
Safety Assessment: Outcome of Assessment of the Extension of use of Polyglycerol Polyricinoleate (E 476) in Edible Ices and Emulsified Sauces

Reference number RP217

Food Standards Agency (FSA) and Food
Standards Scotland (FSS)

Regulated Product Dossier Assessment

Assessment finalised: 19/09/2023

Summary

An application was submitted to the Food Standards Agency (FSA) and Food Standards Scotland (FSS) in February 2021 from Unilever (“the applicant”) for the extension of use of the already authorised additive polyglycerol polyricinoleate (PGPR, E476) within the following food categories:

- Extension of use in food category (FC) 03 - Edible ices, with the restriction “only fat and oil emulsion of water-in-oil type”. The proposed normal and maximum use level of PGPR in the proposed food category are 3000 mg/kg and 4000 mg/kg, respectively.
- Change of use level in food category (FC) 12.6 – Sauces, with the restriction ‘only emulsified sauces with a fat content of 20% and more’. The normal and maximum use levels of PGPR in the proposed food category are 6000 mg/kg and 8000 mg/kg respectively.

This Application is being considered under the food additives regime.

To support the FSA and FSS in evaluating the dossier the Joint Expert Group on Additives, Enzymes and other regulated products (AEJEG) were asked to review the dossier and the supplementary information from the applicant. The AEJEG concluded that the extension of use of PGPR was safe under the proposed uses and use levels. The Committee on Toxicity (COT) also reviewed the AEJEG safety assessment agreeing with the conclusions of the AEJEG.

The views of the AEJEG and COT have been taken into account in this safety assessment which represents the opinion of the FSA and FSS on the extension of use of PGPR in edible ices and sauces.

1. Introduction

The FSA and FSS have undertaken a partial risk assessment for the extension of use of the already authorised food additive, polyglycerol polyricinoleate (PGPR, E 476),

under food additives legislation. To support the risk assessment by FSA and FSS, the AEJEG provided advice to the FSA and FSS outlined in this assessment.

The dossier was evaluated on behalf of the FSA and FSS by the AEJEG. In line with Article 3 of retained EU regulation 1331/2008 (REUL 1331/2008), the assessment has considered the aspects of the food additive and its extension of use. This, and the guidance put in place by EFSA for food additive applications, has formed the basis and structure for the assessment (EFSA, 2012).

With thanks to the members of the AEJEG during the course of the assessment who were: Dr Allain Bueno, Dr Claude Lambré, Dr Martin Rose, Dr Olwenn Martin and Professor Qasim Chaudhry.

This document outlines the conclusions of the AEJEG assessment on the safety of the proposed uses and use levels for PGPR.

2. Assessment

2.1 Identity and Characterisation of the additive

PGPR (E 476) is a mixture of products formed by the esterification of polyglycerol with condensed castor oil fatty acids. This information has not been submitted as part of this application. The applicant declares that the information on the identity and characterisation of PGPR are detailed in the EFSA opinion on the re-evaluation of PGPR (EFSA, 2017). The applicant stated that the source PGPR will be purchased from a number of potential suppliers and will comply with the current specifications laid down within Regulation (EC) No. 231/2012 (as retained EU legislation).

The UK specification for E476 as within Regulation (EC) No. 231/2012 (as retained EU legislation) is presented in Table 1.

Table 1. Current specifications for PGPR (E 476) as presented within UK legislation provided by the Applicant.

| | |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Synonyms | Glycerol esters of condensed castor oil fatty acids; Polyglycerol esters of polycondensed fatty acids from castor oil; Polyglycerol esters of interesterified ricinoleic acid; PGPR |
| 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 |

Table 1 (ctd). Current specifications for PGPR (E 476) as presented within UK legislation provided by the Applicant.

| Purity (ctd) | Details |
|--------------|-----------------------|
| 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 |

2.1.1 Particle Size and distribution

This information was not provided by the applicant. The applicant has stated that information on the physical characteristics of PGPR are detailed in EFSA's re-evaluation of PGPR (EFSA, 2017) however, it is noted that information on the physical characteristics of PGPR or particle size have not been included in the EFSA opinion.

2.2 Production Process

The applicant did not submit a detailed description of the manufacturing process as part of this application, as they have referred to the most recent EFSA Opinion on the re-evaluation of PGPR (EFSA, 2017), where this has been detailed. The applicant stated that PGPR will be purchased from a number of potential suppliers, and it will be ensured the PGPR sourced meets the specifications outlined within Regulation (EC) No. 231/2012 (as retained EU legislation).

2.2.1 Presence of impurities

Information on impurities was not provided as part of this application. The applicant stated that the precise composition of the PGPR (and hence the presence and level of impurities) will depend on the supplier of the material. However, the PGPR used will

adhere to the specifications outlined in Table 1 and Regulation (EC) No. 231/2012 (as retained EU legislation).

The AEJEG further considered the presence of impurities such as active ricin, 3-monochloropropane-1,2-diol (3-MCPD) as well as impurities that might arise during manufacturing (e.g., glycidol and epichlorohydrin) and for which neither GB nor EU Maximum Limits existed at the time of assessment. The AEJEG considered that the levels of these impurities should be monitored both through raw material specifications and manufacturing. They further considered that maximum limits for these should be included in the GB specifications of PGPR.

