

SCIENTIFIC OPINION

Scientific Opinion on the revised exposure assessment of steviol glycosides (E 960) for the proposed uses as a food additive¹

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ABSTRACT

Following a request from the European Commission, the European Food Safety Authority (EFSA) carried out an exposure assessment of steviol glycosides (E 960) from its 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, both in 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 for steviol glycosides based on revised proposed uses and concluded that high level dietary exposure in children may still exceed the ADI. The current refined exposure estimates are based on the currently authorised uses, the proposed extension, and the EFSA Comprehensive Food Consumption Database. The mean dietary exposure to steviol glycosides ranges from 0.1 mg/kg bw/day in adults and the elderly, to 2.4 mg/kg bw/day in toddlers. Estimates at the 95th percentile of exposure range from 0.3 to 4.3 mg/kg bw/day in the elderly and toddlers, respectively. 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, except for toddlers at the upper range of the high level (95th percentile) estimates, in one country. Moreover, the Panel noted that table top sweeteners may represent an important source of exposure and therefore a MPL with a numerical value, rather than *quantum satis*, would be preferable, to allow for a more precise estimation of the potential maximum level of exposure from table top sweeteners.

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KEY WORDS

steviol glycosides, E 960, refined exposure, EFSA Comprehensive European Food Consumption Database

¹ On request from the European Commission, Question No EFSA-Q-2013-00433, adopted on 2 April 2014.

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³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Exposure Assessment: Polly Boon, Jürgen König, Jean-Charles Leblanc, Christina Tlustos, Christophe Matthys for the preparatory work on this scientific opinion and EFSA staff: Davide Arcella, Petra Gergelova, Alexandra Tard and Stavroula Tasiopoulou for the support provided to this scientific opinion.

Suggested citation: EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2014. Scientific Opinion on the revised exposure assessment of steviol glycosides (E 960) for the proposed uses as a food additive. EFSA Journal 2014;12(5):3639, 23 pp. doi:10.2903/j.efsa.2014.3639

Available online: www.efsa.europa.eu/efsajournal

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SUMMARY

Following a request from the European Commission to take into account additional proposed uses of steviol glycosides (E 960) as a food sweetener, a refined exposure assessment for five population groups was carried out based on the maximum permitted levels (MPLs) authorised in Annex II of 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 food category 14.1.5.2 Other).

Steviol glycosides (E 960) are natural sweet-tasting constituents and their use as a food sweetener is regulated under the European Parliament and Council Regulation (EC) No 1333/2002 on food additives. Stevioside was previously evaluated by the Scientific Committee for Food (SCF) in 1984, 1988 and 1999 (SCF, 1984; SCF, 1989; SCF 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; JECFA, 2005; JECFA, 2006; JECFA, 2007; JECFA, 2009). The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) evaluated the safety of steviol glycosides (E 960) used as a food additive in 2010 and established an Acceptable Daily Intake (ADI) of 4 mg/kg bw/day (EFSA, 2010).

The present exposure estimates of steviol glycosides (E 960) are based on the MPLs of use currently authorised in Annex II of the Regulation (EC) No 1333/2008 and taking into consideration the maximum levels as proposed by the applicant for an extension of use, in coffee, herbal infusion beverages, instant coffee and instant cappuccino products and malt-based and chocolate/cappuccino flavoured drinks.

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 refined exposure assessment of steviol glycosides (E 960).

The dietary exposure to steviol glycosides (E 960) ranges for toddlers from 0.6 to 2.4 mg/kg bw/day at the mean, and from 2.0 to 4.3 mg/kg bw/day at the 95th percentile. The exposure levels for children are estimated to be between 0.5-1.8 mg/kg bw/day at the mean, and between 1.3-3.9 mg/kg bw/day at the 95th percentile. Exposure estimates calculated for adolescents give a mean dietary exposure to steviol glycosides (E 960) of 0.2-0.7 mg/kg bw/day and of 0.6-1.8 mg/kg bw/day for high level exposure. In adults, the exposure levels are up to 1.0 mg/kg bw/day at the mean, and up to 2.2 mg/kg bw/day at the high exposure levels. In the elderly, the mean exposure level is estimated up to 0.4 mg/kg/bw and the high exposure level is estimated up to 1.3 mg/kg/bw.

The contribution of individual food categories to the total mean exposure to steviol glycosides (E 960) varies between population groups. Flavoured fermented milk products, edible ices fruit and vegetable nectars, and breakfast cereals were the most important contributors for toddlers and children. For adolescents, breakfast cereals, edible ices and flavoured drinks with sweeteners contribute the most to the total exposure to steviol glycosides (E 960). For the adult population, the most important contributors were flavoured drinks with sweeteners in adults and processed fruit and vegetables in the elderly.

For children and adults, the current exposure estimates differ from those of the previous EFSA statement in 2011, being about four times lower at the high exposure level. However, even if direct comparison is difficult due to the differences of the data available for the exposure assessment, the Panel noted that main differences are mainly due to the fact that maximum levels considered in the current exposure assessment were reduced for all food categories by a factor between 1.1 and 3, when set in Commission Regulation (EU) No 1131/2011 amending Annex II to Regulation (EC) No 1333/2008, compared to those considered in the former EFSA evaluation (EFSA, 2011a). Overall, the

differences in the outcome of the exposure estimates are mainly driven by the use of different use level values, the use of new food consumption data and a refined selection of food items within the FoodEx nomenclature.

In conclusion, considering the extension of use of steviol glycosides (E 960), the Panel concluded that mean exposure estimates are below the ADI of 4 mg/kg bw/day for all population groups, while the high level (95th percentile) is above the ADI only for toddlers at the upper range of the exposure estimates (4.3 mg/kg bw/day), in one country.

The Panel noted that table top sweeteners may represent an important source of exposure to steviol glycosides and therefore considered that providing a MPL with a numerical value, rather than *quantum satis*, would be preferable in order to allow for a more precise estimation of the potential maximum level of exposure to steviol glycosides (E 960) from table top sweeteners.

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BACKGROUND

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008 on food additives⁴. Only food additives that are included in the Union list, in particular in Annex II to that regulation, may be placed on the market and used 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 3300 mg/kg.

EFSA adopted a Scientific Opinion on the safety of steviol glycosides as a food additive in 2010. It established an ADI for steviol glycosides, expressed as steviol equivalents, of 4 mg/kg body weight/day. Conservative estimates of steviol glycosides exposure, both in adults and children, suggest that it is likely that the ADI would be exceeded at the maximum proposed use level.

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.

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

Recently, a manufacturer has requested the authorisation of use of steviol glycosides (E 960) in hot beverages, 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 food category 14.1.5.2 Other).

TERMS OF REFERENCE

The European Commission asks the European Food Safety Authority to provide a scientific opinion, by end of June 2014, on the safety of the proposed extension of use of steviol glycosides (E 960) as a food additive in 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 food category 14.1.5.2 Other) in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings⁴.

That food additive (E 960, sweetener) is to be added at a maximum level in the following products:

Foodstuffs	Maximum Levels (mg/l)
Instant-coffee and instant cappuccino products	10
Tea beverages	10
Malt-based and chocolate/cappuccino flavoured drinks	20
Coffee and herbal infusion beverages	29

⁴ OJ L 354, 31.12.2008, p. 16.

ASSESSMENT

1. Introduction

Steviol glycosides (E 960) are natural sweet-tasting constituents obtained from the leaves of the plant *Stevia rebaudiana*. Stevioside and rebaudioside A are the component glycosides of principal interest for their sweetening property. Associated glycosides include rebaudioside C, dulcoside A, rubusoside, steviolbioside and rebaudioside B, 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 the European Parliament and Council Regulation (EC) No 1333/2008⁵ on food additives. Stevioside as a sweetener was previously evaluated by the Scientific Committee for 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 Acceptable Daily Intake (ADI) for steviol glycosides (E 960) of 4 mg/kg bw/day, expressed as steviol equivalents.

In its opinion of 14 April 2010, the EFSA ANS Panel has established an ADI of 4 mg/kg bw/day for steviol glycosides (E 960), expressed as steviol equivalents. In the same opinion, the ANS Panel evaluated the safety in 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 likely be exceeded at the maximum proposed use levels for both children and adults (EFSA, 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, 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 1131/2011⁶ amending Annex II to Regulation (EC) No 1333/2008. The MPLs set in the legislation were lower than the maximum proposed use levels considered in the 2011 EFSA statement (Table 1).

An applicant has recently submitted 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 fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products (sub food category 14.1.5.2 Other).

Following a request from the European Commission, EFSA performed a refined exposure assessment of steviol glycosides (E 960) from its use as a food additive, taking into account the proposed extension of use at the levels presented in the terms of reference.

⁵ 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.

⁶ Commission 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.

2. Methods

2.1. Maximum permitted levels of use

Maximum permitted levels (MPLs) of steviol glycosides (E 960), expressed as steviol equivalents (at least 75 % of stevioside or rebaudioside A; Regulation (EU) No 231/2012⁷ on food additives specifications), have been defined in Commission Regulation (EU) No 1131/2011⁸ amending Annex II to Regulation (EC) No 1333/2008.

The calculation of the refined dietary exposure estimates for steviol glycosides (E 960) has been performed using the MPLs of use authorised in Annex II of Regulation (EC) No 1333/2008 and summarised in Table 1, combined with the extension of use at the levels proposed by the applicant, as provided in the terms of reference.

In order to compare these values to the ones used in the exposure assessment of steviol glycosides (E 960) performed in 2011 (EFSA, 2011a), the proposed use levels taken into consideration in the 2011 EFSA statement are included in Table 1.

Table 1: MPLs of steviol glycosides (E 960) in foods currently authorised according to Annex II to Regulation (EC) No 1333/2008 and proposed use levels used in the 2011 EFSA statement

FCS category number	Foods	Restrictions/exceptions	MPL	Proposed uses (2011) ^(a)
			(mg/l or mg/kg)	
1.4	Flavoured fermented milk products including heat-treated products	only energy-reduced products or with no added sugar	100	120
3	Edible ices	only energy-reduced or with no added sugar	200	240
4.2.2	Fruit and vegetables in vinegar, oil or brine	only sweet-sour preserves of fruits and vegetables	100	120
4.2.4.1	Fruit and vegetable preparations excluding compote	only energy-reduced	200	240
4.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EC	only energy-reduced jams and jellies and marmalades	200	240
4.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC	only energy-reduced jams, jellies and marmalades	200	240
4.2.5.3	Other similar fruit or vegetable spreads	only dried-fruit-based sandwich spreads, energy-reduced or with no added sugar	200	240
5.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	only energy-reduced or with no added sugars	270	320
5.2.	Other confectionery including breath freshening microsweets	only cocoa or dried fruit based, energy-reduced or with no added sugar	270	320
5.2.	Other confectionery including breath refreshing microsweets	only cocoa, milk, dried fruit or fat based sandwich spreads,	330	-

⁷ 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, 22.3.2012, p.1.

⁸ Commission 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.

FCS category number	Foods	Restrictions/exceptions	MPL	Proposed uses (2011) ^(a)
			(mg/l or mg/kg)	
		energy-reduced or with no added sugar		
5.2.	Other confectionery including breath refreshing microsweets	only confectionery with no added sugar	350	400
5.2.	Other confectionery including breath refreshing microsweets	only breath-freshening microsweets, with no added sugar	2000	2400
5.2.	Other confectionery including breath refreshing microsweets	only strongly flavoured freshening throat pastilles with no added sugar	670	800
5.3.	Chewing gum	only with no added sugar	3300	4000
5.4.	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	only confectionary with no added sugar	330	400
5.4.	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	only cocoa or dried fruit based, energy-reduced or with no added sugar	270	320
6.3	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	400
7.2.	Fine bakery wares	only essoblaten - wafer paper	330	-
9.2.	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	240
11.4.1	Table top sweeteners in liquid form		QS	12 000 ^(b)
11.4.2	Table top sweeteners in powder form		QS	12 000 ^(b)
11.4.3	Table top sweeteners in tablets		QS	12 000 ^(b)
12.5	Soups and broths	only energy-reduced soups	40	44
12.6	Sauces	except soy-bean sauce (fermented and non-fermented)	120	140
12.6	Sauces	only soy-bean sauce (fermented and non-fermented)	175	200
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		330	400
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	320
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	240

FCS category number	Foods	Restrictions/exceptions	MPL	Proposed uses (2011) ^(a)
			(mg/l or mg/kg)	
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	80
14.2.8	Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks		150	180
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	240
17.3	Food supplements supplied in a syrup-type or chewable form		1800	2200

-: not proposed; *QS*: *quantum satis*

(a): The maximum use levels expressed as range of steviol equivalents have been calculated according to the conversion factors considered by the ANS Panel in its 2010 opinion (low conversion factor = 0.33, high conversion factor = 0.40). The higher range is shown here.

(b): Maximum use level as reported by UNESDA (Tennant, 2010)

Maximum levels considered in the current exposure assessment were reduced for all food categories by a factor between 1.1 and 3 compared to those considered in the former EFSA evaluation (EFSA, 2011a). Seven new food uses were included: other confectionery including breath refreshing micro-sweets (only cocoa, milk, dried fruit or fat based sandwich spreads, energy-reduced or with no added sugar), fine bakery wares (only essoblaten - wafer paper), fruit nectars and vegetable nectars and similar products (only energy-reduced or with no added sugar), potato-, cereal-, flour- or starch-based snacks, processed nuts, desserts not covered by categories 1, 3 and 4 (only energy-reduced or with no added sugar), and food supplements supplied in solid form, including capsules and tablets and similar forms, and excluding chewable forms.

For table top sweeteners (Food Classification System (FCS) category 11.4), the value of 12 000 mg/kg steviol glycosides (E 960) expressed as steviol equivalents, retrieved from the previous EFSA statement (EFSA, 2011a), was assigned for the exposure calculations.

2.2. New proposed uses and use levels

The extension of use of steviol glycosides (E 960) as a food additive is 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 food category 14.1.5.2 Other). Steviol glycosides (E 960) is proposed to be added at a maximum level in the following products: tea beverages (maximum level of 10 mg/l), coffee beverages (maximum level of 29 mg/l), herbal infusion beverages (maximum level of 29 mg/l), instant coffee and instant cappuccino products (maximum level of 10 mg/l), and malt-based and chocolate/cappuccino flavoured drinks (maximum level of 20 mg/l) (summarised in the Table in the Terms of reference section).

3. Food consumption

3.1. EFSA's Comprehensive European Food Consumption Database

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 each European country 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, 2011b).

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.

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 the Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates.

3.2. Food items selected for the refined 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 codes), at a detailed level (up to FoodEx level 3) (EFSA, 2011b).

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 are described below (in ascending order of the FCS codes):

- **5.4. Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4:** This category covers any confectionery product generally used for decorating and filling of foodstuff 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.
- **7.2. 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 '7.2. 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 due to 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 codes). This results in an overestimation of exposure:

- **5.2. Other confectionery including breath refreshing 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 5.2. and their respective MPLs; therefore the highest MPL of 2000 mg/kg was assigned to the entire food category.
- **17. Food supplements:** it is not possible to differentiate the form of the food supplements (e.g. supplements supplied in a liquid form vs. supplements supplied in a syrup-type or chewable form) within FoodEx codes, thus the MPL of 1800 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’ applying in several of the food categories in which steviol glycosides (E 960) is 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 also foods with normal energy content and/or with sugar added.

Further refinements were made in the following 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, retrieved from the previous EFSA exposure assessment (EFSA, 2011a), was used.
- **4.2.2. Fruit and vegetable in vinegar, oil or brine, 4.2.4.1. Fruit and vegetable preparations excluding compote, 4.2.5.1. Extra jam and extra jelly as defined by Directive 2001/113/EC, 4.2.5.2. Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC and 4.2.5.3. 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 major part of food categories.
- **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.

4. Dietary exposure assessment

Dietary exposure to steviol glycosides (E 960) from its use as a sweetener was estimated based on the consumption data available within the EFSA Comprehensive Database as presented in Section 3.

For the estimation of chronic dietary exposure, intake statistics have been calculated based on individual food consumption over the total survey period, excluding surveys with only one day per subject, considered as not adequate to assess repeated dietary exposure, as suggested by the EFSA Working Group on Food Consumption and Exposure (EFSA, 2011b).

Chronic exposure to steviol glycosides (E 960) was calculated for the following population groups: toddlers, children, adolescents, adults and the elderly. 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 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, Netherlands, Spain
Children ⁹	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 ⁸	from 65 years of age and older	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

High level exposure was only calculated for those foods and population groups where the sample size was sufficiently large to allow calculation of the 95th percentile (> 60 subjects) (EFSA, 2011b). Therefore, in the present estimate, high level exposure estimates for toddlers from Belgium, Italy and Spain were not included.

Dietary exposure to steviol glycosides (E 960) from its use as a food additive was calculated based on (1) authorised MPLs as listed in Table 1, combined to (2) maximum levels of use for the extension of use in the food category 14.1.5 (sub food category 14.1.5.2 Other), as proposed by the applicant and listed in the terms of reference.

FoodEx food codes were matched to the food categories reported in Section 2.1 and subsequently each individual exposure was calculated by using the corresponding individual body weight. The average and high percentile exposures were calculated for the total population, for the five population groups described in Table 2.

4.1. Exposure to steviol glycosides (E 960) from its use as a food additive

Table 3 summarises the refined exposure of the five population groups to steviol glycosides (E 960), taking also into account the proposed extension of use.

Table 3: Summary of refined exposure to steviol glycosides (E 960) from its use as a food additive in five population groups using MPLs and the extension of use at the levels proposed by the applicant (mg/kg bw/day, expressed as steviol equivalents; min-max 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/day)					
• Mean	0.6-2.4	0.5-1.8	0.2-0.7	0.1-1.0	0.1-0.4
• High level ¹⁰	2.0-4.3	1.3-3.9	0.6-1.8	0.4-2.2	0.3-1.3

⁹ 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).

¹⁰ Typically 95th percentile of consumers only.

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

As a reminder, Table 4 presents the dietary exposure to steviol glycosides (E 960) as estimated in the EFSA statement published in 2011 (EFSA, 2011a), for two population groups: children and adults.

Table 4: Summary of anticipated exposure to steviol glycosides (E 960), expressed as steviol equivalents, in children and adult populations reported in the previous EFSA assessment (EFSA, 2011a)

	Adult UK population (>18 years old)	Children population (1-14 years old) Corrected for high consumers ^(c)
Tier 2. Maximum Proposed use Level^(a)	mg/kg bw/day	
Mean exposure	1.9-2.3	0.4-6.4
Exposure at 95 th or 97.5 th percentile ^(b)	5.6-6.8	1.0-12.7

(a): For the calculation of anticipated exposure to steviol glycosides expressed as steviol equivalents, estimates were made using the same range of conversion factors as in the 2010 opinion of the ANS Panel (0.33 - 0.4) (EFSA, 2010).

(b): For EU children, estimates are based on the EXPOCHI report which gives the 95th percentile intake; for UK, estimates are based on the UNESDA report which gives the 97.5th percentile intake from beverages plus per capita average from the rest of diet (Tennant, 2006).

