

SCIENTIFIC OPINION

Statement on a refined dietary exposure assessment of erythritol (E 968) taking into account additional data provided¹

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)^{2, 3}

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ABSTRACT

Following a request by the European Commission, the Scientific Panel on Food Additives and Nutrient Sources added to Foods (ANS) carried out an assessment of the dietary exposure to erythritol and concluded on the safety of the proposed use in beverages at a maximum use level of 2.5 %, taking into account additional exposure data provided to the Panel. Anticipated exposure to erythritol from its use as food additive including soft-drinks containing a mean concentration of 2.5 % erythritol would be in the range of 0.004-0.04 g/kg bw/day for toddlers, 0-0.05 g/kg bw/day for children, 0-0.08 g/kg bw/day for adolescents, 0-0.14 g/kg bw/day for adults, and 0-0.01 g/kg bw/day for the elderly. At high level, exposure estimates would be in the range of 0.29-0.48 g/kg bw/day (toddlers), 0.13-0.76 g/kg bw/day (children), 0.04-0.50 g/kg bw/day (adolescents), 0.05-0.43 g/kg bw/day (adults), and 0.01-0.25 g/kg bw/day (the elderly). The main categories contributing to the exposure to erythritol were table-top sweeteners and soft drinks for all age groups except toddlers where soft drinks were the only main contributor. The Panel concluded that based on the new data provided on use levels of erythritol in foods and on the basis of the extension of the authorisation for the use of erythritol to soft drinks at a use level of 2.5 % the Margin of Safety of 1.54 is too low to protect children adequately.

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KEY WORDS

Erythritol, laxation, gastrointestinal tolerability.

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SUMMARY

Following a request from the EU Commission, the Scientific Committee on Food (SCF) issued its opinion on erythritol on 5 March 2003 (SCF, 2003). The SCF reached the conclusion that erythritol is safe to use as a food additive. The SCF, however, expressed concerns that the laxative threshold may be exceeded especially by young consumers and through ingestion of erythritol in beverages. Thus, Directive 2006/52/EC of the European Parliament and of the Council amending Directives 94/35/EC and 95/2/EC did not include the use of erythritol in beverages.

The EU Commission has subsequently received a request for the authorisation of the use of erythritol for purposes other than sweetening at a maximum level of 2.5 % in water-based flavoured drinks, energy-reduced or with no added sugar and in milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar. The Panel on Food Additives and Nutrient Sources added to Food (ANS) stated in light of these newly submitted data that erythritol intake resulting from an incorporation rate of 2.5 % in beverages (i.e. 0.59 g/kg bw in a single drinking occasion at the 97.5th percentile) is below the NOAEL for laxative effects (0.71 g/kg bw). The Panel noted that the Margin of Safety (MOS) between this NOAEL and the estimated daily intake of erythritol resulting from an incorporation rate of 2.5 % in beverages is 1.24 and concluded that this MOS is too low to adequately protect children taking into account the fact that erythritol is also used in other food categories. A safety concern was therefore with respect to GI tolerability for the use of erythritol in beverages at a maximum use level of 2.5 %.

Additional data was provided to assist with the consideration of potential effects on total exposure of other food items that could contain erythritol and might be consumed concurrently with a soft drink containing erythritol. The petitioner also provided data on the maximum use level of erythritol which were slightly lower than those reported for the previous ANS opinion together with data on the typical use level. The petitioner concluded that by applying these data to the consumption data from the UK NDNS from 2008-2009 exposures would be lower than those reported by the ANS Panel. Exposure would be up to 0.45 g/kg bw using the newer food consumption data and 95th percentile intakes. When concurrent intake from drinks and all other foods at their maximum use level for only those meals where drinks were consumed was calculated, exposure increased only to 0.46 g/kg bw for a use level in beverages of 2.5 % and to 0.64 g/kg bw for a use levels in beverages of 3.5 %. The petitioner stated that all of these estimates are conservative because they assume that a consumer will choose foods containing the maximum level of erythritol in all possible foods at all times. In view of these new data provided, the Panel performed a refined exposure estimation using the maximum use levels.

For calculation of chronic exposure, intake statistics have been calculated based on individual average consumption over the total survey period excluding surveys with only one day per subject. High level consumption was only calculated for those foods and population groups where the sample size was sufficiently large to allow calculation of the 95th percentile. The Panel estimated chronic exposure for the following population groups: toddlers, children, adolescents, adults and the elderly. Calculations were performed using individual body weights.

Anticipated exposure to erythritol from its use as food additive including soft-drinks containing a mean concentration of 2.5 % erythritol would be in the range of 0.004-0.04 g/kg bw/day for toddlers, 0-0.05 g/kg bw/day for children, 0-0.08 g/kg bw/day for adolescents, 0-0.14 g/kg bw/day for adults, and 0-0.01 g/kg bw/day for the elderly. At high level, exposure estimates would be in the range of 0.29-0.48 g/kg bw/day (toddlers), 0.13-0.76 g/kg bw/day (children), 0.04-0.50 g/kg bw/day (adolescents), 0.05-0.43 g/kg bw/day (adults), and 0.01-0.25 g/kg bw/day (the elderly). The main categories contributing to the exposure to erythritol were table-top sweeteners and soft drinks for all age groups except toddlers where soft drinks were the only main contributor.

The exposure to erythritol decreased when taking into account the newly submitted data on the maximum use levels and the more recent food consumption data in contrast to the data used for the ANS opinion in 2010. However, a wide range of exposure to erythritol was found across the different

surveys in different European member states leading to higher exposures in particular for children. The Panel noted, however, that not all food categories where erythritol is authorised could have been taken into account for its exposure assessment as no usage data were reported for erythritol for all other food categories not indicated in the data provided by the petitioner. Also, MPLs could not be used to estimate exposure since all other food categories are authorised to contain erythritol at the *quantum satis* level.

Based on the exposure data provided by the petitioner resulting from the consumption data from the UK, the MOS would be increased to 1.54 compared to the MOS of 1.24 from the previous ANS opinion. Considering a NOAEL for laxative effects of 0.71 g/kg bw and a use level of 2.5 % in soft drinks, a toddler aged 1-3 years and a default body weight as suggested by the EFSA SC of 12 kg would have to consume 0.34 L soft drink at one drinking occasion to reach this NOAEL. For children aged 3-9 years and a default body weight of 22 kg and for adults and a default weight of 70 kg the amounts of soft drinks to be consumed at one drinking occasion to reach the NOAEL would be 0.63 L and 1.99 L respectively.

The Panel concluded that based on the new data provided on use levels of erythritol in foods and on the basis of the extension of the authorisation for the use of erythritol to soft drinks at a use level of 2.5 % the MOS of 1.54 is too low to protect children (3-9 years) adequately.

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BACKGROUND

In June 2010 the EFSA Panel on Food Additives and Nutrient Sources adopted a statement in relation to the safety of erythritol (E 968) in the light of new data, including a new paediatric study on the gastrointestinal tolerability of erythritol and taking into account the request for the authorisation of use of erythritol in non-alcoholic beverages at a maximum use level of 2.5 % for non-sweetening purposes.

The Panel noted that erythritol intake resulting from an incorporation rate of 2.5 % in beverages is below the No-Observed-Adverse-Effect Level (NOAEL) for laxative effects.

The Panel noted that the margin of safety (MOS) between this NOAEL and the estimated daily intake is too low to ensure that children are adequately protected taking into account the fact that erythritol is also used in other food categories and that therefore there is a safety concern with respect to gastrointestinal tolerability for this use of erythritol in beverages.

The Health and Consumers Directorate-General has received from the same applicant a renewed application that includes a refined exposure assessment. The applicant concludes that intake from drinks and all other foods to which erythritol has been added at the maximum use level would be 0.46 g/kg/bw, per meal period in young children, which is below the NOAEL of for gastrointestinal tolerance of 0.73 g/kg/bw.

TERMS OF REFERENCE

The European Commission asks the European Food Safety Authority to give an opinion, in accordance with Regulation (EC) No 1331/2008⁴ establishing a common authorisation procedure for food additives, food enzymes and food flavourings on the dietary exposure to erythritol and on the safety of the proposed use in beverages at a maximum use level of 2.5 %, taking into account the additional exposure data provided by the applicant.

SUPPORTING DOCUMENTS

Total dietary exposures to erythritol from its use as a sweetening and non-sweetening agent in drinks and foods provided by Cargill R&D Centre Europe.

⁴ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, OJ L 354, 31.12.2008, p.6.

ASSESSMENT

1. Introduction

Following a request by the European Commission, the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) carried out a refined exposure assessment of erythritol as a food additive.

The Scientific Committee on Food (SCF) issued its opinion on erythritol on 5 March 2003 (SCF, 2003). The SCF reached the conclusion that erythritol is safe to use as a food additive. In line with earlier opinions on other polyols, the SCF did not consider it appropriate to set a numerical Acceptable Daily Intake (ADI) for erythritol.

The SCF also noted that erythritol has a laxative effect, but at higher doses than other polyols and concluded that the No Observed Adverse Effect Level (NOAEL) for the laxative effect of erythritol in humans is around 0.5 g/kg bw for a single dose. The SCF expressed concerns that the laxative threshold may be exceeded especially by young consumers and through ingestion of erythritol in beverages. The SCF cautioned that their opinion should not be interpreted as meaning the acceptance of unlimited use in all foods at any technological level because the laxative effect should be borne in mind. Thus, Directive No 2006/52/EC⁵ of the European Parliament and of the Council amending Directives No 94/35/EC⁶ and No 95/2/EC⁷ did not include the use of erythritol in beverages.

The EU Commission has subsequently received a request for the authorisation of the use of erythritol for purposes other than sweetening at a maximum level of 2.5 % in the following beverage categories:

- Water-based flavoured drinks, energy-reduced or with no added sugar
- Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar

In the application dossier additional information was submitted, including a new paediatric study on the gastrointestinal tolerability of erythritol and exposure estimates of erythritol intake per drinking occasion by children.

The Panel on Food Additives and Nutrient Sources added to Food (ANS) stated in 2010 (EFSA Panel on Food Additives and Nutrient Sources (ANS), 2010) in light of these newly submitted data that erythritol intake resulting from an incorporation rate of 2.5 % in beverages (i.e. 0.59 g/kg bw in a single drinking occasion at the 97.5th percentile) is below the NOAEL for laxative effects (0.71 g/kg bw). The Panel noted that the Margin of Safety MOS between this NOAEL and the estimated daily intake of erythritol resulting from an incorporation rate of 2.5 % in beverages is 1.24 and concluded that this MOS is too low for children to be adequately protected, taking into account the fact that erythritol is also used in other food categories. A safety concern was therefore noted with respect to GI tolerability for the use of erythritol in beverages at a maximum use level of 2.5 %.

2. Additional data provided to EFSA

The petitioner provided additional data to assist with the consideration of potential effects on total exposure of other food items that could contain erythritol and might be consumed concurrently with a soft drink containing erythritol. The initial question to be addressed was the definition of a concurrent consumption time interval, since it was necessary to include foods that might have an additive effect

⁵ Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuff. OJ L 204, 26.07.2006, p 10-22.

⁶ European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs. OJ L 237, 10.09.1994.

⁷ European Parliament And Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. OJ L 61, 18.03.1995 pp 1-53.

on the end-point of concern whilst avoiding foods consumed at a sufficient time apart that the effects would not be additive. The petitioner used data from the UK National Diet and Nutrition Survey (NDNS) data for 2008 to 2009. The food consumption diary in this survey records data for each eating occasion over the four survey days. In addition to the survey day, the meal period during which each item is consumed is also reported. The description of ‘meal period’ is unique to this survey and is divided over seven intervals covering the main meal times and the periods in-between.

Two to three hour time intervals were identified for the majority of these meal periods which was considered by the petitioner to provide a convenient method for grouping foods consumed concurrently, whilst avoiding the risk of including foods where there was no potential for an additive effect on gastrointestinal intolerance. This approach has been applied by the petitioner to the estimation of total exposure of UK children aged four to six years to investigate the effect of adding additional uses of erythritol to consumption of non-alcoholic beverages.

The petitioner also provided data on the maximum use level of erythritol which were slightly lower than those reported for the previous ANS opinion together with data on the typical use level. These data are listed in Table 1.

Table 1: Maximum level of erythritol in products from different food categories

| Food category | Typical use level (% by weight) | Maximum use level (% by weight) |
|--|------------------------------------|------------------------------------|
| Table top substitutes | 35 | 97 |
| Sugar free chewing gum | 30 | 60 |
| Sugar free chocolate | 25 | 45 |
| Sweet biscuits/cookies, sugar-free | 3.5 | 7 |
| Low-calorie beverages, including sports drinks | 1.5 | 2.5/3.5 |
| Lozenges/tablets, sugar-free | 50 | 95 |
| Toffee and fudges/chewy candy, sugar-free | 25 | 45 |
| Sweet biscuits/cookies, not sugar-free | 1 | 2 |
| Chocolate, not sugar-free | 1.5 | 4 |
| Hard candies, sugar-free | 25 | 50 |

