Adopted: 21 May 2025

DOI: 10.2903/j.efsa.2025.9487

efsa JOURNAL

SCIENTIFIC OPINION

Scientific opinion on the safety of a proposed amendment of the conditions of use of the food additive sorbitan monostearate (E 491) in enzyme preparations

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract

The EFSA Panel on Food Additives and Flavourings (FAF Panel) provides a scientific opinion on the safety evaluation of a proposed amendment of the conditions of use of the food additive sorbitan monostearate (E 491) in accordance with Annex III, Part 3 to Regulation (EC) No 1333/2008, with respect to the intended use as a food additive in preparations of the food enzyme asparaginase (also known as acrylamide reducing yeast, or ARY). The group of sorbitan esters (E 491–495) was re-evaluated by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) in 2017. The ANS Panel established a group ADI of 10 mg sorbitan/kg body weight (bw) per day applicable to the food additives E 491–495. In the present opinion the Panel calculated an updated dietary exposure estimate of sorbitan resulting from the current authorised uses of the group of sorbitan esters (E 491–495), and from the proposed amendment of the conditions of use of sorbitan monostearate (E 491) in enzyme preparations. In updating the dietary exposure with the latest dietary surveys available, the group ADI of 10 mg sorbitan/kg bw per day was exceeded in toddlers and children at the 95th percentile in the refined non-brand loyal scenario for a limited number of dietary surveys. This observation holds true either considering the proposed amendment of the conditions of use of the food additive E 491 or only the currently permitted uses in the exposure calculations. The same conclusions apply to the dietary exposure estimates for consumers of food supplements, for which the ADI is exceeded in children at the 95th percentile. The Panel however concluded that the conservative assumptions made in the refined scenarios have resulted in a clear overestimation of the dietary exposure and therefore that the calculated exceedance of the acceptable daily intake (ADI) is not of safety concern. The Panel concluded that the proposed amendment of the conditions of use of sorbitan monostearate (E 491) in preparations of the food enzyme ARY has little impact on the current dietary exposure to sorbitan resulting from the already permitted uses and reported use levels of sorbitan esters (E 491–495) and would not be of safety concern.

KEYWORDS

acrylamide reducing yeast, ARY, E 491, food additive, sorbitan, sorbitan esters, sorbitan monostearate

CONTENTS

1 | INTRODUCTION

The present scientific opinion deals with the safety evaluation of a proposed amendment of the conditions of use of the food additive sorbitan monostearate (E 491) in accordance with Annex III, Part 3 to Regulation (EC) No 1333/2008, with respect to the intended use as a food additive in preparations of the food enzyme asparaginase (also known as Acrylamide reducing yeast, or ARY).

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

1.1.1 | Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008[1] on food additives. Only food additives that are included in the Union list, in particular in Annex II to that regulation, may be placed on the market and used in food under the conditions of use specified therein. Moreover, food additives shall comply with the specifications as referred to in Article 14 of that Regulation and laid down in Commission Regulation (EU) No 231/2012.[2] Sorbitan monostearate (E 491) was re-evaluated by EFSA in 2017 that established a group ADI of 10 mg/kg bw per day expressed as sorbitan for sorbitan esters (E 491–495).

The European Commission received a request for the extension of use of sorbitan monostearate (E 491) in enzyme preparations.

1.1.2 | Terms of Reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002,[3] the European Commission asks the European Food Safety Authority to perform a risk assessment and to provide a scientific opinion on the safety of the proposed amendment of the conditions of use of the food additive sorbitan monostearate (E 491), in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.[4]

1.2 | Information on existing evaluations and authorisations

1.2.1 | Information on existing evaluations and authorisations of the food additive sorbitan monostearate (E 491)

Sorbitan monostearate (E 491) is a food additive authorised according to Annex II and Annex III of Regulation (EC) No 1333/20081, its uses regulated in combination within the group of sorbitan esters (E 491–495). Specific purity criteria of sorbitan monostearate (E 491) have been defined in Commission Regulation (EU) No 231/20122.

According to Regulation (EU) No 257/2010,[5] the safety of sorbitan monostearate (E 491) as a food additive was re-evaluated by the Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) in 2017, together with the other food additives of the group sorbitan esters: sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) (EFSA ANS Panel, 2017a).

The ANS Panel noted that after oral administration, sorbitan monostearate (E 491) can be either hydrolysed to its fatty acid moiety and the corresponding anhydrides of sorbitol and excreted via urine or exhaled as CO_2 or excreted intact in the faeces. The ANS Panel considered that sorbitan esters did not raise concern for genotoxicity. Based on the no observed adverse effect level (NOAEL) of 2600 mg sorbitan monostearate/kg bw per day and applying an uncertainty factor of 100, the ANS Panel derived an acceptable daily intake (ADI) of 26 mg sorbitan monostearate/kg bw per day. The ANS Panel noted that the available biological and toxicological data for sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) were limited but considered that a read across with data on sorbitan monostearate could be performed. Therefore, taking into account the ratio between the molecular weight of sorbitan monostearate (430.62 g/mol) and sorbitan (164.16 g/mol), a group ADI of 10 mg/kg bw per day, expressed as sorbitan, was derived for sorbitan esters (E 491–495) singly or in combination. The ANS Panel concluded that the exposure at the mean and the 95th percentile, using a *refined non-brand-loyal* exposure assessment scenario, did not exceed the ADI

[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.

[2]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.

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

[4]Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 354, 31.12.2008, p. 1.

[5]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.

in any of the population groups. It is worth noting that at the time of the re-evaluation, in the absence of any information on the identity(ies) of the sorbitan ester(s) in which the maximum permitted levels (MPLs) and the reported use levels were expressed, the ANS Panel calculated the exposure to sorbitan esters (E 491–495) by assuming that they were expressed as sorbitan monostearate.

Based on the data available at the time of the re-evaluation, the exposure assessment performed by the ANS Panel could not take into account the use of sorbitan esters (E 491–495) according to Annex III of Regulation (EC) No 1333/2008. The ANS Panel issued recommendations to the European Commission for revising the MPLs for sorbitan esters (E 491–495) set in Annex II to Regulation (EC) No 1333/2008 by expressing them as sorbitan equivalents. In addition, it was recommended that data on the uses and use levels as well as analytical data on the actual presence of sorbitan esters (E 491–495), including information on their use according to Annex III to Regulation (EC) No 1333/2008, should be provided in order to perform a more realistic refined exposure assessment (EFSA ANS Panel, 2017a).

1.2.2 | Information on existing evaluations and authorisations of the food enzyme 'acrylamide reducing yeast' (ARY)

With respect to the present application, the proposed change to the permitted conditions of use of sorbitan monostearate (E 491) aims at amending Annex III to Regulation (EC) No 1333/2008, to include E 491 as a food additive for use in an instantaneous dry yeast, rich in asparaginase, also called 'Acrylamide reducing yeast (ARY)'. Among the already authorised uses of E 491 in foods according to Annex II of Regulation (EC) No 1333/2008, the food additive is permitted at *quantum satis* in food category (FC) 12.8 (Yeast and yeast products), restricted to dry yeast and yeast for baking.

Asparaginase (EC 3.5.1.1) is an enzyme which catalyses hydrolysis of asparagine into aspartic acid and ammonia. The food enzyme 'asparaginase', obtained with genetically modified microorganisms, is used by the food industry for acrylamide mitigation measures (EFSA CEP Panel, 2024).

The status of ARY was clarified by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) at its meeting held on 22 June 2022,[6] indicating that: 'ARY is obtained under specific production conditions of a specific strain of *Saccharomyces cerevisiae*. The specific strain is selected on a specific media and treated with UV light to induce and enhance the asparagine-degrading cell-wall asparaginase II activity. Asparaginase activity produced is carried out by the living yeast cells. After production, the catalytic protein remains in the yeast cell wall and is not separated from it (i.e. it is not extracted from its source). The yeast cream is further concentrated, extruded and dried to get the commercial product with a standardised asparaginase activity level. The food additive sorbitan monostearate (E 491) is added to the yeast cells to protect it during drying and assists in the dispersion and rehydration of the product in its application'. During the same meeting, the SCoPAFF further stated that ARY is not considered a microbial culture traditionally used in the production of bakery products (i.e. as baker's yeast) but, because it is specifically produced to display and enhance enzyme asparaginase activity with a standardised level, it should be considered to meet the definition of a food enzyme. In addition, because its main function is to catalyse a specific biochemical reaction for a technological purpose in the food to which it is added, its use represents an intentional use as a food enzyme and as such subject to the applicable legislation. Consequently, only food additives included in Annex II and Annex III to Regulation (EC) No 1333/2008 may be used in the food enzyme ARY, hence the rationale for the present application.

EFSA has received application dossiers for the evaluation of the food enzyme asparaginase for the intended use described above, i.e. prevention of acrylamide formation for the intended use described above, however their assessment is still ongoing at the time of adoption of the present opinion.[7]

2 | DATA AND METHODOLOGIES

2.1 | Data

The present evaluation is based on the data submitted in the application dossier (Documentation provided to EFSA No 1) received in August 2024, plus the additional information received on March 17, 2025 (Documentation provided to EFSA No 2) and on March 27, 2025 (Documentation provided to EFSA No 3).

In addition, food consumption data from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database)[8] were used to estimate the dietary exposure to E 491–495, and information from Mintel's Global New Products Database (GNPD)[9] was used to identify their use in food and beverage products and food supplements.

[6] https://food.ec.europa.eu/document/download/e93493ce-cc0c-4d19-a95c-ac454088fadf_en?filename=reg-com_toxic_20220622_sum.pdf.

[7] https://open.efsa.europa.eu/questions/EFSA-Q-2024-00076; https://open.efsa.europa.eu/questions/EFSA-Q-2023-00656.

[8] https://www.efsa.europa.eu/en/data-report/food-consumption-data.

[9] https://www.gnpd.com/sinatra/home/, accessed in April 2025. The Mintel GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information of over 4.5 million food and beverage products of which more than 1,400,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently having 24 out of its 27 member countries and Norway is also presented in the Mintel GNPD. Missing countries are Cyprus, Luxembourg and Malta.

In accordance with Art. 38 of the Commission Regulation (EC) No 178/20023 and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation and of the Decision of the EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[10] the non-confidential version of the dossier is published on Open.EFSA.[11] According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 10 February to 3 March 2025.[12] No comments on the disclosed information were received.

2.2 | Methodologies

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

The current 'Guidance for submission for food additive evaluation' (EFSA ANS Panel, 2012) has been followed by the FAF Panel for evaluating this application.

The approach and the methodology used to calculate the different dietary exposure scenarios presented in this opinion are described in the 2017 ANS Panel statement on the 'Approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation' (EFSA ANS Panel, 2017b) and in the EFSA Guidance 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011).

To estimate the exposure to the food additive, nomenclature from the FoodEx2 classification system (EFSA, 2015) used in the Comprehensive Database was linked to the food categorisation system of Annex II to Regulation (EC) No 1333/2008, part D. Uncertainties in the exposure assessment were identified and discussed (Section 3.2.2.2).

3 | ASSESSMENT

3.1 | Authorised uses and use levels

Maximum permitted levels (MPLs) for sorbitan monostearate (E 491), as part of the group sorbitan esters (E 491–495), have been defined in Annex II and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives, as amended.

Sorbitan monostearate (E 491), as part of the group sorbitan esters (E 491–495), is currently authorised in 16 different food categories. The MPLs range from 500 to 10,000 mg/kg for 13 food categories, and the use is permitted at *quantum satis* (QS) in the other three food categories. The food additives E 492 and E 493 are authorised in two additional food categories. Table 1 summarises the food categories in which the use of the group sorbitan esters (E 491–495), E 492 and E 493 is permitted and the corresponding MPLs as set out in Annex II to Regulation (EC) No 1333/2008, as amended.

At the time of the 2017 re-evaluation, the ANS Panel assumed that the MPLs for the group E 491–495 were expressed as sorbitan monostearate (E 491). A recommendation was issued to the European Commission for expressing the MPLs in sorbitan equivalents, however this has not yet been followed up.

For the present assessment, in line with the 2017 re-evaluation, the MPLs for the group E491–495 were considered to be expressed as sorbitan monostearate (E 491) and then converted into sorbitan equivalents using the ratio between the molecular weight of the food additive and sorbitan (2.6 for E 491). Also, the MPLs for the individual food additives E 492 and E 493 were converted into sorbitan equivalents using the factors of 5.9 and 2.1, respectively.

TABLE 1 Currently authorised uses and use levels for sorbitan esters (E 491–495), E 492 and E 493 in foods according to Annex II to Regulation (EC) No 1333/2008 (expressed in mg/kg or mg/L).

Food category number	Food category name	E-number/ group	Restrictions/ exception	MPL (mg/L or mg/kg as appropriate)[a]	Sorbitan equivalents (mg/L or mg/kg as appropriate)[b]
01.4	Flavoured fermented milk products including heat-treated products	E 491–495		5000	1923
01.8	Dairy analogues, including beverage whiteners	E 491–495	Only milk and cream analogues	5000[c]	1923

(Continues)

[10]Decision https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements.

[11]The non- confidential version of the dossier, following EFSA's assessment of the applicant's confidentiality requests, is published on Open.EFSA and is available at the following link: https://open.efsa.europa.eu/dossier/FAD-2023-20310.

[12]https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000003go3V/pc1316.

TABLE 1 (Continued)

Food category number	Food category name	E-number/ group	Restrictions/ exception	MPL (mg/L or mg/kg as appropriate)[a]	Sorbitan equivalents (mg/L or mg/kg as appropriate)[b]
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	E 491–495		10,000[c]	3846
03	Edible ices	E 491–495		500[c]	192
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC	E 493	Only jelly marmalade	25	12
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	E 492		10,000	1704
05.2	Other confectionery including breath freshening microsweets	E 491–495	Only sugar confectionery	5000[c]	1923
05.2	Other confectionery including breath freshening microsweets	E 492	Only cocoa-based confectionery	10,000	1704
05.3	Chewing gum	E 491–495		5000[c]	1923
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	E 491–495		5000[c]	1923
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	E 492	Only cocoa-based confectionery	10,000	1704
07.2	Fine bakery wares	E 491–495		10,000[c]	3846
12.6	Sauces	E 491–495	Only emulsified sauce	5000[c]	1923
12.8	Yeast and yeast products	E 491–495	Only dry yeast and yeast for baking	*Quantum satis*[d]	
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	E 491–495		5000[c]	1923
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 491–495		5000[c]	1923
14.1.5.2	Other non-alcoholic beverages	E 491–495	Only liquid tea concentrates and liquid fruit and herbal infusion concentrates	500[c]	192
16	Desserts excluding products covered in categories 1, 3 and 4	E 491–495		5000[c]	1923
17.1	Food supplements supplied in a solid form, excluding food supplements for infants and young children	E 491–495		*Quantum satis*[c,d]	–
17.2	Food supplements supplied in a liquid form, excluding food supplements for infants and young children	E 491–495		*Quantum satis*[c,d]	–

Abbreviation: MPL, maximum permitted level.

[a]In line with the previous ANS Panel opinion on the re-evaluation of E 491–495 (EFSA ANS Panel, 2017a), the MPLs for the group E491–495 were considered to be expressed as sorbitan monostearate (E 491).

[b]MPLs were converted into sorbitan equivalents using the ratio between the molecular weight of the food additive and sorbitan (2.6 for E 491, 5.9 for E 492 and 2.1 for E 493).

[c]The additives may be added individually or in combination.

[d]In the previous ANS Panel opinion on the re-evaluation of E 491–495 (2017a), maximum levels used in the exposure assessment for the food categories (FCs) authorised at *quantum satis* were 13,000, 5000 and 5000 mg/kg for FCs 12.8, 17.1 and 17.2, respectively.

According to Annex III, Part 1 to Regulation (EC) No 1333/2008, sorbitan esters, including sorbitan monostearate (E 491), are also authorised as carriers in food additives (colours and anti-foaming agents; glazing agents for fruit) at *QS*, and as food additives other than carriers (preparations of colours, anti-foaming agents and glazing agents for fruit) at *QS*, according to Part 2 of the same Annex. According to Part 5, Section A, sorbitan esters, including sorbitan monostearate

(E 491), are also authorised as food additives in nutrients (in β-carotene, lutein, lycopene and vitamin E preparations at *QS*; and in vitamin A and D preparations at 2 mg/kg in the final food).

3.1.1 | Proposed amendment of the conditions of use of the food additive sorbitan monostearate (E 491) in food enzyme preparations

The applicant proposed an amendment of the conditions of use of the food additive sorbitan monostearate (E 491) for use as a food additive in food enzyme preparations according to Annex III, Part 3 to Regulation (EC) No 1333/2008. More information on the specific enzyme asparaginase in which the food additive is intended to be added is presented in Section 1.2.2.

The applicant proposed use levels of E 491 in the food enzyme preparations ranging from 12,000 to 20,000 mg per kg of active yeast. Additionally, the applicant indicated that up to 10 g of the yeast preparation is used per kg of flour, leading to a maximum level of 200 mg E 491 per kg of final food, resulting from the use of the enzyme preparation in the six food categories reported in Table 2 (Documentation provided to EFSA No 1, 2, 3). The Panel noted that this maximum use level implied that the final foods consisted for 100% of flour. According to the proposal made by the applicant, E 491 is not intended to be used in food enzyme preparations used in beverages.

TABLE 2 Conditions of use of sorbitan monostearate (E 491) as a food additive in food enzymes according to Annex III, Part 3 to Regulation (EC) 1333/2008, as proposed by the applicant (Documentation provided to EFSA No 1, 2, 3).

E-number of the added food additive	Name of the added food additive	Maximum level of E 491 in enzyme preparation (mg/kg)	Maximum level of E 491 in enzyme preparation expressed as sorbitan equivalents[a] (mg/kg)	Maximum level of E 491 in final food except beverages		
				Food category (FC)	mg/kg expressed as E 491 in final food	mg/kg expressed as sorbitan equivalents[a] in final food
E 491	Sorbitan monostearate	20,000	7700	FC 06.3	200	77
				FC 07.1	200	77
				FC 07.2	200	77
				FC 12.8	200	77
				FC 13.1.3 in biscuits, rusks and cookies[b]	200	77
				FC 15.1	200	77

Abbreviation: FC, food category.

[a]Proposed maximum use levels were converted into sorbitan equivalents by the Panel using the ratio (2.6) between the molecular weight of the food additive E 491 and sorbitan.

[b]The applicant proposed to classify the use under FC 13.1. However, based on the proposed restriction, the Panel considered it more appropriate to re-classify the use under FC 13.1.3.

