

ADOPTED: 18 May 2017

doi: 10.2903/j.efsa.2017.4865

## Safety of the proposed amendment of the specifications for the food additive polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209)

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS),  
Alicja Mortensen, Fernando Aguilar, Riccardo Crebelli, Alessandro Di Domenico,  
Birgit Dusemund, Maria Jose Frutos, Pierre Galtier, Ursula Gundert-Remy, Claude Lambré,  
Jean-Charles Leblanc, Oliver Lindtner, Peter Moldeus, Pasquale Mosesso,  
Dominique Parent-Massin, Agneta Oskarsson, Ivan Stankovic, Ine Waalkens-Berendsen,  
Rudolf Antonius Woutersen, Matthew Wright, Maged Younes, Ana Maria Rincon,  
Alexandra Tard and David Gott

### Abstract

The European Commission asked EFSA to provide a scientific opinion on the request for a modification of the EU specifications for polyvinyl alcohol-polyethylene glycol-*graft-co-polymer* (PVA-PEG *graft-co-polymer*) (E 1209) and its possible impact on the safety. In accordance with Annex II to Regulation (EC) No 1333/2008, PVA-PEG *graft-co-polymer* (E 1209) has a single authorisation for use as a food additive in the EU, in the food category food supplements in solid form. According to the current EU specifications, ethylene glycol and diethylene glycol can be present as impurities in other food additives authorised in the EU, namely in polysorbates (E 432–436) and polyethylene glycol (E 1521). The exposure to ethylene glycol and diethylene glycol from their presence in E 1209 and in the other food additives was estimated considering the maximum limit permitted according to the EU specifications and the new proposed maximum limit in E 1209 of 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol in E 1209. This proposed request would result in a total exposure from food additive uses below the group tolerable daily intake (TDI) of 0.5 mg/kg body weight (bw) per day allocated by the Scientific Committee on Food (SCF) for these contaminants. Therefore, the Panel concluded that the requested amendment of the EU specifications for E 1209 would not result in a safety concern. The Panel noted that the analytical results provided were consistently and considerably lower (up to 360 mg/kg) than the proposed level of 620 mg/kg for ethylene glycol individually or in combination with diethylene glycol in the EU specifications for E 1209.

© 2017 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

**Keywords:** polyvinyl alcohol-polyethylene glycol-*graft-co-polymer*, PVA-PEG *graft-co-polymer*, E 1209, ethylene glycol, diethylene glycol

**Requestor:** European Commission

**Question number:** EFSA-Q-2016-00192

**Correspondence:** [fip@efsa.europa.eu](mailto:fip@efsa.europa.eu)

**Panel members:** Fernando Aguilar, Riccardo Crebelli, Alessandro Di Domenico, Birgit Dusemund, Maria Jose Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Claude Lambré, Jean-Charles Leblanc, Oliver Lindtner, Peter Moldeus, Alicja Mortensen, Pasquale Mosesso, Dominique Parent-Massin, Agneta Oskarsson, Ivan.

**Acknowledgements:** The Panel wishes to thank Camilla Smeraldi for the support provided to this scientific output. The ANS Panel wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output.

**Suggested citation:** EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), Mortensen A, Aguilar F, Crebelli R, Di Domenico A, Dusemund B, Frutos MJ, Galtier P, Gundert-Remy U, Lambré C, Leblanc J-C, Lindtner O, Moldeus P, Mosesso P, Parent-Massin D, Oskarsson A, Stankovic I, Waalkens-Berendsen I, Woutersen RA, Wright M, Younes M, Rincon AM, Tard A and Gott D, 2017. Scientific Opinion on safety of the proposed amendment of the specifications for the food additive polyvinyl alcohol-polyethylene glycol-graft-co-polymer (E 1209). *EFSA Journal* 2017;15(6):4865, 23 pp. <https://doi.org/10.2903/j.efsa.2017.4865>

**ISSN:** 1831-4732

© 2017 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs License](https://creativecommons.org/licenses/by-nd/4.0/), which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.



## Summary

The European Commission asked the European Food Safety Authority (EFSA) to provide a scientific opinion on the safety of a proposed amendment of the EU specifications for the food additive polyvinyl alcohol-polyethylene glycol-*graft-co-polymer* (PVA-PEG *graft-co-polymer*) (E 1209) increasing the maximum limit for ethylene glycol and diethylene glycol, two of the impurities listed in the specifications. According to Commission Regulation (EU) No 231/2012, the maximum amount of ethylene glycol and diethylene glycol permitted to be present in PVA-PEG *graft-co-polymer* (E 1209) is 50 mg/kg for each of them. The applicant has requested an increase up to 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol.

In accordance with Annex II to Regulation (EC) No 1333/2008, PVA-PEG *graft-co-polymer* (E 1209) has a single authorisation for use as a food additive in the European Union (EU), in the food category 17.1 'food supplements supplied in a solid form including capsules and tablets, excluding chewable forms'.

A group tolerable daily intake (TDI) of 0.5 mg/day was set by the Scientific Committee on Food (SCF) when evaluating ethylene glycol and diethylene glycol as components in food packaging materials (SCF, 1986, 2002).

Within the documentation provided by the applicant to the European Commission in 2015 to support the proposed increase of the maximum limits in the specifications, results of the analysis of ethylene glycol and diethylene glycol in freshly produced PVA-PEG *graft-co-polymer* (E 1209), showed that the levels of diethylene glycol ranged from < 50 to 133 mg/kg and of ethylene glycol ranged from < 50 to 130 mg/kg. The Panel noted that the data presented in the present dossier reported levels of ethylene glycol and diethylene glycol in PVA-PEG *graft-co-polymer*, which were much higher (up to four times in one sample) than those provided for the previous evaluation (EFSA ANS Panel, 2013).

A stability report including the results of the analysis of the different impurities for which maximum level has been established in the EU specifications for PVA-PEG *graft-co-polymer* (E 1209) was later submitted to EFSA. The Panel noted that the levels of ethylene glycol measured in several batches were highly variable; however, the highest measured level of ethylene glycol was 310 mg/kg for one of the batches at one time point. The results reported for diethylene glycol analysed in the stability report for PVA-PEG *graft-co-polymer* were always below the limit of detection (LOD) of 50 mg/kg. 1,4-Dioxane and ethylene oxide were only analysed at 63 months [30°C/75% relative humidity (RH)] and the reported levels were below the LODs of 10 and 0.04 mg/kg, respectively.

The applicant stated that the proposed limit, 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol, was identical to the limit for ethylene glycol in pharmaceutical products. The Panel noted that the maximum amount reported from the analytical results for ethylene glycol together with diethylene glycol was 360 mg/kg and that it was below the requested limit of 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol.

A maximum limit for ethylene glycol and diethylene glycol up to 2,500 mg/kg individually or in combination, are included in the EU specifications for polysorbates (E 432–436) and polyethylene glycol (E 1521).

Exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft-co-polymer* (E 1209) as a food additive was calculated considering the current maximum limit for these impurities in PVA-PEG *graft-co-polymer* (E 1209) and also the proposed maximum limit for ethylene glycol and diethylene glycol in PVA-PEG *graft-co-polymer* (E 1209) of 620 mg/kg.

Exposure to ethylene glycol and diethylene glycol from their presence in food additives authorised in the EU [polysorbates (E 432–436), PVA-PEG *graft-co-polymer* (E 1209) and polyethylene glycol (E 1521)] at the maximum limit authorised according to the EU specifications was calculated. An additional exposure to ethylene glycol and diethylene glycol from their presence in the mentioned food additives was estimated considering the new proposed maximum limit in PVA-PEG *graft-co-polymer* (E 1209) of 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol.

Exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft-co-polymer* (E 1209) was very low compared to their exposure from the use of all food additives in which these impurities can be present.

All the exposure estimates to ethylene glycol and diethylene glycol, from the use of the food additives mentioned above, including the highest one [0.221 mg/kg body weight (bw) per day in toddlers at the 95th percentile], were below the group TDI of 0.5 mg/kg bw for ethylene glycol and diethylene glycol. However, EFSA noted that the exposure estimate did not include exposure to ethylene glycol and diethylene glycol resulting from other uses.

The proposed request to increase the maximum level of 620 mg/kg for ethylene glycol individually or in combination with diethylene glycol in the specifications for PVA-PEG *graft-co-polymer* (E 1209), would result in total exposure from food additive uses below the group TDI of 0.5 mg/kg bw per day allocated by the SCF for these contaminants. Therefore, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) concluded that the requested amendment of the EU specifications for PVA-PEG *graft-co-polymer* (E 1209) would not result in a safety concern.

The Panel noted that the analytical results provided were consistently and considerably lower (up to 360 mg/kg) than the proposed level of 620 mg/kg for ethylene glycol individually or in combination with diethylene glycol in the EU specifications for PVA-PEG *graft-co-polymer* (E 1209).

## Table of contents

Abstract.....	1
Summary.....	3
1. Introduction.....	6
1.1. Background and Terms of Reference as provided by the European Commission .....	6
1.1.1. Background .....	6
1.1.2. Terms of Reference .....	6
1.2. Interpretation of the terms of Reference .....	6
1.3. Information on previous safety assessments.....	7
2. Data and methodologies .....	7
2.1. Data.....	7
2.2. Methodologies.....	8
3. Assessment.....	8
3.1. Technical data.....	8
3.1.1. Specifications.....	8
3.1.2. Stability of the substance.....	9
3.2. Authorised uses and use levels of PVA-PEG <i>graft-co-polymer</i> (E 1209) .....	10
3.3. Ethylene glycol and diethylene glycol as impurities on food additives authorised in the EU.....	10
3.4. Food consumption data used for exposure assessment .....	11
3.5. Exposure estimate.....	12
3.5.1. Dietary exposure to PVA-PEG <i>graft-co-polymer</i> (E 1209) from its use as a food additive.....	12
3.5.2. Dietary exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG <i>graft-co-polymer</i> (E 1209) as a food additive.....	13
3.5.3. Dietary exposure to ethylene glycol and diethylene glycol.....	14
3.5.4. Uncertainty analysis.....	15
3.6. Discussion .....	15
4. Conclusions.....	17
Documentation provided to EFSA .....	17
References.....	17
Abbreviations.....	18
Appendix A – MPLs of polyethylene glycols (E 1521) in foods according to the Annex II to Regulation (EC) No 1333/2008.....	19
Appendix B – MPLs of polysorbitans (E 432, E 433, E 434, E 435 and E 436) in foods according to the Annex II to Regulation (EC) No 1333/2008 .....	20
Appendix C – Summary of total estimated exposure to ethylene glycol and diethylene glycol from their presence in food additives authorised in the EU at the MPL in foods and maximum authorised levels in food additives according to Commission Regulation (EU) No 231/2012 per population group and survey: mean and 95th percentile (mg/kg bw per day) .....	21

## 1. Introduction

The present document deals with the safety of a proposed change in the European Union (EU) specifications of the food additive polyvinyl alcohol-polyethylene glycol-*graft-co-polymer* (PVA-PEG *graft-co-polymer*) (E 1209) EU specifications.

According to Commission Regulation (EU) No 231/2012, the maximum level of ethylene glycol and diethylene glycol present in PVA-PEG *graft-co-polymer* (E 1209) is 50 mg/kg for each of them. The applicant has requested an increase up to 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol.

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

#### 1.1.1. Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008<sup>1</sup> on food additives. Only food additives that are included in the Union list, in particular in Annex II to that regulation, may be placed on the market and used in foods under the conditions of use specified therein. Moreover, food additives shall comply with the specifications as referred to in Article 14 of Regulation and laid down in Commission Regulation (EU) No 231/2012.<sup>2</sup>

In September 2011, the company BASF SE applied for an approval for the use of PVA-PEG *graft-co-polymer* in aqueous instant-release film coating for food supplements.

Based on the positive safety assessment by the European Food Safety Authority (EFSA) in 2013, the copolymer was authorised as E 1209 for the intended use in solid food supplements by Regulations (EU) 685/2014. Apart from the amendment of Annex II of Regulation (EC) No 1333/2008, also specification of E 1209 was introduced in the amendment of Regulation (EU) No 231/2012.

The company BASF SE would like to apply for an amendment of the specification regarding the limits for ethylene glycol and diethylene glycol in E 1209 (PVA-PEG-*graft-co-polymer*) from the individual limits of max 50 mg/kg, respectively, to an overall limit of max 620 mg/kg for ethylene glycol individually, or in combination with diethylene glycol.

Current limits according to Regulation (EU) No 231/2012		Proposed amendment of Regulation (EU) No 231/2012	
Ethylene glycol	Not more than 50 mg/kg	Ethylene glycol and diethylene glycol	Total not more than 620 mg/kg individually or in combination
Diethylene glycol	Not more than 50 mg/kg		

The applicant claims that these specifications were included in the original application that was assessed by EFSA and as a consequence the applicant concluded that the newly proposed limits for ethylene glycol and diethylene glycol would not pose a safety concern.

#### 1.1.2. Terms of Reference

The European Commission requests EFSA to provide technical assistance by the end of January 2016<sup>3</sup> on the safety of the proposed change to food additive [PVA-PEG-*graft-co-polymer* (E 1209)] specifications by company BASF SE.

## 1.2. Interpretation of the Terms of Reference

Further to the receipt of the mandate from the European Commission requesting technical assistance, EFSA prepared a draft statement based on the information submitted by the applicant, and

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> After the reception of the mandate, EFSA requested a full dossier and additional data to the applicant. The full set of data was received on 25 July 2016 and, therefore, the new deadline for the finalisation of the assessment is 27 November 2016.

submitted it for endorsement by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) at its 69th plenary meeting in December 2016.<sup>4</sup>

The Panel considered that this mandate would deserve further consideration and suggested to address it by mean of a scientific opinion according to Article 29 of the Regulation (EC) No 178/2002.

Taking into account the advice from the Panel, EFSA communicated to the European Commission on 23 December 2016 that this mandate was to be addressed as a scientific opinion in accordance with Article 29 of Regulation (EC) No 178/2002<sup>5</sup>.

### 1.3. Information on previous safety assessments

The ANS Panel evaluated the safety of PVA-PEG *graft*-co-polymer as a film coating for food supplements and concluded that given the negligible absorption, the lack of genotoxic potential and the absence of effects at the highest doses tested in the subchronic and reproductive toxicity test, there was not safety concern for its use as a film coating at the proposed use levels (EFSA ANS Panel, 2013).

Taking into account the EFSA evaluation, PVA-PEG *graft*-co-polymer was authorised as a food additive (E 1209) in the EU in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives in food category 17.1 'food supplements supplied in a solid form including capsules and tablets, excluding chewable forms'. Specific purity criteria for the food additive have been defined in the Commission Regulation (EU) No 231/2012.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated PVA-PEG *graft*-co-polymer and concluded that the margin of exposure (MOE) calculated for PVA-PEG *graft*-co-polymer would not be meaningful (JECFA, 2015). JECFA decided not to establish an acceptable daily intake (ADI) 'not specified', due to the impurities present, including ethylene glycol and diethylene glycol. JECFA had concerns that establishing an ADI 'not specified' could lead to additional uses beyond the ones considered in the evaluation and consequently could increase exposure to the impurities. JECFA considered that the exposure to ethylene glycol and diethylene glycol, considering a maximum limit of 400 mg/kg singly or in combination, from the use of PVA-PEG *graft*-co-polymer was not of safety concern if the food additive would be used in the applications specified in that evaluation.

Ethylene glycol and diethylene glycol were evaluated as components in food packaging materials by the Scientific Committee on Food (SCF) and a group tolerable daily intake (TDI) of 0.5 mg/kg body weight (bw) per day was allocated (SCF, 1986, 2002).

Ethylene glycol is included in the Union list of authorised substances that may be intentionally used in the manufacture of plastic layers in plastic materials and articles [Annex I to Commission Regulation (EU) No 10/2011<sup>6</sup>]. Ethylene glycol (FCM substance No 00227) has a total specific migration limit [SML (T)], together with ethylene glycol distearate (FCM substance No 00089) and diethylene glycol (FCM substance No 00263) of 30 mg/kg (expressed as ethylene glycol) (EFSA CEF Panel, 2015).

JECFA evaluated diethylene glycol in 1980 and concluded that it was not suitable as a food additive (JECFA, 1980). However, in view that high levels of the substance are required to produce kidney stones or liver damage and the secondary nature of the bladder tumours produced, JECFA considered that its presence as a contaminant in food additives at low levels may be tolerable.

Diethylene glycol was evaluated by the Scientific Committee on Consumer Products (SCCP) that concluded that diethylene glycol should not be used as an ingredient in cosmetic products including oral care products based on the fact that more than 600 deaths occurred after oral or dermal exposure to diethylene glycol (SCCP, 2008). A dose of 1.6 mg diethylene glycol/kg bw per day has been considered safe based on the median estimated lethal dose from a Haiti mass poisoning in 1955 (SCCP, 2008).

## 2. Data and methodologies

### 2.1. Data

Original request from BASF SE requesting the amendment of Commission Regulation (EU) No 231/2012 regarding the specifications for PVA-PEG *graft*-co-polymer (E 1209) (Documentation provided to EFSA No. 1). Stability data for PVA-PEG *graft*-co-polymer as provided by the applicant (Documentation provided to EFSA No. 2 and 3).

<sup>4</sup> <https://www.efsa.europa.eu/sites/default/files/event/161205-m.pdf>

<sup>5</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/mandateLoader?mandate=M-2016-0058>

<sup>6</sup> Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1–89.

The applicant has submitted a dossier in support of its application for the amendment of the specifications for PVA-PEG *graft-co-polymer* (E 1209) that includes the data from the original application (2011) and additional information (Documentation provided to EFSA No. 4).

The EFSA Comprehensive European Food Consumption Database (Comprehensive Database<sup>7</sup>) was used to estimate dietary exposure.

## 2.2. Methodologies

The current 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012) has been followed for assessing the safety of the proposed change in the EU specifications for E 1209.

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.

Dietary exposure to ethylene glycol and diethylene glycol, from their presence in the food additives for which maximum limits for these impurities are established in the Commission Regulation (EU) No 231/2012, 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. Uncertainties on the exposure assessment were identified and discussed.

## 3. Assessment

### 3.1. Technical data

#### 3.1.1. Specifications

The specifications for PVA-PEG *graft-co-polymer* (E 1209) as defined in the Commission Regulation (EU) No 231/2012 are listed in Table 1.

**Table 1:** Specifications for PVA-PEG *graft-co-polymer* (E 1209) according to Commission Regulation (EU) No 231/2012

	Commission Regulation (EU) No 231/2012
<b>Definition</b>	Polyvinyl alcohol-polyethylene glycol- <i>graft-co-polymer</i> is a synthetic co-polymer that consists of approximately 75% PVA units and 25% PEG units
CAS number	96734-39-3
Chemical name	Polyvinyl alcohol-polyethylene glycol- <i>graft-co-polymer</i>
Weight average molecular weight	40,000–50,000 g/mol
<b>Description</b>	White to faintly yellow powder
<b>Identification</b>	
Solubility	Freely soluble in water and dilute acids and dilute solutions of alkali hydroxides; practically insoluble in ethanol, acetic acid, acetone and chloroform
IR spectrum	Must comply
pH value	5.0–8.0
<b>Purity</b>	
Ester value	10–75 mg/g KOH
Dynamic viscosity	50–250 mPa's
Loss of drying	Not more than 5%
Sulphates ash	Not more than 2%
Vinyl acetate	Not more than 20 mg/kg
Acetic acid/total acetate	Not more than 1.5%
Ethylene glycol	Not more than 50 mg/kg
Diethylene glycol	Not more than 50 mg/kg

<sup>7</sup> Available online: <http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm>



	Commission Regulation (EU) No 231/2012
1,4-Dioxane	Not more than 10 mg/kg
Ethylene oxide	Not more than 0.2 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

PVA: polyvinyl alcohol; PEG: polyethylene glycol; CAS: Chemical Abstracts Service.

## Impurities

In the original dossier on PVA-PEG *graft*-co-polymer evaluated by the Panel (EFSA ANS Panel, 2013), the applicant proposed a residual level for vinyl acetate of 20 mg/kg because the substance was used as a starting material of the co-polymer. The maximum limit of 1.5% for the by-products, acetic acid and methyl acetate, was also proposed by the applicant.

The applicant also indicated that ethylene glycol, 1,4-dioxane and ethylene oxide are known potential impurities of PEG, used also as a starting material of PVA-PEG *graft*-co-polymer.

The applicant provided the results of the measurement of the levels of ethylene glycol, diethylene glycol, 1,4-dioxane and ethylene oxide in PVA-PEG *graft*-co-polymer and stated that the source of their presence was from PEG. Based on these results, maximum limits for these impurities were included in the EU specifications for PVA-PEG *graft*-co-polymer (E 1209) [Commission Regulation (EU) No 231/2012].

### 3.1.2. Stability of the substance

In the original dossier on PVA-PEG *graft*-co-polymer evaluated by the Panel (EFSA ANS Panel, 2013), the applicant provided a stability report of PVA-PEG *graft*-co-polymer analysed under two different storage conditions: 30°C/70% relative humidity (RH) for 36 months and 40°C/75% RH for 6 months. Only the results of the variability of vinyl acetate under these conditions were reported.

Within the documentation provided by the applicant to the European Commission (Documentation provided to EFSA No. 1), results of the analysis of ethylene glycol and diethylene glycol in freshly produced PVA-PEG *graft*-co-polymer (E 1209) were provided for 32 samples manufactured between 2011 and 2014. The results showed that diethylene glycol level ranged from < 50 to 133 mg/kg and ethylene glycol from < 50 to 130 mg/kg. The highest levels were observed in samples from 2014.

A stability report including the analysis of different impurities for which maximum levels have been established in the EU specifications for PVA-PEG *graft*-co-polymer (E 1209) was submitted to EFSA (Documentation provided to EFSA No. 2, 3 and 4). However, the analysis of the impurities was not consistently performed during the full period of measurement and for the different batches.

Information on the amount of vinyl acetate (0–24 months storage time) and methyl acetate (0–48 months storage time) was provided for the same batches for which results were submitted in the original dossier on PVA-PEG *graft*-co-polymer evaluated by EFSA ANS Panel in 2013. Ethylene glycol was measured at the beginning of the storage and at 48 months (30°C/70% RH) or at 6 months (40°C/75% RH); an ethylene glycol level of up to 120 mg/kg (30°C/70% RH at 48 months) and up to 74 mg/kg (40°C/75% RH at 6 months) was reported.

Additional results of the analysis of three batches from 0 to 60 months (30°C/75% RH) were submitted to EFSA (Documentation provided to EFSA No. 2). In these cases, acetic acid/total acetate, ethylene glycol and diethylene glycol were analysed.

The level of acetic acid/total acetate did not vary considerably during the storage time and the maximum result reported was up to 6,660 mg/kg, below the maximum limit of 15,000 mg/kg established for the EU specifications.

Ethylene glycol was analysed from 3 to 60 months (30°C/75% RH). Its level was above the limit of detection (LOD) (< 50 mg/kg) after 24 months (Documentation provided to EFSA No. 2). EFSA noted a considerable increase of the level of ethylene glycol at 36 months (up to 310 mg/kg for one of the batches) that decreased again at 48 months. The applicant stated that the analysis performed at 36 months was inaccurate and additional results of the analysis for a new batch from 0 to 36 months (30°C/75% RH) were submitted to EFSA (Documentation provided to EFSA No. 3). The level of ethylene glycol from the latest analyses varied from 50 to 73 mg/kg without an excessive increase at 36 months (Documentation provided to EFSA No. 3).

The results reported for diethylene glycol were always below the LOD of 50 mg/kg from 3 to 60 month (30°C/75% RH) (Documentation provided to EFSA No. 2).

Considering the reported analytical results for ethylene glycol together with diethylene glycol was 360 mg/kg that is below from the requested limit of 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol.

1,4-Dioxane and ethylene oxide were only analysed at 63 months (30°C/75% RH) and the reported levels were below the LODs of 10 and 0.04 mg/kg, respectively (Documentation provided to EFSA No. 2).

### 3.2. Authorised uses and use levels of PVA-PEG *graft-co-polymer* (E 1209)

Maximum levels of PVA-PEG *graft-co-polymer* (E 1209) have been defined in Annex II to Regulation (EC) No 1333/2008 on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

Currently, PVA-PEG *graft-co-polymer* (E 1209) is an authorised food additive in the EU with a MPL of 100,000 mg/kg in only one food category (17.1 'Food supplements') (Table 2)

**Table 2:** MPLs of PVA-PEG *graft-co-polymer* (E 1209) in foods according to the Annex II to Regulation (EC) No 1333/2008

Food Category number	Food category name	E-number/group	Restrictions/exception	MPL (mg/L or mg/kg as appropriate)
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	E 1209	–	100,000

MPL: maximum permitted level.

### 3.3. Ethylene glycol and diethylene glycol as impurities on food additives authorised in the EU

An increase of the maximum limits for ethylene glycol and diethylene glycol in the EU specifications for PVA-PEG *graft-co-polymer* (E 1209) has been requested by the applicant.

According to the Commission Regulation (EU) No 231/2012, PVA-PEG *graft-co-polymer* (E 1209) cannot contain more than 50 mg/kg of ethylene glycol and not more than 50 mg/kg of diethylene glycol. Ethylene glycol and diethylene glycol can also be present in other food additives at limits defined in their EU specifications [Commission Regulation (EU) No 231/2012]. Table 3 summarises the maximum limits permitted for these impurities in food additives authorised in the EU.

**Table 3:** Maximum limits permitted for ethylene glycol and diethylene glycol in food additives according to Commission Regulation (EU) No 231/2012

Food additive	EG	DEG
<b>Polysorbates (E 432–436)</b>		
E 432		2,500 mg/kg
E 433		2,500 mg/kg
E 434		2,500 mg/kg
E 435		2,500 mg/kg
E 436		2,500 mg/kg
<b>PVA-PEG <i>graft-co-polymer</i> (E 1209)</b>	50 mg/kg	50 mg/kg
<b>Polyethylene glycol (E 1521)</b>		2,500 mg/kg

PVA: polyvinyl alcohol; PEG: polyethylene glycol; EG: ethylene glycol; DEG: diethylene glycol.

Exposure to ethylene glycol and diethylene glycol from their presence in PVA-PEG *graft-co-polymer* (E 1209) and food additives for which their presence is permitted [polysorbates (E 432–436), PVA-PEG *graft-co-polymer* (E 1209) and polyethylene glycol (E 1521)] at the maximum limit authorised according to the EU specifications was calculated (see Section 3.4).

The presence of ethylene glycol and diethylene glycol at the 2,500 mg/kg was considered for the group of polysorbates (E 432–436).

An additional exposure to ethylene glycol and diethylene glycol from their presence in PVA-PEG *graft-co-polymer* (E 1209) and in the mentioned food additives was calculated considering the new proposed maximum value of 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol in PVA-PEG *graft-co-polymer* (E 1209).

### 3.4. 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 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). New consumption surveys recently<sup>8</sup> added in the Comprehensive database were also taken into account in this assessment.<sup>9</sup>

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 represents the best available source of food consumption data across Europe at present.

Food consumption data from the following population groups: infants, toddlers, children, adolescents, adults and the elderly were used for the exposure assessment. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 4).

**Table 4:** Population groups considered for the exposure estimates of PVA-PEG *graft-co-polymer* (E 1209) and its impurities

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Denmark, Finland, Germany, Italy, UK
Toddlers	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Denmark, Finland, Germany, Italy, Netherlands, Spain, UK
Children <sup>(a)</sup>	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Spain, Sweden, UK
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK
The elderly <sup>(a)</sup>	From 65 years of age and older	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Romania, Sweden, 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, FoodEx food codes were matched to the FCS food categories.

<sup>8</sup> Available online: <http://www.efsa.europa.eu/en/press/news/150428.htm>

<sup>9</sup> Available online: <https://www.efsa.europa.eu/en/food-consumption/comprehensive-database>

## Food category considered for the exposure assessment of PVA-PEG *graft-co-polymer* (E 1209)

The food category in which the use of PVA-PEG *graft-co-polymer* (E 1209) is authorised was selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system) (EFSA, 2011b). The only food category in which PVA-PEG *graft-co-polymer* (E 1209) is authorised is listed in Table 2.

Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms (FCS 17.1) are not referenced as such in the FoodEx classification system, only food supplements (FCS 17) are available in the EFSA Comprehensive Database, therefore the whole food category 17 was considered in the exposure assessment. This may result in an overestimation of the exposure.

## Food categories considered for the exposure assessment of ethylene glycol and diethylene glycol

In order to estimate the exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft-co-polymer* (E 1209), the only food category in which PVA-PEG *graft-co-polymer* (E 1209) is authorised was considered for the assessment.

In order to estimate the exposure to ethylene glycol and diethylene glycol from the use of food additives authorised in the EU, food categories in which polyethylene glycol (E 1521) and polysorbates (E 432–436) are authorised were considered for the assessment (Appendices A and B, respectively). The food categories in which the impurities ethylene glycol and diethylene glycol might be present, as consequence of the use of food additives, were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system) (EFSA, 2011b).

For the same reason as explained above, the whole food category 17 was considered in the exposure assessment and this may result in an overestimation of the exposure.

Food category 17 (FCS 17.1, 17.2 and 17.3) in which polysorbates (E 432–436) are authorised at *quantum satis* (QS) were included in the dietary exposure assessment of ethylene glycol and diethylene glycol taking into account the reported use level (425,000 mg/kg) considered in the EFSA re-evaluation of these food additives (EFSA ANS Panel, 2015).

Table-top sweeteners (FCS 11.4.2 and 11.4.3) in which polyethylene glycol (E 1521) is authorised at QS were not included in the dietary exposure assessment of ethylene glycol and diethylene glycol as neither quantified MPL nor use levels were available to EFSA.

### 3.5. Exposure estimate

Chronic exposure to PVA-PEG *graft-co-polymer* (E 1209) and to ethylene glycol and diethylene glycol, from their present in food additives, for the following population groups: infants; toddlers, children, adolescents, adults and the elderly was estimated. Dietary exposure was calculated by multiplying the MPL for each food category with its respective consumption amount per kilogram of body weight for each individual in the Comprehensive Database. The exposure 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 per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered as not adequate to assess repeated exposure.

This was carried out for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 4). 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 where the sample size was sufficiently large to allow this calculation (EFSA, 2011a). Therefore, in the present assessment, 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain were not included.

#### 3.5.1. Dietary exposure to PVA-PEG *graft-co-polymer* (E 1209) from its use as a food additive

Dietary exposure to PVA-PEG *graft-co-polymer* (E 1209) from its use as a food additive was calculated in six population groups and it is summarised in Table 5. Detailed results per population group and survey are presented in Appendix C.

**Table 5:** Summary of dietary exposure to PVA-PEG *graft*-co-polymer (E 1209) from its use as a food additive (minimum–maximum across the dietary surveys in mg/kg bw per day)

	<b>Infants (12 weeks– 11 months)</b>	<b>Toddlers (12–35 months)</b>	<b>Children (3–9 years)</b>	<b>Adolescents (10–17 years)</b>	<b>Adults (18–64 years)</b>	<b>The elderly (≥ 65 years)</b>
• Mean	< 0.01–1.8	< 0.01–2.3	< 0.01–2.6	< 0.01–0.9	< 0.01–2.6	< 0.01–9.7
• 95th percentile	< 0.01–3.7	< 0.01–12.1	< 0.01–9.5	< 0.01–5.2	< 0.01–8.5	< 0.01–15.0

bw: body weight; PVA: polyvinyl alcohol; PEG: polyethylene glycol.

The mean exposure to PVA-PEG *graft*-co-polymer (E 1209) from its use as a food additive ranged from < 0.01 mg/kg bw per day in all population groups to 3.8 mg/kg bw per day in children. The 95th percentile of exposure to PVA-PEG *graft*-co-polymer (E 1209) ranged from < 0.01 mg/kg bw per day in all population groups to 13.2 mg/kg bw per day in children.

