIFICATIONS

Regulation (EC) No 231/2012[11], laying down the specifications for **food additives**, does not contain information on the manufacturing process(es) used for the production of malic acid and malates (E 296; E 350–352).

In the EFSA FEEDAP Panel Opinion on malic acid and a mixture of sodium and calcium malate for all animal species, it is reported that '*Malic acid is synthesised by hydration of maleic anhydride under high temperature and pressure to form malic and fumaric acid*' (EFSA FEEDAP, 2014).[14]

It is unclear whether the production via chemical synthesis is the only applicable method for manufacturing ~~of~~ these food additives.

In order to progress with the safety assessment and in the light of the experience accrued with the food additives re-evaluation programme, often leading to recommendations for updating the existing EU Specifications to ensure that they are representative of the materials used as food additives, the following information is sought from the interested business operators and other interested parties:

- provide detailed information on any **production method** used to manufacture the food additives E 296, E 350–352.
- propose a short **description** of each production method used to manufacture the food additives E 296 and E 350–352, including the key steps involved, for possible inclusion in a future revision of the EU specifications.

[14] EFSA FEEDAP, 2014. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/3563

- In case **catalyst(s) is/are used in the manufacturing process**, provide detailed information on the type of catalyst(s) used and any analytical data on their residual presence in the food additive.
- In case **enzyme(s) is/are used in the manufacturing process**, for each enzyme provide detailed information on its identity (IUBMB name, EC number). Indicate if the enzyme used is commercially available or produced in-house, and if an application for its safety evaluation has been submitted under Regulation (EC) No 1332/2008.[15] In case an application has been submitted, indicate the question number assigned by EFSA to the corresponding application.

Interested parties/business operators may wish to consult the 2012 EFSA ANS Panel *Guidance for submission for food additive evaluations*[16] for the preparation of the data submission.

3.2. INFORMATION ON PRODUCTION ORGANISM(S)

No information on production organism(s) used in the manufacturing process is reported in the currently applicable specifications for malic acid and malates (E 296; E 350-352). However, based on publicly available information, it is possible that these food additives could be manufactured through a process involving the use of production organisms.

For **food additives of microbial origin**, the following information regarding the microorganism used to produce the additive is sought:

- Name of the microorganism (species and strain).
- Taxonomical identification of the microorganism at the species level.
- Certificate of deposition of the microorganism in an internationally recognised culture collection stating the deposition number.
- Origin and history of modifications of the production organism. If the organism has been subject to genetic modifications, these should be characterised.
- Any information on possible toxigenicity or pathogenicity.
- For bacteria, genome analysis searching for possible antimicrobial resistance (AMR) genes.

The above characterisation should be based, whenever possible (and compulsory for bacteria) on whole genome sequence (WGS) analysis, following the requirements of Section 1.1 of the 2021 EFSA CEP Panel Scientific Guidance for the submission of dossiers on Food Enzymes.[17]

In addition, the following information should be provided for additives obtained by microbial fermentation:

- Experimental data demonstrating **absence of viable cells of the production strain** in the final product according to Section 1.3.4.1 of the 2021 EFSA CEP Panel *Scientific Guidance for the submission of dossiers on Food Enzymes.*

[15] OJ L 354, 31.12.2008, p.7. ELI: http://data.europa.eu/eli/reg/2008/1332/oj
[16] EFSA ANS Panel, 2012. Available at: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2012.2760
[17] EFSA CEP Panel, 2021. Available at: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6851

- If the microorganism is genetically modified, or if AMR genes have been found in its genome, experimental data demonstrating the **absence of DNA from the microorganism** in the product according to Section 1.3.4.2 of the 2021 EFSA CEP Panel *Scientific Guidance for the submission of dossiers on Food Enzymes.*
- Where relevant, information on the **identity of residual mycotoxins or other metabolites** with possible toxigenic activity in the final product.

3.3. PRESENCE OF TOXICOLOGICALLY RELEVANT IMPURITIES AND RELATED SPECIFICATIONS

The existing specifications for malic acid and malates (E 296; E 350–352) in Regulation (EU) No 231/2012[11] establish limits for the following purity parameters:

TABLE 2. EU Specifications for malic acid and malates (E 296; E 350–352) from Reg. (EU) No 231/2012

	E 296	E 350(i)	E 350(ii)	E 351	E 352(i)	E 352(ii)
ASSAY	Content not less than 99,0 %	Content not less than 98,0 % on the anhydrous basis	Content not less than 99,0 % on the anhydrous basis	Content not less than 59,5 %	Content not less than 97,5 % on the anhydrous basis	Content not less than 97,5 % on the anhydrous basis
LOSS ON DRYING		Hemihydrate: Not more than 7,0 %[(a)] Trihydrate: 20,5-23,5 %[(a)]	Not more than 2,0 %[(b)]		Not more than 2,0 %[(c)]	Not more than 2,0 %[(b)]
ALKALINITY		Not more than 0,2 % as Na_2CO_3		Not more than 0,2 % as K_2CO_3	Not more than 0,2 % as $CaCO_3$	
SULPHATED ASH	Not more than 0,1 %					
FUMARIC ACID	Not more than 1,0 %	Not more than 1,0 %	Not more than 1,0 %	Not more than 1,0 %	Not more than 1,0 %	Not more than 1,0 %
MALEIC ACID	Not more than 0,05 %	Not more than 0,05 %	Not more than 0,05 %	Not more than 0,05 %	Not more than 0,05 %	Not more than 0,05 %
FLUORIDE					Not more than 30 mg/kg	Not more than 30 mg/kg
ARSENIC	Not more than 3 mg/kg	Not more than 3 mg/kg	Not more than 3 mg/kg	Not more than 3 mg/kg	Not more than 3 mg/kg	Not more than 3 mg/kg
LEAD	Not more than 2 mg/kg	Not more than 2 mg/kg	Not more than 2 mg/kg	Not more than 2 mg/kg	Not more than 2 mg/kg	Not more than 2 mg/kg
MERCURY	Not more than 1 mg/kg	Not more than 1 mg/kg	Not more than 1 mg/kg	Not more than 1 mg/kg	Not more than 1 mg/kg	Not more than 1 mg/kg

a) 130 °C, 4 hours
b) 110 °C, 3 hours
c) 100 °C, 3 hours

In order to progress with the safety assessment and in the light of the experience accrued with the food additives re-evaluation programme, often leading to recommendations for updating the existing EU Specifications to lower the potential exposure to toxic elements and other impurities of toxicological concern resulting from the use of these food additives, the following information is sought from interested business operators and other interested parties:

- provide analytical data on the identity and content of impurities (**already listed or currently unlisted in the existing EU specifications**) derived from each production

method used to manufacture the food additives using appropriate analytical methods applying state of the art techniques. The **results of the analyses should be supported by certificates of analysis**. In addition, information on the representativeness of the analysed batches should be provided. Specific data on the methods of analysis used should be provided, e.g., the principle and scope of the method, the concentration units used to express the analytical result(s), validation parameters of the method (in particular, the limits of detection (LOD) and quantification (LOQ).

- among the currently unlisted impurities, analytical data should be provided on **cadmium (Cd)**.
- provide a proposed limit for any impurity based on the results of the analytical data and its lowest technologically achievable level in the food additive.
- provide information on microbiological specifications, e.g., the presence of microorganisms, mycotoxins, and other toxins, where relevant, manufactured via fermentation.

The number of analytical data provided by the interested parties should adequately cover the between-batches variability (at least five independently produced batches of each food additive), associated with the use of different source materials, and should be representative of the food additives malic acid and malates (E 296; E 350-352) currently placed in the EU market.

4. ADEQUATE ESTIMATION OF THE TOTAL DIETARY EXPOSURE

Malic acid and malates (E 296; E 350-352) are currently permitted for use as food additives in accordance with Regulation (EC) No 1333/2008[1] under the following conditions of use:

TABLE 3. Permitted uses and use levels of malic acid and malates (E 296; E 350-352) as laid down in Regulation (EC) No 1333/2008

NAME (E NUMBER)	CONDITIONS OF USE	SPECIFIC MAXIMUM LEVEL INDIVIDUAL RESTRICTIONS / EXCEPTION
MALIC ACID (E 296)	Substance is included in Group I	*quantum satis*
	4.1.2 Peeled cut and shredded fruit and vegetables	*quantum satis*, only prepacked unprocessed and peeled potatoes only
	13.1.3 Processed cereal-based foods and baby foods for infants	*quantum satis*, only processed cereal based foods and baby foods, only for pH adjustment, L(+)-form only
	14.1.2 Fruit juices as defined by directive 2001/112	ML = 3000 mg/L, only pineapple juice
	14.1.3 Fruit nectars as defined by directive 2001/112	*quantum satis,* only traditional Swedish and Finnish fruit syrups
SODIUM MALATES (E 350i,ii)	Substance is included in Group I	*quantum satis*
POTASSIUM MALATE (E 351)	Substance is included in Group I	*quantum satis*
CALCIUM MALATES (E 352i,ii)	Substance is included in Group I	*quantum satis*

In addition to their currently authorised uses as food additive, L-malic acid is also an authorised food flavouring [FL-No 08.025] included in the Union List established in Regulation (EU) No

1334/2008[18], whereas calcium malate is included in the Union list of substances that may be added to food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control established under Regulation (EU) No 609/2013[19]. This information may be relevant to the estimation of the overall dietary exposure.

TABLE 4. Authorised Uses of E 352(i) According to Reg. (EU) 609/2013

SUBSTANCE	INFANT FORMULA AND FOLLOW ON FORMULA	PROCESSED CEREAL-BASED FOOD AND BABY FOOD	FOOD FOR SPECIAL MEDICAL PURPOSES	TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL
CALCIUM MALATE	-	-	**X**	**X**

4.1. ADDITIONAL DATA ON USES AND USE LEVELS

On 5th March 2024, EFSA has published an 'Open call for food additive occurrence data in food and beverages intended for human consumption',[20] in which occurrence (analytical) data on the food additives (E 296; E 350-352) are searched for.

Previously, in response to the "Call for data on miscellaneous food additives" published in 2010, EFSA did not receive any use level data for the food additives (E 296; E 350-352).

A preliminary search of the EFSA Data Warehouse for the analytical data available for inclusion in the overall dietary exposure estimate for the group of food additives (E 296; E 350-352), has returned no entries for the substances E 350-352.

According to the ANS Panel "*Statement on a conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010*"[21], in the absence of MPLs for a food additive and if usage or analytical data received from interested parties refer only to a small proportion of the food categories in which the food additive is authorised, the safety assessment carried out by the Panel will be limited to these uses and use levels.

Should interested parties/business operators hold additional information related to uses and use levels of the food additives included in this call and not yet transmitted to EFSA in response to the earlier call for data, it will be possible to submit it in response to the present call.

Individual food manufacturers and food manufacturer associations are invited to submit data on use levels of food additives in food and beverages for human consumption for the food additive listed above. In order to streamline the data collection exercise, food manufacturers are invited to liaise with the relevant food manufacturer associations for the data submission. In particular, data providers shall ensure that the same data are not sent several times to EFSA (e.g. by both the food manufacturer and also by the association to which the food manufacturer belongs to).

[18] OJ L 354, 31.12.2008, p. 34–50. ELI: http://data.europa.eu/eli/reg/2008/1334/oj
[19] OJ L 181, 29.6.2013, p. 35–56. http://data.europa.eu/eli/reg/2013/609/oj
[20] 'Open call for food additive occurrence data in food and beverages intended for human consumption'. Available at: https://www.efsa.europa.eu/en/call/open-call-food-additive-occurrence-data-food-and-beverages-intended-human-consumption-2
[21] EFSA ANS Panel, 2014. Available at: https://doi.org/10.2903/j.efsa.2014.3697

If an interested party has information that a food additive is not used for one or several food categories, this information is highly relevant for EFSA. Such information will be cross-checked with information sent by all interested parties.

4.2. INFORMATION ON NATURAL OCCURRENCE

According to the ANS Panel "*Statement on a conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010*"[21], if the food additive and/or its breakdown products/metabolites is/are identical to a compound which is a normal constituent in the body (an endogenous compound) and/or is a regular component of the diet, the conclusion will be based on the comparison between naturally occurring exposure and the exposure arising from the uses of the food additive.

Because of the above, information (e.g., bibliographical references, publications) on natural occurrence of malic acid, malates are sought with a view to draw a comparison with the estimated dietary exposure resulting from the use E 296 and E 350-352 as food additives.

CONFIDENTIALITY

In accordance with Article 8 of Regulation (EU) No 257/2010, in the version of the text in force prior to 27 March 2021, setting up a re-evaluation programme of approved food additives, confidential treatment may be given to information the disclosure of which might significantly harm the competitive position of business operators or other interested parties.

Therefore, data providers should indicate any information they wish to be treated as confidential and provide verifiable justification supporting this request. Please also note that the information described in Article 8(2) of Regulation (EU) No 257/2010, in the version of the text in force prior to 27 March 2021, cannot be regarded as confidential in any circumstances.

In application of Article 8(4) of Regulation (EU) 257/2010, in the version of the text in force prior to 27 March 2021, following a proposal from EFSA, the Commission will decide after consulting the interested business operator and/or the other interested parties, which information may remain confidential.

SUBMISSION OF INFORMATION

Submission of information sought at points n. 1-3 and 4.2.
Interested business operators and/or interested parties should submit the information to EFSA, **RAL@efsa.europa.eu**, through their chosen internet-based software (submission by email attachment is not allowed) with:

- The heading of the email to RAL indicating: **Call for data on malic acid and malates**
- A cover letter that should contain:
    - Reference to the specific call Reference to the substance(s) concerned and its E numbers and its EFSA question number.
    - 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.
- Statement of the submitter that they hold all the necessary rights to grant EFSA permission to use and, where appropriate, to disclose the submitted information, data,

document, paper, or study for the purposes better defined in this call. In case the submitter does not enjoy such rights for the submitted subject matter, they should share the contact details of the respective owner(s) of data and/or the holder(s) of any relevant intellectual property rights, so that EFSA may seek their approval directly.

- Separate folders with the confidential and with the non-confidential parts.

Submission of information sought at point n. 4.1

Interested parties should submit this information to EFSA, **Data.collection@efsa.europa.eu**. Data submission of use levels of approved food additives in food and beverages intended for human consumption should be reported in the template developed for this purpose (MS Excel AddUseLevTemplate.xlsm). This format is structured in accordance with the Guidance on Standard Sample Description (SSD Guidance)[22] and includes features that support manual data entry.

To submit use level data please download the zip file 'ADD_use_data_submission.zip', which also contains a technical guidance on the use of the reporting template ('Guidance on using addUseLevTemplate.pdf'). Please follow the instructions described in the first work sheet of the template, and more extensively within the technical guidance for the correct use of the reporting format to avoid compromising its functionalities.

Should you need any support in filling in the reporting format, please contact data.collection@efsa.europa.eu

Use levels datasets should be saved and submitted directly to EFSA using the dedicated e-mail address for this service data.collection@efsa.europa.eu

The documentation needed **to support the data collection on food additive use levels** is summarised below:

ADD_use_data_submission.zip including the following files:

MS Excel® AddUseLevTemplate.xlsm

Guidance on using addUseLevTemplate.pdf

Annex Food Category Description

In case future mutual interests arise in exchanging any relevant information (i.e., technical, or toxicological data) with the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for the re-evaluation of food additives or with other EU agencies (such as the European Medicines Agency (EMA)), we would appreciate your written consent for data sharing between EFSA and other EU agencies or JECFA on this additive.

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

[22] European Food Safety Authority; Standard sample description for food and feed. EFSA Journal 2010;8(1):1457 [54 pp.]. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/1457

Once internet-based software chosen please kindly send the link and login to RAL@efsa.europa.eu. You may provide the password by phone, if so, you are kindly asked to call the following phone nr +39 0521 036 246 as soon as email with the links is sent. Alternatively, it can be sent in a separate email to **RAL@efsa.europa.eu**.

Data providers of uses and use levels (information sought n.4.1) should be aware that EFSA may need to contact them once the initial submission is received. The aim is to clarify foods not well characterised/identified or to check any possible mistakes (e.g. on MPLs) or not plausible data (e.g. on reported levels, proposed dilution factors). Replies to these requests are strongly encouraged as EFSA reserves the right to discard these data if feedback is not received.

For additional questions on this process the following functional mailboxes can be used:

RAL@efsa.europa.eu	- Any enquiries and submission of technical data and data on natural occurrence
data.collection@efsa.europa.eu	- Any enquiries and submission of use levels data