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Follow-up of the re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive

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Abstract

Polyglycerol esters of fatty acids (PEFA, E 475) was re-evaluated in 2017 by the former EFSA Panel on Food Additives and Nutrient sources added to Food (ANS). As a follow-up to this assessment, in this opinion, the Panel on Food Additives and Flavouring (FAF) addresses the data gaps identified to support an amendment of the EU specifications for E 475. The Panel performed a risk assessment of undesirable impurities and constituents potentially present in E 475. The Panel concluded that the maximum limits in the EU specifications for the 4 toxic elements (arsenic, lead, mercury and cadmium) should be lowered based on actual levels in the commercial food additive E 475. The Panel also concluded that maximum limits for erucic acid, 3-monochloropropanediol and glycidyl esters should be included in the EU specifications for E 475. Alternatively, the Panel recommends an amendment of the definition of E 475 to include a requirement that the fats and oils used in the manufacturing of E 475 comply with the respective EU legislation regarding suitability for human consumption. Further, the Panel concluded that there is no need for setting a specification limit for the content of *trans*-fatty acids in E 475 as a limit is established in the Regulation (EU) No 2019/649, i.e. 2 g of *trans*-fat per 100 g fat in food for the final consumer. Finally, the Panel recommends a modification of the definition of E 475 indicating that polyglycerol used for the manufacturing of E 475 should be produced from glycerol meeting the specifications for E 422 (Commission Regulation (EU) No 231/2012). In this case, respective specification limits for epichlorohydrin, acrolein and butanetriol would not be needed for E 475.

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Summary

In this opinion, the EFSA Panel on Food Additives and Flavourings (FAF Panel) was requested to assess the data provided by interested parties in support of an amendment of the EU specifications for polyglycerol esters of fatty acids (PEFA, E 475) in Commission Regulation (EU) No 231/2012.

PEFA (E 475) was re-evaluated in 2017 by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) which concluded that there was no need for a numerical acceptable daily intake (ADI) and there was no safety concern at the reported uses and use levels. The European Commission published a dedicated call for data allowing all interested parties to provide the requested information for completing the assessment. As a follow-up of the above, this opinion addresses the data gaps previously identified during the re-evaluation of E 475. According to Commission Regulation (EU) No 231/2012, PEFA (E 475) is a mixture of reaction products formed by the esterification of polyglycerols with food fats and oils or with fatty acids occurring in foods, fats and oils. The polyglycerol moiety is predominantly di-, tri- and tetraglycerol and contains not more than 10% of polyglycerols equal to or higher than heptaglycerol. Specifications for PEFA (E 475) are defined in Commission Regulation (EU) No 231/2012.

In response to the European Commission call for data, analytical data on potential impurities and undesirable constituents in commercial samples of E 475 were provided by one interested business operator (IBO) and respective limit values were proposed by them. The potential exposure to these compounds from the use of the food additive E 475 has been calculated by assuming that they may be present in the food additive up to the limit value and then by calculation pro-rata to the estimates of exposure to the food additive itself.

Analytical data on levels of toxic elements (arsenic, lead, cadmium and mercury) in commercial samples of E 475 were provided. The Panel noted that the occurrence data on toxic elements are substantially lower than the current limits in the EU specifications. The lowest technologically achievable levels for the 4 toxic elements are proposed by the IBO, being the same level for lead as given in the current EU specifications but proposing lower values for arsenic, cadmium and mercury. However, the actual measured levels for lead in commercial samples of E 475 were substantially below the proposed limit value. The Panel performed a risk assessment considering both the current limits for the 4 toxic elements in the EU specifications for E 475 (Commission Regulation (EU) No 231/2012) and the proposed lowest technologically achievable levels. The potential exposure to these impurities from the use of E 475 were compared against the available health-based guidance values (HBGVs) and reference points (RPs). The Panel concluded that for arsenic, the lower end of the range of the calculated MOE values was insufficient. For the other toxic elements (cadmium, mercury and lead), the limit values proposed by the IBO do not give rise to safety concerns.

Analytical data on levels of glycidyl esters (GEs), expressed as glycidol, in commercial samples of E 475 and a lowest technologically achievable level were also provided. The Panel calculated the potential exposure to GEs from the use of E 475, considering its presence in the food additive at the proposed lowest technologically achievable level (5 mg/kg), and compared it against the available RP. The Panel concluded that the limit value proposed for GEs (expressed as glycidol) does not give rise to a health concern. Similarly, the Panel performed a risk assessment for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) based on the proposed maximum limit (2.5 mg/kg) in E 475. By comparing the potential exposure to 3-MCPD from the use of E 475 with the available HBGV, the Panel concluded that the maximum proposed limit for the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) does not give rise to a health concern.

Considering the potential occurrence of GEs and the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) in E 475, the Panel recommends considering setting specification limit values for these impurities in Commission Regulation (EU) No 231/2012 for E 475.

No analytical data on the current levels of erucic acid in E 475 have been provided because it was stated that manufacturers of E 475 do not produce it with oils from the Brassicaceae family that may contain erucic acid. The Panel performed a risk assessment for the potential content of erucic acid in E 475 considering the maximum proposed limit for erucic acid in vegetable oils and fats as set in Regulation (EC) No 1881/2006, in case these materials were used for the production of E 475. By comparing the potential exposure to erucic acid from the use of E 475 with the available HBGV, the Panel concluded that the limit value proposed by the IBO for erucic acid does not give rise to a health concern. Considering the potential occurrence of erucic acid in E 475, the Panel recommends

considering setting a specification limit value for this component in Commission Regulation (EU) No 231/2012 for E 475.

The Panel noted that, according to the information provided by the IBO, the fats and oils potentially used in the manufacturing of E 475 are expected to comply with the Regulation (EC) No 1881/2006. However, the Panel also noted that according to the current definition of E 475 laid down in Commission Regulation (EU) No 231/2012, there is no such requirement. As an alternative to introducing specification limits for GEs, the sum of 3-MCPD and 3-MCPD fatty acid esters, and erucic acid, the specifications could include a requirement that the fats and oils used in the manufacturing of E 475 comply with the respective EU legislation regarding suitability for human consumption.

Analytical data on the levels of acrolein, butanetriol and epichlorohydrin were also requested in the European Commission call for data in line with the recommendations from the 2017 re-evaluation. According to the information provided, the Panel recommends a modification of the definition of E 475 indicating that polyglycerol used for the manufacturing of E 475 should be produced from glycerol meeting the specifications for E 422 (Commission Regulation (EU) No 231/2012). In this case, respective specification limits for acrolein, butanetriol and epichlorohydrin would not be needed for E 475.

Analytical data on the content of *trans*-fatty acids in commercial samples of E 475 were provided by the IBO. The Panel considered that *trans*-fatty acids shall meet the limit established in the Regulation (EU) No 2019/649, i.e. 2 g of *trans*-fat per 100 g fat in food for the final consumer. Hence, there is no need for setting a specification limit in Commission Regulation (EU) No 231/2012 for the content of *trans*-fatty acids in E 475.

The Panel concluded that the technical data provided by the IBO support an amendment of the specifications for polyglycerol esters of fatty acids (E 475) laid down in Commission Regulation (EU) No 231/2012.

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1. Introduction

The re-evaluation of polyglycerol esters of fatty acids (PEFA) (E 475) as a food additive was completed by EFSA in 2017 (EFSA ANS Panel, 2017a). The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) issued several recommendations to amend the specifications of the food additive PEFA (E 475) in Commission Regulation (EU) No 231/2012¹.

The data gaps and uncertainties identified by the ANS Panel required a follow-up by the European Commission by means of a call for additional data.²

The present opinion deals with the assessment of the data provided by interested parties in support of an amendment of the EU specifications for PEFA (E 475).

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008 on food additives.³ 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 foods 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.

Polyglycerol esters of fatty acids (E 475) is authorised for use as a food additive in the Union. Since polyglycerol esters of fatty acids (E 475) was permitted in the Union before 20 January 2009, it belongs to the group of food additives which are subject to a new risk assessment by the European Food Safety Authority (EFSA), according to Commission Regulation (EU) No 257/2010⁴, and in line with the provisions of Regulation (EC) No 1333/2008.

EFSA completed the re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive and published a scientific opinion on 20 December 2017.⁵ In that opinion, EFSA concluded that the food additive polyglycerol esters of fatty acids (E 475) was not of safety concern at the reported uses and use levels and that there was no need for a numerical acceptable daily intake (ADI). However, EFSA recommended that the specifications for polyglycerol esters of fatty acids (E 475) in Commission Regulation (EU) No 231/2012 are updated to current standards. In order to address that recommendation, additional technical data on the food additive polyglycerol esters of fatty acids (E 475) would be needed.

Therefore, the European Commission published on 23 November 2018 a call for data² addressing the recommendations made by EFSA in the scientific opinion on the re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive, which led to the submission by the interested business operator European Food Emulsifier Manufacturers Association (EFEMA) of new technical data on polyglycerol esters of fatty acids (E 475) in December 2020.

Consequently, the European Commission has decided to consult EFSA on this matter.

1.1.2. Terms of Reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002⁶, the European Commission requests the European Food Safety Authority (EFSA) to provide a scientific opinion to confirm that the technical data provided by interested business operators adequately support an amendment of the specifications of the food additive polyglycerol esters of fatty acids (E 475) to bring them to current standards, in line with the recommendations made by EFSA during the re-evaluation of the safety of this food additive.

¹ Commission Regulation (EU) No 231/2012: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32012R0231>

² Available online: https://ec.europa.eu/food/system/files/2019-04/fs_food-improvement-agents_reeval_call_20181123_e475_data.pdf

³ Council Regulation (EC) No 1333/2008: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1333>

⁴ Commission Regulation (EU) No 257/2010: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010R0257>

⁵ Re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive: <https://www.efsa.europa.eu/en/efsajournal/pub/5089>

⁶ Council Regulation (EC) No 178/2002: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32002R0178> OJ L 31, 1.2.2002, p. 1.

1.2. Summary of the EFSA Re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive

PEFA (E 475) was re-evaluated by the EFSA ANS Panel which concluded that there was no need for a numerical ADI and there was no safety concern at the reported uses and use levels (EFSA ANS Panel, 2017a).

However, EFSA recommended that the specifications for PEFA (E 475) in Commission Regulation (EU) No 231/2012 are updated. The following recommendations were indicated:

- the European Commission considers lowering the current limits for toxic elements (arsenic, lead, mercury and cadmium) in the EU specifications for PEFA (E 475) in order to ensure that the food additive will not be a significant source of exposure to these toxic elements in food.
- the European Commission considers revising the EU specifications for PEFA (E 475) including maximum limits for epichlorohydrin and glycidol, given that during the manufacturing processes of polyglycerols these genotoxic impurities could be present.
- the European Commission considers revising the EU specifications for PEFA (E 475) including maximum limits for *trans*-fatty acids because PEFA (E 475) can be manufactured by glycerolysis of hydrogenated fats and/or oils, which contain significant amounts of *trans*-fatty acids.
- the European Commission considers revising the EU specifications for PEFA (E 475) including maximum limits for glycidyl esters/glycidol and 3-MCPD esters, because it is likely that residues of those substances occur in the food additive PEFA (E 475), if they were present in the raw materials used in the manufacturing of the food additive by transesterification.
- the European Commission considers revising the EU specifications for PEFA (E 475) including maximum limits for erucic acid since erucic acid can be present among the fatty acids in edible oils, which can be used for manufacturing of PEFA (E 475).
- the European Commission considers revising the EU specifications for PEFA (E 475) including maximum limits for impurities currently included in the EU specifications for glycerol (E 422) or recommended by the Panel in the re-evaluation of glycerol (E 422) (EFSA ANS Panel, 2017b).

2. Data and methodologies

2.1. Data

The Panel based its assessment on the information submitted following the public call for data. One interested business operator (IBO) submitted information (Documentation provided to EFSA n. 1).

2.2. Methodologies

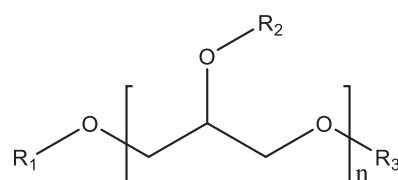
This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing guidance documents from the EFSA Scientific Committee.

3. Assessment

3.1. Identity and specifications of E 475

PEFA (E 475) is a mixture of reaction products formed by the esterification of polyglycerols with food fats and oils or with fatty acids occurring in foods, fats and oils. The polyglycerol moiety is predominantly di-, tri- and tetraglycerol and contains not more than 10% of polyglycerols equal to or higher than heptaglycerol (Commission Regulation (EU) No 231/2012).

A general structural formula is given in Figure 1 (EFSA ANS Panel, 2017a).



$R_1, R_2, R_3 =$ fatty acid moiety or H
 n (predominantly) = 2-4 (Commission Regulation (EU) No 231/2012)

Figure 1: General structural formula of PEFA (E 475)

Specifications for PEFA (E 475) have been defined in Commission Regulation (EU) No 231/2012 as described in Table 1.

