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Follow-up of the re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive

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Abstract

Polyglycerol polyricinoleate (PGPR, E 476) 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 476. Additionally, this opinion deals with the assessment of the proposed extension of use for E 476 in edible ices and a revision of the maximum permitted level in emulsified sauces. The Panel concluded that the proposed extension of use, if authorised, would not give rise to a safety concern. Additionally, the Panel performed a risk assessment of undesirable impurities potentially present in E 476. The Panel concluded that the maximum limits in the EU specifications for the four toxic elements (arsenic, lead, mercury, cadmium) should be lowered based on actual levels in the commercial food additive E 476. The Panel also concluded that maximum limits for glycidyl esters and 3-monochloropropanediol should be included in the EU specifications for E 476. Alternatively, the Panel recommends an amendment of the definition of E 476 to include a requirement that the fats and oils used in the manufacturing of E 476 comply with the respective EU legislation regarding suitability for human consumption. Further, the Panel recommends a modification of the definition of E 476 indicating that polyglycerol used for the manufacturing of E 476 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 476. Finally, the Panel concluded that the proposed method based on the determination of ricinoleic acid is suitable for the determination of E 476 content in food.

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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 polyricinoleate (PGPR, E 476) in Commission Regulation (EU) No 231/2012. Additionally, the present opinion deals with the assessment of the proposed extension of use for polyglycerol polyricinoleate (E 476) in edible ices (Food Category 03) and a revision of the maximum permitted level in emulsified sauces (Food Category 12.6).

PGPR (E 476) was re-evaluated in 2017 by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) which concluded that the data set gave reason to revise the acceptable daily intake (ADI) of 7.5 mg/kg body weight (bw) per day allocated by the Scientific Committee on Food (SCF) to 25 mg/kg bw per day. 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 476 and evaluate the impact of the proposed extension of use. PGPR (E 476) is a mixture of products formed by the esterification of polyglycerols with condensed castor oil fatty acids which are mainly composed of ricinoleic acid (80–90%), oleic acid (3–8%), linoleic acid (3–7%), and stearic acid (0–2%) (EFSA ANS Panel, 2017a). According to Commission Regulation (EU) No 231/2012, the polyglycerol moiety is mainly composed of di-, tri- and tetraglycerol with not more than 10% equal or higher than heptaglycerol. Specifications for PGPR (E 476) are also defined in Commission Regulation (EU) No 231/2012.

Dietary exposure to PGPR (E 476) was estimated because the current authorised uses, according to Annex II to Regulation (EC) No 1333/2008, are different from those considered at the time of the re-evaluation of this food additive. For the current exposure estimate, data provided through the call for data and considered in the re-evaluation of the food additive, and the proposed reported level for the Food Category 12.6 emulsified sauces (FC 12.6) at the time of the request for this authorisation have been used. For the additional regulatory maximum level exposure assessment scenario related to the proposed extension of use, the proposed maximum use levels were considered.

Taking into account the main food categories contributing to the exposure estimates, the Panel considered that brand-loyalty would not be expected. Added to that, PGPR (E 476) is an emulsifier and its use would not influence the selection of foods by the consumers. Therefore, the Panel considered the non-brand-loyal scenario as the most relevant exposure scenario for the safety evaluation of PGPR (E 476). The Panel noted that in none of the scenarios, the exposure exceeded the ADI of 25 mg/kg bw per day for PGPR (E 476) established by the ANS Panel.

Considering the proposed extension of use in FC 03 and the revision of the maximum permitted level in FC 12.6, exposure estimates according to the regulatory maximum level exposure assessment scenario do not exceed the ADI for PGPR (E 476). Therefore, the Panel concluded that the proposed extension of use, if authorised, would not give rise to a safety concern.

In response to the European Commission call for data, analytical data on potential impurities and undesirable constituents in commercial samples of E 476 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 476 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, mercury) in commercial samples of E 476 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 four toxic elements are proposed by the IBO. The Panel performed a risk assessment considering both the current limits for the four toxic elements in the EU specifications for E 476 (Commission Regulation (EU) No 231/2012) and the proposed lowest technologically achievable levels. The potential exposure to these impurities from the use of E 476 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, 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 476 and a lowest technologically achievable level were also provided. The Panel calculated the potential exposure to GEs from the use of E 476, considering its presence in the food additive at the

proposed lowest technologically achievable level (1 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 476. By comparing the potential exposure to 3-MCPD from the use of E 476 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 476, the Panel recommends considering setting specification limit values for these impurities in Commission Regulation (EU) No 231/2012 for E 476. The Panel noted that, according to the information provided by the IBO, the fats and oils potentially used in the manufacturing of E 476 are expected to comply with the Regulation (EC) No 1881/2006. However, the Panel also noted that according to the current definition of E 476 laid down in Commission Regulation (EU) No 231/2012, there is no such requirement. As an alternative to introducing specification limits for GEs and the sum of 3-MCPD and 3-MCPD fatty acid esters, the specifications could include a requirement that the fats and oils used in the manufacturing of E 476 comply with the respective EU legislation regarding suitability for human consumption.

Analytical data on the levels of ricin, acrolein, butanetriol and epichlorohydrin were also requested in the European Commission call for data in line with the recommendations from the 2017 re-evaluation. No analytical data on the current levels of ricin were provided because it was stated that ricin is not present in the castor oil used for the production of E 476 and, therefore, it is not present in E 476. Based on the information available, the Panel considered that there would be no need for including a limit for ricin in the EU specifications for PGPR (E 476). The Panel recommends a modification of the definition of E 476 indicating that polyglycerol used for the manufacturing of E 476 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 476.

In response to the European Commission call for data, an analytical method for the determination of PGPR (E 476) content in food was submitted by the IBO. Due to the impossibility to detect all individual components in E 476, it was proposed a method based on the determination of ricinoleic acid, which can be used as an indicator for the total amount of PGPR in food. The Panel concluded that the proposed method is suitable for the determination of the actual E 476 content in food.

The Panel concluded that the technical data provided by the IBO support an amendment of the specifications for polyglycerol polyricinoleate (E 476) laid down in Commission Regulation (EU) No 231/2012. The potential exposure to impurities from the use of E 476, considering the proposed extension of use, has also been carried out. The Panel noted that an amendment of the specifications for polyglycerol polyricinoleate (E 476) laid down in Commission Regulation (EU) No 231/2012, as presented would still be recommended in case the proposed extension of use for E 476 would be authorised.

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1. Introduction

The re-evaluation of polyglycerol polyricinoleate (PGPR) (E 476) 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 PGPR (E 476) 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 PGPR (E 476).

Additionally, the present opinion deals with the assessment of the proposed extension of use for polyglycerol polyricinoleate (E 476) in edible ices and a revision of the maximum permitted level in emulsified sauces.

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

1.1.1. Background

1.1.1.1. Follow-up of the re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive

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 polyricinoleate (E 476) is authorised for use as a food additive in the Union. Since polyglycerol polyricinoleate (E 476) 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 polyricinoleate (E 476) as a food additive and published a scientific opinion on 24 March 2017.⁵ In that opinion, EFSA concluded that the present data set gave reason to revise the acceptable daily intake (ADI) for polyglycerol polyricinoleate (E 476) of 7.5 mg/kg bw per day allocated by the Scientific Committee on Food to 25 mg/kg bw per day. Exposure estimates did not exceed the ADI of 25 mg/kg bw per day. However, EFSA recommended that the specifications for polyglycerol polyricinoleate (E 476) 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 polyricinoleate (E 476) would be needed.

