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SCIENTIFIC OPINION

Safety of acute exposure to the food additive glycerol (E 422) from beverages

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

Abstract

The European Commission requested EFSA to assess the acute exposure to glycerol (E 422) from slush ice drinks and de-alcoholised wine. The acute exposure assessment was conducted on a single-consumption-event basis considering the reported use levels and analytical data of glycerol in slush ice drinks and the proposed maximum level of 50,000 mg glycerol/L in de-alcoholised wine. The Panel considered that a conservative dose above which unintended pharmacological effects would occur should be used for the determination of the acute reference dose (ARfD). Based on Wald and McLaurin (1982) study, the Panel derived an ARfD of 125 mg glycerol/kg body weight for a single consumption event. The Panel concluded that the acute exposure to glycerol per single consumption event from slush ice drinks, assuming a consumption of 250 mL and 500 mL for children and other population groups, respectively, would exceed the ARfD for all population groups. The Panel also concluded that the P95 acute exposure estimates for glycerol, at the proposed maximum level, from the potential use of de-alcoholised wine, assumed to be consumed by children and adolescents as a substitute for flavoured drinks and by other population groups as a substitute for wine and wine-like drinks, would exceed the ARfD for all population groups. As requested by the European Commission, the Panel calculated the maximum single consumption event volume of beverages containing E 422 that can be consumed by different populations groups without exceeding the ARfD. The Panel also calculated the theoretical maximum levels of E 422 when used as a food additive in beverages, including slush ice drinks and de-alcoholised wine, at which exposure does not exceed the ARfD in different population groups. The Panel recommends the European Commission to consider establishing numerical maximum levels for glycerol (E 422) when used in beverages.

KEYWORDS

acute exposure, beverages, de-alcoholised wine, E 422, glycerol, slush ice drinks

CONTENTS

1 | INTRODUCTION

The present scientific opinion deals with (i) the acute exposure to glycerol (E 422) from slush ice drinks and de-alcoholised wine; (ii) the estimation of the maximum volume of slush ice drinks and de-alcoholised wine containing glycerol (E 422) at selected concentrations that can be consumed without exceeding the acute reference dose (ARfD); and (iii) the calculation of the theoretical maximum levels of glycerol (E 422), when used as a food additive in beverages, at which the exposure does not exceed the ARfD.

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

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.[1] Only food additives that are included in the Union list, in particular in Annex II to that Regulation, may be placed on the market and used in foods under the conditions of use specified therein. Moreover, food additives shall comply with the specifications as referred to in Article 14 of that Regulation and laid down in Commission Regulation (EU) No 231/2012.[2]

Glycerol (E 422) is authorised as a food additive in the European Union (EU) in accordance with Annexes II and III of Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in Commission Regulation (EU) No 231/2012. In Part B of Annex II to Regulation (EC) No 1333/2008, glycerol (E 422) is included in the list of authorised food additives among additives 'other than colours and sweeteners'. As glycerol (E 422) is included in Group I additives, its use is authorised at *quantum satis* in many food categories in the EU.

Since this food additive was permitted in the Union before 20 January 2009, it belongs to the group of food additives which are subject to a re-evaluation by the European Food Safety Authority (EFSA), according to Commission Regulation (EU) No 257/2010,[3] and in line with the provisions of Regulation (EC) No 1333/2008.

In 2017, EFSA re-evaluated glycerol (E 422) as a food additive[4] and concluded that there is no need for a numerical ADI and no safety concern regarding the use of glycerol (E 422) as a food additive at the refined exposure assessment for the reported uses.

Nevertheless, EFSA also concluded that infants and toddlers could be exposed to more than 125 mg/kg bw per hour by drinking less than the volume of one can (330 mL) of a flavoured drink and that the acute bolus exposure to glycerol (E 422) by its use as a food additive should stay below doses at which pharmacological or side effects could occur.[5]

The calculation was conducted using either the highest reported value (12,700 mg/L) or the mean value (rounded up to 5000 mg/L) of glycerol concentration in flavoured drinks, along with the mean body weight of each population. This assessment considered the 95th percentile (Table 11 of the EFSA Opinion of 2017).

In addition, EFSA recommended updating the specifications as regards impurities/compounds of toxicological concern and collecting more information on uses and use levels and analytical data, in order to perform an adequate exposure assessment; in particular, EFSA noted that data on flavoured drinks are needed to estimate acute exposure.

Consequently, the European Commission published on 23 November 2018 a call for data requesting technical data to address the various issues identified by EFSA in the re-evaluation of glycerol (E 422) related to the specifications. Business operators submitted data in reply to this call. The call did not request data on uses and use levels and analytical data needed to address EFSA's recommendation on the exposure assessment. The call clarified that those data would be the subject of a specific call for data issued by EFSA.[6]

In June 2022, EFSA issued an opinion on the follow-up of the re-evaluation of glycerol (E 422)[7] and in June 2023, the Commission adopted Regulation (EU) No 2023/1329 addressing the EFSA recommendations related to the specifications of glycerol (E 422).

In July 2024,[8] the Food Safety Authority of Ireland (FSAI) provided some advice for parents and caregivers to limit young children's consumption of slush ice drinks that contain glycerol (E 422), due to potential side effects including headaches, nausea and vomiting when consumed in large quantities. FSAI further developed voluntary guidelines for the industry which require the industry to use the minimum quantity of glycerol necessary when making slush ice drinks; to ensure that their customers are aware of the FSAI's advice for younger children in relation to slush ice drinks; to display point-of-sale

[1] OJ L 354, 31.12.2008, p. 16.

[2] OJ L 83, 22.3.2012, p. 1.

[3] OJ L 80, 26.3.2010, p. 19.

[4] https://www.efsa.europa.eu/en/efsajournal/pub/4720.

[5] The Panel considered that a conservative estimate of the lowest oral bolus dose of glycerol required for therapeutic effect was 125 mg/kg bw per hour. The Panel considered this dose would also be responsible for the side effects (nausea, headache and/or vomiting) observed in some patients. The Panel considered that the most relevant situation where an acute bolus exposure to glycerol used as a food additive can be similar to the one occurring during therapeutic use is consumption of a beverage.

[6] Analytical data and use levels related to glycerol (E 422) requested as part of the EFSA 'Open call for food additives analytical and use level data in food and beverages intended for human consumption', published on 14 March 2025 (https://www.efsa.europa.eu/en/call/open-call-food-additives-analytical-and-use-level-data-food-and-beverages-intended-human).

[7] https://www.efsa.europa.eu/en/efsajournal/pub/7353.

[8] https://www.fsai.ie/news-and-alerts/latest-news/fsai-provides-advice-on-slush-ice-drinks-for-young.

warnings stating "this product contains glycerol and is not recommended for children aged 4 and under"; and to avoid offering free refills of slush ice drinks to younger children.

On 18 February 2025, the German Federal Institute for Risk Assessment (BfR) published Opinion 004/2025 titled 'Glycerol in slush ice drinks can cause undesirable health effects'.[9] The assessment of the measured glycerol concentrations in a total of 62 slush ice samples[10] showed that younger children can already ingest amounts of glycerol that correspond to or exceed the therapeutically effective dose[11] when consuming quantities of less than 200 millilitres (mL). The assessment further showed that at a glycerol concentration of 50,000 mg/L, adults reach the therapeutically effective dose when consuming 350 mL of slush ice drink. The opinion thus presented significantly higher concentrations of glycerol in slush ice drinks than the reported analytical data for glycerol in flavoured drinks accounted for in the EFSA 2017 opinion.

On 12 March 2025, the research on 'Glycerol intoxication syndrome in young children, following the consumption of slush ice drinks,' was published in the British Medical Journal's Archives of Disease in Childhood.[12]

On 14 March 2025, EFSA published an open call for food additives analytical and use level data in food and beverages intended for human consumption[13] that also included glycerol (E 422).

On 8 June 2025, the Food Standards Agency of the United Kingdom published a report[14] setting out the risk of glycerol in slush ice drinks and the key findings from the recent rapid risk assessment. The report recommended that children under 7 years of age should not consume glycerol containing slush ice drinks. The report advised against consumption of multiple slush ice drinks containing glycerol in a short period of time and stressed the importance of ensuring parents/caregivers as well as businesses understand this recommendation.

In the context of preparations for the 23rd General Assembly of the International Organisation of Vine and Wine (OIV), which took place on 20 June 2025, Member States agreed not to support the draft OIV resolution on specific oenological practices for de-alcoholised wine (OENO-TEHNO 14-54A). This draft OIV resolution would allow the addition of glycerol (E 422) in de-alcoholised wine at a maximum concentration level of 50,000 mg/L, until a proper scientific assessment is made, including an updated exposure assessment and risk characterisation by EFSA.

Considering the EFSA's conclusion in the 2017 opinion on the re-evaluation of glycerol (E 422) indicating that the acute bolus exposure to glycerol (E 422) by its use as a food additive should stay below doses at which pharmacological or side effects could occur and considering that much higher concentration levels of glycerol have been currently reported than those accounted for in 2017 and the related concerns raised as regards the acute exposure to glycerol (E 422) through beverages, the European Commission has decided to consult EFSA on this matter.

1.1.2 | Terms of Reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002[15] and taking into account new information concerning the use of glycerol (E 422) in slush ice drinks and de-alcoholised wine, the European Commission requests the European Food Safety Authority (EFSA) to provide a scientific opinion on the food additive glycerol (E 422).

In particular, the European Commission requests EFSA to:

- Carry-out an acute exposure assessment to glycerol (E 422) from beverages, in particular from slush ice drinks and de-alcoholised wine, taking into account the data submitted in response to the EFSA call for data on the uses, use levels and analytical data of the food additive glycerol (E 422), data collected by Member States and the proposed maximum level for the use of glycerol (E 422) in de-alcoholised wine.
- Estimate the maximum daily volume of beverages containing glycerol (E 422) that can be consumed by different population groups, taking into account the reported levels of glycerol (E 422) in beverages and the proposed maximum level in de-alcoholised wine, without causing undesirable health effects.
- Indicate hypothetical maximum levels of glycerol (E 422), when used as a food additive in slush ice drinks and de-alcoholised wine, at which the exposure stays below doses at which pharmacological or side effects could occur.