The petitioner concluded that by applying these data to the consumption data from the UK NDNS from 2008-2009 exposures (Bates et al. 2011) would be lower than those reported by the ANS Panel. Exposure would be up to 0.45 g/kg bw using the newer food consumption data and 95th percentile intakes. When concurrent intake from drinks and all other foods at their maximum use level for only those meals where drinks were consumed was calculated, exposure increased only to 0.46 g/kg bw for a use level in beverages of 2.5 % and to 0.64 g/kg bw for a use levels in beverages of 3.5 %. The petitioner stated that all of these estimates are conservative because they assume that a consumer will choose foods containing the maximum level of erythritol in all possible foods at all times.

The Panel performed a refined exposure estimation based on the new data provided by the petitioner as listed in Table 1 using the maximum use levels.

3. Exposure to erythritol (E 968)

3.1. Food consumption data used for exposure assessment

In 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been built from existing national information on food consumption at a detailed level. Competent authorities in the European countries provided EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of

EFSA ‘Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment’ (EFSA, 2011a).

Overall, the food consumption data gathered at EFSA were collected by different methodologies and thus direct country-to-country comparison should be made with caution.

For calculation of chronic exposure, intake statistics have been calculated based on individual average consumption over the total survey period excluding surveys with only one day per subject. High level consumption was only calculated for those foods and population groups where the sample size was sufficiently large to allow calculation of the 95th percentile (EFSA, 2011a). The Panel estimated chronic exposure for the following population groups: toddlers, children, adolescents, adults and the elderly. Calculations were performed using individual body weights.

Thus, for the present assessment, food consumption data were available from 26 different dietary surveys carried out in 17 different European countries as mentioned in Table 2:

Table 2: Population groups considered for the exposure estimates of erythritol

| Population | Age range | Countries with food consumption surveys covering more than one day |
|--------------------------|---|---|
| Toddlers | from 12 up to and including 35 months of age | Bulgaria, Finland, Germany, Netherlands |
| Children ⁸ | from 36 months up to and including 9 years of age | Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden |
| Adolescents | from 10 up to and including 17 years of age | Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Italy, Latvia, Spain, Sweden |
| Adults | from 18 up to and including 64 years of age | Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Spain, Sweden, UK |
| The elderly ⁴ | Older than 65 years | Belgium, Denmark, Finland, France, Germany, Hungary, Italy |

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from FoodEx classification system has been linked to the Food Classification System as presented in the Commission Regulation (EU) No 1129/2011⁹, part D, to perform exposure estimates.

3.2. Exposure to erythritol

Exposure to erythritol from its use as food additive has been calculated by using maximum use levels as listed in Table 1 combined with national consumption data for the five population groups (Table 2).

High level exposure (typically 95th percentile of consumers only) was calculated by adding the 95th percentile of exposure from one food group (i.e. the one having the highest value) to the mean exposure resulting from the consumption of all other food groups.

This is based on the assumption that an individual might be a high level consumer of one food category and would be an average consumer of the others. This approach has been tested several times by the Panel in re-evaluation of food colours and has shown reasonable correlation with high level total intakes when using the raw food individual consumption data. Therefore, this approach was

⁸ The terms “children” and “the elderly” correspond respectively to “other children” and the merge of “elderly” and “very elderly” in the Guidance of EFSA on the ‘Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment’ (EFSA, 2011b).

⁹ Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) N°1333/2008 of the European Parliament and of the Council establishing a Union list of food additives. The Panel noted that the Commission Regulation (EU) No 1129/2011 of 11 November 2011 will enter into force on June, 1st 2013 but confirms the approved uses of SSL and CSL as food additive as described in previous Directives still active until end of May 2013.

preferred for the calculations based on the MPLs and maximum reported use levels in order to avoid excessively conservative estimates.

However, the Panel noted that its estimates should be considered as being conservative as it is assumed that all processed foods contain erythritol added at the maximum reported use levels.

The Panel noted uncertainties in its exposure estimates based on the inability to calculate exposure for several food categories at a more detailed level as insufficiently robust data on food consumption is available from the EFSA Comprehensive Food Consumption Database. In particular this applies to the use of erythritol in all food categories except sugar-free chewing gum and table-top sweeteners, as these food categories are the only one corresponding directly to food categories in the EFSA comprehensive food consumption database. For these food categories it was assumed that the additive is used for all foods falling into this category, thus leading to overestimation of exposure.

Table 3 summarises the estimated exposure to erythritol from its use as food additive of all five population groups.

