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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Thaumatin (E 957) as a flavour enhancer in certain food categories

Delegations will find attached document D053883/03.

Encl.: D053883/03



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10634/2017
(POOL/E2/2017/10634/10634-EN.doc)
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[...](2017) **XXX**

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

of **XXX**

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of Thaumatin (E 957) as a flavour enhancer in certain food categories

(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 as regards the use of Thaumatin (E 957) as a flavour enhancer in certain food categories

(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,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food 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 of the European Parliament and of the Council², either on the initiative of the Commission or following an application.
- (3) In accordance with Annex II to Regulation (EC) No 1333/2008 thaumatin (E 957) is authorised for use in the Union as a food additive in various food categories and at specific use levels.
- (4) On 12 November 2014 an application was submitted for the extension of use of thaumatin (E 957) as a flavour enhancer in several food categories at specific use levels. The application was made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) Thaumatin was evaluated in 1984³ and 1988⁴ by the European Union Scientific Committee for Food (SCF). Thaumatin was considered acceptable for use and the acceptable daily intake (ADI) was established as 'not specified'. In the latter evaluation it was also noted that thaumatin, being a protein, undergoes digestion to normal food components.
- (6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is to seek the opinion of the European Food Safety Authority ('the Authority') in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008.

¹ OJ L 354, 31.12.2008, p. 16.

² 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 (OJ L 354, 31.12.2008, p. 1).

³ Reports of the Scientific Committee for Food concerning sweeteners (opinion expressed by the SCF on 14 September 1984). Available online: http://aei.pitt.edu/40825/1/16th_food.pdf

⁴ Reports of the Scientific Committee for Food on Sweeteners (21st series). Opinion expressed on 11 December 1987 and 10 November 1988, and adopted 10 November 1988. Available online: http://aei.pitt.edu/40830/1/21st_food.pdf

- (7) On 13 November 2015 the Authority issued a scientific opinion⁵ on the safety of the proposed extensions of use and use levels of thaumatin (E 957) as a food additive. In providing such opinion the Authority decided that a comparison of the exposure resulting from the current uses and use levels with the exposure resulting from the additional proposed uses would be sufficient to address the safety of thaumatin.
- (8) Estimated exposure at both the currently authorised and at the proposed extended uses and use levels of thaumatin resulted in mean intakes ranging from 0.03 to 0.10 mg/kg bw/day in the elderly up to 0.13 to 0.34 mg/kg bw/day in children. High-level exposure ranged from 0.13 to 0.32 mg/kg bw/day in adolescents up to 0.09 to 1.10 mg/kg bw/day in adults. This is considered to be a minor exposure of the consumer and therefore is not of safety concern.
- (9) The Authority concluded, based on the existing toxicological evaluations, that the proposed extension of uses and changes to use levels would not represent a safety concern.
- (10) Although the Authority calculated the exposure to thaumatin (E 957) using the current maximum use levels and the proposed extension of uses and use levels as provided by the applicant, the use of thaumatin (E 957) as a flavour enhancer should be restricted to those food categories for which there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means and its use will not mislead the consumer.
- (11) The use of thaumatin (E 957) as a flavour enhancer improves the organoleptic properties of savoury food products. Thaumatin can enhance the existing umami and savoury taste in sauces and snacks, making food products more appealing for human taste.
- (12) It is therefore appropriate to authorise the use of thaumatin (E 957) as a flavour enhancer in products of food categories 12.6 'Sauces' and 15.1 'Potato-, cereal-, flour- or starch-based snacks' at a maximum level of 5 mg/kg in each food category.
- (13) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (14) 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 the 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*.

⁵ EFSA Journal 2015;13(11):4290

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER