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Follow-up of the re-evaluation of glycerol (E 422) as a food additive

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Abstract

Glycerol (E 422) was re-evaluated in 2017 by the former EFSA Panel on Food Additives and Nutrient sources added to Food (ANS). As a follow-up to that assessment, in this opinion, the Panel on Food Additives and Flavourings (FAF) addresses the data gaps identified to support an amendment of the EU specifications for E 422 in Commission Regulation (EU) No 231/2012. The Panel performed a risk assessment of undesirable impurities present in E 422. The Panel concluded that the maximum limits in the EU specifications for the four toxic elements (arsenic, lead, mercury and cadmium) should be lowered based on actual levels in the commercial food additive E 422. The Panel recommended setting a numerical limit value for acrolein in the specifications for E 422. The potential exposure to free 3-monochloropropanediol at the maximum limit of 0.1 mg/kg, as laid out in the specifications for E 422, does not give rise to a health concern. The Panel recommended to consider modifying the definition of E 422 in Commission Regulation (EU) No 231/2012 indicating that E 422 is obtained only from vegetable oils and fats and undergoes purification processes that involve distillation, and other clean up steps to obtain refined glycerol. Overall, the Panel concluded that the technical data provided support an amendment of the specifications for glycerol (E 422).

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Summary

In this opinion, the EFSA Panel on Food Additives and Flavourings (FAF Panel) was requested to assess the data provided by interested business operators (IBOs) in support of an amendment of the EU specifications for glycerol (E 422) in Commission Regulation (EU) No 231/2012.

Glycerol (E 422) (also known as glycerine or glycerin) was re-evaluated in 2017 by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) which concluded that there was no need for a numerical ADI for glycerol (E 422) and there is no safety concern regarding the use of glycerol (E 422) as a food additive according to Annex II and III (Part 1, 2, 3, 4 and 5) for the general population at the refined exposure assessment for the reported uses as a food additive. According to the information available at the time of the re-evaluation, glycerol can be produced by a variety of manufacturing processes leading to the possible presence of impurities, some of which are of toxicological concern. For this reason, the ANS Panel had recommended an update of the EU specifications for E 422 to include numerical limit values for any impurity that could be present in the food additive. The European Commission published a dedicated call for data allowing all interested parties to provide the requested information for completing the assessment. As a follow-up of the above, this opinion addresses the data gaps previously identified during the re-evaluation of glycerol (E 422).

The current assessment addresses the EFSA recommendations, indicated during the re-evaluation of glycerol (E 422) as a food additive, to update its EU specifications in Commission Regulation (EU) No 231/2012.

In response to the European Commission call for data, analytical data on impurities in commercial samples of E 422 were provided by two IBOs. Different analytical methods were used, and consequently, there were different limits of detection (LOD) values reported even for the same elements. The potential exposure to these impurities from the use of the food additive E 422 was calculated by assuming that they may be present in the food additive up to a certain limit value and then by calculation pro-rata to the estimates of exposure to the food additive itself.

Analytical data on levels of toxic elements (arsenic, lead, cadmium, mercury) in commercial samples of E 422 were provided by one IBO. The Panel noted that the occurrence data on toxic elements submitted by the IBO are substantially lower than the current limits in the EU specifications. The potential exposure to these impurities from the use of E 422 was compared against the available health-based guidance values (HBGV) and reference points (RP). The Panel considered the presence of these impurities in E 422 at (i) the current EU specification values, the potential exposure to all four toxic elements would be of concern. For lead and arsenic, the MOE values would be too low, and for mercury and cadmium, the exposure would represent more than 50% of the TWI (Table 5). This should also be seen in light of exposure from sources other than glycerol (E 422). If specifications were based on (ii) the highest LOD reported or (iii) on the lowest LOD reported modulated by a factor of 10, in both scenarios the MOE for arsenic would be too low, but the other three elements would not give rise to concern. The Panel noted that the maximum limits in the EU specifications for toxic elements should be established based on actual levels in the commercial food additive. Therefore, the Panel recommended that the maximum limits to be lowered on the basis of the information provided and the considerations made by the Panel.

Analytical data on levels of acrolein in commercial samples of E 422 were also provided by one IBO. The Panel performed the risk assessment for acrolein assuming that this impurity is present in E 422 at the maximum content reported (rounded to 3 mg/kg) and also by choosing the reported limit of quantification (LOQ) and applying a factor of 10 times this value resulting in 5 mg/kg. The Panel noted that the comparison of the estimated potential exposure to acrolein from the use of E 422 with the provisional tolerable concentration (TC) for acrolein (0.0075 mg/kg body weight (bw)) shows that acrolein at the level of 3 or 5 mg/kg could give rise to an exposure up to 18% and 30% of the provisional TC for acrolein, respectively. Considering the potential occurrence of acrolein in E 422, the Panel recommended setting a numerical limit value for this impurity in the Commission Regulation (EU) No 231/2012 for E 422.

Analytical data on levels of free 3-monochloropropanediol (3-MCPD) in commercial samples of E 422 were provided. No analytical data on the presence of esters of 3-MCPD or esters of glycidol were submitted following an EFSA request for this information. The Panel noted that the manufacturing processes of glycerol E 422 include vacuum distillation of the product, amongst other purification steps. The large difference in molecular weight (and therefore in volatility) between glycerol itself and the fatty acid esters of glycidol and of 3-MCPD means that these contaminants are

not to be expected in glycerol purified by a process involving distillation. Similarly, glycerol obtained by distillation is also expected to be free of high-molecular weight contaminants that may be present in the feedstock if the intermediate crude glycerol is obtained from biodiesel production with used cooking oils and the like as feedstock. Based on these considerations, the potential exposure to free 3-MCPD at the maximum limit of 0.1 mg/kg in E 422, as laid out in the Commission Regulation EU No 231/2012, was calculated and it represents only a low percentage of the tolerable daily intake (TDI) for the sum of 3-MCPD and 3-MCPD fatty acid esters and does not give rise to a health concern.

According to the information available at the time of the 2017 re-evaluation of E 422, it was considered that glycerol could be produced by a variety of alternative manufacturing processes leading to the possible presence of impurities, some of which would be of toxicological concern. The IBOs have stated now that glycerol for use as E 422 is manufactured only from vegetable oils and fats, either directly or from the crude glycerol obtained as a by-product of biodiesel production. Therefore, analytical data on those impurities potentially arising from the alternative manufacturing processes involving chemical synthesis or microbiological fermentation have not been submitted. The FAF Panel recommends to consider modifying the definition of E 422 in Commission Regulation (EU) No 231/2012 indicating that E 422 is obtained only from vegetable oils and fats and undergoes purification processes that involve distillation, and other clean up steps to obtain refined glycerol to avoid that glycerol manufacturing from other routes, leading to the potential presence of impurities that have not been assessed in this Opinion, can be used as E 422.

The Panel concluded that the technical data provided by the IBOs support an amendment of the specifications for glycerol (E 422) laid down in Commission Regulation (EU) No 231/2012.

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1. Introduction

The re-evaluation of glycerol (E 422) was completed by EFSA in 2017 (EFSA ANS Panel, 2017). The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) issued several recommendations to amend the specifications of the food additive glycerol (E 422) in Commission Regulation (EU) No 231/2012¹.

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

The present opinion deals with the assessment of the data provided by interested parties in support of an amendment of the EU specifications for glycerol (E 422).

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 on food additives.³ Only food additives that are included in the Union list, in Annex II to that regulation, may be placed on the market and used in foods under the conditions of use specified therein. Moreover, food additives shall comply with the specifications as referred to in Article 14 of that Regulation and laid down in Commission Regulation (EU) No 231/2012.

Glycerol (E 422) is authorised for use as food additive in the Union. Since glycerol (E 422) was permitted in the union before 20 January 2009, this substance belongs to the group of additives which are subject to a new risk assessment by the European Food Safety Authority (EFSA) according to Commission Regulation (EU) No 257/2010⁴, and in line with the provisions of Regulation (EC) No 1333/2008.

EFSA completed the re-evaluation of glycerol (E 422) as food additive and published a scientific opinion on the 15 March 2017 (EFSA ANS Panel, 2017). In that opinion EFSA recommended that the specifications of glycerol (E 422) in the Commission Regulation (EU) No 231/2012 are updated to current standards. In order to address EFSA recommendations additional technical data on the food additive glycerol (E 422) are needed.

Therefore, the European Commission published on 23 November 2018 a call for data⁵ addressing the recommendations made by EFSA in the scientific opinion on the re-evaluation of glycerol (E 422) as a food additive, which led to the submission by interested business operators (APAG – The European Oleochemicals & Allied Products Group and MVO – The Netherlands Oils and Fat Industry) of new technical data on glycerol (E 422) on June 2019.

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

1.1.2. Term of Reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002⁶, the European Commission requests the European Food Safety Authority (EFSA) to provide a scientific opinion to confirm that the technical data provided by the interested business operators adequately support an amendment of the specifications of the food additive glycerol (E 422) to bring them to current standards, in line with the recommendations made by EFSA during the re-evaluation of the safety of the food additive.

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

² Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_reeval_call_20170130_E_171_data.pdf

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

⁴ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a program 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.

⁵ Available online: https://ec.europa.eu/food/system/files/2019-01/fs_food-improvement-agents_reeval_call_20181123_E_422_data.pdf

⁶ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

1.2. Summary of the EFSA re-evaluation of glycerol (E 422) as a food additive

Glycerol (E 422) was re-evaluated by the EFSA ANS Panel that concluded that there was no need for a numerical ADI for glycerol (E 422) and there is no safety concern regarding the use of glycerol (E 422) as a food additive according to Annex II and III (Part 1, 2, 3, 4 and 5) for the general population at the refined exposure assessment for the reported uses as a food additive (EFSA ANS Panel, 2017).

According to the available information at the time of the re-evaluation (EFSA ANS Panel, 2017), glycerol can be produced by a variety of manufacturing processes leading to the possible presence of impurities, some of which are of toxicological concern. For this reason, the ANS Panel had recommended an update of the EU specifications for E 422 to include numerical limit values for any impurity that could be present in the food additive.

Therefore, the EFSA ANS Panel recommended that the specifications for glycerol (E 422) in Commission Regulation (EU) No 231/2012 are updated. The following recommendations were indicated:

- given that during the manufacturing processes of glycerol, genotoxic impurities – e.g. glycidol, epichlorohydrin – could be formed, limits for such impurities should be included in the EU specifications for glycerol (E 422);
- given that during the manufacturing processes of glycerol, other potential impurities of toxicological concern (e.g. dichlorohydrin) could be formed, limits for such impurities should be included in the EU specifications for glycerol (E 422);
- more data should be generated to decrease uncertainty arising from the presence in the food additive (E 422) of compounds of toxicological concern (e.g. acrolein, 3-MCPD or 3-MCPD ester), which can be produced under some food processing conditions (e.g. use of glycerol (E 422) in parallel with lactic acid bacteria; use of glycerol (E 422) in food containing significant amounts of sodium chloride (more than 5%) and treated at temperatures above 160°C...);
- a numerical limit for acrolein should be included in the EU specifications for glycerol (E 422);
- the maximum limits for the impurities of toxic elements (arsenic, lead, mercury and cadmium) in the EU specification for glycerol (E 422) should be revised in order to ensure that glycerol (E 422) as a food additive will not be a significant source of exposure to those toxic elements in food;

2. Data and methodologies

2.1. Data

The Panel based its assessment on the information submitted following the public call for data (Documentation provided to EFSA n. 1, 2) and additional information submitted during the assessment process by interested parties in response to a following request by EFSA (Documentation provided to EFSA n. 3, 4 and 5).

Following the request for additional data sent by EFSA on 4 May 2020, the interested parties requested a clarification teleconference held on 10 June 2020, after which they provided additional data (Documentation provided to EFSA No. 5).

2.2. Methodologies

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

3. Assessment

3.1. Identity and specifications for glycerol (E 422)

The current EU specifications for glycerol (E 422) according to Commission Regulation EU 231/2012 are presented in Table 1. Glycerol is also known as glycerine or glycerin.

Table 1: Specifications for glycerol (E 422) according to Commission Regulation (EU) No 231/2012

Commission Regulation (EU) No 231/2012	
Assay	Content not less than 98% of glycerol on an anhydrous basis
Description	Clear, colourless, hygroscopic syrupy liquid, with not more than a slight characteristic odour, which is neither harsh nor disagreeable
Identification	
Acrolein formation on heating	Heat a few drops of the sample in a test tube with about 0.5 g of potassium bisulfate. The characteristic pungent vapours of acrolein are evolved
Specific gravity (25/25°C)	Not less than 1.257
Refractive index $[n]_D^{20}$	Between 1.471 and 1.474
Purity	
Water	Not more than 5% (Karl Fischer method)
Sulfated ash	Not more than 0.01% determined at $800 \pm 25^\circ\text{C}$
Butanetriols	Not more than 0.2%
Acrolein, glucose and ammonium compounds	Heat a mixture of 5 mL of glycerol and 5 mL of potassium hydroxide solution (1 in 10) at 60°C for 5 min. It neither becomes yellow nor emits an odour of ammonia
Fatty acids and esters	Not more than 0.1% calculated as butyric acid
Chlorinated compounds	Not more than 30 mg/kg (as chlorine)
3-monochloropropane-1,2-diol (3-MCPD))	Not more than 0.1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

3.2. Technical data

Taking into consideration the recommendations for the EFSA ANS Panel (2017), the following was requested in the European Commission call for data:⁷

- in view that in the Scientific Opinion on the re-evaluation of glycerol (E 422) as a food additive it has been noted that glycerol (E 422) can be produced by a variety of methods, and that many of them may lead to the presence or formation of contaminants, which are of toxicological concern, the following information was requested:
 - information on the manufacturing process of glycerol to be used as food additive E 422;
 - analytical data on current levels of any chemical intermediate that could be formed during the manufacturing process of glycerol in commercial samples of the food additive;
 - the lowest technologically achievable level of any chemical intermediate that could be formed during the manufacturing process of glycerol, in order to adequately define maximum limits in the specifications of E 422.
- analytical data on current levels of arsenic, lead, mercury and cadmium in commercial samples of the food additive and their lowest technologically achievable levels in order to adequately define their maximum limits in the specifications;
- analytical data on current levels of acrolein, which is an intermediate chemical in the synthesis of glycerol, in commercial samples of the food additive and its lowest technologically achievable level of acrolein, in order to adequately define its maximum limit in the specifications of E 422;
- the lowest technologically achievable level in food of any compound of toxicological concern (e.g. acrolein, 3-MCPD and glycidyl esters), which can be produced under certain food processing conditions from the food additive glycerol (E 422) (e.g. use of glycerol (E 422) in parallel with lactic acid bacteria; use of glycerol (E 422) in food containing significant amounts of sodium chloride (more than 5%) and treated at temperatures above 160°C , etc.);

⁷ EU call for data. Available online: https://ec.europa.eu/food/system/files/2019-01/fs_food-improvement-agents_reeval_call_20181123_E_422_data.pdf

3.2.1. Information on the manufacturing process of glycerol (E 422)

An IBO indicated that its members use vegetable oils, such as rapeseed, palm and soy, or crude glycerol (which is a by-product of the biodiesel production) to produce food grade glycerol by hydrolysis, saponification or transesterification (Documentation provided to EFSA n. 1).

- Hydrolysis (or high-pressure splitting): water and fat are fed into a splitting column (5–6 MPa and 250–260°C) leading to a 15% solution of glycerol in water (sweet water). This glycerol is marketed as 88% saponification- or hydrolysis-crude glycerol.
- Transesterification: Natural crude glycerol of similar quality can be obtained from the continuous transesterification of oils and fats to their methyl esters. The crude glycerol is obtained at a concentration of ca. 80–92%.
- Saponification: The splitting of fats by saponification of oils is a traditional method: caustic alkali or alkali carbonates are used as in the production of soaps. The use of calcium hydroxide in the form of milk of lime is also possible.

Independent on the source of glycerol (see above), the purification process involves distillation, and further clean up steps to obtain refined glycerol. The distillation process takes place under high vacuum conditions to obtain an intermediate product free from heavy compounds. Only a small amount of free volatile fatty acids and fatty esters remain in the product. The distillation is carried out at temperatures around 160°C. The vapours of glycerol distil from the bulk and are efficiently condensed by means of recirculation of cooled glycerol. A second distillation minimises the content of fatty acids and other compounds having a boiling point near to the boiling point of glycerol. The distilled glycerol is then bleached and deodorised by means of food grade activated carbon in a bleaching system. The finished product is then filtered to remove any remaining impurities and stored in dedicated stainless-steel tanks to be delivered to the customer (Documentation provided to EFSA n. 4).

Another IBO has indicated that crude glycerol is also obtained from vegetable oils and fats as a by-product of biodiesel production. The vegetable oil is degummed, deacidified through free fatty acid removal, and subsequently transesterified with methanol in the presence of a catalyst resulting in the formation of fatty acid methyl esters. The simultaneously liberated free glycerol then follows a pretreatment where residual fatty matter, methanol and moisture are removed. Crude glycerol then undergoes refining including a distillation step, treatment with NaOH, bleaching with granular active carbon to remove traces of colour and odour, and finally filtration to produce refined glycerol (Documentation provided to EFSA n. 2 and 3).

3.2.2. Toxic elements

Analytical data on the current levels of arsenic, lead, mercury and cadmium in 18 commercial samples of E 422 were submitted by one IBO. The analyses were performed by inductively coupled plasma mass spectroscopy (ICP-MS) and/or inductively coupled plasma optical emission spectroscopy (ICP-OES). The levels reported for each element are presented as 'less than' a specific value. The LOD values reported ranged from 0.02 to 0.43 mg/kg for As, 0.02–0.14 mg/kg for Pb, 0.02–0.1 mg/kg for Cd and 0.05–0.19 mg/kg for Hg (Documentation provided to EFSA n. 1). It was explained that the highest detection limit was reported as being 'less than' and that 'the difference in the detection limit in the different laboratories is no reason to imply that higher concentration was found in certain samples' (Documentation provided to EFSA n. 4). LOQs were not reported and no lowest technologically achievable levels were indicated.

3.2.3. Data on acrolein

An IBO indicated that analyses for acrolein are performed as described in the EU specifications (Commission Regulation EU 231/2012). Although all samples passed this test, there is no exact data on the sensitivity of this method and no numerical data on the levels of acrolein in E 422 were available (Documentation provided to EFSA n. 1).

Following a EFSA request for quantitative data on the presence of acrolein in samples of glycerol used as E 422, the IBO identified two methods of analysis of acrolein in glycerol, high-performance liquid chromatography (HPLC) and gas chromatography-mass spectroscopy (GC-MS). Results were cross-checked to conclude which is the most suitable method for glycerol, and results were also compared with the method described in Commission Regulation EU 231/2012 (Documentation provided to EFSA n. 5).

The HPLC method is based on method ISO-1600-4 used for determining aldehydes in air. A certain amount of the glycerol sample was dissolved in an absorbent. The aldehydes were converted in solution with 2,4-dinitrophenylhydrazine to the DNPH-esters which were analysed by HPLC with ultraviolet (UV) detection at 356 nm. The LOQ reported was 0.5 mg/kg; in addition, it was mentioned that with some adjustments, an LOQ of 0.1 mg/kg could be obtained.

The GC-MS method used solid phase microextraction to determine acrolein in glycerol. The IBO stated that the lowest 'detectable limit of the equipment' was 0.1 mg/kg.

Eighteen samples intended for E 422 production were analysed by HPLC and six by GC-MS. Some of the samples were stored at 80°C for 1 week – to simulate the conditions that the samples are likely to be subject to during storage and distribution in bulk, where the product can easily be exposed to high temperatures for a couple of days and increase the probability of acrolein formation. The results of the analysis of these samples by HPLC do not indicate that acrolein is formed under those conditions.

The comparison of the results from both methods for three samples extracted 'from the same main sample' indicated that the GC-MS method is not suitable to detect acrolein in glycerol. The results of samples analysed by HPLC were compared with the method as described in Commission Regulation EU 231/2012. It was indicated that the method described in Commission Regulation EU 231/2012 allows to detect the presence of acrolein as from 1.5 mg/kg.

The samples analysed by HPLC showed concentrations ranging from a minimum of < 0.5 mg/kg (LOQ) to a maximum of 3.1 mg/kg. No lowest technologically achievable level for acrolein has been proposed.

3.2.4. Data on glycidyl esters

According to an IBO (Documentation provided to EFSA n. 1), glycidyl esters are very unlikely to be present in glycerol – since this contaminant is very reactive and does not withstand the splitting or transesterification process. However, due to its chemical constitution, glycidyl esters may react with nucleophiles (such as water or alcohols); which could lead to the formation of glycerol esters or glycerol mixed esters and ethers. The IBO indicated that there is no specific validated test for the presence of glycidyl esters in glycerol. Glycerol is produced by hydrolysis and transesterification of triglycerides. The saponification value is below 0.1%. Glycidyl esters are considered far below these values as they are not likely to be present in high concentration in the oil and will undergo the same reaction as the triglyceride. Therefore, glycidyl esters would be broken down during the processing eventually towards glycerol (Documentation provided to EFSA n. 4).

The Panel noted that no analytical data were provided to support the above argument from the IBO.

3.2.5. Data on 3-MCPD and glycidol

One IBO indicated that in all analyses performed, the levels determined for 3-MCPD are below the maximum level stated in Regulation (EU) No 231/2012. According to the IBO, 3-MCPD would be hydrolysed and partially destroyed under pressure and high temperatures during the processes of hydrolysis saponification and transesterification (Documentation provided to EFSA n. 1 and 4). No further information was submitted after a further request for analytical data (Documentation provided to EFSA n. 4).

Results of the analysis of 'free 3-MCPD' in samples of glycerol (E 422) were submitted by another IBO (Documentation provided to EFSA n. 2 [MVO]). Thirty-eight samples (from monitoring data 2015–2019) were analysed by three different methods with LOQs of 50 or 100 µg/kg. One sample was reported to contain 79 µg/kg while the remainder were below the reported LOQs.

One of the described methods includes besides 3-MCPD (free) also 2-MCPD (free) and 3-MBPD (free), the last one being used as an indirect measure of the glycidol content of the sample following reaction with KBr. The IBO stated that no detectable 2-MCPD or 3-MBPD levels were found at an LOD of ~ 15 µg/kg. The IBO indicated that there is no data available on 3-MCPD esters in glycerol (E 422) (Documentation provided to EFSA n. 2 and 6).

3.2.6. Data on the potential formation on compounds of toxicological concern in food

No information on the potential formation of compounds of toxicological concern under certain processing conditions of food containing glycerol (E 422), as recommended during the re-evaluation of E 422 (EFSA ANS Panel, 2017), were submitted.

3.3. Proposed revision to existing EU specifications for glycerol (E 422)

The potential exposure to impurities from the use of glycerol (E 422) can be calculated by assuming that the impurity is present in the food additive up to a limit value, and then by calculation pro-rata to the estimates of exposure to the food additive itself.

With regard to the dietary exposure to the food additive, the Panel considered the exposure calculations for E 422 as presented in the re-evaluation of the food additive taking into account the reported use levels and analytical data considering food categories for which direct addition of glycerol (E 422) is authorised according to Annex II to Regulation No 1333/2008 and excluding alcoholic beverages (FCS 14.2) (Table 2) (EFSA ANS Panel, 2017). Since the ANS Panel noted that the food categories contributing most to the mean exposure to glycerol (E 422) were bread and rolls and fine bakery wares for which brand-loyalty was not assumed relevant, it is considered the non-brand-loyal scenario the most relevant.

For the current assessment, the highest exposure levels for the mean and 95th percentile among the different population groups were considered, i.e. 308 and 460 mg/kg bw per day, for toddler and children, respectively (Table 2).

Table 2: Summary of exposure to glycerol (E 422) from its use as a food additive considering food categories for which direct addition of glycerol is authorised (from Annex II to Regulation N°1333/2008) excluding alcoholic beverages (under FCS 14.2) in the refined non-brand-loyal exposure scenario, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day) (EFSA ANS Panel, 2017)

	Infants (12 weeks– 11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
• Mean	6–100	89– 308	112–240	74–162	50–100	53–77
• 95th percentile	153–266	261–418	222– 460	149–298	110–197	98–147

The level of the impurity in the food additive combined with the estimated intakes of E 422, presented in Table 2, could result in an exposure which can be compared with the following reference points (RP) or health-based guidance values (HBGV) (Table 2) for the undesirable impurities and constituents potentially present in E 422.

Table 3: Reference points/health-based guidance values for impurities potentially present in E 422

Impurity/constituent/ HBGV/RP (ug/kg bw)	Basis/Reference
Lead (Pb)/0.5 (BMDL ₀₁)	The reference point is based on a study demonstrating perturbation of intellectual development in children with the critical response size of 1 point reduction in IQ. The EFSA CONTAM Panel mentioned that a 1 point reduction in IQ is related to a 4.5% increase in the risk of failure to graduate from high school and that a 1 point reduction in IQ in children can be associated with a decrease of later productivity of about 2%. A risk cannot be excluded if the exposure exceeds the BMDL ₀₁ (MOE lower than 1) EFSA CONTAM Panel (2010)
Mercury (Hg)/4 (TWI)	The HBGV was set using kidney weight changes in male rats as the pivotal effect. Based on the BMDL ₁₀ of 0.06 mg/kg bw per day, expressed as mercury, and an uncertainty factor of 100 to account for inter and intra species differences, with conversion to a weekly basis and rounding to one significant figure, a TWI for inorganic mercury of 4 µg/kg bw per week, expressed as mercury was established EFSA CONTAM Panel (2012)
Cadmium (Cd)/2.5 (TWI)	The derivation of the reference point is based on a meta-analysis to evaluate the dose-response relationship between selected urinary cadmium and urinary beta-2-microglobulin as the biomarker of tubular damage recognised as the most useful biomarker in relation to tubular effects. A group-based BMDL ₅ of 4 µg Cd/g creatinine for humans was derived. A chemical specific adjustment factor of 3.9 was applied to account for human variability in urinary cadmium within each dose-subgroup in the analysis resulting in a reference point of 1.0 µg Cd per g creatinine.

Impurity/constituent/ HBGV/RP (ug/kg bw)	Basis/Reference
Arsenic (As)/ 0.3–8 (BMDL ₀₁)	<p>In order to remain below 1 µg Cd/g creatinine in urine in 95% of the population by age 50, the average daily dietary cadmium intake should not exceed 0.36 µg Cd/kg bw, corresponding to a weekly dietary intake of 2.5 µg Cd/kg bw EFSA CONTAM Panel (2009a)</p> <p>The reference point is based on a range of benchmark dose lower confidence limit (BMDL₀₁) values between 0.3 and 8 µg/kg bw per day identified for cancers of the lung, skin and bladder, as well as skin lesions. In general, the MOE should be at least 10,000 if the reference point is based on carcinogenicity in animal studies. However, as the BMDL for As is derived from human studies, an interspecies extrapolation factor (i.e. 10) is not needed EFSA CONTAM Panel (2009b); EFSA Scientific Committee (2012)</p>
3-MCPD and 3-MCPD fatty acid esters/2 (TDI)	<p>The HBGV is based on increased incidence of kidney tubular hyperplasia. BMD analysis using model averaging resulted in a BMDL₁₀ of 0.20 mg/kg bw per day in male rats, which was selected as the reference point for renal effects. This reference point was considered to derive a group TDI of 2 µg/kg bw per day for 3-MCPD and 3-MCPD fatty acid esters and was considered protective also for effects on male fertility. EFSA CONTAM Panel (2018)</p>
Acrolein/7.5 (provisional TC)	<p>A provisional tolerable concentration (TC) was developed on the basis of the NOEL for non-neoplastic lesions in the gastrointestinal tract of rats WHO (2002)</p>

HBGV: Health-based guidance value; RP: Reference point; BMDL₀₁: benchmark dose (lower confidence limit); bw: body weight; TWI: Tolerable Weekly Intake; TDI: Tolerable Daily Intake; MOE: margin of exposure; 3-MCPD: 3-monochloropropanediol; TC: tolerable concentration.

The risk assessment of the undesirable impurities and constituents helps inform whether there could be a possible health concern if these impurities and constituents would be present at the limit values in the food additive. The assessment is performed by calculating the MOE (margin of exposure) by dividing the reference point (e.g. BMDL Table 3) by the exposure estimate (Table 2), or by estimating the contribution of the use of E 422 to the HBGV (expressed as percentage of the HBGV).

3.3.1. Toxic elements

The Panel noted that the occurrence data on toxic elements submitted by one IBO are substantially lower than the current limits in the EU specifications (Documentation provided to EFSA n. 1 and 4).

The results of analyses for arsenic, cadmium, lead and mercury in 18 samples of E 422 were reported (Section 3.2.2). All data were below the LOD that varied substantially depending on the laboratory that performed the analyses. An overview of the LODs from the different laboratories is presented in Table 4. No lowest technologically achievable levels for toxic elements have been proposed by the IBOs. The Panel performed the risk assessment that would result if these toxic elements were present in the food additive E 422; (i) at the maximum current limit in the EU specifications and also; (ii) since no LOQs were reported, it was considered the highest reported LOD after rounding up (Table 4). Since the range of the LOD for each toxic element is very broad and all analytical samples have been reported below the LODs, the Panel considered an additional approach to calculate the potential exposure to these impurities from the use of E 422 by choosing; (iii) the lowest reported LOD and applying a factor of 10.⁸ The outcome of the risk assessment for the different scenarios is presented in Table 5.

⁸ To provide some 'headroom' (to account for representativeness, homogeneity and analytical measurement uncertainty).

Table 4: Different scenarios for the potential exposure to toxic elements from the use of E 422

	Pb	Hg	Cd	As
Range of reported LODs (mg/kg)	0.02–0.14	0.005–0.19	0.02–0.1	0.02–0.43
Current limits in the EU specifications for E 422 (mg/kg)	2	1	1	3
Considering the highest reported LOD after rounding up (ii) (mg/kg)	0.2	0.2	0.1	0.5
Considering the lowest reported LOD and applying a factor of 10 (iii) (mg/kg)	0.2	0.05	0.2	0.2

Table 5: Risk assessment for toxic elements

(i) Considering the presence of toxic elements at the current limits of the EU specifications for E 422 (Commission Regulation (EU) No 231/2012)				
Exposure to E 422 (mg/kg bw per day)	MOE for Pb at 2 mg/kg	% of the TWI for Hg at 1 mg/kg	% of the TWI for Cd at 1 mg/kg	MOE for As at 3 mg/kg
308 ^(a)	0.81	54	86	0.32–8.7
460 ^(b)	0.54	80	128	0.22–5.8
(ii) Considering the presence of toxic elements at the highest reported LOD after rounding up				
Exposure to E 422 (mg/kg bw per day)	MOE for Pb at 0.2 mg/kg	% of the TWI for Hg at 0.2 mg/kg	% of the TWI for Cd at 0.1 mg/kg	MOE for As at 0.5 mg/kg
308 ^(a)	8.12	10.8	8.6	1.9–52
460 ^(b)	5.43	16.1	12.9	1.3–35
(iii) Considering the presence of toxic elements at the lowest reported LOD and applying a factor of 10				
Exposure to E 422 (mg/kg bw/day)	MOE for Pb at 0.2 mg/kg	% of the TWI for Hg at 0.05 mg/kg	% of the TWI for Cd at 0.2 mg/kg	MOE for As at 0.2 mg/kg
308 ^(a)	8.12	2.70	17.2	4.87–130
460 ^(b)	5.43	4.03	25.8	3.26–87.0

(a): Highest exposure level among the different population groups (refined non-brand-loyal scenario – toddlers – mean (Table 2)).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario – children – 95th percentile (Table 2)).

The potential exposure to these impurities from the use of E 422 was compared with the available health-based guidance values (HBGV) and reference points (RP) (Table 3). At (i) the current EU specification values, the potential exposure to all four toxic elements would be of concern. For lead and arsenic, the MOE values would be too low, and for mercury and cadmium, the exposure would represent more than 50% of the TWI (Table 5). This should also be seen in light of exposure from sources other than glycerol (E 422).

If specifications were based on (ii) the highest LOD after rounding up values reported or; (iii) on the lowest LOD values reported modulated by a factor of 10, in both scenarios, the MOE for As would be too low but the other three elements would not give rise to concern (Table 5).

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

3.3.2. Acrolein

No lowest technologically achievable level for acrolein has been proposed by the IBOs. Taking into account the reported analytical data (ranging from a minimum of < 0.5 mg/kg (LOQ) to a maximum of 3.1 mg/kg), the Panel performed the risk assessment for acrolein assuming that this impurity is present in the food additive E 422 at the maximum content reported (rounded to 3 mg/kg) and by choosing the reported LOQ and applying a factor of 10⁸ times this value (i.e. 5 mg/kg) (Table 6).

Table 6: Risk assessment for acrolein considering the presence of acrolein in E 422 at a level of 3 mg/kg (maximum amount level reported) or 5 mg/kg (10 times the reported LOQ)

Exposure to E 422 (mg/kg bw per day)	% of the TC for acrolein (at 3 mg/kg in E 422)	% of the TC for acrolein (at 5 mg/kg in E 422)
308 ^(a)	12.3	20.5
460 ^(b)	18.4	30.7

(a): Highest exposure level among the different population groups (refined non-brand-loyal scenario – toddlers – mean (Table 2).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario – children – 95th percentile (Table 2).

The Panel noted that the comparison of the estimated potential exposure to acrolein from the use of E 422 with the provisional tolerable concentration (TC) for acrolein (7.5 µg/kg bw, Table 3) (Table 6) shows that acrolein at the level of 3 or 5 mg/kg could give rise to an exposure up to 18% and 30% of the provisional TC for acrolein, respectively. Therefore, the Panel recommends setting a numerical limit value for this impurity in the Commission Regulation (EU) No 231/2012 for E 422.

3.3.3. 3-MCPD

The outcome of the risk assessment for free 3-MCPD is illustrated in Table 7 considering the presence of 3-MCPD in E 422 at the maximum limit of 0.1 mg/kg, as laid out in the Regulation EU no 231/2012.

Table 7: Risk assessment for 3-MCPD based on the current specification limit (0.1 mg/kg) for E 422 (Regulation EU no 231/2012)

Exposure to E 422 (mg/kg bw per day)	% of the TDI for 3-MCPD and fatty acid esters (expressed as 3-MCPD) at 0.1 mg/kg
308 ^(a)	1.5
460 ^(b)	2.3

(a): Highest exposure level among the different population groups (refined non-brand-loyal scenario – toddlers – mean (Table 2).

(b): Highest exposure level among the different population groups (refined non-brand-loyal scenario – children – 95th percentile (Table 2).

The Panel noted that, by reference to the tolerable daily intake (TDI) for the sum of 3-MCPD and 3-MCPD fatty acid esters (2 µg/kg bw per day, Table 3), the current limit for 3-MCPD in E 422 would give rise to a potential exposure that is only a low percentage of the TDI (Table 7) and does not give rise to a health concern. However, the Panel noted that only exposure to free 3-MCPD has been considered but not for 3-MCPD fatty acid esters (see Section 3.4 for further explanation).

3.3.4. Manufacturing process

During the re-evaluation of glycerol (E 422) (EFSA ANS Panel, 2017), information on the manufacturing process of glycerol by chemical synthesis or microbiological fermentation was identified in the literature (Wang et al., 2001; Christoph et al., 2006; Schier et al., 2009). Starting or intermediate products of these routes of manufacturing can result in impurities (e.g. glycidol, epichlorohydrin, dichlorohydrin) of toxicological concern in glycerol for which no data have been submitted since only the manufacturing process of glycerol from vegetable oils or crude glycerol (from biodiesel production) has been stated.

Therefore, the Panel proposed to modify the definition of E 422 (Commission Regulation (EU) No 231/2012) indicating that glycerol (E 422) is obtained only from vegetable oils and fats, either directly or from the crude glycerol obtained as a by-product of biodiesel production and undergoes purification processes that involve distillation, and other clean up steps to obtain refined glycerol to avoid that glycerol manufacturing from other routes leading to the presence of impurities not evaluated in this assessment, can be used as E 422.

3.3.5. Summary of the proposed revisions to the EU specifications

Overall, based on the information provided by the IBOs (Documentation provided to EFSA n. 1, 2, 3, 4, 5 and 6) and the above considerations, the Panel recommends the following revisions of the existing EU specifications for glycerol (E 422) as listed in Table 8. The Panel noted that the choice of maximum limits for impurities in the EU specifications is in the remit of risk management.

Table 8: Proposal for a revised version of the existing EU Specifications for glycerol (E 422)

	Commission Regulation (EU) No 231/2012	Comment/justification for revision
Definition	See Table 1	Definition to be amended to indicate that the food additive is obtained only from vegetable oils and fats and undergoes purification processes that involve distillation, and other clean up steps to obtain refined glycerol
Assay	See Table 1	Unchanged
Description	See Table 1	Unchanged
Identification	See Table 1	Unchanged
Infrared absorption spectrum Acrolein formation on heating	See Table 1	To be deleted*
Specific gravity (25/25 °C)	See Table 1	Unchanged
Refractive index [n] _{D20}	See Table 1	Unchanged
Purity	See Table 1	Unchanged
Water	See Table 1	Unchanged
Sulfated ash	See Table 1	Unchanged
Butanetriols	See Table 1	Unchanged
Acrolein	See Table 1	Maximum numerical limit to be included on the basis of the information provided and on the considerations of the Panel
Glucose and ammonium compounds		To be deleted**
Fatty acids and esters	See Table 1	Unchanged
Chlorinated compounds	See Table 1	Unchanged
3-monochloropropane-1,2-diol (3-MCPD)	Not more than 0.1 mg/kg	Unchanged
Arsenic	Not more than 3 mg/kg	Maximum limit to be lowered on the basis of the information provided and on the considerations of the Panel
Lead	Not more than 2 mg/kg	Maximum limit to be lowered on the basis of the information provided and on the considerations of the Panel
Mercury	Not more than 1 mg/kg	Maximum limit to be lowered on the basis of the information provided and on the considerations of the Panel
Cadmium	Not more than 1 mg/kg	Maximum limit to be lowered on the basis of the information provided and on the considerations of the Panel

*: The Panel considered that a test for acrolein formation on heating as an identification of glycerol (Table 1) is obsolete considering that the content of glycerol in E 422 needs to be more than 98% and this identification and quantification have to be performed with an appropriate analytical method.

** : Because the test in the current EU specifications for the presence of acrolein, glucose and ammonium compounds is proposed to be replaced by another analytical method that allows to quantify acrolein (see Section 3.2.3).

3.4. Discussion

The current assessment addresses the EFSA recommendations indicated during the re-evaluation of glycerol (E 422) as a food additive (EFSA ANS Panel, 2017) to update its EU specifications (E 422) in Commission Regulation (EU) No 231/2012.

In response to the European Commission call for data, analytical data on impurities in commercial samples of E 422 were provided by two IBOs. The potential exposure to these impurities from the use of the food additive E 422 was calculated by assuming that they may be present in the food additive up to a certain limit value and then by calculation pro-rata to the estimates of exposure to the food additive (Table 2) itself.

Analytical data on levels of toxic elements (arsenic, lead, cadmium, mercury) in commercial samples of E 422 were provided by one IBO, and all data were below the LOD that varied substantially depending on the laboratory that performed the analyses. The Panel noted that the occurrence data on toxic elements submitted by the IBO are substantially lower than the current limits in the EU specifications. LOQs were not reported and no lowest technologically achievable levels were indicated.

The potential exposure to these impurities from the use of E 422 were compared against the available health-based guidance values (HBGV) and reference points (RP) (Table 3). The Panel considered the presence of these impurities in E 422 at (i) the current EU specification values, the potential exposure to all four toxic elements would be of concern. For lead and arsenic, the MOE values would be too low, and for mercury and cadmium, the exposure would represent more than 50% of the TWI (Table 5). This should also be seen in light of exposure from sources other than glycerol (E 422). If specifications were based on; (ii) since no LOQs were reported, it was considered the highest LOD after rounding up values reported or; (iii) on the lowest LOD values reported modulated by a factor of 10, in both scenarios, the MOE for As would be too low but the other three elements would not give rise to concern (Table 5). The Panel noted that the maximum limits in the EU specifications for toxic elements should be established based on actual levels in the commercial food additive. Therefore, the Panel recommended that the maximum limits to be lowered on the basis of the information provided and on the considerations of the Panel (see Table 8).

Analytical data on levels of acrolein in commercial samples of E 422 by a HPLC method with an LOQ of 0.5 mg/kg were provided by one IBO (Section 3.2.3). The Panel performed the risk assessment for acrolein assuming that this impurity is present in the food additive E 422 at the maximum content reported (rounded to 3 mg/kg) and by choosing the reported LOQ and applying a factor of 10 times this value (i.e. 5 mg/kg). The Panel noted that the comparison of the estimated potential exposure to acrolein from the use of E 422 with the provisional TC for acrolein (0.0075 mg/kg bw, Table 3) shows that acrolein at the level of 3 or 5 mg/kg could give rise to an exposure up to 18% and 30% of the provisional TC for acrolein, respectively. Considering the potential occurrence of acrolein in E 422, the Panel recommended setting a numerical limit value for this impurity in the Commission Regulation (EU) No 231/2012 for E 422 (see Table 8).

Analytical data on levels of 3-MCPD in commercial samples of E 422 analysed by three different methods with LOQs of 50 or 100 µg/kg were provided (Section 3.2.6). One of the analytical methods used for the analysis of 3-MCPD includes also 2-MCPD (free) and 3-MBPD (free), the last one being used as an indirect measure of the glycidol content of the sample following reaction with KBr. The IBO stated that no detectable 2-MCPD or 3-MBPD levels were found at an LOD of ~ 15 µg/kg.

No analytical data on the presence of esters of 3-MCPD or esters of glycidol were submitted following an EFSA request for this information. The Panel noted that the manufacturing processes of glycerol E 422 include vacuum distillation of the product, amongst other purification steps. The EU specifications of glycerol E 422 include that it should be no less than 98% of glycerol on an anhydrous basis (Table 1). Distillation is an effective form of purification. The large difference in molecular weight (and therefore in volatility) between glycerol itself and the fatty acid esters of glycidol and of 3-MCPD means that these contaminants are not to be expected in glycerol purified by a process involving distillation. Similarly, glycerol obtained by distillation is also expected to be free of high molecular weight contaminants that may be present in the feedstock if the intermediate crude glycerol is obtained from biodiesel production with used cooking oils and the like as feedstock.

Based on the above considerations, the potential exposure to free 3-MCPD considering its presence in E 422 at the maximum limit of 0.1 mg/kg, as laid out in the Commission Regulation EU No. 231/2012, was calculated and it represents only a low percentage of the TDI for the sum of 3-MCPD and 3-MCPD fatty acid esters (2 µg/kg bw per day, Table 3) and does not give rise to a health concern.

According to the information available at the time of the re-evaluation of E 422 (EFSA ANS Panel, 2017), it was considered that glycerol could be produced by a variety of alternative manufacturing processes leading to the possible presence of impurities, some of which would be of toxicological concern. The IBOs have stated now that glycerol for use as E 422 is manufactured only from vegetable oils and fats, either directly or from the crude glycerol obtained as a by-product of biodiesel production. Therefore, analytical data on those impurities potentially arising from the alternative manufacturing process involving chemical synthesis or microbiological fermentation have not been submitted. The Panel recommended to consider modifying the definition of E 422 (Commission Regulation (EU) No 231/2012) indicating that glycerol (E 422) is obtained only from vegetable oils and fats and undergoes purification processes that involve distillation, and other clean up steps to obtain refined glycerol to avoid that glycerol manufacturing from other routes, leading to the potential presence of impurities that have not been assessed in this Opinion, can be used as E 422.

4. Conclusions

The Panel concluded that the technical data provided by the interested business operators support an amendment of the specifications for glycerol (E 422) laid down in Commission Regulation (EU) No 231/2012, as presented by the recommendations made in Table 8.

5. Documentation as provided to EFSA

- 1) The European Oleochemicals and Allied Products Group (APAG), 2019. Submission of data in response to the European Commission call for technical data on the permitted food additive glycerol (E 422). Submitted by APAG, 18 June 2019.
- 2) The Netherlands Oils and Fats Industry (MVO), 2019. Submission of data in response to the European Commission call for technical data on the permitted food additive glycerol (E 422). Submitted by MVO, 21 June 2019.
- 3) Additional information submitted in response to a request from EFSA. Submitted by The Netherlands Oils and Fats Industry (MVO) 30 June 2020.
- 4) Additional information submitted in response to a request from EFSA. Submitted by The European Oleochemicals and Allied Products Group (APAG) 3 July 2020.
- 5) Additional information submitted in response to a request from EFSA. Submitted by The European Oleochemicals and Allied Products Group (APAG) 30 June 2021.
- 6) Additional information submitted in response to a request from EFSA. Submitted by The Netherlands Oils and Fats Industry (MVO), February 2022.

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Abbreviations

3-MCPD	3-monochloropropane diol
ADI	acceptable daily intake
ANS Panel EFSA	Panel on Food Additives and Nutrient Sources added to Food
APAG	à European Oleochemicals and Allied Products Group
BMDL	benchmark dose (lower confidence limit)
BW	body weight
CAS	Chemical Abstract Service
FAF Panel	Panel on Food Additives and Flavourings
FAO/WHO	Food and Drug Organization/World Health Organization
FC	food category
GC-FID	gas chromatography - flame Ionization ionisation detector
GEs	glycidyl esters
GS-MS	gas chromatography/mass spectrometry
HBGV	health- based guidance value
HPLC	high-performance liquid chromatography
IBO	interested business operator
ICP-MS	inductively coupled plasma-mass spectrometry
ICP-OES	inductively coupled plasma optical emission spectrometry
ISO	international organization for standardization.
IQ	intelligence quotient
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
LOQ	limit of quantification
MOE	margin of exposure
MVO	Netherlands Oils and Fat Industry
NaOH	sodium hydroxide
RP	reference point
SC	Scientific Committee of EFSA
SCF	Scientific Committee on Food
TDI	Tolerable Daily Intake
TWI	Tolerable Weekly Intake
UV	ultraviolet