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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.

Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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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.

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