[9] https://www.bfr.bund.de/cm/349/glycerol-in-slush-ice-drinks-can-cause-undesirable-health-effects.pdf.

[10] The mean value of glycerol for all measurement results is 26.24 g/L. About 16% of the measurement results are at a value of 50 g/L and higher, about 10% at a value of 73.9 g/L and higher and about 5% at a value of 92.3 g/L and higher. The highest measured value was 142 g/L. Glycerol could not be detected in 20 samples.

[11] The dose of 250 mg/kg body weight (bw) was used as the reference point for risk characterisation. It represents the lowest dose (calculated on the basis of mean body weights and then rounded) that was therapeutically effective (in reducing increased intracranial pressure) in the human study by Wald and McLaurin (Wald & McLaurin, 1982).

[12] Brothwell, S. L., et al. (2025). Glycerol intoxication syndrome in young children, following the consumption of slush ice drinks. Archives of Disease in Childhood. doi.org/10.1136/archdischild-2024-328109.

[13] https://www.efsa.europa.eu/en/call/open-call-food-additives-analytical-and-use-level-data-food-and-beverages-intended-human.

[14] https://www.food.gov.uk/board-papers/glycerol-in-slush-ice-drinks.

[15] OJ L 31, 1.2.2002, p. 1.

1.2 | Interpretation of the Terms of Reference

In the light of the background information provided by the European Commission regarding the positions of FSAI and BfR on the consumption of slush ice drinks containing glycerol (E 422), the Panel restricted its assessment to slush ice drinks which belong to FC 14.1.4 on 'Flavoured drinks' for the current acute exposure assessment to glycerol (E 422). In addition, as requested, an acute exposure to glycerol (E 422) from the proposed addition to de-alcoholised wine is performed. Currently, glycerol (E 422) is not allowed to be added to de-alcoholised wine.

With regard to the European Commission's request to '*estimate the maximum daily volume of beverages containing glycerol (E 422) that could be consumed by different population groups*' without causing undesirable health effects, the Panel considers that the effects of concern are associated with an exposure based on a consumption-event rather than total exposure over the course of a day. Accordingly, the assessment was conducted on a per-consumption-event basis rather than on a daily exposure basis.

The Panel noted that 'acute exposure' may be interpreted differently across regulatory frameworks. In the current opinion, 'acute exposure' is defined as acute bolus exposure based on a single consumption event.

Regarding the request from the European Commission to '*indicate hypothetical maximum levels of glycerol (E 422), when used as a food additive in slush ice drinks and de-alcoholised wine, at which the exposure stays below doses at which pharmacological or side effects could occur*', the Panel considered that a theoretical calculation better reflects the European Commission's request and can be applied to all beverages, including slush ice drinks and de-alcoholised wine, by assuming a specific volume consumed per single consumption event.

2 | DATA AND METHODOLOGIES

2.1 | Data

Food consumption data from the EFSA Comprehensive European Food Consumption Database (Comprehensive database)[16] and concentration data in different food categories submitted in response to the public call for data[17] were used to estimate the acute exposure to glycerol (E 422).

Information from Mintel's Global New Products Database (GNPD)[18] was examined to identify uses of glycerol (E 422) in beverages, in particular slush ice drinks.

2.2 | Methodologies

The approach and the methodology used to calculate the acute dietary exposure to glycerol (E 422) are described in the 2017 ANS Panel statement on the 'Approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation' (EFSA ANS Panel, 2017) and in the EFSA Guidance 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011). In accordance with the Terms of Reference (see Section 1.1.2) and the interpretation of these terms (see Section 1.2), the present assessment was restricted to slush ice drinks and de-alcoholised wine. For this purpose, specific considerations regarding the approach and methodology were followed, as described in Section 4.5.

Uncertainties in the exposure assessment were identified and discussed in Section 6.

3 | BACKGROUND INFORMATION

In 2017, the EFSA ANS Panel re-evaluated glycerol (E 422) as a food additive and concluded that there is no need for a numerical acceptable daily intake (ADI) and no safety concern regarding the use of glycerol (E 422) as a food additive at the refined exposure assessment for the reported uses (EFSA ANS Panel, 2017).

The ANS Panel also concluded that infants and toddlers could be exposed to more than 125 mg/kg body weight (bw) per hour by drinking less than the volume of one can (330 mL) of a flavoured drink and that the acute bolus exposure to glycerol (E 422) from its use as a food additive should stay below doses at which pharmacological or side effects could occur (EFSA ANS Panel, 2017).

In addition, the ANS Panel issued some recommendations regarding potential impurities of toxicological concern to be considered in the specifications, and the collection of occurrence data on flavoured drinks to enable the estimation of

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

[17] https://www.efsa.europa.eu/en/call/open-call-food-additives-analytical-and-use-level-data-food-and-beverages-intended-human.

[18] Available online: https://www.gnpd.com/sinatra/home/ (accessed in February 2026). The Mintel GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. Mintel started covering EU's food markets in 1996, currently having 24 of its 27 member countries, and Norway is also presented in the Mintel GNPD. Missing countries are Cyprus, Luxembourg and Malta. Mintel's GNPD is not a database managed by EFSA, data retrieved are presented in their original form and are not further scrutinised by the Panel.

acute exposure. On 14 March 2025, EFSA published an open call for analytical and use level data of food additives in food and beverages intended for human consumption that included glycerol (E 422).

As a follow-up of the re-evaluation of glycerol (E 422), the FAF Panel addressed the data gaps identified during the re-evaluation regarding the specifications recommending modifications on the limits of toxic elements and the inclusion of limits for additional impurities (EFSA FAF Panel, 2022). These recommendations have been implemented in the current specifications of E 422 laid down in Commission Regulation (EU) No 231/2012.

Recently, BfR carried out a health risk assessment of measured glycerol levels in slush ice drinks (BfR, 2025). BfR agreed with the ANS Panel that the use of glycerol as a food additive should not lead to an exposure corresponding to a therapeutically effective dose. In the BfR assessment, a dose of 250 mg/kg bw was used as the 'reference point' for risk characterisation based on the lowest dose (calculated on the basis of mean body weights and then rounded) that was therapeutically effective (in reducing increased intracranial pressure (ICP)) in a human study (Wald & McLaurin, 1982). BfR reported measured glycerol levels in 62 slush ice drink samples analysed between 4 November 2023 and 11 October 2024. According to BfR, 'there are health concerns if the consumption of a slush ice drink leads to an exposure that corresponds to or exceeds the therapeutically effective dose of 250 mg/kg bw'.

4 | ASSESSMENT

4.1 | Scientific context

At the time of the re-evaluation (EFSA ANS Panel, 2017), it was noted that glycerol occurs naturally in several types of lipids and is an endogenous metabolite in mammals. Glycerol is rapidly and nearly completely absorbed from the gastrointestinal tract (GIT), distributed into the total body water space and enters endogenous metabolic pathways leading to glucose, pyruvate and triglycerides. The final excretion would be by metabolism and exhalation as CO_2, with only minor intact amounts of glycerol excreted via urine or faeces.

The Panel noted that the volume of distribution of glycerol in humans has been determined to be 0.23–0.5 L/kg bw from additional references retrieved from the literature (Frank et al., 1981; Sommer et al., 1993). Sommer et al. (1993) reported a mean half-life of glycerol of 0.86 + 0.18 h.

Glycerol can be used to treat cerebral oedema. Clinical experience and data from clinical studies were reported in the 2017 EFSA ANS Panel opinion, indicating that intravenous (iv) doses up to 60,000 mg glycerol, infused over 1–4 h, for a treatment duration of 1 week or several weeks (Frank et al., 1981) were used for this purpose. In other studies, bolus oral doses (initial dose 1500 mg/kg bw, followed by 500–700 mg/kg bw every 3 h) (Cantore et al., 1964) or 500–1000 mg/kg bw (Wald & McLaurin, 1982) were used.

The ANS Panel noted that in studies for oral therapies to patients with ocular disease or healthy controls, glycerol was administered as a bolus at 1350 mg/kg bw (Buckell & Walsh, 1964; Charan & Sarda, 1967), 1500 mg/kg bw (Consul & Kulsretha, 1965; Drance, 1964), 1000 mg/kg bw (Kornblueth et al., 1967), 1000–1270 mg/kg bw (McCurdy et al., 1966), 1200 mg/kg bw (Krupin et al., 1970) and 1260 mg/kg bw (Friedman et al., 1980). In these studies, either no side effects were observed or some, including nausea, headache and/or vomiting.

The increased osmolality in plasma that occurs when glycerol is administered orally or intravenously beyond an intended pharmacological effect leads to decreases in intraocular and intracerebral pressures (Buckell & Walsh, 1964; McCurdy et al., 1966; Pitlick et al., 1982). This effect is clearly seen in patients with benign increased intracerebral pressure, where increases in plasma osmolality after oral ingestion of glycerol coincided with decreases in lumbar cerebral-spinal fluid (CSF) pressure (Buckell & Walsh, 1964).

Pitlick et al. (1982) showed a linear relationship between increases in plasma glycerol concentration and decreases in ICP in patients with cerebral oedema. McCurdy et al. (1966) showed that in patients with elevated ocular pressure, the decline in ocular pressure was related to increased serum glycerol concentrations and serum osmolality following treatment with glycerol. In the study of Buckell and Walsh (1964), severe headache occurred 2 h after ingestion of 1.57 g glycerol/kg bw in a healthy volunteer. Thus, undesired central nervous system effects are related to decrease cerebral pressure due to increased plasma osmolality.

