SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 30 January 2018

doi: 10.2903/j.efsa.2018.5180

Re-evaluation of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Maged Younes, Peter Aggett, Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Metka Filipič, Maria Jose Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Gunter Georg Kuhnle, Jean-Charles Leblanc, Inger Therese Lillegaard, Peter Moldeus, Alicja Mortensen, Agneta Oskarsson, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright, Polly Boon, Dimitrios Chrysafidis, Rainer Gürtler, Pasquale Mosesso, Dominique Parent-Massin, Paul Tobback, Claudia Cascio, Ana Maria Rincon and Claude Lambré

Abstract

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific opinion re-evaluating the safety of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) when used as food additives. In 1991, the Scientific Committee on Food (SCF) established a group acceptable daily intake (ADI) 'not specified' for the fatty acids (myristic-, stearic-, palmitic- and oleic acid) and their salts. The sodium, potassium, calcium and magnesium salts of fatty acids are expected to dissociate in the gastrointestinal tract to fatty acid carboxylates and their corresponding cations. There were no data on subchronic toxicity, chronic toxicity, reproductive and developmental toxicity of the salts of fatty acids. There was no concern for mutagenicity of calcium caprylate, potassium oleate and magnesium stearate. From a carcinogenicity study with sodium oleate, a no observed adverse effect level (NOAEL) could not be identified but the substance was considered not to present a carcinogenic potential. Palmitic- and stearic acid which are the main fatty acids in E 470a and E 470b were already considered of no safety concern in the re-evaluation of the food additive E 570. The fatty acid moieties of E 470a and E 470b contributed maximally for 5% to the overall intake of saturated fatty acids from all dietary sources. Overall, the Panel concluded that there was no need for a numerical ADI and that the food additives sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) were of no safety concern at the reported uses and use levels.

Keywords: sodium salts of fatty acids, potassium salts of fatty acids, calcium salts of fatty acids, E 470a, magnesium salts of fatty acids, E 470b, food additives

Requestor: European Commission

Question number: EFSA-Q-2011-00555; EFSA-Q-2011-00556

Correspondence: fip@efsa.europa.eu

Panel members: Peter Aggett, Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund, Metka Filipič, Maria Jose Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Gunter Georg Kuhnle, Claude Lambré, Jean-Charles Leblanc, Inger Therese Lillegaard, Peter Moldeus, Alicja Mortensen, Agneta Oskarsson, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright and Maged Younes.

Acknowledgements: The ANS Panel wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output and Davide Arcella and Zsuzsanna Horvath.

Suggested citation: EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), Younes M, Aggett P, Aguilar F, Crebelli R, Dusemund B, Filipič M, Frutos MJ, Galtier P, Gott D, Gundert-Remy U, Kuhnle GG, Leblanc J-C, Lillegaard IT, Moldeus P, Mortensen A, Oskarsson A, Stankovic I, Waalkens-Berendsen I, Woutersen RA, Wright M, Boon P, Chrysafidis D, Gürtler R, Mosesso P, Parent-Massin D, Tobback P, Cascio C, Rincon AM and Lambré C, 2018. Scientific Opinion on the re-evaluation of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) as food additives. EFSA Journal 2018;16(3):5180, 34 pp. https://doi.org/10.2903/j.efsa.2018.5180

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

Sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) are authorised as food additives according to Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012.

The Scientific Committee on Food (SCF) established a group acceptable daily intake (ADI) 'not specified' for the fatty acids (myristic-, stearic-, palmitic- and oleic acid) and their salts in 1991.

In 1974, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered that myristic, palmitic and stearic acid and their salts were normal products of the metabolism of fats and that their metabolic fate was well established. JECFA further considered that, provided the contribution of the cations did not add excessively to the normal body load, there was no need to consider the use of these substances in any different light to that of dietary fatty acids and established an ADI 'not limited'.

The Panel considered that it is unclear, whether, according to the definition in the Commission Regulation 231/2012, the fatty acids or the salts thereof are occurring in food fats and oils. However, according to the literature, salts of fatty acids are not expected to occur in significant amounts in food fats and oils (low Na, K, Ca or Mg content and acidic conditions due to free fatty acids). Hence, this evaluation has been performed assuming that only the fatty acids (either free or bound) not the salts of fatty acids occur in food fats and oils.

According to information from industry, the fatty acids used for the production of sodium, potassium, calcium and magnesium salts of fatty acids are obtained either from edible (i.e. vegetable or animal) fats and oils or from distilled food fatty acids. In the Regulation, no indication is given as regards the chemical nature of the fatty acids or the level at which an individual fatty acid may be present.

According to information provided by interested parties, salts of fatty acids consist for 95–99% (by weight) of salts, of which 4–5% account for the cation. In commercial products, the fatty acid fraction consists at least of 90% stearic- and palmitic acid with a minimum of 40% stearic acid.

The Panel noted that sodium, potassium, calcium and magnesium salts of fatty acids are expected to dissociate in the gastrointestinal tract into fatty acid carboxylates and their corresponding cations. The resulting low amounts of sodium, potassium, calcium and magnesium ions will enter normal physiological processes. Therefore, the properties of the corresponding cations are not discussed further in the opinion and the Panel considered that a read-across approach could be applied for the evaluation of the sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) using the previous assessment of the food additive fatty acids (E 570).

The Panel (EFSA ANS Panel, 2017) evaluated the absorption, distribution,. metabolism, excretion (ADME) of the fatty acids caprylic-, capric-, oleic-, lauric-, palmitic-, myristic- or stearic acid and considered that they, like other fatty acids, were readily and extensively absorbed from the gastrointestinal tract and metabolised via the β-oxidation pathway and the tricarboxylic acid cycle to carbon dioxide and excreted.

The Panel noted that the number of toxicological studies on the salts of fatty acids was very limited.

The Panel considered that:

- As regards genotoxicity, only the mutagenicity studies on calcium caprylate, potassium oleate and magnesium stearate were available and negative results were obtained. In addition, the Panel noted that available genotoxicity data for caprylic-, capric-, lauric-, myristic-, palmitic-, stearic- or oleic acid used as a food additive (E 570) do not raise a concern for genotoxicity.
- As regards carcinogenicity, the Panel noted that in a study in rats, the pancreatic tumours reported were adenomas not carcinomas; therefore, the Panel considered that sodium oleate did not present a carcinogenic potential. However, it was not possible to identify a no observed adverse effect level (NOAEL) from this study.
- No data were available as regards subchronic toxicity, chronic toxicity, reproductive and developmental toxicity.

However, the EFSA ANS Panel evaluated the safety of the linear free fatty acids caprylic- (C8), capric- (C10), lauric- (C12), myristic- (C14), palmitic- (C16), stearic- (C18) and oleic acid (C18:1) when used as a food additive (E 570) and concluded that the use of these acids are of no safety concern at the reported use and use levels (EFSA ANS Panel, 2017).

For the exposure assessment of E 470a,b, reported uses were available for 24 out of 69 food categories in which E 470a and E 470b are authorised but only 12 food categories were considered in the refined exposure scenarios. The Panel noted that the information from the Mintel's Global New

Products Database (GNPD) supported the observation that sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) are apparently not used in all food categories in which the food additives are authorised.

Based on information from the Mintel's GNPD, the Panel considered that E 470a and E 470b are not likely to be used in combination in the same food product and, therefore, the exposure assessment of E 470a and E 470b was performed considering the maximum reported use level (of the maximum and typical) for either E 470a or E 470b per food category.

As salts of fatty acids are not expected to occur in significant amounts in foods, the Panel only considered the dietary intake of saturated fatty acids as such to assess the contribution of the food additives (E 470a and E 470b) to the intake of saturated fatty acids via all dietary sources.

Considering that:

- sodium, potassium, calcium and magnesium salts of fatty acids are expected to dissociate in the gastrointestinal tract to fatty acid carboxylates and their corresponding cations,
- according to information from industry, palmitic acid and stearic acid are the main fatty acids present in E 470a and E 470b,
- palmitic acid and stearic acid are fatty acids included in the food additive E 570 already evaluated by the Panel and for which it was concluded that its use was of no safety concern,
- the fatty acid moieties of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) contributed at the mean maximally 5% to the overall dietary exposure to saturated fatty acids,

the Panel concluded that there was no need for a numerical ADI and that the food additives sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) were of no safety concern at the reported uses and use levels.

The Panel recommended that:

- the European Commission considers lowering the current limits for toxic elements (arsenic, lead, mercury and cadmium) in the European Union specifications for sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) in order to ensure that the food additive will not be a significant source of exposure to these toxic elements in food.
- the European Commission considers revising the EU specifications for sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) including maximum limits for trans-fatty acids because sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) can be manufactured by glycerolysis of hydrogenated fats and/or oils, which contain significant amounts of trans fatty acids.
- the European Commission considers revising the EU specifications for sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) including maximum limits for erucic acid because as erucic acid can be present among the fatty acids in edible oils, which can be used for manufacturing of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b).
- the European Commission considers revising the EU specifications for sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) by rephrasing the definition in order to clarify that the fatty acids used as source materials be obtained only from edible fats and oils.
- in the event that practices reported in this opinion change (e.g. sources of starting material, uses and use levels), revision of this evaluation would be needed.

Table of contents

1. Introduction

The present opinion deals with the re-evaluation of the safety of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) when used as food additives.

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background

Regulation (EC) No 1333/2008[1] of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under the Regulation (EU) No 257/2010[2]. This Regulation also foresees that food additives are re-evaluated whenever necessary in light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the Scientific Committee on Food (SCF) or by EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU of 2001. The report 'Food additives in Europe 2000' submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with a highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of adoption of Regulation (EU) 257/2010 the 2003 Terms of References are replaced by those below.

1.1.2. Terms of Reference

The Commission asks the EFSA to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

1.2. Information on existing authorisations and evaluations

Sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) are authorised as food additives according to Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012[3] for them.

The SCF established a group acceptable daily intake (ADI) 'not specified' for the fatty acids (myristic-, stearic-, palmitic- and oleic acid) and their salts (SCF, 1991).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated the salts of different fatty acids in the period 1973–2001 (JECFA, 1974, 1984, 1986, 1989, 2001a,b,c). JECFA considered that myristic, palmitic and stearic acid and their salts were normal products of the metabolism of fats and that their metabolic fate was well established. JECFA further considered that, provided the

[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

[2] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.

[3] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

contribution of the cations did not add excessively to the normal body load, there was no need to consider the use of these substances in any different light to that of dietary fatty acids and established an ADI 'not limited' (JECFA, 1974).

Fatty acids and their sodium, potassium, calcium and magnesium salts were also reviewed by the Nordic Council of Ministers (TemaNord, 2002). The Committee stated that no exhaustive systematic toxicological studies seemed to have been carried out. However, there was no reason to expect any health problems when these food additives would be used according to good manufacturing practise.

The EFSA ANS Panel evaluated the safety of the linear free fatty acids caprylic- (C8), capric- (C10), lauric- (C12), myristic- (C14), palmitic- (C16), stearic- (C18) and oleic acid (C18:1) when used as a food additive E 570 and concluded that the use of these acids was of no safety concern (EFSA ANS Panel, 2017).

2. Data and methodologies

2.1. Data

The Panel on Food Additives and Nutrient Sources added to Food (ANS) was not provided with a newly submitted dossier. EFSA launched public calls for data.[4,5]

The Panel based its assessment on information submitted to EFSA following the public calls for data, information from previous evaluations and additional available literature up to January 2018. Attempts were made at retrieving relevant original study reports on which previous evaluations or reviews were based however these were not always available to the Panel.

Food consumption data used to estimate the dietary exposure to sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) were derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database.[6])

The Mintel's Global New Products Database (GNPD) was used to verify the use of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) in food products. The Mintel's GNPD is an online database that contains the compulsory ingredient information present on the label of numerous food products.

2.2. Methodologies

This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing guidance documents from the EFSA Scientific Committee.

The ANS Panel assessed the safety of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b), in line with the principles laid down in Regulation (EU) 257/2010 and in the relevant guidance documents: Guidance on submission for food additive evaluations by the SCF (2001).

When the test substance was administered in the feed or in the drinking water, but doses were not explicitly reported by the authors as mg/kg bw per day based on actual feed or water consumption, the daily intake was calculated by the Panel using the relevant default values as indicated in the EFSA Scientific Committee Guidance document (EFSA Scientific Committee, 2012) for studies in rodents or, in the case of other animal species, by JECFA (2000). In these cases, the daily intake is expressed as 'equivalent'.

Dietary exposure to sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) from their use as food additives was estimated by combining the food consumption data available within the EFSA Comprehensive Database with the maximum permitted levels and/or reported use levels submitted to EFSA following a call for data. The exposure was estimated according to different scenarios (see Section 3.4). Uncertainties in the exposure assessment were identified and discussed.

[4] Call for scientific data on food additives permitted in the EU and belonging to the functional classes of emulsifiers, stabilisers and gelling agents. Published: 22 November 2009. Available from: http://www.efsa.europa.eu/en/dataclosed/call/ans091123

[5] Call for food additives usage level and/or concentration data in food and beverages intended for human consumption Published 12 October 2015. Available online: http://www.efsa.europa.eu/en/data/call/151012

[6] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

3. Assessment

3.1. Technical data

3.1.1. Identity of the substance

According to Commission Regulation (EU) No 231/2012, (E 470a) and (E 470b) 'are sodium, potassium, calcium and magnesium salts of fatty acids occurring in food oils and fats, salts being obtained either from edible fats and oils or from distilled food fatty acids'.

According to information provided by industry (APAG, 2016 (Documentation provided to EFSA n. 2)), there are four different origins of the fatty acids used for the production of the additives E 470a and E 470b: (i) three are derived from vegetable oils, differing in their palmitate/stearate ratio (i.e. high, medium and low), and (ii) one is derived from animal fat with a high content in stearic acid. It is further stated that current commercially available salts of fatty acids consist for 95–99% (by weight) of salts, of which 4–5% account for the metal cation. The fatty acid fraction consists at least of 90% stearic- and palmitic acid with a minimum of 40% stearic acid. It is stated that other fatty acids such as lauric acid, myristic acid, pentadecanoic acid, heptanoic acid, oleic acid and arachidic acid may be present in minor amounts (see Table 1).

The composition and the nature of the fatty acid moieties depend on the source material (vegetable or animal) used for the production of the food additive and on the selection of the fatty acid fraction of the distillation, to which the hydrolysed source material was subjected (EFSA ANS Panel, 2017).

Industry provided analytical data, summarising the composition of 36 commercially available salts of fatty acids (APAG, 2016 (Documentation provided to EFSA n. 2)). These data are shown in Table 1.

The Panel noted that in the information provided by the individual producers regarding the nature of most commercially available substances, these substances are described as salts (i.e. Mg-, Ca-, Na- or K-salts) of stearic acid, whereas, based on the gas–liquid chromatography (GLC) data provided by APAG, 2016 (Documentation provided to EFSA n. 2), all substances consist of a mixture of salts of mainly stearic- and palmitic acid (Table 1).

Table 1: Fatty acids composition of the commercially available salts of fatty acids as provided by industry (APAG, 2016 (Documentation provided to EFSA n. 2))

Fatty acids	**Proportion of fatty acid (%)**			
Type	**Vegetable based (low palmitate)**	**Vegetable based (medium palmitate)**	**Vegetable based (high palmitate)**	**Animal based**
Lauric acid (C12)	–	0.0–0.1	0.0–0.6	0.0–1.1
Myristic acid (C14)	0.0–0.3	0.2–0.5	0.0–1.4	1.1–2.3
Pentadecanoic acid (C15)	–	0.0–0.1	00–1.2	0.2–0.3
Palmitic acid (C16)	**30.2–34.2**	**44.9–45.9**	**53.5–56.9**	**28–31**
Margaric acid (C17)	0.1–0.2	0.1–0.2	0.2–0.3	0.9–1.0
Stearic acid (C18)	**65.1–69.5**	**52.4–53.7**	**41.1–44.8**	**64.2–67.0**
Oleic acid (C18:1)	0.0–0.0	0.0–0.1	0.0–0.1	0.0–0.2
Arachidic acid (C20)	0.0–0.7	0.5–0.9	0.4–05	1.3–1.5
Palmitic + stearic acid (C16 + C18)	**98.8–99.5**	**98.1–99.1**	**97.1–99.4**	**92.1–95.2**

APAG (2016 (Documentation provided to EFSA n. 2)) informed that in one batch of animal-based fatty acids the following acids also were present: 0.1% ketostearic acid (substance not further specified), 0.1% palmitoleic acid (9-*cis*-hexadecenoic acid; $C_{16}H_{30}O_2$) and 0.2% nonadecanoic acid ($C_{19}H_{38}O_2$).

In the batches analysed, the amount of total fatty acids other than palmitic or stearic acid ranged from 0.5% to 8% in the batches analysed.

The chemical identity of the fatty acids present in the commercially available salts of fatty acids – E 470a and E 470b – is given in Table 2.

Table 2: Identity of the fatty acids present in commercially available E 470a and E 470b as listed in Table 1

Fatty acid (common name)	Fatty acid (systematic name)	Structural formula of fatty acid anion	CAS registry number acid/ EINECS number	Salt cation	CAS registry number	EINECS (EC number)
Lauric acid (C12)	Dodecanoic acid	$CH_3–(CH_2)_{10}–COO^-$	143-07-7/205-582-1	Na^+	629-25-4	211-082-4
				K^+	10124-65-9	233-344-7
				1/2 Ca^{2+}	4696-56-4	225-166-3
				1/2 Mg^{2+}	4040-48-6	223-727-7
Myristic acid (C14)	Tetradecanoic acid	$CH_3–(CH_2)_{12}–COO^-$	544-63-8/208-875-2	Na^+	822-12-8	212-487-9
				K^+	13429-27-1	236-550-5
				1/2 Ca^{2+}	15284-51-2	239-328-6
				1/2 Mg^{2+}	4086-70-8	223-817-6
Pentadecylic acid (C15)	Pentadecanoic acid	$CH_3–(CH_2)_{13}–COO^-$	1002-84-2/213-693-1	Na^+	4268-63-7	224-255-4
				K^+	17378-35-7	241-415-9
				1/2 Ca^{2+}	4499-92-7	224-802-7
				1/2 Mg^{2+}	93966-75-7	301-028-9
Palmitic acid (C16)	Hexadecanoic acid	$CH_3–(CH_2)_{14}–COO^-$	57-10-3/200-312-9	Na^+	408-35-5	206-988-1
				K^+	2624-31-9	220-088-6
				1/2 Ca^{2+}	542-42-7	208-811-3
				1/2 Mg^{2+}	2601-98-1	220-010-0
Margaric acid (C17)	Heptadecanoic acid	$CH_3–(CH_2)_{15}–COO^-$	506-12-7/208-027-1	Na^+	1002-82-0	213-692-6
				K^+	17378-36-8	241-416-4
				1/2 Ca^{2+}	4499-95-0	224-804-8
				1/2 Mg^{2+}	94266-34-9	304-441-2
Stearic acid (C18)	Octadecanoic acid	$CH_3–(CH_2)_{16}–COO^-$	57-11-4/200-313-4	Na^+	822-16-2	212-490-5
				K^+	593-29-3	209-786-1
				1/2 Ca^{2+}	1592-23-0	216-472-8
				1/2 Mg^{2+}	557-04-0	209-150-3
Oleic acid (C18:1)	*cis*-9-octadecenoic acid	$CH_3–(CH_2)_7–CH=CH–(CH_2)_7–COO^-$	112-80-1/204-007-1	Na^+	143-19-1	205-591-0
				K^+	143-18-0	205-590-5
				1/2 Ca^{2+}	142-17-6	205-525-0
				1/2 Mg^{2+}	1555-53-9	216-303-8
Arachidic acid (C20)	*n*-eicosanoic acid	$CH_3–(CH_2)_{18}–COO^-$	506-30-9//208-031-3	Na^+	13257-34-6	236-248-3
				K^+	18080-76-7	241-990-6
				1/2 Ca^{2+}	22302-43-8	244-900-3
				1/2 Mg^{2+}	57593-01-8	260-840-0

CAS: Chemical Abstracts Service; EINECS: European Inventory of Existing Chemical Substances.

The Panel noted that natural fats and oils are always a mixture of fatty acids with a discrete carbon chain length. Nevertheless, in the analytical data on the composition of the commercially available salts of fatty acids provided by industry (APAG, 2016 (Documentation provided to EFSA n. 2)), low amounts of two odd-numbered fatty acids (C15 and C17 compounds) have been reported.

According to Commission Regulation (EU) No 231/2012, sodium and potassium salts of fatty acids are soluble in water, while calcium and magnesium salts are insoluble in aqueous media. The Panel noted that, due to their amphipathic (amphiphilic) nature, when dispersed in water, fatty acid salts partially or totally dissolve (depending on their solubility and concentration) and tend to form micelles (Alberts et al., 2002).

3.1.2. Specifications

Specifications for the sodium, potassium and calcium salts of fatty acids (E 470a) and for the magnesium salts (E 470b) are defined in Commission Regulation (EU) No 231/1012. According to

JECFA, specifications for sodium, potassium and calcium salts of fatty acids (INS No 470) and for magnesium distearate (INS No 470(iii)) are available (Table 3).

Table 3: Specifications for sodium, potassium and calcium salts of fatty acids (E 470a) according to Commission Regulation (EU) No 231/2012 and JECFA (2006), and for magnesium salts of fatty acids (E 470b) according to Commission Regulation (EU) No 231/2012 and magnesium distearate (JECFA, 2015)

	Sodium, potassium and calcium salts of fatty acids (E 470a)	**Magnesium salts of fatty acids (E 470b)**	**Salts of fatty acids (INS No 470)**	**Magnesium distearate, dibasic magnesium stearate, INS No 470(iii)**
	Commission Regulation (EU) No 231/2012	**Commission Regulation (EU) No 231/2012**	**JECFA (2006)**	**JECFA (2015)**
Definition	Sodium, potassium and calcium salts of fatty acids occurring in food oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids	Magnesium salts of fatty acids occurring in food oils and fats, these salts being obtained either from edible fats and oils or from distilled food fatty acids	These products consist of calcium, potassium or sodium salts of commercial myristic, oleic, palmitic, stearic, acids or mixtures of these acids from edible fats and oils. The article of commerce can be further specified by: • saponification value, • solidification point for the fatty acids obtained from the salts, • iodine value, • residue on ignition including assay of the cation, and • moisture content	Magnesium stearate is a mixture of magnesium salts of fatty acids obtained from edible fats and oils. The product consists mainly of magnesium stearate and palmitate in varying proportions. It is manufactured by one of the two following processes: (a) direct process wherein fatty acids are directly reacted with a magnesium source, such as magnesium oxide to form magnesium salts of the fatty acids; (b) indirect process where a sodium soap is produced by the reaction of fatty acids with sodium hydroxide in water and the product is precipitated by adding magnesium salts to the soap
Assay	Content on the anhydrous basis not less than 95% (105°C till a constant weight)	Content on the anhydrous basis not less than 95% (105°C till a constant weight)	Not less than 95% total fatty acid salts, dry weight basis	
Description	White or creamy white light powders, flakes or semi-solids	White or creamy white light powders, flakes or semi-solids	Hard, white or faintly yellowish, somewhat glossy and crystalline solids or semi-solids or white or yellowish-white powder	
Identification				
Solubility	Sodium and potassium salts: soluble in water and ethanol Calcium salts: insoluble in water, ethanol and ether	Insoluble in water, partially soluble in ethanol and ether	Potassium and sodium salts are soluble in water and ethanol; calcium salts are insoluble in water, ethanol and ether	Practically insoluble in water

