European Food Safety Authority

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STATEMENT OF EFSA

Revised exposure assessment for steviol glycosides for the proposed uses as a food additive[1]

European Food Safety Authority[2, 3]

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ABSTRACT

Following a request from the European Commission, the European Food Safety Authority (EFSA), carried out a revised exposure assessment of steviol glycosides from its use as a food additive, for children and adults, based on the revised proposed uses presented in the terms of reference. Revised exposures estimates have been calculated for Tier 2 using the same methodology used by the Panel on Food Additives and Nutrient Sources added to food in its opinion on steviol glycosides with revised proposed use levels with the individual food consumption data for children and the adult population. The mean anticipated dietary exposure to steviol glycosides expressed as steviol equivalents in European children (aged 1-14 years) ranged from 0.4 to 6.4 mg/kg bw/day, and from 1.7 to 16.3 mg/kg bw/day at the 95th percentile. Following the examination of the EFSA Comprehensive database, a correction was considered necessary for the consumption of non-alcoholic flavoured drinks (soft drinks) by children. The corrected exposure estimate ranges at the 95th percentile from 1.0 to 12.7 mg/kg bw/day for children. Exposure estimates calculated for the adults UK population give a mean dietary exposure to steviol glycosides, expressed as steviol equivalents of 1.9-2.3 mg/kg bw/day and of 5.6-6.8 mg/kg bw/day for high level consumers (97.5th percentile). The main contributors to the total anticipated exposure to steviol glycosides are non-alcoholic flavoured drinks (soft drinks) for both populations.

KEY WORDS

Steviol glycosides, exposure

1 On request from the European Commission, Question No EFSA-Q-2010-01214, issued on 13 January 2011.

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SUMMARY

Following a request from the European Commission, a revised exposure assessment of steviol glycosides from its use as a food additive was carried out, for children and adults, based on the revised proposed uses presented in the terms of reference.

Several food consumption databases were used to conduct the revised exposure assessment. For children, data from EXPOCHI project and UK NDNS survey were used. Estimates for adults were based on UK data only.

For adults, exposure estimates give a mean dietary exposure to steviol glycosides, expressed as steviol equivalents, of 1.9-2.3 mg/kg bw/day, and of 5.6-6.8 mg/kg bw/day for high level exposures (97.5th percentile), with main contributors being non-alcoholic flavoured drinks, tabletop sweeteners and beer and cider.

For European children (aged 1-14 years), exposure estimates give a mean dietary exposure to steviol glycosides, expressed as steviol equivalents, of 0.4-6.4 mg/kg bw/day; at the high level (95th/97.5th percentile), exposures estimates range from 1.7 to 16.3 mg/kg bw/day.

Considering the limitations of consumption data, estimates can be considered conservative as in the ANS Panel opinion (2010).

The EFSA Comprehensive database was used to identify and assess the uncertainty due to the consumption data from the food group "non-alcoholic flavoured drinks", the main contributor for both children and adults.

From these data, no general tendency was observed regarding the difference between the consumption levels of low-calorie non-alcoholic flavoured drinks (soft drinks) and of normal-calorie soft drinks. Therefore; the consumption levels of normal-calorie soft drinks was considered as an acceptable approximation of the consumption levels of low-calorie soft drinks and thus the exposure estimates for adults were not corrected.

For children, the data from EXPOCHI for the consumption of non-alcoholic flavoured drinks (soft drinks) were found to be generally higher than the consumption of low-calorie soft drink from the EFSA Comprehensive database by a factor 2. Consequently, the data from the EFSA Comprehensive database were used to correct the consumption of this food group. The corrected exposure estimates for children high consumers (95th percentile) range from 1.0 to 12.7 mg/kg bw/day.

The revised mean exposure estimates differ only slightly from the exposure estimates given in the ANS Panel opinion (2010). By using the EFSA Comprehensive database, the upper range of high level exposure estimate decreased from a maximum of 17.2 from the ANS Panel opinion to 12.7 mg/kg bw/day for children but high consumers children exposures are still above the ADI of 4 mg/kg bw/day for several countries.

TABLE OF CONTENTS

BACKGROUND

The European Food Safety Authority assessed the information on the safety in use of steviol glycosides as a new additive acting as sweetener. In its opinion on 14 April 2010, the Panel on food additives and nutrient sources added to food (ANS) established an Acceptable Daily Intake (ADI) of 4 mg/kg body weight/day. On the basis of the intended uses requested by the three applicants, the ANS Panel concluded that the established ADI would likely be exceeded at the maximum proposed use levels by both children and adults.

Following consultation with the Member States, the applicants were requested by the European Commission to revise the proposed uses in order to ensure that the use of steviol glycosides would be safe for the consumers. The applicants have recently submitted additional data addressing the concerns raised.