2.3 Methods of analysis in food

The applicant noted that EFSA concluded that a direct method to quantify the amount of PGPR in foods does not exist, while indirect methods rely on the detection of ricinoleic acid or its esters and known ricinolate ratios in PGPR. However, such a ratio is not specified in either GB or the EU specifications for PGPR and can thus differ between PGPR from different suppliers.

The Applicant refers to a method that has been developed for extraction of PGPR components from chocolate (Davies and Hakes [1977], cited in the EFSA opinion [2017]) based on Soxhlet extraction of lipid material from chocolate in chloroform. They mentioned that a variation of this method was developed to extract emulsifiers from ice cream, where total lipids were extracted from food with a mixture of chloroform/methanol (Dieffenbacher and Bracco, 1978). The lipid extract is then cleaned from non-polar lipids using column chromatography, followed by thin-layer chromatography for identification of the polar lipids.

A more recent method for analysis of PGPR components was identified on pure PGPR and commercial PGPR samples, which may be used on lipids extracted via the method described by Orfanakis et al (2013).

2.3.1 Stability of the additive in food

EFSA reported a review of studies on the stability of PGPR over a 32-month period at 15°C (EFSA, 2017). No change in physicochemical properties was observed, including refractive index, acid value, iodine value, hydroxyl value and saponification value. The applicant notes that the likely degradation of PGPR within food is from the hydrolysis of ricinoleic acid moieties from polyglycerol. In respect of the proposed application in edible ices (FC 03), considering the stability of PGPR at 15°C, it is expected that at temperatures lower than 15°C the PGPR will demonstrate an even longer period of stability as any rates of chemical reaction will be decreased. This is most likely, as within the intended use the product will be frozen, so can be treated as an inert solid.

2.4 Proposed Use Levels

The applicant has proposed the modification of the use of PGPR (E 476) in the following food categories:

- a. Extension of use in food category (FC) 03 - Edible ices, with the restriction *'only fat and oil emulsion of water-in-oil type'*.

The normal and maximum use levels of PGPR in the proposed food category are 3000 mg/kg and 4000 mg/kg, respectively.

The corresponding categories in the FoodEx classification system (exposure hierarchy) are:

- Ice cream, milk-based [A02QA]
- Ice cream, milk-imitate based [A02QB]
- Frozen yoghurt [A02QC]

- b. Change of use level in food category (FC) 12.6 – Sauces, with the restriction *'only emulsified sauces with a fat content of 20 % and more'*.

The normal and maximum use levels of PGPR in the proposed food category are 6000 mg/kg and 8000 mg/kg, respectively.

The corresponding categories in the FoodEx classification system (exposure hierarchy) are:

- Mayonnaise, hollandaise and related sauces [A0F1M]
- Salad dressing [A045K]

The currently authorised maximum permitted levels (MLs) and the proposed extension of use and use levels of PGPR (E 476), are detailed below. The categories listed in Table 2 refer to retained EU Food Category numbers.

Table 2. Currently authorised maximum permitted levels (MLs) and the proposed extension of use and use levels of PGPR (E 476).

| EU Food category number | Food category name | MLs (mg/kg or mg/L as appropriate) | Proposed modification of use (mg/kg or mg/L as appropriate) | Restrictions/exception |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------|------------------------------------|-------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 02.2.2 | Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions | 4000 | - | 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, 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 |
| 03 | Edible ices | - | 4000 | only fat and oil emulsion of water-in-oil type |
| 05.1 | Cocoa and Chocolate products as covered by Directive 2000/36/EC | 5000 | - | |
| 05.2 | Other confectionery including breath refreshing microsweets | 5000 | - | only cocoa-based confectionery |
| 05.4 | Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 | 5000 | - | only cocoa-based confectionery |
| 08.3 | Meat products ^(a) | 500 | - | |
| 09.2 | Processed fish and fishery products including molluscs and crustacean ^(a) | 500 | - | |
| 12.6 | Sauces | 4000 | 8000 | ML = 4000, only emulsified sauces ML = 8000, only emulsified sauces with a fat content of 20 % and more |

(b) Authorised according to Annex III to Regulation No 1333/2008

2.5 Dietary exposure assessment

It should be noted that the applicant has referred to the exposure estimates presented below as the "mean aggregate exposure", which suggests that intakes from all sources have been considered. To avoid confusion, the term "mean aggregate exposure" refers to the mean exposures from food uses, and not aggregate exposure from all sources.

In 2017, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) re-evaluated the safety of PGPR (E 476) and revised the ADI of 7.5 mg/kg bw per day previously established by the Scientific Committee on Food (SCF) to 25 mg/kg bw per day. The Applicant noted that EFSA considered a number of studies, including a 2-year combined chronic toxicity/carcinogenicity study in rats, which was considered the critical study for determining a toxicological reference point. At the only dose tested, 2,500 mg PGPR/kg bw per day, enlargement of the liver and kidney was observed, which was attributed to adaptive hypertrophy. In shorter term studies at higher doses this was shown to be accompanied by an increase in liver cell water, nitrogen content and in the DNA/RNA ratios in the liver. Similar effects were observed to a lesser extent in animals dosed with castor oil. The applicant stated, “Based on the absence of adverse effects under histopathological examinations, a no observed adverse effect level (NOAEL) of 2500 mg/kg bw per day, the only dose tested, was identified and applying an uncertainty factor of 100, the acceptable daily intake (ADI) for PGPR was set at 25 mg/kg bw per day”. The EFSA Panel agreed with this conclusion.

