

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****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10 and Article 30(5) thereof,

Whereas:

- (1) Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) The European Food Safety Authority (hereinafter referred to as 'the Authority') evaluated the safety of steviol glycosides, extracted from the leaves of the *Stevia rebaudiana* Bertoni plant, as sweetener and expressed its opinion on 10 March 2010 ⁽²⁾. The Authority established an Acceptable Daily Intake (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 in children, suggest that it is likely that the ADI would be exceeded at the maximum proposed use levels.
- (3) Taking into account the conclusion of the Authority, the applicants submitted, in September 2010, revised uses and the Authority was requested to consider those uses. A statement on a new exposure assessment was published in January 2011 ⁽³⁾. Despite the revised uses, the conclusion was very similar, namely that both in adults and children the ADI can be exceeded for high-level consumers. The main contributors to the total anticipated exposure to steviol glycosides are non-alcoholic flavoured drinks (soft drinks).
- (4) While considering the need for new products which are energy-reduced to be placed on the market, the use of steviol glycosides as sweetener should be authorised at appropriate maximum use levels. Taking into account the potential significant contribution of soft drinks to the intake of steviol glycosides, a reduction in the use level for flavoured drinks, compared to the previously proposed use levels considered by the Authority, should be established.
- (5) The Commission will request from producers and users of steviol glycosides information about the actual use of the food additive after its authorisation. The Commission will make such information available to the Member States. When necessary, the Commission will ask the Authority to perform a new refined exposure assessment, taking into account the real uses of steviol glycosides in the different subcategories of foodstuffs and the consumption of normal versus energy-reduced foodstuffs.
- (6) The Authority expressed in its opinion the ADI for steviol glycosides as steviol equivalents. The dietary exposure to the steviol glycosides was also expressed as steviol equivalents. It is therefore appropriate that the maximum permitted use levels should also be expressed as steviol equivalents. Maximum levels of steviol glycosides are expressed as the sum of all named steviol glycosides mentioned in the specifications and can be converted to steviol equivalents using the conversion factors mentioned in the specifications.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

*Article 1***Amendment to Regulation (EC) No 1333/2008**

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this Regulation.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.⁽²⁾ Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to food on the safety of steviol glycosides for the proposed uses as a food additive. *The EFSA Journal* (2010); 8(4):1537.⁽³⁾ Statement of EFSA: 'Revised exposure assessment for steviol glycosides for the proposed uses as a food additive'. *The EFSA Journal* (2011); 9(01):1972.

*Article 2***Transitional provision**

By way of derogation to Article 2(1) of Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives ⁽¹⁾, the entries in Parts B and E of Annex II to Regu-

lation (EC) No 1333/2008 concerning steviol glycosides (E 960) shall apply from the date of entry into force of this Regulation.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in the Member States.

Done at Brussels, 11 November 2011.

For the Commission
The President
José Manuel BARROSO

⁽¹⁾ See page 1 of this Official Journal.

ANNEX

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) in Part B2 the following entry for E 960 is inserted after the entry for E 959:

| | |
|-------|---------------------|
| E 960 | Steviol glycosides' |
|-------|---------------------|

(2) in Part E the following entries for E 960 are inserted in numerical order in the food categories referred to:

