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Scientific opinion on the safety of the extension of use of steviol glycosides (E 960) as a food additive

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)

Abstract

Following a request from the European Commission, EFSA carried out an exposure assessment of steviol glycosides (E 960) arising from their use as a food additive, taking into account the proposed extension of uses. In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion on the safety of steviol glycosides (E 960) and established an Acceptable Daily Intake (ADI) of 4 mg/kg body weight (bw) per day. Conservative estimates of exposure, in both adults and children, suggested that it is likely that the ADI would be exceeded at the maximum proposed use level. In 2011, EFSA carried out a revised exposure assessment of steviol glycosides based on revised proposed uses and concluded that, even if the estimates were reduced, the high-level dietary exposure in children may still exceed the ADI. A request for extension of use in hot beverages has already been evaluated by EFSA in 2014. The current revised exposure estimates are based on the currently authorised uses, the EFSA Comprehensive European Food Consumption Database and the proposed extension of use for tea beverages and instant coffee and instant cappuccino products up to 29 mg/L of steviol equivalents, rather than 10 mg/L, as assessed in the previous 2014 EFSA opinion. The Panel noted that, overall, the mean exposure estimates remain below the ADI of 4 mg/kg bw per day for all population groups, with the exception of toddlers (in one country) at the upper range of the high-level exposure estimates (95th percentile: 4.3 mg/kg bw per day), which remains above the ADI. The Panel concluded that dietary exposure to steviol glycosides (E 960) is similar to the exposure estimated in 2014 and therefore does not change the outcome of the safety assessment.

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Keywords: food additive, steviol glycosides, E 960, sweetener, extension of use

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Summary

Following a request from the European Commission to take into account an extension of use of steviol glycosides (E 960) as food sweeteners, a revised exposure assessment for five population groups was carried out based on the maximum permitted levels (MPLs) authorised in Annex II to Regulation (EC) No 1333/2008 and the extension of use at the levels proposed by the applicant for the food category 14.1.5 Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products (sub-category 14.1.5.2 Other).

Steviol glycosides (E 960) are natural sweet-tasting constituents and their use as food sweeteners is regulated under the European Parliament and Council Regulation (EC) No 1333/2008 on food additives. Stevioside was previously evaluated by the Scientific Committee on Food (SCF) in 1984, 1988 and 1999 (SCF, 1984, 1989, 1999). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) reviewed the safety of steviol glycosides (E 960) in 2000, 2005, 2006, 2007 and 2009 (JECFA, 2000, 2005, 2006, 2007, 2009). The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) evaluated the safety of steviol glycosides (E 960) used as food additives in 2010 and established an Acceptable Daily Intake (ADI) of 4 mg/kg body weight (bw) per day (EFSA ANS Panel, 2010). Refinement of the estimated intake was performed by EFSA in 2011 and in a requested extension of use in 2014 (EFSA ANS Panel, 2011a, 2014).

The present exposure estimates of steviol glycosides (E 960) are based on the MPLs of use currently authorised in Annex II to Regulation (EC) No 1333/2008 and take into consideration the maximum levels as proposed by the applicant for an extension of use in tea, coffee, herbal infusion beverages, instant coffee and instant cappuccino products up to 29 mg/L of steviol equivalents, rather than 10 mg/L, as assessed in the previous 2014 EFSA opinion (EFSA ANS Panel, 2014).

The individual raw consumption data for five population groups (toddlers, children, adolescents, adults and the elderly) from the EFSA Comprehensive European Food Consumption Database were used for the calculation of the revised exposure assessment of steviol glycosides (E 960).

According to this requested extension of use, the impact on dietary intake appears to be negligible in comparison with the revised estimate of 2014. The Panel noted that, overall, the mean exposure estimates remain below the ADI of 4 mg/kg bw per day for all population groups, with the exception of toddlers (in one country) at the upper range of the high-level exposure estimates (95th percentile: 4.3 mg/kg bw per day), which remains above the ADI.

The Panel concluded that dietary exposure to steviol glycosides (E 960) is similar to the exposure estimated in 2014 and therefore does not change the outcome of the safety assessment (EFSA ANS Panel, 2010, 2014).

Table of contents

Abstract.....	1
Summary.....	3
1. Introduction.....	5
1.1. Background and Terms of Reference as provided by the requestor	5
1.1.1. Background	5
1.1.2. Terms of Reference.....	6
1.2. Interpretation of the Terms of Reference.....	6
1.3. Additional information	6
2. Data and Methodologies	7
2.1. Data.....	7
2.1.1. Identity of the substance.....	7
2.1.2. Uses and use levels of steviol glycosides (E 960).....	7
2.1.3. Reported data provided by the applicant on the extension of use of steviol glycosides (E 960) in foods.....	9
2.1.4. Food consumption data used for the exposure assessment.....	10
2.2. Methodologies	11
3. Assessment	12
3.1. Exposure assessment	12
3.1.1. Steviol glycosides (E 960) from its use as food additive	12
3.1.2. Main food categories contributing to exposure to steviol glycosides (E 960).....	13
3.1.3. Uncertainty analysis	14
4. Discussion	15
5. Conclusion.....	15
Documentation provided to EFSA	16
References.....	16
Abbreviations	18
Appendix A – Summary of the total estimated exposure of steviol glycosides (E 960) using MPLs and levels proposed for the extension of use per age class and survey: mean and high level (mg/kg bw per day)	19

1. Introduction

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 1333/2008¹ on food additives. Only food additives that are included in the Union list, in particular to Annex II to that Regulation, may be placed on the market and used in foods under the conditions of use specified therein.

Steviol glycosides (E 960) is currently an authorised food additive in the European Union under Annex II of Regulation (EC) 1333/2008 for use in several food categories, at *quantum satis* and maximum levels ranging between 20 and 3 300 mg/kg.

In 2010, the European Food Safety Authority (EFSA) Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion² on the safety of steviol glycosides as a food additive. It established an Acceptable Daily Intake (ADI) for steviol glycosides, expressed as steviol equivalents, of 4 mg/kg bodyweight (bw) per day. Conservative estimates of steviol glycosides exposure, both in adults and in children, suggest that is likely that the ADI would be exceeded at the maximum proposed use levels.

Taking into account that conclusion, EFSA was requested to carry out a revised exposure assessment of steviol glycosides from its use as a food additive, for children and adults, based on revised proposed uses.

In 2011, EFSA published a statement³ on a new exposure assessment. Despite the revised uses and based on the data available, EFSA concluded that in adults and children the ADI can be exceeded for high-level consumers.

In 2013, the Health and Consumer Directorate-General (DG SANCO) received an application from the industry requesting the authorisation of use of steviol glycosides in hot beverages, sub food category 14.1.5.2 Other (food category 14.1.5 Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products).

In 2014, EFSA ANS Panel adopted a scientific opinion⁴ on the revised exposure assessment of steviol glycosides (E 960) for the proposed uses as a food additive, taking into account the request for authorisation of the use of steviol glycosides in sub food category 14.1.5.2 at different maximum levels.

Considering that extension of use of steviol glycosides (E 960), the Panel concluded that dietary exposure to steviol glycosides is considerably lower than that in the previous exposure assessment. Overall, the revised exposure estimates for all age groups remain below the ADI of 4 mg/kg bw per day, except for toddlers at the upper range of the high level (95th percentile) estimates, in one country.

In 2014, DG SANCO received an addendum to that application from the industry (Tata Global Beverages GB Ltd) requesting that, following further sensory research, the maximum level of steviol glycosides for tea beverages and instant coffee & instant cappuccino products is increased from 10 mg/L to 29 mg/L. This is because the previous maximum level submitted (10 mg/L) does not deliver an acceptable level of sweetness to the average European consumer.

¹ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

² EFSA Journal 2010;8(4):1537 [84 pp.].

³ EFSA Journal 2011;9(1):1972 [19 pp.].

⁴ EFSA Journal 2014;12(5):3639 [23 pp.].

1.1.2. Terms of Reference

The European Commission asks the European Food Safety Authority to provide a scientific opinion, in accordance with Regulation (EC) No 1331/2008⁵ establishing a common authorisation procedure for food additives, food enzymes and food flavourings, on the safety of the proposed extension of use of steviol glycosides (E 960) as a food additive in the sub food category 14.1.5.2 Other (as in EFSA-Q-2013-00433), but considering the increase of the maximum use level from 10 mg/L to 29 mg/L for the tea beverages and instant-coffee and instant cappuccino products.

Therefore, that food additive (E 960, sweetener) is to be added at a maximum level of:

- 29 mg/L in tea beverages and instant-coffee and instant cappuccino products
- 29 mg/L in coffee and herbal infusion beverages and
- 20 mg/L in malt-based and chocolate/cappuccino flavoured drinks.

1.2. Interpretation of the Terms of Reference

In order to address the safety of this proposed extension of use, the Panel has decided that a comparison of the exposure estimates, including the increased use levels, with those reported in the EFSA scientific opinion in 2014 (EFSA ANS Panel, 2014) would be an adequate approach.

The Panel considered that the available toxicological assessment of steviol glycosides (EFSA ANS Panel, 2010), which established the ADI of 4 mg/kg bw per day, remains valid and there is no need to reconsider this to address the Terms of Reference.

1.3. Additional information

Steviol glycosides (E 960) are natural sweet-tasting constituents extracted purified from the leaves of the plant *Stevia rebaudiana*. Stevioside and rebaudioside A are the component glycosides of principal interest for their sweetening properties. Associated glycosides include rebaudioside C, dulcoside A, rubusoside, steviolbioside and rebaudioside B, which are generally present in preparations of steviol glycosides at levels lower than stevioside or rebaudioside A.

The use of steviol glycosides (E 960) as a food sweetener is regulated under European Parliament and Council Regulation (EC) No 1333/2008 on food additives. Stevioside as a sweetener was previously evaluated by the Scientific Committee on Food (SCF) in 1984, 1988 and 1999 (SCF, 1984, 1989, 1999). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) reviewed the safety of steviol glycosides in 2000, 2005, 2006, 2007 and 2009 (JECFA, 2000, 2005, 2006, 2007, 2009) and established an ADI for steviol glycosides (E 960) of 4 mg/kg bw per day, expressed as steviol equivalents.

In its opinion of 14 April 2010, the EFSA ANS Panel established an ADI of 4 mg/kg bw per day for steviol glycosides (E 960), expressed as steviol equivalents. In the same opinion, the ANS Panel evaluated the safety of the use of steviol glycosides (E 960) and, on the basis of the intended uses requested by the three applicants, concluded that the established ADI would probably be exceeded at the maximum proposed use levels for both children and adults (EFSA ANS Panel, 2010). In 2011, EFSA carried out a revised exposure assessment of steviol glycosides (E 960), based on revised proposed uses, and concluded that high-level exposure estimates for children are above the ADI for several European countries (EFSA ANS Panel, 2011a).

Since the last exposure assessment of steviol glycosides performed in 2011, maximum permitted levels (MPLs) of steviol glycosides (E 960) in foods have been defined in Commission Regulation (EU) No 1131/2011⁵ amending Annex II to Regulation (EC) No 1333/2008 (Table 1).

In April 2014, the EFSA ANS Panel adopted a scientific opinion after a request for the authorisation of use of steviol glycosides (E 960) as a food additive (sweetener) for the food category 14.1.5 Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant

⁵ Regulation (EU) No 1131/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regard to steviol glycosides. OJ L 295, 12.11.2011, p. 205–211.

fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products (sub-category 14.1.5.2 Other).

In order to ensure an acceptable level of sweetness for the average European consumer, the same applicant recently submitted a new request to revise the maximum use level, changing it from 10 mg/L, as assessed in the EFSA 2014 opinion (EFSA ANS Panel, 2014), to 29 mg/L for tea beverages, instant coffee and instant cappuccino products.

Following this request from the European Commission, EFSA performed a revised exposure assessment of steviol glycosides (E 960) from their use as food additives, taking into account the proposed extension of use at the levels presented in the terms of reference (ranging from 10 mg/L as assessed in the EFSA 2014 opinion to 29 mg/L for different hot beverages).

2. Data and Methodologies

2.1. Data

The applicant has provided a revised exposure estimate for the intake of steviol glycosides (E 960) in the European Union (EU) based on United Kingdom (UK) consumption data and referring to new innovative products within the hot beverages category only. It is reported that “it does not account for the *quantum satis* addition of stevia as a table-top sweetener since stevia has already been approved for use as a table-top sweetener within food and drinks in Europe”.

2.1.1. Identity of the substance

The Panel noted that the specifications of steviol glycosides (E 960) to be used for the extension of use should comply with those set out in Commission Regulation (EU) No 231/2012⁶.

Steviol glycosides (extracted from the leaves of the *Stevia rebaudiana* Bertoni plant) contain several components: steviol, stevioside, rebaudioside A, rebaudioside C, dulcoside A, rubusoside, steviolbioside, rebaudioside B, rebaudioside D, rebaudioside E and rebaudioside F. The composition should be not less than 95 % stevioside, rebaudiosides A, B, C, D, E and F, steviolbioside, rubusoside and dulcoside on the dried basis, and the final product should consist mainly (at least 75 %) of stevioside and/or rebaudioside A.

2.1.2. Uses and use levels of steviol glycosides (E 960)

MPLs of use of steviol glycosides (E 960) have been defined in Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives, as amended.

Steviol glycosides (E 960) is a sweetener authorised in the EU with MPLs ranging from 20 to 3 300 mg/kg in foods. In various forms of table-top sweeteners (Food Categorisation System (FCS) category 11.4), they are authorised at *quantum satis*.

Table 1 summarises foods that are permitted to contain steviol glycosides (E 960) and the corresponding MPLs as set out in Annex II to Regulation (EC) No 1333/2008, as amended.

⁶ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.03.2012, p. 1–295.

