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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	29 April 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

Subject:	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 polyvinylpolypyrrolidone (E 1202) as a carrier in colour tablets for the decorative colouring of poultry eggshells
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Delegations will find attached document D(2025) 106245.

Encl.: D(2025) 106245



EUROPEAN
COMMISSION

Brussels, **XXX**
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(POOL/E2/2025/139/139-EN.docx)
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[...](2025) **XXX** draft

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 polyvinylpyrrolidone (E 1202) as a carrier in
colour tablets for the decorative colouring of poultry eggshells**

(Text with EEA relevance)

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 polyvinylpolypyrrolidone (E 1202) as a carrier in colour tablets for the decorative colouring of poultry eggshells

(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, 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, 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) 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) In October 2023, an application was submitted to the Commission for the authorisation of use of polyvinylpolypyrrolidone (E 1202) as a carrier in colour tablets used for the decorative colouring of poultry eggshells. The application was subsequently made available to Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) Polyvinylpolypyrrolidone (E 1202) is authorised pursuant to Annex II to Regulation (EC) No 1333/2008 as a food additive for use at *quantum satis* level in food category 11.4.3 ‘Table-top sweeteners in tablets’ and for food supplements in tablet and coated tablet form in food category 17.1 ‘Food supplements supplied in a solid form, excluding food supplements for infants and young children’. Pursuant to Annex III to that Regulation, polyvinylpolypyrrolidone (E 1202) is authorised as a food additive for use as a carrier at *quantum satis* level in sweeteners.
- (5) Polyvinylpolypyrrolidone (E 1202), when used as a carrier in tablets, ensures a smooth manufacturing process due to its flowability properties allowing to control the composition and weight of tablets. The resulting tablets are strong, well-shaped and do not remain stuck to the pressing tools. It also facilitates rapid and efficient dissolution of the tablet in water with more complete colour saturation and colouring of the eggshells.

- (6) On 10 August 2020, the European Food Safety Authority ('the Authority') issued a Scientific Opinion on the re-evaluation of polyvinylpyrrolidone (E 1201) and polyvinylpolypyrrolidone (E 1202) as food additives and extension of use of polyvinylpyrrolidone (E 1201)¹. The Authority concluded that there was no need for numerical acceptable daily intakes (ADIs) for polyvinylpyrrolidone (E 1201) and polyvinylpolypyrrolidone (E 1202), and that there was no safety concern for the reported uses and use levels of polyvinylpyrrolidone (E 1201) and polyvinylpolypyrrolidone (E 1202) as food additives. According to the statement on a conceptual framework for the risk assessment of certain food additives re-evaluated under Commission Regulation (EU) No 257/2010², the conclusion 'no need for numerical acceptable daily intakes' is used for substances of a very low safety concern and only if there is reliable information for both exposure and toxicity and a low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals.
- (7) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has to seek the opinion of the Authority in order to update the Union list of food additives set out in Annex III to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health. As the applicant demonstrated that the additional dietary exposure to polyvinylpolypyrrolidone (E 1202), when used in colour tablets for the decorative colouring of poultry eggshells, was negligible and was not liable to have an effect on human health, it is therefore not necessary to seek the opinion of the Authority.
- (8) Therefore, it is appropriate to authorise the use of polyvinylpolypyrrolidone (E 1202) as a carrier in colour tablets used for the decorative colouring of poultry eggshells.
- (9) Regulation (EC) No 1333/2008 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 III 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.

¹ EFSA FAF Panel, Scientific Opinion on the re-evaluation of polyvinylpyrrolidone (E 1201) and polyvinylpolypyrrolidone (E 1202) as food additives and extension of use of polyvinylpyrrolidone (E 1201). EFSA Journal 2020;18(8):6215, <https://doi.org/10.2903/j.efsa.2020.6215>.

² EFSA ANS Panel, 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, doi:10.2903/j.efsa.2014.3697.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN