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Re-evaluation of sucrose esters of fatty acids (E 473) as a food additive in foods for infants below 16 weeks of age and follow-up of its previous evaluations as food additive for uses in foods for all population groups

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Abstract

Sucrose esters of fatty acids (E 473) was re-evaluated in 2004 by the former EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel). In addition, the former EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) issued scientific opinions on the safety of sucrose esters of fatty acids (E 473) in 2010, 2012 and 2018. As a follow-up to these assessments, the Panel on Food Additives and Flavourings (FAF) was requested to assess the safety of sucrose esters of fatty acids (E 473) for its uses as food additive in food for infants below 16 weeks of age. In addition, the FAF Panel was requested to address the issues already identified by the EFSA AFC and ANS Panels when used in food for the general population. The process involved the publication of calls for data to allow the interested business operators to provide the requested information to complete the risk assessment. The Panel concluded that the technical data provided by the interested business operators support an amendment of the specifications for sucrose esters of fatty acids (E 473) laid down in Commission Regulation (EU) No 231/2012. According to the available information, E 473 is not used in food categories (FCs) 13.1.1 and 13.1.5.1, including all types of food for infants below 16 weeks of age, and in FC 13.1.5.2. As a consequence, an assessment of the safety for the uses of E 473 as food additive in these FCs and age group was not performed. When the updated exposure estimates considering the provided use levels for some food categories are taken into account the estimates of exposure to sucrose esters of fatty acids (E 473) exceeded the group acceptable daily intake (ADI) of 40 mg/kg body weight (bw) per day for many population groups.

Keywords: sucrose esters of fatty acids, E 473, food additive, infants

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Note: The full opinion will be published in accordance with Article 8 of Regulation (EU) No 257/2010 once the decision on confidentiality will be received from the European Commission.

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Amendment: Deletion of incorrect link to the Appendices. An editorial correction was carried out that does not materially affect the contents or outcome of this scientific output. To avoid confusion, the original version of the output has been removed from the EFSA Journal, but is available on request.

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Summary

In accordance with Regulation (EU) No 257/2010, the European Food Safety Authority (EFSA) is currently re-evaluating the safety of food additives already permitted in the Union before 20 January 2009 and issuing scientific opinions on their safety when used in food as per Annexes II and III to Regulation (EC) No 1333/2008. The risk assessment approach followed in the re-evaluation has not covered the use of food additives in food for infants below 12 weeks of age. Additionally, while re-evaluating the safety of food additives referred to above, EFSA identified some concerns, namely (1) data gaps that have triggered recommendations in the published scientific opinions; and/or (2) data gaps that have increased uncertainties linked to the risk assessment and/or which prevented the Panel from concluding on some aspects of it.

However, in 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives and the EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) had issued a scientific opinion on the safety of sucrose esters of fatty acids (E 473) when used as food additive.

In addition, in 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) issued scientific opinions on the safety of sucrose esters of fatty acids (E 473) produced by a new manufacturing method and including an extension of the use of this additive in flavoured fruit beverages and on the exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive, in food categories currently specified in Annex II to Regulation (EC) No 1333/2008, which do not cover those for infants below 12 weeks of age. The reason was that the risk assessment approach followed at the time by the EFSA's Scientific Panels in the re-evaluation of food additives did not apply to this age group.

On 31 May 2017, EFSA published a guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age, thus enabling EFSA to assess the safety of food additives used in food for infants below this age. The age up to 16 weeks was selected in the guidance because infants are exposed to formula feeding until this age as the only source of food since complementary feeding is not supposed to be introduced before.

As follow-up of the above, this Opinion addresses the data gaps identified during the previous evaluations of sucrose esters of fatty acids (E 473) as food additive and the safety of its possible use in food for infants below 16 weeks of age.

The process followed involved the publication of dedicated calls for data allowing all interested parties to provide the requested information for completing the assessment and to confirm that the additive is present in food categories 13.1.1 (Infant formulae) and 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants). The data submitted in response to the calls for data on sucrose esters of fatty acids (E 473) comprised technical information, use levels and literature reviews.

Sucrose esters of fatty acids consist of a mixture of essentially mono-, di- and tri-esters of sucrose with food fatty acids. Specifications for sucrose esters of fatty acids (E 473) have been defined in Commission Regulation (EU) No 231/2012.

Data to address the safety of the uses of sucrose esters of fatty acids (E 473) in food for infants below 16 weeks of age were not provided. The Panel noted that according to the available information, E 473 is not used in FCs 13.1.1 and 13.1.5.1, including all types of food for infants below 16 weeks of age, and in FC 13.1.5.2. For this reason, an assessment of the safety for the uses of E 473 as food additive in FCs 13.1.1, 13.1.5.1, 13.1.5.2 and in food for infants below 16 weeks of age was not performed.

In its opinion from 2018, the ANS Panel recommended the collection of more detailed data (reported use levels from industry) for the food category contributing most to the exposure to sucrose esters of fatty acids (E 473): fine bakery wares as well as monitoring data for a certain type of flavoured drinks. Following the call for data (2021), five IBOs provided use levels for six different FCs (05.2, 07.2, 14.1.4, 14.1.5, 17.1 and 17.2). Exposure estimates were performed to account for the newly available information.

The FAF Panel used the refined brand-loyal scenario as the most relevant exposure scenario for the safety evaluation for this food additive. Exposure estimates for the refined brand-loyal scenario ranged at the mean between 0.7 mg/kg bw per day for infants and 59 mg/kg bw per day for toddlers, and at the p95 between 5 mg/kg bw per day for infants and 183 mg/kg bw per day for toddlers.

Analytical data on toxic elements were provided by two IBOs for levels of Pb, Cd, Hg and As for E 473 intended for use in food for the general population. The IBOs proposed the lowest technologically

achievable limits for those parameters as either the currently existing limits for toxic elements in the EU specifications or the limits of quantification (LOQs) of the analytical methods, with the exception of As. The Panel noted that the concentration data on toxic elements submitted by the IBOs are, in almost all cases, substantially lower than the current limits in the EU specifications.

The Panel considered the potential presence of Pb, Cd, Hg and As in E 473 at (I) the current maximum limits in the EU specification, (II) the proposal of one IBO for the lowest technologically achievable levels, which are the same as LOQs reported for Pb, Hg, Cd and As, (III) the same proposed lowest technologically achievable levels by applying a modulation factor of 5 for Cd, As and Hg and by maintaining the proposed lowest technologically achievable level for Pb and (IV) the proposal of another IBO for the lowest technologically achievable levels, which apart from As, is the same as the current maximum limits in the EU specification. The Panel used the refined brand-loyal exposure scenario to calculate the exposure to the toxic elements from the use of E 473. The highest exposure levels for the mean and 95th percentile among the different population groups were considered, i.e. 59 and 183 mg/kg bw per day, for toddlers, respectively.

The potential exposure to these impurities from the use of E 473 was compared against the available health-based guidance values (HBGV) and reference points (RP). The resulting figures show that according to the current specifications, the exposure to As from the consumption of E 473 could be substantial. For the toxic elements Hg and Cd (Scenarios I and IV), the potential exposure is also high considering that E 473 is only one source of exposure. The Panel noted that the maximum limits in the EU specifications for toxic elements should be established based on actual levels in the commercial food additive. Therefore, the Panel recommended the maximum limits to be lowered on the basis of the information provided by the IBOs and on the considerations of the Panel.

As the IBOs claimed that other manufacturing processes, in particular the use of vinyl esters, are not used, these processes were not evaluated by the Panel in the current assessment. Therefore, the Panel could not comment on the current maximum limits for impurities originating from manufacturing processes not used and for which maximum limits are established in the EU specifications for E 473.

No information on the content of erucic acid, 3-MCPD and glycidyl esters in commercial samples of E 473 and very limited information on the content of *trans* fatty acids was submitted. The Panel noted that a maximum level for these impurities in fats and oils suitable for human consumption is set by Regulation (EC) No 1881/2006 and Regulation (EC) No 1925/2006. Hence, the Panel recommended that the fats and oils used for the manufacturing process of E 473 should comply with these Regulations. As an alternative, limit values for these impurities could be introduced in the Commission Regulation (EU) No 231/2012 for E 473. Regarding *trans* fatty acids, the lowest technologically achievable level was claimed to be 0.05% by one IBO. For erucic acid, 3-MCPD and glycidyl esters, no analytical data were submitted by the IBOs in response to the calls for data, and the Panel is not in a position to adequately propose maximum limits for these potential impurities in the specifications for this food additive.

The group ADI of sucrose esters of fatty acids (E 473) and sucroglycerides (E 474) established by the EFSA AFC Panel in 2004 is 40 mg/kg bw per day. When the updated exposure estimates reported above (refined brand-loyal scenario) are compared with this ADI, the conclusion reached by the EFSA ANS Panel in 2018 is confirmed; the estimates of exposure to sucrose esters of fatty acids (E 473) exceeded the group ADI of 40 mg/kg bw per day for many population groups. It is noted that the data received are not extensive and do not allow to map more specifically *use* levels to foods with respect to the previous assessments.

Table of contents

1. Introduction

The present opinion deals with the follow-up on issues that have been expressed in the conclusions and recommendations of the EFSA Scientific Opinions on sucrose esters of fatty acids (E 473) by the EFSA AFC and ANS Panels (EFSA, 2004; EFSA ANS Panel, 2010, 2012, 2018).

Information to address the safety of sucrose esters of fatty acids (E 473) for uses in food for infants below 16 weeks of age and in food categories (FC) 13.1.1 (Infant formulae as defined Directive 2006/141/EC) and 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants) was not provided by the interested business operators (IBOs) during the call for data published on 29 November 2018.[1]

In its answer, one IBO (manufacturer of E 473) clarified that they did not provide information to address the safety of sucrose esters of fatty acids (E 473) for uses in food for infants below 16 weeks of age because foods for infants below that age are out of scope of their business. They also stated that '*we believe that our product is not used in food for infants below 16 weeks of age being not supplied to manufacturers with the intention of use for such food categories*' (Documentation provided to EFSA n. 4). Another IBO (manufacturer of E 473) responded that they do not have information on whether or not their products are used in food for infants below 16 weeks of age (Documentation provided to EFSA n. 2).

Upon request from EFSA, an association representing specialised nutrition industries in EU confirmed that their members are not using E 473 in foods belonging to food categories 13.1.1, 13.1.5.1 and 13.1.5.2 (Documentation provided to EFSA n. 7, 14).

The fact that E 473 is not used in FC 13.1.1 and 13.1.5.1 was confirmed in the answers of the call for data published on 8 December 2021.[2]

The Panel noted that E 473 is not used in FCs 13.1.1 and 13.1.5.1, including all types of food for infants below 16 weeks of age, and 13.1.5.2.

1.1. Background and terms of reference as provided by the requestor

1.1.1. Background

The composition of food intended for infants and young children, as defined by Regulation (EU) No 609/2013[3], is regulated at EU level and such rules include requirements concerning the use of substances as food additives.

The use of food additives is regulated by Regulation (EC) No 1333/2008 on food additives. Only food additives that are included in the Union list, in particular in Annex II and III to that Regulation, may be placed on the market and used in food under the conditions of use specified therein.

In accordance with Regulation (EU) No 257/2010[4], EFSA is currently re-evaluating the safety of food additives already permitted in the Union before 20 January 2009 and issuing scientific opinions on their safety when used in food as per Annexes II and III to Regulation (EC) No 1333/2008. However, the risk assessment approach followed until now has not covered the use of food additives in food for infants below 12 weeks of age. Consequently, EFSA published several scientific opinions on the re-evaluation of

[1] Call for technical and toxicological data on sucrose esters of fatty acids (E 473) as a food additive for uses in foods for all population groups including infants below 16 weeks of age. Published: 29 November 2018. Available online: https://www.efsa.europa.eu/en/consultations/call/181129

[2] Call for technical and toxicological data on sucrose esters of fatty acids (E 473) as a food additive for uses in foods for all population groups including infants below 16 weeks of age. Published: 8 December 2021. Available online: https://www.efsa.europa.eu/en/call/call-technical-data-sucrose-esters-fatty-acids-e-473-uses-food-additive-foods-all-population

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

[4] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a program 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.

the safety of food additives permitted in food category 13.1 but not addressing their use in food for infants below 12 weeks of age.[5]

In addition, in these opinions EFSA identified some concerns, namely (1) Data gaps that have triggered recommendations in the (to be) published scientific opinions, and/or; (2) Data gaps that have increased uncertainties linked to the risk assessment and/or which prevented the EFSA from concluding on some aspects of it.

On 31 May 2017, EFSA published a guidance document (EFSA Scientific Committee, 2017) on the risk assessment of substances present in food intended for infants below 16 weeks of age, thus enabling EFSA to assess the safety of food additives used in food for infants below 12 weeks of age.[6] Now EFSA is expected to launch dedicated calls for data to be able to perform such risk assessments.

The EC considers it is more effective that EFSA, in the context of these dedicated calls for data, also addresses all the issues and data gaps already identified in the relevant (to be) published scientific opinions on the re-evaluation of the safety of food additives permitted in food category 13.1.

In accordance with the current EC approach for the follow-up of EFSA's scientific opinions on the re-evaluation of the safety of permitted food additives for which some concerns have been identified, a specific call for data would be published by the EC on DG SANTE's website[7] on food additives and additional (missing) information would then be provided by interested business operators to the EC.

However, for those scientific opinions on the re-evaluation of the safety of permitted food additives in food category 13.1 for which the risk assessment does not address their uses in food for infants below 12 weeks of age and for which some concerns have been identified by EFSA, the EC considers that for the sake of efficiency it would be appropriate to streamline the approach as described above.

Therefore, the EC requests EFSA to address all the issues and data gaps already identified in the relevant published scientific opinions of those food additives (or groups of additives that can be addressed simultaneously) as part of the upcoming work on the safety assessment of food additives uses in food for infants below 12 weeks of age.

This follow-up aims at completing the re-evaluation of the food additives in question for all food categories and includes calls for data covering the actual use and usage levels of food additives in food for both infants below 12 or 16 weeks of age as well as for older infants, young children and other groups of the population for which EFSA has already finalised its assessment.

The future evaluations of EFSA should systematically address the safety of use of food additives for all age groups, including the infants below 12 or 16 weeks of age.

1.1.2. Terms of reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002[8], and as part of EFSA's work in completing its risk assessments concerning the use of food additives in food for infants below 12 weeks of age[5], covered by the re-evaluation programme and its terms of reference, the European Commission requests the European Food Safety Authority to address all the data gaps specified in the recommendations made in these scientific opinions on the re-evaluation of the safety of food additives permitted in food category 13.1 (food for infants and young children) of annex II to Regulation (EC) No 1333/2008.

1.1.3. Interpretation of terms of reference

Before the publication of the EFSA Scientific Committee Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age (EFSA Scientific Committee, 2017), EFSA has taken 12 weeks as a cut off age for the applicability of the safety assessment. However, according to EFSA Scientific Committee (2017), the assessment was intended to

[5] E 473 was previously evaluated by the former EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) who re-examined the safety of sucrose esters of fatty acids as food additives (EFSA, 2004). In a subsequent opinion, the EFSA Scientific Panel on food additives and nutrient sources added to food (ANS Panel) addressed the safety of sucrose esters of fatty acids produced by a new manufacturing method (EFSA ANS Panel, 2012). With respect to the re-evaluation to be performed by EFSA under Regulation (EC) No 257/2010, the European Commission suggested that taking into account the conclusions of the 2012 ANS Panel opinion, in the case of this food additive, this could be limited to a refined exposure assessment, which was delivered in 2018 by the ANS Panel (EFSA ANS Panel, 2018).

[6] See Section 1.1.3.

[7] https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

[8] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

include infants up to 16 weeks of age because they are exposed to formula feeding until this age as the only source of food since complementary feeding is not supposed to be introduced before this age (see EFSA Scientific Committee, 2017).

According to the available information (Documentation provided to EFSA n. 2, 4, 7, 14), E 473 is not used in FCs 13.1.1 and 13.1.5.1, including all types of food for infants below 16 weeks of age, and 13.1.5.2. Hence, the safety of the use in these food categories including food for the age group of infants below 16 weeks of age will not be addressed. This re-evaluation will, therefore, cover only the follow-up on issues that have been expressed in the conclusions and recommendations in the previous Scientific Opinions assessing sucrose esters of fatty acids (E 473) as food additive by the EFSA AFC and ANS Panels (EFSA, 2004; EFSA ANS Panel, 2010, 2012, 2018).

1.2. Previous evaluations of sucrose esters of fatty acids (E 473)

In 1992, the Scientific Committee for Food (SCF) evaluated sucrose esters of fatty acids and established a group ADI of 0–20 mg/kg bw per day (expressed as sucrose monostearate) for sucrose esters of fatty acids and sucroglycerides derived from palm oil, lard and tallow fatty acids provided that the specifications would limit the presence of tetra and higher esters to 7% (SCF, 1992). In a subsequent evaluation, the uses of sucrose esters of fatty acids as emulsifiers in formulae and follow-on formulae and in food for special medical purposes for infants and young children were evaluated. The Committee concluded that '*the use of sucrose esters of fatty acids is acceptable up to 120 mg/L in powdered and liquid FSMP containing extensively or fully hydrolysed proteins or amino acids for infants and young children, and in liquid infant formula and follow-on formula containing partially hydrolysed proteins intended for infants and young children in good health'* (SCF, 1996).

Sucrose esters of fatty acids (and sucroglycerides) were evaluated by the Joint FAO/WHO expert Commiteee on Food Additives (JECFA) in 1992 and 1995. In the latter evaluation, JECFA allocated a temporary group ADI of 0–20 mg/kg bw per day and requested the results of a well-designed and well-conducted tolerance study (JECFA, 1995). This study was submitted and evaluated by JECFA in 1997, resulting in the establishment of a group ADI of 0–30 mg/kg bw per day (JECFA, 1998). In 2009, JECFA confirmed the group ADI for sucrose esters of fatty acids, sucroglycerides and sucrose oligoesters type I and type II (JECFA, 2009). Sucrose esters of fatty acids were evaluated by JECFA in 2021 (JECFA, 2022); the group ADI of 0–30 mg/kg bw per day was not discussed. The Committee recommended that, in order to refine the dietary exposure estimates of sucrose esters of fatty acids (SEFs) and sucrose oligoesters (SOEs), either alone or summed, the 'sponsors' should submit information on:

- typical or mean and high use levels for foods in which the food additives are used; and
- foods (or food categories) in which the use of SEFs and/or SOEs is permitted but in which they are never used.

1.3. Previous EFSA scientific opinions and follow-up calls for data

In 2004, the former EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) re-examined the safety of sucrose esters of fatty acids as food additives (EFSA, 2004). The EFSA AFC Panel concluded that sucrose esters of fatty acids have low oral toxicity and do not raise concern of carcinogenicity. The available metabolic studies showed that these esters are extensively hydrolysed in the gastrointestinal tract into well-known food constituents prior to absorption. Incompletely hydrolysed sucrose esters appear to be excreted in the faeces. Only small amounts of intact monoesters are absorbed and there is no evidence of tissue accumulation of the absorbed monoesters. Long-term toxicity studies were available, and a NOAEL of 2,000 mg/kg bw per day was identified on the basis of a long-term toxicity study in rats. Concerns about a potential laxative effect in humans were raised on the basis of the results from an inadequate study in which laxation and related abdominal symptoms were reported in humans ingesting doses of sucrose esters of fatty acids higher than 2 g/day equivalent to 33 mg/kg bw per day. In a subsequent well-designed and conducted human tolerance study, no adverse effects were observed in men and women receiving divided daily doses of 1.5 g sucrose esters of fatty acids in bread for 5 days (equal to 27 mg/kg bw per day in men and 29 mg/kg bw per day in women). However, this was the only dose level tested, and it was lower than the dose range (33–75 mg/kg bw per day) reported to produce gastrointestinal symptoms in the first study. Considering all the toxicity data with an overall NOAEL of 2,000 mg/kg bw per day, the AFC Panel established a group ADI of 40 mg/kg bw per day for sucrose esters of fatty acids (E 473) and sucroglycerides (E 474).

In 2010, the ANS Panel issued an opinion dealing with the safety of sucrose esters of fatty acids produced by a new manufacturing method from sucrose and vinyl esters of fatty acids, and an evaluation of the extension of the use of this additive to flavoured fruit beverages. The new manufacturing method resulted in residues of vinyl esters of fatty acids and acetaldehyde in the sucrose esters of fatty acids whilst p-methoxyphenol (used as a stabiliser in the new method) was not detected (< 100 μg/kg). The vinyl portion of the vinyl ester instantly tautomerises to acetaldehyde in the gastrointestinal tract. The ANS Panel concluded that the additional average exposure of 1.4 μg acetaldehyde/kg bw per day resulting from the use of sucrose esters of fatty acids as a food additive would be negligible compared to the exposure from food and the endogenous formation of acetaldehyde. Overall, the ANS Panel concluded that sucrose esters of fatty acids produced by the new manufacturing method do not present any safety concern provided the overall exposure is within the ADI of 40 mg/kg bw per day. The ANS Panel also noted that the intake of sucrose esters of fatty acids is high and for some individuals above the ADI but that an additional intake from fruit beverages only seems to contribute to a few percent of the ADI.

In 2012 and 2018, the ANS Panel issued two opinions dealing with the exposure assessment of sucrose esters of fatty acids (E 473) (EFSA ANS Panel, 2012, 2018).

In the 2012 Scientific Opinion, the ANS Panel concluded that, based on the data available, the additional use of sucrose esters of fatty acids may lead to exposures in excess of the ADI of 40 mg/kg bw per day for sucrose esters of fatty acids (E 473) and sucroglycerides (E 474) established by EFSA in 2004.

