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Refined exposure assessment of polyethylene glycol (E 1521) from its use as a food additive

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Abstract

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific opinion on the refined exposure assessment of polyethylene glycol (E 1521) when used as a food additive. Polyethylene glycols were evaluated by several international bodies and the AFC Panel previously adopted scientific opinions on the safety polyethylene glycol (E 1521). In 2006, the Panel concluded that based on all the data, consumption of PEG through use as plasticisers in film-coating formulations for food supplement tablets and/or capsules at the intended use level are not of safety concern. In 2007, in another opinion of the AFC Panel related to D-alpha-tocopheryl polyethylene glycol 1000 succinate (TPGS) in use for food for particular nutritional purposes, the Panel noted that TPGS intakes would correspond to intake to PEG 1000 at levels equivalent to 3.3–8.5 mg/kg body wieght (bw) per day which are within the range of group acceptable daily intakes (ADIs) of the SCF (1997) and JECFA (1980). This assessment could only take into account the use of polyethylene glycol (E 1521) in food supplements and thus the food supplements consumers only scenario was performed. It resulted in exposure estimates of polyethylene glycol (E 1521) up to 3.5 mg/kg bw per day at the mean and up to 6.1 mg/kg bw per day at the high level. The current exposure assessment is based on the methodology used in the re-evaluation of food additives together with reported use levels received following a call for data in 2017. Considering the uncertainties of the exposure assessment, these estimates very likely overestimated the real exposure to polyethylene glycol (E 1521). The Panel also noted that the highest calculated exposure estimate falls within the range of the group ADI previously established by SCF (5 mg/kg bw per day for PEG 300–4000) and of the one set by JECFA (10 mg/kg bw per day for PEG 200–10000).

Keywords: polyethylene glycol, E 1521, refined exposure assessment

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Summary

Following a request from the European Commission, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) performed a refined exposure assessment of polyethylene glycol (E 1521) when used as a food additive. The Panel was not provided with a newly submitted dossier and based this assessment on concentration data available following a public call for data.

Polyethylene glycol (E 1521) is an authorised food additive in the European Union (EU) according to Annexes II and III to Regulation (EC) No 1333/2008.

The Panel previously adopted several scientific opinions on the safety of polyethylene glycol (E 1521). In 2006, the Panel concluded that based on all the data, consumption of PEG through use as plasticisers in film-coating formulations for food supplement tablets and/or capsules at the intended use level are not of safety concern. In 2007, in another opinion of the EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) related to D-alpha-tocopheryl polyethylene glycol 1000 succinate (TPGS) in use for food for particular nutritional purposes, the Panel noted that TPGS intakes would correspond to intake to PEG 1000 at levels equivalent to 3.3–8.5 mg/kg body weight (bw) per day which are within the range of group acceptable daily intakes (ADIs) of the SCF (1997) and JECFA (1980).

In 2017, EFSA launched a public call for data aiming at collecting reported use levels from industry or analytical data on several food additives, including polyethylene glycol (E 1521). Use levels were reported by industry. Added to these new data, information on the presence of food additives on the label of foods was retrieved from the Mintel's Global New Products Database (GNPD), an online database monitoring new introductions of packaged goods in the market worldwide. Consumption data were available through the EFSA Comprehensive Database.

Considering that use levels of polyethylene glycol (E 1521) were made available only on food supplements, dietary exposure to polyethylene glycol (E 1521) from its use as a food additive was assessed through a food supplements consumers only scenario using the maximum permitted level (MPL) defined in Annex II to Regulation (EC) No 1333/2008 and maximum reported use levels made available by industry.

The highest mean refined exposure estimate was 3.5 mg/kg bw per day in children (3–9 years) and the highest 95th percentile of exposure was 6.1 mg/kg bw per day for the elderly.

In both exposure scenarios, it was assumed that 100% of food supplements contained polyethylene glycol (E 1521) whereas information from the Mintel's GNPD showed that the additive was used in only a small percentage of food supplements.

Taking uncertainties into account, the Panel concluded that these exposure estimates very likely overestimate the real exposure to polyethylene glycol (E 1521) from its use as a food additive according to Annex II. The Panel also noted that the highest calculated exposure estimate falls within the range of the group ADI previously established by SCF (5 mg/kg bw per day for PEG 300–4000) and of the one set by JECFA (10 mg/kg bw per day for PEG 200–10000).

The Panel noted that the exposure to polyethylene glycol (E 1521) from its use according the Annex III (Part 4) was not considered in the exposure assessment.