Table 1: Specifications for PEFA (E 475) according to Commission Regulation (EU) No 231/2012¹

Commission Regulation (EU) No 231/2012	
Definition	Polyglycerol esters of fatty acids are produced by the esterification of polyglycerol with food fats and oils or with fatty acids occurring in foods fats and oils. The polyglycerol moiety is predominantly di-, tri- and tetraglycerol and contains not more than 10% of polyglycerols equal to or higher than heptaglycerol
Assay	Content of total fatty acid ester not less than 90%
Description	Light yellow to amber, oily to very viscous liquids; light tan to medium brown, plastic or soft solids; and light tan to brown, hard, waxy solids
Identification	
Tests for glycerol and polyglycerols	Passes test
Tests for fatty acids	Passes test
Solubility	The esters range from very hydrophilic to very lipophilic, but as a class tend to be dispersible in water and soluble in organic solvents and oils
Purity^(a)	
Sulfated ash	Not more than 0.5% ($800 \pm 25^\circ\text{C}$)
Acids other than fatty acids	Less than 1%
Free fatty acids	Not more than 6% estimated as oleic acid
Total glycerol and polyglycerol	Not less than 18% and not more than 60%
Free glycerol and polyglycerol	Not more than 7%
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

(a): Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids; however, these substances may be present up to a maximum level of 6% (expressed as sodium oleate).

3.2. Technical data submitted

3.2.1. Toxic elements

The following was requested in the European Commission call for data²:

- analytical data on current levels of arsenic, lead, mercury and cadmium in commercial samples of the food additive E 475;
- the lowest technologically achievable level for arsenic, lead, mercury and cadmium in order to adequately define their maximum limits in the specifications of E 475.

Analytical levels in fourteen commercial samples of E 475 for lead, mercury, cadmium, and arsenic were submitted by the IBO (Documentation provided to EFSA n. 1). For lead, four results were reported as 0.29 mg/kg (limit of quantification (LOQ): 0.05 mg/kg) and the remaining ten samples were all reported as below the LOQ, which ranged from 0.01 to 0.05 mg/kg. For mercury, all samples were below the LOQs which ranged from 0.005 to 0.01 mg/kg. For cadmium, all results were below the LOQs ranging from 0.005 to 0.02 mg/kg. For arsenic, all results were below the LOQs ranging from 0.02 to 0.1 mg/kg. All the analyses were performed by inductively coupled plasma-mass spectrometry (ICP-MS) (Documentation provided to EFSA n. 1).

According to the IBO, the levels of toxic elements in the food additive E 475 are mainly dependent on their concentrations in the raw materials used in the manufacturing process. The lowest technologically achievable levels for toxic elements in E 475 for all food uses proposed by the IBO are reported in Table 2. According to the IBO, the proposed levels for mercury, cadmium and arsenic are based on the highest measured value or LOQ, whichever is highest, applying a factor of 10 times this value; the IBO proposed further to maintain the current specification level for lead (Documentation provided to EFSA n. 1).

Table 2: Lowest technologically achievable levels for the toxic elements lead, mercury, cadmium and arsenic in commercial E 475 proposed by the interested business operator (Documentation provided to EFSA n. 1)

Lead	Mercury	Cadmium	Arsenic
2 mg/kg	0.1 mg/kg	0.2 mg/kg	1 mg/kg

3.2.2. Carry-over and process impurities

The following was requested in the European Commission call for data²:

- analytical data on current levels in commercial samples of the food additive E 475 of epichlorohydrin and glycidol, which could be used in the manufacturing processes of polyglycerols (used, in turn, in the manufacturing process of E 475);
- the lowest technologically achievable level for epichlorohydrin and glycidol in order to adequately define their maximum limits in the specifications of E 475;
- analytical data on current levels in commercial samples of the food additive E 475 of glycidyl esters/glycidol and monochloropropane-1,2-diol esters (3-MCPD esters), since residues can be present in the raw materials used in the manufacturing of the food additive by transesterification;
- the lowest technologically achievable level for glycidyl esters/glycidol and monochloropropane-1,2-diol esters (3-MCPD esters), in order to adequately define their maximum limits in the specifications of E 475;
- analytical data on current levels in commercial samples of the food additive E 475 of impurities of toxicological concern (e.g. butanetriols, acrolein, chlorinated compounds and 3-monochloropropane-1,2-diol), as identified in the EU specifications of the food additive glycerol (E 422) 1, which can be used in the manufacturing process of E 475;
- the lowest technologically achievable level for impurities of toxicological concern (e.g. butanetriols, acrolein, chlorinated compounds and 3-monochloropropane-1,2-diol) in order to adequately define their maximum limits in the specifications of E 475;
- analytical data on current levels in commercial samples of the food additive E 475 of any impurity present in glycerol (as mentioned in the call for data on the food additive glycerol (E 422)⁷), which can be used in the manufacturing process of E 475;
- the lowest technologically achievable level for any impurity which could be formed during the manufacturing processes of glycerol and be present in E 475, in order to adequately define their maximum limits in the specifications of E 475.

3.2.2.1. Epichlorohydrin

The IBO stated that 'there is no evidence of formation of epichlorohydrin in the emulsifier E 475 based on the raw materials used, and the process conditions'. Additionally, the IBO asserted that 'the

⁷ Call for technical data on the permitted food additive glycerol (E 422) https://ec.europa.eu/food/system/files/2019-01/fs_food-improvement-agents_reeval_call_20181123_e422_data.pdf

suppliers of polyglycerol have confirmed that they do not use epichlorohydrin in the manufacturing process of polyglycerol' (Documentation provided to EFSA n. 1). The IBO considered that traces of epichlorohydrin in commercial samples of E 475 are not expected and, therefore, epichlorohydrin was not tested for. The IBO also considered that the request for a lowest technologically achievable level for epichlorohydrin is not applicable (Documentation provided to EFSA n. 1).

3.2.2.2. Glycidyl esters

Concentrations of glycidyl esters (GEs), expressed as glycidol, were measured in eight commercial samples of E 475. The analysed samples showed concentrations ranging from a minimum of < 0.1 mg/kg (LOQ) to a maximum of 6.45 mg/kg. All analyses were performed with the modified AOAC Official Method Cd 29b-13 based on gas chromatography/mass spectrometry (GC/MS) (Kuhlmann, 2021; Documentation provided to EFSA n. 1). The IBO indicated that efficient mitigation measures have been developed and are being implemented across all relevant processing lines to prevent formation and/or reduce resulting levels of GEs in food emulsifiers. Thus, the IBO proposed a lowest technologically achievable level for GEs of 5 mg/kg and committed to reach this level for E 475 by the end of 2023 (Documentation provided to EFSA n. 1).

3.2.2.3. Free 3-MCPD and 3-MCPD fatty acid esters

The IBO submitted data on the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) in nine commercial samples of the food additive E 475 (Documentation provided to EFSA n. 1). The concentrations of the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) ranged from < 0.1 to < 0.3 mg/kg (Documentation provided to EFSA n. 1). All analyses were performed with the same modified AOAC Official Method Cd 29b-13 based on GC/MS that was used for the quantification of GEs (Kuhlmann, 2021; Documentation provided to EFSA n. 1). According to the IBO, *'3-MCPD is neither formed nor removed in the manufacturing process of E 475. As such, the resulting content is solely dependent on the content in the raw materials used in the manufacturing process. Fats and oils used by EFEMA members are in compliance with Regulation 1881/2006. (...) As such, the concept of lowest technologically achievable level seems not to be relevant for 3-MCPD in E 475. However, in order to facilitate international trade of E 475 that does have not the same regulatory requirements on the raw materials used, we propose a maximum limit of 3-MCPD of 2.5 mg/kg'* (Documentation provided to EFSA n. 1).

