

Call for data for the re-evaluation of gluconic acid (E 574) and related food additives (E 575-579)

Food Ingredients and Packaging Unit

CONTENTS

<i>Call for additional data needed to complete the re-evaluation</i>	3
Background	3
Overall objective	3
Deadlines for submission of data and disclosure of contact details	4
Re-evaluation strategy	5
Information/data sought	6
1. confirmation of adequacy of conventional risk assessment	6
2. Confirmation of low intrinsic toxicity	6
a. Information on production organism(s)	8
b. Presence of toxicologically relevant impurities and related specifications	9
3. adequate estimation of the total dietary exposure	10
a. Additional data on uses and use levels	11
b. Information on natural occurrence	12
Confidentiality	12
Submission of information	12
Possibility for EFSA to use the data for the safety assessment of the same or other substance under the same or other legal or regulatory frameworks.	13
Correspondence	13

RE-EVALUATION OF GLUCONIC ACID (E 574) AND RELATED FOOD ADDITIVES (E 575-579)

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

CALL FOR ADDITIONAL DATA NEEDED TO COMPLETE THE RE-EVALUATION

BACKGROUND

According to Regulation (EC) No 1333/2008¹, food additives which 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 257/2010². The programme for the re-evaluation of food additives 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 gluconic acid (E 574) and related food additives (E 575-579).

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

Therefore, in accordance to 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(EU) No 257/2010, EFSA launches a public call for data in order to acquire documented information (published and/or unpublished) on gluconic acid (E 574) and related food additives (E 575-579).

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

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:

¹ Regulation (EC) No 1333/2008 on food additives, OJ L 354, 31.12.2008

² Regulation (EU) No 257/2010, setting up a programme for the re-evaluation of approved food additives in accordance with regulation (EC) No 1333/2008, OJ L 80, 26.03.2010

NAME	E NUMBER	SYNONYMS/ CHEMICAL NAME	EFSA-Q-NUMBER
GLUCONIC ACID	E 574	D-gluconic acid; Dextrans acid / Gluconic acid	2011-00684
GLUCONO-DELTA-LACTONE	E 575	Gluconolactone; GDL; D-Gluconic acid delta-lactone; Delta-gluconolactone / D-Glucono-1,5-lactone;	2011-00685
SODIUM GLUCONATE	E 576	Sodium D-gluconate / Sodium salt of D-gluconic acid	2011-00686
POTASSIUM GLUCONATE	E 577	Potassium salt of D-gluconic acid / Potassium D-gluconate	2011-00687
CALCIUM GLUCONATE	E 578	Calcium salt of D-gluconic acid/ Calcium di-D-gluconate	2011-00688
FERROUS GLUCONATE	E 579	Ferrous di-D-gluconate dihydrate; Iron(II) di-gluconate dihydrate	2011-00689

These food additives were already included in a previous call for data published by EFSA in 2012³.

Data on uses and use levels in food were also already collected by EFSA by means of a "Call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 5)"⁴ published in 2016 and closed in 2017.

Interested parties that have already submitted information in response to the above calls do not need to reply again to the present call, unless they can contribute with additional information not previously provided to EFSA.

DEADLINES FOR SUBMISSION OF DATA AND DISCLOSURE OF CONTACT DETAILS

Interested parties and stakeholders should provide by **31/12/2023** the information described below, except for the information requested under point 3.a of this call for which specific timelines for submission will be communicated separately.

Within 4 weeks from the publication of this call, please communicate in writing by e-mail to: **RAL@efsa.europa.eu**, your availability to submit the requested information by the timeline specified above or any proposal for a new deadline providing justified reasons. Depending on the replies received the final deadline will be communicated to you through e-mail and by updating the current call.

³ <https://www.efsa.europa.eu/sites/default/files/consultation/120706a.pdf>

⁴ <https://www.efsa.europa.eu/it/data/call/160524>

In accordance with Article 6(4) of the Regulation (EU) No 257/2010, 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.

RE-EVALUATION STRATEGY

The FAF Panel considers that the safety of gluconic acid (E 574) and related food additives (E 575-579) can be assessed in a joint scientific opinion given that all these substances share a common metabolic fate.