Table 1: MPLs of steviol glycosides (E 960) in foods according to Annex II to Regulation (EC) No 1333/2008

FCS category number^(a)	FCS food category	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
01.4	Flavoured fermented milk products including heat-treated products	Only energy-reduced products or with no added sugar	100
03	Edible ices	Only energy-reduced or with no added sugar	200
04.2.2	Fruit and vegetables in vinegar, oil or brine	Only sweet–sour preserves of fruits and vegetables	100
04.2.4.1	Fruit and vegetable preparations excluding compote	Only energy-reduced	200
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EC	Only energy-reduced jams and jellies and marmalades	200
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC	Only energy-reduced jams, jellies and marmalades	200
04.2.5.3	Other similar fruit or vegetable spreads	Only dried-fruit-based sandwich spreads, energy-reduced or with no added sugar	200
05.1	Cocoa and chocolate products as covered by Directive 2000/36/EC	Only energy-reduced or with no added sugars	270
05.2	Other confectionery including breath-freshening microsweets	Only cocoa or dried fruit based, energy-reduced or with no added sugar	270
05.2	Other confectionery including breath-freshening microsweets	Only cocoa, milk, dried fruit or fat based sandwich spreads, energy-reduced or with no added sugar	330
05.2	Other confectionery including breath-freshening microsweets	Only confectionery with no added sugar	350
05.2	Other confectionery including breath-freshening microsweets	Only breath-freshening microsweets, with no added sugar	2 000
05.2	Other confectionery including breath-freshening microsweets	Only strongly flavoured freshening throat pastilles with no added sugar	670
05.3	Chewing gum	Only with no added sugar	3 300
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 04.2.4	Only confectionery with no added sugar	330
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 04.2.4	Only cocoa or dried fruit based, energy-reduced or with no added sugar	270
06.3	Breakfast cereals	Only breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy-reduced or with no added sugar	330
07.2	Fine bakery wares	Only essoblaten—wafer paper	330
09.2	Processed fish and fishery products including molluscs and crustaceans	Only sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans and molluscs	200
11.4.1	Table-top sweeteners in liquid form		QS ^(b)
11.4.2	Table-top sweeteners in powder form		QS ^(b)
11.4.3	Table-top sweeteners in tablets		QS ^(b)
12.5	Soups and broths	Only energy-reduced soups	40
12.6	Sauces	Except soy-bean sauce (fermented and non-fermented)	120
12.6	Sauces	Only soy-bean sauce (fermented and non-fermented)	175
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		330

FCS category number ^(a)	FCS food category	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)		270
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	Only energy-reduced or with no added sugar	100
14.1.4	Flavoured drinks	Only energy-reduced or with no added sugar	80
14.2.1	Beer and malt beverages	Only alcohol-free beer or with an alcohol content not exceeding 1.2 % vol.; "bière de table/tafelbier/table beer" (original wort content less than 6 %) except for "obergäriges einfachbier"; beers with a minimum acidity of 30 milli- equivalents expressed as naoh; brown beers of the "oud bruin" type	70
14.2.8	Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks		150
15.1	Potato-, cereal-, flour- or starch-based snacks		20
15.2	Processed nuts		20
16	Desserts excluding products covered in categories 1, 3 and 4	Only energy-reduced or with no added sugar	100
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms		670
17.2	Food supplements supplied in a liquid form		200
17.3	Food supplements supplied in a syrup-type or chewable form		1 800

QS: *Quantum satis*

(a): FCS, Food Categorisation System (food nomenclature) presented in Annex II to Regulation (EC) No 1333/2008.

(b): In the previous EFSA Statement on steviol glycosides (EFSA ANS Panel, 2014), the maximum use level of 12 000 mg/kg reported by a data provider was used.

2.1.3. Reported data provided by the applicant on the extension of use of steviol glycosides (E 960) in foods

The applicant proposed an extension of use of the sweetener steviol glycosides (E 960) to include the food category coffee, coffee substitutes, tea, herbal infusions and other hot cereal and grain beverages, excluding cocoa (FCS category 14.1.5).

In order to demonstrate that the existing risk assessment for steviol glycosides is not affected, the applicant calculated what the "typical" contribution of steviol glycosides to the maximum permitted intake level would be if authorisation was extended to include the full "hot beverages" category. The calculation below is reported in the dossier provided by the applicant as an example to demonstrate the typical amount of steviol glycosides that would be required for sweetening purposes to develop innovative new products of:

- tea
- coffee
- herbal infusion beverages

- instant coffee and instant cappuccino products
- malt-based and chocolate-/cappuccino-flavoured beverages.

As reported in the dossier, for a tea beverage sweetened with steviol glycosides, approximately 29 mg/L of steviol equivalents would be needed to provide sufficient sweetness to the beverage. To calculate the amount of steviol equivalents that is likely to be consumed in a day, this concentration is multiplied by the average number of cups of tea that is consumed in a day in the UK, which is 3.5 for a cup volume of 0.235 L, resulting in an daily amount of steviol equivalents consumed of 23.8 mg.

For sweetened instant coffee, this concentration of steviol equivalents (29 mg/L) is multiplied by the average number of cups of coffee that is consumed in a day in the UK, which is 2.72 for a cup volume of 0.235 L, resulting in a daily amount of steviol equivalents consumed of 18.5 mg.

For sweetened malt-based beverages, a concentration of 20 mg/L steviol equivalents is required and, at an estimated consumption per capita of two to three servings per day of 0.2 L each, a steviol consumption of approximately 14 mg per day was derived.

2.1.4. Food consumption data used for the exposure assessment

EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (see Guidance of EFSA "Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment" (EFSA, 2011b)).

The food consumption data gathered by EFSA were collected using different methodologies and, thus, direct country-to-country comparisons should be made with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced by subjects' possible underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database represents the best available source of food consumption data across Europe at present.

Food items selected for the revised exposure assessment of steviol glycosides (E 960)

The food categories in which the use of steviol glycosides (E 960) is authorised and those in which extension of use is proposed were selected from the nomenclature of the Comprehensive Database (FoodEx classification system) at a detailed level (up to FoodEx level 4) (EFSA, 2011c).

Some of these foods are not referenced in the FoodEx classification system and therefore could not be included in the present exposure assessment. This may have led to an underestimation of exposure. These foods are described below (in ascending order of the FCS code):

- 05.4. Decorations, coatings and fillings, except fruit-based fillings covered by category 04.2.4: this category covers any confectionery product generally used for decorating and filling of foodstuffs, e.g. fine bakery wares, edible ices, candy and confections. This food category is not available in the FoodEx nomenclature, but foodstuffs that are likely to be filled or decorated (e.g. edible ices, candies, etc.) are included in the assessment.
- 07.2. Fine bakery wares: the MPL is restricted to "only essoblaten—wafer paper". This is a niche product which is not referenced in the FoodEx classification system. Moreover, considering the whole food category "07.2. Fine bakery wares" for the exposure assessment would lead to a large overestimation. Therefore, this food was not taken into account in the present exposure estimates.

Other limitations of the present exposure estimates, which are the result of the linkage between the FoodEx classification system and the FCS (Annex II of Regulation (EC) No 1333/2008), are listed below (in ascending order of the FCS code). This results in an overestimation of exposure:

- 05.2. Other confectionery including breath-freshening microsweets: it is not possible within the FoodEx classification to reflect all the restrictions/exceptions applying to the use of steviol glycosides (E 960) in the foods under category 05.2 and their MPLs; therefore, the highest MPL of 2 000 mg/kg was assigned to the entire food category.
- 17. Food supplements: it is not possible to differentiate between the forms of the food supplements (e.g. supplements supplied in a liquid form versus supplements supplied in a syrup-type or chewable form) within FoodEx codes; thus, the MPL of 1 800 mg/kg was applied for the whole category of food supplements.

It should be noted that the restrictions/exceptions “only energy-reduced” and “with no sugar added” that apply to several of the food categories in which steviol glycosides (E 960) are authorised (Table 1) could not be, in their majority, respected, with the exception of flavoured drinks, chewing gum and confectionery. The MPLs were therefore applied to the related general food categories, including foods with normal energy content and/or with sugar added.

Further refinements were made in the following food categories:

- 04.2.2. Fruit and vegetables in vinegar, oil or brine; 04.2.4.1. Fruit and vegetable preparations excluding compote; 04.2.5.1. Extra jam and extra jelly as defined by Directive 2001/113/EC; 04.2.5.2. Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC; and 04.2.5.3. Other similar fruit or vegetable spreads: the specific requirements (e.g. only foods in vinegar, oil or brine, excluding compote, etc.) were respected in the FoodEx classification for the majority of food categories.
- 11.4. Table-top sweeteners in powder form or tablets: in these food categories, the use of steviol glycosides (E 960) is authorised at *quantum satis*. In order to include them in the exposure estimates, the value of 12 000 mg/kg steviol glycosides (E 960), expressed as steviol equivalents and retrieved from the previous EFSA exposure assessment (EFSA, 2011b), was used.
- 12.6. Sauces: it was possible to differentiate between soy-bean sauce and other sauces; therefore, different MPLs as set by the legislation were assigned, respecting this restriction.

2.2. Methodologies

The current “Guidance for submission for food additive evaluations” (EFSA ANS Panel, 2012) has been followed by the ANS Panel for the evaluation of the proposed extension of the authorisation of the already authorised food additive steviol glycosides (E 960).

Exposure to steviol glycosides (E 960) from its use as a food additive was calculated using MPLs as listed in Table 1 and using the proposed extension of use as provided by the applicant. The Panel noted that these exposure estimates are conservative, as it is assumed that all processed foods contain steviol glycosides (E 960) at the MPLs or at the proposed use levels in all food categories.

For calculation of chronic exposure, intake statistics have been calculated based on individual consumption data over the total survey period excluding surveys with only one day per subject, which are considered as inadequate to assess repeated dietary exposure as suggested by the EFSA Working Group on Food Consumption and Exposure (EFSA, 2011b). High-level exposure was calculated for only those population groups for which 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.

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

Table 2: Population groups considered for the exposure estimates of steviol glycosides (E 960)

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

(a): The terms "children" and "the elderly" correspond, respectively, to "other children" and the merge of "elderly" and "very elderly" in the Guidance of EFSA on the "Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment" (EFSA, 2011b).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011c). Nomenclature from the FoodEx classification system has been linked to the FCS as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, FoodEx food codes were matched to the FCS food categories and the exposure was calculated by multiplying the current MPLs and the proposed extension of use provided by the applicant for each food group with their respective consumption amount per kilogram body weight separately for each individual in the database, calculating the sum of exposure for each survey day for the individual and then deriving the daily mean for the survey period. Based on the individual exposures, the mean and 95th percentile exposures were calculated for the total survey population for each survey separately and for the five population groups described in Table 2.

3. Assessment

3.1. Exposure assessment

3.1.1. Steviol glycosides (E 960) from its use as food additive

The estimated exposure to steviol glycosides (E 960) from its use as a food additive at the current MPLs and the proposed extension of use for all five population groups is reported on Table 3.

Detailed results by population group and survey are presented in Appendix A.

Table 3: Summary of anticipated exposure to steviol glycosides (E 960) from its use as a food additive at the current MPLs and the proposed extension of use in five population groups (range (minimum–maximum) across the dietary surveys)

	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Estimated exposure (mg/kg bw per day) using MPLs and the proposed extension of use					
Mean	0.6–2.4	0.5–1.8	0.2–0.8	0.1–1.1	0.1–0.5
High level	2.0–4.3	1.4–3.9	0.6–1.9	0.5–2.3	0.4–1.4

For comparative purposes, the intake assessment of steviol glycosides (E 960) as estimated in the EFSA scientific opinion of 2014 (EFSA ANS Panel, 2014) is reported in Table 4.

Table 4: Summary of anticipated exposure to steviol glycosides (E 960) from its use as a food additive reported in the previous EFSA assessment (MPLs and the proposed extension of use: EFSA ANS Panel, 2014) in five population groups (range (minimum–maximum) across the dietary surveys)

	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Estimated exposure (mg/kg bw per day) using MPLs and the proposed extension of use					
Mean	0.6–2.4	0.5–1.8	0.2–0.7	0.1–1.0	0.1–0.4
High level	2.0–4.3	1.3–3.9	0.6–1.8	0.4–2.2	0.3–1.3

The mean estimates of the current exposure assessment to steviol glycosides (E 960) remain below the ADI of 4 mg/kg bw per day in all population groups. At the high levels of exposure (95th percentile), the ADI is exceeded for toddlers at the upper range of the exposure estimates (4.3 mg/kg bw per day) in one country (Appendix A).

3.1.2. Main food categories contributing to exposure to steviol glycosides (E 960)

The main food categories contributing to exposure to steviol glycosides (E 960) using MPLs (> 5 % contributing to the total mean exposure (mg/kg bw per day) in five population groups) and the number of surveys in which each food category is contributing are given in Table 5.

Table 5: Main food categories contributing to exposure to steviol glycosides (E 960) based on MPLs

