



Brussels, **XXX**
SANTE/11416/2021 CIS
(POOL/E2/2021/11416/11416-EN
CIS.docx)
[...](2021) **XXX** draft

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

of **XXX**

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 the use of glycolipids as a preservative in beverages

(Text with EEA relevance)

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

of **XXX**

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 the use of glycolipids as a preservative in beverages

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives¹, and in particular Articles 10(3) and 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings², and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) The Annex to Commission Regulation (EU) No 231/2012³ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) The Union list of food additives and the specifications for food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application from a Member State or an interested party.
- (4) In December 2019, an application was submitted to the Commission for the authorisation of use of glycolipids as a preservative in flavoured drinks, some other products falling under the category 14.1 ‘non-alcoholic beverages’ and alcohol free beer and malt beverages.
- (5) The European Food Safety Authority (‘the Authority’) evaluated the safety of the proposed use of glycolipids as a food additive. In the Authority’s opinion⁴ adopted on 4 May 2021, an acceptable daily intake (‘ADI’) of 10 mg/kg bw per day was established. The Authority noted that the highest estimate of exposure of 3.1 mg/kg bw per day, in toddlers, is within the established ADI and concluded that the exposure to glycolipids does not raise a safety concern at the uses and use levels proposed by the applicant.

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ Commission Regulation (EU) No 231/2012 of 9 March 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 (OJ L 83, 22.3.2012, p. 1).

⁴ EFSA Journal 2021;19(6):6609

- (6) Glycolipids are produced by fungus *Dacryopinax spathularia* in a fermentation process. Glycolipids, when used as a preservative, prolong the shelf life of beverages by protecting them against deterioration caused by micro-organisms and inhibit the growth of pathogenic micro-organisms. Glycolipids are active against yeast, moulds and gram-positive bacteria and can serve as an alternative to other preservatives currently authorised in beverages.
- (7) It is therefore appropriate to authorise the use of glycolipids as a preservative in the beverages covered by the application and to assign E 246 as the E-number to that additive.
- (8) The specifications for glycolipids (E 246) should be included in the Annex to Regulation (EU) No 231/2012 as this additive is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (9) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN