EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2025/2943 EN ANNEX
CIS.docx) [Pool/E2/2025/2943/2943 EN
ANNEX CIS]
[…](2026) XXX draft

ANNEX

ANNEX

to the

COMMISSION REGULATION

amending the Annex to 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 enzymatically produced steviol glycosides to include rebaudioside M produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extract (E 960c(ii)) using the genetically modified yeast K. phaffii CGMCC 7539

ANNEX

In the Annex to Regulation (EU) No 231/2012, the entry for E 960c(ii) REBAUDIOSIDE M PRODUCED VIA ENZYMATIC CONVERSION OF HIGHLY PURIFIED REBAUDIOSIDE A STEVIA LEAF EXTRACTS is amended as follows:

(1) the specification 'Definition' is replaced by the following:

'

Definition	Rebaudioside M produced via enzymatic conversion of highly purified rebaudioside A stevia leaf extracts is a steviol glycoside composed predominantly of rebaudioside M with minor amounts of other steviol glycosides, such as rebaudioside A, rebaudioside B and rebaudioside D. Rebaudioside M is produced via enzymatic conversion of highly purified steviol glycoside rebaudioside A extracts (95% steviol glycosides) obtained from *Stevia rebaudiana Bertoni* plant using UDP-glucosyltransferase and sucrose synthase enzymes produced by the genetically modified strains of *E. coli* (pPM294, pFAF170 and pSK401) or of *K. phaffii* (CGMCC 7539) 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 the steviol glycosides resulting in a final product containing not less than 95% of rebaudioside M. Viable cells of *E. coli* (pPM294, pFAF170 and pSK401) or *K. phaffii* (CGMCC 7539) and their DNA shall not be detected in the food additive.

';

(2) in the specification 'Purity', the following entry is inserted after the entry for 'Residual solvent':

'

Kaurenoic acid	Not more than 0,3 mg/kg (measured by liquid chromatography-mass spectrometry detection)

'.