FCS category number	FCS food categories	Toddlers	Children	Adolescents	Adults	The elderly
		Range of percentage contribution to the total exposure (number of surveys)^(a)				
01.4	Flavoured fermented milk products including heat-treated products	7.9–51.1 (7)	8.0–39.4 (13)	6.1–22.3 (8)	6.0–19.6 (10)	5.5–13.7 (6)
03	Edible ices	6.5–30.2 (4)	5.8–28.3 (15)	6.5–33.1 (11)	5.4–23.1 (7)	7.1–17.7 (2)
04.1	Unprocessed fruit and vegetables			7.3 (1)		
04.2	Processed fruit and vegetables	5.8–17.4 (3)	5.4–17.3 (8)	5.0–14.3 (5)	6.5–19.4 (10)	8.8–24.4 (7)
05.1	Cocoa and chocolate products as covered by Directive 2000/36/EC	6.7–17.9 (6)	8.5–22.2 (13)	5.8–31.5 (12)	5.1–19.2 (12)	5.4–10.7 (2)
05.2.2	Other confectionery without added sugar	7.1 (1)				
05.4.2	Chewing gum without added sugar		9.2 (1)	10.3 (1)	6.0–7.8 (2)	
06.3	Breakfast cereals	5.5–15.5 (5)	5.7–37.9 (14)	7.4–41 (12)	5.3–30 (12)	9.0–25.3 (3)
09.2	Processed fish and fishery products including molluscs and crustaceans	5.4–6.1 (2)	6.9–12.9 (2)	5.9–6.1 (2)		
11.4	Table-top sweeteners				6.4–10.6 (7)	11.8–14.4 (4)
12.5	Soups and broths	8.3 (1)	7.6–17.3 (3)	7.1–17.9 (2)	9.5–23.1 (2)	6.3–16.8 (2)
12.6	Sauces		5.2–9.2 (7)	6.4–13.9 (7)	5.1–11.2 (8)	6.8–8.1 (3)

FCS category number	FCS food categories	Toddlers	Children	Adolescents	Adults	The elderly
		Range of percentage contribution to the total exposure (number of surveys) ^(a)				
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	11.7–48.0 (2)	36.2 (1)		9.3–18 (2)	
14.1.4.2	Flavoured drinks with sweeteners	5.6–22.6 (2)	6.7–12.0 (5)	11.0–31.2 (5)	5.7–36.8 (10)	5.2 (1)
14.1.5	Coffee, tea, herbal and fruit infusions, chicory, tea; tea, herbal and fruit infusions, and chicory extracts; tea, plant, fruit ... etc	15.4 (1)	5.0–20.1 (5)	5.7–24.5 (7)	7.1–45.6 (15)	12.1–33.6 (7)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts				5.7–6.2 (2)	
16	Desserts excluding products covered in categories 1, 3 and 4	14.1–14.1 (2)	5.8–11.5 (5)	8.2 (1)	5.6 (1)	6.5 (1)
17	Food supplements as defined in Directive 2002/46/EC[5] excluding food supplements for infants and young children				5.3–8.4 (2)	8.5–14.5 (2)
99	Unclassified foods			8.7 (1)	17.0–26.7 (2)	29.7 (1)

(a): The total number of surveys may be greater than the total number of countries as listed in Table 2, as some countries submitted more than one survey for a specific age range.

3.1.3. Uncertainty analysis

Uncertainties in the exposure assessment of steviol glycosides (E 960) have been discussed above. The sources of uncertainty that exist, according to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2006), are summarised in Table 6.

Table 6: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate to steviol glycosides (E 960)

Sources of uncertainty	Direction
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/-
Use of data from food consumption surveys of only a few days to estimate long-term (chronic) exposure	+
Correspondence of MPLs to the food items in the EFSA Consumption Database: uncertainties on which precise types of food the levels refer to	+/-
Use of the Food Additives Intake Model (FAIM) tool nomenclature (FoodEx level 2) for some food categories and up to FoodEx level 4 for those for which it is possible/few food categories not available in the EFSA Comprehensive Database	+/-
Food categories selected for the exposure assessment: exclusion of food categories owing to missing FoodEx linkage	-
Food categories selected for the exposure assessment: inclusion of food categories without considering the restriction/exception	+
Occurrence data: MPLs considered applicable for all items within the entire food category	+
Use levels considered for table-top sweeteners	+/-

+: uncertainty with the potential to cause overestimation of exposure;

-: uncertainty with the potential to cause underestimation of exposure.

The Panel considered the impact of the uncertainties in the exposure assessment and concluded that, overall, uncertainty could lead to an overestimation of the calculated exposure estimates.

4. Discussion

Following a request from the European Commission to take into account an extension of use of steviol glycosides (E 960) as a food sweetener, a revised exposure assessment for five population groups was carried out based on the MPLs authorised in Annex II to Regulation (EC) No 1333/2008 and the extension of use at the levels proposed by the applicant for the food category 14.1.5. Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products (sub-category 14.1.5.2. Other).

This request can be considered as a revision of a previous one (EFSA ANS Panel, 2014) with different levels of steviol glycosides (E 960) being requested (increased from 10 mg/L, as assessed by EFSA in 2014, to 29 mg/L) to ensure a different sweetening potential for tea beverages, instant coffee and instant cappuccino products.

According to this requested change, the impact on dietary intake appears to be negligible, and the Panel noted that, overall, the mean exposure estimates remain below the ADI of 4 mg/kg bw per day for all population groups, with the exception of toddlers (in one country) at the upper range of the high-level exposure estimates (95th percentile: 4.3 mg/kg bw per day), which remains above the ADI.