Therefore, the European Commission published on 23 November 2018 a call for data 2 addressing the recommendations made by EFSA in the scientific opinion on the re-evaluation of polyglycerol polyricinoleate (E 476) 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 polyricinoleate (E 476) in December 2020.

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

1.1.1.2. Extension of use for polyglycerol polyricinoleate (E 476)

An application has been received for a modification of the conditions of use of an authorised food additive polyglycerol polyricinoleate (E 476). In particular, the applicant requests an extension of use for this additive in edible ices with the restriction 'only fat and oil emulsion of water-in-oil type' at the maximum level of 4,000 mg/kg (Food Category 03. of Part E of Annex II to Regulation (EC) No 1333/2008) and in sauces with the restriction 'only emulsified sauces with a fat content of 20% and more' at the maximum level of 8,000 mg/kg (Food Category 12.6 of Part E of Annex II to Regulation (EC) No 1333/2008).

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_e476_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 polyricinoleate (E 476) as a food additive: <https://www.efsa.europa.eu/en/efsajournal/pub/4743>

According to the applicant, the use of polyglycerol polyricinoleate (E 476) in edible ices would lead to a more stable product when using low saturated fats and oils as ingredients and with a lower sugar content. The use in emulsified sauces, at a higher maximum level, would allow the production of reduced-oil products without compromising the organoleptic properties.

1.1.2. Terms of Reference

1.1.2.1. Follow-up of the re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive

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 polyricinoleate (E 476) 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.

1.1.2.2. Extension of use for polyglycerol polyricinoleate (E 476)

The European Commission requests the European Food Safety Authority to provide a scientific opinion on the safety of the proposed extension of use for polyglycerol polyricinoleate (E 476) in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.³

1.2. Summary of the EFSA Re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive

PGPR (E 476) was re-evaluated by the EFSA ANS Panel which concluded that the data set gave reason to revise the ADI of 7.5 mg/kg bw per day allocated by the Scientific Committee on Food (SCF) to 25 mg/kg bw per day. Exposure estimates did not exceed the ADI of 25 mg/kg bw per day and a proposed extension of use would not result in an exposure exceeding this ADI (EFSA ANS Panel, 2017a).

The EFSA ANS Panel recommended that the specifications for polyglycerol polyricinoleate (E 476) in Commission Regulation (EU) No 231/2012 are updated. Specifically, the Panel recommended that:

- the maximum limits for the impurities of toxic elements (lead, mercury, cadmium and arsenic) in the European Commission specification for PGPR (E 476) should be revised in order to ensure that PGPR (E 476) as a food additive will not be a significant source of exposure to those toxic elements in food;
- a maximum limit for active ricin should be included in the EU specifications for PGPR (E 476);
- a maximum limit for 3-monochloropropane-1,2-diol (3-MCPD) should be included in the EU specifications for PGPR (E 476);
- given that during the manufacturing processes of glycerol, potential impurities of toxicological concern could be formed, limits for such impurities should be included in the EU specifications for PGPR (E 476);
- given that during the manufacturing processes of polyglycerols, genotoxic impurities – e.g. epichlorohydrin and glycidol – could be present, limits for such impurities should be included in the EU specifications for PGPR (E 476);
- an analytical method for the determination of actual PGPR (E 476) content in food should be developed.

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).

A dossier in support of the application for the extension of use of E 476 as a food additive has been also evaluated (Documentation provided to EFSA n. 2).

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.

Food consumption data used to estimate the dietary exposure to E 476 were derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database⁷).

The Mintel's Global New Products Database (GNPD) was used to verify the use of E 476 in food and beverage products and food supplements within the EU's food market. The Mintel's GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.

2.2. Methodologies

This opinion was 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.

The FAF Panel assessed the safety of the proposed extension of use of the food additive polyglycerol polyricinoleate (PGPR, E 476) in line with the EFSA Guidance for submission for food additive evaluations in 2012 (EFSA ANS Panel, 2012).

Dietary exposure to E 476 from its use as a food additive was estimated combining the food consumption data available within the Comprehensive Database with maximum permitted levels according to Annex II to Regulation (EC) No 1333/2008, reported use levels submitted to EFSA (EFSA ANS Panel, 2017a), and the use levels indicated in the proposed extension of use. The exposure was estimated according to different exposure scenarios (EFSA ANS Panel, 2017b). Uncertainties in the exposure assessment were identified and discussed (Section 3.3.5).

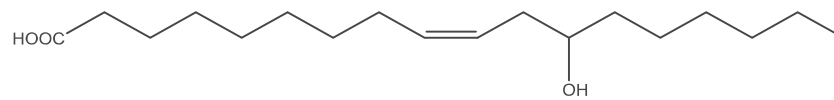
3. Assessment

3.1. Identity and specifications of E 476

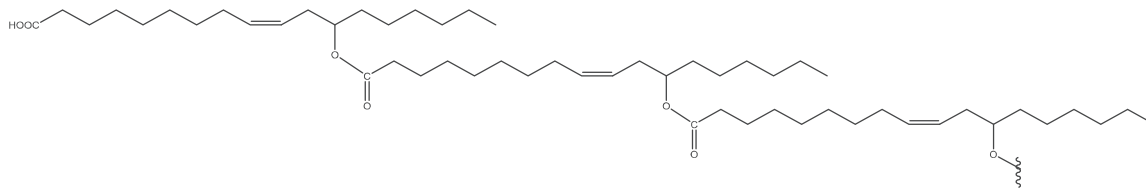
PGPR (E 476) is a mixture of products formed by the esterification of polyglycerols with condensed castor oil fatty acids which are mainly composed of ricinoleic acid (80–90%), oleic acid (3–8%), linoleic acid (3–7%), and stearic acid (0–2%) (EFSA ANS Panel, 2017a). According to Commission Regulation (EU) No 231/2012, the polyglycerol moiety is mainly composed of di-, tri- and tetraglycerol with not more than 10% equal or higher than heptaglycerol.

The general structural formula of PGPR is given in Figure 1 (as presented in EFSA ANS Panel, 2017a).

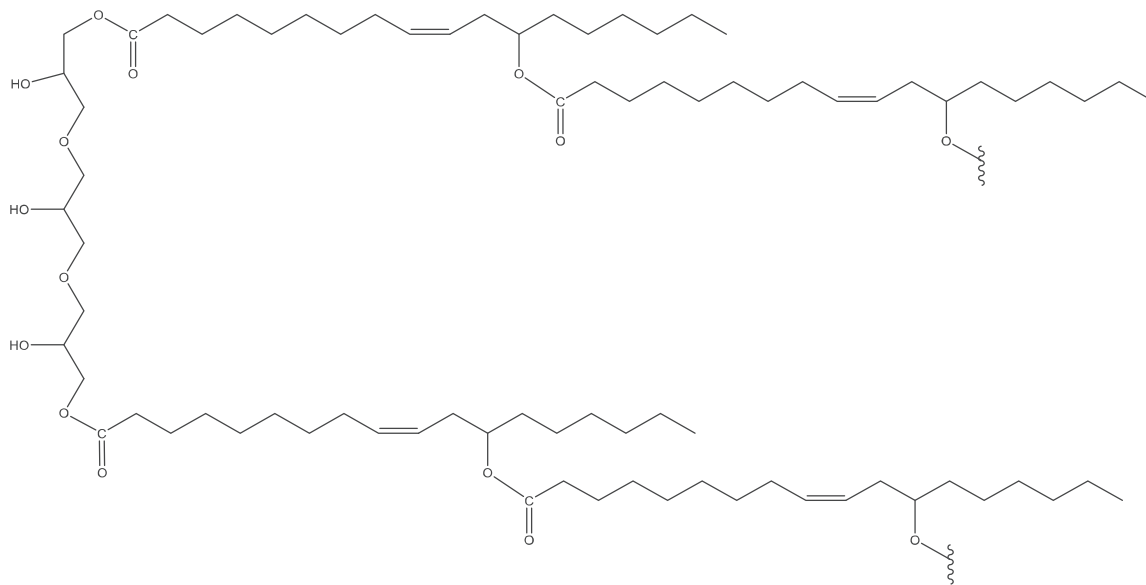
⁷ <https://www.efsa.europa.eu/en/data-report/food-consumption-data>



(a) Ricinoleic acid



(b) Polyricinoleic acid



(c) A polyglycerol polyricinoleate consisting of a polymer of 3 glycerol moieties, with single polyricinoleic acid moieties esterified onto the proximal and distal glycerols

Figure 1: Structural formula of polyglycerol polyricinoleate, adapted from Bastida-Rodriguez, (2013). (Copyright © 2013 Josefa Bastida-Rodriguez, Creative Commons Attribution License CC BY 3.0 as presented in the EFSA ANS Panel, 2017a)

Specifications for PGPR (E 476) have been defined in Commission Regulation (EU) No 231/2012 as described in Table 1.

Table 1: Specifications for PGPR (E 476) according to Commission Regulation (EU) No 231/2012¹

Commission Regulation No 231/2012	
Definition	Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids
Description	Clear, highly viscous liquid
Identification	
Solubility	Insoluble in water and in ethanol; soluble in ether, hydrocarbons and halogenated hydrocarbons
Test for glycerol	Passes test
Test for polyglycerol	Passes test
Test for ricinoleic acid	Passes test
Refractive index	$[n]_D^{65}$ between 1.4630 and 1.4665
Purity	
Polyglycerols	The polyglycerol moiety shall be composed of not less than 75% of di-, tri- and tetraglycerols and shall contain not more than 10% of polyglycerols equal to or higher than heptaglycerol
Hydroxyl value	Not less than 80 and not more than 100
Acid value	Not more than 6
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

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 476;
- the lowest technologically achievable level for arsenic, lead, mercury and cadmium in order to adequately define their maximum limits in the specifications for E 476.

Analytical levels in thirteen commercial samples of E 476 for lead, mercury, cadmium, and arsenic were submitted by the IBO (Documentation provided to EFSA n. 1). All samples had concentrations below the limits of quantification (LOQs), which ranged from 0.01 to 0.05 mg/kg for lead, 0.005 to 0.01 mg/kg for mercury, 0.005 to 0.02 mg/kg for cadmium, and 0.01 to 0.1 mg/kg for arsenic. The analyses were performed by inductively coupled plasma-mass spectrometry (ICP-MS) and inductively coupled plasma optical emission spectrometry (ICP-OES) (Documentation provided to EFSA n. 1).

According to the IBO, the levels of toxic elements in the food additive E 476 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 476 proposed by the IBO are reported in Table 2. According to the IBO, the proposed levels for lead, mercury, cadmium and arsenic are based on the highest measured value or LOQ, whichever is highest, applying a factor of 10 times this value (Documentation provided to EFSA n. 1).

Table 2: Lowest technologically achievable levels for the toxic elements lead, mercury, cadmium and arsenic in commercial E 476 proposed by an interested business operator (Documentation provided to EFSA n. 1)

Lead	Mercury	Cadmium	Arsenic
0.5 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 of active ricin in commercial samples of the food additive E 476;
- the lowest technologically achievable level for active ricin, in order to adequately define its maximum limit in the specifications of E 476;
- analytical data on current levels of monochloropropane-1,2-diol (3-MCPD) in commercial samples of the food additive E 476;
- the lowest technologically achievable level for monochloropropane-1,2-diol (3-MCPD), in order to adequately define its maximum limit in the specifications of E 476;
- analytical data on current levels in commercial samples of the food additive E 476 of epichlorohydrin and glycidol, which could be used in the manufacturing processes of polyglycerols (used, in turn, in the manufacturing process of E 476);
- the lowest technologically achievable level for epichlorohydrin and glycidol in order to adequately define their maximum limits in the specifications of E 476;
- analytical data on current levels in commercial samples of the food additive E 476 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 476;
- 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 476;
- analytical data on current levels in commercial samples of the food additive E 476 of any impurity present in glycerol (as mentioned in the call for data on the food additive glycerol (E 422)⁸), which can be used in the manufacturing process of E 476;
- the lowest technologically achievable level for any impurity which could be formed during the manufacturing processes of glycerol and be present in E 476, in order to adequately define their maximum limits in the specifications of E 476.

3.2.2.1. Ricin

The IBO asserted that 'there is no risk to find active ricin in E 476 and considers that the request for the lowest achievable levels is not applicable'. The IBO had consulted the castor oil suppliers who confirmed the absence of active ricin in the product and referred to the International Castor Oil Association (ICOA) document about ricin, which states that castor oil does not contain any ricin. Additionally, the IBO reported that a castor oil producer specified that the ricin present in castor seeds, during the process of expelling/extraction of the oil from the seeds, remains with the solid mass or the de-oiled cake portion of the seeds. Further, the IBO stated that the refining process of castor oil and ricinoleic acid employs heat (110°C) from water/steam, which is sufficient to destroy the ricin. As a consequence, according to the IBO, ricin is not present in the castor oil used to manufacture E 476 (Documentation provided to EFSA n. 1).

3.2.2.2. 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 eight commercial samples of the food additive E 476 (Documentation provided to EFSA n. 1). The concentrations of the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) were 0.1 and 0.13 mg/kg for two samples while the remaining six samples were all reported as below the LOQs which ranged from < 0.1 to < 0.3 mg/kg (Documentation provided to EFSA n. 1). 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). According to the IBO, '3-MCPD is neither formed nor removed in the manufacturing process of E 476. As such, the resulting content is solely dependent on the content in the raw materials used in the manufacturing process. As such, the concept of lowest technologically achievable level seems not to be relevant for 3-MCPD in E 476. However, in order to facilitate international trade of E 476 that

⁸ 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

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).

3.2.2.3. Epichlorohydrin

The IBO stated that 'there is no evidence of formation of epichlorohydrin in the emulsifier E 476 based on the raw materials used, and the process conditions'. Additionally, the IBO asserted that the suppliers of polyglycerol confirmed that they do not use epichlorohydrin in the manufacturing process of polyglycerols (Documentation provided to EFSA n. 1). The IBO considered that traces of epichlorohydrin in commercial samples of E 476 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).

3.2.2.4. Glycidyl esters

Concentrations of glycidyl esters (GEs), expressed as glycidol, were measured in seven commercial samples of E 476. Two samples measured GE concentrations of 0.23 and 0.37 mg/kg. The remaining five samples were reported to have GE levels as below the LOQ of < 0.1 mg/kg. 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 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) (Kuhlmann, 2021; Documentation provided to EFSA n. 1). The IBO considered that 1 mg/kg is an appropriate lowest technologically achievable level for glycidyl esters in E 476.

3.2.2.5. Butanetriols 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 476 (...) and confirmed that butanetriols were not detected (...)'. (Documentation provided to EFSA n. 1). A short description of the method used for the analysis of free butanetriol in E 476 was provided by the IBO, reporting that free butanetriol was not detected in three samples of E 476 at an 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-flame ionisation detector (GC-FID). The IBO stated that analysis for total butanetriol was also carried out on saponified samples of E 476 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 476 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 476 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 that the request for a lowest technologically achievable level for butanetriol and acrolein is not applicable since these compounds are not found in E 476 (Documentation provided to EFSA n. 1).

3.2.2.6. 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. Analytical method for the determination of PGPR (E 476) in food

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

- an analytical method for the determination of the actual PGPR (E 476) content in food;

An analytical method for the determination of PGPR (E 476) in food was presented by the IBO (Documentation provided to EFSA n. 1). According to the IBO, E 476 is used in dosages down to 0.1% in applicable foods and the single components compose less than 1% of the whole food additive. This makes it 'practically impossible to detect any of the individual components' in food (Documentation provided to EFSA n. 1). The IBO proposed an indirect method based on the determination of ricinoleic acid as an indicator for the total amount of PGPR in food. Ricinoleic acid is the unique part of the food additive as it is the component present in the highest concentration, at typically 80-90% of the fatty acid content in E 476. According to the IBO, the weaknesses of the method using ricinoleic acid (also known as '12-hydroxy oleic acid') as an indicator for the content of PGPR are the following:

- *The amount of ricinoleic acid in PGPR can vary in PGPRs from different producers, which may give results varying a few % from the actual content, depending on the actual content of 12-hydroxy oleic acid in the calibration material.*
- *Castor oil added to the formulation will interfere with the results and indicate a level which is higher than the actual content of PGPR. But use of castor oil in formulations relevant for PGPR is very uncommon, which makes the relevance of this concern minimal.*

The strengths of the method were described by the IBO as the following:

- *Lower limit of detection can be reached because approximately 80% of PGPR is 12-hydroxy oleic acid while no single component in PGPR is present in levels above 1%.*
- *Precision of indirect determination of 12-hydroxy oleic acid is better, because it is impossible to detect all the individual components and the content of any of the components used as indicator is varying relative more than the total content of 12-hydroxy oleic acid.*

In the submitted method of analysis, the food sample is first extracted to obtain the fat/oil fraction that will contain any E 476. The fat phase is then subjected to transmethylation and the sample is analysed by GC/MS for the content of 12-hydroxy oleic acid methyl ester (i.e. ricinoleic acid methyl ester). The method is stated to be applicable to determine E 476 in the range of 0.1–5% w/w in the fat phase. Therefore, the applicable range depends on the fat content of the food analysed. For example, for a fat content of 10% the applicable range corresponds to 0.01–0.5% (100–5,000 mg/kg) of E 476 in the (whole) food.

Taking into account the authorised uses and use levels for E 476 (Table 3), the Panel considered that the method is suitable for the determination of E 476 in foods.

3.3. Exposure assessment

A new exposure assessment to PGPR (E 476) has been performed because the current authorised uses according to Annex II to Regulation (EC) No 1333/2008 are different from those applicable at the time of the re-evaluation of this food additive (EFSA ANS Panel, 2017a).

3.3.1. Authorised use and use levels

Maximum levels of PGPR (E 476) have been defined in Annex II to Regulation (EC) No 1333/2008 on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

Currently, PGPR (E 476) is an authorised food additive in the EU with MPLs ranging from 4,000 to 5,000 mg/kg in 5 food categories (FC).

Table 3 summarises the food categories that are permitted to contain PGPR (E 476) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

Table 3: MPLs of PGPR (E 476) in foods according to the Annex II to Regulation (EC) No 1333/2008

Food category number	Food category name	Restrictions/exception	MPL (mg/L or mg/kg as appropriate)
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	Only spreadable fats as defined in Articles 75(1)(h) and 78(1)(f) and in Part VII and Appendix II of Annex VII to Regulation (EC) No 1308/2013 ⁽¹⁾ , having a fat content of 41% or less and similar spreadable products with a fat content of less than 10% fat; liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70% or less	4,000
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC		5,000
05.2	Other confectionery including breath freshening microsweets	Only cocoa-based confectionery	5,000
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Only cocoa-based confectionery	5,000
12.6	Sauces	Only emulsified sauces	4,000

MPL: maximum permitted level.

According to Annex III, Part 2 of Regulation (EC) No 1333/2008, PGPR (E 476) is also authorised as an emulsifier in preparations of food colours E 100 curcumin and E 120 cochineal, carminic acid, carmines and E 163 anthocyanins at the maximum levels of 50,000 mg/kg in the food colour preparations and at 500 mg/kg in the final food only in:

- Surimi and Japanese-type fish products (Kamaboko) (for the food additive E 120 cochineal, carminic acid, carmines),
- meat products, fish pastes and fruit preparations used in flavoured milk products and desserts (for the food additives E 163 anthocyanins, E 100 curcumin and E 120 cochineal, carminic acid, carmines).

3.3.2. Exposure data

Reported use levels or data on analytical levels of E 476

Data on the occurrence of E 476 in food were collected at the time of the re-evaluation of E 476 by the ANS Panel by means of a call for data launched in 2015.⁹ In response to this call, 149 use levels were submitted to EFSA by industry (EFSA ANS Panel, 2017b). Within the data provided, some levels were referring to ice-cream (FC 03 edible ices) in which E 476 is not currently authorised but the food additive could be present due to carry-over.

One analytical result, on a sample of filled chocolate, was submitted in 2021 but was not considered further for the exposure calculation as coming from suspect sampling.

For the current exposure assessment, the Panel considered the data collected during the EFSA call for data in 2015. Levels used for estimating the dietary exposure assessment of E 476 are presented in Appendix A.

Summarised data extracted from the Mintel's Global New Products Database

The Mintel's Global New Products Database (GNPD) is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information on over 3.6 million food and beverage products of which more than 1,300,000 are or have been available on the

⁹ Available online: <https://www.efsa.europa.eu/sites/default/files/consultation/151012.pdf>

European food market. Mintel started covering EU's food markets in 1996, currently having 24 out of its 27 Member States plus Norway presented in the Mintel's GNPD.¹⁰

For the purpose of this Scientific Opinion, the Mintel's GNPD was used for checking the labelling of food and beverage products and food supplements for E 476 within the EU's food market as the database contains the compulsory ingredient information on the label. According to the Mintel's GNPD, E 476 was labelled on almost 12,000 products of which 4,661 were published in the database between January 2017 and February 2022.¹¹

Appendix B lists the percentage of the food products labelled with E 476 out of the total number of food products per food subcategory according to the Mintel's GNPD food classification for the period January 2017–February 2022. The percentages ranged from 0.1% in several food subcategories to 16.5% in dairy based ices cream and frozen yogurt. Following subcategories of chocolate products contained the following highest levels: Chocolate Countlines (12.3%), Seasonal Chocolate (9.4%), Non-Individually Wrapped Chocolate Pieces (8.0%), Individually Wrapped Chocolate Pieces (6.6%). The average percentage of food products in the EU labelled as containing E 476 was 3.4% of all food products included in the subcategories in Mintel in which E 476 is listed.

As can be seen in Appendix B, some foods are labelled with E 476 because the food item contains ingredients in which E 476 is authorised. This is the case for instance for 'dairy based ice cream and frozen yogurt' (FC 03) or 'Sweet Biscuits/Cookies' (FC 07.2) which can contain chocolate dragees (i.e. confectionery) authorised to contain PGPR (E 476) as belonging to the FC 05.1 or 05.4.

Food consumption data used for the exposure assessment

EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011). The version of the Comprehensive database taken into account in the exposure assessment was published in July 2021.⁷

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons may not be appropriate. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

Food consumption data from the following population groups were used for the exposure assessment: infants, toddlers, children, adolescents, adults and the elderly. For the present assessment, food consumption data were available from 41 different dietary surveys carried out in 23 EU Member States (Table 4). Since more dietary surveys are available in the EFSA comprehensive database compared to 2016, more countries are now considered in each population group. As the 95th percentile of exposure was only calculated for those population groups with a sufficiently large sample size (EFSA, 2011), in the present assessment, it was not estimated for infants from Italy and France, for toddlers from Belgium and Italy and for adolescents from Estonia.

Table 4: Population groups considered for the exposure estimates of PGPR (E 476)

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Portugal, Slovenia
Toddlers ^(a)	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Cyprus, Denmark, Estonia, Finland, France, Germany, Hungary, Italy, Latvia, Netherlands, Portugal, Slovenia, Spain

¹⁰ Missing Cyprus, Luxembourg and Malta.

¹¹ <https://portal.mintel.com/portal/login?next=/> [Accessed: 15 February 2022].

Population	Age range	Countries with food consumption surveys covering more than 1 day
Children ^(b)	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Spain, Sweden
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden
The elderly ^(b)	From 65 years of age and older	Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Netherlands, Portugal, Romania, Slovenia, Spain, Sweden

(a): The term 'toddlers' in the Comprehensive Database (EFSA, 2011) corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013.

(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in Comprehensive Database (EFSA, 2011).

Consumption records were codified according to the FoodEx2 classification system (EFSA, 2015). Nomenclature from the FoodEx classification system was linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform the exposure assessments. In practice, the FoodEx2 food codes were matched to the FCS food categories.

Food categories considered for the exposure assessment of PGPR (E 476)

The food categories for which occurrence data of E 476 are available were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx2 classification system), at the most detailed level possible (EFSA, 2015).

Regarding the exposure assessment considering the current authorised uses, FC 03 (Edible ices) was considered despite being a FC in which E 476 is not authorised but for which reported levels were submitted in 2015 due to carry-over of E 476 from an ingredient to the edible ices.

Regarding the FC 02.2.2, the restrictions related to the percentage fat content are difficult to take into account when estimating the exposure, as foods registered according to FoodEx2 do not indicate the fat percentage. Food products might therefore correspond only approximately to the restrictions as defined in the legislation (Table 3).

Despite no use levels were available for the FC 12.6, emulsified sauces, the proposed reported level (4,000 mg/kg) at the time of the request for this authorisation (EFSA ANS Panel, 2017a), that is the current MPL in Regulation (EC) No 1333/2008, have been considered for the refined exposure scenario.

3.3.3. Exposure estimates to E 476

The Panel estimated the chronic dietary exposure to PGPR (E 476) for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. The methodology to estimate dietary exposure to E 476 for the different scenarios – regulatory maximum level exposure assessment scenario and refined exposure assessment scenarios (brand-loyal and non-brand-loyal) – presented in the current assessment are described in the approach for the refined exposure assessment of food additives under re-evaluation (EFSA ANS Panel, 2017a).

Table 5 summarises the estimated exposure to E 476 from its use as a food additive in six population groups according to the different exposure scenarios. Detailed results per population group and survey are presented in Appendix C.

Table 5: Summary of dietary exposure to E 476 from its use as a food additive in the regulatory maximum level exposure assessment scenario, and refined exposure assessment scenario in six population groups (minimum – maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks–11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Regulatory maximum level exposure assessment scenario						
Mean	0.01–0.7	0.5–7.7	1.6–6.4	0.9–3.5	0.3–2.0	0.2–2.0
95th percentile	0–5.6	2.9–14.6	5.3–16.2	4.0–9.5	1.4–5.5	0.9–6.1
Refined exposure assessment scenario						
Brand-loyal scenario						
Mean	0.01–0.6	0.5–3.7	0.8–4.0	0.8–2.3	0.2–1.7	0.1–1.8
95th percentile	0–5.6	2.1–10.1	3.0–10.6	2.8–6.8	1.2–5.2	0.7–5.6
Non-brand-loyal scenario						
Mean	0.01–0.16	0.2– 3.2	0.2–3.0	0.2–1.7	0.1–1.4	0.04–1.6
95th percentile	0–1.3	1.2– 8.1	0.8–6.8	1.0–5.0	0.5–4.4	0.3–5.3

bw: body weight.

In the *regulatory maximum level exposure assessment scenario*, mean exposure to PGPR (E 476) from its use as a food additive ranged from 0.01 mg/kg bw per day in infants to 7.7 mg/kg bw per day in toddlers. At the 95th percentile, exposure to PGPR (E 476) ranged from 0 mg/kg bw per day in infants to 16.2 mg/kg bw per day for children.

In the *refined estimated exposure scenario*, in the *brand-loyal scenario*, mean exposure to PGPR (E 476) from its use as a food additive ranged from 0.01 mg/kg bw per day in infants to 4.0 mg/kg bw per day in children. At the 95th percentile, exposure to PGPR (E 476) ranged from 0 mg/kg bw per day in infants to 10.6 mg/kg bw per day in children. In the *non-brand-loyal scenario*, mean exposure to PGPR (E 476) from its use as a food additive ranged from 0.01 mg/kg bw per day in infants to 3.2 mg/kg bw per day in toddlers. At the 95th percentile, exposure to PGPR (E 476) ranged from 0 mg/kg bw per day in infants to 8.1 mg/kg bw per day in toddlers.

Main food categories contributing to exposure to PGPR (E 476)

At the *regulatory maximum level exposure assessment scenario*, the main food category contributing to exposure to PGPR (E 476) is cocoa and chocolate products as covered by Directive 2000/36/EC (FC 05.1) for all population groups. For toddlers, children and adolescents, other confectionery including breath freshening microsweets (FC 05.2) is the second contributing food category; for adults and the elderly, sauces (FC 12.6) is the second contributing food category.

In both the *brand-loyal* and *non-brand-loyal refined estimated exposure scenario*, the main contributing food category is cocoa and chocolate products as covered by Directive 2000/36/EC (FC 05.1) in all population groups, other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions (FC 02.2.2) and sauces (FC 12.6) being the other main contributing food categories.

Taking into account the main food categories contributing to the exposure estimates, the Panel considered that brand-loyalty would not be expected. Added to that, PGPR (E 476) is an emulsifier and its use would not influence the selection of foods by the consumers. Therefore, the Panel considered the non-brand-loyal scenario as the most relevant exposure scenario for the safety evaluation of PGPR (E 476).

All food categories contributing to the total exposure to PGPR (E 476) as a food additive are available in Appendix D.

3.3.4. Dietary exposure to PGPR (E 476) considering the proposed extension of use

A new exposure estimate was performed for the assessment of the request for extension of use. The request referred to the proposed use in a new food category (FC) and revision of the maximum permitted level in an already authorised FC as presented below:

- FC 03 edible ice, with the restriction ‘only fat and oil emulsion of water-in-oil type’, at a maximum level of 4,000 mg/kg;
- FC 12.6 Sauces, with the restriction ‘only emulsified sauces with a fat content of 20% and more’, at a maximum level of 8,000 mg/kg;

In order to estimate the anticipated dietary exposure to PGPR (E 476) considering the proposed extension of use, the Panel used the MPLs for the food categories in which PGPR (E 476) is currently authorised together with the proposed use levels for the proposed food categories (*regulatory maximum level exposure assessment scenario* including the proposed extension of use).