The Panel also noted that the refined exposure estimates are based on information provided on the reported levels of use of polyethylene glycol (E 1521). If actual practice changes this refined estimates may no longer be representative and should be updated.

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1. Introduction

The present opinion deals with the refined exposure estimation of polyethylene glycol (E 1521) when used as a food additive.

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

1.1.1. Background

Regulation (EC) No 1333/2008[1] of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under the Regulation (EU) No 257/2010[2]. This Regulation also foresees that food additives are re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the Scientific Committee on Food (SCF) or by EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU[3] of 2001. The report "Food additives in Europe 2000[4]" submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with a highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of adoption of Regulation (EU) 257/2010 the 2003 Terms of References are replaced by those below.

1.1.2. Terms of Reference

The Commission asks the European Food Safety Authority to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

1.1.3. Interpretation of terms of Reference

In 2013, EFSA received a communication from European Commission suggesting to perform a refined exposure assessment of polyethylene glycol (E 1521) by 2018 instead of a full re-evaluation.[5]

Therefore, this opinion provides only a refined exposure assessment.

[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.
[2] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19–27.
[3] COM(2001) 542 final.
[4] Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002, 560.
[5] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00698

1.2. Information on existing authorisations and evaluations

Polyethylene glycol (E 1521) is authorised as a food additive in the European Union (EU) in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012[6]. According to Commission Regulation (EU) No 231/2012, PEG, Macrogol and polyethylene oxide are synonyms of polyethylene glycol (E 1521).

In the EU, the Scientific Committee for Food (SCF), in 1978, advised on the toxicological acceptability of substances proposed for use in the manufacture of regenerated celluloses films intended to come into contact with foodstuffs. Polyethylene oxide (polyethylene glycol – PEG 300–4000) was classified in the list of substances for which a tolerable daily intake (TDI) has been established and which are therefore toxicologically acceptable for use in the manufacture of regenerated celluloses films. The TDI was 5 mg/kg body weight (bw) per day as the sum of these substances.

The SCF also evaluated the use of polyethylene glycol 6000 (PEG 6000) in preparations for sweetener-based sodas in 1994 (SCF, 1997) and concluded that the use of the food additive as excipient for sweetener tablets was acceptable.

Polyethylene glycol (PEG 200–10000) was evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1979 (JECFA, 1980). Based on a no-observed adverse effect level (NOAEL) in rats of 20,000 ppm (2%) in the diet equivalent to 1,000 mg/kg bw, JECFA set an acceptable daily intake (ADI) of 10 mg/kg bw.

Polyethylene glycol 6000 (PEG 6000) has also been reviewed by the Nordic Council of Ministers (TemaNord, 2002) which, based on a long-term study on PEG 4000, considered that the long-term toxicity of polyethylene glycols with high molecular weight is low. The toxicity of PEG 6000 is probably at the same magnitude as the toxicity of PEG 4000. The metabolic studies show that PEG 6000 is not absorbed and if it enters the bloodstream, it is excreted fast. Besides these studies, only very few other studies on polyethylene glycol 6000 as such are available. Added to these results, as PEG 6000 is only permitted as carrier for sweeteners and exposure is thus likely to be very low. Based on this review, the Council concluded that there is no need for further evaluation of this substance.

In November 2006, the AFC Panel (EFSA AFC Panel, 2007a) evaluated the safety of an additional use of polyethylene glycol as a film coating agent for use in food supplement products. Intake estimates based on the applicant's proposed use levels of polyethylene glycol as a food additive and on conservative assumptions lead to a calculated intake estimate up to 120 mg/day, amounting to 2 mg/kg bw per day assuming 60 kg bw. Assuming similar levels of use and intake of pharmaceutical products and food supplements per day, the combined intake from both would be about 4 mg/kg bw per day. The estimated daily intakes of the polyethylene glycols from the use as a coating agent for food supplements were below the ADI of 0–10 mg/kg body weight allocated by JECFA and the group TDI of 5 mg/kg body weight established by the SCF for the polyethylene glycols.

In April 2007, the AFC Panel (EFSA AFC Panel, 2007b) adopted an opinion related to D-alpha-tocopheryl polyethylene glycol 1000 succinate (TPGS) in use for food for particular nutritional purposes. The Panel noted that exposure to PEG 1000 coming from TPGS would correspond to 3.3–8.5 mg/kg bw per day. This is within the range of the group ADIs established by the European Commission SCF (5 mg/kg bw for PEG 300–4000) and JECFA (10 mg/kg bw for PEGs 200–10000).

