



EUROPEAN
COMMISSION

Brussels, **XXX**
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COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and
of the Council as regards the use of the food additive sorbitan monostearate (E 491) in
acrylamide reducing (ARY) baker's yeast**

(Text with EEA relevance)

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amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of the food additive sorbitan monostearate (E 491) in acrylamide reducing (ARY) baker's yeast

(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 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 flavourings², and in particular Article 7(5) thereof,

Whereas:

- (1) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, food flavourings, nutrients 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) Pursuant to Part E of Annex II to Regulation (EC) No 1333/2008, sorbitan monostearate (E 491) is a food additive authorised for use at *quantum satis* in dry yeast and baker's yeast falling under food category 12.8 'Yeast and yeast products'.
- (4) On 11 December 2023, an application was submitted for the authorisation of the use of sorbitan monostearate (E 491) in the food enzyme acrylamide-reducing baker's yeast. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The food enzyme acrylamide-reducing baker's yeast contains asparaginase used to reduce the level of acrylamide in foods, in order to protect the health of the consumer. Sorbitan monostearate (E 491) is commonly used in yeast manufacturing as a stabiliser to protect yeast cells during drying and rehydration. The applicant requested to use sorbitan monostearate (E 491) in the food enzyme acrylamide-reducing baker's yeast at a maximum level of 20 000 mg/kg. The resulting enzyme preparation is intended to be used in bakery wares falling under several food categories of Annex II to Regulation (EC) No 1333/2008, including in food category 13.1.3 'Processed cereal-

¹ OJ L 354 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

based foods and baby foods as defined by Regulation (EU) No 609/2013', in levels up to 10 g/kg of flour, which would result in a maximum level of sorbitan monostearate (E 491) of 200 mg/kg in the final food.

- (6) On 25 June 2025, the European Food Safety Authority ('the Authority') issued a scientific opinion on the safety of a proposed amendment of the conditions of use of the food additive sorbitan monostearate (E 491) in enzyme preparations³. The Authority concluded that the proposed amendment of the conditions of use of sorbitan monostearate (E 491) in preparations of the food enzyme acrylamide reducing baker's yeast has little impact on the current dietary exposure to sorbitan resulting from the already permitted uses and reported use levels of sorbitan esters (E 491–495) and would not be of safety concern.
- (7) It is therefore appropriate to authorise the use of sorbitan monostearate (E 491) as a stabiliser in enzyme preparations of acrylamide reducing baker's yeast at the maximum level of 20 000 mg/kg, resulting in a maximum level of 200 mg/kg of sorbitan monostearate (E 491) in the final foods. To enable mitigation measures for acrylamide reduction by the use of the food enzyme acrylamide reducing baker's yeast in foodstuffs of food category 13.1.3 'Processed cereal-based foods and baby foods as defined by Regulation (EU) No 609/2013', it is appropriate to allow the carry-over of sorbitan monostearate (E 491) to that food category.
- (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

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

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,

For the Commission
The President
Ursula VON DER LEYEN

³ EFSA Panel on Food Additives and Flavourings, (2025). Scientific opinion on the safety of a proposed amendment of the conditions of use of the food additive sorbitan monostearate (E 491) in enzyme preparations. *EFSA Journal*, 2025;23:e9487, <https://doi.org/10.2903/j.efsa.2025.9487>.