Commission Regulation (EU) 2020/1819 of 2 December 2020 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of colours in salmon substitutes (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/1819

of 2 December 2020

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of colours in salmon substitutes

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

(3) Pursuant to Annex II to Regulation (EC) No 1333/2008, as amended by Commission Regulation (EU) No 232/2012[(3)], Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) are currently authorised as food additives in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans', both at a maximum level of 200 mg/kg, for use only in salmon substitutes based on the fish species *Theragra chalcogramma* and *Pollachius virens*. On 15 July 2014 and 23 September 2009, the Authority issued opinions establishing the acceptable daily intake (ADI) for Sunset Yellow FCF/Orange Yellow S (E 110)[(4)] at 4 mg/kg bw/day and the ADI for Ponceau 4R, Cochineal Red A (E 124)[(5)] at 0,7 mg/kg bw/day. On its opinions of 15 July 2014 and of 21 April 2015[(6)], the Authority concluded that none of the exposure estimates for those additives exceeded their respective ADI for any population group.

(4) On 4 February 2019, an application was submitted for the modification of the conditions of use of Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) contained in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans', to authorise the use of those substances in salmon substitutes based on the fish species *Clupea harengus*. The application requires the current maximum level of 200 mg/kg, however, it clarifies that the actual use levels are much lower ranging between one and two tenths of the maximum level for both

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substances. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124), when used as colours, impart the desired stable shade, improve organoleptic properties and make salmon substitutes based on the fish species *Clupea harengus* more visually appealing.

(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) Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) are authorised for use in a wide variety of foods. The most recent exposure assessments carried out by the Authority, as referred to in recital 3, confirmed that the overall exposure is well below their ADI even in the most conservative regulatory maximum levels scenario. The authorised uses in salmon substitutes based on *Theragra chalcogramma* and *Pollachius virens* were included in those exposure estimates. Since salmon substitutes based on *Clupea harengus* are intended as an alternative to salmon substitutes based on *Theragra chalcogramma* and *Pollachius virens*, the consumption of salmon substitutes by consumers should not significantly change. Furthermore, the use levels for Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) needed to achieve the desired effect in salmon substitutes based on *Clupea harengus* are substantially lower than the authorised maximum levels. Therefore, it is not expected that the proposed use will have a significant impact on the overall exposure of consumers to those food additives, which therefore should remain below the ADI.

(8) The entries for Group II, Group III and Lycopene (E 160d) in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans' currently only refer to 'salmon substitutes'. In order to provide clarity and legal certainty as regards this expression, the wording of those entries should be amended to indicate that the authorised use concerns 'salmon substitutes' based on the fish species *Theragra chalcogramma*, *Pollachius virens* or *Clupea harengus*.

(9) Therefore, it is appropriate to amend food category 09.2 'Processed fish and fishery products including molluscs and crustaceans' in Part E of Annex II to Regulation (EC) No 1333/2008 to authorise the use of Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) in salmon substitutes based on the fish species *Clupea harengus* and to list in the entries for Group II, Group III and Lycopene (E 160d), the fish species on which 'salmon substitutes' may be based.

(10) Annex II to Regulation (EC) No 1333/2008 should therefore 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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2020/1819. (See end of Document for details)*

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, 2 December 2020.

For the Commission

The President

Ursula VON DER LEYEN