In 2017, the EFSA Panel on Food Additives and Nutrient Sources added to Food (EFSA ANS Panel, 2017) prepared a scientific opinion on safety of the proposed amendment of the specifications for the food additive polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209). This opinion dealt with common impurities (namely ethylene glycol and diethylene glycol) which are present in several food additives, i.e. polyethylene glycol (E 1521), polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209) and polysorbates (E 432–436). The calculated exposure to ethylene glycol and diethylene glycol showed no exceedance of the group TDI of 0.5 mg/kg bw per day set by the SCF for these impurities (SCF, 1986, 2002).

Polyethylene glycols have been evaluated by the Committee on Medicine of the EMA (formerly EMEA) for setting maximum residue levels from their use in veterinary drugs.

Polyethylene glycols are also referenced in the Martindale[7] under their synonyms of Macrogols. The type of macrogols is defined by a number that indicates the average relative molecular mass. Solutions

[6] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p 1.

[7] Martindale: the complete drug reference, is a source of drug information, available here: https://www.medicinescomplete.com/mc/martindale/2009/

containing macrogol can be used for the treatment of chronic constipation or the management of faecal impaction. For children 2–6 years old, the usual dose for treatment of chronic constipation is 0.55 g/kg bw per day (using the default body weight of 11.9 kg for toddlers). Treatment for prolonged periods may be required in children, although safety and efficacy have only been proved for up to 3 months of treatment. Macrogols can also be used for children aged under 1 year for the treatment of chronic constipation, the dose can be up to 1.37 g/kg bw per day (using the default body weight of 4.8 kg for 0–3 months old infants).

Polyethylene glycol (CAS 25322-68-3) has been registered under the REACH Regulation 1907/2006[8] (ECHA, online) for pharmaceuticals, polymers and cosmetics and personal care products.

Polyethylene glycols are permitted as a binding, emulsion stabilising and solvent in cosmetic products (European Commission database-CosIng[9]).

2. Data and methodologies

Data

The ANS Panel was not provided with a newly submitted dossier. EFSA launched public call for data.[10]

The Panel based its dietary exposure assessment of polyethylene glycol (E 1521) on information submitted to EFSA following the public calls for data.

The EFSA Comprehensive European Food Consumption Database (Comprehensive Database[11]) was used to estimate the dietary exposure.

The Mintel's Global New Products Database (GNPD) is an online resource listing food products and compulsory ingredient information that should be included in labelling. This database was used to verify the use of polyethylene glycol (E 1521) in food products.

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 ANS Panel assessed the dietary exposure to polyethylene glycol (E 1521) as a food additive in line with the principles laid down in Regulation (EU) 257/2010 and in the EFSA Statement on the approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation (EFSA ANS Panel, 2017).

Dietary exposure to polyethylene glycol (E 1521) from its use as a food additive was estimated combining food consumption data available within the EFSA Comprehensive European Food Consumption Database with the maximum levels according to Annex II to Regulation (EC) No 1333/2008[12] and reported use levels by industry submitted to EFSA following a call for data. Different scenarios were used to calculate the exposure (see Section 3.4.1). Uncertainties in the exposure assessment were identified and discussed.

3. Assessment

3.1. Technical data

3.1.1. Identity of the substance

According to Commission Regulation (EU) No 231/2012[13], polyethylene glycol (E 1521) is identified as follows:

Chemical name: alpha-hydro-omega-hydroxypoly (oxy-1,2-ethanediol).

[8] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L 396, 30.12.2006.

[9] Available online: http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple

[10] Call for food additives usage level and/or concentration data in food and beverages intended for human consumption. Published: 23 February 2017: http://www.efsa.europa.eu/sites/default/files/consultation/170223.pdf

[11] Available online: http://www.efsa.europa.eu/en/food-consumption/comprehensive-database

[12] Commission Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16.

[13] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

Description: PEG 400 is a clear, viscous, colourless or almost colourless hygroscopic liquid PEG 3000, PEG 3350, PEG 4000, PEG 6000 and PEG 8000 are white or almost white solids with a waxy or paraffin-like appearance.

Chemical formula: $(C_2H_4O)_n$. H_2O (n = number of ethylene oxide units corresponding to a molecular weight of 6,000, about 140) (Figure 1).

Average Molecular weight: 380–9,000 Da.

Synonyms: PEG; Macrogol; Polyethylene oxide.

According to JECFA specifications (2006), the formula weight is 200-9,500.

No EINECS Number is available, while, according to JECFA specifications (2006), the CAS number is 25322-68-3.

