SCHEDULE 2

Regulation 3

Amendments to Annex to Regulation (EU) No 231/2012 concerning the specification for E 960a steviol glycosides from Stevia (formerly E 960 steviol glycosides) and for the addition of a specification for E 960c rebaudioside M produced via enzyme modification of steviol glycosides from Stevia

1. In Commission Regulation (EU) No 231/2012, the Annex (specifications for food additives including colours and sweeteners listed in Annexes 2 and 3 to Regulation (EC) No 1333/2008) is amended as follows.

2. For the heading of the entry for "E 960 STEVIOL GLYCOSIDES" substitute—

"E 960a STEVIOL GLYCOSIDES FROM STEVIA"

3. In the appropriate place, insert the following entry—

"**E 960c REBAUDIOSIDE M PRODUCED VIA ENZYME MODIFICATION OF STEVIOL GLYCOSIDES FROM STEVIA**

Synonyms			
Definition	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. Rebaudioside M is obtained via enzymatic bioconversion of purified steviol glycoside leaf extracts (95% steviol glycosides) of the *Stevia rebaudiana* Bertoni plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified yeasts *K. phaffi* (formerly known as *Pichia pastoris)* UGT-a and *K. phaffi* UGT-b that facilitate the transfer of glucose from sucrose and UDP-glucose to steviol glycosides via glycosidic bonds. 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 or the DNA of the yeasts *K. phaffi* UGT-a or *K. phaffi* UGT-b must not be detected in the food additive.		
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 number	*Trivial name*	*CAS Number*	*Molecular weight (g/mol)*
	Rebaudioside M	1220616-44-3	1291.29
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 5000 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)”