TERMS OF REFERENCE

In accordance with Article 31 of Regulation (EC) No 178/2002[4], the European Commission requested on 12 October 2010 the European Food Safety Authority to provide technical assistance for the assessment of the exposure to steviol glycosides from its use as a food additive in the food categories specified in the application.

The European Food Safety Authority is asked to carry out a revised dietary exposure assessment based on the revised uses of steviol glycoside proposed by the applicants (Table 1). The contribution of each food category to the total exposure will be specified.

Table 1: Revised food uses and proposed maximum levels of use

Foodstuffs	**Maximum Use Levels**
	Revised proposed uses of Steviol glycosides
Non-alcoholic drinks	
Water-based flavoured drinks, energy-reduced or with no added sugar	600 mg/l (excludes dilutables)
Milk- and milk-derivative-based or fruit juice-based drinks, energy-reduced or with no added sugar	350 mg/l
Soy-based beverages	350 mg/l
Desserts and similar products	
Water-based flavoured desserts, energy-reduced or with no added sugar	Category removed
Milk- and milk-derivate-based preparations, energy-reduced or with no added sugar	300 mg/l
Fruit- and vegetable-based desserts, energy-reduced or with no added sugar	Category removed
Egg-based desserts, energy-reduced or with no added sugar	Category removed
Cereal-based desserts, energy-reduced or with no added sugar	Category removed
Fat-based desserts, energy-reduced or with no added sugar	Category removed
'snacks': certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts	Category removed
Smoked, dried, fried, fermented, and/or salted fish and fish products including molluscs, crustaceans, and echinoderms (category number 09.2.5 under GSFA)	600 mg/kg

[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1.

Foodstuffs	Maximum Use Levels
	Revised proposed uses of Steviol glycosides
Confectionery with no added sugar	1000 mg/kg
Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	800 mg/kg
Starch-based confectionery, energy-reduced or with no added sugar	Category removed
Cocoa-, milk-, dried-fruit-, or fat-based sandwich spreads, energy-reduced or with no added sugar	Category removed
Chewing gum with no added sugar	10 000 mg/kg
Cider and perry	Category removed
Alcohol-free beer or with an alcohol content not exceeding 1.2% vol	200 mg/l
'Bière de table/tafelbier/Table beer' (original wort content less than 6%) except for 'Obergäriges Einfachbier'	200 mg/l
Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH	200 mg/l
Brown beers of the 'oud bruin' type	200 mg/l
Edible ices, energy-reduced or with no added sugar	600 mg/l
Canned or bottled fruit, energy-reduced or with no added sugar	Category removed
Energy-reduced jams, jellies, and marmalades	600 mg/kg
Energy-reduced fruit and vegetable preparations	600 mg/kg
Sweet-sour preserves of fruit and vegetables	300 mg/kg
Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans, and molluscs	600 mg/kg
Sauces	350 mg/kg
Soybean sauce (fermented, non-fermented, and other)	500 mg/kg
Mustard	Category removed
Fine bakery products for special nutritional uses	Category removed
Complete formulae for weight control intended to replace total daily food intake or an individual meal	800 mg/kg
Complete formulae and nutritional supplements for use under medical supervision	1000 mg/kg
Liquid food supplements/dietary integrators	600 mg/kg
Solid food supplements/dietary integrators	2000 mg/kg
Essoblatten (a type of wafer)	Category removed
Food supplements/diet integrators based on vitamin and/or mineral elements, syrup-type or chewable	5500 mg/kg
Breakfast cereals with a fibre content >15% and containing at least 20% bran, energy-reduced or with no added sugar	1000 mg/kg
Energy-reduced soups	110 mg/l
Breath-freshening micro-sweets with no added sugar	6000 mg/kg
Strongly flavoured freshening throat pastilles with no added sugar	2000 mg/kg
Energy-reduced beer	
Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	450 mg/l
Spirit drinks containing <15% alcohol by volume	450 mg/l
Feinkostsalat (delicatessen salads)	Category removed
Tabletop sweeteners	GMP (30000 mg/kg)

ASSESSMENT

1. Introduction

Following a request from the European Commission, the European Food Safety Authority (EFSA), carried out a revised exposure assessment of steviol glycosides from its use as a food additive, for children and adults, based on the revised proposed uses presented in the terms of reference. Use levels considered in this revised exposure assessment were reduced for 16 food by a factor of 1.5-3 compared to those considered in the former EFSA evaluation (EFSA, 2010), 15 other food uses were removed (mainly falling under the category of "desserts and similar products") and no changes were observed for 12 food uses. Moreover, three new food uses were included: Smoked, dried, fermented, and/or salted fish and fish products including molluscs, crustaceans, and echinoderms; Soybean sauce (fermented, non-fermented, and other) and Tabletop sweetener.

In its opinion of 14 April 2010, the Panel on Food Additives and Nutrient Sources added to Food (ANS) has established an ADI of 4 mg/kg body weight/day for steviol glycosides. In the same opinion, the ANS Panel evaluated the safety in use of Steviol glycosides 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.

The applicants have recently submitted revised proposed uses in order to address the concerns raised.

Table 1: Comparison between the uses and use levels proposed originally and the revised proposed uses

Foodstuffs	**Maximum Use Levels**				
	Aspartame	**Initial proposed uses of Steviol glycosides[1]**	**Steviol Equivalents for the initial proposed uses[2]**	**Revised proposed uses of Steviol glycosides[1]**	**Steviol Equivalents for the revised proposed uses[2]**
Non-alcoholic drinks					
Water-based flavoured drinks, energy-reduced or with no added sugar	600 mg/l	600 mg/l	198 - 240 mg/l	600 mg/l (excludes dilutables)	198 - 240 mg/l
Milk- and milk-derivative-based or fruit juice-based drinks, energy-reduced or with no added sugar	600 mg/l	1000 mg/l	330 - 400 mg/l	350 mg/l	115.5 – 140 mg/l
Soy-based beverages	–	600 mg/l	198 - 240 mg/l	350 mg/l	115.5 – 140 mg/l
Desserts and similar products					
Water-based flavoured desserts, energy-reduced or with no added sugar	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	Category removed	–
Milk- and milk-derivate-based preparations, energy-reduced or with no added sugar	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	300 mg/l	99 - 120 mg/kg
Fruit- and vegetable-based desserts, energy-reduced or	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	Category removed	–

Foodstuffs	Maximum Use Levels				
	Aspartame	Initial proposed uses of Steviol glycosides[1]	Steviol Equivalents for the initial proposed uses[2]	Revised proposed uses of Steviol glycosides[1]	Steviol Equivalents for the revised proposed uses[2]
with no added sugar					
Egg-based desserts, energy-reduced or with no added sugar	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	Category removed	–
Cereal-based desserts, energy-reduced or with no added sugar	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	Category removed	–
Fat-based desserts, energy-reduced or with no added sugar	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	Category removed	
'snacks': certain flavours of ready to eat, prepacked, dry, savoury starch products and coated nuts	500 mg/kg	500 mg/kg	165 - 200 mg/kg	Category removed	–
Smoked, dried, fried, fermented, and/or salted fish and fish products including molluscs, crustaceans, and echinoderms (category number 09.2.5 under GSFA)	–	not included	–	600 mg/kg	198 - 240 mg/kg
Confectionery with no added sugar	1000 mg/kg	1000 mg/kg (hard candy)	330 - 400 mg/kg (hard candy)	1000 mg/kg	330 - 400 mg/kg (hard candy)
		1500 mg/kg (soft candy, nougats, and marzipans)	495 - 600 mg/kg (soft candy, nougats, and marzipans)	1000 mg/kg	330 - 400 mg/kg (soft candy, nougats, and marzipans)
Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	2000 mg/kg	2000 mg/kg	660 - 800 mg/kg	800 mg/kg	264 – 320 mg/kg
Starch-based confectionery, energy-reduced or with no added sugar	2000 mg/kg	2000 mg/kg	660 - 800 mg/kg	Category removed	–
Cocoa-, milk-, dried-fruit-, or fat-based sandwich spreads, energy-reduced or with no added sugar	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	Category removed	–
Chewing gum with no added sugar	5500 mg/kg	10 000 mg/kg	3300 - 4000 mg/kg	10 000 mg/kg	3300 – 4000 mg/kg
Cider and perry	600 mg/l	600 mg/l	198 - 240 mg/l	Category removed	
Alcohol-free beer or with an alcohol content not exceeding	600 mg/l	600 mg/l	198 - 240 mg/l	200 mg/l	66 – 80 mg/l

Foodstuffs	Maximum Use Levels				
	Aspartame	Initial proposed uses of Steviol glycosides[1]	Steviol Equivalents for the initial proposed uses[2]	Revised proposed uses of Steviol glycosides[1]	Steviol Equivalents for the revised proposed uses[2]
1,2% vol					
'Bière de table/tafelbier/Table beer' (original wort content less than 6%) except for 'Obergäriges Einfachbier'	600 mg/l	600 mg/l	198 - 240 mg/l	200 mg/l	66 – 80 mg/l
Beers with a minimum acidity of 30 milli-equivalents expressed as NaOH	600 mg/l	600 mg/l	198 - 240 mg/l	200 mg/l	66 - 80 mg/l
Brown beers of the 'oud bruin' type	600 mg/l	600 mg/l	198 - 240 mg/l	200 mg/l	66 – 80 mg/l
Edible ices, energy-reduced or with no added sugar	800 mg/l	800 mg/l	264- 320 mg/l	600 mg/l	198 – 240 mg/l
Canned or bottled fruit, energy-reduced or with no added sugar	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	Category removed	–
Energy-reduced jams, jellies, and marmalades	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	600 mg/kg	198 – 240 mg/kg
Energy-reduced fruit and vegetable preparations	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	600 mg/kg	198 – 240 mg/kg
Sweet-sour preserves of fruit and vegetables	300 mg/kg	600 mg/kg	198 - 240 mg/kg	300 mg/kg	99 - 120 mg/kg
Sweet-sour preserves and semi-preserves of fish and marinades of fish, crustaceans, and molluscs	300 mg/kg	600 mg/kg	198 - 240 mg/kg	600 mg/kg	198 - 240 mg/kg
Sauces	350 mg/kg	350 mg/kg	115.5 - 140 mg/kg	350 mg/kg	115.5 - 140 mg/kg
Soybean sauce (fermented, non-fermented, and other)		not included		500 mg/kg	165 – 200 mg/kg
Mustard	350 mg/kg	350 mg/kg	115.5 - 140 mg/kg	Category removed	–
Fine bakery products for special nutritional uses	1700 mg/kg	1000 mg/kg	330 - 400 mg/kg	Category removed	–
Complete formulae for weight control intended to replace total daily food intake or an individual meal	800 mg/kg	800 mg/kg	264 - 320 mg/kg	800 mg/kg	264 – 320 mg/kg
Complete formulae and nutritional supplements for use	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	1000 mg/kg	330 – 400 mg/kg

Foodstuffs	Maximum Use Levels				
	Aspartame	Initial proposed uses of Steviol glycosides[1]	Steviol Equivalents for the initial proposed uses[2]	Revised proposed uses of Steviol glycosides[1]	Steviol Equivalents for the revised proposed uses[2]
under medical supervision					
Liquid food supplements/dietary integrators	600 mg/kg	600 mg/kg	198 - 240 mg/kg	600 mg/kg	198 – 240 mg/kg
Solid food supplements/dietary integrators	2000 mg/kg	2000 mg/kg	660 - 800 mg/kg	2000 mg/kg	–
Essoblatten (a type of wafer)	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	Category removed	–
Food supplements/diet integrators based on vitamin and/or mineral elements, syrup-type or chewable	5500 mg/kg	5500 mg/kg	1815 - 2200 mg/kg	5500 mg/kg	1815 – 2200 mg/kg
Breakfast cereals with a fibre content >15% and containing at least 20% bran, energy-reduced or with no added sugar	1000 mg/kg	1000 mg/kg	330 - 400 mg/kg	1000 mg/kg	330 – 400 mg/kg
Energy-reduced soups	110 mg/l	110 mg/l	36.3 - 44 mg/l	110 mg/l	36.3 – 44 mg/l
Breath-freshening micro-sweets with no added sugar	6000 mg/kg	10 000 mg/kg	3300 - 4000 mg/kg	6000 mg/kg	1980 – 2400 mg/kg
Strongly flavoured freshening throat pastilles with no added sugar	2000 mg/kg	2000 mg/kg	660 - 800 mg/kg	2000 mg/kg	660 – 800 mg/kg
Energy-reduced beer	25 mg/l	–	–	–	–
Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	600 mg/l	600 mg/l	198 - 240 mg/l	450 mg/l	148.5 – 180 mg/l
Spirit drinks containing <15% alcohol by volume	600 mg/kg	600 mg/l	198 - 240 mg/l	450 mg/l	148.5 – 180 mg/l
Feinkostsalat (delicatessen salads)	350 mg/kg	350 mg/kg	115.5 - 140 mg/kg	Category removed	–
Tabletop sweeteners	–	–	–	GMP (30 000 mg/kg)[(a)]	GMP (9900 – 12 000 mg/kg) [(a)]

[1] Use levels are represented as "steviol glycosides" based on the similarity of sweetness potency between stevioside and rebaudioside A, which are the major constituent glycosides of steviol glycoside sweetness.

[2] 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 opinion (low conversion factor = 0.33, high conversion factor = 0.40).

(a): maximum use level as reported by UNESDA in Tennant, 2010.

2. Methods

2.1. Usage of steviol glycosides

The calculations of anticipated dietary exposure estimates to steviol glycosides have been performed using the revised proposed use levels as defined in the terms of reference (Table 1).