Solubility: According to Commission Regulation (EU) No 231/2012, PEG 400 is miscible with water, very soluble in acetone, in alcohol and in methylene chloride, practically insoluble in fatty oils and in mineral oils. PEG 3000 and PEG 3350 are very soluble in water and in methylene chloride, very slightly soluble in alcohol, practically insoluble in fatty oils and in mineral oils. PEG 4000, PEG 6000 and PEG 8000 are very soluble in water and in methylene chloride, practically insoluble in alcohol and in fatty oils and in mineral oils.

According to JECFA (2006), polyethylene glycols having a molecular weight of 1,000 or above are freely soluble in water; polyethylene glycols are soluble in many organic solvents, including aliphatic ketones and alcohols, chloroform, glycol ethers, esters and aromatic hydrocarbons; they are insoluble in ether and in most aliphatic hydrocarbons; with increased molecular weight, water solubility and solubility in organic solvents decrease.

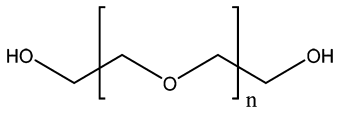

Figure 1: Structural formula of polyethylene glycol (EFSA, 2006)

3.1.2. Specifications

Table 1: Specifications for polyethylene glycol (E 1521) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	**JECFA (2006)**
Definition	Addition polymers of ethylene oxide and water usually designated by a number roughly corresponding to the molecular weight	Addition polymers of ethylene oxide and water usually designated by a number roughly corresponding to the molecular weight
Assay	400: Not less than 95% and not more than 105%. PEG 3000: Not less than 90% and not more than 110%. PEG 3350: Not less than 90% and not more than 110%. PEG 4000: Not less than 90% and not more than 110%. PEG 6000: Not less than 90% and not more than 110%. PEG 8000: Not less than 87.5% and not more than 112.5%	PEG's having molecular weight below 1,000: not less than 95.0% and not more than 105.0% of the declared value. PEG's having molecular weight between 1,000 and 7,000: not less than 90.0% and not more than 110.0% of the declared value. PEG's having molecular weight above 7000: not less than 87.5% and not more than 112.5% of the declared value
Description	PEG 400 is a clear, viscous, colourless or almost colourless hygroscopic liquid. PEG 3000, PEG 3350, PEG 4000, PEG 6000 and PEG 8000 are white or almost white solids with a waxy or paraffin-like appearance	PEG's below 700 molecular weight occur as clear to slightly hazy, colourless, slightly hygroscopic liquids with a slight characteristic odour. PEG's between 700 and 900 are semi-solid. PEG's over 1000 molecular weight are creamy white waxy solids, flakes, or free-flowing powders
Identification		
Melting range	PEG 400: 4–8°C; PEG 3000: 50–56°C; PEG 3350: 53–57°C; PEG 4000: 53–59°C; PEG 6000:55–61°C; PEG 8000: 55–62°C	PEG 400: 4–8°C; PEG 3000: 50–56°C; PEG 3350: 53–57°C; PEG 4000: 53–59°C; PEG 6000: 55–61°C; PEG 8000: 55–62°C

	Commission Regulation (EU) No 231/2012	JECFA (2006)	
Viscosity	PEG 400: 105–130 mPa.s at 20°C; PEG 3000: 75–100 mPa.s at 20°C; PEG 3350: 83–120 mPa.s at 20°C; PEG 4000: 110–170 mPa.s at 20°C; PEG 6000: 200–270 mPa.s at 20°C; PEG 8000: 260–510 mPa.s at 20°C. For polyethylene glycols having an average molecular weight greater than 400, the viscosity is determined on a 50% m/m solution of the candidate substance in water	The viscosity ranges at 100±0.3°, in cSt for PEG's of various molecular weight should be:	
		Average MW	Viscosity range
		200	4.1–4.8
		300	5.4–6.4
		400	6.8–8.0
		500	8.3–9.6
		600	9.9–11.3
		700	11.5–13.0
		800	12.5–14.5
		900	15.0–17.0
		1,000	16.0–19.0
		1,100	18.0–22.0
		1,200	20.0–24.5
		1,300	22.0–27.0
		1,400	24.0–30.0
		1,450	25.0–32.0
		1,500	26.0–33.0
		1,600	28.0–36.0
		1,700	31.0–39.0
		1,800	33.0–42.0
		1,900	35.0–45.0
		2,000	38.0–49.0
		2,100	40.0–53.0
		2,200	43.0–56.0
		2,300	46.0–60.0
		2,400	49–65
		2,500	51–70
		2,600	54–74
		2,700	57–78
		2,800	60–83
		2,900	64–88
		3,000	67–93
		3,250	73–105
		3,350	76–110
		3,500	87–123
		3,750	99–140
		4,000	110–158
		4,250	123–177
		4,500	140–200
		4,750	150–228
		5,000	170–250
		5,500	206–315
		6,000	250–390
		6,500	295–480
		7,000	350–590
		7,500	405–735
		8,000	470–900
		For PEG's not listed in the table, calculate the limits by interpolation	

	Commission Regulation (EU) No 231/2012	JECFA (2006)
Solubility	PEG 400 is miscible with water, very soluble in acetone, in alcohol and in methylene chloride, practically insoluble in fatty oils and in mineral oils. PEG 3000 and PEG 3350: very soluble in water and in methylene chloride, very slightly soluble in alcohol, practically insoluble in fatty oils and in mineral oils. PEG 4000, PEG 6000 and PEG 8000: very soluble in water and in methylene chloride, practically insoluble in alcohol and in fatty oils and in mineral oils	Polyethylene glycols having a molecular weight of 1,000 or above are freely soluble in water; polyethylene glycols are soluble in many organic solvents, including aliphatic ketones and alcohols, chloroform, glycol ethers, esters, and aromatic hydrocarbons; they are insoluble in ether and in most aliphatic hydrocarbons; with increased molecular weight, water solubility and solubility in organic solvents decrease
Purity		
Hydroxyl value	PEG 400: 264–300; PEG 3000: 34–42; PEG 3350: 30–38; PEG 4000: 25–32; PEG 6000: 16–22; PEG 8000: 12–16	–
Sulfated ash	Not more than 0.2%	
pH		4.5–7.5 (1 in 20 soln)
Acidity		Not more than 0.05% w/w (as acetic acid)
1,4-Dioxane	Not more than 10 mg/kg	Not more than 10 mg/kg
Ethylene oxide	Not more than 0.2 mg/kg	Not more than 0.2%
Ethylene glycol and diethylene glycol	Total not more than 0.25% °w/w individually or in combination	Total not more than 0.25%°w/w individually or in combination
Lead	Not more than 1 mg/kg	Not more than 1 mg/kg

PEG: polyethylene glycol; MW: molecular weight.

3.2. Authorised uses and use levels

Maximum levels of polyethylene glycol (E 1521) have been defined in Annex II to Regulation (EC) No 1333/2008[14] on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

Currently, polyethylene glycol (E 1521) is an authorised food additive in the EU in three food categories: at *quantum satis* (*QS*) in the two food categories of table-top sweeteners and at 10,000 mg/kg in food supplements supplied in a solid form (including capsules and tablets and similar forms, excluding chewable forms), only in capsule and tablet form.

Table 2 summarises foods that are permitted to contain polyethylene glycol (E 1521) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

Table 2: MPLs of polyethylene glycol (E 1521) 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)
11.4.2	Table-top sweeteners in powder form		*Quantum satis*
11.4.3	Table-top sweeteners in tablets		*Quantum satis*
17.1[(a)]	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	only in capsule and tablet form	10,000

MPL: maximum permitted level.

(a): FCS 17 refers to food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children.

[14] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16.

According to Annex III, Part 1 of Regulation (EC) No 1333/2008, polyethylene glycol (E 1521) is also authorised as carrier in sweeteners with a maximum level at *QS*.

3.3. Exposure data

3.3.1. Reported use levels or data on analytical levels of polyethylene glycol (E 1521)

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, information on actual use levels is required for performing a more realistic exposure assessment, especially for those food additives for which no MPL is set and which are authorised according to *QS*.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued a public call[15] for occurrence data (usage level and/or concentration data) on polyethylene glycol (E 1521). In response to this call, data on polyethylene glycol (E 1521) were submitted to EFSA by industry. No analytical data on the concentration of polyethylene glycol (E 1521) in foods were made available by the Member States.

Summarised data on reported use levels in foods provided by industry

Industry provided EFSA with five use levels of polyethylene glycol (E 1521) in foods for food supplements. No data were provided for table-top sweeteners.

Updated information on the use levels of polyethylene glycol (E 1521) in foods was made available to EFSA by Food Supplements Europe (FSE) and the Association of the European Self-Medication Industry (AESGP).

Appendix A provides the use levels of polyethylene glycol (E 1521) in foods as reported by industry.

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

The Mintel's GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information of over 2.5 million food and beverage products of which more than 1,000,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently having 20 out of its 28 member countries and Norway presented in the Mintel GNPD.[16]

For the purpose of this Scientific Opinion, the Mintel's GNPD[17] was used for checking the labelling of food and beverages products and food supplements for polyethylene glycol (E 1521) within the EU's food market as the database contains the compulsory ingredient information on the label.

According to the Mintel's GNPD, polyethylene glycol (E 1521) was labelled on 264 products (covering four food subcategories according to the Mintel's GNPD food classification), mainly vitamins and dietary supplements, of which 201 were found to be published in this database between January 2013 and March 2018. The Panel noted that information from the Mintel's GNPD shows that no table-top sweeteners were labelled with E 1521. This is in line with the fact that industry did not report any use levels for this food category.

Appendix B lists the percentage of the food products labelled with polyethylene glycol (E 1521) out of the total number of food products per food subcategories according to the Mintel's GNPD food classification. The percentages ranged from less than 0.1% to 2.3%. This highest percentage related to the Mintel's GNPD food subcategory 'Vitamins & Dietary Supplements'. The average percentage of foods labelled to contain polyethylene glycol (E 1521) was 0.04%.

3.3.3. Food consumption data used for 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

[15] http://www.efsa.europa.eu/sites/default/files/consultation/170223.pdf
[16] Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.
[17] http://www.gnpd.com/sinatra/home/ accessed on 02/03/2018.

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, 2011a). Consumption surveys added in the Comprehensive database in 2015 were also taken into account in this assessment.[18]

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons should be interpreted with caution. 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.

Population groups of infants and toddlers were excluded from the assessment as, according to the legislation, food supplements for infants and young children are excluded from FC 17.

Food consumption data from the following population groups were used for the exposure assessment: children, adolescents, adults and the elderly. For the present assessment, food consumption data were available from 13 different dietary surveys carried out in 8 European countries (Table 3).

Table 3: Population groups considered for the exposure estimates of polyethylene glycol (E 1521)

Population	Age range	Countries with food consumption surveys covering more than 1 day
Children[(a)]	From 36 months up to and including 9 years of age	Finland, Germany, Italy, Netherlands, Sweden, UK
Adolescents	From 10 years up to and including 17 years of age	Finland, Germany, Italy, Netherlands, Sweden, UK
Adults	From 18 years up to and including 64 years of age	Finland, Germany, Ireland, Italy, Netherlands, Romania, UK
The elderly[(a)]	From 65 years of age and older	Finland, Ireland, Italy, Netherlands, UK

(a): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, the FoodEx food codes were matched to the FCS food categories.

Food categories considered for the exposure assessment of polyethylene glycol (E 1521)

The food categories in which the use of polyethylene glycol (E 1521) is authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

The restrictions which apply to the use of polyethylene glycol (E 1521) for the FC 17.1 (Food supplements supplied in a solid form, only in capsule and tablet form) could not be taken into account, neither can the form of the food supplements (between FCs 17.1/17.2/17.3 Food supplements, in solid, liquid, syrup-type or chewable form) consumed be distinguished in the database. Therefore, the whole food category (FC 17) was considered in the exposure scenarios.

3.4. Exposure estimate

3.4.1. Exposure to polyethylene glycol (E 1521) from its use as a food additive

The Panel estimated the chronic dietary exposure to polyethylene glycol (E 1521) for the following population groups: children, adolescents, adults and the elderly. Dietary exposure to polyethylene glycol (E 1521) was calculated by multiplying concentrations of polyethylene glycol (E 1521) for food supplements (Appendix C) with their respective consumption amount per kilogram body weight for each individual in the Comprehensive Database. The exposure for the food category of food supplements was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure

[18] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

per day for the survey period. Dietary surveys with only one day per subject were excluded as they are considered as not adequate to assess repeated exposure.

No data were provided for the two authorised food categories related to table-top sweeteners. As E 1521 is authorised at QS in these two FCs, exposure assessment to polyethylene glycol (E 1521) was only carried out by the ANS Panel based on MPL and the reported use levels of food supplements (FC 17) as detailed below (Appendix C).

Thus, exposure assessment was carried out only for the consumers of food supplements per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 3). On the basis of these distributions, the mean and 95th percentile of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups with a sufficiently large sample size (EFSA, 2011a).

A possible additional exposure from the use of polyethylene glycol (E 1521) as a food additive in food sweeteners in accordance with Annex III to Regulation (EC) No 1333/2008 (Part 4) was not considered, due to the absence of concentration data.

Food supplement consumers only scenario:

Polyethylene glycol (E 1521) is authorised in the FC 17.1 Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children. As exposure via food supplements may deviate largely from the one via food, and that the number of food supplement consumers may be low depending on populations and surveys, this scenario was calculated based on consumers only. This scenario is estimated as follow:

- Consumers only of food supplements are assumed to be exposed to a food additive present at the maximum permitted and reported use level on a daily basis via consumption of food supplements.

