COMMISSION REGULATION (EU) 2016/1814

of 13 October 2016

amending the Annex to Regulation (EU) No 231/2012 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 as regards specifications for steviol glycosides (E 960)

(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 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ([2]), and in particular Article 7(5) thereof,

Whereas:

(1) Commission Regulation (EU) No 231/2012 ([3]) lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.

(2) Those specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.

(3) On 13 November 2013 an application was submitted for the amendment of specifications concerning the food additive steviol glycosides (E 960). The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(4) The current specifications stipulate that steviol glycosides (E 960) preparations contain not less than 95 % of ten named steviol glycosides: stevioside, rebaudiosides A, B, C, D, E and F, steviolbioside, rubusoside and dulcoside, on a dried basis. The specifications further define the preparations/final product consisting mainly (at least 75 %) of stevioside and/or rebaudioside A.

(5) The applicant requests that rebaudioside M is added to the list of permitted steviol glycosides as an additional glycoside that may comprise the assay value of not less than 95 % (total steviol glycoside content). The applicant also requests that the minimum amount of 75 % of stevioside and/or rebaudioside A is deleted, i.e., to change the 'Definition' of steviol glycosides.

(6) The applicant further requests to expand the lists of chemical names and molecular weights and CAS numbers to include, in addition to stevioside and rebaudioside A, the other nine steviol glycosides. Rebaudioside M should also be added to the listing of molecular formulas. To account for the greater sweetness potency of rebaudioside M, the 'Description' of steviol glycosides should be amended.

(7) Since stevioside and rebaudioside A may not necessarily be the principal steviol glycosides, the stevioside and rebaudioside A criterion under the 'Identification' of steviol glycosides should be removed from the specifications.

(8) According to information provided by the applicant, a production process has been developed which allows for the selective isolation of rebaudioside M resulting in the production of steviol glycosides preparations enriched in

([1]) OJ L 354, 31.12.2008, p. 16.
([2]) OJ L 354, 31.12.2008, p. 1.
([3]) 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).

rebaudioside M specifically, at a range of concentrations (from 50 % up to nearly 100 %). According to the applicant, only leaves of the *Stevia rebaudiana* Bertoni plant comprise the starting material for the production of steviol glycoside extracts containing at least 50 % rebaudioside M. Its manufacturing process is similar to the general method of extracting steviol glycosides from the leaves of *S. rebaudiana* which has been previously reviewed by EFSA in 2010 ([1]).

(9) In the new production process, the crushed stevia leaves are extracted with hot water and the resulting extract is subjected to isolation and purification (by use of ion-exchange chromatography). This initial stage is followed by additional purification steps, including further and repeated recrystallisation and separation steps. Through the manipulation of these purification steps (i.e. specific number of crystallisation steps, solvent concentration, as well as temperature and duration of the process) the manufacturer is able to selectively crystallise a preparation high in rebaudioside M. Also, the production process involves use of solvents (ethanol and methanol) that are currently recognised for use in the manufacture of steviol glycoside preparations.

(10) That production process results in a preparation that contains 95 % of steviol glycosides with rebaudioside M representing more than 50 % of the finished product and the remainder comprising the following ten related steviol glycosides in any combination and ratio: stevioside, rebaudiosides A, B, C, D, E, F, dulcoside, steviolbioside and rubusoside. While extracts characterised by a ≥ 95 % content of rebaudioside M contain < 5 % of rebaudiosides D, A and B combined, extracts with a lower rebaudioside M content (approximately 50 %) may comprise close to 40 % rebaudioside D and 7 % rebaudioside A.

(11) In its opinion ([2]) of 8 December 2015 the European Food Safety Authority ('the Authority') concluded that extending the current specifications to include rebaudiosides D and M as alternatives to rebaudioside A in the predominant components of steviol glycosides would not be of a safety concern. The Authority also concluded that provided that the total amount of steviol glycosides (stevioside; rebaudiosides A, B, C, D, E, F and M; steviol-bioside; rubusoside and dulcoside) were greater than 95 %, which are all converted to steviol, and given that there was no evidence of absorption for intact glycosides at realistic use levels, the specific steviol glycosides (E 960) composition would not be of a safety concern. It was also considered that the ADI of 4 mg/kg bw/day (expressed as steviol equivalents) can also be applied where total steviol glycosides (stevioside; rebaudiosides A, B, C, D, E, F and M; steviolbioside; rubusoside and dulcoside) comprise more than 95 % of the material.

(12) Taking into account the submitted application and the evaluation made by the Authority, it is appropriate to amend the specifications of the food additive E 960.

