Glycerol in Slush Ice Drinks

FSA 25-06-08 - Report by Rebecca Sudworth

1. Summary

1.1 This paper sets out the risk of glycerol in slush ice drinks for children, the key findings from the recent rapid risk assessment, proposed next steps and seeks a steer from the Board to inform risk management decisions. It is important to note this advice only concerns slush ice drinks containing glycerol, there is no issue for those products that do not.

1.2 The full rapid risk assessment is still being finalised however, recognising that its conclusions suggest our current advice is insufficient we felt it important to bring this to the Board so we can act ahead of the summer when consumption is likely to rise.

1.3 The Board is asked to:

- Discuss and agree on the proposed immediate interim risk management steps to ensure we take action before the summer holidays
- Provide a steer on whether we should pursue further long-term risk management activity and if so which area(s) to focus

2. Introduction

2.1 Glycerol is a naturally occurring sugar alcohol found in fats and oils. It is used as an additive in the production of low calorie and sugar free slush ice drinks, to prevent the liquid freezing solid. This function was historically performed primarily by sugar, but the increased consumer awareness of the risks of high sugar and moves to low/no sugar drinks more generally has resulted in increased use of glycerol in some slush ice drinks.

2.2 Although toxicity of glycerol is usually considered low, there are concerns about its acute effects on young children when consumed in large amounts over a short period. Despite previous FSA/FSS recommendations that slush ice drinks are unsuitable for children aged 4 or under and that refills are unsuitable for children aged 10 or under, incidents of glycerol intoxication are still being recorded. These cases(around 1 case per 10 million servings in the UK) have been reported in children aged 4 or under, where voluntary labelling containing the FSA advice was not displayed or if present was not followed.

3. Evidence and Discussion

History of glycerol as a food additive

3.1 Glycerol (E 422) is authorised as a food additive per Annex II and Annex III of assimilated Regulation (EC) No. 1333/2008 on food additives. It has a history of use dating back to 1976, when the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated it as a food additive and concluded that it did not require an acceptable daily intake (ADI). Glycerol is authorised for use in 68 food categories.

3.2 Glycerol is permitted for use at '*quantum satis'* level in flavoured drinks, meaning no maximum numerical level is specified. Substances must be used according to good manufacturing practice at levels not higher than necessary to achieve the intended purpose (in this case to maintain the 'slushed' nature of the product) without misleading the consumer. It must be listed as an ingredient (including name and E number), but the amount is not a requirement under the legislation. This information would not be readily available for consumers outside of the home.

3.3 We understand from industry that most slush ice drinks containing glycerol have a concentration of 50,000 mg/L or less.

Incident history

3.4 In early 2023 the FSA/FSS were first notified when two young children became very unwell after consuming slush ice drinks. Symptoms consistent with glycerol intoxication led to their hospitalisation. There have been 9 confirmed UK cases requiring hospitalisation which were subject to incident investigation, with an additional 7 potential cases in the media which were not formally reported to the FSA over the last 3 years. There are 40-50 million servings of slush ice drinks consumed in the UK each year, so these cases equate to around 1 in 10 million servings.

3.5 Cases may be under-reported as the symptoms of mild glycerol intoxication include headaches and feeling sick. Children often consume slush ice drinks at play centres and trampoline parks, where the symptoms may be attributed to other causes and possibly exacerbated by exercise and dehydration. The cases that have been reported to the FSA/FSS are at the more severe end of the spectrum, requiring hospitalisation.

3.6 To note that there have not been similar levels of cases reported in Europe, where use of glycerol in these drinks is less common. We think it is plausible that the soft drink industry levy in the UK that has encouraged reformulation to reduce sugar may have led to higher concentrations of glycerol in these drinks in UK compared to Europe. However, we do not have access to detailed data on glycerol concentrations in drinks in the UK or Europe.

Risk Assessment and Technical Advice

3.7 The use of glycerol as a food additive was re-evaluated by the EFSA Panel on Food Additives and Nutrient Sources added to Food in 2017. This is the most up to date risk assessment available internationally. EFSA concluded, as JECFA had previously, that there was no need for an ADI and there was no safety concern regarding the use of glycerol (E 422) as a food additive. This risk assessment has been the basis of FSA advice.

3.8 An FSA incident risk assessment was commissioned following the initial 2023 case in which a 3.5-year-old child was hospitalised following consumption of approximately 1 litre slush ice drink at a Scottish trampoline park. The risk assessment was based on the 2017 EFSA re-evaluation of glycerol. The conclusion of the risk assessment was that the amount of glycerol a child can consume without experiencing side effects is related to their body weight and there was a potential concern for adverse health impacts in younger children. This initial risk assessment found that, based on average body weight, children above the age of four are considered unlikely to suffer ill effects from drinking one slush ice drink at standard serving size of 350ml.

3.9 In a recent British Medical Journal article, Brothwell et al (2025) reported 21 cases of glycerol intoxication from 2009-2024 (20 between 2018-2024). Some of these cases were known to FSA/ FSS. The median age was 3 years and 6 months, with a range of 2 to 6 years and 9 months. No background information is provided such as the levels of consumption. The authors recommended that slush ice drinks were unsuitable for children under 8 years of age. It is unclear exactly how this conclusion was reached, possibly a combination of body weight and a limit above the age of the oldest known case.

3.10 Given these further cases and interest from the 4 Public Health Agencies, a rapid risk assessment was commissioned in April this year. The assessment concludes that glycerol poses a potential health risk, especially in children aged under 7 with lower-than-average bodyweights. It also concluded that idiosyncratic reactions in children of any age cannot be ruled out, as the mechanism of toxicity remains unknown. This assessment is being finalised and will be published shortly however, given it impacts on our advice to parents we wanted to bring this issue to the Board to ensure our advice was updated ahead of the summer when consumption is likely to rise.

3.11 As the risk assessment makes clear, there is a lack of data regarding the acute toxicity of glycerol and therefore clinical studies are used that were aimed at assessing the dose-response relationship for glycerol when used in a therapeutic setting in adults (for instance in regulating intraocular or intracranial pressure) rather than in a food setting or in children. These studies report a wide range of minimal doses required to produce a physiological response, ranging from 125mg/kg body weight to >1000 mg/kg body weight.

3.12 This range of thresholds leads to a wide range of potential conclusions. The most conservative threshold (125mg/kg) would imply that most adults and children would exceed the level required for a physiological impact after consuming a single serving of a typical glycerol-containing slush ice drink. In contrast, using the higher estimate of 1000mg/kg would predict that only very small children would be at risk of experiencing any physiological effect following consumption of a single slush ice drink. Children on the 5th percentile aged 6 are below the threshold of 1000mg/kg for a single serving of a slush ice drink, however, there is a reported case in a vulnerable 6-year-old. Therefore, under age 7 has been chosen as the upper age bound for the risk management advice on a conservative basis.

3.13 Taking into account the reported rate of adverse events (~1 in 10 million servings) it seems unlikely that the conservative estimate of 125mg/kg represents an accurate safety threshold, even allowing for significant underreporting of milder symptoms. However, without detailed toxicological data it is not currently possible to estimate a more accurate (higher) threshold and therefore there is uncertainty around the scale of potential risk for those age 7 and over, although it will decrease with increasing body weight (and therefore broadly with age).

3.14 Given the wide variation in body weight for children of the same age, using age as a proxy for body weight is always only going to be an approximation. Providing advice based on bodyweight is impractical as many children of the age concerned may not be regularly weighed so a proxy is necessary. The revised risk assessment takes a more precautionary approach to using age as a proxy for body weight by using lower percentiles (5th, 15th and 25th) rather than averages. By always considering the risk for the lowest weight children in an age band the conclusion will inherently be valid for those with higher body weight in that age band so the uncertainty around age as a proxy is reduced, and conclusions should be valid for the vast majority of children of that age. This more conservative approach to linking weight and age is one of the key drivers in identifying the risk to children under 7.

Risk Management Action to date

3.15 At the time of the first incident the FSA/FSS conducted an incident risk assessment using data on typical glycerol levels in this type of product. Assumptions were further refined to take into

account what was known about the incident and the history of use of the product and then used as a basis for the development of proportionate voluntary advice. As a result, the FSA/FSS advised that slush ice drinks are not suitable for children under the age of 4 and should not be sold as such. Manufacturers were also advised to tell retailers that they should not offer free refill promotions to children aged 10 or under.

3.16 The FSA/FSS communicated the issue to local authorities on 13 February 2023, requesting they pass on advice to businesses

- In August 2023, the FSA/FSS published new voluntary industry guidelines for glycerol use in slush ice drinks.
- Educational efforts have included media appearances and seasonal reminders to highlight the risks to parents and caregivers of young children.
- We are aware of at least 2 companies that have reformulated products to reduce glycerol levels to below 50,000 mg/L.

3.17 Following the initial cases associated with slush machines, we have since seen issues with syrups, kits and ready to drink pouches of slush ice drinks which can be used at home. We have responded by advising in our industry guidance that the warnings should be extended to these products and that they also carry the labelling 'product contains glycerol. Not suitable for children 4 years of age and under'. We have built good working relationships with the industry who have been supportive in developing the guidance and addressing issues.

3.18 To gain a better understanding of how glycerol is used by the industry and the inclusion level of glycerol in these types of products on the UK market, Public Analysts will be carrying out sampling of glycerol in slush ice drinks as a part of the 25/26 Retail Surveillance Scheme. It is planned that 70% of samples will be at catering/vending and the remaining 30% will be RTE products and kits for home use. This will provide further evidence to test the assumption of 50,000 mg/L level used in the FSA risk assessments and ascertain whether the market has shifted to lower average inclusion levels. It will also give an indication of whether the current voluntary industry guidance is being followed at point of sale.

Options for the level of precaution in risk management

3.19 The risk assessment gives a clear indication that there is a potential risk to children under 7 from consuming glycerol containing slush ice drinks and provides some quantification of this. Given the uncertainties set out above, particularly the minimal evidence base on thresholds, it does not rule out impacts for children above this age. Further evidence from industry is required to provide more detailed quantification of the risk.

3.20 The evidence is clear that the risk reduces with increasing body weight. We are also not seeing incidents in children of all ages (the oldest report we have is in a vulnerable child age 6yrs 9 months, who would therefore have been included in advice of 'not suitable for under 7'). This absence of older cases implies there is a likely upper limit to the risk, but it is unknown the extent to which this is driven by elements/combinations of behaviour, biological susceptibility or body weight and therefore how reliable this makes age as a proxy for defining this limit. The quantified risk is also based on an assumption of a single portion of a specified size being consumed, we know from the incidents reported that this is not always how these drinks are consumed which adds to the uncertainties.

3.21 In setting a 'should not consume' age limit there is therefore a clear lower limit (under 7). Parents may see our advice and adhere perfectly to the age restriction and other recommended behaviours, such as limiting frequency of consumption. However, they could assume there is a margin for error and allow younger children to consume the drink against the advice. Equally if given an age limit alone parents may assume that consumption is entirely safe above this, whereas if informed of the uncertainties they may also wish to take precautionary action for older children.

3.22 By providing wider advice such as limiting consumption to one drink for children aged 7 to 10 and highlighting the unknowns about the risk to all children, we may help mitigate the risk of the age and other advice on frequency of consumption not being strictly followed by giving parents a broader context for decision making.

3.23 Alternatively, we could also take a more precautionary approach on age (a higher recommended age limit) so that whatever interpretation is given to our advice in terms of actual behaviour it is sufficiently protective. We do not have good evidence on how the public interpret our advice, the assumption we generally make is that they will follow it, so further work would be needed on a suitable margin to apply in balancing the risks, but we could propose an interim more precautionary age change.

3.24 It is not only the behaviour and awareness of parents that is important but also that of businesses. It is their responsibility to ensure the product is safe for its intended consumers. This includes ensuring that sufficient information is available to make an informed decision. Not least whether the slushed ice drinks available do or do not contain glycerol. Labelling needs to be clear and visible to support this, but staff also need to be informed, feel able to pass on information and parents need to be encouraged to ask for it.

Current advice

3.25 Our current advice to the public states that slush ice drinks containing glycerol are not suitable for children under the age of 4 and they should not consume these drinks, due to their potential to cause side-effects such as headaches and sickness, when consumed in excess. Brand owners have been asked to advise customers that sales of such drinks should be accompanied by a written warning visible at point of sale. Business models of free refills are not recommended for children under 10 years of age.

Interim risk management advice

3.26 In line with the conclusions from the rapid risk assessment, and taking account of the uncertainties within it, our current advice requires updating ideally ahead of the summer season. This will require prompt action which in turn requires us to consider action in two parts, interim action that can be taken quickly and further actions that will take longer to develop and implement (see below).

3.27 As an interim risk management approach:

- We **recommend** on the basis of the risk assessment that we revise our advice to state that glycerol containing slush ice drinks **should not be consumed by children under 7**

- We are seeking a **steer** from the Board on whether, given the balance of the risk assessment uncertainties and the evidence from observed cases, we should be more precautionary in our interim risk management approach and consider including in our advice to parents a broader statement of risk for children aged 7 and over.

- We **recommend** retaining and strengthening advice against consumption of multiple slush ice drinks containing glycerol in a short period of time and ensuring this is understood by parents/caregivers as well as businesses.

3.28 With this updated advice we recommend

- We continue with our planned communications campaign to parents, caregivers and businesses ahead of the summer holidays, making sure that the messaging reflects and emphasises the changes to our guidance, and we use these changes to help drive wider media interest.

- We work with the 4 public health agencies to see if there are ways of amplifying and targeting the message at parents and caregivers using their communication networks. We will also ask them to consider whether there is wider health advice that could form part of this, for instance around hydration.