4.2 | New information from case reports and human studies

4.2.1 | Case reports in children

Brothwell et al. (2025) published a retrospective case review for the period 2009–2024 of 21 children across the UK and Ireland who became unwell (93% of children) within 60 min after consuming slush ice drinks and presented for medical assessment. The median age at presentation was 3 years and 6 months (range 2 years–6 years and 9 months); none had a medical history that could explain the symptoms reported.

Presented features as reported included acute decrease in consciousness (94% of children), hypoglycaemia (95% of children), metabolic (lactic) acidosis (94% of children), pseudohypertriglyceridaemia (89% of children) and hypokalaemia (75% of children). Glyceroluria was present in all acute urine samples collected from 17 patients for organic acid samples.

No underlying inherited metabolic disease was identified in those children (14/21) who subsequently underwent enzymatic or genetic testing. One patient (aged 7 years and 3 months at the time of re-exposure) became symptomatic within an hour of consuming a slush ice drink again. No re-occurrence of the symptoms reported above was noted to have occurred in those (95% of children) avoiding further consumption of slush iced drinks.

The Panel noted that exposure to glycerol for these individuals was not estimated. Urine was obtained at presentation for organic acid analysis for 17 patients. All of these samples 'demonstrated a large glycerol peak'. However, actual glycerol concentrations in the urine samples were not reported in the study. Blood levels of glycerol at presentation were also not reported.

Brothwell et al. (2025) considered that glycerol was the most likely cause of the adverse effects reported in the children after consuming a slush ice drink. The Panel concurs with the authors.

4.2.2 | Pharmacological use of glycerol in healthy adults for body rehydration

Several human studies have investigated the use of glycerol in healthy young adult athletes as a hyperhydrating or rehydrating agent, primarily in the context of physical exercise. This use falls outside the remit of glycerol as a food additive but provides relevant information on doses associated with pharmacological effects and tolerability following acute oral exposure (for more details, see Appendix A).

In clinical trials conducted in endurance-trained or physically active adults, glycerol has been administered orally, often in combination with substantial volumes of fluid, to increase total body water and plasma volume before or after exercise (see details of the studies in Appendix A). Reported oral doses in these studies generally ranged from approximately 1.0–1.5 g/kg bw, typically administered as one or two boluses over a short time frame. These regimens consistently resulted in measurable increases in serum glycerol concentrations, plasma osmolality and plasma volume. In several studies, peak serum glycerol concentrations were observed within 1–2 h after ingestion, in line with the known rapid absorption of glycerol from the GIT. Despite the marked physiological changes observed, these studies did not report serious adverse effects in the investigated adults.

Reported side effects following oral glycerol administration in healthy young athletes were mainly mild and transient gastrointestinal symptoms, including nausea, bloating, diarrhoea, vomiting or stomach discomfort. These effects were not consistently observed across studies and, when present, were often described as minor. In most trials, no adverse effects were reported at all. Some studies excluded participants who experienced gastrointestinal discomfort during screening, indicating interindividual variability in tolerance. No severe systemic adverse effects were described in these adult populations under the investigated conditions.

The Panel noted that the studied populations consisted of healthy young adults, often endurance trained athletes, who are not representative of the general population. In addition, glycerol was administered together with large volumes of fluid, which is likely to mitigate increases in blood osmolality compared with glycerol ingestion without adequate fluid intake. These conditions differ from the consumption of glycerol-containing beverages.

4.2.3 | Oral use of glycerol in patients with inner ear disorders, including Ménière's disease

Studies on the use of oral glycerol administration as a diagnostic method or treatment of patients suspected of having Ménière's disease (MD), a use that falls outside the remit of its use as a food additive, were reviewed. MD affects 0.2%–0.5% of the general population, characterised by inner ear disorders (hearing loss, tinnitus, vertigo) due to liquid accumulation in the inner ear. Increasing plasma osmolality with glycerol results in withdrawal of water from the extravascular spaces in the endolymphatic system.

In these studies, glycerol was orally administered as a single bolus to participants. The most common doses of glycerol given orally ranged from 0.5 to 1.5 g/kg bw (Angelborg et al., 1971; Di Girolamo et al., 2001; Futaki et al., 1977; Mohamed et al., 2017; Nagarajan & Thangaraj, 2022; Oz et al., 2015; Padoan, 2003; Snyder, 1982). Most of these studies did not collect information on side effects in patients following the administration of glycerol. Two studies reported side effects (e.g. headaches, nausea and vomiting) attributed to the dehydrating effect of glycerol in the inner ear (Futaki et al., 1977; Padoan, 2003).

Padoan (2003) examined the effects of glycerol in 12 participants (5 females and 7 males; age between 38 and 68 years) suspected of having MD (i.e. 9 with definite diagnosis, 1 probable and 2 possible MD), given as an oral bolus (single dose of 1.2 mL/kg bw at 42.5% in saline solution with lemon drops for taste correction, corresponding to 0.51 g of glycerol/kg bw), and for comparison, an iv administration (10% glycerol in saline solution with 5% of fructose as anti-haemolytic agent). For the iv test, the infusion lasted for 30 min and the dose was 3 mL/kg bw (corresponding to 0.3 g of glycerol/kg bw). Each patient was tested twice, each time in the morning after one night's fasting. Test order (oral/iv or iv/oral) was randomised among patients, with 1–13.7 months between oral and iv tests. During the tests, patients estimated the intensity of their nausea and headache using a visual analogue scale before and every half-hour after glycerol administration, until the end of the test after 2.5 h. The authors reported that glycerol given orally (0.51 g/kg bw) produced a change in osmolality of > 10 mOsm/kg in all participants, while glycerol by iv protocol (0.3 g/kg bw) produced similar changes in only one patient. Positive audiometric results (i.e. hearing gain) were observed after both oral and iv administration, but nausea and

headache were reported to be more prominent (approximately 400% higher) in 11 of the 12 patients when glycerol was administered orally rather than intravenously.

In an earlier study, Futaki et al. (1977) examined the effects of oral glycerol (single dose of 1.3 g/kg bw) for the detection of endolymphatic hydrops in 48 patients with typical MD. Sex and age of the participants were not reported. After ingestion, checks were made for headache, nausea, emesis, dizziness and changes of tinnitus at hourly intervals for 3 h. Headache and nausea were reported in 29% and 6% of the participants, respectively.

Overall, glycerol, when administered to patients with inner ear disorders, including Ménière's, either orally (typically 0.5–1.5 g/kg bw) or by iv injection (0.3 g/kg bw), produced pharmacological effects that were often associated with adverse effects such as headache, nausea and vomiting.

4.3 | Derivation of an acute reference dose (ArfD)

At the time of the 2017 re-evaluation, using the study of Wald and McLaurin (1982), the ANS Panel noted that patients were administered glycerol orally as bolus doses of 500–1000 mg/kg bw every 3–4 h, dependent on the patients' ICPs. Specific individual dosages ranged from 4000 mg to 70,000 mg (average 54,000 mg) and they were administered via a nasogastric tube as a 50% solution (glycerol mixed with an equal volume of either 5% dextrose in water or 5% dextrose in 0.4% normal saline, depending upon the systemic electrolyte status). If no change in ICP was achieved or a significant volume of solution was aspirated from the stomach, intravenous mannitol was administered and another trial of glycerol was initiated 4–24 h later. For the six patients for which data were reported in this study, maximum ICP reduction and maximum serum glycerol concentration occurred around 60–90 min after oral bolus ingestion. In most cases, the serum glycerol concentration returned to pre-treatment levels about 3 h after oral administration. Given the dose- and time period-range reported in this study, the ANS Panel calculated that the dose of glycerol required to induce a therapeutic reduction in ICP was in the range of 125–333 mg/kg bw per hour. The ANS Panel therefore considered that a conservative estimate of the lowest oral bolus dose of glycerol required for therapeutic effect was 125 mg/kg bw per hour (i.e. 500 mg/kg bw divided by 4 h).

The Panel noted that the authors of this study were aware of potential GIT effects of orally administered glycerol. No GIT effects were reported in this study.

Taking into account the following considerations: (i) the study by Wald and McLaurin (1982) was based on just 15 patients of which only 3 were children, which creates some uncertainty and (ii) severe adverse effects as reported in Brothwell et al. (2025) have only been reported in children (without underlying inherited metabolic diseases), suggesting that children are more sensitive to the acute effects of glycerol, the Panel considered that a conservative dose above which unintended pharmacological effects would occur should be used for the determination of the ARfD. Therefore, the Panel considered an oral dose of 125 mg/kg bw for a single consumption event as the ARfD for glycerol (E 422).

Given the uncertainty around the volume of distribution of 0.23–0.5 L/kg bw (Frank et al., 1981; Sommer et al., 1993), the Panel considered that an oral bolus dose of 125 mg glycerol/kg bw would increase the plasma concentration of glycerol and osmolality to a negligible extent.

4.4 | Authorised uses and use levels

Maximum levels of glycerol (E 422) have been defined in Annex II to Regulation (EC) No. 1333/2008 on food additives, as amended. In this document, these levels are called maximum permitted levels (MPLs).

In line with the Terms of Reference (see Section 1.1.2) and the interpretation of the Terms of Reference (see Section 1.2), the present assessment addresses the acute dietary exposure to glycerol (E 422) from slush ice drinks and de-alcoholised wine. Slush ice drinks fall under food category (FC) 14.1.4. 'Flavoured drinks', in which glycerol (E 422) is authorised at *quantum satis* (QS) as set by Annex II to Regulation (EC) No 1333/2008.

Currently, glycerol (E 422) is not authorised as a food additive in de-alcoholised wine (FC 14.2.2 'Wine and other products' defined in Part II of Annex VII to Regulation (EU) No. 1308/2013). The authorised food additives for wine and de-alcoholised wine are laid down in Regulation (EU) No 2019/934 which does not include glycerol (E 422).

