Refined exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive

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Abstract

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific opinion on the exposure assessment of sucrose esters of fatty acids (E 473) when used as a food additive. The Panel previously adopted scientific opinions on the safety of sucrose esters of fatty acids (E 473). In the 2010 opinion, the Panel concluded that, based on the data available, the additional use of the sucrose esters of fatty acids (E 473) may lead to exposures in excess of the acceptable daily intake (ADI) of 40 mg/kg body weight (bw) per day for sucrose esters of fatty acids (E 473) and sucroglycerides (E 474) established by EFSA in 2004. In 2012, an update on the exposure assessment of sucrose esters of fatty acids (E 473) was delivered as new data were submitted to EFSA providing use levels of sucrose esters of fatty acids as a surface treatment for fresh fruits and the resulting residual levels in fruit. This assessment also resulted in exposure estimates of sucrose esters of fatty acids (E 473) exceeding the ADI, although considerably lower than those estimated in 2010. The current exposure assessment is based on the recent methodology used in the re-evaluation of food additives together with reported use levels received following a call for data in 2014. New consumption data were also available since then. The Panel noted that the current exposure estimates to sucrose esters of fatty acids (E 473) exceeded the ADI of 40 mg/kg bw per day for many population groups; especially toddlers and children and that assuming that sucrose esters of fatty acids (E 473) is not used in the 24 food categories where data was not provided, these estimates very likely overestimated the real exposure to sucrose esters of fatty acids (E 473).

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

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Summary

Following a request from the European Commission, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) performed a refined exposure assessment of sucrose esters of fatty acids (E 473) when used as a food additive. The Panel was not provided with a newly submitted dossier and based this assessment on concentration data available following a public call for data.

Sucrose esters of fatty acids (E 473) is an authorised food additive in the European Union (EU) according to Annex II to Regulation (EC) No 1333/2008.

The Panel previously adopted several scientific opinions on the safety of sucrose esters of fatty acids (E 473). In 2010, the ANS Panel concluded that, based on the concentration data available, the use of sucrose esters of fatty acids (E 473) may lead to an exposure in excess of the acceptable daily intake (ADI) of 40 mg/kg body weight (bw) per day for sucrose esters of fatty acids (E 473) and sucroglycerides (E 474) established by EFSA in 2004. In 2012, an update on the exposure assessment of sucrose esters of fatty acids (E 473) was delivered as new concentration data were submitted to the European Food Safety Authority (EFSA) providing use levels of sucrose esters of fatty acids as a surface treatment for fresh fruits and the resulting residual levels in fruit. This assessment also resulted in exposure estimates of sucrose esters of fatty acids (E 473) exceeding the ADI, although considerably lower than those estimated in 2010.

In 2014, EFSA launched a public call for data aiming at collecting reported use levels from industry or analytical data on several food additives, including sucrose esters of fatty acids (E 473). Use levels were reported by industry. Added to these new data, information on the presence of food additives on the label of foods was retrieved from the Mintel’s Global New Products Database (GNPD), an online database monitoring new introductions of packaged goods in the market worldwide. Furthermore, compared to the 2012 opinion, new consumption data were available through the EFSA Comprehensive Database.

Dietary exposure to sucrose esters of fatty acids (E 473) from its use as a food additive was assessed through different scenarios: maximum regulatory exposure assessment scenario and several refined exposure assessment scenarios. The Panel identified brand loyalty to certain types of flavoured drinks in which the use of sucrose esters of fatty acids (E 473) is authorised and therefore selected the refined brand loyal scenario as the most relevant exposure scenario for its safety evaluation.

The highest mean and 95th percentile refined exposure estimates in the brand-loyal scenario were 54 and 124 mg/kg bw per day, respectively, in toddlers (12–35 months) and children (3–9 years). The main contributing food category to the exposure in this scenario was fine bakery wares for all population groups. In children and adolescents, also flavoured drinks, only dairy-based and almond drinks, contributed largely to the exposure.

In all exposure scenarios, it was assumed that all foods belonging to a food category for which use levels were provided contained sucrose esters of fatty acids (E 473), whereas information from the Mintel’s GNPD showed that the additive was used in only a small percentage of the foods.

The Panel concluded that the exposure to sucrose esters of fatty acids (E 473) exceeded the ADI of 40 mg/kg bw per day for many population groups; especially toddlers and children, and that assuming that sucrose esters of fatty acids (E 473) is not used in the 24 food categories where data was not provided, the current exposure estimates very likely overestimate the real exposure to sucrose esters of fatty acids (E 473).

Thus, the Panel recommends the collection of more detailed data (reported use levels from industry) for the food categories contributing most to the exposure to sucrose esters of fatty acids (E 473): fine bakery wares and certain types 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.
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1. Introduction

The present opinion deals with the exposure estimation of sucrose esters of fatty acids (E 473) when used as a food additive.

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

1.1.1. Background

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

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

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

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

In 2010, the ANS Panel published an opinion 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 (EFSA ANS Panel, 2010). The Panel concluded that the new manufacturing method did not present any safety concern. The Panel however also noted that “the current intake of sucrose esters of fatty acids is high and for some individuals above the acceptable daily intake (ADI), but that the additional intake from fruit beverages only seemed to contribute to a few percent of the ADI”.

In 2012, the ANS Panel issued an opinion on the exposure assessment of sucrose esters of fatty acids (E 473) from its use as a food additive (EFSA ANS Panel, 2012a). This opinion showed that the intake of this additive was still above the group ADI of 40 mg/kg bw per day, but was considerably decreased compared to the intake estimated in the previous 2010 ANS Panel opinion. This 2012 opinion was based on new information made available to EFSA on the use of the food additive as surface treatment agent of fruits and on consumption data of one Member State (Ireland).

Following this opinion, EFSA received in 2013 a new mandate from EC to perform a refined exposure assessment of sucrose esters of fatty acids (E 473). Following this request, EFSA launched new call for data to collect relevant information from interested parties since the last 2012 EFSA opinion.

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

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

3 COM(2001) 542 final.

4 Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002, 560.
1.1.2. Terms of Reference

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

1.1.3. Interpretation of Terms of Reference

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) described its risk assessment paradigm in its Guidance for submission for food additive evaluations in 2012 (EFSA ANS Panel, 2012b). This Guidance states that in carrying out its risk assessments, the Panel seeks to define a health-based guidance value, e.g. an acceptable daily intake (ADI) (IPCS, 2004) applicable to the general population. According to the guidance mentioned above, the ADI as established for the general population does not apply to infants below 12 weeks of age (JECFA, 1978; SCF, 1998). In this context, the re-evaluation of the use of food additives in food for infants below 12 weeks represents a special case for which specific recommendations were given by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1972, 1978), by the SCF (1996, 1998) and by EFSA (EFSA Scientific Committee, 2017). The Panel endorsed these recommendations.

In the current EU legislation (Annex II of Regulation (EC) No 1333/2008), use levels of additives in foods for infants under the age of 12 weeks are included in food categories (FCs) 13.1.1., 13.1.5.1 and 13.1.5.2. Sucrose esters of fatty acids (E 473) is also authorised in these categories and therefore a separate risk assessment should be performed for infants under the age of 12 weeks (Section 3.3.1) according to the specific recommendations (EFSA ANS Panel, 2012b). The current refined exposure assessment of sucrose esters of fatty acids (E 473) as a food additive is therefore not applicable for infants under the age of 12 weeks.

Following a clarification letter received from European Commission in 2013, the ANS Panel performed a refined exposure assessment of sucrose esters of fatty acids (E 473) when used as a food additive.6

1.2. Information on existing authorisations and evaluations

Sucrose esters of fatty acids (E 473) is authorised as a food additive in the EU in accordance with Annexes II and III to Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in Commission Regulation (EU) No 231/2012.7

In the EU, sucrose esters of fatty acids (E 473) has been evaluated by the SCF (1992), which established an ADI of 20 mg/kg body weight (bw) per day (expressed as sucrose monostearate) for sucrose esters of fatty acids and sucroglycerides derived from palm oil, lard and tallow fatty acids, providing that specifications would limit the presence of tetra and higher esters to 7%. The basis for establishing a numerical ADI was not specified by the SCF and no report was issued (SCF, 1992).

Sucrose esters of fatty acids (and sucroglycerides) were evaluated by 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 for review (WHO, 1995). This study was submitted and evaluated by JECFA in 1997, resulting in the establishment of a full group ADI of 0–30 mg/kg bw per day (WHO, 1998). In 2009, JECFA confirmed this group ADI for sucrose esters of fatty acids, sucroglycerides and sucrose oligoesters type I and type II (JECFA, 2009).

The EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) issued an opinion on sucrose esters of fatty acid (E 473) and sucroglycerides (E 474) in 2004 (modified in 2006), establishing a group ADI of 40 mg/kg bw per day for these two additives (EFSA, 2004, modified on 25 January 2006).

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5 Food of category 13.1.1: Infant formulae as defined by Directive 2006/141/EC; Food of category 13.1.5.1: Dietary foods for infants for special medical purposes and special formulae for infants. This interpretation also applies to those food additives in food category 13.1.5.2 (Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC) for which exceptional uses in food for infants under the age of 12 weeks are indicated.

6 http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00692

7 Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p 1.
Sucrose esters of fatty acids (and sucroglycerides) (E 473, E 474) have also been reviewed by the Nordic Council of Ministers (TemaNord, 2002), which concluded that ‘if the potential for exceeding the ADI is confirmed an adjustment of the permitted levels should be considered’.

2. Data and methodologies

2.1. Data

The ANS Panel was not provided with a newly submitted dossier, but EFSA launched public calls for data8 to collect relevant information from interested parties since the last 2012 ANS Panel opinion on sucrose esters of fatty acids (E 473).

The Panel based its dietary exposure assessment therefore on information submitted to EFSA following the public calls for data.

Food consumption data used to estimate the dietary exposure to sucrose esters of fatty acids (E 473) were derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database9). The Mintel’s Global New Products Database (GNPD) was used to check the use of sucrose esters of fatty acids (E 473) in food products. The Mintel’s GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.

2.2. Methodologies

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

The ANS Panel assessed the dietary exposure to sucrose esters of fatty acids (E 473) as a food additive in line with the principles laid down in Regulation (EU) 257/2010 and in the relevant guidance document: Guidance on submission for food additive evaluations by the Scientific Committee on Food (SCF, 2001).

Dietary exposure to sucrose esters of fatty acids (E 473) from its use as a food additive was estimated by combining food consumption data available within the EFSA Comprehensive Database with the maximum levels according to Annex II to Regulation (EC) No 1333/200810 and reported use levels submitted to EFSA following a call for data. The exposure was estimated according to different scenarios (see Section 3.3). Uncertainties on the exposure assessment were identified and discussed.

3. Assessment

3.1. Authorised uses and use levels

Maximum levels of sucrose esters of fatty acids (E 473) have been defined in Annex II to Regulation (EC) No 1333/200811 on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

Currently, sucrose esters of fatty acids (E 473) is an authorised food additive in the EU with MPLs ranging from 120 to 20,000 mg/kg in 37 food categories and at quantum satis (QS) on surface treatment of fresh fruit and in food supplements. Apart from foods for infants and young children (FC 13.1), it is always authorised with sucroglycerides (E 474).

Table 1 summarises the food categories that are permitted to contain sucrose esters of fatty acids (E 473) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

8 Call for food additives usage level and/or concentration data in food and beverages intended for human consumption.
Published: 9 March 2014. Available from: http://www.efsa.europa.eu/en/dataclosed/call/datex140310

9 Available online: http://www.efsa.europa.eu/en/food-consumption/comprehensive-database

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

11 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16.
Table 1: MPLs of sucrose esters of fatty acids (E 473 and E 473-474) in foods according to the Annex II to Regulation (EC) No 1333/2008

| Food Category Number | Food Category Name                                                                 | E-Number  | Restrictions/exceptions                                                                 | MPL (mg/l or mg/kg as appropriate) |
|----------------------|------------------------------------------------------------------------------------|-----------|----------------------------------------------------------------------------------------|-----------------------------------|
| 01.4                 | Flavoured fermented milk products including heat-treated products                   | E 473-474|                                                                                         | 5,000(b)                          |
| 01.6.3               | Other creams                                                                       | E 473-474| Only sterilised cream and sterilised cream with reduced fat content                    | 5,000(b)                          |
| 01.8                 | Dairy analogues, including beverage whiteners                                      | E 473-474| Only cream analogues                                                                   | 5,000(b)                          |
| 01.8                 | Dairy analogues, including beverage whiteners                                      | E 473-474| Only beverage whiteners                                                                | 20,000(b)                         |
| 02.2.2               | Other fats and oil emulsions including spreads as defined by Council Regulation (EC)| E 473-474| Only fat emulsions for baking                                                           | 10,000(b)                         |
| 03                   | Edible ices                                                                         | E 473-474|                                                                                         | 5,000(b)                          |
| 04.1.1               | Entire fresh fruit and vegetables                                                   | E 473-474| Only fresh fruits, surface treatment                                                    | QS(b)                            |
| 05.2                 | Other confectionery including breath refreshing microsweets                         | E 473-474| Only sugar confectionery                                                                | 5,000(b)                          |
| 05.3                 | Chewing gum                                                                         | E 473-474|                                                                                         | 10,000(b)                         |
| 05.4                 | Decorations, coatings and fillings, except fruit based fillings covered by category | E 473-474|                                                                                         | 5,000(b)                          |
| 07.2                 | Fine bakery wares                                                                   | E 473-474|                                                                                         | 10,000(b)                         |
| 08.3.2               | Heat-treated meat products                                                          | E 473-474| Except foie gras, foie gras entier, blocs de foie gras, Libamaj, libamaj egészben, libamaj tombben | 5,000(b),(c)                      |
| 12.5                 | Soups and broths                                                                    | E 473-474|                                                                                         | 2,000(b)                          |
| 12.6                 | Sauces                                                                             | E 473-474|                                                                                         | 10,000(b)                         |
| 13.1.1               | Infant formulae as defined by Directive 2006/141/EC                                | E 473     | Only products containing hydrolysed proteins, peptides or amino acids                   | 120(d)                           |
| 13.1.2               | Follow-on formulae as defined by Directive 2006/141/EC                              | E 473     | Only products containing hydrolysed proteins, peptides or amino acids                   | 120(d)                           |
| 13.1.4               | Other foods for young children                                                      | E 473     | Only in products containing hydrolysed proteins, peptides or amino acids                | 120(d)                           |
| 13.1.5.1             | Dietary foods for infants for special medical purposes and special formulae for infants| E 473     | Only products containing hydrolysed proteins, peptides and amino acids                  | 120                              |
| 13.1.5.2             | Dietary foods for babies and young children for special medical purposes as defined | E 473     | Only products containing hydrolysed proteins, peptides and amino acids                  | 120                              |
| 13.2                 | Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5) | E 473-474|                                                                                         | 5,000(b)                          |
According to Annex III, Part 1 of Regulation (EC) No 1333/2008, sucrose esters of fatty acids (E 473) are also authorised as carriers in food additives at QS in colours and fat-soluble antioxidants.

According to Annex III, Part 2 of Regulation (EC) No 1333/2008, sucrose esters of fatty acids (E 473) are also authorised as food additives other than carriers in food additives at QS in preparations of colours and fat-soluble antioxidants.

According to Annex III, Part 3 of Regulation (EC) No 1333/2008, sucrose esters of fatty acids (E 473) are also authorised as a food additive in food enzymes only as a carrier with a maximum

| Food Category Number | Food Category Name                                                                 | E-Number | Restrictions/exceptions                          | MPL (mg/l or mg/kg as appropriate) |
|----------------------|------------------------------------------------------------------------------------|----------|-------------------------------------------------|------------------------------------|
| 13.3                 | Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet) | E 473-474|                                                 | 5,000<sup>(b)</sup>               |
| 14.1.4               | Flavoured drinks                                                                  | E 473-474| Only aniseed-based, dairy-based, coconut and almond drinks | 5,000<sup>(b)</sup>               |
| 14.1.4               | Flavoured drinks                                                                  | E 473-474| Only powders for the preparation of hot beverages | 10,000<sup>(b)</sup>              |
| 14.1.5.2             | Other                                                                             | E 473-474| Only canned liquid coffee                       | 1,000<sup>(b)</sup>              |
| 14.1.5.2             | Other                                                                             | E 473-474| Only powders for the preparation of hot beverages | 10,000<sup>(b)</sup>              |
| 14.2.3               | Cider and perry                                                                   | E 473-474|                                                 | 5,000<sup>(b)</sup>               |
| 14.2.4               | Fruit wine and made wine                                                           | E 473-474|                                                 | 5,000<sup>(b)</sup>               |
| 14.2.5               | Mead                                                                              | E 473-474|                                                 | 5,000<sup>(b)</sup>               |
| 14.2.6               | Spirit drinks as defined in Regulation (EC) No 110/2008                           | E 473-474| Except: whisky, whiskey                         | 5,000<sup>(b)</sup>               |
| 14.2.7.1             | Aromatised wines                                                                  | E 473-474|                                                 | 5,000<sup>(b)</sup>               |
| 14.2.7.2             | Aromatised wine-based drinks                                                       | E 473-474|                                                 | 5,000<sup>(b)</sup>               |
| 14.2.7.3             | Aromatised wine-product cocktails                                                 | E 473-474|                                                 | 5,000<sup>(b)</sup>               |
| 14.2.8               | Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol | E 473-474|                                                 | 5,000<sup>(b)</sup>               |
| 16                   | Desserts excluding products covered in category 1, 3 and 4                         | E 473-474|                                                 | 5,000<sup>(b)</sup>               |
| 17.1<sup>(a)</sup>   | Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms | E 473-474|                                                 | QS<sup>(b)</sup>                  |
| 17.2<sup>(a)</sup>   | Food supplements supplied in a liquid form                                         | E 473-474|                                                 | QS<sup>(b)</sup>                  |
| 17.3<sup>(a)</sup>   | Food supplements supplied in a syrup-type or chewable form                         | E 473-474|                                                 | QS<sup>(b)</sup>                  |

MPL: maximum permitted level; QS: quantum satis.

(a): Food categories 17.1, 17.2 and 17.3 refer to food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children.

(b): The additives may be added individually or in combination. This footnote does not appear for each food category in the current Regulation (EC) No 1333/2008. However, the EC confirmed that the current Regulation contains mistakes that will be corrected in the future version of the regulation.

(c): Expressed on fat basis. A percentage of 30% fat was considered in the current exposure assessment for this food category to consider the MPL of 5,000 mg/kg. This fat percentage was based on the fat percentage of several foods belonging to this food category, ranging from 25 to 35%.

(d): If more than one of the substances E 322, E 471, E 472c and E 473 are added to a foodstuff, the maximum level established for that foodstuff for each of those substances is lowered with that relative part as is present of the other substances together in that foodstuff.

(e): Ingoing amount, residues not detectable.

According to Annex III, Part 1 of Regulation (EC) No 1333/2008, sucrose esters of fatty acids (E 473) are also authorised as carriers in food additives at QS in colours and fat-soluble antioxidants.

According to Annex III, Part 2 of Regulation (EC) No 1333/2008, sucrose esters of fatty acids (E 473) are also authorised as food additives other than carriers in food additives at QS in preparations of colours and fat-soluble antioxidants.

According to Annex III, Part 3 of Regulation (EC) No 1333/2008, sucrose esters of fatty acids (E 473) are also authorised as a food additive in food enzymes only as a carrier with a maximum
level in enzyme preparation of 50,000 mg/kg and of 50 mg/kg in final food and 25 mg/L in beverages.

In addition, according to Annex III, Part 4 of Regulation (EC) No 1333/2008, sucrose esters of fatty acids (E 473) are also authorised as a food additive including carriers in food flavourings, in flavourings for water based clear flavoured drinks that belong to category 14.1.4 with a maximum level in flavourings of 15,000 mg/kg and of 30 mg/L in final food.

Finally, according to Annex III, Part 5, Section A of Regulation (EC) No 1333/2008, sucrose esters of fatty acids (E 473) are also authorised at QS in beta-carotene, lutein, lycopene and vitamin E preparations and at 2 mg/kg in final food in vitamin A and D preparations. It can be used as a carrier.

3.2. Exposure data

3.2.1. Reported use levels or data on analytical levels of sucrose esters of fatty acids (E 473)

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

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued public calls12,13 for occurrence data (usage level and/or concentration data) on sucrose esters of fatty acids (E 473). In response to this public call, updated information on the actual use levels of sucrose esters of fatty acids (E 473) in foods was made available to EFSA by industry. No analytical data on the concentration of sucrose esters of fatty acids (E 473) in foods were made available by the Member States.

Summarised data on reported use levels in foods provided by industry

Industry provided EFSA with data on use levels (n = 61) of sucrose esters of fatty acids (E 473, n = 57 and E 473–474, n = 4) in foods for 18 out of the 37 food categories in which sucrose esters of fatty acids (E 473) is authorised. Data were made available by AgriCoat NatureSeal Ltd, Association of the European Self-Medication Industry (AESGP), BABBI Confectionery Industry, DreiDoppel GmbH, FoodDrinkEurope (FDE), the International Chewing Gum Association (ICGA), Keller and Heckman LLP (KHLAW), and Specialised Nutrition Europe (SNE).

The Panel noted that some data providers (i.e. Keller and Heckman LLP and AgriCoat NatureSeal Ltd) were consultants or food additive producers and do therefore not add sucrose esters of fatty acids (E 473) to food products. However, these data providers clarified that their reported use levels were levels that are added to food. Therefore, their data were included in the current exposure assessment.

In total, 10 use levels on sucrose esters of fatty acids (E 473 and E 473–474) referred to a niche product. Out of these, four use levels on edible ices, fine bakery wares and flavoured drinks were not included in the assessment, because more representative use levels were available for these food categories.

Sucrose esters of fatty acids (E 473) is authorised for use on fresh fruits as surface treatment (FC 04.1.1). AgriCoat NatureSeal Ltd provided EFSA with use levels of this additive for fruits eaten either with or without peel (Appendix A).

The Panel noted that among the food categories for which no data were submitted, SNE confirmed that sucrose esters of fatty acids (E 473) is not used in FCs 13.1.1 and 13.1.2.

Appendix A lists the use levels of sucrose esters of fatty acids (E 473 and E 473–474) in foods as reported by industry. No use levels were reported for uses according to Annex III to Regulation No 1333/2008. However, foods in which sucrose esters of fatty acids (E 473) is authorised according to Annex III were taken into account in the current exposure assessment if they are also authorised to contain this food additive according to Annex II: MPLs defined in Annex II include also the amount of food additive added to foods due to Annex III. Thus, foods in which sucrose esters of fatty acids (E 473) can only be present due to Annex III were not taken into account.

12 http://www.efsa.europa.eu/sites/default/files/consultation/140310.pdf
13 http://www.efsa.europa.eu/sites/default/files/consultation/ans091123.pdf
3.2.2. 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 2.5 million food and beverage products of which more than 900,000 are or have been available on the European food market. Mintel started covering EU’s food markets in 1996, currently having 20 out of its 28 member countries and Norway presented in the Mintel’s GNPD.14

For the purpose of this Scientific Opinion, the Mintel’s GNPD15 was used for checking 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.

According to the Mintel’s GNPD, sucrose esters of fatty acids (E 473) was labelled on around 1,500 food, beverage and food supplement products, of which more than 1,000 were included in the database between January 2012 and October 2017. The main Mintel’s GNPD food subcategories containing the food additive were ‘Pastilles, Gums, Jellies & Chews’, ‘Snack/Cereal/Energy Bars’ and ‘Cakes, Pastries & Sweet Goods’.

No baby food products were labelled with sucrose esters of fatty acids (E 473) between January 2012 and October 2017 according the Mintel’s GNPD. This is in accordance with the feedback provided by Specialised Nutrition Europe (SNE), who indicated that E 473 is not used in FCs 13.1.1 and 13.1.2 (see Section 3.2.1).

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 food classification. The percentages ranged from less than 0.1% in many food subcategories to 6.9% in the Mintel’s GNPD food subcategory ‘Gum’. The average percentage of foods labelled to contain sucrose esters of fatty acids (E 473) was 0.2%.

According to the Mintel’s GNPD, sucroglycerides (E 474) was labelled on two fine bakery wares and one coconut based beverage together with E 473 between January 2012 and October 2017.

3.2.3. Food consumption data used for exposure assessment

EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the ‘Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment’ (EFSA, 2011a)). New consumption surveys16 added to the Comprehensive Database in 2015 were also taken into account in this assessment.17

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

Food consumption data from the following population groups were used in the exposure assessment: infants, toddlers, children, adolescents, adults and the elderly. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 2).

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14 Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.
15 http://www.gnpd.com/sinatra/home/ accessed on 20/10/2017.
16 Available online: http://www.efsa.europa.eu/en/press/news/150428.htm
17 Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm
Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, the FoodEx food codes were matched to the FCS food categories.

Food categories considered for the exposure assessment of sucrose esters of fatty acids (E 473)

The food categories in which the use of sucrose esters of fatty acids (E 473) is authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

Some food categories or their restrictions/exceptions are not referenced, and therefore, the whole food category was not taken into account are (in ascending order of the FCS codes):

- 01.6.3 Other cream, only sterilised cream and sterilised cream with reduced fat: the foods belonging to this food category are very specific and such detail is not available for many eating occasions. Considering the whole food category in the exposure assessment would therefore have resulted in a high overestimation of the exposure.
- 14.1.5.2 Other, only canned liquid coffee: no information is available on the packaging of coffee drink in the EFSA Comprehensive Database. Assuming that the consumption of all liquid coffee referred to canned coffee would have resulted in a large overestimation of the exposure via this specific category.

The following four alcoholic drinks are not listed in the FoodEx nomenclature and could therefore not be included in the assessment:

- 14.2.4 Fruit wine and made wine
- 14.2.5 Mead
- 14.2.7.2. Aromatised wine-based drinks
- 14.2.7.3. Aromatised wine-product cocktails

For the following food categories, the restrictions/exceptions which apply to the use of sucrose esters of fatty acids (E 473) were also not referenced, and therefore, the whole food category was...
considered in the exposure assessment. This was the case for eight food categories and may have resulted in an overestimation of the exposure:

- **02.2.2 Other fat and oil emulsions, including spreads as defined by Council Regulation (EC) No 1234/2007** and liquid emulsions, only fat emulsions for baking. Considering that it is not possible to select only the consumption of fat emulsions for baking and that many fat emulsions could be used for baking, the full food category was taken into account.

- **05.2 Other confectionery including breath refreshening microsweets, only sugar confectionary.** The full food category was taken into account, because the restriction represents a large part of the whole food category.

- **08.3.2 Heat-treated meat products, except foie gras, foie gras entier, blocs de foie gras, Libamaj, Libamaj egészben, libamaj tömbben.** The full food category was taken into account, because it was not possible to remove the foods defined by the restrictions as no FoodEx codes are available and these foods represent only a small part of the full food category.

For the foods authorised under FC 13.1, including foods for infants and young children, no information on the restriction stating **only products containing hydrolysed proteins, peptides or amino acids** is available in the EFSA Comprehensive Database. Considering that this is a sensitive population and that infants usually drink the same formulae (brand-loyalty), all foods classified under this food category were included in the assessment (13.1.1 Infant formulae; 13.1.2 Follow-on formulae; 13.1.4 Other foods for young children; 13.1.5.1 Dietary foods for infants for special medical purposes and special formulae for infants; 13.1.5.2 Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC).

Regarding FC 14.1.4 Flavoured drinks, only aniseed-based, dairy-based, coconut and almond drinks, only the consumption of dairy-based and almond drinks were taken into account. The EFSA Comprehensive Database does not contain information about the consumption of aniseed-based or coconut drinks.

Sucrose esters of fatty acids (E 473) is also allowed in FCs 13.2 and 13.3. Food items belonging to these food categories consumed by the relevant population groups (children, adolescents, adults and the elderly) may be very diverse. Furthermore, there is very limited information on the consumption of these foods available in the EFSA Comprehensive Database. Therefore, eating occasions belonging to these food categories were reclassified under food categories in accordance to their main ingredient (e.g. meal substitute cereal bar (FC 13.2) was reclassified in fine bakery wares (FC 07.2)). Thus, the use levels available for FCs 13.2 and 13.3 were not considered in the exposure assessment.

Fruits belonging to FC 4.1.1 Entire fresh fruits and vegetables that are typically consumed with peel were considered as always consumed with peel in the current assessment (e.g. apple, plum) and those with an inedible peel were assumed as consumed without peel (e.g. banana, mango). All fresh fruits available in the FoodEx nomenclature were included in the current assessment.

Added to the limitations of the food categories described above, 10 additional food categories were not taken into account in the refined scenario, because no concentration data were provided for these food categories (Appendix C). For the remaining food categories, the refinements considering the restrictions/exceptions as set in Annex II to Regulation No 1333/2008 for the use of sucrose esters of fatty acids (E 473) were applied.

Overall, for the regulatory maximum level exposure scenario, 23 food categories were included, while for the refined scenarios, 13 food categories were included in the present exposure assessment to sucrose esters of fatty acids (E 473). (Appendix C).

### 3.3. Exposure estimates to sucrose esters of fatty acids (E 473) from its use as a food additive

The Panel estimated the chronic dietary exposure to sucrose esters of fatty acids (E 473) for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Dietary exposure to sucrose esters of fatty acids (E 473) was calculated by multiplying concentrations of sucrose esters of fatty acids (E 473) per food category (Appendix C) with their respective consumption amount per kilogram body weight for each individual in the EFSA Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day.

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18 Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products. OJ L 299, 16.11.2007, p. 1.
These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered as not adequate to assess repeated exposure.

This was carried out for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 2). On the basis of these distributions, the mean and 95th percentile of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups with a sufficiently large sample size (EFSA, 2011a). Therefore, in the present assessment, the 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain were not estimated.

Exposure assessment to sucrose esters of fatty acids (E 473) was carried out by the ANS Panel based on: (1) MPLs as set down in the EU legislation (defined as the regulatory maximum level exposure assessment scenario); and (2) reported use levels (defined as the refined exposure assessment scenario). These two scenarios are discussed in detail below.

These scenarios do not consider the intake of sucrose esters of fatty acids (E 473) via the consumption of foods for special medical purposes (FSMP) and food supplements. These exposure sources are covered in two additional scenarios detailed below (foods for special medical purposes consumer only scenario and food supplements consumers only scenario).

### 3.3.1. Regulatory maximum level exposure assessment scenario

The regulatory maximum level exposure assessment scenario is based on the MPLs as set in Annex II to Regulation (EC) No 1333/2008. For sucrose esters of fatty acids (E 473), the MPLs used in the assessment are listed in Table 1. For the four food categories authorised according to QS, the maximum of the reported use levels was used (Appendix C). In total, 23 food categories were included in this scenario (see Section 3.2.3).

The Panel considers the exposure estimates derived following this scenario as the most conservative since it is assumed that the population will be exposed to the food additive present in food at the MPL over a longer period of time.

### 3.3.2. Refined exposure assessment scenario

The refined exposure assessment scenario is based on use levels reported by food industry. This exposure scenario can consider only food categories for which these data were available to the Panel. In total, 13 food categories were included in this scenario (see Section 3.2.3).

Appendix C summarises the concentration levels of sucrose esters of fatty acids (E 473) used in the refined exposure assessment scenario. Based on the available data set, the Panel calculated two refined exposure estimates based on two model populations:

- The brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to sucrose esters of fatty acids (E 473) present at the maximum reported use/analytical level for one food category. This exposure estimate is calculated as follows:

  - Combining food consumption with the maximum of the reported use levels for the main contributing food category at the individual level.
  - Using the mean of the typical reported use levels for the remaining food categories.

- The non-brand-loyal consumer scenario: It was assumed that a consumer is exposed long-term to sucrose esters of fatty acids (E 473) present at the mean reported use levels in food. This exposure estimate is calculated using the mean of the typical reported use levels for all food categories.

### 3.3.3. Specific scenarios

#### Food supplement consumers only scenario

Sucrose esters of fatty acids (E 473) is authorised in FC 17 Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children (Table 1). As exposure via the intake of food supplements may deviate largely from that via food, and the number of food supplement consumers may be low depending on populations and surveys, an additional scenario was calculated in order to reflect the exposure to sucrose esters of fatty acids (E 473) via food supplements. This scenario was estimated as follow:
Consumers only of food supplements were assumed to be exposed to a food additive present at the maximum reported usage on a daily basis via consumption of food supplements. For the remaining food categories, the mean of the typical reported use levels was used.

As FC 17 does not consider food supplements for infants and toddlers as defined in the legislation, exposure to sucrose esters of fatty acids (E 473) via the intake of food supplements was not estimated for these two population groups.

In total, 16 food categories were included in this scenario (see Section 3.2.3; Appendix C).

**Foods for special medical purposes consumers only scenario**

As sucrose esters of fatty acids (E 473) is also authorised in the FCs 13.1.5.1 and 13.1.5.2, a refined estimated exposure assessment scenario taking into account these two food categories was performed to estimate the exposure of infants and toddlers who may eat and drink these foods for special medical purposes. The consumption of these foods is not reported in the EFSA Comprehensive Database. To consider potential exposure to sucrose esters of fatty acids (E 473) via these foods, the Panel therefore assumed that the consumed amount of FSMP in infants and toddlers resembles that of comparable foods in infants and toddlers from the general population. Thus, the consumption of FSMP categorised as FC 13.1.5 was assumed to equal that of formulae and food products categorised as belonging to FCs 13.1.1, 13.1.2, 13.1.3 and 13.1.4.