	Sodium, potassium and calcium salts of fatty acids (E 470a)	Magnesium salts of fatty acids (E 470b)	Salts of fatty acids (INS No 470)	Magnesium distearate, dibasic magnesium stearate, INS No 470(iii)
Test for cations	Passes test	–	Heat 1 g of the sample with a mixture of 25 mL of water and 5 mL of hydrochloric acid. Fatty acids are liberated, floating as a solid or oil layer on the surface which is soluble in hexane. After cooling, aqueous layer is decanted and evaporated to dryness. Dissolve the residue in water and test for the appropriate cation	
Test for magnesium	–	Passes test	–	Using the Method of Assay, identify presence of magnesium in the sample
Test for fatty acids	Passes test	Passes test	Using the Method of Assay, identify the individual fatty sample. The fatty acid(s) in primary abundance should conform to those declared on the label of the product	
Purity				
Sodium	Not less than 9% and not more than 14% expressed as Na_2O	–	–	
Potassium	Not less than 13% and not more than 21.5% expressed as K_2O	–	–	
Calcium	Not less than 8.5% and not more than 13% expressed as CaO	–	–	
Magnesium	–	Not less than 6.5% and not more than 11% expressed as MgO	–	Not less than 4.0% and not more than 5.0%, on dried basis
Unsaponifiable matter	Not more than 2%	Not more than 2%	Not more than 2%	Not more than 2%
Free fatty acids	Not more than 3% estimated as oleic acid	Not more than 3% estimated as oleic acid	Not more than 3% Measure free fatty acids as directed in the method Free Fatty Acids. Compute free fatty acid content using an equivalence factor (e) equal to 1/10th the molecular weight of the salt	Not less than 40.0% stearic acid in the fatty acid fraction; and not less than 90.0% as the sum of stearic acid and palmitic acid in the fatty acid fraction

	Sodium, potassium and calcium salts of fatty acids (E 470a)	Magnesium salts of fatty acids (E 470b)	Salts of fatty acids (INS No 470)	Magnesium distearate, dibasic magnesium stearate, INS No 470(iii)
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	Not more than 2 mg/kg Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, 'Instrumental Methods'	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg	Not more than 1 mg/kg	–	
Cadmium	Not more than 1 mg/kg	Not more than 1 mg/kg	–	Not more than 1 mg/kg
Nickel				Not more than 3 mg/kg
Free alkali	Not more than 0.1% expressed as NaOH	Not more than 0.1% expressed as MgO	–	
Matter insoluble in alcohol	Not more than 0.2% (sodium and potassium salts only)	–	–	

The Panel considered that it is unclear, whether, according to the definition in the Regulation 231/2012, the fatty acids or the salts thereof are occurring in food fats and oils. However, according to the literature, salts of fatty acids are not expected to occur in significant amounts in food fats and oils (low Na, K, Ca or Mg content and acidic conditions due to free fatty acids). Therefore, this evaluation has been performed assuming that only the fatty acids (either free or bound) not the salts of fatty acids occur in food fats and oils.

The Panel noted that in Commission Regulation (EU) No 231/2012, the term 'distilled food fatty acids' is used. In the view of the Panel this term should be more clearly described. Indeed, without any further specification of this term, fatty acids that are identical to those present in foods, but that are produced by distillation from non-food sources, could also be used as source material for the production of the food additives E 470a and E 470b. The Panel considered that the safety of use of salts of fatty acids produced using fatty acids, obtained via distillation from non-food sources cannot be assessed. Therefore, the use of these sources should be avoided.

The Panel noted that, according to the EU specifications for E 470a and E 470b, impurities of the toxic elements arsenic, cadmium, lead and mercury are accepted up to concentrations of 3, 2, 1 and 1 mg/kg, respectively. Contamination at these levels could have a significant impact on the exposure to these toxic elements, which are already close to the health-based guidance values or benchmark doses (lower confidence limits) established by EFSA (EFSA CONTAM Panel, 2009a,b, 2010, 2012a,b,c, 2014).

According to information provided by industry (APAG, 2016 (Documentation provided to EFSA n. 2)), nickel present in the starting material could be a potential impurity in the final product. The Panel noted that no maximum limit for nickel is included in the EU specifications for E 470a and E 470b, although it is included in JECFA specifications for magnesium distearate.

According to EU specifications, E 470a and E 470b can be manufactured by using food oils and fats. Beside natural oils and fats, also hydrogenated fats and or oils can be used for manufacturing of E 470a and E 470b.

According to EFSA (EFSA NDA Panel, 2004), industrial hydrogenation (used to produce semi-solid and solid fats that can be used for the production of foods such as margarines, shortenings, and

biscuits) and deodorisation (a necessary step in refining) of unsaturated vegetable oils high in polyunsaturated fatty acids is one of the three main pathways for the formation of trans fatty acids in food. According to EFSA (EFSA NDA Panel, 2010), higher intakes of trans-fatty acids have consistently been found to be associated with an increased risk of coronary heart disease and it was recommended that trans fatty acids intake should be as low as possible within the context of a nutritionally adequate diet. The Panel noted that there is no limit for trans fatty acids in the specifications for E 470a and E 470b.

According to the EU specifications for E 470a and E 470b, rapeseed oil, which contains erucic acid, could be used for the manufacturing E 470a and E 470b according to their EU specifications. Maximum levels for erucic acid have been established in EU according to Commission Regulation (EU) No 696/2014[7] in edible oils and fats as well as in food containing fats and oils. A tolerable daily intake (TDI) of 7 mg/kg body weight (bw) per day for erucic acid has been established by the EFSA CONTAM Panel based on a no observed adverse effect level (NOAEL) of 700 mg/kg bw per day for myocardial lipidosis observed in a 7-day feeding study in young (5–7 weeks) rats and in a 2-week feeding study in newborn piglets (EFSA CONTAM Panel, 2016). The Panel noted that there are no limits for erucic acid in the current EU specifications E 470a and E 470b.

The Panel noted that there is a maximum limit set for sum of dioxins in Regulation (EC) 1881/2006 (Section 5) for marine oils (5.7), fat of bovine animals and sheep, poultry and pigs (5.10), mixed animal fat (5.11) and vegetable oils and fats (5.12).

3.1.3. Manufacturing process

According to information provided by industry (APAG, 2016 (Documentation provided to EFSA n. 2)), the sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) are commonly manufactured by one of two of the following processes: a 'direct process' or a 'precipitation process'.

Direct process

In this process, fatty acids are neutralised to yield a specific salt of fatty acids. As cation sources, oxides (magnesium or calcium oxide) or hydroxides (sodium-, potassium-, magnesium- or calcium hydroxide) may be used.

General reaction equation:

$$\text{fatty acid} + \text{metal oxide/hydroxide} \rightarrow \text{metal fatty acid salt} + \text{water}$$

Precipitation process

This process consists of two consecutive steps. In a first step, a sodium soap is produced by the reaction of the fatty acids with sodium hydroxide in water. In the second step, the salts of fatty acids are precipitated by adding the required metal cation salt.

General reaction equations:

$$\text{Step 1: fatty acid} + \text{NaOH} \rightarrow \text{Fatty acid sodium salt} + \text{water}$$

$$\text{Step 2: fatty acid sodium salt} + X^{2+} \rightarrow X(\text{fatty acid})_2 + 2Na^{+}$$

$$X^{2+}\text{: being } Ca^{2+} \text{ or } Mg^{2+}$$

Nature of raw materials used in the manufacturing processes

In Commission Regulation (EU) No 231/2012, it is stated that the salts of fatty acids are obtained either from edible fats and oils or from distilled food fatty acids.

According to information provided by industry (APAG, 2016 (Documentation provided to EFSA n. 2)), the fatty acids used for the manufacturing of all four salts are derived from edible fats and oils. They are obtained from either vegetable sources (e.g. palm oil) or animal sources such as food grade lard and tallows (e.g. lard, suet or bone fat from beef and pigskin fat). It is stated that the fatty acids derived from edible fats and oils consist mainly of stearic or palmitic acid.

[7] Commission Regulation (EU) No 694/2014 of 24 June 2014 amending Regulation (EC) No 1881/2006 as regards maximum levels of erucic acid in vegetable oils and fats and foods containing vegetable oils and fats. OJ L 184, 25.6.2014, p. 1–2.

3.1.4. Methods of analysis in food

For the method of analysis, interested parties (APAG, 2016 (Documentation provided to EFSA n. 2)) referred to the procedure described in the JECFA method (JECFA, 2006). The method involves esterification by methanol of the fatty acids in the presence of boron trifluoride and alkaline conditions. The fatty acid methyl esters are subsequently analysed by GLC and the percentage area of the fatty acids in the chromatogram is calculated.

The Panel presented an overview of methods for the analysis of individual fatty acids in food in the re-evaluation of fatty acids (E 570) as a food additive (EFSA ANS Panel, 2017).

3.1.5. Reaction and fate in food

Metal salts of saturated fatty acids are stable products for which no decomposition products are expected under normal storage conditions (Rustan and Drevon, 2005). Auto-oxidation products can typically be present in unsaturated fatty acids (Belitz et al., 2008) and are not expected to be found in saturated fatty acids such as stearic acid and palmitic acid. According to APAG (2016 (Documentation provided to EFSA n. 2)), a moisture uptake during longer storage (> 12 months) may take place.

3.2. Authorised uses and use levels

Maximum levels of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) have been defined in Annex II to Regulation (EC) No 1333/2008[8] on food additives, as amended. In this opinion, these levels are named maximum permitted levels (MPLs).

Currently, sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) are authorised as Group I food additive in 67 food categories and have a specific authorised use in only two food categories (of which one has only an authorisation for E 470a). E 470a and E 470b are authorised at *quantum satis* (*QS*) in all food categories. Table 4 summarises foods that are permitted to contain E 470a or E 470b as set by Annex II to Regulation (EC) No 1333/2008.

Table 4: MPLs of E 470a and E 470b in foods according to Annex II to Regulation (EC) No 1333/2008

Food category number	Food category name	E-number/ group	Restrictions/ exception	MPL (mg/L or mg/kg as appropriate)
1.3	Unflavoured fermented milk products, heat-treated after fermentation	Group I		*quantum satis*
1.4	Flavoured fermented milk products including heat-treated products	Group I		*quantum satis*
01.6.3	Other creams	Group I		*quantum satis*
01.7.1	Unripened cheese excluding products falling in category 16	Group I	Except mozzarella	*quantum satis*
01.7.5	Processed cheese	Group I		*quantum satis*
01.7.6	Cheese products (excluding products falling in category 16)	Group I		*quantum satis*
1.8	Dairy analogues, including beverage whiteners	Group I		*quantum satis*
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	Group I		*quantum satis*
2.3	Vegetable oil pan spray	Group I		*quantum satis*
3	Edible ices	Group I		*quantum satis*
04.2.1	Dried fruit and vegetables	Group I		*quantum satis*
04.2.2	Fruit and vegetables in vinegar, oil, or brine	Group I		*quantum satis*

[8] Commission Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16.

