Commission Regulation (EU) 2020/771 of 11 June 2020 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Annatto, Bixin, Norbixin (E 160b) (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/771

of 11 June 2020

amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Annatto, Bixin, Norbixin (E 160b)

(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) and Article 14 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) 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.

(3) Commission Regulation (EU) No 231/2012[(2)] lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(4) The Union lists of food additives and the specifications 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[(3)], either on the initiative of the Commission or following an application.

(5) Annatto, Bixin, Norbixin (E 160b) is a substance authorised as a colour in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.

(6) Annatto, Bixin, Norbixin (E 160b) is extracted from the seeds of the annatto tree (*Bixa orellana* L.) and confers a yellow to red colour to food. The main pigments in annatto extracts are bixin and norbixin. In spite of their similarity in structure, bixin and norbixin have significantly different physico-chemical properties and, therefore, different applications depending on the characteristics of the food matrix.

(7) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority ('the Authority'). Commission

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Regulation (EU) No 257/2010[4] provides that the re-evaluation of food colours had to be completed by 31 December 2015.

(8) On 4 April 2008, an application was submitted for the authorisation of the use of five new annatto extracts categorised as bixin- or norbixin-based, with a view to replacing the currently authorised annatto extracts (E 160b). The application included new proposed uses and use levels for bixin and norbixin separately, while current uses and use levels are listed for a single food additive (Annatto, Bixin, Norbixin (E 160b)). The proposed uses and use levels for bixin and norbixin concern the food categories in which Annatto, Bixin, Norbixin (E 160b) is currently authorised, as well as a few additional food categories in which Annatto, Bixin, Norbixin (E 160b) is currently not authorised, but other food colours are already authorised.

(9) 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 II to Regulation (EC) No 1333/2008 and the specifications set out in the Annex to Regulation (EU) No 231/2012, except where the update in question is not liable to have an effect on human health.

(10) On 19 May 2008, the Commission requested the Authority to evaluate the safety of the five new annatto extracts, at the proposed uses and use levels. Upon analysis of the application, the Authority identified major data gaps and indicated that new toxicological studies would be needed. Consequently, the Commission decided on 14 January 2011 that the safety evaluation of the five new extracts would be carried out as a part of the re-evaluation of Annatto, Bixin, Norbixin (E 160b), as provided for by Regulation (EU) No 257/2010.

(11) On 24 August 2016, the Authority issued a scientific opinion on the safety of annatto extracts (E 160b) as a food additive[5]. As regards the annatto extracts currently authorised the Authority concluded that the safety of their use within the specifications defined in Regulation (EU) No 231/2012 (solvent-extracted bixin and norbixin, alkali-extracted annatto and oil-extracted annatto) could not be assessed due to lack of data, both in terms of identification and toxicological studies. As regards the new annatto extracts and, in particular, aqueous-processed bixin (Annatto E), the Authority could not conclude on its safety due to equivocal genotoxicity results. For the four remaining new extracts (‘solvent-extracted bixin’, ‘solvent-extracted norbixin’, ‘alkali-processed norbixin, acid-precipitated’ and ‘alkali-processed norbixin, not acid-precipitated’), the Authority indicated that they should comply with the specifications recommended in the scientific opinion. Finally, the Authority derived an acceptable daily intake (ADI) of 6 mg bixin/kg body weight (bw) per day and an ADI of 0,3 mg norbixin/kg bw per day. Exposure estimates linked to the proposed uses and use levels for bixin were below the ADI for all population groups and for the two refined exposure scenarios (brand-loyal and non-brand-loyal exposure scenarios). However, for norbixin, those estimates exceeded the ADI at the high level (95th percentile) for infants, toddlers and children in the refined brand-loyal exposure scenario.

(12) Following the publication of this scientific opinion, the Commission requested from the applicant some clarifications about the requested uses and maximum use levels of

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bixin and norbixin. Based on this, on 16 February 2017, the applicant submitted to the Commission modifications to the original application, such as a removal of some of the requested new uses and a modification of some of the requested use levels. On 2 March 2017, the Commission requested the Authority for technical assistance as regards the estimation of the exposure to bixin and norbixin on the basis of the revised uses and use levels proposed by the applicant.

(13) As requested, on 10 August 2017, the Authority published a statement on the exposure assessment of bixin and norbixin[(6)] as regards those revised uses and use levels. It concluded that the dietary exposure for bixin did not exceed the ADI in any exposure scenario. However, it concluded that the dietary exposure for norbixin exceeded the ADI at the high level (95th percentile) for toddlers and children in the two refined exposure scenarios (brand-loyal and non-brand-loyal exposure scenarios).

(14) On 30 August 2017, the applicant submitted data from a new genotoxicity study for Annatto E.