The currently authorised maximum permitted levels (MLs) according to the Annex II and Annex III retained EU regulation 1331/2008 (REUL 1331/2008), and the proposed extension of use and use levels of PGPR (E 476) are presented in Table 2 (above). In addition to the categories listed in Table 2, the applicant also considered exposure from edible ices (FC 03) and coated nuts (FC 15.2), as carried out by EFSA in its re-evaluation of PGPR as a food additive (EFSA, 2017).

Although not authorised in the categories FC03 and FC15.2, PGPR is present through the use of chocolate coatings. The ML attributed to these two categories is the one of cocoa products (FC 05.1), i.e., 5000 mg/kg. EFSA assumed that chocolate as an ingredient represents 15% of all ice-cream products, therefore resulting in an assumed maximum level of 750 mg/kg in FC 03 Edible ices. This level was used in the maximum level exposure assessment scenario. Note that Regulation (EC) No 1333/2008 does not set a maximum permitted level for PGPR for FC 03 edible ices.

The maximum reported use levels of PGPR (E 476) provided by industry and considered by EFSA (EFSA, 2017) are detailed in Table 3 below.

Table 3. Maximum reported use levels of PGPR (E 476) provided by industry and considered by EFSA (EFSA, 2017)

| Food category | Maximum reported use level (mg/kg or mg/L) | Information provided by |
|------------------------------------------------------------------------------------------------|--------------------------------------------|-------------------------|
| 02.2.2 Other fat and oil emulsions | 4000 | EDA, FDE |
| 0.3 Edible ices ^(a) | 525 | FDE |
| 05.1 Cocoa and Chocolate products as covered by Directive 2000/36/EC | 5000 | FDE |
| 05.2 Other confectionery including breath refreshing microsweets | 150 | FDE |
| 05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 | 3000 | FDE |
| 15.2 Processed nuts ^(a) | 4500 | FDE |

(a) Food categories in which PGPR is not authorised but could be present due to chocolate coating.

EDA: European Dairy Association; FDE: FoodDrinkEurope

The applicant has noted that according to the European Food Emulsifiers Manufacturers Association EFEMA (EFEMA, 2019), non-food applications of PGPR include: pharmaceutical and cosmetic preparations, oil and water emulsions and release agents. It was noted by the applicant, that exposure from these sources is unknown and therefore, have not been included in the exposure calculation.

2.5.1 Exposure scenarios

The applicant has estimated the exposure to PGPR (E 476) from its use as a food additive using the Food Additive Intake Model 2.0 (FAIM) tool, considering two main scenarios:

- I. **Regulatory Maximum Level Scenario:** based on the MLs as set in Annex II and Annex III, Part 2, to retained EU regulation 1331/2008 (REUL 1331/2008).
- II. **Refined Scenario:** based on the maximum reported levels from industries.

The applicant considered ten food categories and subcategories for the regulatory scenario and seven food categories for the refined scenario. The estimated range for

the mean “aggregate” exposure to PGPR (E 476) from its use as a food additive for the six population groups is reported in Tables 4 and 5 from use in food.

Table 4. Mean “aggregate” exposure to PGPR (mg/kg bw/day) based on maximum permitted levels (MLs) and new maximum proposed use levels

| Regulatory Maximum Level Scenario using currently authorised levels | | |
|-------------------------------------------------------------------------------------------|--------------------|--------------------|
| <i>Population Group</i> | <i>Min Average</i> | <i>Max Average</i> |
| Infants | 0.35 | 4.98 |
| Toddlers | 2.03 | 15.17 |
| Children ^(a) | 3.68 | 12.92 |
| Adolescents | 2.17 | 8.04 |
| Adults | 1.00 | 5.07 |
| Elderly ^(a) | 0.71 | 4.55 |
| Regulatory Maximum Level Scenario using currently authorised levels and new proposed uses | | |
| <i>Population Group</i> | <i>Min Average</i> | <i>Max Average</i> |
| Infants | 0.47 | 5.59 |
| Toddlers | 3.04 | 19.92 |
| Children ^(a) | 6.01 | 20.01 |
| Adolescents | 2.67 | 11.51 |
| Adults | 1.65 | 7.30 |
| Elderly ^(a) | 1.09 | 6.03 |

(a) The term ‘children’ and ‘elderly’ correspond to ‘other children’ and ‘elderly and very elderly’ in FAIM analysis output.

Table 5. Mean “aggregate” exposure to PGPR (mg/kg bw/day) based on maximum reported levels by industry and new maximum proposed use levels

| Refined Exposure Assessment Scenario using maximum reported levels | | |
|------------------------------------------------------------------------------------------|--------------------|--------------------|
| <i>Population Group</i> | <i>Min Average</i> | <i>Max Average</i> |
| Infants | 0.04 | 4.25 |
| Toddlers | 1.34 | 7.77 |
| Children ^(a) | 1.27 | 7.78 |
| Adolescents | 1.02 | 3.95 |
| Adults | 0.49 | 2.49 |
| Elderly ^(a) | 0.40 | 2.88 |
| Refined Exposure Assessment Scenario using maximum reported levels and new proposed uses | | |
| <i>Population Group</i> | <i>Min Average</i> | <i>Max Average</i> |
| Infants | 0.28 | 4.99 |
| Toddlers | 2.51 | 12.21 |
| Children ^(a) | 3.68 | 14.83 |
| Adolescents | 1.61 | 8.40 |
| Adults | 1.23 | 6.15 |
| Elderly ^(a) | 0.84 | 5.48 |

(a) The term ‘children’ and ‘elderly’ correspond to ‘other children’ and ‘elderly and very elderly’ in FAIM analysis output.

