

COMMISSION REGULATION (EU) 2021/1156**of 13 July 2021****amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards steviol glycosides (E 960) and rebaudioside M produced via enzyme modification of steviol glycosides from Stevia****(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 Articles 10(3) and 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) Annex II to 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 Annex to 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.
- (3) The Union list of food additives and the specifications for food additives 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 from a Member State or an interested party.
- (4) In February 2018, an application was submitted to the Commission for the amendment of the specifications concerning the food additive steviol glycosides (E 960). The Commission made the application available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The current specifications stipulate that steviol glycosides (E 960) are to contain not less than 95 % of eleven named steviol glycosides: stevioside, rubusoside, dulcoside A, steviolbioside and rebaudiosides A, B, C, D, E, F and M, on a dried basis, in any combination and ratio. The manufacturing process of this food additive comprises two main phases, the first involving water extraction from the leaves of the *Stevia rebaudiana* Bertoni plant and preliminary purification of the extract, and the second involving recrystallisation of the steviol glycosides.
- (6) The applicant requested an amendment of the specifications of stevia glycosides (E 960) to include a new method for the production of rebaudioside M. Rebaudioside M is a minor glycoside present at very low levels (< 1%) in the stevia leaf, which has a taste profile that is more reflective of sucrose when compared to the major glycosides (i.e. stevioside and rebaudioside A).
- (7) The new process involves the bioconversion of purified stevia leaf extract ($\geq 95\%$ steviol glycosides) through a multistep enzymatic process with enzymes prepared at the first stage of the process. The resulting rebaudioside M undergoes a series of purification and isolation steps to produce the final rebaudioside M ($\geq 95\%$).

⁽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).

- (8) The European Food Safety Authority ('the Authority') evaluated the safety of the proposed amendment of the specifications of the food additive steviol glycosides (E 960) and adopted its opinion on 24 September 2019 (*). The Authority considered that the enzymatic step process applied for the production of rebaudioside M may result in impurities, different from those that may be present in steviol glycosides (E 960) obtained from water extraction of the leaves of the *Stevia rebaudiana* followed by recrystallisation. Therefore, the Authority considered that separate specifications for rebaudioside M produced with this process are needed. Furthermore, it concluded that the existing Acceptable Daily Intake (ADI) of 4 mg/kg bw per day can also be applied to rebaudioside M produced via enzyme modification of steviol glycosides. The Authority considered that exposure to rebaudioside M (expressed as steviol equivalent) will not be higher than the exposure to steviol glycosides (E 960) if replaced by rebaudioside M produced via the enzymatic step process. The Authority also concluded that rebaudioside M produced by enzyme modification of steviol glycosides, using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts *K. phaffii* UGT-a and *K. phaffii* UGT-b, would not be of safety concern for the same proposed uses and at the same use levels as steviol glycosides (E 960).
- (9) Therefore, it is appropriate to authorise the use of rebaudioside M produced via the enzymatic step process as a sweetener in the food categories where steviol glycosides (E 960) are currently authorised.
- (10) Taking into account the ongoing process for the amendment of the International Numbering System for food additives of the Codex Alimentarius, it is appropriate to include the new food additive as 'E 960c enzymatically produced steviol glycosides' in Part B of Annex II to Regulation (EC) No 1333/2008 for labelling purposes. In the interest of clarity and coherence, the currently authorised food additive 'steviol glycosides (E 960)' should be renamed to 'steviol glycosides from Stevia (E 960a)'. As those food additives may be regulated combined, a new group for steviol glycosides, including both of them, should be inserted in Part C of Annex II to Regulation (EC) No 1333/2008, and all entries for steviol glycosides (E 960) in Part E of Annex II to that Regulation should be replaced accordingly, while maintaining the currently applicable uses and maximum level for authorised uses and use levels.
- (11) The specifications for rebaudioside M produced via enzyme modification of steviol glycosides from Stevia should be included in Regulation (EU) No 231/2012 in parallel with the inclusion of 'E 960c enzymatically produced steviol glycosides' in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008.
- (12) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (13) In order to allow economic operators to adapt to the new rules, it is appropriate to provide for a transitional period during which the food additive 'steviol glycosides from Stevia (E 960a)' and foods containing it may continue to be marketed as 'steviol glycosides (E 960)'.
- (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

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

Article 2

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

(*) EFSA Journal 2019;17(10):5867, 19 pp.

Article 3

The food additive 'steviol glycosides' (E 960) and foods containing it, which are labelled or placed on the market up to 18 months after the entry into force of this Regulation and which comply with the requirements of this Regulation, may be marketed until the stocks are exhausted.

Article 4

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

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

Done at Brussels, 13 July 2021

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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

(a) Part B2 is amended as follows:

(1) The entry for E 960 (Steviol glycosides) is replaced by the following:

'E 960a	Steviol glycosides from Stevia'
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(2) The following entry is inserted after the entry for E 960a:

'E 960c	Enzymatically produced steviol glycosides'
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(b) In point (5) of Part C, the following new point (v) is inserted after point (u) for E 626–635: Ribonucleotides:

'(v) E 960a – 960c: Steviol glycosides

E-number	Name
E 960a	Steviol glycosides from Stevia
E 960c	Enzymatically produced steviol glycosides'

(c) Part E is amended as follows:

(1) In Category 01.4 (Flavoured fermented milk products including heat-treated products), the entry for E 960 (Steviol glycosides) is replaced by the following:

'E 960a – 960c	Steviol glycosides	100	(1) (60)	only energy-reduced products or with no added sugar'
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(2) In Category 03 (Edible ices), the entry for E 960 (Steviol glycosides) is replaced by the following:

'E 960a – 960c	Steviol glycosides	200	(1) (60)	only energy-reduced products or with no added sugar'
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(3) In Category 04.2.2 (Fruit and vegetables in vinegar, oil, or brine), the entry for E 960 (Steviol glycosides) is replaced by the following:

'E 960a – 960c	Steviol glycosides	100	(1) (60)	only sweet-sour preserves of fruit and vegetables'
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(4) In Category 04.2.4.1 (Fruit and vegetable preparations excluding compote), the entry for E 960 (Steviol glycosides) is replaced by the following:

'E 960a – 960c	Steviol glycosides	200	(1) (60)	only energy-reduced'
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- (5) In Category 04.2.5.1 (Extra jam and extra jelly as defined by Directive 2001/113/EC), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	200	(1) (60)	only energy-reduced jams jellies and marmalades'
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- (6) In Category 04.2.5.2 (Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	200	(1) (60)	only energy-reduced jams jellies and marmalades'
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- (7) In Category 04.2.5.3 (Other similar fruit or vegetable spreads), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	200	(1) (60)	only energy-reduced fruit or vegetable spreads and dried-fruit-based sandwich spreads, energy-reduced or with no added sugar'
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- (8) In Category 05.1 (Cocoa and Chocolate products as covered by Directive 2000/36/EC), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	270	(1) (60)	only energy-reduced or with no added sugars'
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- (9) In Category 05.2 (Other confectionery including breath freshening microsweets), the entries for E 960 (Steviol glycosides) are replaced by the following:

	'E 960a – 960c	Steviol glycosides	270	(1) (60)	only cocoa or dried fruit based, energy reduced or with no added sugar
	E 960a – 960c	Steviol glycosides	330	(1) (60)	only cocoa, milk, dried fruit or fat based sandwich spreads, energy-reduced or with no added sugar
	E 960a – 960c	Steviol glycosides	350	(1) (60)	only confectionery with no added sugars only energy-reduced hard confectionery (candies and lollies) only energy-reduced soft confectionery (chewy candies, fruit gums and foam sugar products/marshmallows) only energy-reduced liquorice only energy-reduced nougat only energy-reduced marzipan

	E 960a – 960c	Steviol glycosides	2 000	(1) (60)	only breath-freshening micro-sweets, energy-reduced or with no added sugars
	E 960a – 960c	Steviol glycosides	670	(1) (60)	only strongly flavoured freshening throat pastilles, energy-reduced or with no added sugars'

- (10) In Category 05.3 (Chewing gum), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	3300	(1) (60)	only with no added sugar'
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- (11) In Category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4) the entries for E 960 (Steviol glycosides) are replaced by the following:

	'E 960a – 960c	Steviol glycosides	330	(1) (60)	only confectionary with no added sugar
	E 960a – 960c	Steviol glycosides	270	(1) (60)	only cocoa or dried fruit based, energy reduced or with no added sugar'

- (12) In Category 06.3 (Cereals and cereal products), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	330	(1) (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'
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- (13) In Category 07.2 (Fine bakery wares), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	330	(1) (60)	only essoblaten — wafer paper'
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- (14) In Category 09.2 (Processed fish and fishery products including molluscs and crustaceans), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	200	(1) (60)	only sweet-sour preserves and semi preserves of fish and marinades of fish, crustaceans and molluscs'
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- (15) In Category 11.4.1 (Table-top sweeteners in liquid form), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	<i>quantum satis</i>	(1) (60)'	
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- (16) In Category 11.4.2 (Table-top sweeteners in powder form), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	<i>quantum satis</i>	(1) (60)'	
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- (17) In Category 11.4.3 (Table-top sweeteners in tablets), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	<i>quantum satis</i>	(1) (60)'	
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- (18) In Category 12.4 (Mustard), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	120	(1) (60)'	
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- (19) In Category 12.5 (Soups and broths) the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	40	(1) (60)	only energy-reduced soups'
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- (20) In Category 12.6 (Sauces), the entries for E 960 (Steviol glycosides) are replaced by the following:

	'E 960a – 960c	Steviol glycosides	120	(1) (60)	except soy-bean sauce (fermented and non-fermented)
	E 960a – 960c	Steviol glycosides	175	(1) (60)	Only soy-bean sauce (fermented and non-fermented)'

- (21) In Category 13.2 (Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	330	(1) (60)'	
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- (22) In Category 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), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	270	(1) (60)'	
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- (23) In Category 14.1.3 (Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products), (i) the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar'
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- (24) In Category 14.1.4 (Flavoured drinks), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	80	(1) (60)	only energy-reduced or with no added sugar'
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- (25) In Category 14.1.5.2 (Other), the entries for E 960 (Steviol glycosides) are replaced by the following:

	'E 960a – 960c	Steviol glycosides	30	(1) (60) (93)	only coffee, tea and herbal infusion beverages, energy-reduced or with no added sugars
	E 960a – 960c	Steviol glycosides	30	(1) (60) (93)	only flavoured instant coffee and instant cappuccino products, energy-reduced or with no added sugars
	E 960a – 960c	Steviol glycosides	20	(1) (60) (93)	only malt-based and chocolate/cappuccino flavoured drinks, energy-reduced or with no added sugars'

- (26) In Category 14.2.1 (Beer and malt beverages), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	70	(1) (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'
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- (27) In Category 14.2.8 (Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	150	(1) (60)'	
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- (28) In Category 15.1 (Potato-, cereal-, flour- or starch-based snacks), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	20	(1) (60)'	
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- (29) In Category 15.2 (Processed nuts), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	20	(1) (60)'	
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- (30) In Category 16 (Desserts excluding products covered in categories 1, 3 and 4), the entry for E 960 (Steviol glycosides) is replaced by the following:

	'E 960a – 960c	Steviol glycosides	100	(1) (60)	only energy-reduced or with no added sugar'
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- (31) In Category 17.1 (Food supplements supplied in a solid form, excluding food supplements for infants and young children), the entries for E 960 (Steviol glycosides) are replaced by the following:

	'E 960a – 960c	Steviol glycosides	670	(1) (60)	
	E 960a – 960c	Steviol glycosides	1800	(1) (60)	only food supplements in chewable form'

- (32) In Category 17.2 (Food supplements supplied in a liquid form, excluding food supplements for infants and young children), the entries for E 960 (Steviol glycosides) are replaced by the following:

	E 960a – 960c	Steviol glycosides	200	(1) (60)	
	E 960a – 960c	Steviol glycosides	1800	(1) (60)	only food supplements in syrup form'

ANNEX II

The Annex to Regulation (EU) No 231/2012 is amended as follows:

- (1) In the entry for E 960 Steviol glycosides, the heading is replaced by the following:

'E 960a STEVIOL GLYCOSIDES FROM STEVIA'

- (2) The following new entry is inserted after the entry for E 960:

'E 960c(i) REBAUDIOSIDE M PRODUCED VIA ENZYME MODIFICATION OF STEVIOL GLYCOSIDES FROM STEVIA'

Synonyms			
Definition	<p>Rebaudioside M is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides such as rebaudioside A, rebaudioside B, rebaudioside D, rebaudioside I, and stevioside.</p> <p>Rebaudioside M is obtained via enzymatic bioconversion of purified steviol glycoside leaf extracts (95% steviol glycosides) of the <i>Stevia rebaudiana</i> Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts <i>K. phaffii</i> (formerly known as <i>Pichia pastoris</i>) UGT-a and <i>K. phaffii</i> UGT-b that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds.</p> <p>After removal of the enzymes by solid-liquid separation and heat treatment, the purification involves concentration of the rebaudioside M by resin adsorption, followed by recrystallisation of rebaudioside M resulting in a final product containing not less than 95 % of rebaudioside M. Viable cells of the yeasts <i>K. phaffii</i> UGT-a and <i>K. phaffii</i> UGT-b or their DNA shall not be detected in the food additive.</p>		
Chemical name	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
	Rebaudioside M	C ₅₆ H ₉₀ O ₃₃	0,25
Molecular weight and CAS No	Trivial name	CAS Number	Molecular weight (g/mol)
	Rebaudioside M	1220616-44-3	1,291.29
Assay	Not less than 95 % rebaudioside M on the dried basis.		
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 solvent	Not more than 5 000 mg/kg ethanol		

Arsenic	Not more than 0,015 mg/kg
Lead	Not more than 0,2 mg/kg
Cadmium	Not more than 0,015 mg/kg
Mercury	Not more than 0,07 mg/kg
Residual protein	Not more than 5 mg/kg
Particle size	Not less than 74 µm [using a mesh #200 sieve with a particle size limit of 74 µm]'