An additional source of exposure to PVA-PEG *graft*-co-polymer is expected from its pharmaceutical use but quantification of exposure via this source is unknown and, therefore, could not be taken into account in the current estimate.

### 3.5.2. Dietary exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft*-co-polymer (E 1209) as a food additive

Dietary exposure to ethylene glycol and diethylene glycol was calculated considering their presence in the food category in which PVA-PEG *graft*-co-polymer (E 1209) is authorised and applying the maximum limit authorised in the EU specifications for this food additives to the MPL for this food category. Additional exposure to ethylene glycol and diethylene glycol was calculated taking into account the proposed maximum limit for ethylene glycol and diethylene glycol in PVA-PEG *graft*-co-polymer (E 1209) of 620 mg/kg (Tables 6 and 7).

Table 6 summarises the dietary exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft*-co-polymer (E 1209) as a food additive in six population groups (Table 4).

**Table 6:** Summary of dietary exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft*-co-polymer (E 1209) as a food additive, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	<b>Infants (12 weeks– 11 months)</b>	<b>Toddlers (12–35 months)</b>	<b>Children (3–9 years)</b>	<b>Adolescents (10–17 years)</b>	<b>Adults (18–64 years)</b>	<b>The elderly (≥ 65 years)</b>
<b>Considering ethylene glycol and diethylene glycol present at 100 mg/kg<sup>(a)</sup> in PVA-PEG <i>graft</i>-co-polymer (E 1209)</b>						
• Mean	< 0.0001–0.0002	< 0.0001–0.0002	< 0.0001–0.0003	< 0.0001–0.0001	< 0.0001–0.0003	< 0.0001–0.001
• 95th percentile	< 0.0001–0.0004	< 0.0001–0.0012	< 0.0001–0.0009	< 0.0001–0.0005	< 0.0001–0.0009	< 0.0001–0.001
<b>Considering ethylene glycol and diethylene glycol present at 620 mg/kg in PVA-PEG <i>graft</i>-co-polymer (E 1209)</b>						
• Mean	< 0.0001–0.001	< 0.0001–0.0014	< 0.0001–0.002	< 0.0001–0.0006	< 0.0001–0.002	< 0.0001–0.006
• 95th percentile	< 0.0001–0.002	< 0.0001–0.007	< 0.0001–0.006	< 0.0001–0.003	< 0.0001–0.005	< 0.0001–0.009

bw: body weight; PVA: polyvinyl alcohol; PEG: polyethylene glycol.

(a): 50 mg ethylene glycol/kg E 1209 and 50 mg diethylene glycol/kg E 1209.

Considering the maximum limit for these impurities in PVA-PEG *graft*-co-polymer (E 1209), the mean exposure to ethylene glycol and diethylene glycol ranged from 0.0001 mg/kg bw per day in adolescents to 0.001 mg/kg bw per day in the elderly and the 95th percentile ranged from 0.0004 mg/kg bw per day in infants to 0.0015 mg/kg bw per day in toddlers. Taking into account the proposed maximum limit for ethylene glycol and diethylene glycol in PVA-PEG *graft*-co-polymer (E 1209) of 620 mg/kg, the exposure was increased in a factor of around 6.2.

The Panel considered that as ethylene glycol and diethylene glycol are impurities of concern, it was needed to present the exposure to them for the consumers only of foods in which PVA-PEG *graft*-co-polymer (E 1209) is authorised to be added as a food additive (Table 7). Thus, considering the maximum limit for these impurities in PVA-PEG *graft*-co-polymer (E 1209), the mean exposure to ethylene glycol and diethylene glycol for consumers only ranged from 0.0001 mg/kg bw per day in adults to 0.005 mg/kg bw per day in toddlers and the 95th percentile consumers only ranged from 0.0004 mg/kg bw per day in infants to 0.006 mg/kg bw per day in the elderly. Taking into account the

proposed maximum limit for ethylene glycol and diethylene glycol in PVA-PEG *graft-co-polymer* (E 1209) of 620 mg/kg, the mean exposure to ethylene glycol and diethylene glycol for consumers ranged from 0.0007 mg/kg bw per day in adults to 0.03 mg/kg bw per day in toddlers and the 95th percentile consumers ranged from 0.002 mg/kg bw per day in infants to 0.04 mg/kg bw per day in the elderly.

**Table 7:** Summary of dietary exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft-co-polymer* (E 1209) as a food additive, **in consumers only** of six population groups (minimum–maximum across the dietary surveys in **mg/kg bw per day**)

	<b>Infants (12 weeks– 11 months)</b>	<b>Toddlers (12–35 months)</b>	<b>Children (3–9 years)</b>	<b>Adolescents (10–17 years)</b>	<b>Adults (18–64 years)</b>	<b>The elderly (≥ 65 years)</b>
<b>Considering ethylene glycol and diethylene glycol present at 100 mg/kg<sup>(a)</sup> in PVA-PEG <i>graft-co-polymer</i> (E 1209)</b>						
• Mean	0.0002–0.0008	0.0002–0.0052	0.0004–0.0035	0.0003–0.0008	0.0001–0.0009	0.0003–0.0025
• 95th percentile	0.0004–0.004	0.001–0.0052	0.0012–0.0049	0.0006–0.001	0.0007–0.0043	0.001–0.0063
<b>Considering ethylene glycol and diethylene glycol present at 620 mg/kg in PVA-PEG <i>graft-co-polymer</i> (E 1209)</b>						
• Mean	0.0012–0.005	0.0015–0.032	0.0026–0.021	0.0016–0.0052	0.0007–0.0055	0.002–0.015
• 95th percentile	0.0024–0.025	0.0061–0.032	0.0075–0.030	0.004–0.0063	0.0045–0.027	0.006–0.039

bw: body weight; PVA: polyvinyl alcohol; PEG: polyethylene glycol.

(a): 50 mg ethylene glycol/kg E 1209 and 50 mg diethylene glycol/kg E 1209.

### 3.5.3. Dietary exposure to ethylene glycol and diethylene glycol

Dietary exposure to ethylene glycol and diethylene glycol was calculated considering their presence in each food category in which polysorbates (E 432–436), PVA-PEG *graft-co-polymer* (E 1209) and polyethylene glycol (E 1521) are authorised and applying the maximum percentage authorised in the EU specifications for those food additives to the MPL for each food category (Table 8).

Table 8 summarises the dietary exposure to ethylene glycol and diethylene glycol from the use of polysorbates (E 432–436), PVA-PEG *graft-co-polymer* (E 1209) and polyethylene glycol (E 1521) as food additives in six population groups (Table 4).

The 95th percentile of the exposure expressed as percentage of the group TDI of 0.5 mg/kg bw per day allocated by the SCF for ethylene glycol and diethylene glycol is also summarised in Table 8.

**Table 8:** Summary of dietary exposure to ethylene glycol and diethylene glycol from their presence in food additives [polysorbates (E 432–436), PVA-PEG *graft-co-polymer* (E 1209) and polyethylene glycol (E 1521)], in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	<b>Infants (12 weeks– 11 months)</b>	<b>Toddlers (12–35 months)</b>	<b>Children (3–9 years)</b>	<b>Adolescents (10–17 years)</b>	<b>Adults (18–64 years)</b>	<b>The elderly (≥ 65 years)</b>
<b>Considering ethylene glycol and diethylene glycol present at 100 mg/kg<sup>(a)</sup> in PVA-PEG <i>graft-co-polymer</i> (E 1209)</b>						
• Mean	0.009–0.022	0.019–0.074	0.012–0.067	0.006–0.035	0.002–0.050	0.002–0.050
• 95th percentile	0.040–0.083	0.051–0.215	0.031–0.168	0.014–0.085	0.007–0.110	0.005–0.127
• (% TDI) <sup>(b)</sup>	(7.9–16.5)	(10.2–43.1)	(6.3–33.7)	(2.8–17.0)	(1.4–22.0)	(1.1–25.3)
<b>Considering ethylene glycol and diethylene glycol present at 620 mg/kg in PVA-PEG <i>graft-co-polymer</i> (E 1209)</b>						
• Mean	0.009–0.022	0.019–0.074	0.012–0.067	0.006–0.036	0.002–0.052	0.002–0.052
• 95th percentile	0.040–0.084	0.051–0.221	0.031–0.175	0.014–0.086	0.007–0.114	0.005–0.132
• (% TDI)	(7.9–16.8)	(10.2–44.1)	(6.3–35.0)	(2.8–17.2)	(1.4–22.9)	(1.1–26.3)

bw: body weight; PVA: polyvinyl alcohol; PEG: polyethylene glycol; TDI: tolerable daily intake.