The uses and use levels for steviol glycosides proposed by the three applicants are lower than those currently permitted for aspartame in the EU (Directive 94/35/EC[5] on sweeteners for use in foodstuffs), with major exceptions for smoked, dried, fermented, and/or salted fish and fish products including molluscs, crustaceans, and echinoderms, and tabletop sweeteners, which are not included in this Directive; and the exclusion of use of steviol glycosides in dilutable drinks (under the "water-based flavoured drinks, energy-reduced or with no added sugar" food item). Other minor exceptions are for chewing-gum with no added sugar (10 000 mg steviol glycosides/kg product instead of 5500 mg aspartame/kg product), sweet-sour preserves and semi-preserves of fish, crustaceans, and molluscs (600 mg steviol glycosides/kg product instead of 300 mg aspartame/kg product).

2.2. Application of the approach used in the opinion of the ANS Panel

The exposure to steviol glycosides was assessed using the approach used in the opinion of the ANS Panel (EFSA, 2010), which is derived from the approach originally developed in the report of the Scientific Co-Operation (SCOOP) Task 4.2, to estimates intake of food additives (EC, 1998).

For the purpose of obtaining exposure estimates based on the revised proposed uses, only Tier 2 calculations have been performed.

Exposure assessments were carried out for children and adults.

For children, consumption data used come from the EXPOCHI consortium (data from Belgium, France, the Netherlands, Spain, Czech Republic, Italy, Finland, Germany, Greece, Cyprus, Sweden) (Huybrechts et al., 2010) and for UK children, from the NDNS survey (Gregory et al., 1995). For adults, exposure estimate is based on UK population (NDNS survey) (Henderson et al., 2002)

The two conversion factors (lowest conversion factor = 0.33, highest conversion factor = 0.40) used by the ANS Panel for the calculation of steviol equivalents were applied (EFSA, 2010).

As corresponding detailed consumption data are not available in the EXPOCHI database, no distinction has been made between the dilutable drinks and the other drinks for the water-based flavoured drinks, energy-reduced or with no added sugar food item.

2.3. Dietary exposure

Revised exposures estimates have been calculated using the revised proposed use levels with national food consumption data for children and the adult population.

Table 3 summarises the anticipated exposure of children and adults to steviol glycosides and table 4 summarises the main food groups contributing to the total anticipated dietary exposure.

The mean dietary exposure to steviol glycosides expressed as steviol equivalents in European children (aged 1-14 years) ranged from 0.4 to 6.4 mg/kg bw/day, and from 1.7 to 16.3 mg/kg bw/day at the

[5] European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs. OJ L 237, 10.9.1994, p. 3.

95th/97.5th percentile. The main contributors (>10% in all countries) to the total anticipated exposure to steviol glycosides, expressed as steviol equivalents, are non-alcoholic flavoured drinks (40-82%). Desserts, including flavoured milk products accounted for 10 to 38% for 11 countries (all countries, except for UK). Extruded, puffed and/or fruit-flavoured breakfast cereals accounted for 10 to 19% in 3 countries. Three others food categories accounted for more than 10% in one country: sauces, seasonings, pickles, relishes, chutney, piccalilli for 19%, tabletop sweeteners for 12%, and confectionery for 10%.

The highest exposure estimates for children refer to UK pre-school children (for mean and 95th percentile). The mean exposure estimate is also above the ADI of 4 mg/kg bw/day for the 2-6 years old children in The Netherlands when the highest conversion factor is applied. At the 95th percentile, the exposure estimates are above the ADI for the following countries: Germany, Belgium, Finland, Sweden, Spain, Czech Republic.

Exposure estimates calculated for the adults UK population give a mean dietary exposure to steviol glycosides, expressed as steviol equivalents of 1.9-2.3 mg/kg bw/day and of 5.6-6.8 mg/kg bw/day for high level consumers (97.5th percentile). The main contributors (>10%) to the total anticipated exposure to steviol glycosides, expressed as steviol equivalents, are non-alcoholic flavoured drinks (42%), tabletop sweeteners (26%) and beer, cidre bouché (12%).

Table 2: Summary of anticipated exposure to steviol glycosides expressed as steviol equivalents in children and adult populations

Tier 2. Maximum Proposed use Level*	**Adult UK population** (>18 years old)	**Children population** (1-14 years old)
	mg/kg bw/day	
Mean exposure	1.9-2.3	0.4-6.4
Exposure at 95th or 97.5th percentile**	5.6-6.8	1.7-16.3

* 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 opinion of the ANS Panel (0.33 - 0.4).

** 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).

Table 3: Food groups contributing to the total anticipated exposure to steviol glycosides from its use as a sweetener, for children and adults; for children population, the minimum and maximum contributions per food group are shown, based on data from the 12 different European countries.