Food category number	Food category name	E-number/ group	Restrictions/ exception	MPL (mg/L or mg/kg as appropriate)
04.2.4.1	Fruit and vegetables preparations excluding compote	Group I		*quantum satis*
04.2.5.4	Nut butters and nut spreads	Group I		*quantum satis*
04.2.6	Processed potato products	Group I		*quantum satis*
5.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	Group I	Only energy-reduced or with no added sugar	*quantum satis*
5.2	Other confectionery including breath freshening microsweets	Group I		*quantum satis*
5.3	Chewing gum	Group I		*quantum satis*
5.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Group I		*quantum satis*
6.2.2	Starches	Group I		*quantum satis*
6.3	Breakfast cereals	Group I		*quantum satis*
6.4.2	Dry pasta	Group I	Only gluten free and/ or pasta intended for hypoproteic diets in accordance with Directive 2009/39/EC	*quantum satis*
6.4.4	Potato gnocchi	Group I	Except fresh refrigerated potato gnocchi	*quantum satis*
6.4.5	Fillings of stuffed pasta (ravioli and similar)	Group I		*quantum satis*
6.5	Noodles	Group I		*quantum satis*
6.6	Batters	Group I		*quantum satis*
6.7	Pre-cooked or processed cereals	Group I		*quantum satis*
7.1	Bread and rolls	Group I	Except products in 7.1.1 and 7.1.2	*quantum satis*
7.2	Fine bakery wares	Group I		*quantum satis*
8.3.1	Non-heat-treated meat products	Group I		*quantum satis*
8.3.2	Heat- treated meat products	Group I	Except foie gras, foie gras entier, blocs de foie gras, libamáj, libamáj egészben, libamáj tömbben	*quantum satis*
8.3.3	Casings and coatings and decorations for meat	Group I		*quantum satis*
9.2	Processed fish and fishery products including molluscs and crustaceans	Group I		*quantum satis*
9.3	Fish roe	Group I	Only processed fish roe	*quantum satis*
10.2	Processed eggs and egg products	Group I		*quantum satis*
11.2	Other sugars and syrups	Group I		*quantum satis*
11.4.3	Table-top sweeteners in tablets	E 470a E 470b		*quantum satis*
12.1.2	Salt substitutes	Group I		*quantum satis*
12.2.1	Herbs and Spices	E 470a	Only when dried	*quantum satis*
12.2.2	Seasonings and condiments	Group I		*quantum satis*
12.3	Vinegars	Group I		*quantum satis*

Food category number	Food category name	E-number/ group	Restrictions/ exception	MPL (mg/L or mg/kg as appropriate)
12.4	Mustard	Group I		*quantum satis*
12.5	Soups and broths	Group I		*quantum satis*
12.6	Sauces	Group I		*quantum satis*
12.7	Salads and savoury-based sandwich spreads	Group I		*quantum satis*
12.8	Yeast and yeast products	Group I		*quantum satis*
12.9	Protein products, excluding products covered in category 1.8	Group I		*quantum satis*
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	Group I		*quantum satis*
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	Group I		*quantum satis*
13.4	Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009	Group I	Including dry pasta	*quantum satis*
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices	Group I	Only vegetable juices	*quantum satis*
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	Group I	Only vegetable nectars	*quantum satis*
14.1.4	Flavoured drinks	Group I		*quantum satis*
14.1.5.2	Other	Group I	Excluding unflavoured leaf tea; including flavoured instant coffee	*quantum satis*
14.2.3	Cider and perry	Group I		*quantum satis*
14.2.4	Fruit wine and made wine	Group I		*quantum satis*
14.2.5	Mead	Group I		*quantum satis*
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	Group I	Except whisky or whiskey	*quantum satis*
14.2.7.1	Aromatised wines	Group I		*quantum satis*
14.2.7.2	Aromatised wine-based drinks	Group I		*quantum satis*
14.2.7.3	Aromatised wine-product cocktails	Group I		*quantum satis*
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol	Group I		*quantum satis*
15.1	Potato-, cereal-, flour- or starch-based snacks	Group I		*quantum satis*
15.2	Processed nuts	Group I		*quantum satis*
16	Desserts excluding products covered in category 1, 3 and 4	Group I		*quantum satis*
17.1[(a)]	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	Group I		*quantum satis*

Food category number	Food category name	E-number/ group	Restrictions/ exception	MPL (mg/L or mg/kg as appropriate)
17.2[(a)]	Food supplements supplied in a liquid form	Group I		*quantum satis*
17.3[(a)]	Food supplements supplied in a syrup-type or chewable form	Group I		*quantum satis*
18	Processed foods not covered by categories 1 to 17, excluding foods for infants and young children	Group I		*quantum satis*

MPL: maximum permitted level.
(a): FCS 17 refers to food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children.

According to Annex III, Part 1 of Regulation (EC) No 1333/2008, sodium, potassium and calcium salts of fatty acids (E 470a) is authorised as carrier of glazing agents for fruits with a maximum level at *QS* and magnesium salts of fatty acids (E 470b) is also authorised as carrier of colours and fat soluble antioxidants with a maximum level at *QS*.

According to Annex III, Part 2 of Regulation (EC) No 1333/2008, sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) are also authorised as food additives having a function other than carriers in food additive preparations with a maximum level at *QS*.

According to Annex III, Part 3 of Regulation (EC) No 1333/2008, sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) are authorised as food additives in food enzymes with a maximum level in the enzyme preparation and in final foods including beverages at *QS*.

According to Annex III, Part 4 of Regulation (EC) No 1333/2008, sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) are authorised as in food flavourings with a maximum level at *QS.*

In addition, according to Annex III, Part 5, Section A of Regulation (EC) No 1333/2008, sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) are authorised as food additives in all nutrients, except those intended to be used in foodstuffs for infants and young children listed in point 13.1 of Part E of Annex II, at *QS*.

3.3. Exposure assessment

3.3.1. Reported use levels of E 470a and E 470b

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, information on actual use levels is required for performing a more realistic exposure assessment, especially for those food additives for which no MPL is set and which are authorised at *QS*.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued a public call[9] for occurrence data (usage level and/or analytical data) on sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b). In response to this public call, updated information on the actual use levels of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) in foods was made available to EFSA by industry. No analytical data of these food additives in foods were made available by the Member States.

Summarised data on reported use levels in foods provided by industry

Industry provided EFSA with data on use levels (n = 373) of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) in 24 food categories out of the 69 in which the additives are authorised. In particular, a total of 38 use levels were provided for E 470a in 20 food categories and 335 use levels for E 470b in 15 food categories. For E 470b, the majority (208 out of 335) of the use levels reported were for FC 17.1 (Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms). For 11 food categories, use levels for both additives were provided.

[9] https://www.efsa.europa.eu/de/data/call/151012

Updated information on the actual use levels of E 470a and E 470b in foods was made available to EFSA by the Association of the European Self-Medication Industry (AESGP), Dr Loges Naturheilkunde neu entdecken (LOGES), European federation of Associations of Health Products Manufacturers (EHPM), Food Drink Europe (FDE), Food Supplements Europe (FSE), International Chewing Gum Association (ICGA), International Food Additives Council (IFAC), KRÜGER GmbH & Co. and Saqual GmbH.

The Panel noted that some data providers of use levels of E 470a and E 470b, namely Saqual GmbH and IFAC, were not food industries using E 470a or E 470b in food products, but food additive producers or representatives of food additive producers. Usage levels reported by these parties could not be considered in the same way as those provided by food industry, because food additive producers might recommend usage levels to the food industry, but the final levels in the food products may be quite different. Because, Saqual GmbH and IFAC did not confirm that the recommended levels were used by the food industry, their data were not considered in the refined exposure scenarios. Data from food additive producers were only used in the *maximum level exposure assessment scenario* in case of *QS* authorisation when no data were available from food industry or Member States. For E 470a and E 470b, only data from food additive producers were available for FC 03 (Edible Ices), FC 11.2 (Other sugars and syrups), FC 12.2.1 (Herbs and spices), FC 12.2.2 (Seasonings and Condiments), FC 12.6 (Sauces) and FC 12.8 (Yeast and yeast products). These data were therefore only used in the *maximum level exposure assessment scenario*. In the refined scenarios, these six food categories were not considered.

The Panel noted that the use levels provided for 26 food products referred to niche products[10] in the following food categories: FC 03 (Edible ices), FC 05.3 (Chewing gum), FC 07.2 (Fine bakery wares), FC 17.1 (Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms) and FC 17.3 (Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms). These niche levels were considered in the *maximum level exposure assessment scenario*. In the refined scenarios, use levels of niche products were only considered when no use levels of more widely consumed foods were available within the corresponding food category. This was the case for the use levels for FC 05.3 (Chewing gum). For FC 03 (Edible ices), the only use level was also related to a niche product; however, because this use level was reported by an food additive producer, it was not considered in the refined scenarios.

Appendix A provides data on the use levels of E 470a and E 470b in foods as reported by industry.

3.3.2. Summarised data extracted from the Mintel's Global New Products Database

The Mintel's GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information on over 2.5 million food and beverage products of which more than 900,000 are or have been available on the European food market. The Mintel's GNPD started covering EU's food markets in 1996, currently having 20 out of its 28 member countries and Norway presented in the Mintel's GNPD.[11]

For the purpose of this Scientific Opinion, the Mintel's GNPD[12] was used to check the labelling of food and beverage products, including food supplements, for E 470a and E 470b within the EU's food market as the database contains the compulsory ingredient information on the label.

According to the Mintel's GNPD, E 470a was labelled on 329 products published in this database between January 2012 and August 2017. These foods belonged to 39 food subcategories of the Mintel's GNPD. The top-4 subcategories in term of number of products containing E 470a were Cakes, Pastries & Sweet Goods (n = 103), Vitamins & Dietary Supplements (n = 37), Dairy Based Ice Cream & Frozen Yogurt (n = 14) and Chilled Desserts (n = 14). When considering the percentage of foods containing E 470a according to the label per food subcategory, the top-4 subcategories were Other Natural Sweeteners (1.6%), Standard & Power Mints (1.2%), Frozen Desserts (0.8%) and Cakes, Pastries & Sweet Goods (0.7%). Overall according to the indication of the label, 0.1% of the products, which are present in the Mintel's GNPD contained E 470a.

E 470b was present in 3,324 products covering 26 food subcategories during the same period. The top-4 subcategories in terms of number of products containing E 470b were Vitamins & Dietary Supplements (n = 2,532), Standard & Power Mints (n = 335), Other Sugar Confectionery (n = 159) and Medicated Confectionery (n = 61). When considering the percentage of products containing E 470b according to the label per food subcategory, the top-4 subcategories were Standard & Power

[10] Whether a use level is applicable to a niche product is provided by industry.
[11] Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.
[12] http://www.gnpd.com/sinatra/home/ accessed on 21/8/2017.

Mints (40.6%), Vitamins & Dietary Supplements (29.6%), Mixed Assortments (13.3%) and Other Sugar Confectionery (12.9%). Overall, according to the indication of the label, 0.7% of the products, which are present in the Mintel's GNPD contained E 470b.

Only one food (sponge cake in food sub-category Cakes, Pastries & Sweet Goods) was reported to contain a combination of E 470a and E 470b.

Appendix B lists the number and percentage of products labelled with E 470a and/or E 470b between January 2012 and August 2017, out of the total number of products per food subcategories according to the Mintel's GNPD food classification.

According to the Mintel's GNPD, E 470a and E 470b are also used in food and beverage products in the following food subcategories (covering 26 food products), whereas no information on usage levels was available for the corresponding food categories:

- 01.3 Unflavoured fermented milk products, heat-treated after fermentation,
- 01.7.1 Unripened cheese excluding products falling in category 16,
- 04.2.4.1 Fruit and vegetables preparations excluding compote,
- 04.2.6 Processed potato products,
- 09.2 Processed fish and fishery products including molluscs and crustaceans,
- 10.2 Processed eggs and egg products,
- 12.7 Salads and savoury-based sandwich spreads,
- 8.3.2 Heat-treated meat products
- 8.3.3 Casings and coatings and decorations for meat.

This may have resulted in an underestimation of the exposure.

3.3.3. Food consumption data used for exposure assessment

EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a). New consumption surveys added in the Comprehensive database in 2015 were also taken into account in this assessment.[6]

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons should be interpreted with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

Food consumption data from the following population groups were used for the exposure assessment: infants, toddlers, children, adolescents, adults and the elderly. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 5).

Table 5: Population groups considered for the exposure estimates of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b)

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Denmark, Finland, Germany, Italy, UK
Toddlers[(a)]	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Denmark, Finland, Germany, Italy, Netherlands, Spain, UK
Children[(b)]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK

Population	Age range	Countries with food consumption surveys covering more than 1 day
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK
The elderly[(b)]	From 65 years of age and older	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Netherlands, Romania, Sweden, UK

(a): The term 'toddlers' comes from the EFSA Comprehensive Database and corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013.
(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, the FoodEx food codes were matched to the FCS food categories.

Food categories considered for the exposure assessment of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b)

The food categories for which use level of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) were provided, were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

Some food categories are not referenced in the EFSA Comprehensive Database and could therefore not be taken into account in the present estimate. This was the case for FC 12.1.2 Salt substitutes (Appendix C). Not considering this food category may have resulted in an underestimation of the exposure.

Moreover, for the following food categories, the restrictions/exceptions which apply to the use of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) could not be taken into account, and therefore the whole food category was considered in the exposure assessment. This applies to three food categories (Appendix C) and may have resulted in an overestimation of the exposure:

- 5.1 Cocoa and Chocolate products as covered by Directive 2000/36/EC (E 470a and E 470b only permitted in energy-reduced products or products with no added sugar)
- 7.1 Bread and rolls (E 470a and E 470b not allowed in foods belonging to FCs 7.1.1 and 7.1.2)
- 12.2.1 Herbs and Spices (E 470a only allowed in the dried forms of these foods).

In addition, the restrictions which apply to the use of E 470a and E 470b for the FCs 17.1, 17.2 and FC 17.3 (Food supplements, in solid, liquid and syrup-type or chewable form) could not be taken into account, and therefore, the whole food category (FC 17) was considered in the specific exposure scenario including food supplements.

According to information from the Mintel's GNPD database, E 470a and E 470b are not used in soft drinks. Thus, considering this and the fact that E 470a and E 470b are used as emulsifiers, only milk-based beverages and other cloudy drinks were considered under FC 14.1.4 Flavoured drinks. E 470a and E 470b are also allowed in FCs 13.2, 13.3 and 13.4. Food items belonging to these food categories, consumed by the population groups children, adolescents, adults and the elderly, may be very diverse and, in addition, there is very limited information on their consumption. Therefore, eating occasions belonging to these food categories were reclassified under the food categories in accordance to their main ingredient. The reported use levels of E 470a and E 470b for FCs 13.2 and 13.3 (Appendix A) were not considered in the exposure assessment.

Both food additives are also authorised for use in FC 18 (Processed foods not covered by categories 1–17, excluding foods for infants and young children). This food category is very unspecific and the foods belonging to this food category in the EFSA Comprehensive Database (e.g. processed foods, prepared or composite dishes) were therefore also reclassified under food categories in accordance to their main ingredient. No use levels of the food additives in this food category were provided to EFSA (Appendix A).

For the other food categories, the refinements considering the restrictions/exceptions as set in Annex II to Regulation No 1333/2008 were applied.

Overall, in the *maximum level exposure scenario*, 18 food categories were included, while in the refined (*brand loyal* and *non-brand loyal*) scenarios, 12 food categories were included in the exposure assessment of E 470a,b (Appendix C). Compared to the refined scenario, three additional food categories were considered (FC 17.1, 17.2 and 17.3) in the *food supplement consumers only scenario*.

3.4. Exposure estimate

3.4.1. Exposure to sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) from their use as food additives

The Panel carried out a chronic dietary exposure to E 470a and E 470b for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Based on information from the Mintel's GNPD, the Panel considered that E 470a and E 470b are not likely to be used in combination in the same food product and, therefore, the exposure assessment of E 470a,b was performed considering the reported use level for either E 470a or E 470b independently per food category (Appendix C).

Dietary exposure to E 470a,b was calculated by multiplying concentrations of E 470a,b per food category (Appendix C) with their respective consumption amount per kilogram body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only one day per subject were excluded as they were considered as not adequate to assess repeated exposure.

This was carried out for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 5). On the basis of these distributions, the mean and 95th percentile of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups with a sufficiently large sample size (EFSA, 2011a). Accordingly, in this assessment, the 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain were not estimated.

Exposure assessment of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a,b) was carried out by the ANS Panel based on: (1) maximum reported use levels (defined as the *maximum level exposure assessment scenario*) and (2) maximum and typical reported use levels (defined as the refined exposure assessment scenario). These two scenarios are discussed in detail below. These scenarios did not consider the exposure to E 470a,b via the intake of food supplements. This exposure source is covered in an additional scenario detailed below (food supplements consumers only scenario).

A possible additional exposure from the use of E 470a or E 470b in food additives, food enzymes, food flavourings and in nutrients in accordance with Annex III to Regulation (EC) No 1333/2008 (Parts 1, 2, 3, 4 and 5A) was not considered in any of the exposure scenarios due to the absence of concentration data.

Maximum level exposure assessment scenario

The *regulatory maximum level exposure assessment scenario* is typically based on the MPLs as set in Annex II to Regulation (EC) No 1333/2008 and listed in Table 4. As E 470a and E 470b are authorised at *QS* in all food categories, a maximum level exposure estimate was calculated based on the maximum reported use levels provided by industry (food industry and food additive manufacturers), excluding exposure via food supplements, as described in the EFSA Conceptual framework (EFSA ANS Panel, 2014). This exposure scenario can therefore consider only food categories for which the above data were made available to the Panel. Appendix C summarises the concentration levels of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) used in this scenario.

The Panel considered that the exposure estimates derived following this scenario was the most conservative, based on the available data, since it is assumed that that the population will be exposed to E 470a or E 470b present in food at the maximum reported use levels over a longer period of time.

Refined exposure assessment scenario

The present refined exposure assessment scenario is based on use levels reported by food industry. This exposure scenario can consider only food categories for which the above data were made available to the Panel.

Appendix C summarises the concentration levels of E 470a,b used in the refined exposure assessment scenario. Based on the available data set, the Panel calculated two refined exposure estimates based on different model populations:

- The *brand-loyal consumer scenario:* it was assumed that a consumer is exposed long-term to E 470a,b present at the maximum reported use for one food category. This exposure estimate was calculated as follows:
  - Combining food consumption with the maximum of the reported use levels for the main contributing food category at the individual level.
  - Using the mean of the typical reported use levels for the remaining food categories.
- The *non-brand-loyal consumer* scenario: it was assumed that a consumer is exposed long-term to levels of E 470a,b present at the mean reported use levels in food. This exposure estimate was calculated using the mean of the typical reported use levels for all food categories.

Food supplement consumers only scenario

Sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b) are authorised in FC 17 (Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children). As exposure via food supplements may deviate largely from that via food, and the number of food supplement consumers may be low depending on populations and surveys, an additional scenario was calculated in order to reflect additional exposure to food additives from the intake of food supplements. This scenario was estimated assuming that consumers of food supplements were exposed to E 470a,b present at the maximum reported usage levels in food supplements on a daily basis. For the remaining food categories, the mean of the typical reported use levels was used.

As FC 17 does not consider food supplements for infants and toddlers as defined in the legislation, the exposure to E 470a,b from food supplements was not estimated for these two population groups. Appendix C summarises the concentration levels of E 470a,b used in this scenario.

Dietary exposure to sodium, potassium, calcium and magnesium salts of fatty acids (E 470a, E 470b)

Table 6 summarises the estimated exposure to levels of E 470a,b from their use as food additives in six population groups (Table 5) according to the different exposure scenarios. Detailed results per population group and survey are presented in Appendices D and E.

Table 6: Summary of the estimated dietary exposure to sodium, potassium, calcium and magnesium salts of fatty acids (E 470a,b) from their use as food additives in the *maximum level exposure assessment scenario* and in the refined exposure scenarios, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks–11 months)		Toddlers (12–35 months)		Children (3–9 years)		Adolescents (10–17 years)		Adults (18–64 years)		The elderly (≥ 65 years)	
	Min	**Max**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**
Maximum level exposure assessment scenario												
Mean	3	23	6	97	16	72	8	41	11	27	13	22
95th percentile	22	61	18	160	38	146	20	80	24	64	29	43
Refined estimated exposure assessment scenario												
Brand-loyal scenario												
Mean	1	22	3	69	7	53	4	27	9	18	8	17
95th percentile	8	58	9	116	20	127	13	63	20	36	17	33

	Infants (12 weeks–11 months)		Toddlers (12–35 months)		Children (3–9 years)		Adolescents (10–17 years)		Adults (18–64 years)		The elderly (≥ 65 years)	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Non-brand-loyal scenario												
Mean	1	22	3	68	5	53	3	27	10	18	8	17
95th percentile	8	58	9	116	13	127	8	63	19	36	17	33

bw: body weight.

In the *maximum level exposure assessment scenario*, the mean exposure to E 470a,b from their use as food additives ranged from 3 mg/kg bw per day in infants to 97 mg/kg bw per day in toddlers. The 95th percentile of exposure ranged from 18 to 160 mg/kg bw per day in toddlers.

In the *brand-loyal scenario*, mean exposure to E 470a,b ranged from 1 mg/kg bw per day in infants to 69 mg/kg bw per day in toddlers. The 95th percentile ranged from 8 mg/kg bw per day in infants to 127 mg/kg bw per day in children. The corresponding exposure levels in the *non-brand-loyal scenario* were 1 mg/kg bw per day in infants and 68 mg/kg bw per day in toddlers at the mean level, and 8 mg/kg bw per day in infants and adolescents to 127 mg/kg bw per day in children at the 95th percentile of exposure, respectively.

The exposure estimates for the two refined exposure scenarios were similar because FC 07.1 bread and rolls contributed by far the most to the exposure in all population groups in both scenarios. For this food category, the reported maximum and typical use levels were the same.

In the food supplements consumers only exposure scenario, mean exposure to E 470a,b ranged for children between 8 and 58 mg/kg bw per day and between 13 and 17 mg/kg bw per day for adults. The corresponding 95th percentiles of exposure were 19 and 83 mg/kg bw per day and 30 and 39 mg/kg bw per day for the same two population groups (Appendix E).

In the *maximum level exposure assessment scenario*, FC 07.1 bread and rolls contributed most to the total mean exposure in all population groups. In children, adolescents, adults and elderly, another important contributor was FC 12.6 sauces. This food category was not included in the refined scenarios, because the reported use levels were from a food additive producer.

In the *brand-loyal scenario*, the main contributing food category was by far FC 07.1 bread and rolls. FC 05.2.1 other confectionery with added sugar was also an important contributor for children and adolescents. FC 05.2.1 had the highest maximum reported use level, except for the food supplements.

In the *non-brand-loyal scenario*, apart from FC 07.1 bread and rolls, FC 14.1.4 flavoured drinks and FC 05.2.1 other confectionery with added sugar contributed also largely to the exposure, especially for children and adolescents.

An overview of the main food categories contributing to the exposure to E 470a,b in the different exposure scenarios is presented in Appendix F.

Uncertainty analysis

Uncertainties in the exposure assessment of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a,b) have been discussed above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 7.

Table 7: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction[a]
Consumption data:	
Different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Use of data from food consumption surveys covering only a few days to estimate high percentiles (95th) long-term (chronic) exposure	+
Correspondence of reported use levels to the food items in the EFSA Comprehensive Database: uncertainties to which types of food the levels refer	+/–
Uncertainty in possible national differences in use levels within food categories	+/–

Sources of uncertainties	Direction[a]
Concentration data:	
• Levels considered applicable to all foods within the entire food category	+
• Levels not fully representative of foods on the EU market	+/–
Food categories included in the exposure assessment: no data for certain food categories which were therefore not considered in the exposure estimates (n = 45 for max scenario/51 for the refined scenarios out of 69 authorised food categories)	–
Food categories selected for the exposure assessment: exclusion of food categories due to missing FoodEx linkage (n = 1/69 food categories)	–
Food categories selected for the exposure assessment: inclusion of food categories without considering the restriction/exception (n = 3 max scenario/n = 2 refined scenarios out of 69 authorised food categories)	+
Foods which may contain the food additives according to Annex III to Regulation (EC) No 1333/2008 not taken into account	–
Maximum level exposure assessment scenario:	
• exposure calculations based on the maximum reported use levels (reported use from food industry and food additive producers	+
Refined exposure assessment scenarios:	
• exposure calculations based on the maximum or mean levels (reported use from food industries)	+/–

(a): +, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) are authorised as Group I food additive in 67 food categories and have a specific authorised use in two food categories (of which one has only an authorisation for E 470a) (Table 4). Since, the majority of food categories correspond to the general Group I food additives authorisation (Table 4), E 470a or E 470b may not necessarily be used in these food categories. This may explain why use levels of E 470a and E470b were only reported in 24 food categories. However, the Panel noted that information from the Mintel's GNPD (Appendix B) showed that a limited number of foods belonging to some of the remaining 45 food categories were labelled with either E 470a or E 470b, such as unripened cheese, processed potato products, and processed fish and fishery products including molluscs and crustaceans. This may indicate a possible minor underestimation of exposure. In the refined exposure scenarios and the food supplements consumers only scenario, 12 and 15 food categories were considered in the exposure assessment, respectively.