(a): 50 mg ethylene glycol/kg and 50 mg diethylene glycol/kg.

(b): Calculation based on the 95th percentile.

Considering the maximum limit authorised for these impurities in the food additives authorised in the EU, the mean exposure to ethylene glycol and diethylene glycol ranged from 0.002 mg/kg bw per day in adults and the elderly to 0.074 mg/kg bw per day in toddlers and the 95th percentile ranged from 0.005 mg/kg bw per day in the elderly to 0.215 mg/kg bw per day in toddlers.

Taking into account the proposed maximum limit for ethylene glycol and diethylene glycol in PVA-PEG *graft-co-polymer* (E 1209) of 620 mg/kg, the mean and 95th exposure estimates were almost the same as the estimates reported above considering the current maximum level authorised of 100 mg/kg (50 mg

ethylene glycol/kg and 50 mg diethylene glycol/kg). The maximum estimate at the 95th would reach 0.221 mg/kg bw per day in toddlers.

Comparing the results presented in Tables 6 and 8, the exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft-co-polymer* (E 1209) was very low compared to their exposure resulting from the use of all food additives in which these impurities can be present.

### 3.5.4. Uncertainty analysis

Uncertainties in the exposure assessment of ethylene glycol and diethylene glycol 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 9.

**Table 9:** Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction <sup>(a)</sup>
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/-
Use of data from food consumption survey of a few days to estimate long-term (chronic) exposure for high percentiles (95th percentile)	+
Food categories selected for the exposure assessment: <ul style="list-style-type: none"> <li>• inclusion of the whole food category 17 (Food supplements)</li> <li>• exclusion of the food categories 11.4.2 and 11.4.3 (table-top sweeteners) in which polyethylene glycols (E 1521) is authorised (no MPL available)</li> </ul>	+ -
Food category authorised at MPL according to Annex II to Regulation (EC) No 1333/2008	+
Ethylene glycol and diethylene glycol present at the maximum levels permitted in food additives according to Commission Regulation (EU) No 231/2012	+

MPL: maximum permitted level.

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

Overall, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to ethylene glycol and diethylene glycol from their presence in the food additives authorised in the EU, considering the maximum limits taken into account in the exposure scenario.

## 3.6. Discussion

The European Commission asked EFSA to assess the safety of a proposed amendment of the EU specifications for the food additive PVA-PEG *graft-co-polymer* (E 1209) increasing the maximum limit for ethylene glycol and diethylene glycol, two of the impurities listed in the specifications. According to Commission Regulation (EU) No 231/2012, the maximum amount of ethylene glycol and diethylene glycol present in PVA-PEG *graft-co-polymer* (E 1209) is 50 mg/kg for each of them. The applicant has requested an increase up to 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol.

In the original dossier on PVA-PEG *graft-co-polymer* evaluated by the Panel (EFSA ANS Panel, 2013), the results of the measurement of the levels of ethylene glycol and diethylene glycol in PVA-PEG *graft-co-polymer* were provided and it was stated that the source of their presence was PEG used as a raw material for the manufacturing process of the copolymer. Based on information provided in the dossier, maximum limits for these impurities were included in the EU specifications for PVA-PEG *graft-co-polymer* (E 1209).

Within the documentation provided by the applicant to the European Commission in 2015 to support the proposed increase of the maximum limits in the specifications, results of the analysis of ethylene glycol and diethylene glycol in freshly produced PVA-PEG *graft-co-polymer* (E 1209), showed that the levels of diethylene glycol ranged from < 50 to 133 mg/kg and of ethylene glycol ranged from < 50 to 130 mg/kg. The Panel noted that the data presented in the present dossier reported levels of ethylene glycol and diethylene glycol in PVA-PEG *graft-co-polymer*, which were much higher (up to four times in one sample) than those provided for the previous evaluation (EFSA ANS Panel, 2013).

A stability report including the results of the analysis of the different impurities for which maximum level has been established in the EU specifications for PVA-PEG *graft-co-polymer* (E 1209) was later submitted to EFSA (Documentation provided to EFSA No. 2, 3 and 4). The Panel noted that the levels of ethylene glycol measured in several batches were highly variable. However, the highest measured level of ethylene glycol was 310 mg/kg for one of the batches at one time point. The results reported for diethylene glycol analysed in the stability report of PVA-PEG *graft-co-polymer* were always below the LOD of 50 mg/kg.

1,4-Dioxane and ethylene oxide were only analysed at 63 months (30°C/75% RH) and the reported levels were below the limits of detection of 10 and 0.04 mg/kg, respectively.

The applicant stated that the proposed limit, 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol, was identical to the limit for ethylene glycol in pharmaceutical products (ICH, 2011). The Panel noted that diethylene glycol was not included in the solvents to be limited or solvent that should not be employed but however if their use was unavoidable their levels should be restricted in the pharmaceutical products (ICH, 2011). The Panel also noted that the SCCP proposed a maximum concentration of up to 0.1% diethylene glycol, as an impurity in ingredients, in the finished cosmetic product. Furthermore, the Panel noted that the maximum amount reported from the analytical results for ethylene glycol and diethylene glycol was 360 mg/kg for both of them and that it was below the requested limit of 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol.

A maximum limit for ethylene glycol and diethylene glycol up to 2,500 mg/kg individually or in combination, are included in the EU specifications for polysorbates (E 432–436) and polyethylene glycol (E 1521).

Exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft-co-polymer* (E 1209) as a food additive was calculated. Considering the maximum limit for these impurities in PVA-PEG *graft-co-polymer* (E 1209), the mean exposure to ethylene glycol and diethylene glycol ranged from 0.0001 mg/kg bw per day in adolescents to 0.001 mg/kg bw per day in the elderly and the 95th percentile ranged from 0.0004 mg/kg bw per day in infants to 0.0015 mg/kg bw per day in toddlers. Taking into account the proposed maximum limit for ethylene glycol and diethylene glycol in PVA-PEG *graft-co-polymer* (E 1209) of 620 mg/kg, the exposure was increased in a factor of around six.

Exposure to ethylene glycol and diethylene glycol from their presence in food additives authorised in the EU [polysorbates (E 432–436), PVA-PEG *graft-co-polymer* (E 1209) and polyethylene glycol (E 1521)] at the maximum limit authorised according to the EU specifications was calculated. An additional exposure to ethylene glycol and diethylene glycol from their presence in the mentioned food additives was estimated considering the new proposed maximum limit in PVA-PEG *graft-co-polymer* (E 1209) of 620 mg/kg for the ethylene glycol individually or in combination with diethylene glycol.

Considering the maximum limit authorised for these impurities in the food additives mentioned above, the exposure to these impurities ranged at the mean from 0.002 mg/kg bw per day in adults and the elderly to 0.074 mg/kg bw per day in toddlers and at the 95th percentile ranged from 0.005 mg/kg bw per day in the elderly to 0.215 mg/kg bw per day in toddlers. Taking into account the proposed maximum limit for ethylene glycol and diethylene glycol in PVA-PEG *graft-co-polymer* (E 1209) of 620 mg/kg, the mean and 95th exposure to ethylene glycol and diethylene glycol, from the use of the food additives mentioned above, were almost the same as the estimates reported above considering the current maximum limit authorised of 100 mg/kg (50 mg ethylene glycol/kg and 50 mg diethylene glycol/kg). The maximum estimate at the 95th percentile could reach 0.221 mg/kg bw per day in toddlers.

Exposure to ethylene glycol and diethylene glycol from the use of PVA-PEG *graft-co-polymer* (E 1209) was very low compared to their exposure resulting from the use of all food additives in which these impurities can be present.

All the exposure estimates to ethylene glycol and diethylene glycol, from the use of the food additives mentioned above, including the highest one (0.221 mg/kg bw per day in toddlers at the 95th percentile), were below the group TDI of 0.5 mg/kg bw per day allocated by the SCF (1986, 2002) for ethylene glycol and diethylene glycol (Table 8). However, the Panel noted that the exposure estimate did not include exposure to ethylene glycol and diethylene glycol resulting from other uses.

## 4. Conclusions

The proposed request to increase the maximum limit of 620 mg/kg for ethylene glycol individually or in combination with diethylene glycol in the specifications for PVA-PEG *graft-co-polymer* (E 1209),



would result in total exposure from food additive uses below the group TDI allocated by the SCF for ethylene glycol and diethylene glycol. Therefore, the Panel concluded that the requested amendment of the EU specifications for PVA-PEG *graft*-co-polymer (E 1209) would not result in a safety concern.

The Panel noted that the analytical results provided were consistently and considerably lower (up to 360 mg/kg) than the proposed level of 620 mg/kg for ethylene glycol individually or in combination with diethylene glycol in the EU specifications for PVA-PEG *graft*-co-polymer (E 1209).

## Documentation provided to EFSA

- 1) Letter of the company BASF SE requesting the amendment of Commission Regulation (EU) No 231/2012 regarding the specifications of E 1209. Submitted to EFSA by the European Commission on 1 December 2015.
- 2) Stability data for polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer and response to the EFSA request for additional information on 22 March 2016. Submitted to EFSA by BASF SE, 1 June 2016.
- 3) Stability data for polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer and response to the EFSA request for additional information on 15 June 2016. Submitted to EFSA by BASF SE, 25 July 2016.
- 4) Dossier on polyvinyl alcohol-polyethylene glycol *graft* co-polymer for use as a film coating agent for food supplements products. Dossier including the data from the original application (2011) and the additional data submitted to EFSA (Documentation provided to EFSA No. 2 and 3). Submitted by BASF SE, 25 July 2016.

## References

- EFSA (European Food Safety Authority), 2007. Scientific opinion of the Scientific Committee related to uncertainties in dietary exposure assessment. EFSA Journal 2007;5(1):438, 54 pp. <https://doi.org/10.2903/j.efsa.2007.438>
- EFSA (European Food Safety Authority), 2011a. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. <https://doi.org/10.2903/j.efsa.2011.2097>
- EFSA (European Food Safety Authority), 2011b. Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database. EFSA Journal 2011; 9(3):1970, 27 pp. <https://doi.org/10.2903/j.efsa.2011.1970>
- EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources Added to Food), 2012. Guidance for submission for food additive evaluations. EFSA Journal 2012;10(7):2760, 60 pp. <https://doi.org/10.2903/j.efsa.2012.2760>
- EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources Added to Food), 2013. Scientific Opinion on the safety of polyvinyl alcohol-polyethylene glycol-*graft*-co-polymer as a food additive. EFSA Journal 2013; 11(7):3303, 31 pp. <https://doi.org/10.2903/j.efsa.2013.3303>
- EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources Added to Food), 2015. Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives. EFSA Journal 2015;13(7):4152, 74 pp. <https://doi.org/10.2903/j.efsa.2015.4152>
- EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2015. Scientific Opinion on the safety assessment of the substance ethylene glycol dipalmitate, CAS No 624-03-3, for use in food contact materials. EFSA Journal 2015;13(2):4019, 8 pp. <https://doi.org/10.2903/j.efsa.2015.4019>
- EFSA Scientific Committee, 2009. Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles. EFSA Journal 2009;7(7):1051, 22 pp. <https://doi.org/10.2903/j.efsa.2009.1051>
- ICH (International Conference on Harmonised of Technical Requirements for Registration of Pharmaceutical for Human Use), 2011. ICH Harmonised Tripartite Guideline. Impurities: Guideline for residual solvents, Q3C(R5). Current Step 4 version dated 4 February 2011.
- JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1980. Evaluation of certain food additives. Twenty-third report of the Joint FAO/WHO Expert Committee on Food Additives. No. 648. World Health Organization, Geneva, Switzerland.
- JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2015. Evaluation of certain food additives and contaminants. (Eightieth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 995. Polyvinyl alcohol (PVA)-polyethylene glycol (PEG) *graft* copolymer, 31-36.
- SCCP (Scientific Committee on Consumer Products), 2008. Opinion on diethylene glycol. SCCP/1181/08.

SCF (Scientific Committee for Food), 1986. Reports of the Scientific Committee for food. Seventeenth series. Certain monomers and other starting substances to be used in the manufacturing of plastic materials and articles intended to come into contact with foodstuffs (opinion expressed 14 December 1984).

SCF (Scientific Committee for Food), 2002. Opinion of the Scientific Committee on Food on Impurities of 1,4-dioxane, 2-chloroethanol and mono- and diethylene glycol in currently permitted food additives and in proposed use of ethyl hydroxyethyl cellulose in gluten-free bread (expressed on 4 December 2002).

## Abbreviations

ADI	acceptable daily intake
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
CAS	Chemical Abstracts Service
FAO	Food and Agriculture Organization of the United Nations
FCM	food contact material
FCS	food categorisation system
ICH	International Conference on Harmonised of Technical Requirements for Registration of Pharmaceutical for Human Use
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
MOE	margin of exposure
MPL	maximum permitted level
PEG	polyethylene glycol
PVA	polyvinyl alcohol
QS	<i>quantum satis</i>
RH	relative humidity
SCCP	Scientific Committee on Consumer Products
SCF	Scientific Committee on Food
SML(T)	total specific migration limit
TDI	tolerable daily intake
WHO	World Health Organization

## Appendix A – MPLs of polyethylene glycols (E 1521) in foods according to the Annex II to Regulation (EC) No 1333/2008

Food Category number	Food category name	E-number/group	Restrictions/exception	MPL (mg/L or mg/kg as appropriate)
11.4.2	Table-top sweeteners in powder form	E 1521	–	QS <sup>(a)</sup>
11.4.3	Table-top sweeteners in tablets	E 1521	–	QS <sup>(a)</sup>
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	E 1521	–	10,000

MPL: maximum permitted level; QS: *quantum satis*.

(a): No use levels available; the food categories were not taken into account.

## Appendix B – MPLs of polysorbitans (E 432, E 433, E 434, E 435 and E 436) in foods according to the Annex II to Regulation (EC) No 1333/2008

Food Category number	Food category name	E-number/group	Restrictions/exception	MPL (mg/L or mg/kg as appropriate)
01.4	Flavoured fermented milk products including heat-treated products	E 432–436	–	1,000
01.8	Dairy analogues, including beverage whiteners	E 432–436	Only milk and cream analogues	5,000
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions	E 432–436	Only fat emulsions for baking	10,000
03	Edible ices	E 432–436	–	1,000
04.2.4.1	Fruit and vegetable preparations excluding compote	E 432–436	Only coconut milk	500
05.2	Other confectionery including breath freshening microsweets	E 432–436	Only sugar confectionery	1,000
05.3	Chewing gum	E 432–436	–	5,000
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 04.2.4	E 432–436	–	1,000
07.2	Fine bakery wares	E 432–436	–	3,000
12.5	Soups and broths	E 432–436	Only soups	1,000
12.6	Sauces	E 432–436	Only emulsified sauces	5,000
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	E 432–436	–	1,000
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)	E 432–436	–	1,000
16	Desserts excluding products covered in categories 01, 03 and 04	E 432–436	–	3,000
17.1 <sup>(a)</sup>	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	E 432–436	–	QS <sup>(b)</sup>
17.2 <sup>(a)</sup>	Food supplements supplied in a liquid form	E 432–436	–	QS <sup>(b)</sup>
17.3 <sup>(a)</sup>	Food supplements supplied in a syrup-type or chewable form	E 432–436	–	QS <sup>(b)</sup>

MPL: maximum permitted level; QS: *quantum satis*.

(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. In the EFSA Comprehensive database, no information is provided on the type of food supplements consumed by infants and young children. In the exposure assessment, it was therefore assumed that the food supplements consumed in these population groups were the same as those consumed in the older population groups.

(b): According to EFSA Panel on Food Additives and Nutrient Sources Added to Food (EFSA ANS Panel, 2015), the levels used for the food supplements for were equal to 425,000 mg/kg.

## Appendix C – Summary of total estimated exposure to ethylene glycol and diethylene glycol from their presence in food additives authorised in the EU at the MPL in foods and maximum authorised levels in food additives according to Commission Regulation (EU) No 231/2012 per population group and survey: mean and 95th percentile (mg/kg bw per day)

	No of subjects	Considering EG/DEG at 100 mg/kg in PVA-PEG graft-co-polymer (E 1209)		Considering EG/DEG at 620 mg/kg in PVA-PEG graft-co-polymer (E 1209)	
		Mean	P95	Mean	P95
<b>Infants</b>					
Bulgaria (NUTRICHILD)	659	0.009	0.040	0.009	0.040
Germany (VELS)	159	0.009	0.041	0.009	0.041
Denmark (IAT 2006–07)	826	0.010	0.045	0.010	0.045
Finland (DIPP 2001–2009)	500	0.020	0.042	0.021	0.044
United Kingdom (DNSIYC 2011)	1,366	0.022	0.083	0.022	0.084
Italy (INRAN SCAI 2005–06)	12	0.020	–	0.020	–
<b>Toddlers</b>					
Belgium (Regional Flanders)	36	0.071	–	0.071	–
Bulgaria (NUTRICHILD)	428	0.025	0.070	0.025	0.070
Germany (VELS)	348	0.044	0.094	0.044	0.095
Denmark (IAT 2006–07)	917	0.019	0.051	0.019	0.051
Spain (enKid)	17	0.036	–	0.036	–
Finland (DIPP 2001–2009)	500	0.038	0.131	0.039	0.138
United Kingdom (NDNS-RollingProgrammeYears1-3)	185	0.062	0.215	0.063	0.221
United Kingdom (DNSIYC 2011)	1,314	0.046	0.121	0.046	0.121
Italy (INRAN SCAI 2005–06)	36	0.037	–	0.037	–
Netherlands (VCP kids)	322	0.074	0.166	0.074	0.166
<b>Children</b>					
Austria (ASNS Children)	128	0.026	0.059	0.026	0.059
Belgium (Regional Flanders)	625	0.058	0.123	0.058	0.123
Bulgaria (NUTRICHILD)	433	0.029	0.070	0.029	0.070
Czech Republic (SISP04)	389	0.032	0.070	0.032	0.070
Germany (EsKiMo)	835	0.032	0.102	0.033	0.106
Germany (VELS)	293	0.047	0.099	0.047	0.099
Denmark (DANSDA 2005–08)	298	0.012	0.031	0.012	0.031
Spain (enKid)	156	0.032	0.079	0.032	0.079
Spain (NUT INK05)	399	0.032	0.070	0.032	0.070
Finland (DIPP 2001–2009)	750	0.062	0.168	0.064	0.175
France (INCA2)	482	0.043	0.084	0.043	0.084
United Kingdom (NDNS-RollingProgrammeYears1-3)	651	0.049	0.129	0.050	0.134
Greece (Regional Crete)	838	0.027	0.062	0.027	0.062
Italy (INRAN SCAI 2005–06)	193	0.019	0.047	0.019	0.047
Latvia (EFSA TEST)	187	0.037	0.084	0.037	0.084
Netherlands (VCP kids)	957	0.067	0.144	0.067	0.144
Netherlands (VCPBasis AVL2007–2010)	447	0.066	0.152	0.067	0.155
Sweden (NFA)	1,473	0.059	0.116	0.060	0.117

	No of subjects	Considering EG/DEG at 100 mg/kg in PVA-PEG graft-co-polymer (E 1209)		Considering EG/DEG at 620 mg/kg in PVA-PEG graft-co-polymer (E 1209)	
		Mean	P95	Mean	P95
<b>Adolescents</b>					
Austria (ASNS Children)	237	0.013	0.035	0.013	0.035
Belgium (Diet National 2004)	576	0.021	0.051	0.021	0.051
Cyprus (Childhealth)	303	0.006	0.017	0.006	0.017
Czech Republic (SISP04)	298	0.021	0.047	0.021	0.047
Germany (National Nutrition Survey II)	1,011	0.018	0.048	0.018	0.048
Germany (EsKiMo)	393	0.020	0.063	0.020	0.066
Denmark (DANSDA 2005–08)	377	0.006	0.014	0.006	0.014
Spain (AESAN FIAB)	86	0.011	0.027	0.011	0.027
Spain (enKid)	209	0.020	0.045	0.020	0.045
Spain (NUT INK05)	651	0.018	0.040	0.018	0.040
Finland (NWSSP07 08)	306	0.023	0.057	0.024	0.060
France (INCA2)	973	0.021	0.048	0.021	0.048
United Kingdom (NDNS-RollingProgrammeYears1-3)	666	0.021	0.056	0.022	0.056
Italy (INRAN SCAI 2005–06)	247	0.011	0.030	0.011	0.030
Latvia (EFSA TEST)	453	0.024	0.059	0.024	0.059
Netherlands (VCPBasis AVL2007–2010)	1,142	0.035	0.085	0.036	0.086
Sweden (NFA)	1,018	0.028	0.062	0.028	0.063
<b>Adults</b>					
Austria (ASNS Adults)	308	0.024	0.052	0.025	0.052
Belgium (Diet National 2004)	1,292	0.017	0.041	0.017	0.041
Czech Republic (SISP04)	1,666	0.012	0.026	0.012	0.026
Germany (National Nutrition Survey II)	10,419	0.024	0.040	0.025	0.040
Denmark (DANSDA 2005–08)	1,739	0.004	0.009	0.004	0.009
Spain (AESAN)	410	0.011	0.022	0.011	0.022
Spain (AESAN FIAB)	981	0.009	0.021	0.009	0.021
Finland (FINDIET2012)	1,295	0.040	0.110	0.042	0.114
France (INCA2)	2,276	0.013	0.029	0.013	0.029
United Kingdom (NDNS-RollingProgrammeYears1-3)	1,266	0.027	0.065	0.028	0.067
Hungary (National Repr Surv)	1,074	0.002	0.010	0.002	0.010
Ireland (NANS 2012)	1,274	0.039	0.107	0.040	0.111
Italy (INRAN SCAI 2005–06)	2,313	0.009	0.018	0.009	0.018
Latvia (EFSA TEST)	1,271	0.014	0.034	0.014	0.034
Netherlands (VCPBasis AVL2007–2010)	2,057	0.029	0.069	0.030	0.070
Romania (Dieta Pilot Adults)	1,254	0.002	0.007	0.002	0.007
Sweden (Riksmaten 2010)	1,430	0.050	0.042	0.052	0.042
<b>The elderly</b>					
Austria (ASNS Adults)	92	0.017	0.035	0.017	0.035
Belgium (Diet National 2004)	1,215	0.017	0.039	0.017	0.039
Germany (National Nutrition Survey II)	2,496	0.015	0.035	0.015	0.035
Denmark (DANSDA 2005–08)	286	0.003	0.008	0.003	0.008
Finland (FINDIET2012)	413	0.039	0.096	0.040	0.100
France (INCA2)	348	0.010	0.024	0.010	0.024

	No of subjects	Considering EG/DEG at 100 mg/kg in PVA-PEG graft-co-polymer (E 1209)		Considering EG/DEG at 620 mg/kg in PVA-PEG graft-co-polymer (E 1209)	
		Mean	P95	Mean	P95
United Kingdom (NDNS-Rolling Programme Years 1-3)	305	0.029	0.080	0.030	0.083
Hungary (National Repr Surv)	286	0.002	0.010	0.002	0.010
Ireland (NANS 2012)	226	0.050	0.127	0.052	0.132
Italy (INRAN SCAI 2005-06)	518	0.009	0.018	0.009	0.018
Netherlands (VCP Basis AVL 2007-2010)	173	0.029	0.081	0.030	0.084
Netherlands (VCP-Elderly)	739	0.033	0.096	0.034	0.099
Romania (Dieta Pilot Adults)	128	0.002	0.005	0.002	0.005
Sweden (Riksmaten 2010)	367	0.015	0.035	0.015	0.035

P95: 95th percentile; EG: ethylene glycol; DEG: diethylene glycol; PVA: polyvinyl alcohol; PEG: polyethylene glycol; bw: body weight.