3.2.2.4. Butanetriol and Acrolein

The IBO reported that *'butanetriols are molecules with four C atoms, while emulsifiers are based on glycerol which is three C atoms. Formation of the C-C bond involves several chemical steps which is unlikely to take place in the esterification reaction that forms emulsifiers'* (Documentation provided to EFSA n. 1). The IBO further stated that *'an extensive literature and patent search on butanetriols (...) did not identify a viable synthetic pathway to produce 1,2,4-butanetriol or 1,2,3-butanetriol from glycerol or glycerol derivatives. In addition, an EFEMA member has developed a method to quantify butanethiols [sic] in E 475 (...) and confirmed that butanetriols were not detected (...)'* (Documentation provided to EFSA n. 1). A short a description of the method used for the analysis of 3 butanetriols in E 475 was provided by the IBO, reporting that free butanetriol was not detected in three samples of E 475 at a limit of detection (LOD) estimated to be ca. 0.07% w/w (Documentation provided to EFSA n. 1). The method involved derivatisation of the sample to make the trimethylsilyl ethers followed by gas chromatography and flame ionisation detection (GC-FID). The IBO stated that analysis for total butanetriol was also carried out on saponified samples of E 475 and that no butanetriol was detected. However, the saponification conditions and other details were not described and the LOD/LOQ was not stated. Considering that the analytical method used for total (i.e. free and bound) butanetriols was the same as described for free butanetriols but with the simple addition of a hydrolysis step, it can be anticipated that the LOD was similar for each approach, in the range of 0.07% w/w. Since E 475 comprises only up to 20% polyglycerol component and since the current specification limit value for butanetriols in glycerol E 422 is not more than 0.2%, the Panel considers that this LOD is adequate for the purpose of demonstrating the absence of butanetriols.

The IBO provided an analytical method to determine free acrolein in different kinds of samples by Static Headspace GC/MS (Documentation provided to EFSA n. 1). The analysis was performed on two commercial samples of E 475 and acrolein was not detected. An LOD of 0.4 mg/kg and an LOQ of 1.3 mg/kg were reported (Documentation provided to EFSA n. 1).

The IBO considered the request for a lowest technologically achievable level for butanetriol and acrolein not applicable since these compounds are not found in E 475 (Documentation provided to EFSA n. 1).

3.2.2.5. Other impurities potentially present in glycerol

Regarding the request to provide analytical data on current levels of any impurity present in glycerol as mentioned in the call for data on glycerol (E 422), the IBO stated that they do not possess any information on any impurities in glycerol, being only users of it (Documentation provided to EFSA n. 1).

3.2.3. Fatty acids as constituents of polyglycerol esters of fatty acids (PEFA) (E 475)

The following was requested in the European Commission call for data²:

- analytical data on current levels in commercial samples of the food additive E 475 of *trans*-fatty acids, which can be present in hydrogenated fats and/or oils used in the manufacturing process of E 475 by glycerolysis;
- the lowest technologically achievable level for *trans*-fatty acids, in order to adequately define their maximum limits in the specifications of E 475;
- analytical data on current levels of erucic acid in commercial samples of the food additive E 475, given that a residue that can be present among the fatty acids in edible oils, which can be used in the manufacturing process of the food additive;
- the lowest technologically achievable level for erucic acid, in order to adequately define their maximum limits in the specifications of E 475.

3.2.3.1. *Trans*-fatty acids

Analytical data on levels of *trans*-fatty acids tested in eleven commercial samples of E 475 were provided by the IBO (Documentation provided to EFSA n. 1). The levels of *trans*-fatty acids for ten commercial samples of E 475 produced from 'fully hardened' fats and oils ranged from 0.05% to < 1%. For the remaining sample, it was simply reported as not detected (ND) with no indication of the detection limit. In 9 commercial samples of E 475 produced from 'non-hardened' fats and oils, the content of *trans*-fatty acids ranged from 0.43% to 2.19% of the total fatty acids. Analyses were performed with GC-FID (Documentation provided to EFSA n. 1). The IBO stated that 'the amount of *trans*-fatty acids in E 475 is almost entirely dependent on the *trans*-fatty acid content of the fats, oils or fatty acids used in the production of this emulsifier. However, small amounts of *trans*-fatty acids may be formed during the production process. Controls are applied in the production to minimise the level of *trans*-fatty acids produced'. Since *trans*-fat is regulated in food for the final consumer, the IBO was of the opinion that a legal limit for emulsifiers is not applicable, as the consumer safety is already ensured by the existing legal limit in food for final consumer (Regulation (EU) No 2019/649⁸ amending Annex III to Regulation (EC) No 1925/2006⁹). The Panel noted that a proposal for the lowest technologically achievable level for *trans*-fatty acids in E 475 was not provided by the IBO (Documentation provided to EFSA n. 1).

3.2.3.2. Erucic acid

According to the IBO, '*erucic acid is almost exclusively found in the oils and fats of plants belonging to the Brassicaceae family. (...) Currently, the manufacturers of E 475 do not produce it with oils from the Brassicaceae family*' (Documentation provided to EFSA n. 1). The IBO declared that, for this reason, its members were not able to collect analytical data on the current levels of erucic acid in E 475. Since erucic acid is not generated in the manufacturing process of E 475 and is already regulated in oils of the Brassicaceae family as per Regulation (EC) No 1881/2006¹⁰ (i.e. 20 g/kg in vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food, with the exception of camelina oil, mustard oil and borage oil; 50.0 g/kg limit for camelina oil, mustard oil and borage oil), the IBO considered that the request for the lowest achievable level is not

⁸ Commission Regulation (EU) 2019/649: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R0649#:~:text=Commission%20Regulation%20\(EU\)%202019%2F,\(Text%20with%20EEA%20relevance.\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R0649#:~:text=Commission%20Regulation%20(EU)%202019%2F,(Text%20with%20EEA%20relevance.))

⁹ Council Regulation (EC) No 1925/2006: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1925>

¹⁰ Commission Regulation (EC) No 1881/2006 <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1881>

applicable. In order to facilitate international trade of E 475 that does not have the same regulatory requirements on the raw materials used, the IBO proposed a maximum limit of erucic acid of 20 g/kg corresponding to the maximum limit for vegetable oils and fats as set in Regulation (EC) No 1881/2006 (section 8) (Documentation provided to EFSA n. 1).

3.3. Proposed revision to existing EU Specifications for polyglycerol esters of fatty acids (PEFA) (E 475)

The potential exposure to impurities from the use of the food additive E 475 can be calculated by assuming that the impurity is present in the food additive up to a limit value and then by calculation pro-rata to the estimates of exposure to the food additive itself.

With regard to the dietary exposure to the food additive, the Panel considered the exposure calculations for E 475 as presented in the re-evaluation of the food additive (EFSA ANS Panel, 2017a). The ANS Panel considered the non-brand-loyal scenario covering the general population as the most appropriate and realistic scenario for risk characterisation of the food additive E 475 as it did not identify brand loyalty to a specific food category for the exposure to the food additive (EFSA ANS Panel, 2017a).

For the current assessment, the highest exposure levels for the mean and 95th percentile among the different population groups were considered, i.e. 2.6 and 6.4 mg/kg bw per day respectively, for children (Table 3).

Table 3: Summary of dietary exposure to PEFA (E 475) from its use as a food additive in the non-brand-loyal refined exposure scenarios, in 6 population groups (minimum–maximum across the dietary surveys in mg/kg bw per day) (EFSA ANS Panel, 2017a)

	Infants		Toddlers		Children		Adolescents		Adults		The elderly	
	(12 weeks–11 months)		(12–35 months)		(3–9 years)		(10–17 years)		(18–64 years)		(≥ 65 years)	
	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max	Min	Max
Refined estimated exposure assessment scenario												
Non-brand-loyal scenario												
Mean	0	0.9	0.1	2.5	0.1	2.6	0.1	1.3	0.1	0.9	0.1	0.9
95th percentile	0	3.9	0.5	6.2	0.4	6.4	0.3	3.4	0.4	2.7	0.4	2.4

bw: body weight.

The level of the impurity in the food additive combined with the estimated intakes of E 475, presented in Table 3, could result in an exposure which can be compared with the following reference points (RPs) or health-based guidance values (HBGVs) (Table 4) for the undesirable impurities and constituents potentially present in E 475.

Table 4: Reference points/health-based guidance values for impurities and constituents potentially present in E 475

Impurity/constituent/HBGV/ RP (ug/kg bw)	Basis/Reference
Lead (Pb)/0.5 (BMDL ₀₁)	The reference point is based on a study demonstrating perturbation of intellectual development in children with the critical response size of 1 point reduction in IQ. The EFSA CONTAM Panel mentioned that a 1 point reduction in IQ is related to a 4.5% increase in the risk of failure to graduate from high school and that a 1 point reduction in IQ in children can be associated with a decrease of later productivity of about 2%. A risk cannot be excluded if the exposure exceeds the BMDL ₀₁ (MOE lower than 1). EFSA CONTAM Panel (2010)

Impurity/constituent/HBGV/ RP (ug/kg bw)	Basis/Reference
Mercury (Hg)/4 (TWI)	The HBGV was set using kidney weight changes in male rats as the pivotal effect. Based on the BMDL ₁₀ of 0.06 mg/kg bw per day, expressed as mercury, and an uncertainty factor of 100 to account for inter and intra species differences, with conversion to a weekly basis and rounding to one significant figure, a TWI for inorganic mercury of 4 µg/kg bw per week, expressed as mercury was established. EFSA CONTAM Panel (2012)
Cadmium (Cd)/2.5 (TWI)	The derivation of the reference point is based on a meta-analysis to evaluate the dose-response relationship between selected urinary cadmium and urinary beta-2-microglobulin as the biomarker of tubular damage recognised as the most useful biomarker in relation to tubular effects. A group-based BMDL ₅ of 4 µg Cd/g creatinine for humans was derived. A chemical specific adjustment factor of 3.9 was applied to account for human variability in urinary cadmium within each dose-subgroup in the analysis resulting in a reference point of 1.0 µg Cd per g creatinine. In order to remain below 1 µg Cd/g creatinine in urine in 95% of the population by age 50, the average daily dietary cadmium intake should not exceed 0.36 µg Cd/kg bw, corresponding to a weekly dietary intake of 2.5 µg Cd/kg bw. EFSA CONTAM Panel (2009a)
Arsenic (As)/0.3–8 (BMDL ₀₁)	The reference point is based on a range of benchmark dose lower confidence limit (BMDL ₀₁) values between 0.3 and 8 µg/kg bw per day identified for cancers of the lung, skin and bladder, as well as skin lesions. In general, the MOE should be at least 10,000 if the reference point is based on carcinogenicity in animal studies. However, as the BMDL for As is derived from human studies, an interspecies extrapolation factor (i.e. 10) is not needed. EFSA CONTAM Panel, 2009b; EFSA Scientific Committee, 2012
3-MCPD and 3-MCPD fatty acid esters/2 (TDI)	The HBGV is based on increased incidence of kidney tubular hyperplasia. BMD analysis using model averaging resulted in a BMDL ₁₀ of 0.20 mg/kg bw per day in male rats, which was selected as the reference point for renal effects. This reference point was considered to derive a group TDI of 2 µg/kg bw per day for 3-MCPD and 3-MCPD fatty acid esters and was considered protective also for effects on male fertility. EFSA CONTAM Panel, 2018
Glycidyl-esters (GEs)/10,200 (T25)	Based on the EFSA Guidance on substances that are genotoxic and carcinogenic, T25 values were calculated for the incidence of tumors observed in rats and mice following long-term exposure to glycidol. A T25 of 10.2 mg/kg bw per day for peritoneal mesothelioma in male rats was used as the reference point. A MoE of 25,000 or higher is considered of low health concern. EFSA CONTAM Panel, 2016a
Erucic acid/7,000 (TDI)	The heart is the principal target organ for toxic effects after exposure to erucic acid. Myocardial lipidosis was identified by EFSA as the critical effect for chronic exposure to erucic acid. This effect is reversible and transient during prolonged exposure. A tolerable daily intake (TDI) of 7000 µg/kg bw per day for erucic acid was established, based on a no observed adverse effect level of 0.7 g/kg bw per day for lipidosis in young rats and newborn piglets. EFSA CONTAM Panel, 2016b

HBGV: health-based guidance value; RP: reference point; BMDL₀₁: benchmark dose (lower confidence limit); bw: body weight; TWI: Tolerable Weekly Intake; TDI: Tolerable Daily Intake; T25: the chronic dose rate in mg/kg bw per day, which will give 25% of the animal tumours at a specific tissue site, after specific correction for the spontaneous incidence within the standard life time of that species; MOE: margin of exposure; 3-MCPD: 3-monochloropropanediol.

The risk assessment of the undesirable impurities and constituents helps inform whether there could be a possible health concern if these impurities and constituents would be present at the limit values in the food additive. The assessment is performed by calculating the MOE (margin of exposure)

by dividing the RP (e.g. BMDL Table 4) by the exposure estimate (Table 3), or by estimating the contribution of the use of E 475 to the HBGV (expressed as percentage of the HBGV).

3.3.1. Toxic elements

The Panel noted that the occurrence data on toxic elements submitted by the IBO are substantially lower than the current limits in the EU specifications (Documentation provided to EFSA n. 1).

