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**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 powdered cellulose (E 460(ii)) and glucono-delta-lactone (E 575) in unripened soft spreadable cheese products**

(Text with EEA relevance)

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## **amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of powdered cellulose (E 460(ii)) and glucono-delta-lactone (E 575) in unripened soft spreadable cheese products**

(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<sup>1</sup>, and in particular Articles 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<sup>2</sup>, 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 Union list of 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.
- (3) Pursuant to Annex II to Regulation (EC) No 1333/2008, powdered cellulose (E 460(ii)) and glucono-delta-lactone (E 575) are authorised for use as food additives in a wide variety of foods.
- (4) On 28 July 2022, two applications were submitted to the Commission for the authorisation of the use of powdered cellulose (E 460(ii)) and glucono-delta-lactone (E 575) in unripened soft spreadable cheese products, under food category 01.7.6 ‘Cheese products (excluding products falling in category 16)’. The applications were subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) Powdered cellulose (E 460(ii)) and glucono-delta-lactone (E 575) are intended for use in the production of unripened soft spreadable cheese products. Glucono-delta-lactone (E 575) acidifies milk mixture and coagulates casein in short time by a controlled pH reduction without using lactic acid bacteria. Powdered cellulose (E 460(ii)) binds whey and prevents its separation from curd, ensuring a stable product over its shelf-life. The intended use of powdered cellulose (E 460(ii)) and glucono-delta-lactone (E

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<sup>1</sup> OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>.

<sup>2</sup> OJ L 354, 31.12.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/1331/oj>.

575) thus results in more efficient production process requiring less raw material, energy and time.

- (6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has 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, except where the update in question is not liable to have an effect on human health.
- (7) On 16 January 2018, the Authority published a scientific opinion re-evaluating among others the safety of powdered cellulose (E 460(ii)) as a food additive<sup>3</sup>. The Authority concluded that there was no need for a numerical 'acceptable daily intake' (ADI) and that there would be no safety concern at the reported uses and use levels for the unmodified and modified celluloses (E 460(i), E 460(ii), E 461–466, E 468 and E 469). Such conclusion is reached for substances of a very low safety concern and only if there is reliable information for both exposure and toxicity and there is a low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals<sup>4</sup>.
- (8) The safety of glucono-delta-lactone (E 575) was evaluated in 1990 by the Scientific Committee for Food, which established its ADI as 'not specified'<sup>5</sup>. The term 'not specified' means that, on the basis of the available toxicological, biochemical and clinical data, the total daily intake of the substance, arising from its natural occurrence and its present use or uses in food at the levels necessary to achieve the desired technological effect, does not present a hazard to health. In Commission Regulation (EU) No 257/2010<sup>6</sup>, the Commission considered that glucono-delta-lactone (E 575) was of low concern and that its re-evaluation was not a high priority given the lack of new substantive evidence questioning the evaluation and in light of the Report from the Commission on Dietary Food Additive Intake in the EU<sup>7</sup> of 2001 and of the report 'Food additives in Europe 2000'<sup>8</sup> submitted by the Nordic Council of Ministers to the Commission, providing additional information for the prioritisation of additives for re-evaluation. For the same reasons and pending the re-evaluation of glucono-delta-lactone (E 575) under that programme, the Commission considers that the conclusion reached by the Scientific Committee for Food still remains valid.
- (9) Since the use of powdered cellulose (E 460(ii)) as a stabiliser and of glucono-delta-lactone (E 575) as an acidity regulator in unripened soft spreadable cheese products is

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<sup>3</sup> Scientific Opinion on the re-evaluation of celluloses E 460(i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 466, E 468 and E 469 as food additives. EFSA Journal 2018;16(1):5047, 104 pp., <https://doi.org/10.2903/j.efsa.2018.5047>.

<sup>4</sup> Statement on a conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010. EFSA Journal 2014;12(6):3697, 11 pp., <https://www.efsa.europa.eu/en/efsajournal/pub/3697>

<sup>5</sup> Reports of the Scientific Committee for Food, Twenty-fifth series, 1991 ([https://food.ec.europa.eu/system/files/2020-12/sci-com\\_scf\\_reports\\_25.pdf](https://food.ec.europa.eu/system/files/2020-12/sci-com_scf_reports_25.pdf)).

<sup>6</sup> Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up the program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19, ELI: <http://data.europa.eu/eli/reg/2010/257/oj>).

<sup>7</sup> COM(2001) 542 final.

<sup>8</sup> Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002:560.

not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.

- (10) Therefore, Annex II to Regulation (EC) No 1333/2008 should be amended accordingly.
- (11) 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*.

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*