Glycerol (E 422) is an authorised food additive in the EU in many other different FCs either within the list of authorised food additives 'other than colours and sweeteners' or within the Group I additives at MPL equal to QS (see Appendix B) as set by Annex II to Regulation (EC) No 1333/2008. Glycerol (E 422) is also authorised in accordance with Annex III to Regulation (EC) No 1333/2008.

4.5 | Acute exposure assessment of glycerol (E 422) from slush ice drinks and de-alcoholised wine

4.5.1 | Exposure data

4.5.1.1 | *Concentration data*

To assess the acute dietary exposure to glycerol (E 422) via slush ice drinks and de-alcoholised wine, concentration data (use levels and/or analytical data) in these drinks are required.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued public calls for concentration data (use levels and/or analytical data)[19] on glycerol (E 422). In addition, analytical data on glycerol (E 422) are submitted yearly to EFSA through the open calls for food additive occurrence data in food and beverages intended for human consumption.[20]

For the acute exposure assessment of glycerol (E 422) via slush ice drinks, only occurrence data reported for FC 14.1.4 'Flavoured drinks' were considered. In response to the public calls, information on use levels in this FC were made available by one interested business operator (IBO) (Documentation provided to EFSA No. 1). Analytical data in FC 14.1.4 'Flavoured drinks' were submitted by one Member State (Germany) and extracted in November 2025.

No concentration data for glycerol (E 422) in de-alcoholised wine were reported.

Reported use levels of glycerol (E 422) in slush ice drinks and other flavoured drinks

One IBO provided 25 use levels of glycerol (E 422) in FC 14.1.4 'Flavoured drinks' (Documentation provided to EFSA No. 1). Out of these, two use levels related specifically to slush ice drinks: 17,400 and 20,000 mg/kg.[21] The other 23 use levels related to other flavoured drinks (e.g. energy drinks, carbonated soft drinks). Table 1 provides a summary of the use levels of glycerol (E 422) in FC 14.1.4 'Flavoured drinks' as reported by the IBO. The Panel noted that the use levels reported for slush ice drinks are much higher than those reported for other flavoured drinks.

TABLE 1 Summary statistics of the use levels of glycerol (E 422) in FC 14.1.4 Flavoured drinks.

Food category number	Food category name	Type of flavoured drinks	Number of data	Mean of use levels (mg/kg)	Maximum of use levels (mg/kg)
14.1.4	Flavoured drinks	Slush ice drinks	2	18,700	20,000
14.1.4	Flavoured drinks	Other flavoured drinks	23	70	3410

Analytical results of glycerol (E 422) in slush ice drinks and other flavoured drinks

In total, 58 analytical results for glycerol (E 422) in FC 14.1.4. 'Flavoured drinks' were reported by Germany. The samples were obtained between 2020 and 2024, and 98% of them were analysed the year that they were collected. Out of these, 31 analytical results for glycerol were specifically classified as slush ice drinks with five samples (16%) being left-censored (reported as not detected (< LOD)). One high analytical result of 318 g/kg was for 'Beverages concentrates' and the data provider confirmed that this was a concentrate for slush ice drink, which should be diluted before consumption. Accordingly, a standard dilution factor of 3[22] was applied to this analytical result (EFSA, 2018). Detailed information on the methods of analysis was not made available, but all results were derived from accredited laboratories.

To consider the left-censored analytical results, the substitution method was used (EFSA, 2010; WHO/IPCS, 2009). These results were either assigned a value of zero (lower bound (LB)) or the numerical value of the LOD (upper bound (UB)). The LB and UB levels provide in this way a minimum and maximum possible value for the left-censored results.

The 31 analytical results for glycerol in slush ice drinks were considered by the Panel in the exposure assessment. The LB and UB mean glycerol levels were 33,000 and 33,100 mg/kg, respectively and the LB and UB P90 (highest reliable percentile (HRP)) was 52,900 mg/kg. The other 27 analytical results were reported for other flavoured drinks. Table 2 provides a summary of the analytical levels of glycerol in FC 14.1.4 'Flavoured drinks'.

[19] https://www.efsa.europa.eu/en/consultations/call/call-food-additives-usage-level-andor-concentration-data-food-and.

[20] https://www.efsa.europa.eu/en/call/open-call-food-additives-analytical-and-use-level-data-food-and-beverages-intended-human. Last call for data was open until 31 August 2025.

[21] Both reported use levels (17,400 and 20,000 mg/kg) were indicated as typical and as maximum.

[22] The Panel acknowledges uncertainty in the dilution factor. However, in the absence of information on commercial use recommendations, the standard dilution factor for juices, used for other food additives, was applied. This choice does not have a relevant impact on the calculated mean and P90 values (Table 2) used in the present assessment.

TABLE 2 Summary statistics of the analytical results of glycerol reported by the Member State.

Food category number	Food category name	Type of flavoured drinks	N of data	% LC	Mean (mg/kg)		P75 (mg/kg)		P90 (mg/kg)	
					LB	UB	LB	UB	LB	UB
14.1.4	Flavoured drinks	Slush ice drinks	31	16	33,000	33,100	48,400	48,400	52,900[a]	52,900[a]
14.1.4	Flavoured drinks	Other flavoured drinks	27	48	8980	9180	40[a,b]	1210[a,b]	–	–

Abbreviations: N, number; LB, lower bound; LC, Left-censored; P75, 75th percentile; P90, 90th percentile; UB, upper bound.

[a]Highest reliable percentile (Meeker et al., 2017).

[b]Due to several high glycerol concentrations, the distributions of both LB and UB analytical results are right-skewed, with high values substantially influencing the mean.

The Panel noted that the analytical data reported for slush ice drinks were higher than those reported for other flavoured drinks, despite the occasional presence of glycerol at a high concentration in other flavoured drinks.

4.5.1.2 | *Summarised data extracted from Mintel's Global New Products Database*

According to Mintel's GNPD, glycerol (E 422) was labelled on 92 products of flavoured drinks, mainly belonging to 'Beverage Concentrates' ($n = 24$) 'Nutritional & Meal Replacement Drinks' ($n = 20$) and 'Fruit/Flavoured Still Drinks' ($n = 18$), between January 2022 and January 2026. None of these 92 products referred to slush ice drinks, likely because slush ice drinks are mostly not consumer packaged goods.

The Panel noted that two de-alcoholised wine products were labelled to contain glycerol (E 422) in Mintel's GNPD.

4.5.1.3 | *Food consumption data used for exposure assessment*

The present assessment relates to the acute exposure to glycerol (E 422) via slush ice drinks and de-alcoholised wine. Accordingly, the Panel examined the availability of relevant consumption data for these types of drinks in the Comprehensive database.

No consumption data was available for slush ice drinks and only very limited consumption data for alcohol-free wines and wine-like drinks were available. Therefore, the Panel performed the assessment according to specific assumptions as described below in this section.

In line with the Terms of Reference (see Section 1.1.2) and its interpretation (see Section 1.2), an acute exposure assessment of glycerol (E 422) from slush ice drinks and de-alcoholised wine was performed on a consumption event basis.

Consumption data used for the acute exposure assessment of glycerol (E 422) from slush ice drinks

For estimating the acute exposure to glycerol (E 422) from slush ice drinks, a volume of 250 mL was considered representative of a single consumption event for toddlers (≥ 1–< 3 years of age)[23] and children (≥ 3–< 10 years of age),[24] while a volume of 500 mL was considered representative for adolescents (≥ 10–< 18 years of age), adults (≥ 18–<64 years of age) and the elderly (≥ 64 years of age).[25]

Infants were not included in the assessment, as it was deemed unlikely that they would consume slush ice drinks.

Consumption data used for the acute exposure assessment of glycerol (E 422) from de-alcoholised wine

To estimate acute exposure to glycerol (E 422) from de-alcoholised wine for adults and the elderly, the Panel used data from the Comprehensive database on all wine and wine-like drinks, i.e. both alcoholic and alcohol-free, as a proxy for de-alcoholised wine consumption, since it is assumed that de-alcoholised products can replace regular wine.

For toddlers, children and adolescents, de-alcoholised wine is assumed to be a potential alternative for flavoured drinks in certain situations; therefore, the consumption of flavoured drinks from the same database served as a proxy for de-alcoholised wine consumption in these population groups.

Food consumption data were available from 49 different dietary surveys carried out in 24 European countries. The details of the population groups considered and the countries with food consumption surveys available are presented in Annex A, Table A.1. Summary statistics of volumes of wine and wine-like drinks (for adults and the elderly) and of flavoured drinks (for toddlers, children and adolescents) across the surveys with a minimum of 59 consumption events are reported in Annex A, Table A.2.

Infants were not included in the assessment, as it was deemed unlikely that they would consume de-alcoholised wine.

[23]The assumption that the full portion of 250 mL is consumed by toddlers is likely to be an overestimation.

[24]Smallest size https://www.marketingscoop.com/blog/what-are-711-slurpee-sizes/.

[25]Medium size https://www.marketingscoop.com/blog/what-are-711-slurpee-sizes/.

4.5.2 | Exposure estimates

4.5.2.1 | *Acute exposure assessment of glycerol (E 422) from slush ice drinks*

The acute exposure to glycerol (E 422) from slush ice drinks was estimated based on the use levels and analytical data reported for slush ice drinks. For this assessment, the Panel used both the maximum reported use level of 20,000 mg/kg (see Table 1) and the calculated UB HRP value of 52,900 mg/kg from the available analytical data (see Table 2).

Acute exposure from slush ice drinks was calculated for children and adults drinking a portion of slush ice drink by multiplying these two concentrations with:

- 250 mL of slush ice drink for toddlers and children;
- 500 mL of slush ice drink for adolescents, adults and the elderly;

To express the exposure per kg body weight, the estimates were divided by a mean body weight[26] retrieved from the Comprehensive database for each population group.