In the 2018 ANS Opinion, it is reported that the additive is authorised for use in food categories 13.1.1 and 13.1.5.1 which include foods for infants under the age of 12 weeks and that this age group had to be excluded from the exposure assessment at that time (see Section 1.1.3). The ANS Panel concluded that the exposure to sucrose esters of fatty acids (E 473) exceeded the group ADI of 40 mg/kg bw per day for many of the remaining population groups, especially for toddlers and children. The ANS Panel noted that, assuming that the food additive sucrose esters of fatty acids (E 473) is not used in the 24 food categories where data were not provided, the current exposure estimates very likely overestimate the real exposure to sucrose esters of fatty acids (E 473). The Panel recommended the collection of more detailed data (reported use levels from industry) for the food category contributing most to the exposure to sucrose esters of fatty acids (E 473): fine bakery wares as well as monitoring data for certain type of flavoured drinks. These data should allow for a more precise mapping of use levels to foods as recorded in the EFSA Comprehensive Database, and thus result in more realistic estimates of exposure to sucrose esters of fatty acids (E 473) via food.

A call for data was published by EFSA on 28 November 2018 with the aim to collect information to address the data gaps specified in the recommendations made in its previous scientific opinions (EFSA, 2004; EFSA ANS Panel, 2010, 2012, 2018) and to complete the evaluation of E 473 as food additive (see also Appendix F). The following information relevant for the general population was requested in the call for data:

- analytical data on current levels of lead, mercury, cadmium and arsenic in commercial samples of the food additive
- the lowest technologically achievable level for lead, mercury, cadmium and arsenic in order to adequately define their maximum limits in the specifications
- the lowest technologically achievable level for impurities currently included in the EU specifications for sucrose esters of fatty acids (E 473)
- the lowest technologically achievable level for vinyl esters of fatty acids when sucrose esters of fatty acids (E 473) are manufactured from sucrose and the vinyl esters of food fatty acids
- the risk characterisation at the lowest technologically achievable level of any residual of toxicological concern included in the EU specifications of sucrose esters of fatty acids (E 473) as food additive
- literature searches should be conducted relevant for the safety evaluation of sucrose esters of fatty acids (E 473) for all uses in foods for all population groups from 9 January 2017 up to the date of the data submission, as described in the Guidance for submission for food additive evaluations (Section 5.3)

Additionally, information specific for the risk assessment of sucrose esters of fatty acids (E 473) for uses as food additive in foods for infants below 16 weeks of age was requested namely:

- information and justification on the concentration of sucrose esters of fatty acids (E 473) alone or in combination with food additives E 322, E 471 and E 472c.
- information on the fate and the reaction products of sucrose esters of fatty acids (E 473) in these foods.
- proposals for particular specification requirements for identity and purity of sucrose esters of fatty acids (E 473) when used in these food categories. In particular, the absence of residuals such as vinyl esters of fatty acids, acetaldehyde and p-Methoxyphenol.
- within the frame of the EFSA Guidance of the Scientific Committee on the risk assessment of substances present in food intended for infants below 16 weeks of age the following information on the toxicological properties of sucrose esters of fatty acids (E 473) and its adverse effects relevant for its use in food categories for infants below 16 weeks of age 13.1.1 and 13.1.5.1 is required:
    - clinical data to assess the safety of sucrose esters of fatty acids (E 473)
    - post-marketing surveillance reports on undesired and adverse reactions, indicating the ages and other relevant data of the exposed infants and young children and the use levels in the marketed products
    - published and unpublished case reports (e.g. available nutrivigilance data) on undesired and adverse effects, associated with the oral administration of sucrose esters of fatty acids in any form, to infants and young children.
- literature searches relevant for the safety evaluation of sucrose esters of fatty acids (E 473) when used in foods for infants below 16 weeks of age, should be conducted as described in the Guidance for submission for food additive evaluations (Section 5.3)

Data to address the safety of impurities of toxicological concerns identified as relevant in recent assessments of food additives similar to E 473 (EFSA FAF Panel, 2020, 2021) were not requested in the call for data published on 29 November 2018. For this reason, a follow-up call for data was published on 8 December 2021 to request the following information (see also Appendix G):

- the source of the fatty acids used for the manufacturing of E 473 along with detailed information of any production method used to manufacture E 473, including indication of the solvents used, time/temperature patterns applied, chemical/physical reactions and/or treatments involved;
- analytical data, supported by certificate of analysis, on current levels of trans-fatty acids in commercial samples of E 473;
- analytical data, supported by certificate of analysis, on current levels of erucic acid in commercial samples of E 473;
- analytical data, supported by certificate of analysis, on current levels of any compound of toxicological concern (e.g. 3-MCPD[9] or glycidyl esters) in commercial samples of E 473;
- in addition, depending on the manufacturing process (see first bullet point), information on the presence of any other additional impurity in E 473, along with corresponding analytical data, supported by certificate of analysis;
- the lowest technologically achievable levels for the impurities listed above to adequately propose maximum limits in the current EU specifications for E 473.

In addition, also in the light of the updated exposure assessment (EFSA ANS Panel, 2018), the following information regarding the uses of E 473 was requested:

- occurrence data (use levels or analytical data) are requested for authorised food categories e.g. for the food categories contributing most to the exposure to sucrose esters of fatty acids (E 473), like fine bakery wares and certain type of flavoured drinks (see EFSA ANS Panel, 2018). These data should allow for a more precise mapping of use levels to foods as recorded in the EFSA Comprehensive Database, and thus will allow to calculate a more realistic estimate of exposure to E 473 via food. This is also considered relevant for the risk assessment of any impurity of toxicological concern.

[9] 3-monochloropropane diol.

In the same call for data, the following was reported:

- as indicated in the 'Overall objective', EFSA notes that according to the information currently available at its level, E 473 is not used in food categories 13.1.1 and 13.1.5.1. Hence, the safety of the use in these food categories will not be addressed in any future assessment, unless further information is received.

Finally, an update of the literature search since the cut-off date indicated in the previous call for data (i.e. 31.12.2019) was requested.

2. Data and methodologies

2.1. Data

The Panel based its assessment on the:

- information submitted in response to the EFSA public calls for data[1,2] and the conclusions and recommendations from previous evaluations.
- information from Mintel's Global New Products Database (GNPD) to identify the use of the food additive sucrose esters of fatty acids (E 473) in 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.

In order to conclude on the safety of sucrose esters of fatty acids (E 473) for all population groups and to address the data gaps identified during the re-evaluation, the FAF Panel assessed the information provided for the follow-up on issues that have been expressed in the conclusions and recommendations of the EFSA Scientific Opinions on sucrose esters of fatty acids (E 473) by the EFSA AFC and ANS Panels (EFSA, 2004; EFSA ANS Panel, 2010, 2012, 2018).

According to the available information (Documentation provided to EFSA n. 2, 4, 7, 14), E 473 is not used in FCs 13.1.1 and 13.1.5.1, including all types of food for infants below 16 weeks of age, and in FC 13.1.5.2. Hence, the safety of the use in these food categories and in the age group of infants below 16 weeks of age will not be addressed. This re-evaluation will, therefore, cover only the follow-up on issues that have been expressed in the conclusions and recommendations of the Scientific Opinions on the re-evaluation of sucrose esters of fatty acids (E 473) as food additive by the EFSA AFC and ANS Panels (EFSA, 2004; EFSA ANS Panel, 2010, 2012, 2018).

3. Assessment

3.1. Identity and specifications of E 473

According to Commission Regulation (EU) No 231/2012[10], the food additive E 473 is named sucrose esters of fatty acids. Sucrose esters of fatty acids consist of a mixture of essentially mono-, di- and tri-esters of sucrose with food fatty acids.

The specifications for sucrose esters of fatty acids (E 473) as defined in the Commission Regulation (EU) No 231/2012 and proposed by JECFA (2017) are listed in Table 1.

[10] 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 Text with EEA relevance. OJ L 83, 22.3.2012, p. 1–295.

Table 1: Specifications for sucrose esters of fatty acids (E 473) according to Commission Regulation (EU) No 231/2012 and as proposed by JECFA (2017)

	Commission Regulation (EU) No 231/2012[(a)]	**JECFA (2017)**
Synonyms	Sucroesters; sugar esters	Sucrose fatty acid esters, INS No. 473
Definition	Essentially the mono-, di- and tri-esters of sucrose with fatty acids occurring in food fats and oils. They may be prepared from sucrose and the methyl, ethyl and vinyl esters of food fatty acids (including lauric acid) or by extraction from sucroglycerides. No organic solvent other than dimethylsulphoxide, methylformamide, ethyl acetate, propan-2-ol, 2-methyl-1-propanol, propylene glycol, methyl ethyl ketone and supercritical carbon dioxide may be used for their preparation. *p*-methoxy phenol can be used as a stabiliser during the manufacturing procedure	Mono-, di- and tri-esters of sucrose with food fatty acids, prepared from sucrose and methyl and ethyl esters of food fatty acids by esterification in the presence of a catalyst or by extraction from sucroglycerides. Only the following solvents may be used for the production: dimethylformamide, dimethyl sulphoxide, ethyl acetate, isopropanol, propylene glycol, isobutanol and methyl ethyl ketone
Assay	Content not less than 80%	Not less than 80% of sucrose esters
Description	Stiff gels, soft solids or white to slightly greyish-white powders	White to greyish white or pale yellow powder, stiff gel or soft solid
Identification		
Test for sugar	Passes test	–
Test for fatty acids	Passes test	–
Solubility	Sparingly soluble in water, soluble in ethanol	Very soluble in ethanol at 50°
Fatty acids	–	Add 1 mL of ethanol to 0.1 g of the sample, dissolve by warming, add 5 mL of dilute sulfuric acid TS, heat in a water bath for 30 min and cool. A yellowish white solid or oil is formed, which has no odour of isobutyric acid, and which dissolves when 3 mL of diethyl ether are added. Use the aqueous layer separated from the diethyl ether in the test for sugars
Sugars	–	To 2 mL of the aqueous layer separated from the diethyl ether in the test for fatty acids, carefully add 1 mL of anthrone TS down the inside of a test tube; the boundary surface of the two layers turns blue or green.
Purity		
Sulphated ash	Not more than 2% (800 ± 25°C)	Not more than 2% Test 1 g of the sample (Method I)[(b)]
Acid value	–	Not more than 6
Free sugar	Not more than 5%	Not more than 5%
Free fatty acids	Not more than 3% estimated as oleic acid	–
p-Methoxyphenol	Not more than 100 μg/kg	–
Acetaldehyde	Not more than 50 mg/kg	–
Arsenic	Not more than 3 mg/kg	–
Lead	Not more than 2 mg/kg	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg	–
Cadmium	Not more than 1 mg/kg	–
Methanol	Not more than 10 mg/kg	Not more than 10 mg/kg

	Commission Regulation (EU) No 231/2012[a]	JECFA (2017)
Dimethylsulphoxide	Not more than 2 mg/kg	Not more than 2 mg/kg
Dimethylformamide	Not more than 1 mg/kg	Not more than 1 mg/kg
2-Methyl-1-propanol	Not more than 10 mg/kg	Not more than 10 mg/kg
Ethyl acetate	Not more than 350 mg/kg, singly or in combination	Not more than 350 mg/kg, singly or in combination
Propan-2-ol		
Propylene glycol		
Methyl ethyl ketone	Not more than 10 mg/kg	Not more than 10 mg/kg

(a): Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids; however, these substances may be present up to a maximum level of 6% (expressed as sodium oleate).
(b): Further information on the test methods to be used is provided in the JEFCA specifications directly and/or by reference to 'Volume 4 (under "General Methods")' (JECFA, 2004, 2017). These method details are omitted here for reasons of brevity and clarity.

The revisions of the existing EU specifications proposed by the Panel are provided under Section 3.5.

3.2. Technical data submitted

3.2.1. Manufacturing process

The call for data (2021) requested:

- detailed information of any production method used to manufacture E 473, including indication of the solvents used, time/temperature patterns applied, chemical/physical reactions and/or treatments involved.

The Panel noted that information on various manufacturing processes using different routes, materials used and purification steps is available in the literature (Norn, 2014). This would be the reason for the several impurities listed in the EU specifications for E 473. The interesterification route is the one indicated by two interested business operators (IBOs) (Documentation provided to EFSA n. 5, 6). The starting materials used are sucrose, fat and oils (see Section 3.2.3.3) or methyl esters of fatty acids and as solvents DMSO along with another already permitted in the EU specifications. In the current assessment, the Panel considered the possible impurities formed by this specific manufacturing route. As the IBOs claimed that they do not use other manufacturing processes, in particular vinyl esters as starting material, the impurities derived from these processes were not evaluated by the Panel in the current assessment (Documentation provided to EFSA n. 5, 6, 17).

3.2.2. Toxic elements

The call for data (2018) requested:

- analytical data on current levels of lead, mercury, cadmium and arsenic in commercial samples of the food additive;
- the lowest technologically achievable level for lead, mercury, cadmium and arsenic in order to adequately define their maximum limits in the specifications.

Analytical data were provided by two IBOs on levels of lead (Pb), mercury (Hg), cadmium (Cd) and arsenic (As) in commercial samples of sucrose esters of fatty acids for uses as a food additive E 473.

One IBO submitted data on these four toxic elements in nine batches from three products of different hydrophilicity. Pb and Cd were analysed by inductively coupled plasma – atomic emission spectrophotometry (ICP-AES), Hg by cold vapour atomic absorption spectroscopy (CV-AAS) and As by atomic absorption hydride technique (Documentation provided to EFSA n. 3). Each batch was analysed in triplicate. One sample of a batch contained Pb at 1.3 mg/kg, while the other two replicates of this batch were below the limit of detection (LOD) of 0.6 mg/kg. The other samples were below the LOD of 0.6 mg/kg, or below the limit of quantification (LOQ) of 1.0 mg/kg. For Hg, all batches were below the LOQ of 0.1 mg/kg, and for Cd, all results were below the LOD of 0.005 mg/kg. The LOQ of Cd was reported as 0.01 mg/kg. For As, all nine batches were reported as below the LOQ of 0.1 mg/kg. Based on their results, the IBO proposed the lowest technologically achievable levels of the toxic elements

Pb, Hg, Cd and As as 1.0, 0.1, 0.01 and 0.1 mg/kg, respectively (Table 2). The Panel noted that these proposed lowest technologically achievable levels are the same as the LOQs (Documentation provided to EFSA n. 3, 4, 16).

Another IBO submitted results on Pb, Hg, Cd and As in five batches of E 473. Pb and Cd were analysed by graphite furnace atomic absorption spectrometry (GF-AAS), Hg by cold vapour atomic absorption spectroscopy (CV-AAS) and As by the dopamine dithiocarbamate functionalised silver nanoparticles (DDTC-Ag NPs)-based colorimetric method. The Panel noted that the method used for As is not quantitative. For Pb, all results were below the LOQ of 0.1 mg/kg. For Hg and Cd, all results were below the LOQ of 0.05 mg/kg. It was claimed by the applicant that the levels of Pb, Hg and Cd in their products did not exceed the specification limits set for E 473, and thus, they proposed lowest technologically achievable levels of 2.0, 1.0 and 1.0 mg/kg for Pb, Hg and Cd, respectively (Table 2). All results for As (expressed as As_2O_3) were below the LOD of 1 mg/kg. For Pb, all results were below the LOQ of 0.1 mg/kg. The IBO indicated the possibility that the toxic elements are derived from the raw materials as the food additive is not contaminated with elements during the manufacturing process. As the suppliers of the raw materials assure a maximum limit for As as 1 mg As_2O_3/kg, the IBO considered this value as the lowest technologically achievable level (Table 2). The Panel noted that the actually measured concentrations reported for the toxic elements are substantially lower than the proposed lowest technologically achievable levels (Documentation provided to EFSA n. 1).

Table 2: Lowest technologically achievable levels of the toxic elements Pb, Hg, Cd and As in commercial sucrose esters of fatty acids (E 473), as proposed by two IBOs (Documentation provided to EFSA n. 1, 3, 4, 16)

IBO	Lead (mg/kg)	Mercury (mg/kg)	Cadmium (mg/kg)	Arsenic (mg/kg)
1 Documentation provided to EFSA n. 3, 4, 16	1.0	0.1	0.01	0.1
2 Documentation provided to EFSA n. 1	2.0	1.0	1.0	0.76[(a)]

(a): Equivalent to 1 mg As_2O_3/kg, as proposed by the IBO.

3.2.3. Carry-over and process impurities

3.2.3.1. Impurities currently included in the EU specifications on E 473

The call for data (2018) requested:

- the lowest technologically achievable level for impurities currently included in the EU specifications for sucrose esters of fatty acids (E 473).

One IBO submitted data on the residual solvents methanol and dimethylsulphoxide (DMSO), sulphated ash, free sugar and free fatty acids, which are currently listed as purity criteria in the EU specifications for E 473. These parameters were analysed in the same nine batches as the ones for the toxic elements. Methanol was below the LOQ of 1 mg/kg. For DMSO, the concentration ranged between 0.15 and 0.77 mg/kg. The concentration of sulphated ash ranged between 0.37% and 0.87%. The concentrations of free sugar and free fatty acids ranged between 0.20% and 0.49%, and 1.05% and 1.31%, respectively. The IBO proposed to maintain the current specification limits for these parameters laid down in Commission Regulation (EU) No 231/2012. Additionally, the IBO submitted data on the residual sodium, potassium and calcium salts of fatty acids, analysed in the same nine batches, and indicated that the concentration ranged from 1.97% to 3.15%. These concentrations are lower than the maximum limit value of 6% for salts of fatty acids (expressed as sodium oleate) established by the footnote to the EU specifications (see Table 1). The IBO did not analyse other impurities currently included in the EU specifications for sucrose esters of fatty acids (E 473), such as p-methoxyphenol, acetaldehyde, dimethylformamide, ethyl acetate, propan-2-ol, propylene glycol and methyl ethyl ketone, since these chemicals are not used by the IBO for manufacturing E 473, and, according to the IBO, are not expected to be generated during the manufacturing process (see Section 3.2.1). Therefore, the IBO did not propose specification limits for these impurities (Documentation provided to EFSA n. 3, 16).

Another IBO submitted data on methanol, [redacted], DMSO, sulphated ash, free sugar and free fatty acids, which are currently listed as purity criteria in the EU specifications on food additives, in 189 batches of six different products (Documentation provided to EFSA n. 1, 2, 8). The Panel noted that the results provided were below the EU specification limits for all parameters. Based

on their results, the IBO proposed lowest technologically achievable levels for methanol (10 mg/kg), DMSO (2 mg/kg), sulphated ash (1.5%), free sugar (5.0%), free fatty acids (2.52%, estimated as oleic acid) and [redacted]. Except for sulphated ash and free fatty acids, the proposed values are the same as the current limits laid down in the EU specifications. The IBO did not analyse other impurities currently included in the EU specifications for sucrose esters of fatty acids (E 473), since the IBO does not use them for manufacturing E 473 or, according to the IBO, they are not expected to be produced during the manufacturing process (see Section 3.2.1). Therefore, the IBO did not propose specification limits for these impurities (Documentation provided to EFSA n. 1).

3.2.3.2. Vinyl esters

The call for data (2018) requested:

- the lowest technologically achievable level for vinyl esters of fatty acids when sucrose esters of fatty acids (E 473) are manufactured from sucrose and the vinyl esters of food fatty acids.

As their production process for sucrose esters of fatty acids does not include vinyl esters of fatty acids as starting materials, one IBO did not analyse vinyl esters of fatty acids as residual raw materials, acetaldehyde (as its decomposition product) and p-methoxyphenol (as a stabiliser for vinyl esters) (see Section 3.2.1) (Documentation provided to EFSA n. 3).

Another IBO also noted that they do not use vinyl esters of fatty acids in the production process of E 473 and thus cannot provide data on these compounds and related potential impurities (see Section 3.2.1) (Documentation provided to EFSA n. 1).

3.2.3.3. Fatty acids and their source

During the re-evaluation of certain food additives (EFSA ANS Panel, 2017; EFSA FAF Panel, 2020, 2021), the ANS and FAF Panels raised some concern regarding the potential presence of impurities carried over from the food oils and fats used in manufacturing processes of certain food additives. In consideration of this, the FAF Panel in a call for data (2021) requested further clarifications from the IBOs with respect to:

- the source of the fatty acids used for the manufacturing of E 473.

One IBO stated that the raw materials used for manufacturing of E 473 are sucrose and methyl esters of fatty acids. According to the provided information, the fatty acids include myristic, palmitic and stearic acids, as well as a small portion of fatty acids with 20 or more carbons in their chain. No further information on the source of the fatty acids was provided by the IBO (Documentation provided to EFSA n. 6).

The methyl esters of fatty acids that are used for E 473 produced by another IBO were reported to be methyl esters of lauric, palmitic, stearic and oleic acids. The fatty acids used for the production of the methyl esters originate either from palm oil, and/or palm kernel oil, and/or coconut oil (Documentation provided to EFSA n. 5).

3.2.3.4. *Trans* fatty acids

The call for data (2021) requested:

- analytical data, supported by certificate of analysis, on current levels of *trans* fatty acids in commercial samples of E 473 and the lowest technologically achievable level for *trans* fatty acids in E 473 in order to adequately propose a maximum limit in the specifications for this food additive.

One IBO submitted analytical results on *trans* fatty acids for three batches of the food additive (Documentation provided to EFSA n. 6). In all three batches, *trans* fatty acids were below the LOQ of 0.05% (i.e. 0.05 g of *trans* fat per 100 g of fat). According to the IBO, the LOQ is also regarded as the lowest technologically achievable level for *trans* fatty acids.

Another IBO provided results on *trans* fatty acids for six batches. In one batch, *trans* fatty acids constituted 0.87% of the fatty acid content. In the other five batches, *trans* fatty acids were below the LOD of 0.05% (Documentation provided to EFSA n. 5). The same IBO stated that they cannot determine the lowest technologically achievable levels for *trans* fatty acids in E 473, and therefore, they cannot exclude the possibility that *trans* fatty acids are derived from methyl esters of fatty acids in the raw materials (Documentation provided to EFSA n. 5).