This scenario was estimated as follows:

- Consumers only of FSMP were assumed to be exposed to sucrose esters of fatty acids (E 473) present at the maximum reported use level on a daily basis via consumption of FCs 13.1.5.1 and 13.1.5.2 (infant formulae, follow-on formulas and processed cereal-based foods and baby foods for infants and young children as defined by Commission Directive 2006/125/EC).
- For the remaining food categories, the mean of the typical reported use levels was used.

In total, 15 food categories were included in this scenario (see Section 3.2.3; Appendix C).

### 3.3.4. Dietary exposure to sucrose esters of fatty acids (E 473)

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 (Table 2) 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) |
|---------------------------------|-------------------|-----------------|------------------|-----------------|-----------------|-----------------|
|                                | Infants (12 weeks–11 months) | Toddlers (12–35 months) | Children (3–9 years) | Adolescents (10–17 years) | Adults (18–64 years) | The elderly (≥ 65 years) |
| **Regulatory maximum level exposure assessment scenario** | Mean | 4.5–24.6 | 29.0–147.4 | 33.5–129.2 | 14.4–50.1 | 3.7–39.1 | 2.9–36.5 |
|                                | 95th percentile | 12.0–83.3 | 101.3–304.7 | 79.2–296.3 | 31.6–111.9 | 10.0–107.9 | 8.1–94.0 |
| **Refined estimated exposure assessment scenario** | Brand-loyal scenario | Mean | 0.2–13.6 | 3.0–54.6 | 8.1–51.6 | 3.2–25.9 | 1.8–15.6 | 1.7–14.0 |
|                                | 95th percentile | 0.8–57.1 | 11.1–123.6 | 19.6–124.3 | 8.6–59.6 | 6.3–41.7 | 5.6–34.9 |
|                                | Non-brand-loyal scenario | Mean | 0.1–6.6 | 1.7–42.7 | 4.6–38.7 | 1.8–16.9 | 0.9–8.3 | 0.9–7.2 |
|                                | 95th percentile | 0.4–27.6 | 6.3–96.7 | 11.4–112.6 | 4.7–42.6 | 3.4–23.4 | 2.8–19.4 |
In 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 2.9 mg/kg bw per day in the elderly to 147.4 mg/kg bw per day in toddlers. The 95th percentile of exposure to sucrose esters of fatty acids (E 473) ranged from 8.1 to 304.7 mg/kg bw per day in the same two population groups.

In the brand-loyal scenario of the refined estimated exposure scenario, mean exposure to sucrose esters of fatty acids (E 473) from its use as a food additive ranged from 0.2 mg/kg bw per day in infants to 54.6 mg/kg bw per day in toddlers. The 95th percentile of exposure to sucrose esters of fatty acids (E 473) ranged from 0.8 mg/kg bw per day in infants to 124.3 mg/kg bw per day in children. In the non-brand-loyal scenario, the corresponding mean exposure levels were 0.1 and 42.7 mg/kg bw per day, respectively, for infants and toddlers, and the 95th percentiles of exposure were 0.4 and 112.6 mg/kg bw per day, respectively, for infants and children.

In the FSMP consumers only scenario, mean exposure to sucrose esters of fatty acids (E 473) from its use as a food additive ranged between 5 and 12 mg/kg bw per day in infants and between 5 and 40 mg/kg bw per day in toddlers. The corresponding 95th percentiles of exposure were 17 and 27 mg/kg bw per day and 30 and 119 mg/kg bw per day, respectively.

In the food supplements consumers only scenario, mean exposure to sucrose esters of fatty acids (E 473) from its use as a food additive ranged from 2 mg/kg bw per day in adults and adolescents to 34 mg/kg bw per day in children. The 95th percentile of exposure ranged from 5 mg/kg bw per day in adolescents to 58 mg/kg bw per day in children.

3.3.5. Main food categories contributing to exposure for the general population

In the regulatory maximum level exposure assessment scenario, the main contributing food categories to the total mean exposure to sucrose esters of fatty acids (E 473) were infant formulae and fine bakery wares for infants. For toddlers, children and adolescents, the main contributing food categories were fine bakery wares and flavoured fermented milk products as well as flavoured drinks for adolescents, while, for adults and the elderly, the main contributing food categories were fine bakery wares and chicory extracts, tea, herbal- and fruit-infusions; coffee substitutes, coffee mixes and mixes for hot beverages (namely FC 14.1.5.2 Other, only powders for the preparation of hot beverages).

The main contributing food categories according to the refined estimated exposure scenario, in both the brand-loyal and non-brand-loyal scenarios were fine bakery wares for all population groups and also flavoured drinks, only dairy-based and almond drinks, for children and adolescents.

The main food categories contributing to the exposure to sucrose esters of fatty acids (E 473) are presented in Appendix E. Appendix E can be found in the online version of this output (‘Supporting information’ section): https://doi.org/10.2903/j.efsa.2018.5087

3.3.6. Main food categories contributing to specific scenarios

The main contributing food categories in the FSMP and food supplement scenarios taking into account consumers only were fine bakery wares.

3.3.7. Uncertainty analysis

Uncertainties in the exposure assessment of sucrose esters of fatty acids (E 473) have been discussed above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 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                                                     |              |
| Use of data from food consumption surveys covering only a few days to estimate high     | +/–          |
| percentile (95th) of long-term (chronic) exposure                                        |              |
| Correspondence of reported use levels to the food items in the EFSA                      | +/-          |
| Comprehensive Database: uncertainties to which types of food the levels refer             |              |
| Uncertainty in possible national differences in use levels of food categories             | +/-          |
The Panel noted that 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) was labelled were included in the current exposure assessment. Few foods, both authorised according to the EU legislation and labelled with sucrose esters of fatty acids (E 473) according to the Mintel's GNPD, were not included in the current estimates, because no data were made available to EFSA (e.g. liqueur and meat products). On the other hand, some foods not authorised according to the EU legislation were found to be labelled with sucrose esters of fatty acids (E 473) according to the Mintel's GNPD (e.g. snacks, breakfast cereals, bread and bread products, juice, fish products). Furthermore, for the food categories contributing most to the exposure in the different population groups (FC 07.2 fine bakery wares and FC 14.1.4 flavoured drinks), the Panel noted that the information retrieved from the Mintel's GNPD showed that the percentages of foods belonging to the most comparable food subcategories for fine bakery wares according to the Mintel's GNPD classification (i.e. 'Cakes, Pastries & Sweet Goods', 'Snack/Cereal/Energy Bars', some products in 'Bread & Bread Products' and 'Sweet Biscuits/Cookies') were maximally 2.3%. For FC 14.1.4 flavoured drinks, the percentage was maximally 3.1% for 'Plant Based Drinks (Dairy Alternatives)', consisting mainly of milk/almond drinks. These percentages, together with the overall percentage of 0.2% of food labelled with sucrose esters of fatty acids (E 473) (see Section 3.2.2), demonstrate that the general assumption that all foods belonging to a food category contain the food additive has likely resulted in an overestimation of the exposure to sucrose esters of fatty acids (E 473) in all exposure scenarios.