5. Conclusion

The Panel concluded that dietary exposure to steviol glycosides (E 960) is similar to the exposure estimated in 2014 and therefore does not change the outcome of the safety assessment (EFSA ANS Panel 2010, 2014).

Documentation provided to EFSA

1. Technical dossier for the Extension of Authorisation of Steviol Glycosides to include the Hot Beverages Category (in accordance with (EU) No 234/2011). Version of May 2015. Submitted by Tata Global Beverages GB Ltd.

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Abbreviations

ADI	Acceptable Daily Intake
ANS Panel	Scientific Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FCS	Food Categorisation System (food nomenclature) presented in Annex II to Regulation (EC) No 1333/2008
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MPL	maximum permitted level
SCF	Scientific Committee on Food
UK	United Kingdom
WHO	World Health Organization

Appendix A – Summary of the total estimated exposure of steviol glycosides (E 960) using MPLs and levels proposed for the extension of use per age class and survey: mean and high level (mg/kg bw per day)

	Number of subjects	Exposure estimates	
		Mean	High level
Toddlers			
Belgium (Regional Flanders)	36	2.4	
Bulgaria (NUTRICHILD)	428	0.6	2.0
Germany (DONALD 2006 2008)	261	0.8	2.2
Spain (enKid)	17	1.0	
Finland (DIPP)	497	0.9	2.7
Italy (INRAN SCAI 2005 06)	36	0.6	
Netherlands (VCP kids)	322	1.9	4.3
Children			
Belgium (Regional Flanders)	625	1.7	3.7
Bulgaria (NUTRICHILD)	433	0.6	1.9
Czech Republic (SISP04)	389	1.0	2.4
Germany (DONALD 2006 2008)	660	1.2	2.7
Denmark (Danish Dietary Survey)	490	0.7	1.5
Spain (enKid)	156	0.9	2.3
Spain (NUT INK05)	399	0.9	2.1
Finland (DIPP)	933	1.1	2.4
Finland (STRIP)	250	1.8	3.9
France (INCA2)	482	1.0	2.1
Greece (Regional Crete)	839	0.5	1.4
Italy (INRAN SCAI 2005 06)	193	0.5	1.5
Latvia (EFSA TEST)	189	1.0	2.0
Netherlands (VCP kids)	957	1.7	3.7
Sweden (NFA)	1 473	1.6	3.4
Adolescents			
Belgium (Diet National 2004)	584	0.6	1.4
Cyprus (Childhealth)	303	0.3	0.7
Czech Republic (SISP04)	298	0.6	1.3
Germany (National Nutrition Survey II)	1 011	0.8	1.9
Denmark (Danish Dietary Survey)	479	0.4	0.9
Spain (AESAN FIAB)	86	0.2	0.6
Spain (enKid)	209	0.4	1.1
Spain (NUT INK05)	651	0.5	1.3
France (INCA2)	973	0.5	1.2
Italy (INRAN SCAI 2005 06)	247	0.2	0.6
Latvia (EFSA TEST)	470	0.6	1.2
Sweden (NFA)	1 018	0.7	1.6
Adults			
Belgium (Diet National 2004)	1 304	0.5	1.3
Czech Republic (SISP04)	1 666	0.3	0.7
Germany (National Nutrition Survey II)	10 419	0.6	1.6
Denmark (Danish Dietary Survey)	2 822	0.3	0.7
Spain (AESAN)	410	0.3	0.7
Spain (AESAN FIAB)	981	0.2	0.5
Finland (FINDIET 2007)	1 575	0.4	1.0
France (INCA2)	2 276	0.4	1.0
United Kingdom (NDNS)	1 724	0.7	1.6
Hungary (National Repr Surv)	1 074	0.3	0.9
Ireland (NSIFCS)	958	0.6	1.3
Italy (INRAN SCAI 2005 06)	2 313	0.1	0.5
Latvia (EFSA TEST)	1 306	0.3	0.8
Netherlands (DNFCS 2003)	750	1.1	2.3
Sweden (Riksmaten 1997 98)	1 210	0.7	1.6

	Number of subjects	Exposure estimates	
		Mean	High level
Elderly			
Belgium (Diet National 2004)	1 230	0.5	1.4
Germany (National Nutrition Survey II)	2 496	0.5	1.2
Denmark (Danish Dietary Survey)	329	0.2	0.6
Finland (FINDIET 2007)	463	0.3	0.7
France (INCA2)	348	0.3	0.8
Hungary (National Repr Surv)	286	0.2	0.7
Italy (INRAN SCAI 2005 06)	518	0.1	0.4