	Children			**Adults***
	Contribution to the total anticipated exposure in individual countries		**No of countries with a contribution > 10%****	**Contribution to the total anticipated exposure ****
Food groups	**Minimum**	**Maximum**		
Non-alcoholic flavoured drinks	**40.0%**	**82% (Czech Republic)**	12	**42%**
Desserts inc. flavoured milk products	5.4%	**38% (Finland)**	11	3%
Extruded, puffed and/or fruit-flavoured breakfast cereals	0.0%	**19% (Cyprus)**	3	5%

Sauces, seasonings (e.g. curry powder, tandoori), pickles, relishes, chutney, piccalilli	0.2%	**19% (Germany)**	1	1%
Tabletop sweetener*	0.0%	**12% (UK)**	1	**26%**
Confectionery	0.0%	**10% (Finland)**	1	3%
Jams, jellies, and marmalades as mentioned in Directive 79/693/EEC and other similar fruit preparations including low-calorie products	0.0%	5% (Finland)	-	-
Soups	0.1%	5% (Greece)	-	-
Fruit-flavoured breakfast cereals	0.0%	3% (Czech Republic)	-	-
Edible ices	0.0%	3% (The Netherlands)	-	1%
Surimi	0.0%	2% (France)	-	
Beer, Cidre bouche	-	-	-	**12%**
Spirituous beverages (inc. products less than 15% alcohol by volume), except any mentioned in Schedule 2 or 3	-	-	-	1%
Fruit wines (still or sparkling), Cider (except cidre bouche) and perry, Aromatized fruit wines, cider and perry	-	-	-	2.5%

*consumption data only available from the UK population

**only food groups contributing to more than 1% are presented

3. Discussion

In comparison to the opinion of the ANS Panel (EFSA, 2010), the results of the revised exposure assessment for steviol glycosides, expressed as steviol equivalents, are slightly lower, but of the same order of magnitude. The revised exposure estimates range from 1.9 to 2.3 mg/kg bw/day for adults while in the opinion of the ANS Panel, the estimated exposures for the adult population ranged from 2.2 to 2.7 mg/kg bw/day. For children, mean exposure estimates decreased from 0.7-7.2 mg/kg bw/day to 0.4-6.4 mg/kg bw/day for the revised exposure estimates. For children high consumers, the exposure estimates range between 1.7 and 16.3 mg/kg bw/day, whereas the estimates in the ANS Panel opinion ranged between 3.3 and 17.2 mg/kg bw/day. The largest decrease is observed for the adult high consumers (97.5th percentile) whose exposure to steviol glycosides at the upper range decreased from 9.7 mg/kg bw/day in the ANS opinion, to 6.8 mg/kg bw/day in the revised exposure assessment.

For children, the main contributors to the total anticipated exposure remain soft drinks and desserts. The food items “sauces, seasonings, pickles, relishes, chutney, piccalilli”, “extruded, puffed and/or fruit-flavoured breakfast cereals” contribute in the revised exposure assessment for more than 10% in one country, while they were contributing less than 10% in the ANS Panel opinion. Tabletop sweeteners, which were not considered previously, contribute here for more than 10% of the total anticipated exposure for one country. On the other hand, candied fruits and vegetables account for less than 10% in the revised exposure assessment, while these were contributing 17% of the total anticipated exposure in the opinion of the ANS Panel.

For the adult population, the main contributors are the same as the ones identified in the ANS panel opinion (EFSA, 2010) (soft drinks and beer and cider) but tabletop sweeteners, which previously were not considered, contribute now for more than 10% of the total anticipated exposure for the UK adult population.

Several food consumption databases were used to conduct the current exposure assessment. The data of the EXPOCHI project present a good geographical spread of the food consumption of children in Europe, a standardised approach in food categorisation via use applications in Directive 94/36/EC and in executing exposure assessments. However, the different food consumption databases used within the EXPOCHI project were based on different survey designs using different dietary assessment methods, and although the highest level of detail possible was provided, this level differed for the various countries. In the food consumption databases, there was insufficient detail in most food descriptors at the time of the project to be able to make very detailed food selections, thus contributing to the uncertainties in the final exposure estimates.

For example, it must be noted that due to the limitations in the EXPOCHI food categorisation system, it is not possible to distinguish the dilutable drinks from the non-dilutable drinks within the category "water-based flavoured drinks, energy-reduced or with no added sugar". Therefore, they have been included in the foodgroup "non-alcoholic flavoured drinks" as containing steviol glycosides.

"Chewing gum with no added sugar" has a proposed revised level of use of 3300 mg/kg, expressed as steviol equivalents. However chewing gum is included in the confectionery food group of the EXPOCHI consumption database and cannot be distinguished from other confectioneries. As a result, the revised proposed use level of confectionery (330 mg/kg, expressed as Steviol equivalents) has been allocated to the whole food group "confectionery", including "chewing gum with no added sugar", in order to avoid too conservative estimates. It can be noted that "chewing gum with no added sugar" is a very specific food category which consumption is unlikely to be high, compared to the total consumption of all foodstuffs under the group "confectionery".