Table 3 summarises the estimated acute exposure to glycerol (E 422) from slush ice drinks in five population groups.

TABLE 3 Summary of acute exposure to glycerol (E 422) from slush ice drinks, in five population groups (mg/kg bw per consumption event), based on maximum reported use level and UB HRP of the analytical results.

Glycerolconcentration used for the calculation	Toddlers (≥ 1–< 3 years)	Children (≥ 3–< 10 years)	Adolescents (≥ 10–< 18 years)	Adults (≥ 18–< 64 years)	The elderly (≥ 65 years)
Maximum reported use level (**20,000 mg/L**)	404	209	187	132	131
UB HRP (**52,900 mg/L**)	1069	553	494	348	346

Abbreviations: bw, body weight; UB HRP, upper bound highest reliable percentile.

4.5.2.2 | *Acute exposure assessment of glycerol (E 422) from de-alcoholised wine*

The acute exposure to glycerol (E 422) from de-alcoholised wine was estimated by multiplying the proposed maximum level of 50,000 mg/L, on a consumption event basis, with the individual consumption data retrieved from the Comprehensive database (for more details see Section 4.5.1.3). These estimates were divided by the individual body weights from this database to express the exposure per kg body weight. The P95 exposure was subsequently calculated separately for each survey and different population groups.

Table 4 summarises the theoretical estimated acute exposure to glycerol (E 422) from de-alcoholised wine in five population groups. Detailed results per population group and survey are presented in Annex A, Table A.3.

TABLE 4 Summary of theoretical P95 acute exposure to glycerol (E 422) from de-alcoholised wine for five population groups (minimum, median and maximum across the dietary surveys in mg/kg bw per consumption event) based on a proposed maximum level of 50,000 mg/kg. Food consumption data of flavoured drinks (for toddlers, children and adolescents) and wine and wine-like drinks (for adults and the elderly) were used as a proxy for the assessment.

Population group	Number of surveys[a]	Minimum (mg/kg bw per consumption event)	Median (mg/kg bw per consumption event)	Maximum (mg/kg bw per consumption event)
Toddlers (≥ 1–< 3 years)	15	51.4	968	1270
Children (≥ 3–< 10 years)	22	490	781	1250
Adolescents (≥ 10–< 18 years)	23	349	532	971
Adults (≥ 18–< 64 years)	22	156	298	475
The elderly (≥ 65 years)	20	129	223	349

Abbreviations: bw, body weight; P95, 95th percentile.

[a]Only surveys with a minimum of 59 consumption events were considered statistically robust for calculating the P95 exposure.

[26]Toddlers: 12.4 kg; Children: 23.9 kg; Adolescents 53.6 kg; Adults 75.9 kg; Elderly: 76.5 kg.

4.6 | Estimation of the maximum volume of slush ice drinks and de-alcoholised wine containing glycerol (E 422) that can be consumed without exceeding the ARfD depending on the concentration of glycerol in the beverage

The Panel estimated the maximum volume of slush ice drinks and de-alcoholised wine containing glycerol (E 422) that can be consumed by different population groups without exceeding the ARfD, taking into account the reported levels of glycerol (E 422) in slush ice drinks and the proposed maximum level in de-alcoholised wine. The dose of 125 mg/kg bw for a single consumption event was selected by the Panel as the ARfD (see Section 4.3).

The volume of slush ice drinks and de-alcoholised wine that at a given glycerol (E 422) concentration results in an exposure that corresponds to this ARfD was estimated for each population group considering the mean body weights[26] from the Comprehensive database.

The volumes were calculated as follows: $$\frac{\text{body weight (kg) x 125 mg glycerol / kg bw}}{\text{glycerol concentration (mg / 1000 mL)}} = \text{volume (mL)}.$$

This formula can be applied to any other beverages to calculate the volume that can be consumed without exceeding the acute reference depending on the glycerol (E 422) concentration in the beverage.

For slush ice drinks, the volumes were calculated assuming different glycerol (E 422) concentrations (see Section 4.2.1), and the volume of de-alcoholised wine was calculated for the proposed maximum level of 50,000 mg/L. The results are listed in Table 5.

TABLE 5 Volumes (mL) of slush ice drinks and de-alcoholised wine that, at selected glycerol (E 422) concentrations, result in an exposure corresponding to 125 mg/kg bw for a single consumption event at a mean body weight in five population groups.

Glycerol concentration (mg/L)	Toddlers (≥ 1–< 3 years)	Children (≥ 3–< 10 years)	Adolescents (≥ 10–< 18 years)	Adults (≥ 18–< 64 years)	The elderly (≥ 65 years)
Slush ice drinks based on analytical results					
33,100 (mean)	46.7	90.4	202	287	289
48,400 (P75)	31.9	61.8	138	196	198
52,900 (P90, HRP)	29.2	56.5	127	179	181
Slush ice drinks based on use levels					
18,700 (Mean of use levels)	82.7	160	358	507	511
20,000 (Maximum of use levels)	77.3	150	335	475	478
De-alcoholised wine based on proposed maximum level					
50,000	30.9	59.8	134	190	191

Abbreviations: bw, body weight; HRP, highest reliable percentile; P75, 75th percentile; P90, 90th percentile.

4.7 | Theoretical maximum levels of glycerol (E 422), when used as a food additive in beverages, including slush ice drinks and de-alcoholised wine, at which the exposure does not exceed the ARfD

The Panel calculated the theoretical maximum concentration of glycerol (E 422) in beverages, including slush ice drinks and de-alcoholised wine, at which exposure to glycerol (E 422) does not exceed the ARfD of 125 mg/kg bw for five population groups. For this, the Panel used a volume of 250 mL for a single consumption event for toddlers and children and 500 mL for the remaining population groups as a possible high consumption amount during a single consumption event for any beverage. All calculations were based on mean body weights26 retrieved from the Comprehensive database per population group.

As described in Section 2.1, the Panel considered that a theoretical calculation better reflects the European Commission's request and can be applied to any beverage by assuming a specific volume consumed during a single consumption event.

The glycerol concentrations were calculated as follows:

$$\frac{\text{body weight (kg) x 125 mg glycerol / kg bw}}{\text{volume (L)}} = \text{concentration (mg / L)}$$

This formula can be applied to calculate glycerol concentrations at any consumption volume of a beverage without exceeding the acute reference.

The calculated theoretical maximum concentrations at the specified volumes are summarised in Table 6.

TABLE 6 Theoretical maximum concentration of glycerol (E 422) in beverages, including slush ice drinks and de-alcoholised wine, at which exposure to glycerol does not exceed the ARfD for five population groups.

Population group	Volume (mL)	Glycerol concentration (mg/L) at which exposure does not exceed the ARfD
Toddlers (≥ 1–< 3 years)	250	6200
Children (≥ 3–< 10 years)	250	12,000
Adolescents (≥ 10–< 18 years)	500	13,400
Adults (≥ 18–< 64 years)	500	19,000
The elderly and very elderly (≥ 65 years)	500	19,100

5 | DISCUSSION

The present scientific opinion deals with (i) the acute exposure to glycerol (E 422) from slush ice drinks and de-alcoholised wine; (ii) the estimation of the maximum volume of slush ice drinks and de-alcoholised wine containing glycerol (E 422) at selected concentrations that can be consumed without exceeding the ARfD and (iii) the calculation of theoretical maximum levels of glycerol (E 422), when used as a food additive in beverages, at which the exposure does not exceed the ARfD.

In 2017, the EFSA ANS Panel re-evaluated glycerol (E 422) as a food additive and concluded that there was no need for a numerical ADI and no safety concern regarding its use at reported use level in the refined exposure assessment scenario (EFSA ANS Panel, 2017). The ANS Panel also concluded that infants and toddlers could be exposed to glycerol at more than 125 mg/kg bw per hour by drinking less than the volume of one can (330 mL) of a flavoured drink and that the acute bolus exposure to glycerol (E 422) by its use as a food additive should stay below this dose so that no pharmacological or side effects could occur.

In July 2024, the FSAI advised limiting young children's consumption of slush ice drinks containing glycerol (E 422) due to potential side effects. FSAI also issued voluntary guidelines for industry, including minimising glycerol use in slush ice drinks, providing warnings that this drink is not recommended for children aged 4 and under, and avoiding free refills for younger children (5–10 years old). In February 2025, BfR carried out a health risk assessment of measured glycerol levels in slush ice drinks (BfR, 2025). This was done in response to cases of children being reported to have been hospitalised after consuming slush ice drinks. The BfR considered that '*there are health concerns if the consumption of a slush ice drink leads to an exposure that corresponds to or exceeds the therapeutically effective dose of 250 mg/kg bw*'.

Glycerol is rapidly absorbed following oral administration, distributed and eliminated mainly through metabolism to carbon dioxide with a short half-life of approximately 0.86 h. Glycerol is pharmacologically active through its osmotic effects, increasing plasma osmolality and thereby reducing intracranial and intraocular pressure. This mechanism underlies its therapeutic uses in the treatment of patients with cerebral oedema, elevated intracranial pressure and ocular hypertension.

Clinical studies in adults have reported pharmacological effects at oral bolus doses generally ranging from 500 to 1500 mg/kg bw. At these doses, glycerol has been shown to produce measurable increases in plasma osmolality and corresponding pharmacological effects.

Human studies examined the use of glycerol as a hyperhydrating or rehydrating agent in healthy young athletes. In these studies, oral doses in the range of approximately 1.0–1.5 g/kg bw were used, typically administered with large volumes of fluid. These regimens resulted in increased plasma volume and osmolality but generally did not lead to severe adverse effects in this specific adult population, which were limited to mild gastrointestinal symptoms, such as bloating, nausea, diarrhoea or stomach discomfort, and were not consistently observed across studies. The Panel noted that the study participants (athletes) are not representative of the general population.