The 12 food categories which were taken into account in the refined exposure assessment scenarios out of all authorised food categories (N = 69), corresponded to only 6–37% of the amount (grams of foods by body weight) of foods consumed documented in the EFSA Consumption Database.

FC 07.1 bread and rolls was by far the major contributor to the exposure in the refined exposure scenarios. The Panel however noted that the use levels for this food category had been provided by only one food industry with an identical maximum and typical level. Furthermore, according to the Mintel's GNPD, only 0.1% of the foods belonging to comparable food subcategories as used in Mintel were reported to contain E 470a (Appendix B).

Certain FCs (FCs 03 Edible ices, 11.2 Other sugars and syrups, FCs 12.2.1 Herbs and Spices, 12.2.2 Seasonings and condiments, 12.6 Sauces and 12.8 Yeast and yeast products) were only considered in the *maximum exposure assessment scenario*. For FCs 03, 12.6 and 12.8 with only a (very) limited use of E 470a or E 470b according to the Mintel's GNPD, this may not have resulted in an underestimation of the exposure in the refined scenarios. However, E 470a and E 470b were used to a larger extent in FC 11.2 (Other sugars and syrups). Ignoring this food category may have resulted in an underestimation of the exposure in the refined scenarios.

The top-10 Mintel's GNPD food subcategories in terms of percentage of products containing E 470a or E 470b in a given subcategory (i.e. Standard & Power Mints, Vitamins & Dietary Supplements, Mixed Assortments, Other Sugar Confectionery, Medicated Confectionery, Other Natural Sweeteners, Lollipops, Boiled Sweets, Gum, Liquorice) were included in the food categories considered in the

refined exposure scenarios (Appendix C) except for 'Other Natural Sweeteners', for which no use levels were available.

Overall, based on the assumption that the food additives are not used in the food categories in which they are permitted but for which no usage data were provided by industry, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to E 470a,b as food additives in all exposure scenarios.

3.4.2. Exposure via the regular diet

The Panel considered that because salts of fatty acids are not expected to occur in normal diet, the exposure of the fatty acid moiety of the food additive was relevant for comparison with the intake of fatty acids coming from the diet. As, based on the information coming from the industry, salts of fatty acids (E 470a and E 470b) contain mainly saturated fatty acids, the saturated fatty acid intake from the diet has been considered.

In 2010, the EFSA NDA Panel issued an opinion on the dietary reference values (DRVs) for fats, including saturated fatty acids (EFSA NDA Panel, 2010) among European populations for several age classes and gender. As already done in the ANS opinion on the re-evaluation of fatty acids (E 570) (EFSA ANS Panel, 2017), the Panel calculated the mean dietary intake of saturated fatty acids taking into account DRVs for fats in energy percentage in different age classes among European populations. Accordingly, the minimum–maximum mean intakes of saturated fatty acids derived from all fats in mg/kg bw per day were approximately 2,500–3,000 mg/kg bw per day in infants, 1,100–1,300 mg/kg bw per day in toddlers, 900–1,300 mg/kg bw per day in children, 400–700 mg/kg bw per day in adolescents, 400–1,000 mg/kg bw per day in adults and 300–1,300 mg/kg bw per day in the elderly. In order to compare the exposure to the salts of fatty acids (as food additives) to the dietary intakes of saturated fatty acids, a conversion factor was calculated taking into account the EU specifications on the ranges of the metals expressed as metal oxides. After consideration of the molecular weights and the percentage of the metal in the oxides, the average metal content in the food additive was calculated to be about 8.7%, meaning that 91.3% of the food additive consisted of the fatty acid moiety. The conversion factor of 0.91 was applied to the mean exposures to E 470a,b to allow comparison with the intake of saturated fatty acids from the diet. Based on the estimated intakes of saturated fatty acids via the regular diet and those via the salts of fatty acids (E 470a and E 470b) as a food additives (Section 3.4.1, *non-brand-loyal scenario*), the Panel estimated that at the mean the intake of E 470a and E 470b as food additives may contribute up to 5% to the overall dietary exposure to saturated fatty acids, calculated as described above.

3.5. Biological and toxicological data

The Panel considered that sodium, potassium, calcium and magnesium salts of fatty acids are expected to dissociate in the gastrointestinal tract into fatty acid carboxylates and their corresponding cations as far as the salts are dissolved. The resulting low amounts of sodium, potassium, calcium and magnesium ions will enter normal physiological processes. Therefore, the properties of the corresponding cations are not discussed further in the opinion.

3.5.1. Absorption, distribution, metabolism and excretion

No data were available.

3.5.2. Acute oral toxicity

No data were available.

3.5.3. Short-term and subchronic toxicity

No data were available.

3.5.4. Genotoxicity

Belisario et al. (1985) assessed the mutagenicity of **calcium caprylate** in a *Salmonella* Typhimurium bacterial reverse mutation assay (strains TA98, TA100, TA1535, TA1537 and TA1538), with and without metabolic activation. No mutagenic activity was reported (no further information given).

Zeiger and Margolin (2000) tested **potassium oleate** (no details about purity given) in the bacterial reverse mutation assay using *S*. Typhimurium strains TA97, TA98, TA100 and TA1535. The authors reported that the test substance did not induce mutagenic effects in the presence and absence of metabolic activation (S9). No details were given about doses and cytotoxicity.

Magnesium stearate was tested for mutagenicity in *S*. Typhimurium strains TA1535, TA1537 and TA1538 and *Saccharomyces cerevisiae* strain D4 (Litton Bionetics, 1976 (Documentation provided to EFSA n. 9)). The highest concentration of the test substance was determined based on the concentration resulting in 50% survival. Two further concentrations tested were one-half and one-quarter of this concentration. Accordingly, the substance was tested in the assays at concentrations of 0, 1.25, 2.5 and 5% (w/v), which based on the description of the method, might be equivalent to 0, 25, 50 and 100 mg/plate. The assay was performed in the absence and presence of three metabolic activation systems (S9-mix) which were prepared with liver of mice, rats and monkeys, respectively. It was not reported if the S9-mixes were isolated from animals pretreated with inducers. The assays were performed as plate and pre-incubation (suspension) assays. The results of all assays were reported to be negative, however, the tables were not clearly presented and therefore difficult to be interpreted. The study was performed before the OECD guideline No 471 was established. It has some limitations, e.g. concerning the strains used, the concentrations tested and the reporting of methods and results.

Overall, the Panel noted that the data on the genotoxicity of the salts of fatty acids were limited to three studies. The mutagenicity of calcium caprylate, potassium oleate and magnesium stearate was tested in the bacterial reverse mutation assay and negative results were obtained.

3.5.5. Chronic toxicity and carcinogenicity

Sodium oleate (commercial product consisting of 80% sodium oleate; the other constituents being 5% sodium linoleate, 8% stearate, 5% linolenate, 2% palmitate with arachidonate) was administered, via the drinking water, for 108 weeks to groups of 50 male and 50 female F344 rats at levels of 0%, 2.5% and 5.0% (equivalent to 0, 1,250 and 2,500 mg/bw per day and 0, 1,000 and 2,000 mg/kg bw per day for sodium oleate, for males and females, respectively) (Hiasa et al. 1985). Histopathology was restricted to neoplastic changes and no data on non-neoplastic changes were reported. Data on clinical signs were not reported. Sodium oleate slightly depressed water consumption (not significantly) in the females, but not in the males. No statistically significant effects were found on survival and body weight. There were no statistically significant differences between treated and control rats in urinalysis and haematology. A slight but significant depression in serum bilirubin was the only finding in clinical chemistry in males. The significant decrease in lactic dehydrogenase activity and the increase in blood urea nitrogen, which were seen in females at the 2.5%, were not apparent at the 5% dose level. Data on relative organ weights were not reported. The absolute liver weight in the 5% dose in males was significantly reduced (means $\pm$ standard error of means: 8.8 $\pm$ 1.3 vs 10.8 $\pm$ 1.6 g in controls); however, the interindividual variability was high. In females, minor organ weight effects were reported for heart, adrenal, thymus and pancreas at the 5% level. The incidences of tumours of the pituitary gland (in males), thyroid gland (in females), adrenal gland (in males), pancreas (in males) and uterus were slightly higher in treated rats than in the controls, but the differences were not statistically significant with the exception of pancreatic tumours in males (0 in control, 10% in the low dose and 16% for the high dose) in males. However, according to the authors, this incidence did not differ significantly from the reported spontaneous incidence in the same strain (4.3–13.0% as reported for example by Maekawa et al. (1983)). The authors did not identify a NOAEL.

The Panel noted that the pancreatic tumours that were reported were adenoma not carcinoma and, therefore, considered that sodium oleate did not present a carcinogenic potential. In addition, due to the limitations in the protocol used (only two doses tested), the Panel considered that it was not possible to identify a NOAEL from this study.

3.5.6. Reproductive and developmental toxicity

No data were available.

3.5.7. Other studies

Case reports

Okumura et al. (1998), and also Kurai et al. (2006), reported case reports in which **sodium oleate** or **calcium stearate** induced lung reactions. The Panel considered these reports not relevant for the evaluation of the safety of salts of fatty acids used as food additives.

Effects on the intestinal tract

Endo et al. (2002) studied the local toxic effects of **sodium laurate** on colon epithelium in male Wistar rats in an *in situ* colon loop assay. Anaesthetised rats (no data about number of animals) received (after washing of colon) 1 mL of sodium laurate into a 10-cm loop of the colon for 90 min. Toxic effects were assessed by measuring the elution of phospholipids and total protein in the loop solution. At a concentration of 10 mM sodium laurate, both parameters were significantly increased suggesting local effects at a high concentrations.

Haematological effects

It has been reported that **sodium caprylate** and **sodium stearat**e may have some effects on platelet functions (Tangen et al., 1975) and sodium laurate have been used in a model for induction of coronary microembolization (Zhu et al., 2017). However, these effects occurred only under very specific experimental conditions, which were not relevant for the evaluation of the safety of these salts of fatty acids used as food additives.

3.5.8. Studies with other emulsifiers

Sodium, potassium, calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) are included in the list of EFEMA index of food emulsifiers (EFEMA, 2015).

In several recent studies, some other emulsifiers have been reported to alter the gut microbiota, to promote gut inflammation, obesity and to impair glycaemic control (Swidsinski et al., 2009a,b; Renz et al., 2012; Merga et al., 2014; Cani and Everard, 2015; Chassaing et al., 2015, 2017; Romano-Keeler and Weitkamp, 2015; Lecomte et al., 2016; Nejrup et al., 2017; Shah et al., 2017; Jiang et al., 2018). The Panel noted that, even though some of these effects are not systematically studied in toxicity studies performed according to toxicity testing guidelines, they would be investigated on a case-by-case basis if indicated by the results of the general toxicity testing as recommended in the Guidance for submission of food additives (EFSA ANS Panel, 2012). The Panel considered that additional studies would be needed to show the relevance of the effects seen in mice for human health and if salts of fatty acids can induce such effects.

3.6. Discussion

The Panel considered that it is unclear, whether, according to the definition in Regulation 231/2012, the fatty acids or the salts thereof are occurring in food fats and oils. However, according to the literature, salts of fatty acids are not expected to occur in significant amounts in food fats and oils (low Na, K, Ca or Mg content and acidic conditions due to free fatty acids). Therefore, this evaluation has been performed assuming that only the fatty acids (either free or bound) and not the salts of fatty acids occur in food fats and oils.

According to information from industry, the fatty acids used for the production of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) are obtained either from edible (i.e. vegetable or animal) fats and oils or from distilled food fatty acids. In the Regulation, no indication is given as regards the chemical nature of the fatty acids or the level at which an individual fatty acid may be present in the food additive E 470a and E 470b.

