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From:	European Commission
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To:	General Secretariat of the Council
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Subject:	ANNEX to the COMMISSION REGULATION (EU) .../... amending Annex to Commission 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)

Delegations will find attached document D045780/02 - Annex 1.

Encl.: D045780/02 - Annex 1



Brussels, **XXX**
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ANNEX 1

ANNEX

to the

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

amending Annex to Commission 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)

ANNEX

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

Synonyms			
Definition	<p>The manufacturing process comprises two main phases: the first involving water extraction of the leaves of the <i>Stevia rebaudiana</i> 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.</p> <p>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 <i>Stevia rebaudiana</i> plant have been identified in small amounts (0,10 to 0,37 % w/w).</p>		
Chemical name	<p>Steviolbioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid</p> <p>Rubusoside: 13-β-D-glucopyranosyloxykaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Dulcoside A: 13-[(2-O-α-L-rhamnopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>Stevioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <p>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</p> <p>Rebaudioside B: 13-[(2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid</p> <p>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</p> <p>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</p> <p>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</p> <p>Rebaudioside F: 13[(2-O-β-D-xylofuranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, β-D-glucopyranosyl ester</p> <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>		
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 5000 mg/kg ethanol		
Arsenic	Not more than 1 mg/kg		
Lead	Not more than 1 mg/kg		