In contrast, case reports in children indicate a different pattern of response (Brothwell et al., 2025). A retrospective case series described 21 children aged between approximately 2 and 6 years who became acutely unwell shortly after consuming slush ice drinks. Symptoms typically developed within 1 h of consumption and included a marked decrease in consciousness, hypoglycaemia, metabolic acidosis, elevated lactate levels, hypokalaemia and pseudohypertriglyceridaemia. Glycerol was detected in urine samples from all children for whom such analyses were available, indicating systemic exposure. The severity of symptoms observed in these children was notable, with the majority showing reduced consciousness and requiring medical intervention. No underlying metabolic disorders were identified in the children who underwent further testing, and avoidance of slush ice drinks prevented recurrence of symptoms in almost all cases. One child who later consumed another slush ice drink experienced a rapid recurrence of symptoms, supporting a causal association with glycerol exposure. The actual dose of glycerol ingested by the affected children was not quantified, as neither the volume of slush ice drink consumed nor the glycerol concentration in the specific product was known. Brothwell et al. (2025) considered the most likely cause of the adverse effects reported after consuming a slush ice drink was attributable to glycerol. The Panel concurs with the authors.

Taking into account the human data summarised in Sections 4.1 and 4.2, the Panel considered that a conservative dose above which unintended pharmacological effects would occur should be used for the derivation of an ARfD, i.e. 125 mg glycerol/kg bw for a single consumption event based on the study by Wald and McLaurin (1982).

This approach was considered appropriate taking into account that: (i) the study by Wald and McLaurin (1982) involved only 15 patients, of whom only three were children, which creates some uncertainty; (ii) severe adverse effects reported by

Brothwell et al. (2025) occurred in children (without underlying inherited metabolic diseases), suggesting that children may be more sensitive to the acute effects of glycerol.

Given the uncertainty around the volume of distribution of 0.23–0.5 L/kg bw (Frank et al., 1981; Sommer et al., 1993), the Panel considered that an oral bolus dose of 125 mg glycerol/kg bw would increase the plasma concentration of glycerol and osmolality only to a negligible extent.

Using the study by Wald and McLaurin (1982), the BfR considered 250 mg/kg bw as the 'reference point' for risk characterisation based on the lowest dose (calculated on the basis of mean body weights and then rounded) that was therapeutically effective, in reducing ICP. The Panel noted that the BfR risk characterisation was based on the lowest therapeutically effective dose observed in this study, whereas the Panel approach addressed the ToR (see Section 1.1.2) by identifying, from the same study by Wald and McLaurin (1982), an ARfD at which no undesirable effects are to be expected.

The Panel also considered that, given the half-life of glycerol of 0.86 h in adults (Sommer et al., 1993), a repeated consumption of a beverage containing glycerol (E 422) resulting in an exposure equal to the ARfD within about 3 h (3 half-lives) would increase the risk of undesirable effects, since this may lead to accumulation of glycerol in the body.

For the current assessment, data received through open calls for use levels and analytical data of food additives, including glycerol (E 422), in food and beverages have been considered.

Slush ice drinks fall under FC 14.1.4 'Flavoured drinks' authorised at QS as set by Annex II to Regulation (EC) No 1333/2008. For the acute exposure assessment of glycerol (E 422) from slush ice drinks, the occurrence data reported for FC 14.1.4 were therefore considered. Both use levels and analytical data were available for this FC from one IBO and one MS (Germany), respectively. The two reported use levels for slush ice drinks were 17,400 and 20,000 mg/kg (18,700 mg/kg, mean of the reported levels). Regarding the 31 analytical results of glycerol in slush ice drinks considered, the LB and UB mean glycerol levels were 33,000 and 33,100 mg/kg, respectively, and the LB and UB P90 HRP was 52,900 mg/kg. The Panel noted that the analytical results for slush ice drinks were higher than those reported for other flavoured drinks, despite the occasional presence of glycerol at a high concentration in other flavoured drinks.

The Panel noted that the number of analytical results reported to EFSA by Germany was different from the number (i.e. 62 for slush ice drinks) indicated in the BfR report (BfR, 2025). It was confirmed that not all the data presented in the BfR report were submitted to EFSA due to different timeframes of the data collection. The Panel noted that the mean glycerol (E 422) concentration of the data submitted to EFSA (33,100 mg/L) approximated to the mean of the concentrations reported by the BfR (26,240 mg/L).

Currently, glycerol (E 422) is not authorised as a food additive in de-alcoholised wine (FC 14.2.2 'Wine and other products' defined in Part II of Annex VII to Regulation (EU) No. 1308/2013). The authorised food additives for wine and de-alcoholised wine are laid down in Regulation (EU) 2019/934 which does not include glycerol (E 422). Therefore, no occurrence data of glycerol (E 422) in de-alcoholised wine were reported, and the acute exposure calculation was based on a maximum level of 50,000 mg/L proposed by OIV in June 2025. However, the Panel noted that two de-alcoholised wine products were labelled as containing glycerol (E 422) in Mintel's GNPD.

The acute exposure assessment to glycerol (E 422) via slush ice drinks and de-alcoholised wine was calculated on a consumption event basis and is presented in Tables 3 and 4.

For slush ice drinks, the acute exposure was based on two fixed volumes of consumption because no data on the consumption of these drinks was available in the Comprehensive database (see Section 4.2.1). These volumes, 250 mL for toddlers and children and 500 mL for adolescents, adults and the elderly, respectively, were considered as representative of a single consumption event for this kind of beverage. However, these volumes may not fully account for instances of higher consumption, potentially resulting in an underestimation of acute exposure. Furthermore, the Panel noted that information on reported use levels and analytical data of glycerol (E 422) in slush ice drinks was limited, with only two use levels submitted by one IBO and analytical data submitted by only one MS. This introduced an uncertainty in the calculated acute exposure. In addition, the Panel noted that the maximum reported use level of glycerol (E 422) in slush ice drinks (i.e. 20,000 mg/kg) was much lower than the HRP of the analytical results (i.e. 52,900 mg/kg) used in the exposure assessment. For this reason, two different assessment scenarios (Table 3), based on use levels and analytical results, were carried out. The Panel noted that, even considering the maximum reported level of glycerol (E 422), which is lower than the levels reported in the analytical data, the acute exposure to glycerol (E 422) per event via slush ice drinks would exceed the ARfD for all population groups.

There is no FC code for de-alcoholised wine, alcohol-free wine and wine-like drinks in the Comprehensive database. Even using facets and additional information provided, only very limited data on consumption for alcohol-free wine and wine-like drinks was available. Therefore, the Panel considered it appropriate to use individual consumption data of wine and wine-like drinks as a proxy for adults and the elderly since it is assumed that de-alcoholised products can replace wine. However, for toddlers, children and adolescents, the Panel considered it more appropriate to use consumption data of flavoured drinks as a proxy for de-alcoholised wine, as these beverages may represent a potential alternative in these population groups (see Section 4.5.2). These consumption levels combined with the proposed maximum level of 50,000 mg/kg of glycerol (E 422) in de-alcoholised wine resulted in P95 estimates of acute exposure to glycerol (E 422) that exceeded the ARfD in all population groups. Only in one survey, the P95 was below the ARfD in toddlers (see Table A.3).

As requested by the European Commission, the Panel estimated the maximum volume of slush ice drinks and de-alcoholised wine containing glycerol (E 422) that can be consumed by different population groups without exceeding the ARfD, taking into account the available information of glycerol (E 422) in slush ice drinks and the proposed maximum level in de-alcoholised wine of 50,000 mg/kg (Table 5).

These calculations showed that the maximum volume of slush ice drinks, to be consumed in a single consumption event without exceeding the ARfD, ranged from 29 mL for toddlers based on the HRP to 289 mL in the elderly based on the mean of the analytical data. Based on the reported maximum use level of 20,000 mg/kg, the volumes ranged from 77 mL in toddlers to 478 mL in the elderly.

These results indicated that, even when considering the maximum reported use level of glycerol (E 422) in slush ice drinks, which is lower than the levels reported in the analytical data, toddlers and children should consume less than a portion of 250 mL to avoid exceeding the ARfD. Similarly, adolescents should consume less than a portion of 500 mL. When the higher glycerol concentrations reported in analytical data were considered, also adults and the elderly would need to consume less than a portion of 500 mL.

Results in Table 5 also indicated that, at the proposed maximum level (50,000 mg/kg) of glycerol (E 422) in de-alcoholised wine, toddlers, children and adolescents should consume less than 31, 60 and 134 mL, respectively, in a single consumption event to avoid exceeding the ARfD. For adults and the elderly, consumption should be limited to less than one glass (190 mL).

The Panel calculated the theoretical maximum levels of glycerol (E 422), when used as a food additive in beverages, including slush ice drinks and de-alcoholised wine, at which the exposure does not exceed the ARfD, assuming a possible high consumption volume during a single consumption event (Table 6).

Results indicated that, to ensure that toddlers and children do not exceed the ARfD after consuming a volume of 250 mL of beverages, as a single consumption event, glycerol (E 422) concentrations should be below the lowest reported use level in slush ice drinks (17,400 mg/L). Also, for adolescents, the glycerol (E 422) concentration would need to be below this lowest reported use level to ensure that the exposure to glycerol does not exceed the ARfD after consuming a volume of 500 mL of beverages. Based on the assumed consumption volumes per single event, glycerol (E 422) concentrations resulting in exposures to glycerol below the ARfD were below the proposed maximum level of 50,000 mg/L for de-alcoholised wine, for all population groups.

The Panel is of the view that similarly to the results listed in Table 6, theoretical maximum concentrations of glycerol (E 422) in beverages that may be consumed in a single consumption event without exceeding the ARfD can be calculated for different population groups using different consumption volumes for a single consumption event.

6 | UNCERTAINTY

The Panel identified several uncertainties in this assessment.

A key uncertainty concerns the ARfD for glycerol (E 422) (125 mg/kg bw for a single consumption event), which is based on data from only 15 patients with severe craniocerebral trauma or intracerebral or intraventricular haemorrhages.