PART E: AUTHORISED FOOD ADDITIVES AND CONDITIONS OF USE IN FOOD CATEGORIES

| Category number | E-number | Name | Maximum level (mg/l or mg/kg as appropriate) | Footnotes | restrictions/exception |
|-----------------|---|--|--|-----------|---|
| 01.4 | Flavoured fermented milk products including heat treated products | | | | |
| | E 960 | Steviol glycosides | 100 | (60) | only energy-reduced products or with no added sugar |
| | | (60): expressed as steviol equivalents | | | |
| 03. | Edible ices | | | | |
| | E 960 | Steviol glycosides | 200 | (60) | only energy-reduced or with no added sugar |
| | | (60): expressed as steviol equivalents | | | |
| 04.2.2 | Fruit and vegetables in vinegar, oil, or brine | | | | |
| | E 960 | Steviol glycosides | 100 | (60) | only sweet-sour preserves of fruit and vegetables |
| | | (60): expressed as steviol equivalents | | | |
| 04.2.4.1 | Fruit and vegetable preparations excluding compote | | | | |
| | E 960 | Steviol glycosides | 200 | (60) | only energy-reduced |
| | | (60): expressed as steviol equivalents | | | |
| 04.2.5.1 | Extra jam and extra jelly as defined by Directive 2001/113/EC | | | | |
| | E 960 | Steviol glycosides | 200 | (60) | only energy-reduced jams jellies and marmalades |
| | | (60): expressed as steviol equivalents | | | |
| 04.2.5.2 | Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC | | | | |
| | E 960 | Steviol glycosides | 200 | (60) | only energy-reduced jams, jellies and marmalades |
| | | (60): expressed as steviol equivalents | | | |

| Category number | E-number | Name | Maximum level (mg/l or mg/kg as appropriate) | Footnotes | restrictions/exception |
|-----------------|--|--|--|-----------|--|
| 04.2.5.3 | Other similar fruit or vegetable spreads | | | | |
| | E 960 | Steviol glycosides | 200 | (60) | only dried-fruit-based sandwich spreads, energy-reduced or with no added sugar |
| | | (60): expressed as steviol equivalents | | | |
| 05.1 | Cocoa and Chocolate products as covered by Directive 2000/36/EC | | | | |
| | E 960 | Steviol glycosides | 270 | (60) | only energy-reduced or with no added sugars |
| | | (60): expressed as steviol equivalents | | | |
| 05.2 | Other confectionery including breath refreshing microsweets | | | | |
| | E 960 | Steviol glycosides | 270 | (60) | only cocoa or dried fruit based, energy reduced or with no added sugar |
| | E 960 | Steviol glycosides | 330 | (60) | only cocoa, milk, dried fruit or fat based sandwich spreads, energy-reduced or with no added sugar |
| | E 960 | Steviol glycosides | 350 | (60) | only confectionery with no added sugar |
| | E 960 | Steviol glycosides | 2 000 | (60) | only breath-freshening micro-sweets, with no added sugar |
| | E 960 | Steviol glycosides | 670 | (60) | only strongly flavoured freshening throat pastilles with no added sugar |
| | | (60): expressed as steviol equivalents | | | |
| 05.3 | Chewing gum | | | | |
| | E 960 | Steviol glycosides | 3 300 | (60) | only with no added sugar |
| | | (60): expressed as steviol equivalents | | | |
| 05.4 | Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4 | | | | |
| | E 960 | Steviol glycosides | 330 | (60) | only confectionery with no added sugar |
| | E 960 | Steviol glycosides | 270 | (60) | only cocoa or dried fruit based, energy reduced or with no added sugar |
| | | (60): expressed as steviol equivalents | | | |