3.2.3.5. Erucic acid, 3-MCPD and glycidyl esters and additional impurities of toxicological concern

The call for data (2021) requested:

- analytical data, supported by certificate of analysis, on current levels of erucic acid in commercial samples of E 473 and the lowest technologically achievable level for erucic acid since erucic acid can be present among the fatty acids in edible oils, which could be used for manufacturing of E 473 in order to adequately propose a maximum limit in the specifications for this food additive.
- analytical data, supported by certificate of analysis, on current levels of any compound of toxicological concern (e.g. 3-MCPD or glycidyl esters) in commercial samples of E 473 and the lowest technologically achievable level of any compound of toxicological concern (e.g. 3- MCPD or glycidyl esters), which could be produced under certain processing conditions from the food additive E 473 in order to adequately propose a maximum limit in the specifications for this food additive.
- in addition, depending on the manufacturing process information of any other additional impurities of toxicological concerns.

One IBO noted that they did not directly analyse levels of erucic acid in their commercial samples of E 473. However, the IBO declared that the percentage of fatty acids with chain lengths of more than 20 carbon atoms is only 0.4% of the fatty acids profile. They therefore concluded indirectly that the level for erucic acid (22 carbons) is quite low, while acknowledging that this fraction may also include saturated fatty acids, such as arachidic acid, behenic acid and others. Analytical data on the levels of 3-MCPD and glycidyl esters were not provided. The IBO claimed that there is no other additional impurity anticipated to be of toxicological concern in E 473 due to the various purification steps of their manufacturing process (Documentation provided to EFSA n. 6).

Another IBO did not provide any analytical data on erucic acid, 3-MCPD and glycidyl esters. Moreover, they stated that there is no information on other impurities of toxicological concern in the manufacturing process of their E 473 products (Documentation provided to EFSA n. 5).

3.2.4. Information on particular specification requirements for the food additive for use in the food categories 13.1.1 and 13.1.5.1

The call for data (2018) requested:

- proposals for particular specification requirements for identity and purity of sucrose esters of fatty acids (E 473) when used in these food categories. In particular, the absence of residuals such as vinyl esters of fatty acids, acetaldehyde and p-methoxyphenol.

The IBOs that responded, claimed that the food additive is not used in the food categories 13.1.1 (Infant formulae) and 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants), and as a result, no technical information was provided for this part of the call of data (Documentation provided to EFSA n. 2, 4, 7).

3.2.5. Stability of the substance and reaction and fate in food

The call for data (2018) on E 473 requested information on the fate and the reaction products of sucrose esters of fatty acids (E 473) in food for infants below 16 weeks of age (FCs 13.1.1 and 13.1.5.1). No information was submitted by the IBOs.

3.3. Authorised uses and use levels

Maximum levels of sucrose esters of fatty acids (E 473) in foods are defined in Regulation (EC) No 1333/2008 on food additives, as amended. In this opinion, these levels are termed maximum permitted levels (MPLs).

All authorised uses of sucrose esters of fatty acids (E 473) in foods can be seen in the exposure section of the 2018 opinion (EFSA ANS Panel, 2018; Table 1).

3.4. Exposure data

Some food additives are authorised in the EU in infants formulae as defined by Commission Directive 2006/141/EC (FC 13.1.1) and in dietary foods for infants for special medical purposes and special formulae for infants (FC 13.1.5.1) at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, actual use levels are required for performing a more realistic exposure assessment.

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, in 2018, EFSA issued a call for technical and toxicological data on sucrose esters of fatty acids (E 473) as a food additive for uses in foods for all population groups including infants below 16 weeks of age. In response to this call, the IBOs confirmed to EFSA that sucrose esters of fatty acid (E 473) were not used in FC 13.1.1 and 13.1.5.1 (see Section 1). No analytical data on the concentration of sucrose esters of fatty acids (E 473) in these or other FCs were made available by the Member States. Therefore, for the FCs 13.1.1 and 13.1.5.1 and for the population group below 16 weeks of age, an exposure assessment was not performed.

3.4.1. Reported use levels

In its opinion from 2018 (EFSA ANS Panel, 2018), the ANS Panel recommended the collection of more detailed data (reported use levels from industry) for the food category contributing most to the exposure to sucrose esters of fatty acids (E 473): fine bakery wares as well as monitoring data for a certain type of flavoured drinks. These data should allow for a more precise mapping of use levels to foods as recorded in the EFSA Comprehensive Database, and thus result in more realistic estimates of exposure to sucrose esters of fatty acids (E 473) via food.

Following an EFSA call for data (2021), five IBOs provided use levels (n = 13) for six different FCs (Documentation provided to EFSA n. 9, 15). Data were provided for 'Other confectionery including breath refreshening microsweets' (FC 05.2), 'Fine bakery wares' (FC 07.2), 'Flavoured drinks' (FC 14.1.4; reported as dairy based drinks or non-dairy based drinks), 'Other' (FC 14.1.5.2 which are beverages like tea, infusions, instant coffee), 'Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms' (FC 17.1) and 'Food supplements supplied in a liquid form' (FC 17.2).

Appendix A lists the use levels of sucrose esters of fatty acids (E 473 and E 473–474) in foods as reported by the industry (including levels provided in 2014 and used in the 2018 EFSA opinion). Appendix C indicates the use levels used in the exposure assessment.

3.4.2. 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 of over 4 million food and beverage products of which more than 1,200,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently having 24 of its 27 member countries along with Norway and UK presented in the Mintel GNPD.[11]

For the purpose of this Scientific Opinion, Mintel's GNPD[12] was used to check the labelling of food and beverage products and food supplements for sucrose esters of fatty acids (E 473) within the EU's food market as the database contains the compulsory ingredient information on the label.

No products intended for use in infants below 16 weeks were found in Mintel's GNPD as labelled with sucrose esters of fatty acids (E 473) between January 2018 and January 2023, which supports the information from IBOs that E 473 is not used in foods for infants.

According to the Mintel's GNPD, sucrose esters of fatty acids (E 473) was labelled on around 675 food, beverage and food supplement products, between January 2018 and January 2023. The main Mintel's GNPD food subcategories containing the food additive were 'Pastilles, Gums, Jellies & Chews', 'Gum', 'Snack/Cereal/Energy Bars' and 'Cakes, Pastries & Sweet Goods'.

Appendix B lists the percentage of the food products labelled with sucrose esters of fatty acids (E 473) out of the total number of food products per food subcategory according to the Mintel's GNPD

[11] Missing Cyprus, Luxembourg and Malta.
[12] https://www.gnpd.com/sinatra/home/ accessed on 30 January 2023.

food classification. The percentages ranged from less than 0.1% in many food subcategories to 11.7% in the Mintel's GNPD food subcategory 'Gum'. The average percentage of foods labelled to contain sucrose esters of fatty acids (E 473) was 0.3%.

According to the Mintel's GNPD, sucroglycerides (E 474) was labelled on six products between January 2018 and January 2023; none of them was also labelled with sucrose esters of fatty acids (E 473).

3.4.3. Exposure estimates for the general population above 12 weeks of age

Table 3 summarises the estimated dietary exposure to sucrose esters of fatty acids (E 473) from its use as a food additive in six population groups according to the different exposure scenarios (Section 3.3). Detailed results per population group and survey are presented in Appendix D.

Table 3: Summary of dietary exposure to sucrose esters of fatty acids (E 473) from its use as a food additive 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)[(a)]

	Infants (12 weeks to 11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Regulatory maximum level exposure assessment scenario						
• Mean	6–52	31–124	34–111	15–53	7–31	4–26
• 95th percentile	25–101	86–333	73–281	34–157	19–95	17–71
Refined estimated exposure assessment scenario						
Brand-loyal scenario						
• Mean	0.2–13	4–59	8–52	3–24	3–12	2–12
• 95th percentile	5–57	13–183	19–129	9–60	12–35	10–33
Non-brand-loyal scenario						
• Mean	0.1–6	3–49	4–43	2–17	1–7	1–6
• 95th percentile	2–27	8–171	11–117	4–50	6–23	5–19

(a): Exposure estimated is considering the whole diet (also for infants).

At the *regulatory maximum level exposure assessment scenario*, mean exposure to sucrose esters of fatty acids (E 473) from its use as a food additive ranged from 4 mg/kg bw per day in the elderly to 124 mg/kg bw per day in toddlers. The 95th percentile of exposure ranged from 17 mg/kg bw per day for the elderly to 333 mg/kg bw per day in toddlers.

In the *refined exposure assessment*, *brand-loyal scenario*, mean exposure to sucrose esters of fatty acids (E 473) ranged from 0.2 mg/kg bw per day for infants to 59 mg/kg bw per day in toddlers. The high exposure (p95) ranged from 5 mg/kg bw per day for infants to 183 mg/kg bw per day in toddlers. In the *non-brand-loyal scenario*, mean exposure to sucrose esters of fatty acids (E 473) ranged from 0.1 mg/kg bw per day infants to 49 mg/kg bw per day in toddlers. The high exposure (p95) ranged from 2 mg/kg bw per day for infants to 171 mg/kg bw per day in toddlers.

The main food categories contributing to the exposure to sucrose esters of fatty acids (E 473) are presented in Appendix E.

3.4.4. Exposure estimates for consumers of food supplements and FSMPs

For consumers' only of food supplements, mean exposure to sucrose esters of fatty acids (E 473) as a food additive ranged from 5 mg/kg bw per day to 50 mg/kg bw per day in children. The high exposure (p95) ranged from 11 mg/kg bw per day to 128 mg/kg bw per day in children.

Upon request from EFSA, an association representing specialised nutrition industries in EU confirmed that their members are not using E 473 in foods belonging to food categories 13.1.5.2 (Documentation provided to EFSA n. 14); therefore, an exposure assessment was not carried out for infants and toddlers consuming FSMPs.

3.4.5. Uncertainty analysis

In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainty have been considered and summarised in Table 4.

Table 4: 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	+/–
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+
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 of food categories	+/–
Reported use levels: – use levels considered applicable to all foods within the entire food category, whereas on average 0.3% of the foods, belonging to food categories with foods labelled with additive, was labelled with the additive – in case E 473 and E 474 are both authorised, some reported use levels do not show whether E 473 only has been used	+ +/–
Food categories included in the exposure assessment: no occurrence data for certain food categories which were therefore not considered in the exposure estimates	–
Regulatory maximum level exposure assessment scenario: exposure calculations based on the MPL according to Annex III to Regulation (EC) No 1333/2008	+
Refined exposure assessment scenario: – exposure calculations based on the maximum (brand-loyal scenario) and – exposure calculations based on the mean levels (brand-loyal scenario and non-brand-loyal scenario)	+ +/–

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

Sucrose esters of fatty acids (E 473) is authorised in 36 food categories. Information from the Mintel's GNPD (Appendix B) indicated that most of the food subcategories, categorised according to the Mintel's GNPD nomenclature, in which sucrose esters of fatty acids (E 473) are labelled were included in the current exposure assessment; this is true for the main subcategories in which E 473 is labelled (e.g. gum, confectionaries). The FCs (e.g. FC 1.4 'Flavoured fermented milk products including heat-treated products', FC 14.2.6 'Spirit drinks as defined in Regulation (EC) No 110/2008', FC 14.2.7.1 'Aromatised wines', FC 14.2.7.2 'Aromatised wines_based drinks', FC 14.2.7.3 'Aromatised wines-products cocktails') not included in the current estimates because of no data made available to EFSA, contained few or no foods labelled with E 473 according to Mintel GNPD. Therefore, the uncertainties related to not considering these FCs are minor. The overall percentage of the foods labelled with sucrose esters of fatty acids (E 473) is 0.3% across the subcategories. In the current assessment, all foods within a FC are considered. This overestimates the dietary exposure to sucrose esters of fatty acids (E 473). Therefore, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to sucrose esters of fatty acids (E 473) from its use as a food additive according to Annex II in both the regulatory maximum level exposure assessment and refined exposure assessment scenarios.

3.5. Proposed revision to existing EU specifications for sucrose esters of fatty acids (E 473)

The potential exposure to impurities from the use of the food additive E 473 can be calculated by assuming that the impurity is present in the food additive up to a limit value and then by calculation pro-rata to the estimates of exposure to the food additive itself.

In the current opinion, the dietary exposure to E 473 for the general population was estimated (see Table 3). The Panel used the refined brand-loyal exposure assessment scenario covering the general population as the most appropriate and realistic scenario for risk characterisation of the food additive E 473. For the current assessment, the highest exposure levels for the mean and 95th percentile among the different population groups were considered, i.e. 59 and 183 mg/kg bw per day, for toddlers, respectively.

The Panel noted that E 473 is not used in foods for infants below 16 weeks of age, and thus, no assessment was performed for this age group.

The levels of the impurities in the food additive combined with the estimated intakes of E 473, presented in Table 3 could result in an exposure which can be compared with the following reference points (RP) or health-based guidance values (HBGV) (Table 5) for the undesirable impurities and constituents potentially present in E 473.

Table 5: Reference points/health-based guidance values for impurities and constituents potentially present in E 473

Impurity/constituent/ HBGV/RP (μg/kg bw)	Basis/Reference
Lead (Pb)/0.5 ($BMDL_{01}$)	The reference point is based on a study demonstrating perturbation of intellectual development in children with the critical response size of 1 point reduction in IQ. The EFSA CONTAM Panel mentioned that a 1 point reduction in IQ is related to a 4.5% increase in the risk of failure to graduate from high school and that a 1 point reduction in IQ in children can be associated with a decrease of later productivity of about 2%. A risk cannot be excluded if the exposure exceeds the $BMDL_{01}$ (MOE lower than 1). EFSA CONTAM Panel (2010)
Mercury (Hg)/4 (TWI)	The HBGV was set using kidney weight changes in male rats as the pivotal effect. Based on the $BMDL_{10}$ of 0.06 mg/kg bw per day, expressed as mercury, and an uncertainty factor of 100 to account for inter and intra species differences, with conversion to a weekly basis and rounding to one significant figure, a TWI for inorganic mercury of 4 μg/kg bw per week, expressed as mercury was established. EFSA CONTAM Panel (2012)
Cadmium (Cd)/2.5 (TWI)	The derivation of the reference point is based on a meta-analysis to evaluate the dose–response relationship between selected urinary cadmium and urinary beta-2-microglobulin as the biomarker of tubular damage recognised as the most useful biomarker in relation to tubular effects. A group-based $BMDL_5$ of 4 μg Cd/g creatinine for humans was derived. A chemical-specific adjustment factor of 3.9 was applied to account for human variability in urinary cadmium within each dose-subgroup in the analysis resulting in a reference point of 1.0 μg Cd per g creatinine. In order to remain below 1 μg Cd/g creatinine in urine in 95% of the population by age 50, the average daily dietary cadmium intake should not exceed 0.36 μg Cd/kg bw, corresponding to a weekly dietary intake of 2.5 μg Cd/kg bw. EFSA CONTAM Panel (2009a)
Arsenic (As)/0.3–8 ($BMDL_{01}$)	The reference point is based on a range of benchmark dose lower confidence limit ($BMDL_{01}$) values between 0.3 and 8 μg/kg bw per day identified for cancers of the lung, skin and bladder, as well as skin lesions. In general, the MOE should be at least 10,000 if the reference point is based on carcinogenicity in animal studies. However, as the BMDL for As is derived from human studies, an interspecies extrapolation factor (i.e. 10) is not needed, i.e. a MOE of 1,000 would be sufficient. EFSA CONTAM Panel (2009b); EFSA Scientific Committee (2012)

HBGV: Health-based guidance value; RP: Reference point; $BMDL_{01}$: benchmark dose (lower confidence limit); TWI: Tolerable Weekly Intake; MOE: margin of exposure.

The risk assessment of the undesirable impurities and constituents helps inform whether there could be a possible health concern if these impurities and constituents would be present at the limit values in the food additive. The assessment is performed by calculating the MOE (margin of exposure) by dividing the reference point (e.g. BMDL) by the exposure estimate (Table 4), or by estimating the contribution of the use of E 473 to the HBGV (expressed as percentage of the HBGV).

3.5.1. Toxic elements

The Panel noted that almost all occurrence data on toxic elements submitted by the IBOs are substantially lower than the current limits in the EU specifications (Documentation provided to EFSA n. 1, 3, 4, 16). Analytical results for arsenic, cadmium, lead and mercury in commercial samples of E 473 were reported by the IBOs and are compiled in Section 3.2.2.

Considering the data submitted by the IBOs on toxic elements (Section 3.2.2), the Panel performed the risk assessment that would result if these toxic elements were present in E 473, using four different scenarios: at (I) the current maximum limits in the EU specifications, (II) the proposal of one IBO for the lowest technologically achievable levels, which are the same as the LOQs reported for Pb, Hg, Cd and As, (III) the same proposed lowest technologically achievable levels by applying a modulation factor of 5 for Cd, As and Hg and by maintaining the proposed lowest technologically achievable level for Pb and (IV) the proposal of another IBO for the lowest technologically achievable levels, which apart from As, are the same as the current maximum limits in the EU specifications. The outcome of the risk assessment for these four different scenarios is presented in Table 6. The Panel emphasised that the choice of the maximum limit values as well as other considerations, such as on multiple sources of exposure to conclude on the maximum limits for toxic elements in the specifications, is in the remit of risk management. The numbers used here are merely taken to support the risk assessment of these toxic elements as presented below. The outcome of the risk assessment (see Table 6) illustrates the health impact that could result if revised maximum limits for toxic elements were to be used.

Table 6: Risk assessment for toxic elements

Exposure to E 473 (mg/kg bw per day)	**Scenario I based on the current limits for toxic element in the EU specifications for E 473 (Commission Regulation (EU) No 231/2012)**			
	MOE for Pb at 2 mg/kg	**% of the TWI for Hg at 1 mg/kg**	**% of the TWI for Cd at 1 mg/kg**	**MOE for As at 3 mg/kg**
59[(a)]	4.2	10	17	1.7–45
183[(b)]	1.4	32	51	0.5–15
Exposure to E 473 (mg/kg bw per day)	**Scenario II based on the lowest technologically achievable levels for the toxic elements in E 473 proposed by the IBO 1 (Documentation provided to EFSA n. 3, 4)**			
	MOE for Pb at 1.0 mg/kg	**% of the TWI for Hg at 0.1 mg/kg**	**% of the TWI for Cd at 0.01 mg/kg**	**MOE for As at 0.1 mg/kg**
59[(a)]	8.5	1	0.2	51–1,356
183[(b)]	2.7	3.2	0.5	16–437
Exposure to E 473 (mg/kg bw per day)	**Scenario III based on the lowest technologically achievable levels for the toxic elements in E 473 proposed by the IBO 1, modulated by a factor of 5 only for Hg, Cd and As (Documentation provided to EFSA n. 3, 4)**			
	MOE for Pb at 1.0 mg/kg	**% of the TWI for Hg at 0.5 mg/kg**	**% of the TWI for Cd at 0.05 mg/kg**	**MOE for As at 0.5 mg/kg**
59[(a)]	8.5	5.2	0.8	10–271
183[(b)]	2.7	16	2.6	3.3–87
Exposure to E 473 (mg/kg bw per day)	**Scenario IV based on the lowest technologically achievable levels for the toxic elements in E 473 proposed by the IBO 2 (Documentation provided to EFSA n. 1)**			
	MOE for Pb at 2.0 mg/kg	**% of the TWI for Hg at 1.0 mg/kg**	**% of the TWI for Cd at 1.0 mg/kg**	**MOE for As at 0.76[(c)] mg/kg**
59[(a)]	4.2	10	17	6.7–178
183[(b)]	1.4	32	51	2.2–58

(a): Highest exposure level among the different population groups (refined brand-loyal scenario – toddlers – mean), see Table 3, Section 3.4.3.

(b): Highest exposure level among the different population groups (refined brand-loyal scenario – toddlers – 95th percentile), see Table 3, Section 3.4.3.

(c): Equivalent to 1 mg As_2O_3/kg, as proposed by the IBO.

The resulting figures show that according to the current specifications, the exposure to As from the consumption of E 473 could be substantial. For the toxic elements Hg and Cd (Scenarios I and IV), the potential exposure is also high considering that E 473 is only one source of exposure.

Based on the analytical data provided by the IBOs in response to the EFSA calls for data (2018, 2021), which in almost all cases are substantially lower than the current limits, the Panel recommends the revisions of the existing EU specifications for sucrose esters of fatty acids (E 473). The Panel considered that the maximum limits in the EU specifications for toxic elements should be established based on actual levels in the commercial food additive. If the European Commission decides to revise the current limits in the EU specifications, the estimates of toxic elements intake as above could be considered.

3.5.2. Carry-over and process impurities

According to the data submitted by the IBOs, the manufacturing process used for the production of E 473 is an interesterification using sucrose, fat and oils or methyl esters of fatty acids and DMSO as solvent (Documentation provided to EFSA n. 5, 6). The Panel noted that in the current definition of E 473 in Commission Regulation (EU) No 231/2012, ethyl and vinyl esters of food fatty acids are mentioned as source materials in the manufacturing process of E 473 which was not confirmed by the submitted data from the IBOs. In addition, acetaldehyde and p-methoxyphenol, as impurities of the vinyl esters of fatty acids route, have not been evaluated in this assessment since they are not considered relevant by the IBOs (see Section 3.2.1). Thus, the Panel could not comment on the current maximum limits for these impurities established in the EU specifications for E 473.

Similarly, no information on the presence of other potential impurities, such as dimethylformamide, ethyl acetate, propan-2-ol, propylene glycol and methyl ethyl ketone (see Table 1), originating from other routes of manufacturing of sucrose esters of fatty acids and for which maximum limits are established in the EU specifications for E 473, was provided. Therefore, the Panel could not comment on the current maximum limits for these impurities.

Very limited information on the content of *trans* fatty acids in commercial samples of E 473 was submitted (see Section 3.2.3.4). The Panel noted that a maximum limit of 2 g of *trans* fat per 100 g of fat in food for the final consumer is set by Regulation (EU) No 2019/649 amending Annex III to Regulation (EC) No 1925/2006[13]. No information on the content of erucic acid, 3-MCPD and glycidyl esters in commercial samples of E 473 was submitted (see Section 3.2.3.5). The Panel also noted that maximum levels for erucic acid, the sum of 3-MCPD and 3-MCPD fatty acid esters, expressed as 3-MCPD and glycidyl fatty acid esters, expressed as glycidol in vegetable oils and fats are set by Regulation (EC) No 1881/2006[14]. Considering the potential occurrence of these impurities in E 473, the Panel recommended to consider revising the specifications to include a requirement that the fats and oils used for the manufacturing of E 473 comply with the respective EU legislation regarding suitability for human consumption. As an alternative, limit values for these impurities could be introduced in the Commission Regulation (EU) No 231/2012 for E 473. Regarding *trans* fatty acids, the lowest technologically achievable level was claimed to be 0.05% by one IBO. Regarding erucic acid, 3-MCPD and glycidyl esters, since no analytical data were submitted by the IBOs in response to the calls for data, the Panel is not in a position to adequately propose maximum limits for these potential impurities in the specifications for this food additive.

[13] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.

[14] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance). OJ L 364, 20.12.2006, p. 5–24.

3.5.3. Summary of the proposed revisions to the EU specifications

Overall, the Panel recommends the following revisions of the existing EU specifications for sucrose esters of fatty acids (E 473) as listed in Table 7.

Table 7: Proposal for a revision of the existing EU Specifications for sucrose esters of fatty acids E 473

	Commission Regulation (EU) No 231/2012	Comment/justification for revision
Synonyms	See Table 1	Unchanged
Definition	See Table 1	The Panel recommends an amendment of the definition of E 473, in particular to include a requirement that the fats and oils used in the manufacturing of E 473 comply with the respective EU legislation regarding suitability for human consumption[(a)]
Assay	Content not less than 80%	Proposed revision: Content of sucrose esters of fatty acids not less than 80%
Sodium, potassium and calcium salts of fatty acids (footnote)	See footnote of Table 1	Unchanged
Description	See Table 1	Unchanged
Identification	See Table 1	Unchanged
Test for sugar	See Table 1	Unchanged
Test for fatty acids	See Table 1	Unchanged
Solubility	See Table 1	Unchanged
Fatty acids	See Table 1	Unchanged
Sugars	See Table 1	Unchanged
Purity		
Sulphated ash	See Table 1	Unchanged
Acid value	See Table 1	Unchanged
Free sugar	See Table 1	Unchanged
Free fatty acids	See Table 1	Unchanged
p-Methoxyphenol	See Table 1	Unchanged[(b)]
Acetaldehyde	See Table 1	Unchanged[(b)]
Arsenic	Not more than 3 mg/kg	Lowered on the basis of the information provided and on the considerations of the Panel
Lead	Not more than 2 mg/kg	Lowered on the basis of the analytical data provided by the IBOs
Mercury	Not more than 1 mg/kg	Lowered on the basis of the information provided and on the considerations of the Panel
Cadmium	Not more than 1 mg/kg	Lowered on the basis of the information provided and on the considerations of the Panel
Methanol	See Table 1	Unchanged[(b)]
Dimethylsulphoxide	See Table 1	Unchanged[(b)]
Dimethylformamide	See Table 1	Unchanged[(b)]
2-Methyl-1-propanol	See Table 1	Unchanged[(b)]
Ethyl acetate	See Table 1	Unchanged[(b)]
Propan-2-ol	See Table 1	Unchanged[(b)]
Propylene glycol	See Table 1	Unchanged[(b)]
Methyl ethyl ketone	See Table 1	Unchanged[(b)]

(a): As an alternative, limit values for certain potential impurities could be introduced in Commission Regulation (EU) No 231/2012 for E 473 (See Section 3.5.2).
(b): Unchanged on the basis of the analytical data provided by the IBOs or due to the fact that the relevant manufacturing process, possibly giving rise to the presence of this impurity in E473 has not been claimed by any of the IBOs.

3.6. Biological and toxicological data

The following information on the toxicological properties of sucrose esters of fatty acids (E 473) and its adverse effects relevant for the safety of its use as a food additive in food for infants below 16 weeks (food categories 13.1.1 and 13.1.5.1) was requested in the call for data (2018):

- clinical data to assess the safety of sucrose esters of fatty acids (E 473)
- post-marketing surveillance reports on undesired and adverse reactions, indicating the ages and other relevant data of the exposed infants and young children and the use levels in the marketed products
- published and unpublished case reports (e.g. available nutrivigilance data) on undesired and adverse effects, associated with the oral administration of sucrose esters of fatty acids in any form, to infants and young children

The requested data addressing the use of E 473 in infants below 16 weeks of age were not submitted by IBOs. The Panel noted that, as previously reported, according to the available information (Documentation provided to EFSA n. 2, 4, 7), sucrose esters of fatty acids (E 473) is not used in FCs 13.1.1 and 13.1.5.1 including all types of food for infants below 16 weeks of age (see Section 1).

Literature searches were provided by the IBOs in response to the calls for data (2018, 2021); no relevant papers for the assessment of the safety evaluation of sucrose esters of fatty acids (E 473) as food additive were identified by the IBOs (Documentation provided to EFSA n. 1, 3, 10). The publication of Ocampo et al. (2017) is a 28-day repeated-dose study in mice of sucrose esters from *Physalis peruviana* L. and does not provide additional relevant information for the safety assessment of E 473 as food additive.

3.7. Discussion

Data to address the safety of the uses of sucrose esters of fatty acids (E 473) in food for infants below 16 weeks of age were not provided. The Panel noted that according to the available information, E 473 is not used in FCs 13.1.1 and 13.1.5.1, including all types of food for infants below 16 weeks of age, and in FC 13.1.5.2. For this reason, an assessment of the safety for the uses of E 473 as food additive in FCs 13.1.1, 13.1.5.1, 13.1.5.2 and in food for infants below 16 weeks of age was not performed.

In its opinion from 2018 (EFSA ANS Panel, 2018), the ANS Panel recommended the collection of more detailed data (reported use levels from industry) for the food category contributing most to the exposure to sucrose esters of fatty acids (E 473): fine bakery wares as well as monitoring data for a certain type of flavoured drinks. These data should allow for a more precise mapping of use levels to foods as recorded in the EFSA Comprehensive Database, and thus result in more realistic estimates of exposure to sucrose esters of fatty acids (E 473) via food. Following the call for data (2021), five IBOs provided use levels for six different FCs (05.2, 07.2, 14.1.4, 14.1.5, 17.1 and 17.2). Exposure estimates were performed to account for the newly available information. The FAF Panel used the refined brand-loyal scenario as the most relevant exposure scenario for the safety evaluation for this food additive. Exposure estimates for the brand-loyal scenario ranged at the mean between 0.2 mg/kg bw per day for infants and 59 mg/kg bw per day for toddlers, and at the p95 between 5 mg/kg bw per day for infants and 183 mg/kg bw per day for toddlers.

Analytical data on toxic elements were provided by two IBOs for levels of Pb, Cd, Hg and As for E 473 intended for use in food for the general population. The IBOs proposed the lowest technologically achievable limits for those parameters as either the currently existing limits for toxic elements in the EU specifications or the LOQs of the analytical methods, with the exception of As. The Panel noted that the concentration data on toxic elements submitted by the IBOs are, in almost all cases, substantially lower than the current limits in the EU specifications.

The Panel considered the potential presence of Pb, Cd, Hg and As in E 473 at (I) the current maximum limits in the EU specification, (II) the proposal of one IBO for the lowest technologically achievable levels, which are the same as LOQs reported for Pb, Hg, Cd and As, (III) the same proposed lowest technologically achievable levels by applying a modulation factor of 5 for Cd, As and Hg and by maintaining the proposed lowest technologically achievable level for Pb and (IV) the proposal of another IBO for the lowest technologically achievable levels, which apart from As, are the same as the current maximum limits in the EU specification (see Table 2).

The Panel used the refined brand-loyal exposure scenario to calculate the exposure to the toxic elements from the use of sucrose esters of fatty acids (E 473). The highest exposure levels for the mean and 95th percentile among the different population groups were considered, i.e. 59 and 183 mg/kg bw per day, for toddlers, respectively.

The potential exposure to these impurities from the use of sucrose esters of fatty acids (E 473) was compared against the available health-based guidance values (HBGV) and reference points (RP) (see Table 6). The resulting figures (see Table 7) show that according to the current specifications, the exposure to As from the consumption of E 473 could be substantial. For the toxic elements Hg and Cd (Scenarios I and IV), the potential exposure is also high considering that E 473 is only one source of exposure. The Panel noted that the maximum limits in the EU specifications for toxic elements should be established based on actual levels in the commercial food additive. Therefore, the Panel recommended the maximum limits to be lowered on the basis of the information provided by the IBOs and on the considerations of the Panel (see Table 7).

As the IBOs claimed that other manufacturing processes, in particular the use of vinyl esters, are not used, these processes were not evaluated by the Panel in the current assessment. Therefore, the Panel could not comment on the current maximum limits for impurities originating from manufacturing processes not used and for which maximum limits are established in the EU specifications for E 473 (see Section 3.5.3).

No information on the content of erucic acid, 3-MCPD and glycidyl esters in commercial samples of E 473 was submitted and very limited information on the content of *trans* fatty acids. The Panel noted that a maximum level for these impurities in fats and oils suitable for human consumption are set by Regulation (EC) No 1881/2006 and Regulation (EC) No 1925/2006. Hence, the Panel considered that if the fats and oils used for the manufacturing process of E 473 comply with these Regulations, there would be no need for setting a specification limit in Commission Regulation (EU) No 231/2012 for the content of these potential impurities in E 473, but the definition of the food additive should be revised as recommended in Table 7. As an alternative, limit values for these impurities could be introduced in Commission Regulation (EU) No 231/2012 on specifications for E 473. Regarding *trans* fatty acids, the lowest technologically achievable level was claimed to be 0.05% by one IBO. For erucic acid, 3-MCPD and glycidyl esters no analytical data were submitted by the IBOs in response to the calls for data, and the Panel is not in a position to adequately propose maximum limits for these potential impurities in the specifications for this food additive.

The group ADI of sucrose esters of fatty acids (E 473) and sucroglycerides (E 474) established by the EFSA AFC Panel (EFSA, 2004) is 40 mg/kg bw per day. When the updated exposure estimates reported above (refined brand-loyal scenario) are compared with this ADI, the conclusion of the EFSA ANS Panel (2018) is confirmed; the estimates of exposure to sucrose esters of fatty acids (E 473) exceeded the group ADI of 40 mg/kg bw per day for many population groups. It is, however, noted that the data received in the call for data (2021) are not extensive (n = 13 of which two for fine bakery wares (FC 07.2) and three for flavoured drinks (FC 14.1.4)). Therefore, it does not allow to map more specifically use levels to foods.

4. Conclusions

The Panel concluded that the technical data provided by the IBOs support an amendment of the specifications for sucrose esters of fatty acids (E 473) laid down in Commission Regulation (EU) No 231/2012, as presented by the recommendations made in Table 7.

Data to address the safety of the uses of sucrose esters of fatty acids (E 473) in food for infants below 16 weeks of age were not provided. The Panel noted that according to the available information E 473 is not used in FCs 13.1.1 and 13.1.5.1 including all types of food for infants below 16 weeks of age, and in FC 13.1.5.2. As a consequence, an assessment of the safety for the uses of E 473 as food additive in FCs 13.1.1, 13.1.5.1, 13.1.5.2 and in food for infants below 16 weeks of age was not performed.