Among the six food categories in Table 2, the use of E 491 is already authorised as part of the authorisation for the group E 491–495 in FC 7.2 'Fine bakery wares' (MPL = 10,000 mg/kg) and FC 12.8 'Yeast and yeast products' (authorised use at QS), as indicated in Annex II to Regulation (EC) No 1333/2008. The Panel noted that for the food categories with numerical MPLs in Annex II to Regulation (EC) No 1333/2008, the MPLs also account for the amount resulting from the uses of the additives as specified in Annex III.

3.2 | Exposure assessment

To address the Terms of Reference of the present mandate, the estimated dietary exposure to sorbitan potentially resulting from the proposed amendment of conditions of use of E 491 in preparations of the food enzyme ARY was compared to the exposure to sorbitan resulting from the currently permitted uses of the group sorbitan esters (E 491–495), when used individually or in combination. Both exposure estimates were compared with the group ADI. To this end, the previous dietary exposure estimates resulting from the currently permitted uses of E 491–495 were updated.

For the present dietary exposure assessment, the Panel considered it appropriate to express the exposure in sorbitan equivalents resulting from either E 491 or any other food additive from the group E 491–495 used alone or in combination. In the 2017 re-evaluation opinion, the dietary exposure was expressed as sorbitan monostearate (EFSA ANS Panel, 2017a). In addition, food consumption data in the Comprehensive Database have been updated with the inclusion of more recent dietary surveys.

The Panel noted that the applicant provided dietary exposure estimates for sorbitan monostearate (E 491) using the Food Additive Intake Model 2.0 (FAIM) (Documentation provided to EFSA No 1) however these were not considered sufficiently refined for the present assessment.

3.2.1 | Exposure data

3.2.1.1 | *Available information on use levels of sorbitan esters (E 491–495) in food*

Data on the occurrence of sorbitan esters (E 491–495) in food were collected at the time of their re-evaluation by the ANS Panel via calls for data[13,14,15] issued between 2009 and 2014. In response to these calls, 42 use levels of sorbitan esters (E 491–495) were submitted to EFSA by interested business operators (IBOs) for 15 out of the 18 food categories in which sorbitan esters (E 491–495) are authorised individually or in combination (EFSA ANS Panel, 2017a).

In the 2017 re-evaluation, the ANS Panel noted that no information was provided on the identity(ies) of the sorbitan ester(s) in which the reported use levels were expressed, and therefore assumed that all the levels were expressed as sorbitan monostearate (E 491) (EFSA ANS Panel, 2017a). The same assumption was applied by the FAF Panel in the current assessment.

A summary of the reported use levels of sorbitan esters (E 491–495) is provided in Annex A, Table A1.

3.2.1.2 | *Summarised data extracted from the Mintel's global new products database (GNPD)*

According to Mintel's GNPD, E 491–495, individually or in combination, were labelled on 992 products between January 2020 and April 2025, mainly belonging to the subcategories 'Cakes, Pastries & Sweet Goods', 'Sweet Biscuits/Cookies', 'Baking Ingredients & Mixes' and 'Seasonal Chocolate'.

Restricting the search to E 491 returned approximately 230 products, nearly half of which belong to 'Baking Ingredients & Mixes'. Within the products labelled with one or more of the additives E 491–495, E 492 is present in nearly 80% of cases.

On average, only 0.7% of all foods across the subcategories with at least one food labelled to contain a sorbitan ester, were labelled with at least one of the food additives belonging to the group E 491–495.

Detailed information can be found in Table A3, Annex A.

3.2.1.3 | *Food consumption data used for the exposure assessment*

3.2.1.3.1 | *EFSA Comprehensive European Food Consumption Database*

Food consumption data of infants, toddlers, children, adolescents, adults and the elderly in the Comprehensive Database were used for this exposure assessment. Food consumption data were available from 43 different dietary surveys carried out in 22 European countries.[16] The details of the population groups considered and the countries with food consumption surveys available are presented in Annex A, Table A12.

3.2.1.3.2 | *Food categories considered for the exposure assessment of sorbitan from sorbitan esters (E 491–495)*

The food categories in which the use of sorbitan esters (E 491–495) is currently authorised (Table 1), and in which the amendment of the condition of use of sorbitan monostearate (E 491) is proposed (Table 2), were selected from the nomenclature of the Comprehensive Database (FoodEx2 classification system), at the most detailed level possible (up to FoodEx2 Level 7) (EFSA, 2015).

The Panel noted that no use levels were provided for three food categories by the IBOs in reply to the calls for data for the re-evaluation of E 491–495, and therefore could not be considered in the refined exposure scenarios (missing use levels for FCs 01.4, 13.2 and 17.2).

In the 2017 re-evaluation of sorbitan esters (E 491–495), the ANS Panel noted that for four FCs (FCs 3, 12.6, 13.3 and 14.1.5.2), use levels were provided only by a food ingredient manufacturer and were therefore not considered in the refined exposure scenarios, in accordance with the 'Approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation' (EFSA ANS Panel, 2017b).

Sorbitan esters (E 491–495) are permitted for use in FCs 17.1 'Food supplements supplied in a solid form, excluding food supplements for infants and young children' and 17.2 'Food supplements supplied in a liquid form, excluding food supplements for infants and young children'. Since exposure to a food additive via food supplements may deviate largely from that via food, and the number of consumers of food supplements may be low depending on populations and surveys, the use levels submitted for food supplements (FC 17) were excluded from the exposure assessment for the general

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

[14]Call for food additives usages level and/or concentration data in food and beverages intended to human consumption. Published: 27 March 2013. Available online: http://www.efsa.europa.eu/en/dataclosed/call/130327.

[15]Call for scientific data on selected food additives permitted in the EU- Extended deadline: 1 September 2014 (batch A), 1 November 2014 (batch B) Available online: http://www.efsa.europa.eu/en/dataclosed/call/140324.htm.

[16]Not all Member States provided consumption information for all population groups, and in some cases the same country provided food consumption data from more than one consumption survey. In most cases, when, for one country and age class, different dietary surveys were available, only the most recent was used. However, when two national surveys from the same country gave a better coverage of the age range than using only the most recent one, both surveys were kept. For details on each survey, see Annex A.

population and were instead included in a separate exposure scenario ('*food supplements consumers only*' exposure assessment scenario, see Section 3.2.2) (EFSA ANS Panel, 2017b).