Given these observations, the Panel considered overall 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, including the FSMP and food supplement scenarios.

| Sources of uncertainties | Direction\(^{(a)}\) |
|--------------------------|------------------|
| Concentration data:      |                  |
| — use levels considered applicable to all foods within the entire food category, whereas on average 0.2% 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 excluded from the exposure assessment due to missing FoodEx linkage (n = 6 food categories) | –               |
| Food categories included in the exposure assessment without considering the restriction/exception (n = 9 food categories) | +               |
| Food categories included in the exposure assessment considering only partly the restriction/exception (n = 1 food category) | –               |
| Food categories not included in the refined exposure assessment due to lack of use levels (n = 10 food categories) | –               |
| Fruits that can be consumed with peel were considered to be always consumed with peel | +               |
| Regulatory maximum level exposure assessment scenario: |                  |
| — exposure calculations based on MPLs according to Annex II to Regulation (EC) No 1333/2008 | +               |
| — foods which may contain the food additive according to Annex III to Regulation (EC) No 1333/2008 partly taken into account | –               |
| Refined exposure assessment scenarios and the specific FSMP and food supplements scenarios: |                  |
| — exposure calculations based on the maximum or mean levels (reported use from industries) | +               |
| — foods which may contain the food additive according to Annex III to Regulation (EC) No 1333/2008 partly taken into account | –               |

\(^{(a)}\): \(\pm\): uncertainty with potential to cause overestimation of exposure; \(\mp\): uncertainty with potential to cause underestimation of exposure.
3.4. Discussion

In this opinion, the dietary exposure to sucrose esters of fatty acids (E 473) from its use as a food additive was calculated according to different scenarios. The assessments were hampered by several uncertainties, and overall it was estimated that the exposure was overestimated due to the reported use levels used and assumptions made in the exposure assessment. For an elaborate discussion of the uncertainties, see Section 3.3.7.

The group ADI of sucrose esters of fatty acids (E 473) and sucroglycerides (E 474) is 40 mg/kg bw per day (Section 1.2). Since sucrose esters of fatty acids (E 473) is authorised and used in a certain type of flavoured drinks, especially the milk-based one, (Table 1) to which consumers may be brand loyal, the Panel selected the refined brand-loyal scenario as the most relevant exposure scenario for the safety evaluation of this food additive. As the exposure in the FSMP and food supplements scenarios did not exceed the exposure estimates in the brand-loyal scenario, the FSMP and food supplements scenarios were not deemed critical to assess the safety of the use of sucrose esters of fatty acids (E 473).

The exposure estimates in the refined brand-loyal scenario exceeded the group ADI of 40 mg/kg bw per day at the mean for toddlers and children and at the 95th percentile for all population groups, except the elderly (Table 3). The Panel noted that the estimated long-term exposures based on this scenario are very likely conservative as all foods and beverages listed under Annex II to Regulation No 1333/2008 were assumed to contain sucrose esters of fatty acids (E 473) as a food additive at the mean and at the maximum for the most contributing food category (see Section 3.3.7).

The Panel noted also that in the less conservative non-brand loyal exposure assessment scenario the high-level exposure (95th percentile) exceeded the group ADI for toddlers and children. The maximally mean exposure estimated for these two population groups was close to the group ADI: 42.7 and 38.7 mg/kg bw per day, respectively.

The Panel noted furthermore that the group ADI was also exceeded at the high exposure level (95th percentile) for toddlers in the FSMP scenario and for children and adolescents in the food supplements scenario.

The Panel noted that the main food category contributing to exposure at the brand-loyal scenario was fine bakery wares which is a highly consumed food category and for which the second highest use level (after the one for food supplements) was reported (mean = 4,250 mg/kg food). More specific data on the foods belonging to this food category that contain the additive will result in a more refined exposure estimate.

As mentioned above, the refined exposure assessment scenario is based on use levels reported by food industry. This exposure scenario can consider only food categories for which these data were available to the Panel. Regarding sucrose esters of fatty acids (E 473), infant formulae and flavoured fermented drinks were important contributors, respectively, for infants and toddlers in the regulatory maximum exposure assessment scenario. It was noted that these two food categories were not included in the refined exposure scenario due to the absence of reported use levels. For the infant formulae, the Panel received information on the non-use of the food additive in FCs 13.1.1 and 13.1.2.

The Panel also noted that the brand-loyal exposure estimates were above the previous estimates (EFSA ANS Panel, 2012a) in which an exceedance of the group ADI of 40 mg/kg bw per day was only observed at the 95th percentile exposure for children. In 2012, reported use levels from industry were available for only a few food categories and MPLs were used when no other data were available. That the exposure estimates of 2012 were anyway lower was due to the consumption data used at that time: only Irish consumption data. The current Irish mean brand-loyal exposure estimates were lower than the 2012 results (and in the same range at the high level).

The Panel noted that the refined exposure estimates were based on information provided on the reported level of use of sucrose esters of fatty acids (E 473). If actual practice changes, these refined estimates should be updated.

The Panel noted that in Annex II of Regulation (EC) No 1333/2008 use levels of sucrose esters of fatty acids (E 473) in food for infants under the age of 12 weeks are included in FCs 13.1.1, 13.1.5.1 and 13.1.5.2. The Panel considered that these uses would require a specific risk assessment in line with the recommendations given by JECFA (1978) and the SCF (1998) and endorsed by the Panel (EFSA ANS Panel, 2012b). Therefore, the current re-evaluation of sucrose esters of fatty acids (E 473) as a food additive is not applicable for infants below the age of 12 weeks.
4. Conclusions

Considering that:

- 13 out of the 37 food categories in which sucrose esters of fatty acids (E 473) is authorised were considered in the refined exposure assessment,
- the brand-loyal refined exposure estimates were relevant for the risk assessment as sucrose esters of fatty acids (E 473) is authorised in certain types of flavoured drinks to which consumers may be brand loyal,
- the highest mean refined exposure estimate was 55 mg/kg bw per day and the highest 95th percentile of exposure was 124 mg/kg bw per day, respectively in toddlers (12–35 months) and children (3–9 years) (brand-loyal scenario),
- it was assumed in the refined exposure assessment that all foods belonging to a food category for which use levels were provided contained sucrose esters of fatty acids (E 473), whereas information from the Mintel’s GNPD showed that the additive was used in only a small percentage of the foods,

the 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 population groups; especially toddlers and children,
- assuming that sucrose esters of fatty acids (E 473) is not used in the 24 food categories where data was not provided, the current exposure estimates very likely overestimate the real exposure to sucrose esters of fatty acids (E 473).