The results of analysis of arsenic, cadmium, lead and mercury in commercial samples of E 475 were reported (Section 3.2.1). As indicated in Table 2, the IBO proposed lowest technologically achievable levels for mercury (0.1 mg/kg), cadmium (0.2 mg/kg), and arsenic (1 mg/kg) by choosing the highest measured value or LOQ, whichever was highest, and applying a factor of 10 times this value. The IBO proposed to maintain the current EU specification level for lead (2 mg/kg). Taking into account the reported data, the Panel considered that this approach is acceptable. However, the Panel emphasised that the choice of the factor as well as other considerations, such as on multiple sources of exposure to conclude on the maximum limits for toxic elements in the specifications, is in the remit of risk management. The numbers used here are merely taken to support the risk assessment of these toxic elements as presented below.

The outcome of the risk assessment of the Panel is illustrated in Table 5 considering the current limits of these toxic elements in the EU specifications for E 475 (Commission Regulation (EU) No 231/2012) and the lowest technologically achievable levels proposed by the IBO (Table 2).

Table 5: Risk assessment for toxic elements

Exposure to E 475 (mg/kg bw per day)	Based on the current limits for toxic element in the EU specifications for E 475 (Commission Regulation (EU) No 231/2012)			
	MOE for Pb at 2 mg/kg	% of the TWI for Hg at 1 mg/kg	% of the TWI for Cd at 1 mg/kg	MOE for As at 3 mg/kg
2.6 ^(a)	96	0.46	0.73	38–1,026
6.4 ^(b)	39	1.1	1.8	16–417
Exposure to E 475 (mg/kg bw per day)	Based on the lowest technologically achievable levels for the toxic elements in E 475 proposed by the IBO (Documentation provided to EFSA n. 1)			
	MOE for Pb at 2 mg/kg	% of the TWI for Hg at 0.1 mg/kg	% of the TWI for Cd at 0.2 mg/kg	MOE for As at 1 mg/kg
2.6 ^(a)	96	0.05	0.15	115–3,077
6.4 ^(b)	39	0.11	0.36	47–1,250

bw: body weight; MOE: margin of exposure; TWI: Tolerable Weekly Intake.

(a): Highest exposure level among the different population groups (refined non-brand-loyal scenario - children - mean (Table 3)).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario - children - 95th percentile (Table 3)).

The lowest technologically achievable level proposed by the IBO for lead is the same as given in the current EU specifications. However, the Panel noted that the actual measured levels for lead in commercial samples of E 475 were substantially below the limit value proposed by the IBO.

The Panel concluded that for arsenic, the lower end of the range of the calculated MOE values was insufficient. For the other toxic elements (cadmium, mercury, lead), the limit values proposed by the IBO do not give rise to safety concerns (Table 5).

The Panel considered that the maximum limits in the EU specifications for toxic elements should be established based on actual levels in the commercial food additive. If the European Commission decides to revise the current limits in the EU specifications, the estimates of toxic elements intake as above could be considered.

3.3.2. Carry-over and process impurities

3.3.2.1. Glycidyl esters

The outcome of the risk assessment of the FAF Panel for GEs is illustrated in Table 6 considering the lowest technologically achievable level in E 475 proposed by the IBO, i.e. 5 mg/kg (see Section 3.2.2.2).

Table 6: Risk assessment for GEs (expressed as glycidol) based on the lowest technologically achievable level (5 mg/kg) in E 475 proposed by the IBO (Documentation provided to EFSA n. 1)

Exposure to E 475 (mg/kg bw per day)	MOE for GEs (expressed as glycidol) at 5 mg/kg
2.6 ^(a)	784,615
6.4 ^(b)	318,750

GE: glycidyl esters; bw: body weight; MOE: margin of exposure.

(a): Highest exposure level among the different population groups (refined non-brand-loyal scenario – children – mean (Table 3)).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario – children – 95th percentile (Table 3)).

The Panel noted that the MOE is well above the value of 25,000 given in Table 4 for GEs, indicating that the limit value proposed by the IBO for GEs (expressed as glycidol) does not give rise to a health concern.

Considering the potential occurrence of GEs in E 475, the Panel recommends to consider setting a specification limit value for this impurity in Commission Regulation (EU) No 231/2012 for E 475. As an alternative to introducing an individual specification limit value for GEs, the definition of E 475 could include a requirement that the fats and oils used in the manufacturing of E 475 comply with the respective EU legislation regarding suitability for human consumption.

3.3.2.2. Free 3-MCPD and 3-MCPD fatty acid esters

The Panel performed a risk assessment for the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) that would result if these impurities would be present in the food additive at the maximum limit of 2.5 mg/kg proposed by the IBO (Table 7).

Table 7: Risk assessment for the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) based on the maximum limit (2.5 mg/kg) in E 475 proposed by the IBO (Documentation provided to EFSA n. 1)

Exposure to E 475 (mg/kg bw per day)	% of the TDI for the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) at 2.5 mg/kg
2.6 ^(a)	0.33
6.4 ^(b)	0.80

3-MCPD: 3-monochloropropanediol; bw: body weight; TDI: Tolerable Daily Intake.

(a): Highest exposure level among the different population groups (refined non-brand-loyal scenario – children – mean (Table 3)).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario – children – 95th percentile (Table 3)).

The Panel noted that, by reference to the tolerable daily intake (TDI) for the sum of 3-MCPD and 3-MCPD fatty acid esters (2 µg/kg bw per day, Table 4), the limit value proposed by the IBO for the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) would give rise to a potential exposure that is only a low percentage of the TDI (Table 7) and does not give rise to a health concern.

Considering the potential occurrence of the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) in E 475, the Panel recommends to consider setting a specification limit value for these impurities in Commission Regulation (EU) No 231/2012 for E 475. As an alternative to introducing an individual specification limit value for 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD), the definition of E 475 could include a requirement that the fats and oils used in the manufacturing of E 475 comply with the respective EU legislation regarding suitability for human consumption.

3.3.2.3. Acrolein, butanetriol and epichlorohydrin

During the re-evaluation of E 475 by the EFSA ANS Panel in 2017, it was noted that epichlorohydrin may be present in E 475 from the possible chemical synthesis of polyglycerols to be used to produce E 475. In addition, impurities present in glycerol, to be used for the manufacturing of polyglycerols, could also be present as carry-over impurities in E 475 (EFSA ANS Panel, 2017a). According to the

IBO, epichlorohydrin is not used in the manufacturing process of polyglycerols to be used for the production of E 475 (see Section 3.2.2.1). However, the Panel noted that the present definition of E 475 in the EU specifications does not define how the polyglycerol is manufactured and therefore the use of epichlorohydrin as a raw material cannot be excluded.

According to the data submitted, acrolein and butanetriol (potential impurities in glycerol (E 422) according to Commission Regulation (EU) No 231/2012) were not detected in the limited number of analysed samples of E 475 (see Section 3.2.2.4). The Panel acknowledged that a numerical limit for acrolein is currently being considered as part of the follow up of the re-evaluation of glycerol (E 422).¹¹

Regarding epichlorohydrin, acrolein and butanetriol, the Panel recommends a modification of the definition of E 475 indicating that polyglycerol used for the manufacturing of E 475 should be produced from glycerol meeting the specifications for E 422 (Commission Regulation (EU) No 231/2012). In this case, respective specification limits for epichlorohydrin, acrolein and butanetriol would not be needed for E 475.

3.3.3. Fatty acids as constituents of polyglycerol esters of fatty acids (PEFA) (E 475)

3.3.3.1. *Trans*-fatty acids

Analytical data on the content of *trans*-fatty acids in commercial samples of E 475 were provided by the IBO (Documentation provided to EFSA n. 1). The Panel noted that the levels of *trans*-fatty acids cover a wide range depending on the degree of hydrogenation of the fat/oil raw material (non- or fully hardened). The content of *trans*-fatty acids in commercial samples E 475 produced from fully hardened and non-hardened fats and oils submitted by the IBO ranged from 0.05% to < 1% and from 0.43% to 2.19% of the total fatty acids, respectively (see Section 3.2.3.1). The Panel noted that no analytical data have been provided on the content of *trans*-fatty acids in partially hardened samples.

The Panel noted that a maximum limit of 2 grams of *trans* fat per 100 g fat in food for the final consumer is set by Regulation (EU) No 2019/6497 amending Annex III to Regulation (EC) No 1925/20068. Hence, the Panel considered that there is no need for setting a specification limit in Commission Regulation (EU) No 231/2012 for the content of *trans*-fatty acids in E 475.

3.3.3.2. Erucic acid

The FAF Panel performed a risk assessment for the potential content of erucic acid in E 475 considering the maximum limit proposed by the IBO (i.e. 20 g/kg) which corresponds to the maximum level set for erucic acid in vegetable oils and fats in Regulation (EC) No 1881/2006. The outcome of this exercise is illustrated in Table 8.

Table 8: Risk assessment for erucic acid based on the maximum limit (20 g/kg) for vegetable oils and fats as set in Regulation (EC) No 1881/2006 proposed by the IBO to be used as maximum limit also in E 475 (Documentation provided to EFSA n. 1)

Exposure to E 475 (mg/kg bw per day)	% of the TDI for Erucic acid at 20 g/kg
2.6 ^(a)	0.74
6.4 ^(b)	1.8

bw: body weight; TDI: Tolerable Daily Intake.

(a): Highest exposure level among the different population groups (refined non-brand-loyal scenario – children – mean (Table 3)).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario – children – 95th percentile (Table 3)).

The Panel noted that the comparison of the estimated potential exposure with the TDI for erucic acid (7,000 µg/kg bw, Table 4) shows (Table 8) that the limit value proposed by the IBO for erucic acid does not give rise to a health concern.

The Panel noted that, according to the information provided by the IBO, the fats and oils potentially used in the manufacturing of E 475 are expected to comply with the Regulation (EC) No 1881/2006. However, the Panel also noted that according to the current definition of E 475 laid down in Commission Regulation (EU) No 231/2012, there is no such a requirement. Considering the potential

¹¹ EFSA-Q-2019-00815

occurrence of erucic acid in E 475, the Panel recommends to consider setting a specification limit value for this component in Commission Regulation (EU) No 231/2012 for E 475. As an alternative to introducing individual specifications for erucic acid, the definition of E 475 could include a requirement that the fats and oils used in the manufacturing of E 475 comply with the respective EU legislation regarding suitability for human consumption.

3.3.4. Proposed revisions to the EU specifications

Overall, based on the information provided by the IBO in response to the call for data (Documentation provided to EFSA n. 1) and the above considerations, the Panel recommends the following revisions of the existing EU specifications for polyglycerol esters of fatty acids (E 475) as listed in Table 9. The Panel noted that the choice of maximum limits for impurities/constituents in the EU specifications is in the remit of risk management.

Table 9: Proposal for a revised version of the existing EU Specifications for polyglycerol esters of fatty acids (E 475)

	Commission Regulation (EU) No 231/2012	Comment/justification for revision
Definition	See Table 1	The Panel recommends a modification of the definition of E 475 indicating that polyglycerol used for the manufacturing of E 475 should be produced from glycerol meeting the specifications for E 422 in Commission Regulation (EU) No 231/2012. In this case, respective specification limits for epichlorohydrin, acrolein and butanetriol would not be needed for E 475.
Assay	See Table 1	Unchanged
Description	See Table 1	Unchanged
Identification	See Table 1	Unchanged
Infrared absorption spectrum	See Table 1	Unchanged
Tests for glycerol and polyglycerols		
Tests for fatty acids	See Table 1	Unchanged
Erucic acid	Not presently specified	Maximum limit to be included on the basis of the information provided and the considerations of the Panel*
Solubility	See Table 1	Unchanged
Purity	See Table 1	Unchanged
Sulfated ash	See Table 1	Unchanged
Acids other than fatty acids	See Table 1	Unchanged
Free fatty acids	See Table 1	Unchanged
Total glycerol and polyglycerol	See Table 1	Unchanged
Free glycerol and polyglycerol	See Table 1	Unchanged
Arsenic	Not more than 3 mg/kg	Maximum limit to be lowered on the basis of the information provided and on the considerations of the Panel
Lead	Not more than 2 mg/kg	Maximum limit to be lowered on the basis of the information provided and on the considerations of the Panel
Mercury	Not more than 1 mg/kg	Maximum limit to be lowered on the basis of the information provided and on the considerations of the Panel
Cadmium	Not more than 1 mg/kg	Maximum limit to be lowered on the basis of the information provided and on the considerations of the Panel

	Commission Regulation (EU) No 231/2012	Comment/justification for revision
Sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD)	Not presently specified	Maximum limit to be included on the basis of the information provided and the considerations of the Panel*
Glycidyl esters (expressed as glycidol)	Not presently specified	Maximum limit to be included on the basis of the information provided and the considerations of the Panel*

*: As an alternative to introducing individual specifications for the impurities/constituents indicated by the *, the definition of E 475 could include a requirement that the fats and oils used in the manufacturing of E 475 comply with the respective EU legislation regarding suitability for human consumption.

3.4. Discussion

The current assessment addresses the EFSA recommendations indicated during the re-evaluation of PEFA (E 475) as a food additive (EFSA ANS Panel, 2017a) to update its EU specifications (E 475) in Commission Regulation (EU) No 231/2012.

In response to the European Commission call for data, analytical data on potential impurities and undesirable constituents in commercial samples of E 475 were provided by one IBO and respective limit values were proposed. The potential exposure to these compounds from the use of the food additive E 475 was calculated by assuming that they may be present in the food additive up to the limit value and then by calculation pro-rata to the estimates of exposure to the food additive itself.