Sorbitan esters (E 491–495) are permitted for use in FCs 13.2 'Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)' and FC 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)'. Eating occasions belonging to these two food categories are for foods for special medical purposes (FSMPs). Since these foods are very diverse and their consumption is not always well reported in dietary surveys, eating occasions belonging to these food categories have been mostly reclassified under food categories according to their main component (e.g. meal replacement drinks as flavoured drinks).

The Panel noted that at the time of the re-evaluation in 2017, a food ingredient manufacturer provided a use level for FC 17.3 'Food supplements supplied in a syrup-type or chewable form'. Because this food category is no longer present in the current food categorisation system according to Regulation (EC) No 1333/2008, this use level was not considered in the present assessment.

The refinements considering the restrictions/exceptions as set in Annex II to Regulation No 1333/2008 and the proposed new uses were applied.

Overall, out of the 18 food categories in which E 491–495, E 492 and E 493 are currently authorised, 16 food categories were considered in the *regulatory maximum exposure assessment* scenario, 10 food categories in the *refined exposure assessment* scenario and 11 in the '*food supplements consumers only*' scenario. When taking into account also the proposed amendment of the uses of E 491, an extra four food categories were considered.

Similarly to the previous re-evaluation, the Panel noted that, based on the available data, the current exposure assessment could not account for the use of sorbitan esters (E 491–495) according to Annex III to Regulation (EC) No 1333/2008, except for the uses deriving from the proposed amendment of the conditions of use of sorbitan monostearate (E 491) (see Table 2).

An overview of the concentration levels of sorbitan esters (E 491–495) and food categories used in each exposure assessment scenario is provided in Annex A, Table A2.

3.2.2 | Dietary exposure estimates

Exposure assessment to sorbitan deriving from the current authorised uses of E 491–495 was carried out by the Panel based on two different sets of concentration data: (1) MPLs as set down in the EU legislation or maximum reported use levels for food categories with a permitted use at QS (defined as the *regulatory maximum level exposure assessment scenario*) and (2) reported use levels (defined as the *refined exposure assessment scenario*). To estimate the overall dietary exposure to sorbitan, the one resulting from the current authorised uses of E 491–495 was complemented with the additional exposure resulting from the proposed amendment of the conditions of use of E 491.

In the 2017 re-evaluation of sorbitan monoesters (E 491–495), the ANS Panel considered the *refined non-brand-loyal* scenario as the most relevant, and this scenario was therefore used to conclude on the safety of the food additives (EFSA ANS Panel, 2017a). In light of this, the Panel decided to only estimate the refined exposure via the refined *non-brand loyal* scenario.

The '*food supplements consumers only*' scenario only covers the following population groups: children, adolescents, adults and the elderly (EFSA ANS Panel, 2017b). This additional exposure scenario assumes that consumers of food supplements were chronically exposed to E 491–495 present at the maximum reported use level in food supplements. Only FC 17.1 could be considered in the assessment as no use levels were provided for FC 17.2 (Table A2, Annex A). For the remaining food categories, the mean of the typical reported use levels was used. The Panel noted that the '*food supplements consumers only*' scenario was not performed by the EFSA ANS Panel in the 2017 re-evaluation.

The different exposure scenarios estimated by the Panel are summarised in Table 3 and the estimates are presented in Table 4.

TABLE 3 Summary table of the exposure assessment scenarios.

Uses	Population groups considered	Scenario	Concentration data used	Food categories considered
Currently permitted uses for E 491–495	General population	Regulatory maximum exposure assessment scenario	• MPLs according to Annex II to Regulation (EC) No 1333/2008 • Maximum Use levels provided by IBOs for the group E 491–495, E 492 and E 493 at the time of the re-evaluation in 2017, where the regulatory limit is at QS	All authorised food categories except food supplements (FC 17)
		Refined non-brand- loyal scenario	• Typical use levels provided by IBOs for the group E 491–495, E 492 and E 493 at the time of the re-evaluation in 2017	All authorised food categories for which reliable numerical use levels are available except food supplements (FC 17)
	Consumers of food supplements	Food supplements consumers only scenario	• Typical use levels provided by IBOs for the group E 491–495, E 492 and E 493 at the time of the re-evaluation in 2017	All authorised food categories for which reliable numerical use levels are available
Currently permitted uses for E 491–495 + proposed amendment of the conditions of use of E 491	General population	Regulatory maximum exposure assessment scenario	• MPLs according to Annex II to Regulation (EC) No 1333/2008 • Maximum Use levels provided by IBOs for the group E 491–495, E 492 and E 493 at the time of the re-evaluation in 2017, where the regulatory limit is at QS • Maximum level of E 491 expected in final food as a result of the proposed use of E 491 according to Annex III	• All authorised food categories except food supplements (FC 17) • Food categories where E 491 is expected to be present as a result of the proposed use of E 491 according to Annex III in enzyme preparations
		Refined non-brand-loyal scenario	• Typical use levels provided by IBOs for the group E 491–495, E 492 and E 493 at the time of the re-evaluation in 2017 • Maximum level of E 491 expected in final food as a result of the proposed use of E 491 according to Annex III	All authorised food categories for which reliable numerical use levels are available except food supplements (FC 17)
	Consumers of food supplements	Food supplements consumers only scenario	• Typical use levels provided by IBOs for the group E 491–495, E 492 and E 493 at the time of the re-evaluation in 2017 • Maximum level of E 491 expected in final food as a result of the proposed use of E 491 according to Annex III	• All authorised food categories for which reliable numerical use levels are available • Food categories where E 491 is expected to be present as a result of the proposed use of E 491 according to Annex III

Abbreviations: FC, food category; IBO, interested business operator; MPL, maximum permitted level.

TABLE 4 Summary of the dietary exposure to sorbitan deriving from: (i) the current authorised uses of E 491–495, individually or in combination and (ii) the current authorised uses of E 491–495, individually or in combination, and proposed amendment of the conditions of use of E 491. The table reports the results according to the different exposure assessment scenarios used, per population group (mean and 95th percentile) (mg/kg bw per day).