5. Recommendations

The Panel recommends 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.

Documentation provided to EFSA

1) AgriCoat NatureSeal Ltd, 2014. Data on usage levels of sucrose esters of fatty acids (E 473) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 22 August 2014.
2) Association of the European Self-Medication Industry (AESGP), 2013. Data on usage levels of sucrose esters of fatty acids (E 473) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 29 September 2014.
3) BABBi Confectionery Industry, 2014. Data on usage levels of sucrose esters of fatty acids (E 473) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 12 August 2014.
4) Dreidoppel GmbH, 2014. Data on usage levels of sucrose esters of fatty acids (E 473) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 29 July 2014.
5) FoodDrinkEurope (FDE), 2013. Data on usage levels of sucrose esters of fatty acids (E 473) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 30 September 2014.
6) International Chewing Gum Association (ICGA), 2014. Data on usage levels of sucrose esters of fatty acids (E 473) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 30 September 2014.
7) Keller and Heckman LLP, 2014. Data on usage levels of sucrose esters of fatty acids (E 473) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 31 October 2014.

8) Specialised Nutrition Europe (SNE), 2014. Data on usage levels of sucrose esters of fatty acids (E 473) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2014). Submitted to EFSA on 30 September 2014.

References

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). The EFSA Journal 2004;2(10):106, 24 pp. Modified on 25 January 2006. Available online: http://www.efsa.europa.eu/en/efsajournal/doc/106.pdf

EFSA (European Food Safety Authority), 2007. Scientific opinion of the Scientific Committee related to uncertainties in dietary exposure assessment. EFSA Journal 2007;5(1):438, 54 pp. https://doi.org/10.2903/j.efsa.2007.438

EFSA (European Food Safety Authority), 2010. Scientific Opinion on the safety of sucrose esters of fatty acids prepared from vinyl esters of fatty acids and on the extension of use of sucrose esters of fatty acids in flavourings. EFSA Journal 2010;8(3):1512, 36 pp. http://www.efsa.europa.eu/en/scdocs/doc/1512.pdf

EFSA (European Food Safety Authority), 2011a. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. https://doi.org/10.2903/j.efsa.2011.2097

EFSA (European Food Safety Authority), 2011b. Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database. EFSA Journal 2011;9(3):1970, 27 pp. https://doi.org/10.2903/j.efsa.2011.1970

EFSA ANS Panel (EFSA ANS Panel on Food additives and Nutrient Sources added to Food), 2012a. Scientific Opinion on the exposure assessment of sucrose esters of fatty acids (E 473) from its use as food additive. EFSA Journal 2012;10(5):2658, 11 pp. https://doi.org/10.2903/j.efsa.2012.2658

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2012b. Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760, 60 pp. https://doi.org/10.2903/j.efsa.2012.2760

EFSA Scientific Committee, 2009. Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles. EFSA Journal 2009;7(7):1051, 22 pp. https://doi.org/10.2903/j.efsa.2009.1051

EFSA Scientific Committee, 2017. Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age. EFSA Journal 2017;15(5):4849, 58 pp. https://doi.org/10.2903/j.efsa.2017.4849

IPCS, 2004. IPCS Risk Assessment Terminology (Part 1: IPCS/OECD Key Generic terms used in Chemical Hazard/Risk Assessment. Available online: http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf

JECA (Joint FAO/WHO Expert Committee on Food Additives), 1972. WHO Technical Report Series, Evaluation of certain food additives and the contaminants mercury, lead, and cadmium. Sixteenth report of the Joint FAO/WHO Expert Committee on Food Additives. No. 505. World Health Organization, Geneva, Switzerland.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1978. Evaluation of certain food additives. Twenty-first report of the Joint FAO/WHO Expert Committee on Food Additives. No. 617. World Health Organization, Geneva, Switzerland.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2009. The Summary report of the 71st JECFA meeting, 16 – 24 June 2009. Issued 1 July 2009. JECFA/71/SC. Available online: http://www.fao.org/ag/agns/jecfa/JECFA71_Summary_report_final.pdf

SCF (Scientific Committee for Food), 1992. Minutes of the 83rd Meeting of the Scientific Committee for Food held on 10 April 1992 in Brussels. Commission of the European Communities, Directorate-General for Internal market and industrial affairs. Opinion on sucroglycerides and sucrose esters, point 7.2.

SCF (Scientific Committee for Food), 1996. Opinion on additives in nutrient preparations for use in infant formulae, follow-on formulae and weaning foods. 7 June 1996. Available online: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_40.pdf

SCF (Scientific Committee for Food), 1998. Opinion of the Scientific Committee of Food on the applicability of the ADI (Acceptable Daily Intake) for food additives to infants. 17 September 1998. Available online: http://ec.europa.eu/food/fs/sc/scf/out13_en.html

SCF (Scientific Committee for Food), 2001. Guidance on submissions for food additive evaluations by the Scientific Committee on Food. SCF/CS/ADD/GEN/26 Final. 12 July 2001.

TemaNord, 2002. Food Additives in Europe 2000 - Status of safety assessments of food additives presently permitted in the EU, 474-478.
WHO (World Health Organisation), 1998. Safety evaluation of certain food additives and contaminants. Sucrose esters of fatty acids and sucroglycerides. Prepared by the forty-ninth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Food Additives Series, No. 40. Available online: http://www.inchem.org/documents/jecfa/jecmono/v040je04.htm

WHO (World Health Organisation), 1995. Evaluation of certain food additives and contaminants. Sucrose esters of fatty acids and sucroglycerides. Forty-fourth report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical Report Series, 859, 12–14.

**Abbreviations**

| Acronym | Definition |
|---------|------------|
| ADI     | acceptable daily intake |
| AESGP   | Association of the European Self-Medication Industry |
| AFC     | EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food |
| ANS     | EFSA Panel on Food Additives and Nutrient Sources added to Food |
| bw      | body weight |
| FAO     | Food and Agriculture Organization of the United Nations |
| FC      | Food category |
| FDE     | FoodDrinkEurope |
| FSMP    | foods for special medical purposes |
| GNPD    | Global New Products Database |
| ICGA    | International Chewing Gum Association |
| JECFA   | Joint FAO/WHO Expert Committee on Food Additives |
| MPL     | maximum permitted limit |
| QS      | quantum satis |
| SCF     | Scientific Committee on Food |
| SNE     | Specialised Nutrition Europe |
| TemaNord| is a publishing series for results of the often research-based work that working groups or projects under Nordic Council of Ministers have put in motion |
| WHO     | World Health Organization |
Appendix A – Summary of the 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 2017

Appendix C – Concentration levels used in the MPL and refined exposure scenario (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)

Appendices can be found in the online version of this output (‘Supporting information’ section): http://onlinelibrary.wiley.com/doi/10.2903/j.efsajournal.2018.5087/suppinfo/