Table 3: Summary of anticipated exposure to erythritol from its use as food additive using reported use levels in five population groups (g/kg bw/day)

| | Toddlers (12-35 months) | Children (3-9 years) | Adolescents (10-17 years) | Adults (18-64 years) | The elderly (>65 years) |
|---|----------------------------|-------------------------|------------------------------|-------------------------|----------------------------|
| Estimated exposure using reported use levels | | | | | |
| • Mean | 0.004-0.04 | 0-0.05 | 0-0.08 | 0-0.14 | 0-0.01 |
| • High level ¹⁰ | 0.29-0.48 | 0.13-0.76 | 0.04-0.50 | 0.05-0.43 | 0.01-0.25 |

The main categories contributing to the exposure to erythritol were table-top sweeteners and soft drinks for all age groups except toddlers where soft drinks were the only main contributor.

4. Discussion

An assessment of the exposure to erythritol was made by the Panel taking into account the newly submitted data on the maximum use levels and the more recent food consumption data in contrast to the data used for the ANS opinion in 2010. However, a wide range of exposure to erythritol was found across the different surveys in different European member states leading to higher exposures in particular for children. The Panel noted, however, that these exposure estimates relate to exposure over the entire day and not to a single occasion of consumption and that it is rather unlikely that a frequent concurrent consumption of several food categories containing erythritol at the maximum use level would lead to an exceedance of the NOAEL for laxative effects.

The Panel also noted, however, that not all food categories where erythritol is authorised could have been taken into account for its exposure assessment. No usage data were reported for erythritol for all other food categories not indicated in the data provided by the petitioner. Also, MPLs could not be used to estimate exposure since all other food categories are authorised to contain erythritol at the *quantum satis* level. The main contributor to the exposure to erythritol in this scenario was the food category non-alcoholic flavoured drinks, where the additive at present is not authorised.

The petitioner provided erythritol exposure estimates for children aged 4-6 years based on a use level of 2.5 % in soft drinks of up to 0.45 g/kg bw per meal at the 95th percentile and of up to 0.46 g/kg bw for concurrent intake from drinks and all other foods at their maximum use levels. These exposure estimates based on consumption data from the UK are in line with the exposure estimated based on

¹⁰ Typically 95th percentile of consumers only

consumption data from the EFSA Comprehensive Food Consumption database for several dietary surveys across Europe. Based on the exposure data provided by the petitioner resulting from the consumption data from the UK, the MOS would be increased to 1.54 compared to the MOS of 1.24 from the previous ANS opinion. Considering the exposure estimates listed in Table 3 at the high levels and including those foods where usage data were available, MOS for all day consumption would be 1.48 for toddlers, 0.93 for children, 1.42 for adolescents, 1.65 for adults, and 2.84 for the elderly.

Considering a NOAEL for laxative effects of 0.71 g/kg bw and a use level of 2.5 % in soft drinks, a toddler aged 1-3 years and a default body weight as suggested by the EFSA Scientific Committee of 12 kg would have to consume 0.34 L soft drink at one drinking occasion to reach this NOAEL. For children aged 3-9 years and a default body weight of 22 kg and for adults and a default weight of 70 kg the amounts of soft drinks to be consumed at one drinking occasion to reach the NOAEL would be 0.63 L and 1.99 L respectively.

CONCLUSIONS

The Panel concluded that based on the new data provided on use levels of erythritol in foods and on the basis of the extension of the authorisation for the use of erythritol to soft drinks at a use level of 2.5 % the Margin of Safety of 1.54 is too low to protect children (3-9 years) adequately.

DOCUMENTATION PROVIDED TO EFSA

1. Total dietary exposures to erythritol from its use as a sweetening and non- sweetening agent in drinks and foods. July 2012. Submitted by Cargill R & D Centre Europe.
2. Application for use of erythritol in beverages at a level of maximum 2.5 %. July 2009. Submitted by Cargill R & D Centre Europe.

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GLOSSARY AND ABBREVIATIONS

| | |
|-------|---|
| ADI | Acceptable Daily Intake |
| ANS | Scientific Panel on Food Additives and Nutrient Sources added to Food |
| EC | European Commission |
| EFSA | European Food Safety Authority |
| EU | European Union |
| MOS | Margin of Safety |
| NDNS | National Diet and Nutrition Survey |
| NOAEL | No-Observed-Adverse-Effect Level |
| SCF | Scientific Committee on Food |