Estimated exposure (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, general population						
Current authorised uses of E 491–495						
Mean	0.4–8.2	7.6–33.4	9.5–26.1	4.4–12.3	1.3–6.3	1.2–6.3
95th percentile	1.6–34.6	23.6–69.8	21.7–50.8	9.9–28.6	4.7–15.5	5.7–13.9
Current authorised uses of E 491–495 and proposed amendment of the conditions of use of E 491 in food enzyme preparations						
Mean	0.5–8.4	7.9–34.0	9.9–26.3	4.6–12.6	1.4–6.4	1.4–6.4
95th percentile	1.7–34.9	23.9–69.8	22.7–51.2	10.2–28.9	4.9–15.9	5.9–14.0
Refined exposure assessment scenario (*non-brand-loyal*), general population						
Current authorised uses of E 491–495						
Mean	0.1–1.5	0.8–6.1	1.4–4.2	0.6–2.0	0.3–1.2	0.2–1.2
95th percentile	0.4–7.9	2.0–13.7	4.1–10.3	2.0–5.5	0.9–4.2	0.9–3.7
Current authorised uses of E 491–495 and proposed amendment of the conditions of use of E 491 in food enzyme preparations						
Mean	0.1–1.9	0.9–6.8	1.7–4.8	0.8–2.4	0.4–1.4	0.4–1.4
95th percentile	0.5–8.9	2.2–13.9	4.7–11.0	2.4–6.1	1.2–4.5	1.2–3.8
'Food supplements consumers only' scenario						
Current authorised uses of E 491–495						
Mean	–	–	< 0.01–4.3	0.4–2.5	0.2–3.3	0.1–1.5
95th percentile	–	–	4.1–13.4	2.4–6.0	1.2–3.3	1.2–3.0
Current authorised uses of E 491–495 and proposed amendment of the conditions of use of E 491 in food enzyme preparations						
Mean	–	–	0.2–5.0	0.6–2.9	0.3–3.4	0.2–1.7
95th percentile	–	–	4.4–14.4	2.9–6.7	1.3–3.5	1.4–3.2

3.2.2.1 | *Main food categories contributing to exposure*

The main food categories contributing to the total mean exposure per scenario were identical for both the current authorised uses and for the current authorised uses plus the proposed amendment of the conditions of use of E 491.

For the general population, the main food categories in the *regulatory maximum level exposure assessment* scenarios were FCs 7.2 'Fine Bakery Wares' and 1.4 'Flavoured Fermented Milk Products including heat-treated products'. In the *refined non-brand-loyal* scenarios, the main food category was FC 7.2 'Fine bakery wares'. In the four surveys with the highest exposure levels, the other main contributors were FCs 5.1 'Cocoa and Chocolate products as covered by Directive 2000/36/EC', 16 'Desserts excluding products covered in category 1, 3 and 4', 1.8 'Dairy analogues, including beverage whiteners' and 2.2.2 'Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions'.

Detailed results per scenario and by population group and survey are presented in Annex A, Table A6–A11.

3.2.2.2 | *Uncertainty analysis*

In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 5.

TABLE 5 Qualitative evaluation of influence of uncertainties on the dietary exposure assessment of sorbitan.

Sources of uncertainties	Direction[a]
Consumption data	
Different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
FCs 13.2 and 13.3 partially considered through other food categories	–
Methodology	
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+

(Continues)

TABLE 5 (Continued)

Sources of uncertainties	Direction[a]
Concentration data	
Correspondence of (proposed) 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	+/–
Use levels considered applicable to all foods within each food category, whereas most probably not all foods belonging to a proposed food category will contain E 491–E495, individually or as a group, as food additives (according to Mintel's GNPD, on average only 0.7% of foods across all subcategories with at least one food labelled to contain sorbitan esters, were labelled with at least one sorbitan ester)	+
MPLs and all use levels for the group E 491–495 were converted to sorbitan equivalents using a conversion factor based on the molecular weight for sorbitan monostearate, which is more than 2-fold lower than the one for E 492, but in the same range for E 493–495 – According to Mintel's GNPD, E 492 is the most frequently used food additive within the group (E 491–495), therefore using the sorbitan conversion factor for E 491 for the whole group provides for conservative occurrence data	+
Regulatory maximum level exposure assessment scenarios: – Exposure calculations based on the MPLs according to Annex II to Regulation (EC) No 1333/2008 – Inclusion of all the food categories in which the use of sorbitan esters is authorised according to Annex II of Regulation (EC) No 1333/2008	+ + +
Refined scenarios: – Exposure calculations based on the use levels provided – Reliable data on use levels for seven food categories not available and therefore not included in the refined exposure assessment	+/– –
Proposed MPLs for amendment of Annex III with proposed inclusion of E 491: – The assumptions proposed by the applicant and used by the Panel to calculate the carry-over from the enzyme preparation, i.e. taking the highest proposed use levels of E 491 in the food enzyme preparations, the highest use level of the yeast preparation to treat flour and assuming the final food is comprised of 100% flour	+
Other potential sources of dietary exposure to sorbitan esters – Uses according to Annex III Part 1, 2 and 5 of sorbitan esters (E 491–495) not considered in exposure assessment scenarios because no data were available.	–

[a]+, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Overall, the Panel considered that the uncertainties identified resulted in an overestimation of the exposure to sorbitan resulting from (i) the current authorised uses of sorbitan esters (E 491–495) and (ii) the current authorised uses of E 491–495 and proposed amendment of the conditions of use of E 491, in European countries for which food consumption data are available in the EFSA Comprehensive database.

In all exposure scenarios, including the *refined non-brand-loyal* scenario, the overestimation was mainly due to the assumptions that:

1. all foods belonging to an authorised food category contained sorbitan esters whereas, on average, only 0.7% of all foods across the subcategories with at least one food labelled with a sorbitan ester, was labelled to contain sorbitan esters in Mintel; and
2. use levels for the group E 491–495 were converted to sorbitan equivalents using a conversion factor based on the molecular weight of E 491 (430.62 g/mol), which is more than two-fold lower than that of E 492 (963.56 g/mol), whereas, according to Mintel, E 492 is the most frequently used food additive within the group of sorbitan esters (E 491–495).

4 | DISCUSSION

The present opinion deals with the evaluation of a proposed amendment of the conditions of use of the food additive sorbitan monostearate (E 491) in food enzyme preparations.

The currently permitted uses and use levels of this food additive (E 491) are set in Regulation (EC) No 1333/2008 for the group of sorbitan esters (E 491–495).

