COMMISSION REGULATION (EU) 2022/1038

of 29 June 2022

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyvinylpyrrolidone (E1201) in food for special medical purposes, in tablet and coated tablet forms

(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 additives ([1]), and in particular Article 10(3) 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 flavourings ([2]), 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) That list 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.

(3) In accordance with Annex II to Regulation (EC) No 1333/2008, polyvinylpyrrolidone (E1201) is authorised for use as a food additive in table-top sweeteners in tablets and in food supplements supplied in a solid form, excluding food supplements for infants and young children.

(4) On 29 October 2018, an application was submitted for authorisation of the use of polyvinylpyrrolidone (E1201) as a food additive in food for special medical purposes, in tablet and coated tablet forms, as a tablet binder. The application was made available to the Member States pursuant to Article 4(1), second subparagraph, of Regulation (EC) No 1331/2008.

(5) Polyvinylpyrrolidone (E 1201) was evaluated by the Scientific Committee for Food in 1990 ([3]). In its 1 July 2020 scientific opinion ([4]), the European Food Safety Authority ('the Authority') re-evaluated the safety of polyvinylpyrrolidone (E1201) as a food additive and considered the extension of its use in food for special medical purposes in tablet and coated tablet forms. In that opinion, the Authority concluded that such an extension of use, at the proposed maximum permitted level and recommended consumption level, is not expected to be of a safety concern.

(6) There is a technological need for the addition of polyvinylpyrrolidone (E1201) during the production of the tablets for special medical purposes to strongly bind the ingredients, ensure their cohesion and slow down their disintegration. It is therefore appropriate to authorise the use of this additive as a stabiliser of food for special medical purposes in tablet and coated tablet forms.

([1]) OJ L 354, 31.12.2008, p. 16.
([2]) OJ L 354, 31.12.2008, p. 1.
([3]) Report of the Scientific Committee for Food, twenty-sixth series. Report EUR 13 913.
([4]) EFSA Journal 2020;18(8):6215.

(7) The authorisation of the use of polyvinylpyrrolidone (E1201) as a food additive in category 13.2 'Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)' of Part E of Annex II to Regulation (EC) No 1333/2008 does not entail the classification of a product processed with that food additive as a food for special medical purposes under Regulation (EU) No 609/2013 of the European Parliament and of the Council ([5]).

(8) Regulation (EC) No 1333/2008 should therefore be amended accordingly.

(9) 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

In Part E of Annex II to Regulation (EC) No 1333/2008, in food category 13.2 'Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)', the following entry is added:

	'E 1201	Polyvinylpyrrolidone	*quantum satis*		only in tablet and coated tablet forms'

Article 2

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, 29 June 2022.

For the Commission
The President
Ursula VON DER LEYEN

([5]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).