| Category number | E-number | Name | Maximum level (mg/l or mg/kg as appropriate) | Footnotes | restrictions/exception |
|-----------------|---|--|--|-----------|---|
| 06.3 | Breakfast cereals | | | | |
| | E 960 | Steviol glycosides | 330 | (60) | only breakfast cereals with a fibre content of more than 15 %, and containing at least 20 % bran, energy reduced or with no added sugar |
| | | (60): expressed as steviol equivalents | | | |
| 07.2 | Fine bakery wares | | | | |
| | E 960 | Steviol glycosides | 330 | (60) | only essoblaten - wafer paper |
| | | (60): expressed as steviol equivalents | | | |
| 09.2. | Processed fish and fishery products including molluscs and crustaceans | | | | |
| | E 960 | Steviol glycosides | 200 | (60) | only sweet-sour preserves and semi preserves of fish and marinades of fish, crustaceans and molluscs |
| | | (60): expressed as steviol equivalents | | | |
| 11.4.1 | Table Top Sweeteners in liquid form | | | | |
| | E 960 | Steviol glycosides | QS | (60) | |
| | | (60): expressed as steviol equivalents | | | |
| 11.4.2 | Table Top Sweeteners in powder form | | | | |
| | E 960 | Steviol glycosides | QS | (60) | |
| | | (60): expressed as steviol equivalents | | | |
| 11.4.3 | Table Top Sweeteners in tablets | | | | |
| | E 960 | Steviol glycosides | QS | (60) | |
| | | (60): expressed as steviol equivalents | | | |
| 12.5 | Soups and broths | | | | |
| | E 960 | Steviol glycosides | 40 | (60) | only energy-reduced soups |
| | | (60): expressed as steviol equivalents | | | |

| Category number | E-number | Name | Maximum level (mg/l or mg/kg as appropriate) | Footnotes | restrictions/exception |
|-----------------|---|--|--|-----------|---|
| 12.6 | Sauces | | | | |
| | E 960 | Steviol glycosides | 120 | (60) | except soy-bean sauce (fermented and non-fermented) |
| | E 960 | Steviol glycosides | 175 | (60) | only soy-bean sauce (fermented and non-fermented) |
| | | (60): expressed as steviol equivalents | | | |
| 13.2 | Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5) | | | | |
| | E 960 | Steviol glycosides | 330 | (60) | |
| | | (60): expressed as steviol equivalents | | | |
| 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) | | | | |
| | E 960 | Steviol glycosides | 270 | (60) | |
| | | (60): expressed as steviol equivalents | | | |
| 14.1.3 | Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products | | | | |
| | E 960 | Steviol glycosides | 100 | (60) | only energy-reduced or with no added sugar |
| | | (60): expressed as steviol equivalents | | | |
| 14.1.4 | Flavoured drinks | | | | |
| | E 960 | Steviol glycosides | 80 | (60) | only energy reduced or with no added sugar |
| | | (60): expressed as steviol equivalents | | | |
| 14.2.1 | Beer and malt beverages | | | | |
| | E 960 | Steviol glycosides | 70 | (60) | 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 |
| | | (60): expressed as steviol equivalents | | | |
| 14.2.8 | Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks | | | | |
| | E 960 | Steviol glycosides | 150 | (60) | |
| | | (60): expressed as steviol equivalents | | | |

| Category number | E-number | Name | Maximum level (mg/l or mg/kg as appropriate) | Footnotes | restrictions/exception |
|-----------------|---|--|--|-----------|--|
| 15.1 | Potato-, cereal-, flour- or starch-based snacks | | | | |
| | E 960 | Steviol glycosides | 20 | (60) | |
| | | (60): expressed as steviol equivalents | | | |
| 15.2 | Processed nuts | | | | |
| | E 960 | Steviol glycosides | 20 | (60) | |
| | | (60): expressed as steviol equivalents | | | |
| 16. | Desserts excluding products covered in category 1, 3 and 4 | | | | |
| | E 960 | Steviol glycosides | 100 | (60) | only energy-reduced or with no added sugar |
| | | (60): expressed as steviol equivalents | | | |
| 17.1 | Food supplements supplied in a solid form including capsules and tablets and similar forms | | | | |
| | E 960 | Steviol glycosides | 670 | (60) | |
| | | (60): expressed as steviol equivalents | | | |
| 17.2 | Food supplements supplied in a liquid form | | | | |
| | E 960 | Steviol glycosides | 200 | (60) | |
| | | (60): expressed as steviol equivalents | | | |
| 17.3 | Food supplements supplied in a syrup-type or chewable form | | | | |
| | E 960 | Steviol glycosides | 1 800 | (60) | |
| | | (60): expressed as steviol equivalents | | | |