According to information provided by interested parties, salts of fatty acids consist for 95–99% (by weight) of salts, of which 4–5% account for the cation. In commercial products, the fatty acid fraction consists at least of 90% stearic- and palmitic acid with a minimum of 40% stearic acid.

The composition and the nature of the fatty acid moieties depend on the source material used for the production of the food additive. Next to stearic- and palmitic acid following fatty acids may be present in concentrations varying between 0% and 1.5%: i.e. lauric (C12) acid, myristic (C14) acid, pentadecanoic (C15) acid, margaric (C17) acid, oleic acid (C18:1) and arachidic (C20) acid.

E 470a and E 470b can be manufactured by using food oils and fats. Beside natural oils and fats, also hydrogenated fats and or oils can be used for manufacturing of E 470a and E 470b.

Some edible oils, such as rapeseed, which can be used for the manufacturing of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) may contain erucic acid. A TDI of 7 mg/kg bw per day for erucic acid has been established by the EFSA CONTAM Panel (EFSA CONTAM Panel, 2016), therefore, the Panel considered that a maximum limit for erucic acid should be included in the specifications.

According to information provided by industry (APAG, 2016 (Documentation provided to EFSA n. 2)), nickel present in the starting material could be a potential impurity in the final product and no maximum limit for nickel is included in the specifications for E 470a and E 470b.

The Panel noted that in Commission Regulation (EU) No 231/2012, the term 'distilled food fatty acids' is used. In the view of the Panel this term should be more clearly described. Indeed, without any further specification of this term, fatty acids that are identical to those present in foods, but that are produced by distillation from non-food sources, could also be used as source material for the production of the food additives E 470a and E 470b. The Panel considered that the safety of use of salts of fatty acids produced using fatty acids, obtained via distillation from non-food sources cannot be assessed. Therefore, the use of these sources should be avoided.

The Panel noted that recent studies with other emulsifiers had demonstrated effects on the microbiota, which might also be relevant to emulsifiers in general; however, there were no specific studies on E 470a or E 470b and effects on the microbiota itself.

The Panel noted that sodium, potassium, calcium and magnesium salts of fatty acids are expected to dissociate in the gastrointestinal tract into fatty acid carboxylates and their corresponding cations. The resulting low amounts of sodium, potassium, calcium and magnesium ions will enter normal physiological processes. Therefore, the properties of the corresponding cations are not discussed further in the opinion and the Panel considered that a read-across approach could be applied for the evaluation of the sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) using the previous assessment of the food additive fatty acids (E 570) (EFSA ANS Panel, 2017).

The Panel evaluated the ADME of the fatty acids, caprylic-, capric-, oleic-, lauric-, palmitic-, myristic- and stearic acid, and considered that they, like other fatty acids, were readily and extensively absorbed from the gastrointestinal tract and metabolised via the β-oxidation pathway and the tricarboxylic acid cycle to carbon dioxide and excreted (EFSA ANS Panel, 2017).

The Panel noted that the number of toxicological studies on the salts of fatty acids was very limited.

The Panel considered that:

- As regards genotoxicity, only the mutagenicity studies on calcium caprylate, potassium oleate and magnesium stearate were available and negative results were obtained. In addition, the Panel noted that available genotoxicity data for caprylic-, capric-, lauric-, myristic-, palmitic-, stearic- or oleic acid used as a food additive (E 570) do not raise a concern for genotoxicity (EFSA ANS Panel, 2017).
- As regards carcinogenicity, the Panel noted that in a study in rats, the pancreatic tumours reported were adenomas not carcinomas, therefore the Panel considered that sodium oleate did not present a carcinogenic potential. However, it was not possible to identify a NOAEL from this study.
- No data were available as regards subchronic toxicity, chronic toxicity, reproductive and developmental toxicity.

However, the EFSA ANS Panel evaluated the safety of the linear free fatty acids caprylic- (C8), capric- (C10), lauric- (C12), myristic- (C14), palmitic- (C16), stearic- (C18) and oleic acid (C18:1) when used as a food additive (E 570) and concluded that the use of these acids were of no safety concern at the reported use and use levels (EFSA ANS Panel, 2017).

For the exposure assessment of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a,b), reported uses were available for 24 out of 69 food categories in which E 470a and E 470b are authorised but only 12 food categories were considered in the refined exposure scenarios. The Panel noted that the information from the Mintel's GNPD supported the observation that sodium, potassium, calcium and magnesium salts of fatty acids (E 470a or E 470b) are apparently not used in all food categories in which the food additives are authorised.

Based on information from the Mintel's GNPD, the Panel considered that E 470a and E 470b are not likely to be used in combination in the same food product and, therefore, the exposure assessment of E 470a,b was performed considering the reported use level for either E 470a or E 470b independently per food category.

As salts of fatty acids are not expected to occur in significant amounts in foods, the Panel only considered the dietary intake of saturated fatty acids (not the salts) to assess the contribution of the food additives to the intake of saturated fatty acids via all dietary sources. The Panel noted that the dietary exposure to the fatty acid moieties of E 470a and E 470b represented up to 5% to the overall dietary exposure to saturated fatty acids, calculated as previously described in Section 3.4.2.

4. Conclusions

Considering that:

- sodium, potassium, calcium and magnesium salts of fatty acids are expected to dissociate in the gastrointestinal tract to fatty acid carboxylates and their corresponding cations,
- according to information from industry, palmitic acid and stearic acid are the main fatty acids present in E 470a and E 470b,
- palmitic acid and stearic acid are fatty acids included in the food additive E 570 which was already evaluated by the Panel and for which it was concluded that its use was of no safety concern,
- the fatty acid moieties of sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) contributed at the mean maximally to 5% of the overall dietary exposure of saturated fatty acids,

the Panel concluded that there was no need for a numerical ADI and that the food additives sodium, potassium, calcium and magnesium salts of fatty acids (E 470a and E 470b) were of no safety concern at the reported uses and use levels.

5. Recommendations

The Panel recommended that:

- the European Commission considers lowering the current limits for toxic elements (arsenic, lead, mercury and cadmium) in the EU specifications for sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) in order to ensure that the food additive will not be a significant source of exposure to these toxic elements in food.
- the European Commission considers revising the EU specifications for sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) including maximum limits for nickel.
- the European Commission considers revising the EU specifications for sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) including maximum limits for trans-fatty acids because sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) can be manufactured by glycerolysis of hydrogenated fats and/or oils, which contain significant amounts of trans fatty acids.
- the European Commission considers revising the EU specifications for sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) including maximum limits for erucic acid because as erucic acid can be present among the fatty acids in edible oils, which can be used for manufacturing of sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b).
- the European Commission considers revising the EU specifications for sodium, potassium and calcium salts of fatty acids (E 470a) and magnesium salts of fatty acids (E 470b) by rephrasing the definition in order to clarify that the fatty acids used as source materials be obtained only from edible fats and oils.
- in the event that practices reported in this opinion change (e.g. sources of starting material, uses and use levels) revision of this evaluation would be needed.

Documentation provided to EFSA

1) AESGP (Association of the European Self-Medication Industry), 2016. Data on usage levels sodium, potassium and calcium salt of fatty acids (E 470a) and magnesium salt of fatty acids (E 470b) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 4). Submitted to EFSA on 27th May 2016.

2) APAG (European Oleochemicals and Allied Products Group), 2016. Sodium, potassium and calcium salt of fatty acids (E 470a). Magnesium salt of fatty acids (E 470b). Prepared by APAG represented by the European Chemical Industry Council (CEFIC). Submitted by APAG, 30th September 2016.
3) EHPM (European federation of Associations of Health Products Manufacturers) 2016, Data on usage levels of sodium, potassium and calcium salt of fatty acids (E 470a) and magnesium salt of fatty acids (E 470b) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 4), Submitted to EFSA on 31st May 2016.
4) FDE (Food Drink Europe), 2016. Data on usage levels of sodium, potassium and calcium salt of fatty acids (E 470a) and magnesium salt of fatty acids (E 470b) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 4) Submitted to EFSA on 31st May 2016
5) FSE (Food Supplements Europe), 2016. Data on usage levels of sodium, potassium and calcium salt of fatty acids (E 470a) and magnesium salt of fatty acids (E 470b) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 4), Submitted to EFSA on 15th July 2016.
6) ICGA (International Chewing Gum Association), 2016. Data on usage levels of sodium, potassium and calcium salt of fatty acids (E 470a) and magnesium salt of fatty acids (E 470b) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 4), Published 12 October 2015. Submitted to EFSA on 31st May 2016.
7) IFAC (International Food Additives Council), 2016. Data on usage levels of sodium, potassium and calcium salt of fatty acids (E 470a) and magnesium salt of fatty acids (E 470b) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 4), Published 12 October 2015. Submitted to EFSA on 31st May 2016.
8) KRÜGER (KRÜGER GmbH & Co. KG), 2016. Data on usage levels of sodium, potassium and calcium salt of fatty acids (E 470a) and magnesium salt of fatty acids (E 470b) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 4). Submitted to EFSA on 25th May 2016.
9) Litton Bionetic, 1776. Mutagenic evaluation of compound FDA 75-33 00057-04-0 magnesium stearate. LBI Project No 2468. Submitted by the FDA, 1st December 2017.
10) LOGES (Dr. Loges - Naturheilkunde neu entdecken), 2016. Data on usage levels of sodium, potassium and calcium salt of fatty acids (E 470a) and magnesium salt of fatty acids (E 470b) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 4). Submitted to EFSA on 27th April 2016.
11) Pre-evaluation document prepared by the Technical University of Denmark (DTU), March 2014.
12) SAQUAL (Saqual GmbH), 2016 Data on usage levels of sodium, potassium and calcium salt of fatty acids (E 470a) and magnesium salt of fatty acids (E 470b) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (Batch 4). Submitted to EFSA on 31st May 2016.

References

Alberts B, Johnson A, Lewis J, Raff M, Roberts K and Walter P, 2002. Molecular biology of the cell. 4th edition. Garland Science, New York. Membrane Proteins. Available online: https://www.ncbi.nlm.nih.gov/books/NBK26878/

Belisario MA, Pecce R, De GA and Mugnoz B, 1985. [Evaluation of the mutagenicity of nine additives used in the fabrication of plastic food containers]. Bollettino Della Societa Italiana Di Biologia Sperimentale, 61, 1647–1653.

Belitz HD, Grosch W and Schieberle P, 2008. *Lehrbuch der Lebensmittelchemie*, 6th Edition. Springer Verlag, Berlin, Heidelberg.

Cani PD and Everard A, 2015. Keeping gut lining at bay: impact of emulsifiers. Trends in Endocrinology and Metabolism, 26, 273–274.

Chassaing B, Koren O, Goodrich JK, Poole AC, Srinivasan S, Ley RE and Gewirtz AT, 2015. Dietary emulsifiers impact the mouse gut microbiota promoting colitis and metabolic syndrome. Nature, 519, 92–96.

Chassaing B, de Wiele TV, De Bodt J, Marzorati M and Gewirtz AT, 2017. Dietary emulsifiers directly alter human microbiota composition and gene expression ex vivo potentiating intestinal inflammation. Gut, 1–14.

EFEMA, 2015. Available online: http://www.emulsifiers.org/files/Index_of_food_emulsifiers_7th%20Edition_FINAL.pdf
EFSA (European Food Safety Authority), 2007. Scientific opinion of the Scientific Committee related to uncertainties in dietary exposure assessment. EFSA Journal 2007;5(1):438, 54 pp. https://doi.org/10.2903/j.efsa.2007.438
EFSA (European Food Safety Authority), 2011a. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. https://doi.org/10.2903/j.efsa.2011.2097
EFSA (European Food Safety Authority), 2011b. Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database. EFSA Journal 2011;9(3):1970, 27 pp. https://doi.org/10.2903/j.efsa.2011.1970
EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2012. Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760, 60 pp. https://doi.org/10.2903/j.efsa.2012.2760
EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources), 2014. Statement on a conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010. EFSA Journal 2014;12(6):3697, 11 pp. https://doi.org/10.2903/j.efsa.2014.3697
EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), Mortensen A, Aguilar F, Crebelli R, Di Domenico A, Dusemund B, Frutos MJ, Galtier P, Gott D, Gundert-Remy U, Leblanc J-C, Lindtner O, Moldeus P, Mosesso P, Parent-Massin D, Oskarsson A, Stankovic I, Waalkens-Berendsen I, Woutersen RA, Wright M, Younes M, Boon P, Chrysafidis D, Gurtler R, Tobback P, Gergelova P, Rincon AM and Lambre C, 2017. Scientific Opinion on the re-evaluation of fatty acids (E 570) as a food additive. EFSA Journal 2017;15(5):4785, 48 pp. https://doi.org/10.2903/j.efsa.2017.4785
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2009a. Scientific opinion on cadmium in food. EFSA Journal 2009;7(10):980, 139 pp. https://doi.org/10.2903/j.efsa.2009.98
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2009b. Scientific Opinion on arsenic in food. EFSA Journal 2009;7(10):1351, 199 pp. https://doi.org/10.2903/j.efsa.2009.1351
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2010. Scientific Opinion on lead in food. EFSA Journal 2010;8(4):1570, 151 pp. https://doi.org/10.2903/j.efsa.2010.1570
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2012a. Scientific Opinion on the risk for public health related to the presence of mercury and methylmercury in food. EFSA Journal 2012;10(12):2985, 241 pp. https://doi.org/10.2903/j.efsa.2012.2985
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2012b. Scientific Opinion on lead dietary exposure in the European population. EFSA Journal 2012;10(7):2831, 59 pp. https://doi.org/10.2903/j.efsa.2012.2831
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2012c. Scientific Opinion on cadmium dietary exposure in the European population. EFSA Journal 2012;10(1):2551, 59 pp. https://doi.org/10.2903/j.efsa.2012.2831
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2014. Scientific Opinion on dietary exposure to inorganic arsenic in the European population. EFSA Journal 2014;12(3):3597, 68 pp. https://doi.org/10.2903/j.efsa.2014.3597
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Knutsen HK, Alexander J, Barreg_ard L, Bignami M, Bröuschweiler B, Ceccatelli S, Dinovi M, Edler L, Grasl-Kraupp B, Hogstrand C, Hoogenboom L (Ron), Nebbia CS, Oswald I, Petersen A, Rose M, Roudot A-C, Schwerdtle T, Vollmer G, Wallace H, Cottrill B, Dogliotti E, Laakso J, Metzler M, Velasco L, Baert K, Ruiz JAG, Varga E, Dörr B, Sousa R and Vleminckx C, 2016. Scientific Opinion on erucic acid in feed and food. EFSA Journal 2016;14(11):4593, 173 pp. https://doi.org/10.2903/j.efsa.2016.4593
EFSA NDA Panel (Scientific Panel on Dietetic Products, Nutrition and Allergies), 2004. Opinion on a request from the Commission related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids. EFSA Journal 2004;81, 1–4, https://doi.org/10.2903/j.efsa.2004.81
EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on dietary reference values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol. EFSA Journal 2010;8(3):1461, 107 pp. https://doi.org/10.2903/j.efsa.2010.1461
EFSA Scientific Committee, 2009. Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: general principles. EFSA Journal 2009;7(7):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051
EFSA Scientific Committee, 2012. Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579, 32 pp. https://doi.org/10.2903/j.efsa.2012.2579
Endo Y, Hanada K, Miyake M, Ogawara K-I, Higaki K and Kimura T, 2002. Mechanisms of cytoprotective effect of amino acids on local toxicity caused by sodium laurate, a drug absorption enhancer, in intestinal epithelium. Journal of Pharmaceutical Sciences, 91, 730–743.
Hiasa Y, Konishi N, Kitahori Y and Shimoyama T, 1985. Carcinogenicity study of a commercial sodium oleate in fischer rats. Food and Chemical Toxicology, 23, 619–623.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1974. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents. Salts of Myristic, Palmitic, and Stearic acids. WHO Food Additives Series No. 5.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1984. Evaluation of certain food additives and contaminants. Twenty-eighth Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No. 710.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1986. Evaluation of Certain Food Additives and Contaminants. Twenty-eighth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No. 733.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1989. Evaluation of certain food additives and contaminants. Thirty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series No.776.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2000. Guidelines for the preparation of toxicological working papers for the Joint FAO/WHO Expert Committee on Food Additives. Geneva, Switzerland.
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2001a. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Salts of Myristic, Palmitic and Stearic Acids (Aluminium, Magnesium).
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2001b. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Salts of Capric, Caprylic, Lauric and Oleic Acids (Aluminium, Magnesium).
JECFA(Joint FAO/WHO Expert Committee on Food Additives), 2001c. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives. Salts of Capric, Caprylic and Lauric Acids (Calcium, Potassium, Sodium).
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2006. Monograph 1. Combined compendium of food additive specifications. All specifications monographs from the 1st to the 65th meeting (1956-2005). Volume 4, Available online: http://www.fao.org/ag/agn/jecfa-additives/search.html
JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2015. Combined compendium of food additive specifications. Magnesium stearate. Monograph 17. Available online: http://www.fao.org/ag/agn/jecfa-additives/search.html
Jiang Z, Zhao M, Zhang H, Li Y, Liu M and Feng F, 2018. Antimicrobial emulsifier- glycerol monolaurate induces metabolic syndrome, gut microbiota dysbiosis and systemic low-grade inflammation in low-fat diet fed mice. Molecular Nutrition and Food Research, 62, https://doi.org/10.1002/mnfr.201700547
Kurai J, Chikumi H, Kodani M, Sako T, Watabe M, Miyata M, Makino H, Touge H, Hitsuda Y and Shimizy E, 2006. Acute eonisophilic phneumonia caused by calcium stearate, an additive agent for an oral antihistaminic medication. Internal Medicine, 45, 1011–1016.
Lecomte M, Couedelo Leslie, Meugnier E, Plaisancie P, Letisse M, Bérengère B, Gabert L, Penhoat A, Durand A, Pineau G, Joffre F, Géloën A, Vaysse C, Laugerette F and Michalski MC, 2016. Dietary emulsifiers from milk and soybean differently impact adiposity and inflammation in association with modulation of colonic goblet in high-fat fed mice. Molecular Nutrition and Food Research, 60, 606–620.
Maekawa A, Kukorawa Y, Takahashi M, Kokubo T, Ogiu T, Onodera H, Tanigawa H, Ohno Y, Furukawa F and Hayashi Y, 1983. Spontaneous tumors in F-344/DuCrj rats. Gann, 74, 365–372.
Merga Y, Campbell BJ and Rhodes JM, 2014. Mucosal barrier, bacteria and inflammatory bowel disease: possibilities for therapy. Digestive Diseases, 32, 475–483.
Nejrup RG, Licht TR and Hellgren LI, 2017. Fatty acid composition and phospholipid types used in infant formulas modifies the establishment of human gut bacteria in germ-free mice. Scientific Reports, 7, 1–11.
Okumura T, Suzuki K, Kumada K, Kobayashi R, Fukuda A, Fujii C and Kohama A, 1998. Severe respiratory distress following sodium oleate ingestion. Journal of Toxicology Clinical Toxicology, 36, 587–589.
Renz H, Brandtzaeg P and Hornef M, 2012. The impact of perinatal immune development on mucosal homeostasis and chronic inflammation. Nature Reviews-Immunology, 12, 9–23.
Romano-Keeler J and Weitkamp JH, 2015. Maternal influences on fetal microbial colonization and immune development. Pediatric Research, 77, 189–195.
Rustan AC and Drevon CA, 2005. Fatty acids: structures and properties. Encyclopedia of Life Sciences, 1–7.
SCF (Scientific Committee for Food), 1991. Food science and techniques. Reports of the Scientific Committee for Food, 25th Series.
SCF (Scientific Committee for Food), 2001. Guidance on submissions for food additive evaluations by the Scientific Committee on Food. SCF/CS/ADD/GEN/26 Final. 12 July 2001.
Shah R, Kolanos R, DiNovi MJ, Mattia A and Kaneko KJ, 2017. Dietary exposures for the safety assessment of seven emulsifiers commonly added to foods in the United States and implications for safety. Food Additives and Contaminants: Part A, 34, 905–917.
Swidsinski A, Loening-Baucke V and Herber A, 2009a. Mucosal flora in Crohn's disease and ulcerative colitis - an overview. Journal of Physiology and Pharmacology, 60(supplement 6), 61–71.

Swidsinski A, Ung V, Sydora BC, Loening-Baucke V, Doerffel Y, Verstraelen H and Fedorak RN, 2009b. Bacterial overgrowth and inflammation of small intestine after carboxymethylcellulose ingestion in genetically susceptible mice. Inflammatory Bowel Diseases, 15, 359–364.

Tangen O, Wallenbeck IA and Bergqvist D, 1975. Platelet reactivity ex vivo and in vivo after acute and chronic treatment with sodium caprylate. Scandinavian Journal of Clinical and Laboratory Investigation, 35, 19–23.

TemaNord (Nordic Council of Ministers), 2002. E 475 Polyglycerol esters of fatty acids. Food Additives in Europe 2000 - Status of safety assessments of food additives presently permitted in the EU, 460-464.

Zeiger E and Margolin BH, 2000. The proportions of mutagens among chemicals in commerce. Regulatory Toxicology and Pharmacology, 32, 219–225.

Zhu H, Ding Y, Xu X, Li M, Fang Y, Gao B, Mao H, Tong G, Zhou L and Huang J, 2017. Prostaglandin E1 protects coronary microvascular function via the glycogen synthase kinase 3β-mitochondrial permeability transition pore pathway in rat hearts subjected to sodium laurate-induced coronary microembolization. American Journal of Translational Research, 9, 2520–2534.

Abbreviations

ADI	acceptable daily intake
ADME	absorption, distribution,. metabolism, excretion
AESGP	Association of the European Self-Medication Industry
ANS	EFSA Scientific Panel on Food Additives and Nutrient Sources added to Food
AV	acid value
bw	body weight
CAS	Chemical Abstracts Service
CONTAM	EFSA Panel on Contaminants in Food Chain
DMSO	dimethyl sulfoxide
DRV	dietary reference value
EHPM	European federation of Associations of Health Products Manufacturers
EINECS	European Inventory of Existing Chemical Substances
FAO	Food and Agriculture Organization of the United Nations
FCs	food categories
FCS	food categorisation system
FDE	Food Drink Europe
FSE	Food Supplements Europe
GC	gas chromatography
GLC	gas liquid chromatography
GNPD	Global New Products Database
IARC	International Agency for Research on Cancer
ICGA	International Chewing Gum Association
IFAC	International Food Additives Council
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOGES	Dr. Loges - Naturheilkunde neu entdecken
MPL	maximum permitted level
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
QS	*quantum satis*
TDI	tolerable daily intake
SCF	Scientific Committee on Food
TemaNord	is a publishing series for results of the often research-based work that working groups or projects under Nordic Council of Ministers have put in motion
WHO	World Health Organization

Appendix A – Summary of reported use levels of E 470a and E 470b provided by industry (mg/kg)

Appendix B – Number and Percentage of food products labelled with E 470a and E 470b as present on the Mintel GNPD per food sub-category between 2012 and 2017

Appendix C – Concentration levels of E 470a,b used in the MPL and in the refined exposure scenarios (mg/kg or mL/kg as appropriate)

Appendix D – Summary of total estimated exposure of E 470a,b from their use as food additives for the maximum level exposure scenario and the refined exposure assessment scenarios per population group and survey: mean and 95th percentile (mg/kg bw per day)

Appendix E – Summary of total estimated exposure of E 470a,b from their use as food additives for the food supplement consumer only scenario per population group and survey: mean and 95th percentile (mg/kg bw per day)

Appendix F – Main food categories contributing to exposure to E 470a,b using the maximum level exposure scenario and the refined exposure assessment scenarios (> 5% to the total mean exposure)

Appendices A–F can be found in the online version of this output ('Supporting information' section): http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5180/suppinfo/