The present application proposes the inclusion of E 491 in Part 3 of Annex III, among the food additives permitted for use in enzyme preparations. The intended use of E 491 is in the food enzyme asparaginase used for the reduction of the formation of acrylamide (also known as ARY). To this end, the applicant has provided one maximum use level of E 491 in all final foods for six food categories in which ARY is expected to be applied.

The current group ADI of 10 mg sorbitan/kg bw per day was derived by the ANS Panel in 2017 and is applicable to the whole group of sorbitan esters (E 491–495). To address the Terms of Reference of the present mandate, the estimated dietary exposure to sorbitan potentially resulting from the proposed amendment to the currently permitted conditions of use of E 491 in preparations of the food enzyme ARY was compared to the exposure to sorbitan resulting from the currently permitted uses of the group sorbitan esters (E 491–495), when used individually or in combination. Both exposure estimates were also compared with the group ADI established by the ANS Panel in 2017.

For the present assessment, the Panel considered it appropriate to update the previous dietary exposure estimates using the currently applicable MPLs and the reported use levels for the food additives belonging to the group of sorbitan esters (E 491–495) that were provided by IBOs at the time of their re-evaluation in 2017. As in 2017, the Panel assumed that the levels referring to the group E 491–495 were expressed as sorbitan monostearate (E 491) and converted them to sorbitan equivalents to allow a comparison with the group ADI of 10 mg sorbitan/kg bw per day. For this reason, also MPLs and use levels for the individual food additives E 492 and E 493 were converted to sorbitan equivalents. In addition, the Panel noted that the food consumption data from the Comprehensive Database used in the present assessment has been updated and differed from those used at the time of the 2017 ANS Panel re-evaluation with the introduction of more recent dietary surveys.

Different exposure assessment scenarios were used by the Panel as described in Section 3.2.2 and the *refined non-brand-loyal* scenario was selected as the most relevant for the risk assessment, in line with the previous ANS Panel opinion.

Taking into account the proposed amendment of the conditions of use of E 491, the highest estimated 95th percentile of exposure in this scenario, 13.9 mg/kg bw per day in toddlers, exceeded the ADI of 10 mg sorbitan/kg bw per day. The Panel noted that the highest 95th percentile for children, 11 mg/kg bw per day, was also above the ADI.

The Panel noted that the updated estimates of the exposure to sorbitan deriving solely from the current authorised uses of E 491–495 are higher than those previously estimated by the ANS Panel in 2017. It is worth noting that the observed exceedances of the ADI were due to three dietary surveys that were not available at the time of the 2017 re-evaluation. In these surveys, the main contributors to the exposure in toddlers and children were FCs 7.2 'Fine bakery wares', 5.1 'Cocoa and Chocolate products as covered by Directive 2000/36/EC', 16 'Desserts excluding products covered in category 1, 3 and 4' and 1.8 'Dairy analogues, including beverage whiteners'.

When considering the proposed amendment of the conditions of use of E 491, a slight exceedance of the ADI was observed in toddlers in an additional survey that was not available at the time of the 2017 re-evaluation. In all the surveys in which the ADI was exceeded, the main contributing food categories were the same as for the scenario considering only the current authorised uses.

Taking into account all the uncertainties identified and described in Section 3.2.2, the Panel considered that the exposure estimates for all exposure scenarios resulted in an overestimation of the exposure to sorbitan both at the currently authorised use of E491–495 and when taking into account – the proposed amendment of the conditions of use of E 491 in preparations of the food enzyme ARY. In the *refined non-brand-loyal scenario*, this overestimation was mainly due to the assumption that all foods belonging to an authorised food category contained sorbitan esters and that the use levels for the group E 491–495 were converted to sorbitan equivalents using the molecular weight for E 491. For more details see Section 3.2.2.

Considering that the updated dietary exposure estimates are overestimates of the actual exposure and that exceedance of the group ADI was observed in toddlers and children at the 95th percentile only in a limited number of surveys, the Panel does not consider that a further refinement of the exposure assessment is needed.

Therefore, the recommendations issued by the ANS Panel in 2017 with respect to the exposure assessment, should now be limited to the revision of the maximum levels for sorbitan esters (E 491–495) set in Regulation (EC) No 1333/2008 by expressing them as sorbitan equivalents.

Overall, the Panel noted that the proposed amendment of the conditions of use of sorbitan monostearate (E 491) in preparations of the food enzyme ARY has little impact on the exposure estimates in all the scenarios when comparing to the exposure estimates at the currently authorised uses.

5 | CONCLUSIONS

In updating the dietary exposure with the latest dietary surveys available, the group ADI of 10 mg sorbitan/kg bw per day was exceeded in toddlers and children at the 95th percentile in the refined non-brand loyal scenario for a limited number of dietary surveys. This observation holds true either considering the proposed amendment of the conditions of use of the food additive E 491 or only the currently permitted uses in the exposure calculations. The same conclusions apply to the dietary exposure estimates for consumers of food supplements, for which the ADI is exceeded in children at the 95th percentile. The Panel however concluded that the conservative assumptions made in the refined scenarios have resulted in a clear overestimation of the dietary exposure and therefore that the calculated exceedance of the ADI is not of safety concern.

The Panel concluded that the proposed amendment of the conditions of use of sorbitan monostearate (E 491) in preparations of the food enzyme ARY has little impact on the current dietary exposure to sorbitan resulting from the already permitted uses and reported use levels of sorbitan esters (E 491–495) and would not be of safety concern.

6 | DOCUMENTATION AS PROVIDED TO EFSA

1. Dossier 'Application for authorisation for the extension of use of the food additive Sorbitan Monostearate (E 491) in enzyme preparations in accordance with regulation (EC) NO 1331/2008'. Submitted by Renaissance BioScience Corporation. August 2024.

2. Additional information submitted by Renaissance BioScience Corporation in response to a request from EFSA. March 17th, 2025.
3. Additional information submitted by Renaissance BioScience Corporation in response to a request from EFSA. March 27th, 2025.

ABBREVIATIONS

ADI	acceptable daily intake
ANS Panel	Panel on Food Additives and Nutrient Sources added to Food
ARY	acrylamide reducing yeast
bw	body weight
CEP Panel	Panel on Food Contact Materials, Enzymes and Processing Aids
FAF Panel	Panel on Food Additives and Flavourings
FAIM	Food Additives Intake Model
FAO/WHO	Food and Agriculture Organization/World Health Organization
FC	Food Categories
GNPD	Global New Products Database
IBOs	interested business operators
MPLs	maximum permitted levels
No	number
NOAEL	no observed adverse effect level
QS	*quantum satis*
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed

ACKNOWLEDGEMENTS

The Panel wishes to thank the following for the support provided to this scientific output: Gabriele Gagliardi and Sam Vermeiren.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2024-00303

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REFERENCES

EFSA (European Food Safety Authority). (2007). Opinion of the scientific committee related to uncertainties in dietary exposure assessment. *EFSA Journal*, *5*(1), 438. https://doi.org/10.2903/j.efsa.2007.438

EFSA (European Food Safety Authority). (2011). Use of the EFSA comprehensive European food consumption database in exposure assessment. *EFSA Journal*, *9*(3), 2097. https://doi.org/10.2903/j.efsa.2011.2097

EFSA (European Food Safety Authority). (2015). The food classification and description system FoodEx2 (revision 2). *EFSA Supporting Publications*, *12*(5), EN-804. https://doi.org/10.2903/sp.efsa.2015.EN-804

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

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food). (2017a). Scientific opinion on the re-evaluation of sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) when used as food additives. *EFSA Journal*, *15*(5), 4788. https://doi.org/10.2903/j.efsa.2017.4788

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food). (2017b). Statement on approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation. *EFSA Journal*, *15*(10), 5042. https://doi.org/10.2903/j.efsa.2017.5042

EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Lambré, C., Barat Baviera, J. M., Bolognesi, C., Cocconcelli, P. S., Crebelli, R., Gott, D. M., Grob, K., Lampi, E., Mengelers, M., Mortensen, A., Rivière, G., Steffensen, I.-L., Tlustos, C., Van Loveren, H., Vernis, L., Zorn, H., Herman, L., Aguilera, J., … Chesson, A. (2024). Safety evaluation of the food enzyme asparaginase from the genetically modified aspergillus Niger strain ASP. *EFSA Journal*, *22*(7), 8874. https://doi.org/10.2903/j.efsa.2024.8874

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*, *7*(5), 1051. https://doi.org/10.2903/j.efsa.2009.1051

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Castle, L., Andreassen, M., Aquilina, G., Bastos, M. L., Boon, P., Fallico, B., FitzGerald, R., Frutos Fernandez, M. J., Grasl-Kraupp, B., Gundert-Remy, U., Gürtler, R., Houdeau, E., Kurek, M., Louro, H., Morales, P., Passamonti, S., Barat Baviera, J. M., Leblanc, J.-C., … Ruggeri, L. (2025). Scientific opinion on the safety of a proposed amendment of the conditions of use of the food additive sorbitan monostearate (E 491) in enzyme preparations. *EFSA Journal*, *23*(6), e9487. https://doi.org/10.2903/j.efsa.2025.9487

ANNEX A

Exposure data

- Table A1. Summary of the reported use levels (mg/kg or mg/L as appropriate) of sorbitan esters (E 491–495) provided by industry according to Annex II in reply to the calls for data issued between 2009 and 2014. The table also reports the levels expressed as sorbitan equivalents.
- Table A2. Concentration levels of sorbitan used for calculating the dietary exposure to sorbitan deriving from (i) the current authorised uses of E 491–495 and (ii) the current authorised uses of E 491–495 and proposed amendment to the conditions of use of E 491. Estimates refer to the general population, using the maximum level exposure scenario and the refined exposure assessment scenarios (mg/kg or mL/kg as appropriate).
- Table A3. Number and percentage of food products labelled with E 491–495, alone or in combination, out of the total number of food products present in Mintel's GNPD per subcategory where at least one food product is labelled with E 491–495, used alone or in combination. Information refers to the period between January 2020 and April 2025. The table also reports the number of products labelled with each of the additives, used alone or in combination, and the percentage out of the total number of food products labelled with either of E 491–495.
- Table A4. Summary of dietary exposure to sorbitan deriving from (i) the current authorised uses of E 491–495 and (ii) the current authorised uses of E 491–495 and proposed amendment to the conditions of use of E 491. Estimates refer to the general population, using the maximum level exposure scenario and the refined exposure assessment scenarios. Results are reported per population group and survey: mean and 95th percentile (mg/kg bw per day).
- Table A5. Summary of dietary exposure to sorbitan deriving from (i) the current authorised uses of E 491–495 and (ii) the current authorised uses of E 491–495 and proposed amendment to the conditions of use of E 491. Estimates are reported for the 'food supplements consumers only' scenario, per population group and survey: mean and 95th percentile (mg/kg bw per day).
- Table A6. Main food categories contributing to exposure to sorbitan deriving from the current authorised uses of E 491–495. Contributions (%) are reported by population class and by FC (only for FCs contributing > 5% to the total mean exposure). Scenario: NBL – current uses.
- Table A7. Main food categories contributing to exposure to sorbitan deriving from (i) the current authorised uses of E 491–495 and (ii) the current authorised uses of E 491–495 and proposed amendment to the conditions of use of E 491. Contributions (%) are reported by population class and by FC (only for FCs contributing > 5% to the total mean exposure). Scenario: NBL – ext. of use.
- Table A8. Main food categories contributing to exposure to sorbitan deriving from the current authorised uses of E 491-495. Contributions (%) are reported by population class and by FC (only for FCs contributing > 5% to the total mean exposure). Scenario: MPL – current uses.
- Table A9. Main food categories contributing to exposure to sorbitan deriving from (i) the current authorised uses of E 491–495 and (ii) the current authorised uses of E 491–495 and proposed amendment to the conditions of use of E 491. Contributions (%) are reported by population class and by FC (only for FCs contributing > 5% to the total mean exposure). Scenario: MPL – ext. of use.
- Table A10. Main food categories contributing to exposure to sorbitan deriving from the current authorised uses of E 491–495. Contributions (%) are reported by population class and by FC (only for FCs contributing > 5% to the total mean exposure). Scenario: FS consumers only – current uses.
- Table A11. Main food categories contributing to exposure to sorbitan deriving from (i) the current authorised uses of E 491–495 and (ii) the current authorised uses of E 491–495 and proposed amendment to the conditions of use of E 491. Contributions (%) are reported by population class and by FC (only for FCs contributing > 5% to the total mean exposure). Scenario: FS consumers only – ext. of use.
- Table A12. Population groups considered for the exposure estimates of sorbitan monostearate (E 491).