COMMISSION REGULATION (EU) 2020/268

of 26 February 2020

amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sorbic acid (E 200) in liquid colour preparations for the decorative colouring of egg shells

(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,

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 of the European Parliament and of the Council ([2]), either on the initiative of the Commission or following an application.

(3) Pursuant to Part 2 of Annex III to Regulation (EC) No 1333/2008, sorbic acid (E 200) is an already authorised food additive in colour preparations at a maximum level of 1 500 mg/kg in the preparation, singly or in combination with potassium sorbate (E 202), benzoic acid (E 210), sodium benzoate (E 211) and potassium benzoate (E 212), and at a maximum level of 15 mg/kg in the final product, expressed as the free acid.

(4) On 27 April 2017, an application was submitted for the authorisation of the use of a higher maximum level of sorbic acid (E 200), 2 500 mg/kg, in liquid colour preparations for sale to the final consumer for the decorative colouring of egg shells. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) Sorbic acid (E 200) is used as a preservative in colour preparations. The applicant has demonstrated that the currently authorised maximum level of sorbic acid (E 200) in colour preparations of 1 500 mg/kg is not sufficient to consistently ensure appropriate preservation, and consequently microbiological safety, of liquid colour preparations for the decorative colouring of egg shells. This is due to the use of food colours from natural origin in the preparations, which are not sterile, and the needed shelf life for such a seasonal product. The application shows that the level of sorbic acid (E 200) needed to achieve the intended technological function was 2 500 mg/kg in the colour preparations. It results from the tests carried out by the applicant that, under normal use (colouring of undamaged to slightly damaged eggs), the migration of sorbic acid (E 200) from the egg shell to the edible part of the egg is below the level of detection of 5 mg/kg. Consequently, according to the application, the requested higher level of sorbic acid (E 200) in liquid colour preparations for the decorative colouring of egg shells would not lead to an increase of the exposure of consumers to sorbic acid (E 200).

(6) On 30 June 2015, the European Food Safety Authority ('the Authority') issued a Scientific Opinion on the re-evaluation of, among others, sorbic acid (E 200) and potassium sorbate (E 202) ([3]), as a result of which it established a new temporary group acceptable daily intake ('ADI') for sorbic acid (E 200) and potassium sorbate (E 202), expressed as 3 mg sorbic acid/kg bw/day. The Authority concluded that this temporary group ADI for sorbic acid (E 200) and potassium sorbate (E 202) was exceeded at the high intake level in the toddler and children population groups in one country. The Authority recommended that a further reproductive toxicity study is performed in order to reconsider the temporary group ADI for sorbic acid (E 200) and potassium sorbate (E 202).

([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]) *EFSA Journal* 2015;13(6):4144.

(7) On 10 June 2016, the Commission launched a public call for scientific and technological data on, among others, sorbic acid (E 200) and potassium sorbate (E 202) ([4]), targeting the data needs identified by the Authority. Business operators have carried out the reproductive toxicity study in rats recommended by the Authority for sorbic acid (E 200) and potassium sorbate (E 202), the data from which were sent to the Authority for evaluation. As a result, on 1 March 2019, the Authority published a scientific opinion on the follow-up of the re-evaluation of sorbic acid (E 200) and potassium sorbate (E 202) as food additives ([5]). On the basis of the new reproductive toxicity data, the Authority established a group ADI, expressed as 11 mg sorbic acid/kg bw per day for sorbic acid (E 200) and potassium sorbate (E 202). The Authority compared this new group ADI to the most realistic exposure assessment scenario estimated in its Scientific Opinion of 30 June 2015, and noted that such exposure did not exceed the group ADI in any population group, neither at the mean nor at the high intake levels.

(8) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission is 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.

(9) The extended use of sorbic acid (E 200) in liquid colour preparations for the decorative colouring of egg shells, requested by the applicant, requires an update of the Union list. The extended use of sorbic acid (E 200) does not lead to an increase of the exposure to sorbic acid (E 200) and is not liable to have an effect on human health. Moreover, according to the Authority, the exposure to sorbic acid (E 200) and to potassium sorbate (E 202) under the already authorised uses and use levels is not of safety concern, as it does not lead to the exceedance of the ADI. Consequently, is not necessary to seek the opinion of the Authority.

(10) Therefore, it is appropriate to authorise the use of sorbic acid (E 200) as a preservative in liquid colour preparations for the sale to the final consumer for the decorative colouring of egg shells at the maximum level of 2 500 mg/kg in the preparation.

(11) Annex III to Regulation (EC) No 1333/2008 should therefore be amended accordingly.

(12) 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.

Done at Brussels, 26 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

([4]) http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en
([5]) *EFSA Journal* 2019;17(3):5625.

ANNEX

In Part 2 of Annex III to Regulation (EC) No 1333/2008, the following entry is inserted after the entries for food additives ‘E 200-202 Sorbic acid – potassium sorbate’, ‘E 210 Benzoic acid’, ‘E 211 Sodium benzoate’ and ‘E 212 Potassium benzoate’:

‘E 200	Sorbic acid	2 500 mg/kg in the preparation	Liquid colour preparations for sale to the final consumer for the decorative colouring of egg shells’