Further uncertainties concern the glycerol (E 422) exposure of children who experienced severe adverse effects reported by Brothwell et al. (2025), as their actual exposure was not determined. It therefore remains unclear whether children are more sensitive to the acute effects of glycerol and therefore the Panel took a conservative approach.

Additional uncertainty arises from the limited availability of data on glycerol (E 422) levels in slush ice drinks.

Finally, there is also uncertainty in relation to the volumes of slush ice drinks and de-alcoholised wine that may be consumed in a single consumption event.

7 | CONCLUSIONS

Based on the available data, the Panel derived an ARfD for glycerol (E 422) of 125 mg/kg bw as an oral dose for a single consumption event.

The Panel concluded that the acute exposure to glycerol per single consumption event from slush ice drinks, assuming a consumption of 250 mL and 500 mL for children (≥ 1–< 10 years) and other population groups (≥ 10 years), respectively, would exceed the ARfD for all population groups.

The Panel also concluded that the P95 acute exposure estimates for glycerol (E 422) from the potential use of de-alcoholised wine, assumed to be consumed by children and adolescents (≥ 1–< 18 years) as a substitute for flavoured drinks and by other population groups (≥ 18 years) as a substitute for wine and wine-like drinks, would exceed the ARfD for all population groups at the proposed maximum level of 50,000 mg glycerol/L.

The Panel concluded that the maximum single consumption event volume of beverages containing glycerol (E 422) that can be consumed by different populations groups without exceeding the ARfD are 29, 57, 127, 179 and 181 mL in toddlers, children, adolescents, adults and the elderly, respectively, based on the 90th percentile concentration (UB P90, i.e. 52,900 mg/L) for slush ice drinks. For de-alcoholised wine, the corresponding volumes are 31, 60, 134, 190 and 191 mL, in toddlers, children, adolescents, adults and the elderly, respectively, considering the proposed maximum level of 50,000 mg/kg of glycerol.

The theoretical maximum levels of glycerol (E 422) when used as a food additive in beverages, including slush ice drinks and de-alcoholised wine, at which exposure does not exceed the ARfD are 6200, 12,000, 13,400, 19,000 and 19,100 mg/L in toddlers, children, adolescents, adults and the elderly, respectively, based on volumes provided in Table 6.

8 | RECOMMENDATION

The Panel recommends the European Commission to consider establishing numerical maximum levels for glycerol (E 422) when used in beverages.

9 | DOCUMENTATION AS PROVIDED TO EFSA

1. UNESDA Soft Drinks Europe. Submission of data in response to call for food additives usage level and/or concentration data in food and beverages intended for human consumption. Data submitted on 29 August 2025.

ABBREVIATIONS

ADI	acceptable daily intake
ANS	EFSA Panel on Food Additives and Nutrient Sources added to Food
ARfD	acute reference dose
BfR	German Federal Institute for Risk Assessment
CSF	cerebral-spinal fluid
FAF	EFSA Panel on Food Additives and Flavourings
FC	food category
FSAI	Food Safety Authority of Ireland
GIT	gastrointestinal tract
GNPD	Global New Products Database
Hb	haemoglobin (blood concentration)
Hct	haematocrit
HRP	highest reliable percentile
IBO	interested business operator
ICP	intracranial pressure
iv	intravenous
LB	lower bound
LC	left-censored
LOD	level of detection
MD	Ménière's disease
MPL	maximum permitted level
N	number
No.	number
OIV	International Organisation of Vine and Wine
P75	75th percentile
P90	90th percentile
P95	95th percentile
Pins	plasma insulin
Posm	plasma osmolarity
QS	*quantum satis*
UB	upper bound

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REQUESTOR

European Commission

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

Human studies on the pharmacological use of glycerol as a hyperhydrating or rehydrating agent

At the time of the re-evaluation, a review by Van Rosendal et al. (2010) on the use of glycerol in hyperhydration and rehydration, a use that falls outside the remit of its use as a food additive, in association with exercise was considered. Side effects – nausea, diarrhoea gastrointestinal distress or light-headedness – after rapid administration of glycerol as a concentrated bolus, were reported in some subjects.

Van Rosendal et al. (2015) examined the effects of different oral and intravenous (iv) rehydration regimens, with or without oral glycerol, on hydration status, urinary parameters and endocrine markers. Nine endurance-trained men (22.8 ± 3.9 years of age; 74.1 ± 4.9 kg bw) were dehydrated such that they lost 4% of their bodyweight during a 2-h cycling challenge. The participants were then rehydrated over 2 h with 150% of the fluid lost using four different protocols before a 1-h equilibration period (during which they consumed a standardised lunch) and 1.5-h exercise performance test. The study used a randomised, crossover design so that each participant was tested once for each of the 4 rehydration protocols, with each trial conducted at least 2 weeks apart. Participants received either oral fluid only, oral fluid supplemented with glycerol (1.5 g/kg bw), 50% of the oral fluid in conjunction with 50% saline delivered by iv administration or 50% of the oral fluid supplemented with glycerol (1.5 g/kg bw) in conjunction with 50% saline delivered by iv administration.

The oral fluid used in oral only protocols consisted of 64% of a carbohydrate-electrolyte sports drink and 36% distilled water. The oral fluid used in oral/iv protocols consisted of 88% of a carbohydrate-electrolyte sports drink and 12% distilled water. For the iv with oral glycerol trials, the iv solutions comprised glycerol doses of 1 g/kg bw (first hour; 0.80 mL/kg bw/min delivered over 50 min) and 0.5 g/kg bw (second hour; 0.40 mL/kg/min delivered over 50 min).

In the first hour of the oral and oral glycerol trials, subjects consumed 100% of the fluid they lost during dehydration in six separate oral fluid volumes, consumed every 10 min. The first bolus was the first experimental solution comprising a volume of carbohydrate-electrolyte beverage (Gatorade®) equal to 40% of the total first hour rehydration volume, with (oral glycerol) or without (oral) a glycerol dose of 1 g/kg bodyweight. The remaining 60% of the first hour fluid volume was broken into five boluses of 12% each. The second, fourth and sixth fluid boluses were distilled water while the third and fifth fluid boluses were a carbohydrate-electrolyte beverage (Gatorade®). In the second hour of rehydration, a volume of fluid equal to 50% of the bodyweight lost during dehydration was consumed so that the total fluid replacement equalled 150% of bodyweight lost. The second hour fluid regime mirrored that used in the first hour, except half the volume of fluid was given during each 10-min period. For the oral glycerol trials, the glycerol dose for the second experimental solution was also halved to 0.5 g/kg so that the total glycerol dose was 1.5 g/kg bodyweight. Serum glycerol concentrations increased significantly after the first hour of rehydration in both the oral glycerol and iv with oral glycerol trials. For the oral glycerol condition, peak glycerol concentration (16.4 ± 1.7 mmol/L; 1470 mg/L) occurred at the end of the second hour of rehydration. For iv with oral glycerol, the peak concentration was similar (16.3 ± 1.9 mmol/L; 1500 mg/L) but occurred 30 min later at the mid-equilibration timepoint. There were no differences in blood glycerol concentrations between oral glycerol and iv with oral glycerol at any stage.

The Panel noted that addition of glycerol to the rehydration solutions resulted in statistically significantly increased plasma volume than the corresponding fluid regime without glycerol.

The Panel noted that no adverse effects were reported from the oral administration of glycerol in this study.

Jardine et al. (2023) completed a systematic review of the effect of pre-exercise hyperhydration on exercise performance, physiological outcomes and gastrointestinal symptoms (38 studies in total, some of them already considered in Van Rosendal et al. (2010) taken into account during the re-evaluation of glycerol (E 422)). Pre-exercise hyperhydration (an increase in total body water above that of normal levels) is thought to provide a strategy to delay or reduce the adverse effects of exercise-induced hypohydration. Glycerol may be used to induce a hyperhydration state and was used in 16 studies, either alone or in combination with other agents for pre-exercise (doses ranging from 1 to 2 g glycerol/kg bw; mean dose of 1.25 g/kg bw).

Side effects recorded after glycerol ingestion were bloating (severity described as 'minor' and subsiding early during exercise), nausea (severity described as 'minor', subsiding early during exercise and resulting in participant withdrawal), diarrhoea, vomiting and stomach fullness (persisting for 15–20 min). After a 7-day treatment period involving glycerol (1 g/kg bw twice per day), one participant reported gastrointestinal distress and a similar study reported participant withdrawal after gastrointestinal distress. Gastrointestinal distress resulted in participant withdrawal from two further studies after a 7-day supplementation period with creatine in addition to glycerol and glucose. However, 13 studies reported no gastrointestinal symptoms after glycerol ingestion. Six studies did not investigate gastrointestinal symptoms after glycerol ingestion.

Otsuka et al. (2024) investigated changes in plasma volume, beverage hydration index and blood glucose and sodium after ingestion of beverages containing glycerol as a hydration agent.

Fourteen active adults (11 male, 3 female; 21.5 ± 1.0 years of age; body mass: 64.5 ± 4.8 kg), consumed 1 litre of one of four test beverages, comprised of either plain water; a mixture of 70 g (760 mmol/L) glycerol and sodium chloride 5 g (85 mmol/L); glycerol and sodium chloride together with either 70 g (204 mmol/L) sucrose or 70 g (204 mmol/L) isomaltulose, respectively (Table 1). The dose of glycerol in glycerol-containing test beverages was approximately 1.1 g/kg bw. Participants consumed 250 mL of test beverages every 10 min over a period of 40 min. Exercises were undertaken by participants after consumption of beverages, following a short rest period. Four experimental trials were separated by a minimum of 6 days and were performed in a randomised, single-blinded, crossover fashion.

The Panel noted that no adverse effects were reported.

Blood samples were collected during the final 5 min of a 30 min baseline resting period and prior to test beverage consumption. Blood was sampled every 30 min over 3 h. Blood glucose, blood lactate, plasma insulin (Pins), plasma sodium (P[Na+]), plasma osmolality (Posm), blood haemoglobin concentration (Hb) and haematocrit (Hct) were determined. Total urine volume was reduced in participants that consumed beverages containing glycerol and sodium compared to those that only consumed water while thirst was higher with all glycerol- and sodium-containing drinks than with water.

The Panel noted that there were no statistically significant changes in blood glucose, blood lactate or plasma insulin in participants consuming a beverage containing glycerol and sodium chloride and the ones consuming plain water.

Otsuka et al. (2025) examined hyperhydration and a variety of metabolic and physiological parameters in adult men after consuming test beverages that contained glycerol. Thirteen non-heat-acclimated healthy young adult males (21.3 ± 1.1 years of age; body mass: 68.1 ± 5.0 kg) consumed 1 L of one of four test beverages, comprised of either plain water, a mixture of 70 g (760 mmol/L) glycerol and 5 g (85 mmol/L) salt (glycerol and sodium chloride), glycerol and sodium chloride plus 70 g (204 mmol/L) sucrose or glycerol and sodium chloride plus 70 g (204 mmol/L) isomaltulose. To blind participants to beverage conditions, artificial sweeteners were added to all beverages, except for the mixture of glycerol, sodium and sucrose (as it was already sweet).

The dose of glycerol in glycerol-containing test beverages was approximately 1.1 g/kg bw. Participants consumed 250 mL of test beverages every 10 min over a period of 40 min. Exercises were undertaken by participants after consumption of beverages, following a short rest period. Four experimental trials were separated by a minimum of 7 days and were performed in a randomised, double-blinded, cross over fashion.

The Panel noted that a screening session was conducted to determine whether participants experienced any gastrointestinal distress after ingesting 1 L of a beverage containing glycerol, sodium and isomaltulose over 40 min. Participants were asked to self-report any gastrointestinal symptoms (e.g. diarrhoea, nausea) within 24 h after test beverage consumption. Of the 15 participants who participated in the screening at this stage, two complained of gastrointestinal distress and were excluded from further participation.

Blood samples were collected at pre- and post-beverage ingestions, pre-exercise and at the end of each exercise bout. Blood glucose, blood lactate, Pins, P[Na+], Posm, blood Hb and Hct were determined.

The Panel noted pre-exercise urine volume was statistically significantly reduced in all hyperhydrating beverages compared with control with an additional reduction observed with isomaltulose but not sucrose compared with glycerol together with sodium.

The Panel further noted that there was a statistically significant increase in plasma volume and plasma osmolality at some point between pre-ingestion and prior to exercising in participants that consumed a beverage containing glycerol and sodium chloride vs plain water.

There were no statistically significant changes in blood glucose or plasma insulin at any point between pre-ingestion and prior to exercising in participants that consumed a beverage containing glycerol and sodium chloride vs plain water. There was, however, a small but statistically significant increase in blood lactate between pre-ingestion and prior to exercising in participants that consumed a beverage containing glycerol and sodium chloride vs plain water. There was also a statistically significant increase in blood sodium from pre-ingestion extending beyond the exercise period in participants that consumed a beverage containing glycerol and sodium chloride vs plain water.

The Panel noted that the participants in these studies were healthy young athletes that are not fully representative of the target population of this assessment. The administration of glycerol is done in conjunction with fluid with the aim of hyperhydration and therefore the osmolality in the blood will not increase.

APPENDIX B

TABLE B.1 MPLs of glycerol (E 422) in food categories according to Annex II to Regulation (EC) No 1333/2008.

Food category number	Food category name	Restrictions/exception	E-number	MPL (mg/L or mg/kg as appropriate)
01.3	Unflavoured fermented milk products heat-treated after fermentation		Group I	QS
01.4	Flavoured fermented milk products including heat-treated products		Group I	QS
01.6.3	Other creams		Group I	QS
01.7.1	Unripened cheese excluding products falling in category 16	Except *mozzarella*	Group I	QS
01.7.5	Processed cheese		Group I	QS
01.7.6	Cheese products (excluding products falling in category 16)		Group I	QS
01.8	Dairy analogues, including beverage whiteners		Group I	QS
02.2.2	Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions		Group I	QS
02.3	Vegetable oil pan spray		Group I	QS
03	Edible ices		Group I	QS
04.2.1	Dried fruit and vegetables		Group I	QS
04.2.2	Fruit and vegetables in vinegar, oil, or brine		Group I	QS
04.2.4.1	Fruit and vegetable preparations excluding compote		Group I	QS
04.2.5.4	Nut butters and nut spreads		Group I	QS
04.2.6	Processed potato products		Group I	QS
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	Only energy-reduced or with no added sugar	Group I	QS
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC		E 422	QS
05.2	Other confectionery including breath refreshening microsweets		Group I	QS
05.3	Chewing gum		Group I	QS
s05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4		Group I	QS
06.2.2	Starches		Group I	QS
06.3	Breakfast cereals		Group I	QS
06.4.2	Dry pasta	Only gluten-free pasta (as food specially produced to reduce the gluten content of gluten-containing ingredients or substitute the gluten-containing ingredients) and pasta intended for hypoproteic diets	Group I	QS
06.4.4	Potato Gnocchi	Except fresh refrigerated potato gnocchi	Group I	QS
06.4.5	Fillings of stuffed pasta (ravioli and similar)		Group I	QS
06.5	Noodles		Group I	QS
06.6	Batters		Group I	QS
06.7	Pre-cooked or processed cereals		Group I	QS
07.1	Bread and rolls	Except products in 7.1.1 and 7.1.2	Group I	QS
07.2	Fine bakery wares		Group I	QS
08.3.1	Non-heat-treated processed meat		Group I	QS
08.3.2	Heat-treated processed meat	Except *foie gras, foie gras entier, blocs de foie gras, Libamáj, libamáj egészben, libamáj tömbben*	Group I	QS
08.3.3	Casings and coatings and decorations for meat		Group I	QS

(Continues)

TABLE B.1 (Continued)

Food category number	Food category name	Restrictions/exception	E-number	MPL (mg/L or mg/kg as appropriate)
09.2	Processed fish and fishery products including molluscs and crustaceans		Group I	QS
09.3	Fish roe	Only processed fish roe	Group I	QS
10.2	Processed eggs and egg products		Group I	QS
11.2	Other sugars and syrups		Group I	QS
11.4.1	Table-top sweeteners in liquid form		E 422	QS
12.1.2	Salt substitutes		Group I	QS
12.2.2	Seasonings and condiments		Group I	QS
12.3	Vinegars and diluted acetic acid (diluted with water to 4–30% by volume)		Group I	QS
12.4	Mustard		Group I	QS
12.5	Soups and broths		Group I	QS
12.6	Sauces		Group I	QS
12.7	Salads and savoury-based sandwich spreads		Group I	QS
12.8	Yeast and yeast products		Group I	QS
12.9	Protein products, excluding products covered in category 1.8		Group I	QS
13.2	Foods for special medical purposes as defined by Regulation (EU) No 609/2013 (excluding products from food category 13.1.5)		Group I	QS
13.3	Total diet replacement for weight control food as defined by Regulation (EU) No 609/2013		Group I	QS
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices	Only vegetable juices	Group I	QS
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	Only vegetable nectars	Group I	QS
14.1.4	Flavoured drinks		Group I	QS
14.1.5.2	Other	Excluding unflavoured leaf tea; including flavoured instant coffee	Group I	QS
14.2.3	Cider and perry		Group I	QS
14.2.4	Fruit wine and made wine		Group I	QS
14.2.5	Mead		Group I	QS
14.2.6	Spirit drinks as defined in Regulation (EU) 2019/787	Except whisky or whiskey	Group I	QS
14.2.7.1	Aromatised wines		Group I	QS
14.2.7.2	Aromatised wine-based drinks		Group I	QS
14.2.7.3	Aromatised wine-product cocktails		Group I	QS
14.2.8	Other alcoholic beverages including mixtures of alcoholic beverages with non-alcoholic beverages and other alcoholic beverages based on distilled alcohol with alcoholic strength by volume less than 15%		Group I	QS
15.1	Potato-, cereal-, flour- or starch-based snacks		Group I	QS
15.2	Processed nuts		Group I	QS
16	Desserts excluding products covered in category 1, 3 and 4		Group I	QS
17.1	Food supplements supplied in a solid form, excluding food supplements for infants and young children		Group I	QS
17.2	Food supplements supplied in a liquid form, excluding food supplements for infants and young children		Group I	QS

TABLE B.1 (Continued)

Food category number	Food category name	Restrictions/exception	E-number	MPL (mg/L or mg/kg as appropriate)
18.1	Processed foods not covered by categories 18.2 and 18.3, excluding foods for infants and young children		Group I	QS
18.2	Meal replacement for weight control as referred to in Regulation (EU) No 432/2012		Group I	QS
18.3	Foods specially produced to reduce the gluten content of gluten-containing ingredients or substitute the gluten-containing ingredients'	Including dry pasta	Group I	QS

Abbreviation: MPL, maximum permitted level.

ANNEX A

Exposure assessment results and underlying data

Table A1: Dietary surveys used for the estimation of hypothetical P95 acute exposure to glycerol

Table A2: Dietary surveys used for the estimation of hypothetical P95 acute exposure to glycerol

Table A3: Summary of hypothetical P95 acute exposure to glycerol (E 422) from de-alcoholised wines in five population groups (minimum, median and maximum across the dietary surveys in mg/kg bw per consumption event) based on a proposed maximum level of 50,000 mg/kg. Food consumption data of flavoured drinks (for toddlers, children and adolescents) and wines and wine-like drinks (for adults and the elderly) were used as proxy for the assessment. Results are expressed per population group and survey.