Gluconic acid (E 574), glucono-delta-lactone (E 575), sodium gluconate (E 576), potassium gluconate (E 577), and calcium gluconate (E 578) as food additives in the EU and were previously evaluated by JECFA in 1998⁵ and the SCF in 1990⁶. The SCF established a group ADI “not specified” for gluconic acid, sodium gluconate, potassium gluconate, calcium gluconate, and glucono-delta-lactone. In 1999, JECFA extended the previous ADI “not specified” for glucono-delta-lactone to a group ADI for glucono-delta-lactone and the calcium, magnesium, potassium and sodium salts of gluconic acid.

For ferrous gluconate, in 1990 the SCF referred to a provisional maximum tolerable daily intake (PMTDI) of 0.8 mg/kg bw per day calculated as Fe from all sources previously established by JECFA in 1975⁷. The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) has concluded that there were no adequate data to establish a tolerable upper level (UL) for iron (EFSA NDA Panel, 2004⁸; 2015⁹). A review of the existing scientific evidence is currently ongoing¹⁰ by EFSA and should provide conclusions on either the establishment of an UL for iron or an indication on the highest level of intake where there is reasonable confidence in data on the absence of adverse effect.

Based on previous evaluations, gluconic acid (E 574) and related food additives (E 575-579) will be *a priori* considered by the Panel to be of low intrinsic toxicity.

In order for the FAF Panel to confirm that **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 needed for confirming that (a) the material does not contain a fraction of small particles including nanoparticles, or (b) a fraction of small particles, including nanoparticles, is present but properly covered by the conventional risk assessment (see **Information/data sought n.1**).

⁵ <https://www.inchem.org/documents/jecfa/jecmono/v042je12.htm>

⁶ https://food.ec.europa.eu/system/files/2020-12/sci-com_scf_reports_25.pdf

⁷ <https://www.inchem.org/documents/jecfa/jecmono/v08je03.htm>

⁸ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2004.125>

⁹ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4254>

¹⁰ <https://open.efsa.europa.eu/questions/EFSA-Q-2021-00370>

Up-to-date information on the manufacturing process and specifications will be used to assess 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 analytical data submitted to EFSA and information on natural occurrence (see **Information/data sought n.3**).

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)¹¹. This Guidance specifies information requirements for conventional materials which do not meet the definition of engineered nanomaterial set out in the Novel Food Regulation (EU) 2015/2283, and outlines appraisal routes (e.g. solubility) to confirm that an assessment of the fraction of small particles including nanoparticles is not needed.

Based on the available information in the literature regarding solubility in water for the food additives E 574-577, their reported solubility is 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 conventional risk assessment is considered applicable to E 574-577.

No robust data showing that solubility of either **calcium gluconate (E 578)** or **ferrous gluconate (E 579)** in water is above the threshold value of 33.3 g/L were retrieved from the literature. In order to confirm that conventional risk assessment is also adequate to re-evaluate the safety of these two food additives, and that an additional assessment related to the presence of particles at the nanoscale is not needed, information demonstrating that calcium gluconate (E 578) and ferrous gluconate (E 579) meet at least one of the Decision criteria listed in Table 1 of the EFSA SC Guidance on particle-TR is requested¹¹.

Interested parties and/or business operators are kindly invited to provide scientific evidence, supported by data, e.g. confirming that the food additives E 578 and E 579 meet at least one of the Decision criteria listed in Table 1 of the EFSA SC Guidance on particle-TR¹¹.

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

2. CONFIRMATION OF LOW INTRINSIC TOXICITY

Toxicity data on gluconic acid and gluconates were reviewed by JECFA in its 1998 assessment, indicating the lack of systemic and local adverse effects. A screening review of the available

¹¹ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6769>

toxicity data for glucono-delta-lactone, including literature data and predictive toxicology models has been conducted by the US EPA in 2020¹² and may serve as a reference for the re-evaluation of the safety of these related food additives.

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*»¹³, for a food additive to be considered of low intrinsic toxicity, the lack of toxicologically relevant impurities/residuals must be confirmed.

2.1 Information on manufacturing process and related specifications

Existing EU Specifications for gluconic acid (E 574) and related food additives (E 575-579) contain very limited information on the manufacturing process(es) in their definition:

	E 574	E 575	E 576	E 577	E 578	E 579
DEFINITION	Gluconic acid is an aqueous solution of gluconic acid and glucono-delta-lactone.	Glucono-delta-lactone is the cyclic 1,5-intramolecular ester of D-gluconic acid. In aqueous media it is hydrolysed to an equilibrium mixture of D-gluconic acid (55 % - 66 %) and the delta- and gamma-lactones	Manufactured by fermentation or chemical catalytic oxidation	-	-	-

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 recommendation for updating existing EU Specifications to ensure they are representative of the actual materials used as food additives, the following information is sought from interested business operators and other interested parties:

- provide detailed information on any **production method** used to manufacture the food additives E 574-579;
- propose a short description of each production method used to manufacture the food additives E 574-579, 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

¹² https://www.epa.gov/sites/default/files/2019-08/documents/support_document_for_proposed_designation_of_d-gluconic_acid_delta_lactone.pdf

¹³ <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3697>

- 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. 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*¹⁴ for the preparation of the data submission.

A. INFORMATION ON PRODUCTION ORGANISM(S)

According to existing EU specifications, sodium gluconate (E 576) can be manufactured either via fermentation or catalytic oxidation. No further information on the production organism(s) used in the manufacturing process is reported in the currently applicable EU specifications.

For the other related food additives included in this call, the existing EU specifications do not make any reference to the manufacturing process employed and whether this includes the use of production organism(s). However, based on publicly available information it seems plausible that these food additives may also be of microbial origin.

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*¹⁵

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*¹⁵
- 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*¹⁵
- Where relevant, information on the identity of residual mycotoxins or other metabolites with possible toxigenic activity in the final product.

¹⁴ <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2012.2760>

¹⁵ <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6851>

B. PRESENCE OF TOXICOLOGICALLY RELEVANT IMPURITIES AND RELATED SPECIFICATIONS

Existing EU Specifications for gluconic acid (E 574) and related food additives (E 575-579) establish limits for the following purity parameters

	E 574	E 575	E 576	E 577	E 578	E 579
ASSAY	Content not less than 49,0 % (as gluconic acid)	Content not less than 99,0 % on the anhydrous basis	Content not less than 99,0 %	Content not less than 97,0 % and not more than 103,0 % on dried basis	anhydrous: Content not less than 98 % and not more than 102 % on the dried basis; monohydrate: not less than 98 % and not more than 102 % on the 'as is' basis.	Content not less than 95 % on the dried basis
RESIDUE ON IGNITION	Not more than 1,0 % 550 °C +/- 20 °C till disappearance of organic residues (black spots).	-	-	-	-	-
WATER CONTENT/ LOSS ON DRYING	-	Not more than 0,2 % ^{a)}	-	Anhydrous: not more than 3,0 % ^{c)} Monohydrate: not less than 6 % and not more than 7,5 % ^{c)}	Anhydrous: Not more than 3,0 % ^{d)} Monohydrate: Not more than 2,0 % ^{d)}	Not more than 10 % ^{d)}
REDUCING MATTER	Not more than 2,0 % ^{b)}	Not more than 0,5 % ^{b)}		Not more than 1,0 % ^{b)}		Not more than 0,5 % ^{b)}
CHLORIDE	Not more than 350 mg/kg	-	-	-	-	-
SULPHATE	Not more than 240 mg/kg	-	-	-	-	-
SULPHITE	Not more than 20 mg/kg	-	-	-	-	-
OXALIC ACID	-	-	-	-	-	Not detectable
IRON (FE III)	-	-	-	-	-	Not more than 2 %
ARSENIC	Not more than 3 mg/kg	-	-	-	-	Not more than 3 mg/kg
CADMIUM	-	-	-	-	-	Not more than 1 mg/kg
LEAD	Not more than 1 mg/kg			Not more than 2 mg/kg		
MERCURY	Not more than 1 mg/kg	-	-	-	-	Not more than 1 mg/kg

a) Karl Fischer method

b) as D-glucose

c) 105 °C, 4 hours, vacuum

d) 105 °C, 16 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 recommendation for updating existing EU Specifications to lower the 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 current 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 tested 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 limit of detection (LOD) and quantification (LOQ));
- among the impurities, some of which are unlisted for some of the food additives, provide analytical data on As, Cd, Hg, Pb
- 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, e.g. in the case of food additives 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 gluconic acid (E 574) and related food additives (E 575-579) currently placed in the EU market.

