

Brussels, **XXX**
SANTE/10144/2021 ANNEX CIS
(POOL/E2/2021/10144/10144-EN
ANNEX CIS.docx)
[...](2021) **XXX** draft

ANNEXES 1 to 2

ANNEXES

to the

COMMISSION REGULATION (EU) .../...

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 as a sweetener

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’
---------	---------------------------------

(2) The following entry for E 960c is inserted after the entry for E 960a:

‘E 960c	Enzymatically produced steviol glycosides’
---------	--

(b) In Part C, Table 5: Other additives that may be regulated combined, the following point for E 960a – E 960c: Steviol glycosides is inserted after the 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) Category 01.4 (Flavoured fermented milk products including heat-treated products) is amended as follows:

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’
--	-------------------	--------------------	-----	-------------	--

(2) Category 03 (Edible ices), is amended as follows:

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’
--	-------------------	--------------------	-----	-------------	--

(3) Category 04.2.2 (Fruit and vegetables in vinegar, oil, or brine) is amended as follows:

(i) 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’
--	-------------------	--------------------	-----	-------------	---

- (4) Category 04.2.4.1 (Fruit and vegetable preparations excluding compote) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	200	(1) (60)	only energy-reduced'
--	-------------------	--------------------	-----	-------------	----------------------

- (5) Category 04.2.5.1 (Extra jam and extra jelly as defined by Directive 2001/113/EC) is amended as follows:

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'
--	-------------------	--------------------	-----	-------------	---

- (6) Category 04.2.5.2 (Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC) is amended as follows:

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'
--	-------------------	--------------------	-----	-------------	---

- (7) Category 04.2.5.3 (Other similar fruit or vegetable spreads) is amended as follows:

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'
--	-------------------	--------------------	-----	-------------	---

- (8) Category 05.1 (Cocoa and Chocolate products as covered by Directive 2000/36/EC) is amended as follows:

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'
--	-------------------	--------------------	-----	-------------	---

- (9) Category 05.2 (Other confectionery including breath freshening microsweets) is amended as follows:

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 00 0	(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) Category 05.3 (Chewing gum) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	330 0	(1) (60)	only with no added sugar'
--	----------------	--------------------	----------	-------------	---------------------------

(11) Category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4) is amended as follows:

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) Category 06.3 (Cereals and cereal products) is amended as follows:

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'
--	-------------------	--------------------	-----	-------------	--

- (13) Category 07.2 (Fine bakery wares) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	330	(1) (60)	only essoblaten — wafer paper'
--	-------------------	--------------------	-----	-------------	--------------------------------

- (14) Category 09.2 (Processed fish and fishery products including molluscs and crustaceans) is amended as follows:

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'
--	-------------------	--------------------	-----	-------------	---

- (15) Category 11.4.1 (Table-top sweeteners in liquid form) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	<i>qua ntu m satis</i>	(1) (60)'	
--	-------------------	--------------------	------------------------------------	--------------	--

- (16) Category 11.4.2 (Table-top sweeteners in powder form) is amended as follows:

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

	E 960a – 960c	Steviol glycosides	<i>qua ntu m satis</i>	(1) (60)'	
--	------------------	--------------------	------------------------------------	--------------	--

- (17) Category 11.4.3 (Table-top sweeteners in tablets) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	<i>qua ntu m satis</i>	(1) (60)'	
--	-------------------	--------------------	------------------------------------	--------------	--

- (18) Category 12.4 (Mustard) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	120	(1) (60)'	
--	-------------------	--------------------	-----	--------------	--

- (19) Category 12.5 (Soups and broths) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	40	(1) (60)	only energy-reduced soups'
--	-------------------	--------------------	----	-------------	----------------------------

- (20) Category 12.6 (Sauces) is amended as follows:

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) Category 13.2 (Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	330	(1) (60)'	
--	-------------------	--------------------	-----	--------------	--

- (22) 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) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	270	(1) (60)'	
--	-------------------	--------------------	-----	--------------	--

- (23) Category 14.1.3 (Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products) is amended as follows:

- (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'
--	-------------------	--------------------	-----	-------------	---

- (24) Category 14.1.4 (Flavoured drinks) is amended as follows:

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'
--	-------------------	--------------------	----	-------------	---

(25) Category 14.1.5.2 (Other) is amended as follows:

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) Category 14.2.1 (Beer and malt beverages) is amended as follows:

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'
--	-------------------	--------------------	----	-------------	--

(27) Category 14.2.8 (Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	150	(1)(60)'	
--	-------------------	--------------------	-----	--------------	--

(28) Category 15.1 (Potato-, cereal-, flour- or starch-based snacks) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	20	(1) (60)'	
--	-------------------	--------------------	----	--------------	--

- (29) Category 15.2 (Processed nuts) is amended as follows:

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

	'E 960a – 960c	Steviol glycosides	20	(1) (60)	
--	-------------------	--------------------	----	-------------	--

- (30) Category 16 (Desserts excluding products covered in categories 1, 3 and 4) is amended as follows:

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'
--	-------------------	--------------------	-----	-------------	--

- (31) Category 17.1 (Food supplements supplied in a solid form, excluding food supplements for infants and young children) is amended as follows:

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	180 0	(1) (60)	only food supplements in chewable form'

- (32) Category 17.2 (Food supplements supplied in a liquid form, excluding food supplements for infants and young children) is amended as follows:

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	180 0	(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 current entry for food additive 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) 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	<p>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</p> <p>13-[(O-b-D-Glucopyranosyl-(1-2)-O-[b-D-glucosylpyranosyl-(1-3)]-b-Dglucosylpyranosyl)oxy]kaur-16-en-18-oic acid (4-)-O-b-D-glucosylpyranosyl-(1-2)-O-[b-Dglucosylpyranosyl-(1-3)]-b-Dglycosylpyranosyl ester</p>		
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	1 291,30 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] ’