Analytical data on levels of toxic elements (arsenic, lead, cadmium, mercury) in commercial samples of E 475 were provided by the IBO. The Panel noted that the occurrence data on toxic elements submitted by the IBO are substantially lower than the current limits in the EU specifications. The IBO proposed lowest technologically achievable levels for mercury, cadmium, and arsenic by choosing the highest measured value or LOQ, whichever was highest, and applying a factor of 10 times this value. The IBO proposed to maintain the current EU specification level for lead. However, the actual measured levels for lead in commercial samples of E 475 were substantially below the limit value proposed by the IBO indicating that the limit in the specification could be lowered. The Panel performed a risk assessment considering both the current limits for the 4 toxic elements in the EU specifications for E 475 (Commission Regulation (EU) No 231/2012) and the lowest technologically achievable levels proposed by the IBO (Table 2). The potential exposure to these impurities from the use of E 475 were compared against the available health-based guidance values (HBGV) and reference points (RP) (Table 4). The Panel concluded that for arsenic, the lower end of the range of the calculated MOE values was insufficient. For the other toxic elements (cadmium, mercury, lead), the limit values proposed by the IBO do not give rise to safety concerns (Table 5). 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 (see Table 9).

Analytical data on levels of GEs, expressed as glycidol, in commercial samples of E 475 and a lowest technologically achievable level were provided by the IBO. The Panel performed a risk assessment considering the lowest technologically achievable level (5 mg/kg) proposed by the IBO. The potential exposure to GEs from the use of E 475 was compared against the available RP. The Panel concluded that the limit value proposed by the IBO for GEs (expressed as glycidol) does not give rise to a health concern.

With respect to 3-MCPD, the Panel performed a risk assessment for the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) based on the maximum limit (2.5 mg/kg) in E 475 proposed by the IBO. By comparing the potential exposure to 3-MCPD from the use of E 475 with the available HBGV, the Panel concluded that the maximum limit value proposed by the IBO for the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) does not give rise to a health concern.

Considering the potential occurrence of GEs and the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) in E 475, the Panel recommends to consider setting specification limit values for these impurities in Commission Regulation (EU) No 231/2012 for E 475 as indicated in Table 9. As an alternative to introducing specification limits for these impurities, the specifications could include a requirement that the fats and oils used in the manufacturing of E 475 comply with the respective EU legislation regarding suitability for human consumption.

Analytical data on the levels of acrolein, butanetriol and epichlorohydrin were requested in line with the recommendations from the re-evaluation (EFSA ANS Panel, 2017a). According to the IBO, acrolein and butanetriol (impurities in glycerol (E 422) according to Commission Regulation (EU) No 231/2012) were not detected in the limited number of the analysed samples of E 475 (see Section 3.2.2.4). The Panel acknowledged that a numerical limit for acrolein in glycerol (E 422) is currently being considered as part of the follow up of the re-evaluation of this food additive.⁹ According to the IBO, epichlorohydrin is not used in the manufacturing process of polyglycerols to be used for the production of E 475 and, therefore, it is not expected to be present in E 475 (see Section 3.2.2.1). However, the Panel noted that the present definition of E 475 in the EU specifications does not define how the polyglycerol is manufactured and therefore the use of epichlorohydrin as a raw material cannot be excluded. The Panel recommends a modification of the definition of E 475 indicating that polyglycerol used for the manufacturing of E 475 should be produced from glycerol meeting the specifications for E 422 (Commission Regulation (EU) No 231/2012). In this case, respective specification limits for epichlorohydrin, acrolein and butanetriol would not be needed for E 475.

Analytical data on the content of *trans*-fatty acids in commercial samples of E 475 were provided by the IBO. The Panel noted that a maximum limit of 2 grams of *trans*-fat per 100 g fat in food for the final consumer is set by Regulation (EU) No 2019/649 amending Annex III to Regulation (EC) No 1925/2006. Hence, there is no need for setting a specification limit in Commission Regulation (EU) No 231/2012 for the content of *trans*-fatty acids in E 475.

The IBO did not provide analytical data on the current levels of erucic acid in E 475 because it was stated that manufacturers of E 475 do not produce it with oils from the Brassicaceae family that may contain erucic acid. The Panel performed a risk assessment for the potential content of erucic acid in E 475 considering the maximum limit for erucic acid in vegetable oils and fats as set in Regulation (EC) No 1881/2006, as proposed by the IBO in the case that these material would be used for the production of E 475. By the comparison of the potential exposure to erucic acid from the use of E 475 with the available HBGV, the Panel concluded that the limit value proposed by the IBO for erucic acid does not give rise to a health concern. The Panel noted that, according to the information provided by the IBO, the fats and oils potentially used in the manufacturing of E 475 are expected to comply with the Regulation (EC) No 1881/2006. However, the Panel also noted that according to the current definition of E 475 laid down in Commission Regulation (EU) No 231/2012, there is no such requirement. Considering the potential occurrence of erucic acid in E 475, the Panel recommends to consider setting a specification limit value for this component in Commission Regulation (EU) No 231/2012 for E 475. As an alternative to introducing specification limits for erucic acid, the specifications could include a requirement that the fats and oils used in the manufacturing of E 475 comply with the respective EU legislation regarding suitability for human consumption.

Overall, the Panel considered it feasible to amend the EU specifications based on the information submitted in response to the call for data and supports an amendment of the specifications for PEFA (E 475) laid down in Commission Regulation (EU) No 231/2012, as presented by the recommendations made in Table 9.

4. Conclusions

The Panel concluded that the technical data provided by the IBO support an amendment of the specifications for polyglycerol esters of fatty acids (E 475) laid down in Commission Regulation (EU) No 231/2012, as presented by the recommendations made in Table 9.

5. Documentation as provided to EFSA

- 1) European Food Emulsifiers Manufacturers Association (EFEMA), 2020. Submission of data in response to the call for technical data on the permitted food additive polyglycerol esters of fatty acids (E 475). Submitted by EFEMA, 17 December 2020.

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Abbreviations

3-MCPD	3-monochloropropane diol
ADI	acceptable daily intake
ANS Panel EFSA	Panel on Food Additives and Nutrient Sources added to Food
BMDL	benchmark dose (lower confidence limit)
Bw	body weight
CAS	Chemical Abstract Service
GC-FID	gas chromatograph(y)-flame ionisation detector
GEs	glycidyl esters
GC/MS	gas chromatography/mass spectrometry
HBGV	health-based guidance value
IBO	interested business operator
ICP-MS	inductively coupled plasma-mass spectrometry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
LOQ	limit of quantification
MOE	margin of exposure
ND	not Detected
PEFA	polyglycerol esters of fatty acids
RP	reference point

SC	Scientific Committee of EFSA
T25	the chronic dose rate in mg/kg bw per day, which will give 25% of the animal tumours at a specific tissue site, after specific correction for the spontaneous incidence within the standard life time of that species
TDI	Tolerable Daily Intake
TWI	Tolerable Weekly Intake