3. ADEQUATE ESTIMATION OF THE TOTAL DIETARY EXPOSURE

Gluconic acid (E 574) and related food additives (E 575-578) are currently permitted for use as food additives in accordance with Regulation (EC) No 1333/2008 under the following conditions of use:

NAME (E NUMBER)	CONDITIONS OF USE	SPECIFIC MAXIMUM LEVEL INDIVIDUAL RESTRICTIONS/ EXCEPTION
GLUCONIC ACID (E 574)	Substance is included in Group I	<i>quantum satis</i>
GLUCONO-DELTA-LACTONE (E 575)	Substance is included in Group I	<i>quantum satis</i>
	1.7.1Unripened cheese excluding products falling in category 16	<i>quantum satis</i> , only mozzarella
	1.7.2Ripened cheese	<i>quantum satis</i>
	1.7.4Whey cheese	<i>quantum satis</i>
	1.7.6Cheese products (excluding products falling in category 16)	<i>quantum satis</i> , only ripened products
	4.2.3Canned or bottled fruit and vegetables	<i>quantum satis</i>
	6.4.1Fresh pasta	<i>quantum satis</i>
	6.4.3Fresh pre-cooked pasta	<i>quantum satis</i>
	11.4.1Table-top sweeteners in liquid form	<i>quantum satis</i>

SODIUM GLUCONATE (E 576) POTASSIUM GLUCONATE (E 577) CALCIUM GLUCONATE (E 578)	11.4.2 Table-top sweeteners in powder form	<i>quantum satis</i>
	11.4.3 Table-top sweeteners in tablets	<i>quantum satis</i>
	13.1.3 Processed cereal-based foods and baby foods for infants	ML = 5000 mg/kg, only biscuits and rusks ^{a)}
	Substance is included in Group I	<i>quantum satis</i>
	11.4.2 Table-top sweeteners in powder form	<i>quantum satis</i>
	11.4.3 Table-top sweeteners in tablets	<i>quantum satis</i>

a) As a residue

Moreover, the food additives above (E 574-578) are also included in Annex III of Regulation (EC) No 1333/2008, permitted at *quantum satis* for use in: food additives, food flavourings, food enzymes and in nutrients.

The food additive **ferrous gluconate (E 579)** has a single, very limited, authorised use in the EU and maximum level expressed as iron (Fe):

FERROUS GLUCONATE (E 579)	4.2.2 Fruit and vegetables in vinegar oil or brine	ML = 150 mg/kg (expressed as Fe), only olives darkened by oxidation
----------------------------------	--	---

In addition to their currently authorised uses as food additives, the following substances are also included in the Union list of substances that may be added to on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control established under Regulation (EU) No 609/2013¹⁶. This information may be relevant to the estimation of the overall dietary exposure expressed as gluconic acid.

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
SODIUM GLUCONATE	X	-	X	X
POTASSIUM GLUCONATE	X	X	X	X
CALCIUM GLUCONATE	X	X	X	X
FERROUS GLUCONATE	X	X	X	X

A. ADDITIONAL DATA ON USES AND USE LEVELS

In response to the "Call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 5)"¹⁴ published in 2016 and closed in 2017, EFSA has already received some use level data for E 574-579.

¹⁶ 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

A preliminary search of the EFSA Data Warehouse for the analytical data available for inclusion in the overall dietary exposure estimate for these food additives, has returned some analytical data for gluconic acid only.

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*», 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 E 574-579 not yet transmitted to EFSA in response to the earlier call for data⁴, it will be possible to submit it in response to the present call. Detailed instructions for the transmission of the data for this specific point of the call will be made available by EFSA closer to the date of the opening of the data collection on uses and use levels, indicatively planned for October 2023.

B. 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*»¹³, 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 gluconic acid in food is sought with a view to draw a comparison with the estimated dietary exposure resulting from the use of gluconic acid (E 574) and related food additives (E 575-579).

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

Interested business operators and/or interested parties should submit the information to EFSA through their chosen internet-based software (submission by email is not allowed) with

- 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[9] (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.

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

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 036 291 as soon as email with the links is sent. Alternatively, it can be sent in a separate email to RAL@efsa.europa.eu.