The applicant stated that the mean exposure to PGPR (E 476) from the currently authorised maximum use levels ranged from 0.3 mg/kg bw/day in infants to 15.2 mg/kg bw/day in toddlers in the regulatory scenario.

In the regulatory scenario, including the proposed extension of use in edible ices (FC 03) to a maximum level of 4000 mg/kg and change of use level in sauces (FC 12.6) to a maximum level of 8000 mg/kg, average exposure to PGPR (E 476) ranged from 0.4 mg/kg bw/day in infants to 20 mg/kg bw/day in children. Compared to the exposure estimates considering only the current authorised uses, the maximum intakes increased up to a factor of 1.5 in children.

In the refined scenario, mean exposure to PGPR (E 476) from the maximum use levels reported by industries ranged from 0.04 mg/kg bw per day in infants to 7.8 mg/kg bw/day in children and toddlers. In the applicant’s refined exposure assessment scenario, including the proposed extension of use in edible ices to a maximum level of 4000 mg/kg and change of use level in sauces (FC 12.6) to a maximum level of 8000 mg/kg, average exposure to PGPR (E 476) ranged from 0.3 mg/kg bw/day in infants to 14.8 mg/kg bw/day in children. Compared to the exposure estimates

considering only the currently reported use levels, the maximum intakes increased up to a factor of 2.5 in adults.

2.5.2 High percentile estimates for each food category

High percentile estimates for each food category were calculated using both the regulatory maximum level scenario and the refined scenario, including the new proposed uses according to the 'Guidance for submission for food additive evaluations' (EFSA, 2012). These are presented in Tables 6 – 9.

Table 6. Regulatory maximum level scenario: 95th percentile of exposure to PGPR (E 476) using currently authorised levels

| | | Range of 95 th percentile (min-max) exposure to PGPR (mg/kg bw/day) | | | | | |
|---------------|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|------------|------------|-------------|-----------|-----------|
| Food category | | Infants | Toddlers | Children | Adolescents | Adults | Elderly |
| 02.2 | Fat and oil emulsions mainly of type water-in-oil | 0 - 9.7 | 3.9 - 10.4 | 0.8 - 8.7 | 0.8 - 5.3 | 0.8 - 4.7 | 0.8 - 6.2 |
| 03 | Edible ices ^(a) | 0 - 0.6 | 1.1 - 2.7 | 1 - 2.9 | 0 - 1.5 | 0 - 0.7 | 0 - 0.6 |
| 05.1 | Cocoa and Chocolate products as covered by Directive 2000/36/EC | 0 - 2.3 | 0.9 - 7.4 | 2.6 - 11.3 | 1.9 - 7.1 | 0.9 - 3.2 | 0.4 - 2 |
| 05.2.1 | Other confectionery with added sugar | 0 - 0.2 | 0 - 14.9 | 2.1 - 13.9 | 0 - 9.5 | 0 - 3.7 | 0 - 1.4 |
| 05.2.2 | Other confectionery without added sugar | 0 | 0 | 0 - 2 | 0 - 0.8 | 0 - 0.4 | 0 - 0.3 |
| 05.4 | Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 | 0 | 0 - 1.9 | 0 - 1.7 | 0 | 0 | 0 |
| 08.3 | Meat products ^(b) | 0.5 - 1.9 | 1.6 - 4.1 | 1.5 - 3.9 | 0.7 - 2.6 | 0.6 - 2.2 | 0.4 - 1.9 |
| 09.2 | Processed fish and fishery products including molluscs and crustacean ^(b) | 0 - 0.7 | 0 - 1.3 | 0 - 1.3 | 0.1 - 0.8 | 0 - 0.6 | 0 - 0.7 |
| 12.6 | Sauces | 0 - 7.8 | 0 - 10.9 | 0 - 11.2 | 0.4 - 9.6 | 0.1 - 7.2 | 0 - 5.2 |
| 15.2 | Processed nuts ^(a) | 0 | < 0.01 | < 0.01 | < 0.01 | < 0.01 | < 0.01 |

(a) Food category in which PGPR is not authorised but could be present due to chocolate coating.

(b) Authorised according to Annex III to Regulation No 1333/2008.

Table 7. Regulatory maximum level scenario: 95th percentile of exposure to PGPR (E 476) considering the new proposed uses.

| Range of 95 th percentile (min-max) exposure to PGPR (mg/kg bw/day) | | | | | | |
|--------------------------------------------------------------------------------|----------|------------|------------|-------------|------------|----------|
| Food category | Infants | Toddlers | Children | Adolescents | Adults | Elderly |
| 03 Edible ices | 0 - 3.9 | 6.7 - 17.1 | 6.5 - 18.4 | 0 - 9.4 | 0 - 4.2 | 0 - 4.0 |
| 12.6 Sauces | 0 - 15.5 | 0 - 21.8 | 0 - 22.5 | 0.8 - 19.2 | 0.3 - 14.3 | 0 - 10.3 |

Table 8. Refined scenario: 95th percentile of exposure to PGPR (E 476) using maximum reported levels from industry

| Range of 95 th percentile (min-max) exposure to PGPR (mg/kg bw/day) | | | | | | |
|------------------------------------------------------------------------------------------------|---------------------------|------------|------------|-------------|-----------|-----------|
| Food category | Infants | Toddlers | Children | Adolescents | Adults | Elderly |
| 02.2 Fat and oil emulsions mainly of type water-in-oil | 0 - 9.7 | 3.9 - 10.4 | 0.8 - 8.7 | 0.8 - 5.3 | 0.8 - 4.7 | 0.8 - 6.2 |
| 03 Edible ices ^(a) | 0 - 0.4 | 0.7 - 1.9 | 0.7 - 2 | 0 - 1 | 0 - 0.5 | 0 - 0.4 |
| 05.1 Cocoa and Chocolate products as covered by Directive 2000/36/EC | 0 - 2.3 | 0.9 - 7.4 | 2.6 - 11.3 | 1.9 - 7.1 | 0.9 - 3.2 | 0.4 - 2 |
| 05.2.1 Other confectionery with added sugar | < 0.01 | 0 - 0.4 | 0.1 - 0.4 | 0 - 0.3 | 0 - 0.1 | < 0.1 |
| 05.2.2 Other confectionery without added sugar | 0 | 0 | <0.1 | <0.1 | <0.1 | <0.01 |
| 05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 | 0 | 0 - 1.1 | 0 - 1.0 | 0 | 0 | 0 |
| 08.3 Meat products ^(b) | <i>No reported levels</i> | | | | | |
| 09.2 Processed fish and fishery products including molluscs and crustacean ^(b) | <i>No reported levels</i> | | | | | |
| 12.6 Sauces | <i>No reported levels</i> | | | | | |
| 15.2 Processed nuts ^(a) | 0 - 0.1 | 0 - 2.1 | 0 - 2.4 | 0 - 2 | 0 - 2.3 | 0 - 2.4 |

(a) Food category in which PGPR is not authorised but could be present due to chocolate coating.

(b) Authorised according to Annex III to Regulation No 1333/2008.

Table 9. Refined scenario: 95th percentile of exposure to PGPR (E 476) considering the new proposed uses

| Range of 95 th percentile (min-max) exposure to PGPR (mg/kg bw/day) | | | | | | | |
|--------------------------------------------------------------------------------|---------------|----------|------------|------------|-------------|------------|----------|
| | Food category | Infants | Toddlers | Children | Adolescents | Adults | Elderly |
| 03 | Edible ices | 0 - 3.7 | 6.4 - 16.3 | 6.1 - 17.5 | 0 - 8.9 | 0 - 4 | 0 - 3.8 |
| 12.6 | Sauces | 0 - 15.5 | 0 - 21.8 | 0 - 22.5 | 0.8 - 19.2 | 0.3 - 14.3 | 0 - 10.3 |

2.5.3 Main food groups contributing to the dietary exposure of PGPR

The percentage contributions of each food category to the mean exposure to PGPR, calculated using the FAIM tool, is presented in Tables 10 and 11 (regulatory maximum scenario):

Table 10. Regulatory maximum level scenario using currently authorised levels: main food categories contributing to exposure to PGPR (> 5% to the total mean exposure, Table 6) and number of surveys in which each food category is contributing.

| Food category | | Range (min-max) of % contribution to the total exposure (number of surveys) ^(a) | | | | | |
|---------------|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|---------------|---------------|---------------|----------------|----------------|
| | | Infants | Toddlers | Children | Adolescents | Adults | Elderly |
| 02.2 | Fat and oil emulsions mainly of type water-in-oil | 10.9-92.8 (5) | 12.0-56.8 (9) | 9.6-38.2 (15) | 5.1-36.7 (16) | 12.2-44.5 (17) | 18.9-53.3 (14) |
| 03 | Edible ices | - | 7.9 (1) | 5.9-11.5 (5) | 14.0 (1) | 10.7 (1) | 8.7 (1) |
| 05.1 | Cocoa and Chocolate products as covered by Directive 2000/36/EC | 9.1-64.3 (3) | 5.7-52.6 (10) | 6.7-33.7 (18) | 8.6-44.4 (17) | 6.4-30.6 (17) | 5.3-13.8 (12) |
| 05.2 | Other confectionery including breath refreshing microsweets | - | 5.7-37.7 (9) | 6.8-38.5 (17) | 7.0-30.8 (15) | 5.0-16.7 (13) | 6.1-9.3 (5) |
| 05.4 | Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 | - | - | - | - | - | - |
| 08.3 | Meat products | 6.6-56.4 (5) | 7.4-20.9 (10) | 5.7-37.4 (18) | 5.1-32.3 (16) | 5.8-27.8 (17) | 6.3-29.0 (14) |
| 09.2 | Processed fish and fishery products including molluscs and crustacean ^(d) | - | 6.8 (1) | 6.5 (1) | 5.9 (1) | 6.2-8.8 (3) | 7.8 (1) |
| 12.6 | Sauces | 23.6-39.7 (4) | 7.8-34.6 (9) | 5.0-32.0 (16) | 7.3-41.5 (16) | 6.3-39.9 (16) | 8.2-36.1 (12) |
| 15.2 | Processed nuts | 10.8 (1) | 6.4 (1) | 7.3 (1) | 5.5 (1) | 5.4-14.5 (11) | 14.0-5.5 (7) |

- : Food categories not contributing or contributing less than 5% to the total mean exposure.

Table 11. Regulatory maximum level scenario using currently authorised levels and new proposed uses: main food categories contributing to exposure to PGPR (> 5% to the total mean exposure, Table 6) and number of surveys in which each food category is contributing.

| Food category | Range (min-max) of % contribution to the total exposure (number of surveys) ^(a) | | | | | |
|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|---------------|---------------|---------------|---------------|----------------|
| | Infants | Toddlers | Children | Adolescents | Adults | Elderly |
| 02.2 Fat and oil emulsions mainly of type water-in-oil | 8.0-89.8 (5) | 4-48.6 (10) | 1.5-29.1 (18) | 5.1-29.7 (15) | 8.3-40.1 (17) | 12.9-49.3 (14) |
| 03 Edible ices | 7.7-10.1 (2) | 6.2-33.4 (9) | 6.5-44.6 (18) | 6.5-48.6 (17) | 5.3-41.1 (14) | 5.1-35.5 (13) |
| 05.1 Cocoa and Chocolate products as covered by Directive 2000/36/EC | 6.8-50.5 (3) | 6.2-46.6 (8) | 6.7-25.9 (1) | 5.8-38.1 (17) | 5.8-25.2 (15) | 5.0-11.3 (10) |
| 05.2 Other confectionery including breath refreshing microsweets | - | 5.0-28.7 (9) | 5.1-28.0 (17) | 5.2-26.0 (15) | 6.0-13.7 (10) | 6.3-7.6 (2) |
| 05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 | - | - | - | - | - | - |
| 08.3 Meat products | 5.2-41.4 (5) | 5.4-15.8 (10) | 5.0-22.9 (15) | 7.4-27.7 (14) | 8.7-25.0 (15) | 5.2-27.4 (13) |
| 09.2 Processed fish and fishery products including molluscs and crustacean ^(c) | - | 5.1 (1) | - | - | 5.3-6.7 (3) | 5.0 (1) |
| 12.6 Sauces | 36.7-53.1 (4) | 10.3-47.6 (9) | 6.1-43.9 (16) | 8.3-54.6 (16) | 9.9-54.4 (16) | 10.6-49.2 (12) |
| 15.2 Processed nuts | 8.4 (1) | 5.7 (1) | - | - | 5.5-13.4 (8) | 5.1-13.6 (5) |

– : Food categories not contributing or contributing less than 5% to the total mean exposure.

The percentage contributions of each food category to the mean exposure to PGPR, calculated using the FAIM tool, are presented in Tables 12 and 13 (refined scenario).

Table 12. Refined scenario using maximum reported levels: main food categories contributing to exposure to PGPR (> 5% to the total mean exposure, Table 8) and number of surveys in which each food category is contributing.

| Food category | | Range (min-max) of % contribution to the total exposure (number of surveys) ^(a) | | | | | |
|---------------|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|---------------|----------------|----------------|----------------|----------------|
| | | Infants | Toddlers | Children | Adolescents | Adults | Elderly |
| 02.2 | Fat and oil emulsions mainly of type water-in-oil | 68.5-98.3 (5) | 7.1-82.6 (10) | 7.3-60.7 (18) | 8.7-62.7 (17) | 23.1-71.4 (17) | 46.9-85.2 (14) |
| 03 | Edible ices | 5.6 (1) | 6.0-8.4 (4) | 5.8-23.2 (11) | 5.0-20.8 (8) | 15.3 (1) | 10.9 (1) |
| 05.1 | Cocoa and Chocolate products as covered by Directive 2000/36/EC | 14.2-97.3 (3) | 8.7-83.4 (10) | 21.7-79.3 (18) | 30.3-75.0 (17) | 12.1-57.1 (17) | 6.4-23.7 (14) |
| 05.2 | Other confectionery including breath refreshing microsweets | - | 5.2 (1) | - | - | - | - |
| 05.4 | Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 | - | - | - | - | - | - |
| 08.3 | Meat products | No reported levels | | | | | |
| 09.2 | Processed fish and fishery products including molluscs and crustacean | No reported levels | | | | | |
| 12.6 | Sauces | No reported levels | | | | | |
| 15.2 | Processed nuts | 15.1 (1) | 7.8-9.2 (3) | 6.0-19.0 (7) | 5.6-14.5 (8) | 5.8-24.8 (17) | 5.9-20.8 (10) |

- : Food categories not contributing or contributing less than 5% to the total mean exposure.

Table 13. Refined scenario using maximum reported levels and new proposed uses: food categories contributing to exposure to PGPR (> 5% to the total mean exposure, Table 8) and number of surveys in which each food category is contributing.

| Food category | Range (min-max) of % contribution to the total exposure (number of surveys) ^(a) | | | | | |
|------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|---------------|---------------|----------------|----------------|----------------|
| | Infants | Toddlers | Children | Adolescents | Adults | Elderly |
| 02.2 Fat and oil emulsions mainly of type water-in-oil | 13.6-94.5 (5) | 5-64.9 (10) | 8.1-37.4 (15) | 6.8-38.8 (15) | 10.4-58.2 (17) | 16.4-75.5 (14) |
| 03 Edible ices | 7.2-10.7 (3) | 10.0-38.5 (9) | 9.9-69.2 (18) | 8.0-61.6 (16) | 6.0-52.7 (15) | 5.9-44.2 (13) |
| 05.1 Cocoa and Chocolate products as covered by Directive 2000/36/EC | 7.9-53.2 (3) | 8.2-59.2 (8) | 5.7-34.6 (18) | 7.5-57.3 (17) | 5.6-35.6 (17) | 5.0-13.4 (12) |
| 05.2 Other confectionery including breath refreshing microsweets | - | - | - | - | - | - |
| 05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 | - | - | - | - | - | - |
| 08.3 Meat products | <i>No reported levels</i> | | | | | |
| 09.2 Processed fish and fishery products including molluscs and crustacean | <i>No reported levels</i> | | | | | |
| 12.6 Sauces | 5.4-78.7 (5) | 12.5-63.3 (9) | 8.4-59.3 (16) | 11.1-68.3 (16) | 13.4-69.5 (16) | 13.9-62.5 (12) |
| 15.2 Processed nuts | 8.4 (1) | 6.5 (1) | 6.6 (1) | - | 5.0-15.9 (10) | 5.5-16.7 (6) |

-: Food categories not contributing or contributing less than 5% to the total mean exposure.

The AEJEG noted that although the exposure estimates are an over estimation, it is not known to what extent the over-estimation is. It was also noted that if a conservative approach is adopted, the exposure would be very close to the ADI of 25 mg/kg bw/day. The AEJEG concluded that the exposure assessment was conservative but acceptable.

2.5.4 Exposure to contaminants

In line with EU specifications for PGPR (E 476), element impurities arsenic, lead, mercury and cadmium are accepted up to a concentration of 3, 2, 1 and 1 mg/kg, respectively. These regulatory levels are retained within GB legislation.

In their 2017 opinion, EFSA noted that PGPR is a significant source of exposure to those heavy metals in food and recommended a revision of their maximum limits in the EC specification for PGPR.

The range of (min-max) anticipated mean exposure (ng/kg bw/day) to toxic metal contaminants in PGPR from its use as a food additive using maximum permitted levels (MLs) and the new proposed uses is summarised in Table 14.

Table 14. The range of (min-max) anticipated mean exposure (ng/kg bw/day) to toxic metal contaminants in PGPR from its use as food additive using maximum permitted levels (MLs) and new proposed uses

| Range (min-max) of mean exposure to toxic contaminants (ng/kg bw/day) | | | | | | |
|-----------------------------------------------------------------------|------------|------------|-------------|-------------|------------|------------|
| | Infants | Toddlers | Children | Adolescents | Adults | Elderly |
| Arsenic | 1.4 – 16.8 | 9.1 – 59.8 | 18.0 – 60.0 | 8.0 – 34.5 | 5.0 – 21.9 | 3.3 – 18.1 |
| Lead | 0.9 – 11.2 | 6.1 – 39.8 | 12.0 – 40.0 | 5.3 – 23.0 | 3.3 – 14.6 | 2.2 – 12.1 |
| Mercury | 0.5 – 5.6 | 3.0 – 19.9 | 6.0 – 20.0 | 2.7 – 11.5 | 1.7 – 7.3 | 1.1 – 6.0 |
| Cadmium | 0.5 – 5.6 | 3.0 – 19.9 | 6.0 – 20.0 | 2.7 – 11.5 | 1.7 – 7.3 | 1.1 – 6.0 |

2.5.5 Uncertainty Analysis

The Applicant listed a number of uncertainties regarding the exposure assessment. These mainly related to the conservative nature of the exposure assessment and are presented below.

- In both scenarios, it is assumed that PGPR is contained in all items within the entire food category at the maximum permitted level by the legislation or at the maximum level reported by industries. This results in an overestimation of the intake in both scenarios.

Based on the food code list available in the FAIM tool:

- The food category 02.2.2 is not available in the FAIM tool, and the restrictions '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, 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' could not be taken into account. Therefore, the whole category 02.2 'Fat and oil emulsions mainly of type water-in-oil' was included in the intake assessment. This results in an overestimation of the intake for this food category in both scenarios.

- For the food category 03 'Edible Ices', exposure to PGPR via chocolate from ice-cream was considered. In its opinion, EFSA assumed that chocolate as an ingredient represents 15% of all ice-cream products (EFSA, 2017). This is likely to result in an overestimation of the exposure in the regulatory scenario.
- For the food category 03 'Edible Ices', the proposed restriction 'only water-in-oil type ice cream' could not be taken into account and therefore, the whole food category was considered. This results in an overestimation of the exposure in both scenarios. Edible ices consisting of "a fat and oil emulsion of water-in-oil type" are unusual compared to a typical edible ice emulsion, where the oil is dispersed as droplets in a continuous water phase (oil-in-water type) e.g., ice cream, gelato, milk ice. Furthermore, edible ices such as sorbets and water ices typically contain very little or no fat or oil and, again, this fat is dispersed within a water phase (oil-in-water emulsion type). Considering those two points, it is expected that the proportion of products falling under the definition "only water-in-oil ice cream" would represent considerably less than 5% of the total ice-cream sales in Europe.
- For the food category 05.2 'Other confectionery including breath refreshing microsweets', the restriction 'only cocoa-based confectionery' could not be taken into account. Therefore, the whole food category was considered for the intake assessment. This results in an overestimation of the exposure in both scenarios.

- For the food categories 12.6 'Sauces', the restriction 'only emulsified sauces' and the proposed restriction 'only emulsified sauces with a fat content of 20 % and more' could not be taken into account. Therefore, the whole food category was considered in the analysis. This results in an overestimation of the exposure.
- Based on a Mintel GNPD analysis, between 2015 and 2019 overall 1,348 products were launched in Europe that fit into category 12.6 and can be considered emulsified sauces according to their name, ingredient list and nutritional values for fat. Emulsified sauces with a fat content of 20% and more account for around 80% of all launches between 2015 and 2019. None of these however contains PGPR. Between 2012 and 2014 only 3 dressings and 1 table sauce with PGPR have been launched. These findings suggest an overestimate of the exposure.
- For the food categories 08.3, 09.2 and 12.6, no use levels were provided by industries (data reported by EFEMA, an association of food emulsifiers manufacturers, (EFSA, 2017)). The three categories were not taken into account in the refined scenario, which may result in an underestimation of the exposure. However, with regard to food category 12.6 – Sauces, a Mintel GNPD search performed by EFSA showed that only 3 of 3,442 Dressings and Vinegar, and only 1 of 6,312 Table Sauces actually contained PGPR (date from 2011 to 2016) (EFSA, 2017), even though the addition of PGPR to Dressings was permitted in the EU.
- Other source of exposure resulting from non-food applications of PGPR (E 476) were not included in the present analysis. This may result in an underestimation of the exposure in both scenarios.

Overall, the Applicant concluded that the uncertainties identified in the exposure assessment are likely to result in an overestimation of the exposure to PGPR (E 476) as a food additive in both scenarios.

2.6 Biological and Toxicological Data

The applicant stated that for modification of the conditions of use of an already authorised food additive, this data is not required according to retained EU Regulation 234/2011 (Article 2, paragraph 4). Information on the biological and toxicological properties of PGPR were recently reviewed by EFSA (2017), and the Applicant has not conducted any additional study in support of safety.

3. Discussion

With regard to the toxicological information provided, the EFSA evaluation (2017) was used by the Applicant to support the safety of the proposed extension of use. The AEJEG was satisfied with the use of the ADI established by EFSA to support the current application.

In terms of exposure, the Applicant considered two main exposure scenarios: the regulatory maximum level scenario, based on the maximum permitted level (ML) set by the regulation, and the refined scenario, based on the maximum reported levels from industry. The Applicant concluded that toddlers and children would be the groups with the highest exposure to PGPR, with exposures of up to 21.8 mg/kg bw/d in toddlers and 22.5 mg/kg bw/d in children and in both scenarios, at the maximum level (95th percentile), dietary intakes did not exceed the ADI (25 mg/kg bw/day) in any population group.

It was noted that the proposed extension of use would only apply to specific foodstuffs within the food categories considered for exposure assessment. However, due to limitations within the FAIM tool it has been assumed that PGPR will be present in all the foodstuffs within the categories of interest. Therefore, this approach would lead to a significant overestimation of the dietary exposure to PGPR resulting from the proposed extension of use.

The AEJEG discussed the comments made by the applicant with regards to the conservative nature of exposure assessment. The Group considered that the exposure approach used led to an overestimation of the dietary exposure to PGPR,

which provided added confidence to the risk assessment. However, the group noted that the exposure estimates did not include other non-food sources.

The AEJEG concluded that the levels of impurities such as active ricin and 3-MCPD, which are not currently included in the PGPR specifications should be monitored both through raw material specifications and during the manufacturing process. They further considered that maximum limits for these should be included in the GB specifications of PGPR.

4. Conclusions

The FSA and FSS agreed with the assessment undertaken by the AEJEG on the safety of an extension of use of the already authorised additive polyglycerol polyricinoleate (PGPR, E 476) and concluded that the proposed uses and use levels are safe at the anticipated levels of intake.

The AEJEG considered the above information and concluded that sufficient information had been provided to allow for an evaluation of the proposal for the extension of use of the food additive. They noted that the proposed extension of use would only apply to specific foodstuffs within the food categories considered for exposure assessment. However, due to limitations within the food exposure (FAIM) tool it has been assumed that PGPR will be present in all the foodstuffs within the categories of interest. Therefore, the approach used would lead to a significant overestimation of the dietary exposure to PGPR resulting from the proposed extension of use. Exposure to PGPR from other sources e.g., through incidental or cosmetic use were not considered by the applicant in this assessment. The aggregate average exposures are close to but do not exceed the ADI of 25 mg/kg bw/day.

Overall, the AEJEG agreed that on the basis of the information presented the use of PGPR under the conditions of the proposed extension of use would not pose a risk to health, with the provision that the presence of impurities discussed in this assessment are monitored both through raw material specifications and during manufacturing.

The FSA and FFS therefore conclude that the extension of use is safe under the proposed conditions of use and at the anticipated levels of intake as described within this safety assessment, noting the AEJEG considered this decision would be valid in the case that the presence of impurities discussed within the safety advice document are monitored both through raw material specifications and during manufacturing.

These conclusions were based on the information in the food additive dossier plus the supplementary information and could not have been reached without the data claimed as proprietary by the applicant.

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6. Abbreviations

ADI - Acceptable daily intake

AEJEG - Joint Expert Group on Additives, Enzymes and other Regulated products

EC - European Commission

EFEMA - European Food Emulsifiers Manufacturers Association

EFSA - The European Food Safety Authority

EU - European Union

FAIM - The Food Additives Intake Model

GNPD - Mintel Global New Products Database

JECFA - The Joint FAO/WHO Expert Committee on Food Additives

mg/kg bw/day - mg per kg body weight per day

ML - Maximum permitted level

ng/kg bw/day - nanograms per kilogram of body weight per day

NOAEL - No observed adverse effect level

PGPR - Polyglycerol polyricinoleate

SCF - Scientific Committee on Food

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