When considering the results, it is important to note that these revised exposure estimates, like the ones calculated in the opinion of the ANS Panel, should be considered as conservative. Indeed, an assumption made was that all processed foods and beverages contain the sweetener steviol glycosides added at the maximum proposed use levels (i.e. all beverages and not only energy-reduced beverages were considered; the latter was proposed by the applicants).

The EFSA Comprehensive European food consumption database[6] has been used to characterise uncertainty due to the difference in consumption of diet product vs. non-diet product (normal-calorie) for the food group "non-alcoholic flavoured drinks".

[6] The "EFSA Comprehensive European food consumption database" has been built on existing information on food consumption at a detailed level. By the end of 2008, competent organisations in EU Member States were approached to provide EFSA with data from the most recent national dietary survey in their country, including at least the adult population, at the level of consumption by the individual consumer. In addition, food consumption data for children, obtained through the Article 36 project "Individual food consumption data and exposure assessment studies for children" (acronym EXPOCHI), have been included in the Comprehensive Database which now contains data from 32 different dietary surveys carried out in 22 different Member States.

As non-alcoholic flavoured drinks represent by far the food group with the highest contribution to the total anticipated dietary exposure in both populations, a comparison has been made between the consumption of normal and low-calorie soft drinks by country[7] using the data available in the EFSA Comprehensive Database (not yet published).

Table 4: Ranges of the consumption levels of normal soft drinks and low-calorie soft drinks for adults and children in Europe (in g/day, comprehensive database)

	Mean - all population		95th percentile - consumers only	
	Normal-calorie soft drink (with sugar)	Low-calorie soft drink (sugar-free)	Normal-calorie soft drink (with sugar)	Low-calorie soft drink (sugar-free)
others children*	[0-206]	[0 - 34]	[225-783]	[33 - 983]
adolescents**	[<1-349]	[<1 - 185]	[125-1302]	[50 - 1250]
adults	[8 - 200]	[<1 - 374]	[330-1225]	[150-1312]

*others children: from 36 month up to and including10 years of age
**adolescents: from 11 up to and including 17 years of age

Detailed data for some countries are shown in table 5.

It should be noted that important differences exist in the consumption of normal and low-calorie soft drinks between countries. In most countries, the consumption of normal soft drinks is generally higher than the consumption of low-calorie soft drinks (Belgium, Denmark) (Table 5). However, the opposite conclusion can be made for other countries (Germany, The Netherlands) (Table 5). Similarly the percentage of consumers for normal-calorie soft drinks and for low-calorie soft drinks can vary widely between countries. For instance, in Belgium and Denmark the percentage of consumers is higher for normal-calorie soft drinks than for low-calorie soft drinks while in Germany and the Netherlands (adults), it is the other way around. As seen in Table 5, important differences result from several country surveys thus leading to important exposure estimate ranges. Overall, no tendency can be drawn from these data between low-calorie soft drinks consumption levels and normal-calorie soft drinks consumption levels. Therefore, the consumption levels of normal-calorie soft drinks can be considered as an acceptable approximation of the consumption levels of low-calorie soft drinks and thus the exposure estimates for adults do not need to be corrected.

Table 5: Detailed data on the consumption of normal and low-calorie soft drinks for Belgium, Denmark, Germany, the Netherlands and United Kingdom

		Mean - all population		95th percentile - consumers only			
Country	population	Normal-calorie soft drink (with sugar)	Low-calorie soft drink (sugar-free)	Normal-calorie soft drink (with sugar)	% consumers	Low-calorie soft drink (sugar-free)	% consumers
Belgium*	others children	101	20	508	58	400	14
	adolescents	349	62	1303	72	870	19
	adults	200	72	1225	46	1080	19
Denmark**	others children	139	24	421	87	336	21
	adolescents	242	32	757	90	500	20
	adults	125	30	700	57	579	18

[7] Indeed, due to the different methodologies used in surveys from the EFSA Comprehensive European food consumption database, it is recommended not to compare data from different countries.