(c): Children high level exposure estimates were corrected for the consumption of soft drinks by comparing consumption data from EXPOCHI and from the EFSA Comprehensive database (EFSA, 2011a).

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

The main food categories contributing to the mean exposure to steviol glycosides (E 960) (>5% of total exposure) when considering MPLs and the extension of use at the levels proposed by the applicant, and the number of surveys in which each food category is a main contributor, are presented in Table 5.

The contribution of individual food categories to the total mean exposure to steviol glycosides (E 960) varies between population groups due to different consumption patterns. Flavoured fermented milk products, edible ices, breakfast cereals and fruit nectars were the most important contributors to total mean exposure to steviol glycosides (E 960) for toddlers and children. In adolescents, breakfast cereals edible ices and flavoured drinks with sweeteners contribute the most to the total exposure to steviol glycosides (E 960). Regarding the adult population, the main contributors were flavoured drinks with sweeteners in adults and processed fruit and vegetables in the elderly. Other important contributors in the adult population groups were breakfast cereals, soups and broths, flavoured fermented milk products and the food category in which the use of steviol glycosides (E 960) is requested to be authorised (coffee, tea, herbal and fruit infusions, chicory, tea; 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).

Table 5: Main food categories contributing to exposure to steviol glycosides (E 960) from its use as a sweetener, using MPLs and the levels proposed by the applicant for the extension of use (> 5 % to the total mean exposure) and number of surveys in which each food category is contributing

FCS Category number	Foods	Toddlers	Children	Adolescents	Adults	The elderly
		range of % contribution to the total exposure (Number of Surveys) ^(a)				
1.4	Flavoured fermented milk products including heat-treated products	8.7-51.1 (7)	8.1-41.1 (13)	5.5-27.2 (9)	7.2-27.6 (11)	5.7-16.1 (7)
3	Edible ices	7.2-30.4 (4)	6.1-28.9 (15)	6.9-36.0 (11)	5.7-25.5 (7)	5.6-20.7 (3)
4.2	Processed fruit and vegetables	6.5-17.4 (3)	5.8-17.4 (8)	5.3-14.7 (6)	5.9-33.7 (11)	10.3-48.8 (7)
5.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC	7.4-17.9 (6)	8.5-23.1 (13)	6.5-32.2 (12)	5.4-20.7 (14)	5.0-13.7 (5)
5.2.2	Other confectionery without added sugar	7.9 (1)	-	-	-	-
5.3.2	Chewing gum without added sugar	-	9.2 (1)	10.7 (1)	6.6-9.3 (2)	-
6.3	Breakfast cereals	5.5-15.5 (5)	5.9-38.4 (14)	8.0-46.8 (12)	5.3-31.5 (13)	6.3-28.3 (4)
9.2	Processed fish and fishery products including molluscs and crustaceans	5.5-6.1 (2)	7.1-13.4 (2)	5.2-6.4 (3)	-	-
11.4	Table top sweeteners	-	-	-	7.8-12.2 (7)	13.9-16.3 (4)
12.5	Soups and broths	8.3 (1)	7.6-20.0 (3)	7.6-21.9 (2)	10.4-30.4 (2)	8.4-18.1 (2)
12.6	Sauces	-	5.4-9.2 (7)	5.0-14.9 (9)	5.2-13.6 (11)	7.5-9.8 (3)
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	11.8-53.4 (2)	39.2 (1)	-	16.1-19.0 (2)	8.6 (1)
14.1.4.2	Flavoured drinks with sweeteners	5.9-22.6 (2)	6.7-12.0 (5)	11.5-35.1 (5)	6.0-41.9 (11)	5.6-6.6 (2)
14.1.5	Coffee, tea, herbal and fruit infusions, chicory, tea; 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	5.9 (1)	5.8-9.0 (2)	6.3-10.4 (2)	6.0-22.4 (10)	6.4-21.9 (7)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	-	-	-	5.7-6.5 (4)	5.1-5.2 (2)
16	Desserts excluding products covered in category 1, 3 and 4	14.1-14.7 (2)	5.8-12.0 (5)	5.9-8.5 (2)	6.4 (1)	8.0 (1)
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	-	-	-	5.9-9.2 (2)	9.9-16.3 (2)

(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.

5. Discussion

EFSA performed a refined exposure assessment for steviol glycosides (E 960) on the basis of the MPLs currently authorised in Annex II to the Regulation (EC) No 1333/2008 and taking into consideration the extension of use at the levels proposed by the applicant in tea, coffee, herbal infusion beverages, instant coffee and instant cappuccino products and malt-based and chocolate/cappuccino flavoured drinks.

The dietary exposure to steviol glycosides (E 960) ranges in European toddlers from 0.6 to 2.4 mg/kg bw/day at the mean, and from 2.0 to 4.3 mg/kg bw/day at the 95th percentile. The exposure levels for children are estimated to be between 0.5-1.8 mg/kg bw/day at the mean and between 1.3-3.9 mg/kg bw/day at the 95th percentile. Exposure estimates calculated for adolescents show a mean dietary exposure to steviol glycosides of 0.2-0.7 mg/kg bw/day and of 0.6-1.8 mg/kg bw/day for high level exposure (95th percentile). In adults, the exposure levels are up to 1.0 mg/kg bw/day at the mean, and up to 2.2 mg/kg bw/day at the high exposure level. In the elderly, the mean exposure level is estimated up to 0.4 mg/kg bw/day and the high exposure level is estimated up to 1.3 mg/kg bw/day.

In comparison to the previous EFSA statement on the exposure assessment of steviol glycosides (E 960) performed in 2011, the current exposure estimates are considerably lower. This is mainly due to the fact that maximum levels considered in the current exposure assessment were reduced for all food categories by a factor between 1.1 and 3, as set in Commission Regulation (EU) No 1131/2011¹¹ amending Annex II to Regulation (EC) No 1333/2008, compared to those considered in the former EFSA evaluation (EFSA, 2011a) (Table 1). The mean exposure estimates range from 0.1 to 1.0 mg/kg bw/day for adults, while in the previous EFSA statement, mean exposure ranged from 1.9 to 2.3 mg/kg bw/day (EFSA, 2011a). For children, a direct comparison is not accurate, as different age groups were considered. However, a rough comparison showed that the exposure levels are much lower; while in the previous estimates the mean levels of exposure were up to 6.4 mg/kg bw/day for 1-14 years old children, in the current assessment the mean levels are up to 2.4 mg/kg bw/day for toddlers, up to 1.8 mg/kg bw/day for 3-9 years old children, and up to 0.7 mg/kg bw/day for adolescents (10-17 years old). The high level exposure estimates are about four times lower in the current estimates, for both adults and children.

The main contributors to the total mean exposure to steviol glycosides (E 960) in the current assessment are similar to those reported in the previous assessments, even though direct comparison is not possible due to differences in the definition of the food categories. For toddlers and children, the main contributors to the total exposure are flavoured fermented milk products and edible ices, both previously considered as a part of the desserts food category. Breakfast cereals remain an important contributor for children and adolescents exposure, and flavoured drinks with sweeteners, for adolescents. Regarding the adult population, the most important contributors are flavoured drinks with sweeteners, which is in agreement with the results of the previous assessments. For the elderly, processed fruits and vegetables are found to be the most important contributors. The category 'coffee, tea, herbal and fruit infusions, chicory, tea; 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', which is the food category in which the extension of use was requested, contributes more than 5 % to the total exposure for all population groups. Table top sweeteners, which are currently authorised at *quantum satis*, but for which a use level of 12 000 mg/kg was considered in the present exposure estimate, contribute more than 5 % to the total exposure only for adult population groups (adults and the elderly). Alcoholic beverages contribute up to 6.5 % to the total mean exposure of adults in four countries and up to 5.2 % for the elderly in two countries, while in the previous assessment the alcoholic beverages were one of the important contributors. Alcoholic drinks

¹¹ Commission 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.

contributed in the previous EFSA statement (EFSA, 2011a) with 12 % to the total exposure to steviol glycosides in adults, but it is important to mention, that the assessment was based only on consumption data for UK adults.

As mentioned above, the use of steviol glycosides (E 960) in table top sweeteners is currently authorised at *quantum satis* (Annex II to Regulation (EC) No 1333/2008). The ANS Panel considered important to include this food category in the assessment and decided to use the value of 12 000 mg/kg. This value was retrieved from the Tennant report (Tennant, 2010) and used in the 2011 exposure assessment of steviol glycosides (E 960) (EFSA, 2011a). In the current assessment, table top sweeteners were found to contribute up to around 16 % to the total mean exposure for the adult population (adults and the elderly), in comparison to 26 %, as estimated in the 2011 exposure assessment (for UK adults). The Panel noted that table top sweeteners may represent an important source of exposure to steviol glycosides and that a MPL of numerical value would allow for a more precise estimation of the potential maximum level of exposure to steviol glycosides (E 960) from table top sweeteners.

It is important to mention that due to the differences in the food consumption data and the use levels of steviol glycosides (E 960) considered in the current and previous exposure assessments, a direct comparison of the results is not possible. Nonetheless, the exposure estimates are much lower in the current assessment, both at mean and high level, for all population groups. It is therefore important to highlight the main differences in order to clarify possible reasons for the decrease of the exposure estimates to steviol glycosides (E 960) in the present assessment. These are listed below:

- Levels of steviol glycosides in foods: the current exposure assessment is based on the MPLs currently authorised in Annex II to Regulation (EC) 1333/2008 and the maximum levels as proposed by the applicant for the requested extension of use, while the previous assessment (EFSA, 2011a) was based on the use levels proposed by different applicants requesting the authorisation of use of steviol glycosides (E 960) as a food additive (sweetener). The Panel calculated also the exposure to steviol glycosides (E 960) based only on the MPLs currently authorised in the legislation in order to assess the exposure without the contribution of the extension of use at the proposed levels. The differences in the exposure calculations were negligible (Appendix B) and the Panel concluded that the extension of use as presented in the terms of reference does not have any impact on the total exposure to steviol glycosides (E 960) of the European population.
- Food consumption data: individual data for five population groups (including toddlers, children, adolescents, adults and the elderly) are now available, while in the previous assessment only two population groups, children and adults, were considered. The refined assessment is performed based on individual food consumption data from the EFSA Comprehensive Database, whereas in the 2011 EFSA statement, only summary statistics were used. Some of the food consumption surveys for children, currently included in the EFSA Comprehensive Database, were also used in the previous assessment, but no detailed data as regards food classification (i.e. following the FoodEx nomenclature) were used at that time. Moreover, for adults, only UK consumption data were available, retrieved from various reports (Tennant, 2006; Tennant, 2007).
- Refinements: the current exposure assessment is based on the FoodEx classification system which has been linked to the FCS, defined in the Annex II to Regulation (EC) No 1333/2008, part D. The FoodEx classification system allows performing the refinements (section 3.2) in the selection of food items according to the restrictions/exceptions defined in the legislation. This was not possible in the previous assessments.
- High exposure levels: in the current assessment, the high percentile of exposure (95th percentile) was based on the individual exposures calculated for the total population for each

of the five population groups. Following the EFSA guidelines, the high level exposure was only calculated for those foods and population groups where the sample size was sufficiently large to allow calculation of the 95th percentile exposure (EFSA, 2011b). In the previous assessments, only summary statistics were available for the calculation. Moreover, the Tennant, 2006 report used for these assessments, reported the 97.5th percentile intake from non-alcoholic beverages; the 95th percentile was not available for the adult population.

Overall, the Panel noted that the main differences between the outcomes of the previous and the current exposure assessment of steviol glycosides (E 960) are mainly due to the different maximum use levels considered for the calculation, the new food consumption data used and the refinement in the selection of food items within the FoodEx nomenclature.

When considering the results, it is important to note that these refined exposure estimates should be considered as conservative. Despite the fact that the FoodEx classification system and the EFSA Comprehensive Database provide very detailed information on food items, it was not always possible to find an appropriate linkage in order to reflect the restrictions/exceptions set in the legislation. Therefore, in some cases, the highest MPL was assigned to the whole food category. Two food categories, where the use of steviol glycosides (E 960) is authorised, could not be included in the exposure assessment. However, the impact on the exposure estimates is considered to be minor, one of them being ‘only essoblaten – wafer paper’, considered a “niche product”, and the second one (‘decorations, coating, fillings’), is likely to be included in the assessment as a part of edible ices, candies etc. Moreover, for many food categories, the use of steviol glycosides (E 960) is limited by the restriction/exception ‘only energy-reduced’ and/or ‘with no sugar added’. However, due to lack of relevant additional information on the foods consumed, it was not possible to make further refinements. Therefore, for the majority of the above food categories, the MPLs were considered for the entire food categories. It should be kept in mind when interpreting the results that this approach leads to an overestimation.

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

6. Uncertainty analysis

According to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2006), the following sources of uncertainties have been considered. These were already presented in the sections above and are summarised below:

Table 6: Qualitative evaluation of influence of uncertainties

Sources of uncertainties	Direction ^(a)
Consumption data: different methodologies/representativeness/under reporting/misreporting/no portion size standard	+/-
Extrapolation from food consumption survey of few days to estimate chronic exposure	+
Linkage between reported use levels and food items in the consumption database: uncertainties on which precise types of food the use levels refer	+/-
Exposure model: uncertainty in possible national differences in use levels of food categories, dataset not fully representative of foods on the EU market	+/-
Use of MPLs in exposure assessment	+

(a): + = uncertainty with potential to cause overestimation of exposure; - = uncertainty with potential to cause underestimation of exposure

CONCLUSIONS

Following a request from the European Commission to take into account an extension of uses of steviol glycosides (E 960) as a food sweetener, a refined 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 food category 14.1.5.2 Other).

For children and adults, the current exposure estimates differ from those of the previous EFSA statement in 2011, being about four times lower at the high exposure level. However, even if direct comparison is difficult due to the differences of the data available for the exposure assessment, the Panel noted that main differences are mainly due to the fact that maximum levels considered in the current exposure assessment were reduced for all food categories by a factor between 1.1 and 3, when set in Commission Regulation (EU) No 1131/2011¹² amending Annex II to Regulation (EC) No 1333/2008, compared to those considered in the former EFSA evaluation (EFSA, 2011a). Overall, the differences in the outcome of the exposure estimates are mainly driven by the use of different use level values, the use of new food consumption data and a refined selection of food items within the FoodEx nomenclature.

In conclusion, considering the extension of use of steviol glycosides (E 960), the Panel concluded that mean exposure estimates are below the ADI of 4 mg/kg bw/day for all population groups, while the high level (95th percentile) is above the ADI only for toddlers at the upper range of the exposure estimates (4.3 mg/kg bw/day) in one country.

The Panel noted that table top sweeteners may represent an important source of exposure to steviol glycosides and therefore considered that providing a MPL with a numerical value, rather than *quantum satis*, would be preferable in order to allow for a more precise estimation of the potential maximum level of exposure to steviol glycosides (E 960) from table top sweeteners.

DOCUMENTATION PROVIDED TO EFSA

1. Technical Dossier for the extension of authorisation of steviol glycosides to include the hot beverages category. March 2013. Submitted by Tata Global Beverages GB Ltd.

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¹² Commission 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.

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APPENDICES

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

	Number of subjects	Exposure estimate	
		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	-*
The Netherlands (VCP_kids)	322	1.8	4.3
Children			
Belgium (Regional_Flanders)	625	1.7	3.7
Bulgaria (NUTRICHILD)	433	0.5	1.7
Czech Republic (SISP04)	389	0.9	2.2
Germany (DONALD_2006_2008)	660	1.2	2.6
Denmark (Danish_Dietary_Survey)	490	0.7	1.4
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	1.3
Italy (INRAN_SCAI_2005_06)	193	0.5	1.3
Latvia (EFSA_TEST)	189	0.8	1.9
The Netherlands (VCP_kids)	957	1.6	3.7
Sweden (NFA)	1473	1.6	3.3
Adolescents			
Belgium (Diet_National_2004)	584	0.5	1.2
Cyprus (Childhealth)	303	0.2	0.6
Czech Republic (SISP04)	298	0.5	1.2
Germany (National_Nutrition_Survey_II)	1011	0.7	1.8
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	1.1
Italy (INRAN_SCAI_2005_06)	247	0.2	0.6
Latvia (EFSA_TEST)	470	0.5	1.1
Sweden (NFA)	1018	0.7	1.6

	Number of subjects	Exposure estimate	
		Mean	High level
Adults			
Belgium (Diet_National_2004)	1304	0.5	1.2
Czech Republic (SISP04)	1666	0.2	0.6
Germany (National_Nutrition_Survey_II)	10419	0.5	1.4
Denmark (Danish_Dietary_Survey)	2822	0.2	0.6
Spain (AESAN)	410	0.2	0.7
Spain (AESAN_FIAB0)	981	0.1	0.4
Finland (FINDIET_20070)	1575	0.4	0.9
France (INCA2)	2276	0.3	0.9
United Kingdom (NDNS)	1724	0.6	1.4
Hungary (National_Repr_Surv)	1074	0.2	0.5
Ireland (NSIFCS)	958	0.4	1.0
Italy (INRAN_SCAI_2005_06)	2313	0.1	0.5
Latvia (EFSA_TEST)	1306	0.2	0.6
The Netherlands (DNFCS_2003)	750	1.0	2.2
Sweden (Riksmaten_1997_98)	1210	0.7	1.6
The elderly			
Belgium (Diet_National_2004)	1230	0.4	1.3
Germany (National_Nutrition_Survey_II)	2496	0.4	1.0
Denmark (Danish_Dietary_Survey)	329	0.2	0.4
Finland (FINDIET_2007)	463	0.3	0.7
France (INCA2)	348	0.2	0.7
Hungary (National_Repr_Surv)	286	0.1	0.3
Italy (INRAN_SCAI_2005_06)	518	0.1	0.3

* The 95th percentile estimates obtained based on dietary surveys/age classes with less than 60 observations may not be statistically robust (EFSA, 2011b) and therefore should not be considered in the risk characterisation. Those estimates were not included in this table.

(a): the value of 12 000 mg/kg was assigned to the food category of table top sweeteners.

Appendix B. Summary of refined exposure to steviol glycosides (E 960) from its current authorised uses¹³ as a food additive in five population groups using MPLs^(a) (min-max across the dietary surveys in mg/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 (mg/kg bw/day)					
• Mean	0.5-2.4	0.5-1.8	0.2-0.7	0.1-0.9	0.1-0.4
• High level	1.9-4.3	1.3-3.9	0.6-1.7	0.4-2.1	0.3-1.3

(a): the value of 12 000 mg/kg was assigned to the food category of table top sweeteners.

¹³ Commission 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.

GLOSSARY AND ABBREVIATIONS

ADI	Acceptable Daily Intake
ANS	Panel on Food Additives and Nutrient Sources added to Foods
bw	body weight
EC	European Commission
EFSA	European Food Safety Authority
EXPOCHI	Individual food consumption data and exposure assessment studies for children
FAO	Food and Agricultural Organisation
FCS	Food Classification System
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MPL	Maximum Permitted Level
SCF	Scientific Committee for Food
UNESDA	Union of European Soft Drinks Associations
UK	United Kingdom
WHO	World Health Organization