Dietary exposure to polyethylene glycol (E 1521)

Table 4 summarises the estimated exposure to polyethylene glycol (E 1521) from its use as a food additive in four population groups (Table 3) according to the food supplements consumers only exposure scenario. Detailed results per population group and survey are presented in Appendix D.

Table 4: Summary of dietary exposure to polyethylene glycol (E 1521) from its use as a food additive in the food supplements consumers only, in four population groups as infants and young children are excluded according to Regulation (EC) No 1333/2008 (minimum–maximum across the dietary surveys in mg/kg bw per day).

	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Food supplements consumers only scenario using MPL				
• Mean	0.4–3.6	0.3–0.8	0.1–0.9	0.3–2.5
• 95th percentile	1.3–4.9	0.6–1.1	0.8–4.3	1.0–6.2
Food supplements consumers only scenario using maximum reported use levels				
• Mean	0.3–3.5	0.3–0.8	0.1–0.9	0.3–2.5
• 95th percentile	1.3–4.8	0.6–1.0	0.7–4.3	1.0–6.1

Using the MPL of 10,000 mg/kg, the mean exposure to polyethylene glycol (E 1521) from its use as a food additive via the intake of food supplements ranged between 0.1 and 3.6 mg/kg bw per day, respectively, for adults and children. The 95th percentile of exposure to polyethylene glycol (E 1521) ranged between 0.6 and 6.2 mg/kg bw per day respectively for adolescents and the elderly.

At the maximum reported use level, the mean exposure to polyethylene glycol (E 1521) from its use as a food additive ranged between 0.1 and 3.5 mg/kg bw per day, respectively, for adults and children. The 95th percentile of exposure to polyethylene glycol (E 1521) ranged between 0.6 and 6.1 mg/kg bw per day respectively for adolescents and the elderly.

Uncertainty analysis

Uncertainties in the exposure assessment of polyethylene glycol (E 1521) have been discussed above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 5.

Table 5: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction [(a)]
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Use of data from food consumption surveys covering only a few days to estimate high percentiles (95th) long-term (chronic) exposure	+
Uncertainty in possible national differences in use levels of food categories	+/–
Concentration data: – use levels considered applicable to all food supplements within the entire food category, whereas on average 2.3% of them were labelled with the additive	+
Food categories selected for the exposure assessment: inclusion of food supplements without considering their form (solid/liquid/syrup-type or chewable form)	+
Food categories included in the exposure assessment: no data for table-top sweeteners which were therefore not considered in the exposure estimates (n = 2/3 food categories)	–
Foods which may contain the food additive according to Annex III to Regulation (EC) No 1333/2008 not taken into account	–
Food supplement consumers only scenario at the MPL: – exposure calculations based on the MPL according to Annex II to Regulation (EC) No 1333/2008	+
Food supplement consumers only scenario at the maximum reported use levels: – exposure calculations based on the maximum (reported use from industries)	+/–

(a): +, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Polyethylene glycol (E 1521) is authorised in three food categories. The Panel assessed the exposure to this food additive based on data available for the food category on food supplements only, as no data for the two food categories regarding table-top sweeteners which are authorised according to *QS* were submitted. The Panel noted that the information from the Mintel's GNPD is consistent with industry submission showing that polyethylene glycol (E 1521) is mainly used in food supplements, and that no uses were reported in table-top sweeteners.

Given this observation and the fact that the percentage of food supplements within the food category labelled to contain polyethylene glycol (E 1521) was about 2.3% (Appendix B), while in the assessment it was assumed that 100% of the food supplements present in the market contained the food additive, the Panel considered that overall the exposure to polyethylene glycol (E 1521) from its use as a food additive according to Annex II in both scenario of the food supplement consumers' only exposure assessment was overestimated.

The Panel noted that food categories which may contain polyethylene glycol (E 1521) due to carry-over (Annex III, Part 4) were not considered in the current exposure assessment.

3.4.2. Exposure via other sources

Polyethylene glycols are also used in cosmetic products and in veterinary drugs. The exposure via these routes was not available to the Panel, and could therefore not be taken into account in this opinion.

Polyethylene glycols are also used in medicinal products for the treatment of chronic constipation or the management of faecal impaction for prolonged periods up to 3 months. According the usual dose for treatment of chronic constipation, exposure via this source was estimated in children 2–6 years at 0.55 g/kg bw per day up to 1.37 g/kg bw per day in infants.