(13) Regulation (EU) No 231/2012 should therefore be amended accordingly.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 231/2012 is amended in accordance with the Annex to this Regulation.

Article 2

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

([1]) EFSA Panel on Food Additives and Nutrient Sources (ANS); Scientific Opinion on safety of steviol glycosides for the proposed uses as a food additive. *EFSA Journal* 2010;8(4):1537. [85 pp.]. doi:10.2903/j.efsa.2010.1537

([2]) EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to food), 2015. Scientific opinion on the safety of the proposed amendment of the specifications for steviol glycosides (E 960) as a food additive. *EFSA Journal* 2015;13(12):4316, 29 pp. doi:10.2903/j.efsa.2015.4316

This Regulation shall be binding in its entirety and directly applicable in all Members States.

Done at Brussels, 13 October 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In the Annex to Regulation (EU) No 231/2012, the entry for E 960 steviol glycosides is replaced by the following:

'E 960 STEVIOL GLYCOSIDES

Synonyms

Definition

The manufacturing process comprises two main phases: the first involving water extraction of the leaves of the *Stevia rebaudiana* Bertoni plant and preliminary purification of the extract by employing ion exchange chromatography to yield a steviol glycoside primary extract, and the second involving recrystallisation of the steviol glycosides from methanol or aqueous ethanol resulting in a final product containing not less than 95 % of the below identified 11 related steviol glycosides, in any combination and ratio.

The additive may contain residues of ion-exchange resins used in the manufacturing process. Several other related steviol glycosides that may be generated as a result of the production process, but do not occur naturally in the *Stevia rebaudiana* plant have been identified in small amounts (0,10 to 0,37 % w/w).

Chemical name

Steviolbioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid

Rubusoside: 13-β-D-glucopyranosyloxykaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Dulcoside A: 13-[(2-O-α–L-rhamnopyranosyl-β–D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Stevioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D- glucopyranosyl ester

Rebaudioside B: 13-[(2-O-β–D-glucopyranosyl-3-O-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid

Rebaudioside C: 13-[(2-O-α–L-rhamnopyranosyl-3-O-β–D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Rebaudioside D: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Rebaudioside E: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Rebaudioside F: 13[(2-O-β-D-xylofurananosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester

Rebaudioside M: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester

Molecular formula

Trivial name	**Formula**	**Conversion factor**
Steviol	$C_{20}H_{30}O_3$	1,00
Steviolbioside	$C_{32}H_{50}O_{13}$	0,50
Rubusoside	$C_{32}H_{50}O_{13}$	0,50
Dulcoside A	$C_{38}H_{60}O_{17}$	0,40
Stevioside	$C_{38}H_{60}O_{18}$	0,40
Rebaudioside A	$C_{44}H_{70}O_{23}$	0,33
Rebaudioside B	$C_{38}H_{60}O_{18}$	0,40
Rebaudioside C	$C_{44}H_{70}O_{22}$	0,34
Rebaudioside D	$C_{50}H_{80}O_{28}$	0,29

	Rebaudioside E	C_{44} H_{70} O_{23}	0,33
	Rebaudioside F	C_{43} H_{68} O_{22}	0,34
	Rebaudioside M	C_{56} H_{90} O_{33}	0,25
Molecular weight and CAS No	**Trivial name**	**CAS Number**	**Molecular weight** (g/mol)
	Steviol		318,46
	Steviolbioside	41093-60-1	642,73
	Rubusoside	64849-39-4	642,73
	Dulcoside A	64432-06-0	788,87
	Stevioside	57817-89-7	804,88
	Rebaudioside A	58543-16-1	967,01
	Rebaudioside B	58543-17-2	804,88
	Rebaudioside C	63550-99-2	951,02
	Rebaudioside D	63279-13-0	1 129,15
	Rebaudioside E	63279-14-1	967,01
	Rebaudioside F	438045-89-7	936,99
	Rebaudioside M	1220616-44-3	1 291,30
Assay	Not less than 95 % steviolbioside, rubusoside, dulcoside A, stevioside, rebaudiosides A, B, C, D, E, F and M on the dried basis, in any combination and ratio.		
Description	White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5 % sucrose equivalency).		
Identification			
Solubility	Freely soluble to slightly soluble in water		
pH	Between 4,5 and 7,0 (1 in 100 solution)		
Purity			
Total ash	Not more than 1 %		
Loss on drying	Not more than 6 % (105 °C, 2h)		
Residual solvents	Not more than 200 mg/kg methanol		
	Not more than 5 000 mg/kg ethanol		
Arsenic	Not more than 1 mg/kg		
Lead	Not more than 1 mg/kg’		