(15) Taking into account the outcome of the exposure assessment published by the Authority on 10 August 2017, the applicant revised again the proposed uses and uses levels for bixin and norbixin, and submitted to the Commission on 20 July 2018 three alternative scenarios of uses and use levels.

(16) On 1 August 2018, the Commission requested the Authority to carry out an evaluation on the new genotoxicity data for Annatto E generated by the applicant and to indicate whether it is possible to conclude on the safety of this annatto extract. The Authority was also requested to carry out a new exposure assessment for bixin and norbixin, on the basis of the revised uses and use levels of bixin and norbixin submitted by the applicant in the form of three alternative scenarios.

(17) On 13 March 2019, the Authority published a scientific opinion on the safety of Annatto E and the exposure to bixin and norbixin[(7)]. As regards the safety of Annatto E, the Authority concluded that it does not raise concern for genotoxicity and it stated that the ADIs established in 2016 for bixin and norbixin can be applied also to Annatto E. As regards the exposure at the revised uses and use levels submitted by the applicant on 20 July 2018, for bixin, the Authority stated that none of the exposure estimates exceeded the ADI of 6 mg/kg bw per day. For norbixin, the Authority found that the ADI was reached at the high level (95th percentile) for toddlers in the two refined exposure assessment scenarios but only in one country. However, considering the uncertainties and the very likely overestimation of the exposure, the Authority concluded that the level of exposure does not raise a health concern for any of the three scenarios of uses and use levels for bixin and norbixin.

(18) It results from the above considerations that it is appropriate to amend the Annexes to Regulation (EC) No 1333/2008. First, since Annatto bixin (E 160b(i)) and Annatto norbixin (E 160b(ii)) have different toxicological properties and, therefore, different ADIs, the food additive ‘Annatto, Bixin, Norbixin (E 160b)’ should be deleted from the Union list of authorised food additives in Part B of Annex II to that Regulation and two separate food additives, namely Annatto bixin (E 160b(i)) and Annatto norbixin (E 160b(ii)) should be listed. As a consequence, the authorised uses and conditions of use

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for the food additive 'Annatto, Bixin, Norbixin (E 160b)' should be deleted from the list of authorised conditions of use in food in Part E of Annex II to Regulation (EC) No 1333/2008, and any references to it contained in the Annexes to the Regulation should be replaced by references to the two new food additives. As regards these two new additives, their authorised uses and use levels should be laid down. On the basis of the Authority's assessments referred to above, the uses as requested by the applicant on its last revision of the application should be authorised but only at the levels used in the third, and most conservative, use and use levels scenario thereof.

(19) Regulation (EU) No 231/2012 should also be amended. On the one side, the three annatto extracts referred to therein ('solvent-extracted bixin and norbixin', 'alkali-extracted annatto and oil-extracted annatto') should no longer be authorised, since their safety could not be assessed, and, therefore, their specifications should be deleted. On the other side, the two new Annatto bixin extracts ('solvent-extracted bixin' and 'aqueous-processed bixin') and the three new Annatto norbixin extracts ('solvent-extracted norbixin', 'alkali-processed norbixin, acid-precipitated' and 'alkali-processed norbixin, not acid-precipitated') do not pose a safety concern and specifications for them as regards each of the two new additives should be added to the Annex to that Regulation. Those specifications should be those recommended by the Authority in the scientific opinion on the safety of annatto extracts (E 160b) as a food additive, issued on 24 August 2016.

(20) Annexes II and III to Regulation (EC) No 1333/2008 as well as the Annex to Regulation (EU) No 231/2012 should therefore be amended accordingly.

(21) Even if the annatto extracts authorised until the date of application of this Regulation should no longer be authorised, since their safety could not be assessed, it is very unlikely that they would have different toxicological properties and therefore pose a health concern which would require that, with immediate effect as of the date of application of this Regulation, they are not at all placed on the market or remain on it. Therefore, in order to allow for a smooth transition between those three extracts and the new ones, it is appropriate to allow that during a transitional period both the old and the new extracts can legally be placed, and remain, on the market.

(22) For the same reasons, it is also appropriate that foods containing the annatto extracts authorised until the date of application of this Regulation that have been lawfully placed on the market before or during that transitional period may continue to be marketed until the existing stocks are exhausted.

(23) 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

Annexes II and III to Regulation (EC) No 1333/2008 are amended in accordance with Annex I to this Regulation.

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Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

1 Until 2 January 2021, the food additive Annatto, Bixin, Norbixin (E 160b) may continue to be placed on the market as such in accordance with the rules applicable before 2 July 2020.

2 Until 2 January 2021, foods containing Annatto, Bixin, Norbixin (E 160b) which are produced and labelled in accordance with the rules applicable before 2 July 2020, may continue to be placed on the market. After that date, they may remain on the market until the exhaustion of stocks.

Article 4

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, 11 June 2020.

For the Commission

The President

Ursula VON DER LEYEN