- We will work with industry and businesses to update the voluntary industry guidelines for glycerol use in slush ice drinks including on how to make ingredients and warnings more visible to the public outside the home

- We will be clear that our advice may change further as the evidence base and risk management work continues (see further action below)

3.29 Does the Board **agree** with our recommendations to deliver interim risk management ahead of the summer

Longer term risk management

3.30 In determining risk management actions, we need to think about the proportionality of the action relative to the scale of the risk, the feasibility and whether the action is likely to be effective in mitigating the risk. All the actions set out above, in our view, are clearly proportionate to the risk, rapidly implementable and likely to have a positive impact in mitigating the risk. There are a number of options for taking further action which we have set out below. Further work would be needed to establish exactly what is feasible, and we would welcome a Board steer on which if any areas to focus on.

Supporting an enhanced voluntary approach

3.31 Alongside any ongoing voluntary approach, we could do more to ensure our messages are received and acted upon. We already have in place guidance for industry and parents/caregivers so there is a strong base to build on and to date the industry had been very constructive in their approach to the voluntary scheme. Potential enhancements could include:

- Improved communications

- Improved voluntary labelling

- Stricter point of sale guidance
- Stronger manufacturers guidance
- Working with manufacturers to build the evidence base

3.32 The detail of these would take time to develop to ensure they addressed the wide range of issues, maximised efficacy and drove the correct behaviour change

Mandatory Labelling

3.33 Currently glycerol must be listed as an ingredient (including name and/or E number) but identifying the amount is not a requirement under the legislation and any warnings are currently voluntary.

3.34 We could consider implementing mandatory warning labels for slush ice drink kits and ready to consume products in line with our safety advice along with provision of a requirement for warning at point of sale for vending machines and catering outlets.

3.35 This will require changes to the assimilated Regulation 1169/2011 on the provision of food information to the public. This option would bring in consistency and the ability to enforce the requirement but similarly to voluntary labelling relies on parents/guardians managing consumption and allowing young children to consume them so would need to work in combination with enhanced public awareness of the risks.

Maximum levels

3.36 There is currently no maximum level for glycerol in drinks. We would need to undertake a full risk assessment to ascertain an acceptable use level for glycerol in slush ice drinks for all sectors of the community, ensuring that any proposed level would not cause problems even in the very young.

3.37 We would then need to change legislation to introduce a maximum level for use in food category 14.1.4 flavoured drinks. This option may also come with unintended consequences as it is likely that setting a low maximum level to protect the public will encourage manufacturers to re-introduce sugar into formulations in order to maintain the 'slush' properties of the drink as alternatives may not be readily available. There is currently no evidence on the impact of replacing glycerol with sugar in terms of wider health goals. It could be assumed that these are not generally a 'day to day' drink so large-scale impacts of such a reversion to sugar on individuals might be minimal. However, the increase in availability of home kits will need to be considered in this context.

Banning glycerol in drinks

3.38 Changing legislation to remove the food additive provisions for glycerol in slush ice drinks within food category 14.1.4 flavoured drinks under Market Authorisations would essentially ban its use. This would not require a further risk assessment to derive a safe use level so is potentially a more rapidly available approach. As with the previous option, there may be unintended consequences if glycerol is replaced by sugar in response to such a ban.

Implications of divergence from EU law

3.39 It is worth noting that all the options for longer term risk management, aside from further enhancing the current voluntary approach would require legislation. It would ultimately be for ministers in England, Wales and Scotland to decide whether to bring forward legislation on the advice of the FSA/FSS. In Northern Ireland, the EU food additives legislation, would continue to apply under the terms of the Windsor Framework. In the EU glycerol (E 422) is authorised in accordance with Annex II and Annex III of EU Regulation (EC) No. 1333/2008 and is permitted for use at quantum satis levels in flavoured drinks. However, we note similar precautionary advice against the consumption of slush iced drinks containing glycerol by those under four has been issued in the Republic of Ireland.

3.40 Any GB based legislative changes would lead to divergence from the EU and Northern Ireland. It is worth noting that drinks manufactured in Northern Ireland under EU legislation could continue to be sold in England, Wales and Scotland under the Internal Market Act so we would still need suitable consumer advice. Early engagement with the EU if considering any legislative option would be advisable, particularly given the proposed SPS Agreement announced by the UK Government in May 2025.

4. Conclusions

4.1 The Board is asked to:

- **Discuss and agree** on the proposed immediate interim risk management steps to ensure we take action before the summer holidays

- **Provide a steer** on whether we should pursue further long-term risk management activity and if so which area(s) to focus