Germany	Children +	111	23	783	49	983	8
	Adolescents ++	16	185	750	6	1250	45
	Adults ++	8	112	700	3	1313	26
The Netherlands	children 2-6 years old[#]	67	12	313	86	425	10
	adults [##]	750	374	854	4	1258	60
United Kingdom***	adults	75	65	522	48	651	33

* Diet national 2004-2005, 24-hour recall (Huybrechts et al., 2008)
** Danish dietary survey, 2000-2002, food record (7 days) (Lyhne et al., 2005)
+ DONALD, 2006-2008, food record (3 days) (Kroke et al., 2004; Sichert-Hellert and Kersting, 2004)
++ National nutrition survey II, 2005-2007, 24-hour recall (MRI, 2008; Krems et al., 2006)
# DNFCS (Dutch National Food Consumption Survey) young children, food record (3 days) (Ocké et al., 2008)
DNFCS 2003, 24-hour recall (Ocké et al., 2005)
*** NDNS, 2000-2001, food record (7 days) (Henderson et al., 2002)

For adults, when considering the UK adult population, consumers only, the consumption of low-calorie soft drinks is higher than the consumption of normal soft drinks (Table 5), whereas the percentage of users is lower. Consumption data from the comprehensive database shows that consumption levels at the 95th percentile in consumers only are higher in some other countries than in the UK. Therefore, UK might not be considered as the worst case since e.g. Germans consume 50% more of soft drinks. Therefore, the Tier 2 calculations may underestimate the intake of steviol glycosides from the "non-alcoholic flavoured drinks" food group at the higher percentiles. However, it is important to bear in mind that the comparison is made between two different countries whose consumption surveys have been done following different methodologies. Therefore, it was decided not to apply a correction factor on the revised exposure estimate.

For children, comparisons between consumption data from EXPOCHI and from the Comprehensive database have been made by country as data are available for different countries on both consumption databases. For consumers only, the consumption levels of soft drinks at the 95th percentile used in the Tier 2 calculations are generally around 2 times greater (with exceptions for Germany (< 1), Greece (≈ 9) and Italy (≈ 5)) than 95th percentile consumption levels observed from the Comprehensive database. Therefore, the Tier 2 calculations for children, consumers only, may overestimate the intake of steviol glycosides from the "non-alcoholic flavoured drinks" food group at the 95th percentile by a factor of 2.

It was therefore decided to calculate corrected children exposure estimates using the consumption data extracted from the Comprehensive database for countries for which data were available and reducing the EXPOCHI figures by a factor 2 for the others (UK children, Czech Republic, Cyprus).

The results are presented in table 6.

Table 6: Anticipated exposure, corrected for high consumer, to steviol glycosides expressed as steviol equivalents in children population (1-14 years old)

Tier 2. Maximum Proposed use Level*	**Original Tier-2 estimates**	**Corrected exposures**
	mg/kg bw/day	mg/kg bw/day
Mean exposure	0.4-6.4	0.4-6.4
Exposure at 95th or 97.5th percentile**	1.7-16.3	1.0-12.7

Mean exposure estimates remain unchanged and UK pre-school children and The Netherlands children mean exposure estimates remain above the ADI of 4 mg/kg bw/day. At the 95th percentile, countries with exposure estimates above the ADI for children are Germany, UK, The Netherlands, Belgium, Spain and Finland.

By correcting high consumption level (95th/97.5th percentile) of soft drinks, the exposure estimates at the high level (95th/97.5th percentile) decreased from the range of 1.7 - 16.3 mg/kg bw/day to 1.0-12.7 mg/kg bw/day.

CONCLUSIONS

Following a request from the European Commission, a revised exposure assessment of steviol glycosides, expressed as steviol equivalents, from its use as a sweetener, for children and adults, was carried out based on the revised proposed use levels defined in the terms of reference, and with reference to the exposure assessment presented in the former opinion on steviol glycosides by the EFSA's ANS Panel.

When considering the revised proposed maximum use levels, the mean dietary exposure to steviol glycosides, expressed as steviol equivalents, for European children (aged 1-14 years) ranged from 0.4 to 6.4 mg/kg bw/day, and from 1.7 to 16.3 mg/kg bw/day at the 95th percentile. The main contributors are the non-alcoholic flavoured drinks and the desserts including flavoured milk products. Taking into account uncertainties of non-alcoholic flavoured drink consumption, corrected exposure estimates for children high consumers (95th percentile) were calculated that range from 1.0 to 12.7 mg/kg bw/day.

Exposure estimates for the UK adult population give a mean dietary exposure to steviol glycosides, expressed as steviol equivalents, of 1.9-2.3 mg/kg bw/day, and of 5.6-6.8 mg/kg bw/day for high level exposures (97.5th percentile), with main contributors being non-alcoholic flavoured drinks, tabletop sweeteners and beer and cider.

The mean exposure estimates differ only slightly from the exposure estimates from the ANS Panel opinion (2010). By using data from the EFSA Comprehensive database, ranges of high level exposure estimates decreased from a maximum of 17.2 mg/kg bw/day from the ANS Panel opinion to 12.7 mg/kg bw/day for children but high level children exposures for several countries are still above the ADI of 4 mg/kg bw/day.

DOCUMENTATION PROVIDED TO EFSA

1. CANTOX health Sciences International, September 2010. Applicants' response to the European Commission Request to revise proposed uses of steviol glycosides.

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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