3.5. Discussion

Polyethylene glycol (E 1521) is authorised in three food categories of which two at *QS*. Dietary exposure to polyethylene glycol (E 1521) from its use as a food additive was assessed based on MPLs set for food supplements (FC 17) and the data made available by industry on this food category. No use levels were submitted to EFSA for its authorised use in the two *QS* food categories on table-top sweeteners. Thus, table-top sweeteners could not be taken into account in none of the estimates.

Polyethylene glycol (E 1521) is only authorised in food supplements 'in capsule and tablet form' (Table 2). Reported use levels were related to this form of food supplements. However, in the assessment it was not possible to distinguish between the different forms of food supplements

(solid – including capsule and tablet form – liquid, syrup-type or chewable form), and therefore, the whole food supplements category (irrespective of form) was taken into account.

Based on these data, the Panel calculated two exposure estimates based on the MPL and on the maximum reported use level from industry of food supplements. These were calculated for consumers' only of food supplements. The Panel considered the consumers' only exposure assessment approach to be protective to food supplement users.

Considering the uncertainties of the exposure assessment, the assumption that 100% of the food supplements contain polyethylene glycol (E 1521) as opposed to only a few percent according to the Mintel's GNPD and the fact that according to the Mintel's GNPD polyethylene glycol (E 1521) is not used in table-top sweeteners, the Panel considered that the exposure estimates resulted in overestimates of the exposure to polyethylene glycol (E 1521) from its use as a food additive according to Annex II to Regulation (EC) No 1333/2008.

The Panel noted that the exposure to polyethylene glycol (E 1521) from its use according the Annex III (Part 4) was not considered in the exposure assessment.

The Panel also noted that the refined exposure estimates are based on information provided on the reported levels of use of polyethylene glycol (E 1521). If actual practice changes this refined estimates may no longer be representative and should be updated.

4. Conclusions

Based on the data provided by food industry, the Panel was able to refine the exposure estimates of polyethylene glycol (E 1521), covering a MW range of PEG 300–8000, considering a consumers' only approach to be protective of food supplement users. The highest mean refined exposure estimate was 3.5 mg/kg bw per day in children (3–9 years) and the highest 95th percentile of exposure was 6.1 mg/kg bw per day for the elderly. Taking uncertainties into account, the Panel concluded that these exposure estimates very likely overestimate the real exposure to polyethylene glycol (E 1521) from its use as a food additive according to Annex II. The Panel also noted that the highest calculated exposure estimate falls within the range of the group ADI previously established by SCF (5 mg/kg bw per day for PEG 300–4000) and of the one set by JECFA (10 mg/kg bw per day for PEG 200–10000).

Documentation provided to EFSA

1) Food Supplements Europe (FSE), 2017. Data on usage levels of polyethylene glycol (E 1521) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2017). Submitted to EFSA on 30 November 2017.
2) Association of the European Self-Medication Industry (AESGP), 2017. Data on usage levels of polyethylene glycol (E 1521) in foods in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2018). Submitted to EFSA on 16 November 2017.

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Abbreviations

ADI	acceptable daily intake
AESGP	Association of the European Self-Medication Industry
AFC	EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
ANS	EFSA Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
CAS	Chemical Abstracts Service
EINECS	European Inventory of Existing Commercial Chemical Substances
FC	food category
FCS	food categorisation system
FSE	Food Supplements Europe
GNPD	Global New Products Database
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MPL	maximum permitted limit
NOAEL	no observed adverse effect level
PEG	polyethylene glycol
QS	*quantum satis*
SCF	Scientific Committee on Food
TDI	Tolerable Daily Intake
TPGS	D-alpha-tocopheryl polyethylene glycol 1000 succinate
TemaNord	Nordic Council of Ministers

Appendix A – Summary of the reported use levels (mg/kg or mg/L as appropriate) of polyethylene glycol (E 1521) provided by industry

Appendix B – Number and percentage of food products labelled with polyethylene glycol (E 1521) out of the total number of food products present in the Mintel GNPD per food sub-category between 2013 and 2018

Appendix C – Concentration levels of polyethylene glycol (E 1521) used in the food supplements consumers' only exposure scenario (mg/kg or ml/kg as appropriate)

Appendix D – Summary of total estimated exposure of polyethylene glycol (E 1521) from its use as a food additive for the food supplements consumers only scenario using MPLs and food supplements consumers only scenario using maximum reported use levels per population group and survey: mean and 95th percentile (mg/kg bw per day)

Appendix A – D can be found in the online version of this output ('Supporting information' section).