Call for data for the re-evaluation of fumaric acid (E 297) and succinic acid (E 363) as food additives

CONTENTS

RE-EVALUATION OF FUMARIC ACID (E 297) AND SUCCINIC ACID (E 363) 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 ADDITIVE

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 fumaric acid (E 297) and succinic acid (E 363).

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(EU) No 257/2010, EFSA launches a public call for data, in order to acquire documented information (published and/or unpublished) on fumaric acid (E 297) and succinic acid (E 363).

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institutions, academia) and/or other stakeholders, the opportunity to submit documented information (published and/or unpublished) relevant to the re-evaluation of the following food additives: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	EFSA-Q-NUMBER
FUMARIC ACID	E 297	*trans*-Butenedioic acid	2011-00599
SUCCINIC ACID	E 363	Butanedioic acid	2011-00641

These food additives were already included in previous calls for data published by EFSA in 2010[3] and in 2012[4].

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 Fumaric and Succinic Acid

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**Error! Bookmark not defined.** 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 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.

[3] Call for scientific data on miscellaneous food additives permitted in the EU and belonging to several functional classes. (Published: 9 June 2010).
[4] Call for scientific data on miscellaneous food additives permitted in the EU and belonging to several functional classes 2012-2013; (Published: 5 July 2012). Available at: https://www.efsa.europa.eu/en/consultations/call/call-scientific-data-miscellaneous-food-additives-permitted-eu-and

PREVIOUS RELEVANT EVALUATIONS

In the EU, the safety of **fumaric acid (E 297)** as a food additive has been evaluated by the Scientific Committee for Food (SCF) in 1990. The SCF report stated the following:

> *"Fumarates are normal components of intermediate metabolism. The testicular atrophy in rabbits reported after intraperitoneal administration of high doses was not seen after oral administration as high as 6-9 % in the diet of rabbits and other species."*

The SCF confirmed the ADI of 6 mg/kg body weight, previously established by JECFA but no further details were given in the report.

Fumaric acid was evaluated as a food additive by JECFA in 1967 (10th meeting)[5], 1974 (18th meeting)[6], 1980 (23rd meeting)[7], 1990 (35th meeting)[8] and as a flavouring agent in 2000 (53rd meeting) (JECFA (2000)) [9]. A toxicological monograph was prepared by JECFA in (1974). At the 10th meeting, JECFA established an ADI of 0-6 mg/kg, which was confirmed as the ADI at the 18th meeting. At the 23rd meeting (1980) a group ADI of 0-6 mg/kg for fumaric acid and its salts was established. At the 35th meeting the group ADI was changed to "not specified". This ADI "not specified" was upheld at the 53rd meeting (2000).

The 2000 JECFA evaluation was considered by EFSA also for the evaluation of fumaric acid as a food flavouring substance [FL-No 08.025] within the Flavouring Group Evaluation 10 (FGE.10) for aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids, and esters containing an additional oxygenated functional group and lactones from chemical groups 9, 13 and 30 (EFSA CEF Panel, 2012)[10].

Also the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) evaluated the safety of fumaric acid as a feed additive for all animal species (EFSA FEEDAP Panel, 2013)[11]. The FEEDAP opinion stated the following:

> *"Fumaric acid is rapidly metabolised by well-recognised pathways, and neither fumarate nor its metabolites would be expected to accumulate in animal tissues. Consequently, human exposure is not expected to be measurably increased by the use of fumaric acid in animal nutrition."*

Succinic acid (E 363) had been previously evaluated by the SCF in 1991[12] when a group ADI "not specified" was established. The SCF report stated the following:

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[5] JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1967. Specifications for the identity and purity of food additives and their toxicological evaluation: some emulsifiers and stabilizers and certain other substances. Available at: https://iris.who.int/bitstream/handle/10665/40668/WHO_TRS_373.pdf?sequence=1

[6] JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1974. Evaluation of certain food additives, 18th report. Available at: https://www.who.int/publications/i/item/9241205571

[7] JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1980. Evaluation of certain food additives, 24th report. Available at: https://www.who.int/publications/i/item/9241206535

[8] JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1990. Evaluation of certain food additives and contaminants, 35th report. Available at: https://www.who.int/publications/i/item/9241207892

[9] JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2000. Evaluation of certain food additives and contaminants, 53rd report. Available at: https://iris.who.int/bitstream/handle/10665/42378/WHO_TRS_896.pdf;jsessionid=EAA851B9B66191F189AA8F81D2BF924C?sequence=1

[10] EFSA CEF Panel, 2012. Available at: https://doi.org/10.2903/j.efsa.2012.2563

[11] EFSA FEEDAP Panel, 2013. Available at: https://doi.org/10.2903/j.efsa.2013.3102

[12] SCF (Scientific Commitee for Food), 1991. Food-science and techniques, 25th report. 1-25. Available at: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_25.pdf

> "*This anion occurs in nature and plays a role as an intermediate metabolite in the citric acid cycle. It also participates in the glucose and fatty acid synthesis. No systematic toxicological studies are available. However, in view of its role as an intermediate metabolite the Committee established a group ADI not specified for succinate.*"

The conclusions from the SCF confirmed those previously reached by JECFA that, in its 1986 toxicological evaluation of succinic acid (E 363), had also established an ADI "not specified" for this substance[13]. The JECFA report stated the following:

> *"Succinic acid is a natural constituent of plants and animals that are commonly used as food. Experimental animals can tolerate high dietary concentrations of succinic acid. Succinic acid does not represent a hazard at levels at which it is likely to be used as a food additive because of its normal role in metabolism. An ADI "not specified" was established for the succinate moiety."*
>
> *"The Committee had no information on the manufacture or use of the food-grade materials. No toxicological monograph was prepared. No specifications were prepared.".*

Succinic acid [FL-no: 08.024] was also included in the same FGE.10 evaluation by the CEF Panel which also included the related food flavourings succinic acid, disodium salt [FL-no: 08.113]. The latter was considered to raise no safety concerns at a level of intake of 1500 µg/day/person, as estimated by the maximised survey-derived daily intake (MSDI) (EFSA CEF Panel, 2012).[10]

PRELIMINARY APPROACH FOR THE RE-EVALUATION

The FAF Panel considers that the safety of the food additives fumaric acid (E 297) and succinic acid (E 363) can be assessed in a joint scientific opinion, given that all these substances share a common metabolic fate, both being endogenous compounds involved in the citric acid cycle.

In order for the FAF Panel to confirm that the **conventional risk assessment** is adequate to re-evaluate the safety in use of this already permitted food additive, 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.1**).

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.2**).

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.3**).

[13] JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1986. Evaluation of certain food additives and contaminants, 29th report. WHO Technical report series, no. 733, 1-59. Available at: http://whqlibdoc.who.int/trs/WHO_TRS_733.pdf

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. 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)[14]. 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[15], and outlines appraisal routes (e.g., solubility) to confirm that an assessment of the fraction of small particles including nanoparticles is not needed.

The existing EU specifications for fumaric acid (E 297) and for succinic acid (E 363) set in Regulation (EU) No 231/2012[16] do not list any information on the solubility of these food additives.

Based on the information available in the public domain, the solubility in water of succinic acid is reported to be substantially 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, and therefore the conventional risk assessment is considered applicable to E 363.

With respect to **fumaric acid (E 297)** instead, JECFA specifications report the solubility of this food additive as "*insoluble to slightly soluble in water; soluble in alcohol; slightly soluble in oils*". The information from the public domain indicates a reported solubility in water lower than the threshold value of 33.3 g/L.

Interested parties and/or business operators are kindly invited to provide additional scientific evidence, supported by data, e.g., confirming that the food additive fumaric acid (E 297) meets at least one of the Decision criteria listed in Table 1 of the EFSA SC Guidance on particle-TR[14].

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

2. POTENTIAL PRESENCE OF TOXICOLOGICALLY RELEVANT IMPURITIES

2.1. INFORMATION ON MANUFACTURING PROCESS AND RELATED SPECIFICATIONS

Regulation (EC) No 231/2012[15], laying down the specifications for food additives, does not contain information on the manufacturing process(es) used for the production of fumaric acid (E 297) and succinic acid (E 363).

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

From the information available in the published literature, it seems plausible that the food additives may be manufactured either through chemical synthesis or using production organisms.

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 fumaric acid (E 297) and/or succinic acid (E 363).
- propose a short description of each production method used to manufacture the food additives, including the key steps involved, for possible inclusion in a future revision of the EU specifications.
- 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(s).
- 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.[17] 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*[18] for the preparation of the data submission.

2.2. INFORMATION ON PRODUCTION ORGANISM(S)

No information on the production organism(s) used in the manufacturing process is reported in the currently applicable EU specifications for fumaric acid (E 297) and succinic acid (E 363). However, based on publicly available information, it is possible these food additives could be manufactured through a process involving a microorganism.

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.

[17] OJ L 354, 31.12.2008, p.7. ELI: http://data.europa.eu/eli/reg/2008/1332/oj
[18] EFSA ANS (2012). Available at: https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2012.2760

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.[19]

In addition, the following information should be provided for additive 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.*
- 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.

2.3. PRESENCE OF TOXICOLOGICALLY RELEVANT IMPURITIES AND RELATED SPECIFICATIONS

The existing specifications for fumaric acid (E 297) and succinic acid (E 363), set in Regulation (EU) No 231/2012[16], establish limits for the following purity parameters (see Table 2)

TABLE 2. EU Specifications for fumaric acid (E 297) and succinic acid (E 363) from Reg (EU) No 231/2012

	FUMARIC ACID (E 297)	SUCCINIC ACID (E 363)
ASSAY	Content not less than 99.0 % on the anhydrous basis	Content not less than 99.0 %
PURITY:		
LOSS ON DRYING	Not more than 0.5 %[(a)]	
SULPHATED ASH	Not more than 0.1 %	
RESIDUE ON IGNITION		Not more than 0,025 %[(b)]
MALEIC ACID	Not more than 0.1 %	
ARSENIC	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
MERCURY	Not more than 1 mg/kg	Not more than 1 mg/kg

a) 120 °C, 4 hours
b) 800 °C, 15 min

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 exposure to toxic elements and other impurities of toxicological concern resulting from the use of the 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 additive using appropriate analytical methods applying state of the art techniques. The **results of the analyses should be supported**

[19] EFSA CEP Panel, 2021. Available at: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6851

by certificates of analysis. In addition, information on the representativeness of the tested batches should be provided. Specific data on the used methods of analysis 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 the food additive), associated with the use of different source materials, and should be representative of the food additive fumaric acid (E 297) and succinic acid (E 363) currently placed in the EU market.

3. ADEQUATE ESTIMATION OF THE TOTAL DIETARY EXPOSURE

Fumaric acid (E 297) is currently permitted for use as food additive in accordance with Regulation (EC) No 1333/2008[1] under the following conditions of use:

TABLE 3. Permitted used and use levels of fumaric acid (E 297) in foods as laid down in Regulation (EC) No 1333/2008

CATEGORY NUMBER	FOODS	RESTRICTIONS/EXCEPTION	MAXIMUM LEVEL (mg/L or mg/kg as appropriate)
1.4	Flavoured fermented milk products including heat-treated products	Only fruit-flavoured desserts	4000
5.2	Other confectionery including breath freshening microsweets	Only sugar confectionery	1000
5.3	Chewing gum		2000
5.4	Decorations, coatings and fillings		1000
		Only fillings and toppings for fine bakery ware	2500
14.1.4	Flavoured drinks	Only instant powders for fruit-based drinks	1000
14.1.5.2	Other	Only instant products for preparation of flavoured tea and herbal infusions	1000
16	Desserts excluding products covered in categories 1, 3 and 4	Only gel-like desserts, fruit-flavoured desserts, dry powdered dessert mixes	4000

Succinic acid (E 363) is currently permitted for use as food additive in accordance with Regulation (EC) No 1333/2008[1] under the following conditions of use:

TABLE 4. Permitted used and use levels of succinic acid (E 363) in foods as laid down in Regulation (EC) No 1333/2008

CATEGORY NUMBER	FOODS	RESTRICTIONS/EXCEPTION	MAXIMUM LEVEL (mg/L or mg/kg as appropriate)
1.4	Flavoured fermented milk products including heat-treated products		6000
12.5	Soups and broths		5000
14.1.4	Flavoured drinks	only powders for home preparation of drinks	3000
14.1.5.2	Other	only powders for home preparation of drinks	3000
16	Desserts excluding products covered in categories 1, 3 and 4	Only gel-like desserts, fruit-flavoured desserts, dry powdered dessert mixes	6000

In addition to their currently authorised uses as food additives, both fumaric acid and succinic acid are also authorised food flavourings included in the Union List established in Regulation (EU) No 1334/2008[20], corresponding to the flavouring numbers [FL-No 08.023] and [FL-no: 08.024].

In the case of fumaric acid (E 297) and succinic acid (E 363), a *regulatory maximum level exposure assessment scenario*, as described in the 2017 EFSA ANS Panel "*Statement on the approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation*"[21] can already be estimated using the Food Additives Intake Model 2.1 (FAIM) tool[22] and using the maximum permitted levels reported above in Table 3 and Table 4, respectively.

Preliminary dietary exposure assessment of fumaric acid (E 297)

The output of the FAIM tool for fumaric acid (E 297) is presented below in Table 5.

TABLE 5. Summary of dietary exposure to fumaric acid (E 297) from its maximum use levels as a food additive in six population groups, estimated with FAIM (minimum-maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks-11 months)	Toddlers[(a)] (12–35 months)	Children[(b)] (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly[(b)] (≥ 65 years)
Regulatory maximum exposure assessment scenario						
Mean	0.5-18.7	3.6-46.6	3.5-42.5	1.7-19.8	1.3-11.6	0.8-11.0
95th percentile	0.0-60.0	20.7-123.4	15.0-102.3	8.0-46.9	6.4-30.9	4.6-23.4

(a): The term 'toddlers' in the Comprehensive Database (EFSA, 2011) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013[23]

[20] OJ L 354, 31.12.2008, p. 34–50. ELI: http://data.europa.eu/eli/reg/2008/1334/oj
[21] EFSA ANS Panel, 2017. Available at: https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5042
[22] https://www.efsa.europa.eu/en/applications/food-improvement-agents/tools#food-additives-intake-model
[23] OJ L 181, 29.6.2013, p. 35–56. http://data.europa.eu/eli/reg/2013/609/oj

(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in Comprehensive Database (EFSA, 2011).

Because the use of fumaric acid (E 297) is subject to exceptions and restrictions, as shown in Table 3, and because in the FAIM tool these cannot be accounted for, an additional exposure assessment was performed using the Dietary Exposure (DietEx) tool[24] and is reported below in Table 6.

The food categories in which the use of fumaric acid (E 297) is permitted were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx2 classification system), at the most detailed level possible (up to FoodEx2 Level 7), based on the food categories and exceptions/restrictions given in table 3.

TABLE 6. Summary of dietary exposure to fumaric acid (E 297) from its maximum use levels as a food additive in seven population groups, estimated with DietEx (minimum-maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks-11 months)	Toddlers[(a)] (12–35 months)	Children[(b)] (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	Elderly (65-74 years)	Very elderly (≥75 years)
Regulatory maximum exposure assessment scenario							
Mean	0.1-8.8	3.1-21.4	0.4-15.9	0.2-2.5	0.0-2.5	0.0-2.1	0.2-2.1
95th percentile	0.0-50.0	18.5-81.6	1.6-68.1	0.0-25.1	0.0-13.5	0.0-10.8	0.0-11.2

(a): The term 'toddlers' in the Comprehensive Database (EFSA, 2011) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013[23]
(b): The term 'children' corresponds to 'other children' in the Comprehensive Database (EFSA, 2011).

At the current MPL, the mean exposure to fumaric acid (E 297) from its use as a food additive ranged from 0.0 mg/kg bw per day in adults and the elderly to 21.4 mg/kg bw per day in toddlers. The 95th percentile of exposure to fumaric acid (E 297) ranged from 0.0 mg/kg bw per day in infants, adolescents, adults, the elderly, and the very elderly to 81.6 mg/kg bw per day in toddlers.

Flavoured yoghurt made from cow's milk was the principal contributor to the exposure for each age category. In toddlers, (other) children, adolescents, adults, and the elderly yoghurt drinks, including sweetened and/or flavoured variants were another dominant source of exposure.

Preliminary dietary exposure assessment of succinic acid (E 363)

The output of the FAIM tool for succinic acid (E 363) is presented below in Table 7.

TABLE 7. Summary of dietary exposure to succinic acid (E 363) from its maximum use levels as a food additive in six population groups, estimated with FAIM (minimum-maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks - 11 months)	Toddlers[(a)] (12–35 months)	Children[(b)] (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly[(b)] (≥ 65 years)
Regulatory maximum exposure assessment scenario						
Mean	1.4 - 53.3	8.3 - 107	9.3 - 94.3	4.5 - 48.7	3.5 - 30.1	2.4 - 32.5
95th percentile	5.6 - 180	42.1 - 260.4	35.9 - 208.8	20.1 - 107.5	18.2 - 74.5	12.9 - 66.8

(a): The term 'toddlers' in the Comprehensive Database (EFSA, 2011) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013[23]

[24] https://www.efsa.europa.eu/en/science/tools-and-resources/dietex

(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in Comprehensive Database (EFSA, 2011).

Because the use of succinic acid (E 363) is subject to exceptions and restrictions, as shown in Table 4, and because in the FAIM tool these cannot be accounted for, an additional exposure assessment was performed using the DietEx tool and is reported below in Table 8.

The food categories in which the use of succinic acid (E 363) is permitted were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx2 classification system), at the most detailed level possible (up to FoodEx2 Level 7), based on the food categories and exceptions/restrictions given in Table 6.

TABLE 8. Summary of dietary exposure to succinic acid (E 363) from its maximum use levels as a food additive in seven population groups, estimated with DietEx (minimum - maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks - 11 months)	Toddlers[(a)] (12–35 months)	Children[(b)] (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	Elderly (65 - 74 years)	Very elderly (≥75 years)
Regulatory maximum exposure assessment scenario							
Mean	1.7 – 77.0	15.0 – 85.0	7.4 - 52.1	1.8 - 10.6	2.1 - 10.1	1.9 - 12.4	1.7 - 14.6
95th percentile	11.8 - 386.3	61.1 - 246.7	31.2 - 139.2	11.9 - 42.2	11.2 - 29.3	9.6 - 33.8	11.0 – 37.0

(a): The term 'toddlers' in the Comprehensive Database (EFSA, 2011) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013[25]

(b): The term 'children' corresponds to 'other children' in the Comprehensive Database (EFSA, 2011).

At the current MPL, the mean exposure to succinic acid (E 363) from its use as a food additive ranged from 1.7 mg/kg bw per day in infants to 85.0 mg/kg bw per day in toddlers. The 95th percentile of exposure to succinic acid (E 363) ranged from 9.6 mg/kg bw per day in adults to 386.3 mg/kg bw per day in infants.

Flavoured fermented milk products are the principal contributors to the exposure for each age category.

However, additional data on uses and use levels, if available, will provide useful information to calculate a refined exposure assessment scenario.

[25] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. OJ L 181, 29.6.2013, p. 35–56.

3.1. 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',[26] in which occurrence (analytical) data on the food additives fumaric acid (E 297) and succinic acid (E 363) are sought.

Should interested parties/business operators hold additional information related to uses and use levels of these food additives 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).

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.

3.2. 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*"[27], 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 fumaric and succinic acid is sought with a view to draw a comparison with the estimated dietary exposure resulting from the use of fumaric acid (E 297) and succinic acid (E 363) 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.

[26] '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
[27] EFSA ANS Panel, 2014. Available at: https://doi.org/10.2903/j.efsa.2014.3697

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. 1-2 and 3.2.
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 fumaric and succinic acid**
- 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. 3.1
Interested parties should submit the 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)[28] 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

[28] 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

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

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. 3.1) 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