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## SCHEDULE 2

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*

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

### “E 960c REBAUDIOSIDE M PRODUCED VIA ENZYME MODIFICATION OF STEVIOL GLYCOSIDES FROM STEVIA

<b>Synonyms</b>			
<b>Definition</b>	<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. phaffi</i> (formerly known as <i>Pichia pastoris</i>) UGT-a and <i>K. phaffi</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 or the DNA of the yeasts <i>K. phaffi</i> UGT-a or <i>K. phaffi</i> UGT-b must 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	<i>Trivial name</i>	<i>Formula</i>	<i>Conversion factor</i>
	Rebaudioside M	C <sub>56</sub> H <sub>90</sub> O <sub>33</sub>	0.25
Molecular weight and CAS number	<i>Trivial name</i>	<i>CAS Number</i>	<i>Molecular weight (g/mol)</i>
	Rebaudioside M	1220616-44-3	1291.29
Assay	Not less than 95% rebaudioside M on the dried basis		
<b>Description</b>	White to light yellow powder, approximately between 200 and 350 times sweeter than sucrose (at 5% sucrose equivalency)		
<b>Identification</b>			
Solubility	Freely soluble to slightly soluble in water		
pH	Between 4.5 and 7.0 (1 in 100 solution)		
<b>Purity</b>			

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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)”