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)

COMMISSION REGULATION (EU) No 1131/2011

of 11 November 2011

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(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 bodyweight/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.

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[(4)], the entries in Parts B and E of Annex II to Regulation (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

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 1131/2011. (See end of Document for details)*

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			
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 refreshening 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