For applying the proposed restriction for the FC 12.6 (as mentioned above), the same difficulty applies as above in the selection of the foods. The proposed use of 8,000 mg/kg for sauces with a fat content above 20% was attributed to all sauces except the one indicated as low fat (a mayonnaise).

Table 6 summarises the estimated exposure to PGPR (E 476), according to the *regulatory maximum level exposure assessment scenario*, from its use as a food additive in six population groups (Table 4) taken into account the proposed extension of use on the FC 03 Edible ice with the restriction ‘only fat and oil emulsion of water-in-oil type’, at a maximum level of 4,000 mg/kg and FC 12.6 Sauces, with the restriction ‘only emulsified sauces with a fat content of 20% and more’, at a maximum level of 8,000 mg/kg according to the different exposure scenarios.

Regarding FC 03 Edible ices, only the milk-based ice cream was considered in order to apply the proposed restriction, but not sorbet, at the proposed maximum level of 4,000 mg/kg. For the FC 12.6 Sauces, the restriction was considered by applying a proposed maximum level of 8,000 mg/kg to all emulsified sauces except low fat salad dressing, which was considered to have a fat content below 20% and, therefore, with the current maximum permitted level of 4,000 mg/kg.

Detailed results per population group and survey are presented in Appendix E.

Table 6: Summary of anticipated dietary exposure to E 476 from its use as a food additive in the regulatory maximum level exposure assessment scenario considering the proposed extension of use, in six population groups (minimum – maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks– 11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Regulatory maximum level exposure assessment scenario + proposed extension of use						
• Mean	0.02–1.4	0.8–8.9	3.2– 9.1	1.2–4.8	0.5–3.0	0.2–2.6
• 95th percentile	0–5.6	4.8–21.8	12.8– 23.2	5.4–12.4	2.7–9.9	1.1–7.8

bw: body weight.

3.3.5. Uncertainty analysis

In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and are summarised in Table 7.

Table 7: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction^(a)
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/-
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+
Correspondence of reported use levels to the food items in the EFSA Comprehensive Database: uncertainties to which types of food the levels refer	+/-
Uncertainty in possible national differences in use levels of food categories	+/-
Occurrence data: – use levels considered applicable to all foods within the entire food category, whereas the average percentage of food products in the EU labelled as containing E 476 was only 3.4% of all the food products in the subcategories in Mintel in which E 476 is listed	+

Sources of uncertainties	Direction ^(a)
Food categories selected for the exposure assessment: inclusion of food categories with considering only approximately the restriction/exception (n = 1 MPL scenario/n = 1 refined scenarios out of 5 food categories)	+
Food categories included in the exposure assessment: no data for the food category of sauces (FC 12.6) which was considered in the refined exposure estimates using the MPL of 4,000 mg/kg	+
Foods which may contain the food additive according to Annex III to Regulation (EC) No 1333/2008 not taken into account	-
Regulatory maximum level exposure assessment scenario: – exposure calculations based on the MPL according to Annex II to Regulation (EC) No 1333/2008	+
Refined exposure assessment scenarios: – exposure calculations based on the maximum or mean levels (reported use from industries)	+/-

E 476 is authorised in five food categories (Table 3). In the current exposure assessment, all authorised food categories were considered in the refined scenarios, considering the level of 4,000 mg/kg for the sauces (FC 12.6). In addition, edible ices (FC 03) was also considered as data were provided by industry.

The Panel noted that information from the Mintel's GNPD (Appendix B) indicated that approximately 22 out of 42 food subcategories, categorised according to the Mintel's GNPD nomenclature, in which E 476 was labelled were included in the current exposure assessment. These 22 food subcategories represented approximately 67% of the food products labelled with E 476 in the database. Furthermore, the percentage of foods per subcategory labelled to contain E 476 was maximally about 16.5% in Dairy Based Ice Cream & Frozen Yogurt (on average, the percentage of food products in the EU labelled as containing E 476 was 3.4% of all the food products included in the subcategories in Mintel in which E 476 is listed), while in the assessment, it was assumed that 100% of the foods belonging to an authorised food category contained the food additive.

Given these observations, the Panel considered overall that the uncertainties identified resulted in an overestimation of the exposure to E 476 from its use as a food additive according to Annex II to Regulation No 1333/2008 for all scenarios.

3.4. Proposed revision to existing EU Specifications for polyglycerol polyricinoleate (E 476)

The potential exposure to impurities from the use of the food additive E 476 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 476 as presented in Table 5.

The 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 476 as it did not identify brand loyalty to a specific food category for the exposure to the food additive.

For the current assessment, the highest exposure levels in the non-brand-loyal refined scenario for the mean and 95th percentile among the different population groups were considered, i.e. 3.2 and 8.1 mg/kg bw per day respectively, for toddlers (Table 5). The revision of the proposed specifications for E 476 considering the proposed extension of use is presented in Section 3.4.4.

The level of the impurity in the food additive combined with the estimated or potential intakes of E 476, presented in Table 5, could result in an exposure which can be compared with the following reference points (RP) or health-based guidance values (HBGV) (Table 8) for the undesirable impurities present in E 476.

Table 8: Reference points/health-based guidance values for impurities and constituents potentially present in E 476

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)
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 (2016)

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 reference point (e.g. BMDL, Table 8) by the exposure estimate (Table 5), or by estimating the contribution of the use of E 476 to the HBGV (expressed as percentage of the HBGV).

3.4.1. 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 476 were reported (Section 3.2.1). As indicated in Table 2, the IBO proposed lowest technologically achievable levels for lead (0.5 mg/kg), 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. 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 9 considering the current limits of these toxic elements in the EU specifications for E 476 (Commission Regulation (EU) No 231/2012) and the lowest technologically achievable levels proposed by the IBO (Table 2).

Table 9: Risk assessment for toxic elements

Exposure to E 476 (mg/kg bw per day)	Based on the current limits for toxic elements in the EU specifications for E 476 (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
3.2 ^(a)	78	0.56	0.90	31–833
8.1 ^(b)	31	1.4	2.3	12–329
Exposure to E 476 (mg/kg bw per day)	Based on the lowest technologically achievable levels for toxic elements in E 476 proposed by the IBO (Documentation provided to EFSA n. 1)			
	MOE for Pb at 0.5 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
3.2 ^(a)	312	0.06	0.18	94–2,500
8.1 ^(b)	123	0.14	0.45	37–988

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 – toddlers – mean (Table 5)).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario – toddlers – 95th percentile (Table 5)).

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 9).

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.

3.4.2. Carry-over and process impurities

3.4.2.1. 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) considering that these impurities would be present in the food additive at the maximum limit of 2.5 mg/kg proposed by the IBO (Table 10).

Table 10: 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 476 proposed by the IBO (Documentation provided to EFSA n. 1)

Exposure to E 476 (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
3.2 ^(a)	0.40
8.1 ^(b)	1

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

(a): Highest exposure level among the different population groups (refined non-brand-loyal scenario – toddlers – mean (Table 5)).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario – toddlers – 95th percentile (Table 5)).

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 8), 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 10) 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 476, the Panel recommends to consider setting a specification limit value for these impurities in Commission Regulation (EU) No 231/2012 for E 476. 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 476 could include a requirement that the fats and oils used in the manufacturing of E 476 comply with the respective EU legislation regarding suitability for human consumption.

3.4.2.2. Glycidyl esters

The outcome of the risk assessment of the FAF Panel for GEs is illustrated in Table 11 considering the lowest technologically achievable levels in E 476 proposed by the IBO, i.e. 1 mg/kg (see Section 3.2.2.4).

Table 11: Risk assessment for GEs (expressed as glycidol) based on the lowest technologically achievable level (1 mg/kg) in E 476 proposed by the IBO (Documentation provided to EFSA n. 1)

Exposure to E 476 (mg/kg bw per day)	MOE for GEs (expressed as glycidol) at 1 mg/kg
3.2 ^(a)	3,187,500
8.1 ^(b)	1,259,259

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

(a): Highest exposure level among the different population groups (refined non-brand-loyal scenario – toddlers – mean (Table 5)).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario – toddlers – 95th percentile (Table 5)).

The Panel noted that the MOE is well above the value of 25,000 given in Table 8 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 476, the Panel recommends to consider setting a specification limit value for this impurity in Commission Regulation (EU) No 231/2012 for E 476. As an alternative to introducing an individual specification limit value for GEs, the definition of E 476 could include a requirement that the fats and oils used in the manufacturing of E 476 comply with the respective EU legislation regarding suitability for human consumption.

3.4.2.3. Ricin, acrolein, butanetriol and epichlorohydrin

According to the IBO, ricin is not present in the castor oil used for the production of E 476 and, therefore, it is not present in E 476 (see Section 3.2.2.1). The Panel concurs with the statement of the IBO being also supported by the EFSA CONTAM Panel opinion on ricin as undesirable substance in animal feed (EFSA CONTAM Panel, 2008). Based on the information available, the Panel considered that there would be no need for including a limit for ricin in the specifications for E 476.

During the re-evaluation of E 476 by the EFSA ANS Panel in 2017, it was noted that epichlorohydrin may be present in E 476 from the possible chemical synthesis of polyglycerols to be used to produce E 476. In addition, impurities present in glycerol, to be used for the manufacturing of polyglycerols, could also be present as carry-over impurities in E 476 (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 476 (see Section 3.2.2.3). However, the Panel noted that the present definition of E 476 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 476 (see Section 3.2.2.5). 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).¹²

Regarding epichlorohydrin, acrolein and butanetriol, the Panel recommends a modification of the definition of E 476 indicating that polyglycerol used for the manufacturing of E 476 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 476.

3.4.3. 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 polyricinoleate (E 476) as listed in Table 12. The Panel noted that the choice of maximum limits for impurities in the EU specifications is in the remit of risk management.

Table 12: Proposal for a revised version of the existing EU Specifications for polyglycerol polyricinoleate (E 476)

	Commission Regulation (EU) No 231/2012	Comment/justification for revision
Definition	See Table 1	The Panel recommends a modification of the definition of E 476 indicating that polyglycerol used for the manufacturing of E 476 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 476.
Description	See Table 1	Unchanged
Identification	See Table 1	Unchanged
Solubility	See Table 1	Unchanged
Test for glycerol	See Table 1	Unchanged
Test for polyglycerol	See Table 1	Unchanged
Test for ricinoleic Acid	See Table 1	Unchanged
Refractive index	See Table 1	Unchanged
Purity	See Table 1	Unchanged
Polyglycerols	See Table 1	Unchanged
Hydroxyl value	See Table 1	Unchanged
Acid value	See Table 1	Unchanged
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

¹² EFSA-Q-2019-00815.

	Commission Regulation (EU) No 231/2012	Comment/justification for revision
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
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
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
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 specification values for the impurities indicated by the *, the definition of E 476 could include a requirement that the fats and oils used in the manufacturing of E 476 comply with the respective EU legislation regarding suitability for human consumption.

3.4.4. Impact of the proposed extension of use in the proposed revisions to the EU specifications

The potential exposure to impurities from the use of PGPR (E 476) considering the proposed extension of use has been carried out similarly to what is presented in Sections 3.4.1 and 3.4.2. In this context, the highest exposure levels in the regulatory maximum level exposure assessment scenario for the mean and 95th percentile among the different population groups have been considered, i.e. 9.1 and 23.2 mg/kg bw per day, respectively, for children (Table 6).

The outcome of the risk assessment of the Panel is illustrated in Appendix F.

When comparing the potential exposure to impurities (Tables F.1–F.3, Appendix F) considering the exposure to E 476 including the proposed extension of uses with the RP/HBGV for the undesirable impurities presented in Table 8, the Panel noted that the entire calculated range of MOEs for arsenic (Table F.1) was insufficient.

The Panel noted that an amendment of the specifications for PGPR (E 476) laid down in Commission Regulation (EU) No 231/2012, as presented by the considerations made in Table 12 would still be recommended in case the proposed extension of use for E 476 would be authorised.

3.5. Discussion

The current assessment addresses the EFSA recommendations indicated during the re-evaluation of PGPR (E 476) as a food additive (EFSA ANS Panel, 2017a) to update its EU specifications (E 476) in Commission Regulation (EU) No 231/2012. Additionally, the present opinion deals with the assessment of the proposed extension of use for PGPR (E 476) in edible ices and emulsified sauces.

Dietary exposure to PGPR (E 476) was estimated because the current authorised uses, according to Annex II to Regulation (EC) No 1333/2008, are different from those considered at the time of the re-evaluation of this food additive (EFSA ANS Panel, 2017a). For the current exposure estimate, data provided through the call for data and considered in the re-evaluation of the food additive, and the proposed reported level¹³ for emulsified sauces (FC 12.6) at the time of the request for this authorisation¹⁴ have been used (EFSA ANS Panel, 2017a). For the additional *regulatory maximum level exposure assessment* scenario related to the proposed extension of use, the proposed maximum use levels (Documentation provided to EFSA n. 2) were considered.

Taking into account the main food categories contributing to the exposure estimates, the Panel considered that brand-loyalty would not be expected. Added to that, PGPR (E 476) is an emulsifier and its use would not influence the selection of foods by the consumers. Therefore, the Panel considered the non-brand-loyal scenario as the most relevant exposure scenario for the safety evaluation of PGPR

¹³ Currently MPL in Regulation (EC) No 1333/2008.

¹⁴ This level being the current MPL for emulsified sauces (FC 12.6).

(E 476). In that scenario, mean exposure to PGPR (E 476) from its use as a food additive ranged from 0.01 mg/kg bw per day in infants to 3.2 mg/kg bw per day in toddlers. At the 95th percentile, exposure to PGPR (E 476) ranged from 0 mg/kg bw per day in infants to 8.1 mg/kg bw per day in toddlers (Table 5). The Panel noted that in none of the scenarios, the exposure exceeded the ADI of 25 mg/kg bw per day for PGPR (E 476) established by the ANS Panel (EFSA ANS Panel, 2017a).

Considering the proposed extension of use in FC 03 and a revision of the maximum permitted level in FC 12.6, exposure estimates according to the *regulatory maximum level exposure assessment scenario* do not exceed the ADI for PGPR (E 476). Therefore, the Panel concluded that the proposed extension of use, if authorised, would not give rise to a safety concern.

In response to the European Commission call for data, analytical data on potential impurities in commercial samples of E 476 were provided by one IBO and respective limit values were proposed. The potential exposure to impurities from the use of the food additive E 476 was calculated by assuming that these compounds 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 476 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 the four toxic elements by choosing the highest measured value or LOQ, whichever was highest, and applying a factor of 10 times this value. The Panel performed a risk assessment considering both the current limits for the four toxic elements in the EU specifications for E 476 (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 476 were compared against the available HBGVs and RPs (Table 8). 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 9). 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 12).

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 476 proposed by the IBO. By comparing the potential exposure to 3-MCPD from the use of E 476 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.

Analytical data on levels of GEs, expressed as glycidol, in commercial samples of E 476 and a lowest technologically achievable level were provided by the IBO. The Panel performed a risk assessment considering the lowest technologically achievable level (1 mg/kg) proposed by the IBO. The potential exposure to GEs from the use of E 476 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.

Considering the potential occurrence of GEs and the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) in E 476, the Panel recommends to consider setting specification limit values for these impurities in Commission Regulation (EU) No 231/2012 for E 476 as indicated in Table 12. 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 476 comply with the respective EU legislation regarding suitability for human consumption.

Analytical data on the levels of ricin, acrolein, butanetriol and epichlorohydrin were requested in line with the recommendations from the re-evaluation (EFSA ANS Panel, 2017a). According to the IBO, ricin is not present in the castor oil used for the production of E 476 and, therefore, it is not present in E 476 (see Section 3.2.2.1). Based on the information available, the Panel considered that there would be no need for including a limit for ricin in the EU specifications for PGPR (E 476).

Further, the IBO reported that 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 476 (see Section 3.2.2.5). 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 476 and, therefore, it is not expected to be present in E 476 (see Section 3.2.2.3). However, the Panel noted that the present definition of E 476 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 476 indicating that polyglycerol used for the manufacturing of E 476 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 476.

In response to the European Commission call for data, an analytical method for the determination of PGPR (E 476) content in food was submitted by the IBO. Due to the impossibility to detect all individual components in E 476, the IBO proposed a method based on the determination of ricinoleic acid, which can be used as an indicator for the total amount of PGPR in food. The Panel concluded that the proposed method is suitable for the determination of the actual E 476 content in food.

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 PGPR (E 476) laid down in Commission Regulation (EU) No 231/2012, as presented by the recommendations made in Table 12.

The potential exposure to impurities from the use of E 476, considering the proposed extension of use, has been carried out similarly to what is presented in Sections 3.4.1 and 3.4.2. The Panel noted that the entire calculated range of MOEs for arsenic (Table F.1, Appendix F) is insufficient. The Panel noted that an amendment of the specifications for polyglycerol polyricinoleate (E 476) laid down in Commission Regulation (EU) No 231/2012, as presented by the considerations made in Table 12 would still be recommended in case the proposed extension of use for E 476 would be authorised.

4. Conclusions

The Panel concluded that the technical data provided by the IBO support an amendment of the specifications for polyglycerol polyricinoleate (E 476) laid down in Commission Regulation (EU) No 231/2012, as presented by the recommendations made in Table 12.

Additionally, the Panel concluded that the proposed extension of use for E 476 in FC 03 'edible ices' and a revision of the maximum permitted level in FC 12.6 'emulsified sauces', if authorised, would not give rise to a safety concern.

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 polyricinoleate (E 476). Submitted by EFEMA, 17 December 2020.
- 2) Unilever NV, 2020. Technical dossier for the request on the extension of use: Modification of the condition of use of PGPR (E 476) in edible ices and emulsified sauces. Submitted by Unilever NV, 18 March 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
EFEMA	European Food Emulsifier Manufacturers Association
FAF Panel	Panel on Food Additives and Flavourings
FAO/WHO	Food and Drug Organization/World Health Organization
FC	food category
GC-FID	gas chromatograph(y)-flame ionisation detector
GEs	glycidyl esters
GS/MS	gas chromatography/mass spectrometry
HBGV	health-based guidance value
ICP-MS	inductively coupled plasma-mass spectrometry
ICP-OES	inductively coupled plasma optical emission spectrometry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
Mintel GNPD	Mintel's Global New Products Database
LOD	limit of detection
LOQ	limit of quantification
MOE	margin of exposure
ND	not detected
PGPR	polyglycerol polyricinoleate

RP	reference point
SC	Scientific Committee of EFSA
SCF	Scientific Committee on Food
T ₂₅	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

Appendix A – Concentration levels of PGPR (E 476) used in the exposure assessment scenarios (mg/kg or mL/kg as appropriate)

Appendix B – Number and percentage of food products labelled with PGPR (E 476) out of the total number of food products present in the Mintel GNPD per food subcategory between 2017 and 2022

Appendix C – Summary of total estimated exposure of PGPR (E 476) from their use as a food additive for the maximum permitted level exposure scenario and the refined exposure assessment scenarios per population group and survey: mean and 95th percentile (mg/kg bw per day)

Appendix D – Main food categories contributing to exposure to PGPR (E 476) using the maximum permitted level exposure assessment scenario and the refined exposure assessment scenarios (> 5% to the total mean exposure)

Appendix E – Summary of total estimated exposure of PGPR (E 476) from their use as a food additive for the regulatory maximum permitted level exposure scenario + proposed use levels per population group and survey: mean and 95th percentile (mg/kg bw per day)

Appendices A–E can be found in the online version of this output ('Supporting information' section): <https://doi.org/10.2903/j.efsa.2022.7294>

Appendix F – Risk assessment of undesirable impurities considering the proposed extension of use of PGPR (E 476)

Table F.1: Risk assessment for toxic elements considering the proposed extension of use

Proposed extension of use	Based on the current limits for the toxic elements in the EU specifications for E 476 (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
9.1 ^(a)	27	2	3	11–293
23.2 ^(b)	11	4	7	4–115
Proposed extension of use	Based on the lowest technologically achievable levels for the toxic elements in E 476 proposed by the IBO (Documentation provided to EFSA n. 1)			
	MOE for Pb at 0.5 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
9.1 ^(a)	110	0.16	0.51	33–879
23.2 ^(b)	43	0.41	1.3	13–345

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

(a): Highest exposure level among the different population groups (regulatory maximum level scenario – children - mean (Table 6)).

(b): Highest exposure level among the different population groups (regulatory maximum level scenario – children – 95th percentile (Table 6)).

Table F.2: 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 476 proposed by the IBO (Documentation provided to EFSA n. 1) considering the proposed extension of use

Proposed extension of use	% of the TDI for the sum of 3-MCPD and 3-MCPD fatty acid esters (expressed as 3-MCPD) at 2.5 mg/kg
9.1 ^(a)	1.1
23.2 ^(b)	2.9

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

(a): Highest exposure level among the different population groups (regulatory maximum level scenario - children - mean (Table 6)).

(b): Highest exposure level among the different population groups (regulatory maximum level scenario – children – 95th percentile (Table 6)).

Table F.3: Risk assessment for GEs (expressed as glycidol) based on the lowest technologically achievable level (1 mg/kg) in E 476 proposed by the IBO (Documentation provided to EFSA n. 1) considering the proposed extension of use

Proposed extension of use	MOE for GEs (expressed as glycidol) at 1 mg/kg
Potential exposure to E 476 (mg/kg bw per day)	
9.1 ^(a)	1,120,879
23.2 ^(b)	439,655

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

(a): Highest exposure level among the different population groups (regulatory maximum level scenario – children – mean (Table 6)).

(b): Highest exposure level among the different population groups (regulatory maximum level scenario – children – 95th percentile (Table 6)).