When the updated exposure estimates considering the provided use levels for FCs 05.2, 07.2, 14.1.4, 14.1.5, 17.1 and 17.2 are taken into account, the conclusion of the EFSA ANS Panel (2018) is confirmed; the estimates of exposure to sucrose esters of fatty acids (E 473) exceeded the group ADI of 40 mg/kg bw per day for many population groups. It is noted that the data received are not extensive and do not allow to map more specifically use levels to foods with respect to the previous assessments.

5. Documentation as provided to EFSA

1) Mitsubishi Chemical Corporation, 2019. Submission of data in response to the call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 26 November 2019.
2) Mitsubishi Chemical Corporation, 2020. Clarification on the data submitted in response to the call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 31 August 2020.
3) DKS, 2019. Submission of data in response to the call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 27 November 2019.
4) DKS, 2020. Clarification on the data submitted in response to the call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 05 August 2020.
5) Mitsubishi Chemical Corporation, 2021. Clarification on the data submitted in response to the call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 30 July 2021.
6) DKS, 2021. Clarification on the data submitted in response to the call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 08 June 2021.
7) Specialised Nutrition Europe, 2021. Clarification on the uses of sucrose esters of fatty acids (E 473) under FCs 13.1.1 and 13.1.5.1. Submitted on 13 September 2021.
8) Mitsubishi Chemical Corporation, 2022. Clarification on the data submitted in response to the call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 08 June 2022.
9) CAOBISCO, 2022. Submission of data in response to the call for technical data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 08 September 2022.
10) DKS, 2022. Submission of data in response to the call for technical data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 22 September 2022.
11) FOOD SUPPLEMENTS EU, 2022. Submission of data in response to the call for technical data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 08 September 2022.
12) KHLAW, 2022. Submission of data in response to the call for technical data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 02 September 2022.
13) UNESDA, 2022. Submission of data in response to the call for technical data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 08 September 2022.
14) Specialised Nutrition Europe, 2021. Clarification on the uses of sucrose esters of fatty acids (E 473) under FC 13.1.5.2. Submitted on 1 March 2023.
15) CAOBISCO, 2023. Clarification on the data submitted in the call for technical data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 27 January 2023.
16) DKS, 2023. Clarification on the data submitted in response to the call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 22 March 2023.

17) Mitsubishi Chemical Corporation, 2023. Clarification on the data submitted in response to the call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age. Submitted on 17 March 2023.

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EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on food additives, flavourings, processing aids and material in contact with food (AFC) on sucrose esters fatty acids, E 473 and glucoglycerides, E 474 based on a request from the Commission related to sucrose esters of fatty acids (E 473). EFSA Journal 2004;2(10):106, 24 pp. https://doi.org/10.2903/j.efsa.2004.106 Modified on 25 January 2006

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Abbreviations

3-MCPD	3-monochloropropane diol
ADI	acceptable daily intake
AFC Panel	Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
ANS Panel	EFSA Panel on Food Additives and Nutrient Sources added to Food
APC	Aerobic Plate Count
BMDL	benchmark dose lower confidence limit
bw	body weight
CAS	Chemical Abstract Service
CFU	Colony forming unit
CV-AAS	cold vapour atomic absorption spectroscopy
DDTC-Ag NPs	dopamine dithiocarbamate functionalised silver nanoparticles
DMSO	Dimethylsulphoxide
FAF Panel	Panel on Food Additives and Flavourings
FAO/WHO	Food and Drug Organisation/World Health Organisation
FC	Food category
FSMP	Food for special medical purposes
GF-AAS	graphite furnace atomic absorption spectrometry
HBGV	health-based guidance values
IBO	Interested business operator
ICP-AES	coupled plasma – atomic emission spectrophotometry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
Mintel GNPD	Mintel's Global New Products Database
MOE	margin of exposure
MPL	maximum permitted levels
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level

RP	reference point
SC	Scientific Committee of EFSA
SCF	Scientific Committee on Food
TWI	Tolerable Weekly Intake
WG	Working Group

Appendix A – Summary of reported use levels (mg/kg or mg/L as appropriate) of sucrose esters of fatty acids (E 473) provided by industry

Appendix B – Number and percentage of food products labelled with sucrose esters of fatty acids (E 473) out of the total number of food products present in the Mintel GNPD per food subcategory between 2012 and 2023

Appendix C – Concentration levels of sucrose esters of fatty acids (E 473) used in the MPL and refined exposure scenarios (mg/L or mg/kg as appropriate)

Appendix D – Total estimated exposure of sucrose ester of fatty acids (E 473) from its use as a food additive for the regulatory 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 – Main food categories contributing to exposure to sucrose esters of fatty acids (E 473) using the regulatory maximum level exposure scenario and the refined exposure assessment scenarios (> 5% to the total mean exposure)

Appendixes A–E can be found in the online version of this output (in the 'Supporting information' section).

Appendix F – Data requested in the call for data (Call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age, 2018)[15]

Kind of data	Data requested in the call for data	Responses from interested parties	Comment
A. Information regarding the follow-up of the conclusions and the recommendations of the EFSA ANS Panel opinion on the safety of sucrose esters of fatty acids (E 473) as food additive			
1.Technical data	• analytical data on current levels of lead, mercury, cadmium and arsenic in commercial samples of the food additive; • the lowest technologically achievable level for lead, mercury, cadmium and arsenic in order to adequately define their maximum limits in the specifications; • the lowest technologically achievable level for impurities currently included in the EU specifications for sucrose esters of fatty acids (E 473); • the lowest technologically achievable level for vinyl esters of fatty acids when sucrose esters of fatty acids (E 473) are manufactured from sucrose and the vinyl esters of food fatty acids.	Provided	Assessed, no further follow-up
2.Toxicological data	The risk characterisation at the lowest technologically achievable level of any residual of toxicological concern included in the EU specifications of sucrose esters of fatty acids (E 473) as food additive.	Provided	Assessed, no further follow-up
3. Literature searches	Literature searches should be conducted relevant for the safety evaluation of sucrose esters of fatty acids (E 473) for all uses in foods for all population groups from 9 January 2017 up to the date of the data submission, as described in the Guidance for submission for food additive evaluations (Section 5.3)	Provided	Assessed, no further follow-up
B. Information required for the risk assessment of sucrose esters of fatty acids (E 473) as food additive for use in foods for infants below 16 weeks of age			
1. Technical data	• For the uses of sucrose esters of fatty acids (E 473), in foods for infants below 16 weeks (food categories 13.1.1 and 13.1.5.1) EFSA seeks; • information and justification on the concentration of sucrose esters of fatty acids (E 473) alone or in combination with food additives E 322, E 471 and E 472c; • information on the fate and the reaction products of sucrose esters of fatty acids (E 473) in these foods; • proposals for particular specification requirements for identity and purity of sucrose esters of fatty acids (E 473) when used in these food categories. In particular, the absence of residuals such as vinyl esters of fatty acids, acetaldehyde and p-Methoxyphenol.	Provided	Assessed, no further follow-up

[15] Available online: https://www.efsa.europa.eu/en/consultations/call/181010-4 and responses from interested parties

Kind of data	Data requested in the call for data	Responses from interested parties	Comment
2. Toxicological data	Within the frame of the EFSA Guidance of the Scientific Committee on the risk assessment of substances present in food intended for infants below 16 weeks of age the following information on the toxicological properties of sucrose esters of fatty acids (E 473) and its adverse effects relevant for its use in food categories for infants below 16 weeks of age 13.1.1 and 13.1.5.1 is required: • clinical data to assess the safety of sucrose esters of fatty acids (E 473); • post-marketing surveillance reports on undesired and adverse reactions, indicating the ages and other relevant data of the exposed infants and young children and the use levels in the marketed products; • published and unpublished case reports (e.g. available nutrivigilance data) on undesired and adverse effects, associated with the oral administration of sucrose esters of fatty acids in any form, to infants and young children;	Provided	Assessed, no further follow-up
3. Literature searches	Literature searches relevant for the safety evaluation of sucrose esters of fatty acids (E 473) when used in foods for infants below 16 weeks of age, should be conducted as described in the Guidance for submission for food additive evaluations (Section 5.3)	Provided	Assessed, no further follow-up

Appendix G – Data requested in the call for data (Call for technical and toxicological data on sucrose esters of fatty acids (E 473) for uses as a food additive in foods for all population groups including infants below 16 weeks of age, 2021[16]

Kind of data	Data requested in the call for data	Responses from interested parties	Comment
A. Technical data	Fatty acids are used for the manufacturing of E 473. During the re-evaluation of certain food additives e.g. E 471 (EFSA ANS Panel, 2017; EFSA FAF Panel, 2021), E 472a-f (EFSA FAF Panel, 2020), some concerns regarding the potential presence of carry over and process impurities have been identified. The interested parties are invited to provide information on: • the source of the fatty acids used for the manufacturing of E 473 along with detailed information of any production method used to manufacture E 473, including indication of the solvents used, time/temperature patterns applied, chemical/physical reactions and/or treatments involved • analytical data, supported by certificate of analysis, on current levels of *trans*-fatty acids in commercial samples of E 473 • analytical data, supported by certificate of analysis, on current levels of erucic acid in commercial samples of E 473 • analytical data, supported by certificate of analysis, on current levels of any compound of toxicological concern (e.g. 3-MCPD or glycidyl esters) in commercial samples of E 473 • in addition, depending on the manufacturing process (see first bullet point), information on the presence of any other additional impurity in E 473, along with corresponding analytical data, supported by certificate of analysis • the lowest technologically achievable levels for the impurities listed above to adequately propose maximum limits in the current EU specifications for E 473	Provided	Assessed, no further follow-up
B. Use levels	Occurrence data (use levels or analytical data) are requested for authorised food categories e.g. for the food categories contributing most to the exposure to sucrose esters of fatty acids (E 473), like fine bakery wares and certain type of flavoured drinks (see EFSA ANS Panel, 2018). These data should allow for a more precise mapping of use levels to foods as recorded in the EFSA Comprehensive Database, and thus will allow to calculate a more realistic estimate of exposure to E 473 via food. This is also considered relevant for	Provided	Assessed, see Conclusions section

[16] Available online: https://www.efsa.europa.eu/en/call/call-technical-data-sucrose-esters-fatty-acids-e-473-uses-food-additive-foods-all-population and responses from interested parties.

Kind of data	Data requested in the call for data	Responses from interested parties	Comment
	the risk assessment of any impurity of toxicological concern (see also point A). As indicated in the 'Overall objective', EFSA notes that according to the information currently available at its level, E 473 is not used in food categories 13.1.1 and 13.1.5.1. Hence, the safety of the use in these food categories will not be addressed in any future assessment, unless further information is received; this might imply the withdrawal of the authorisation under these food categories.		
C. Literature searches	Request for relevant publications from the literature had already been requested in the previous call for data on E 473. An update of the literature search since the cut-off date indicated in the previous call (i.e. 31.12.2019) should be conducted. Relevant publications retrieved should be provided	Provided	Assessed, no further follow-up