

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 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.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽³⁾ 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).

⁽⁴⁾ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a 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).

- (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 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

⁽⁵⁾ EFSA Journal 2016;14(8):4544.

⁽⁶⁾ EFSA Journal 2017;15(8):4966.

⁽⁷⁾ EFSA Journal 2019;17(3):5626.

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 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.

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

(1) Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(a) in point 2 of Part A, point 5 is replaced by the following:

‘5. The colours E 123, E 127, E 160b(i), E 160b(ii), E 161g, E 173 and E 180 and mixtures thereof may not be sold directly to the consumer.’

(b) in Part B, point 1: ‘Colours’, the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following two entries:

E 160b(i)	Annatto bixin
E 160b(ii)	Annatto norbixin’

(c) Part E is amended as follows:

1) Category 01.4 (Flavoured fermented milk products including heat-treated products) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	4	(94)	

(ii) the following footnote (94) is added after footnote (74):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

2) Category 01.7.2 (Ripened cheese) is amended as follows:

(i) the entries for E 160b (Annatto, Bixin, Norbixin) are replaced by the following:

	E 160b(i)	Annatto bixin	15	(94)	only ripened orange, yellow and broken-white cheese and red and green pesto cheese
	E 160b(ii)	Annatto norbixin	15	(94)	only ripened orange, yellow and broken-white cheese and red and green pesto cheese
	E 160b(ii)	Annatto norbixin	50		only <i>red Leicester</i> cheese
	E 160b(ii)	Annatto norbixin	35		only Mimolette cheese’

(ii) the following footnote (94) is added after footnote (83):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

3) Category 01.7.3 (Edible cheese rind) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	20	(94)	
	E 160b(ii)	Annatto norbixin	20	(94)	

(ii) the following footnote (94) is added after footnote (67):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

4) Category 01.7.5 (Processed cheese) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	8	(94)	

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

5) in Category 01.7.6 (Cheese products (excluding products falling in category 16)), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(ii)	Annatto norbixin	8		only ripened orange, yellow and broken-white products'
--	-------------	------------------	---	--	--

6) in category 02.1 (Fats and oils essentially free from water (excluding anhydrous milkfat)), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	10		only fats'
--	------------	---------------	----	--	------------

7) in category 02.2.2 (Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	10		excluding reduced fat butter'
--	------------	---------------	----	--	-------------------------------

8) in category 03 (Edible ices), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(ii)	Annatto norbixin	20'		
--	-------------	------------------	-----	--	--

9) Category 04.2.5.2 (Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	20	(94)	except chestnut purée
	E 160b(ii)	Annatto norbixin	20	(94)	except chestnut purée'

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

10) Category 04.2.5.3 (Other similar fruit or vegetable spreads) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 142 (Green S):

	E 160b(i)	Annatto bixin	20	(94)	except <i>crème de pruneaux</i>
	E 160b(ii)	Annatto norbixin	20	(94)	except <i>crème de pruneaux</i> '

(ii) the following footnote (94) is added after footnote (60):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

11) Category 04.2.6 (Processed potato products) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	10	(94)	only dried potato granules and flakes
	E 160b(ii)	Annatto norbixin	10	(94)	only dried potato granules and flakes'

(ii) the following footnote (94) is added after footnote (46):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

12) Category 05.2 (Other confectionery including breath freshening microsweets) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entries for E 124 (Ponceau 4R, Cochineal Red A):

	E 160b(i)	Annatto bixin	30	(94)	
	E 160b(ii)	Annatto norbixin	25	(94)	

(ii) the following footnote (94) is added after footnote (72):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

13) Category 05.4 (Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	80	(94)	only decorations and coatings
	E 160b(ii)	Annatto norbixin	20	(94)	only decorations and coatings'

(ii) the following footnote (94) is added after footnote (73):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

14) in category 06.3 (Breakfast cereals), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(ii)	Annatto norbixin	20		only extruded puffed and or fruit-flavoured breakfast cereals'
--	------------	------------------	----	--	--

15) Category 06.5 (Noodles) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for group II (Colours at *quantum satis*):

	E 160b(i)	Annatto bixin	20	(94)	
	E 160b(ii)	Annatto norbixin	20	(94)	

(ii) the following footnote (94) is added after footnote (81):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

16) Category 06.6 (Batters) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	50	(94)	only batters for coating
	E 160b(ii)	Annatto norbixin	50	(94)	only batters for coating'

(ii) the following footnote (94) is added after footnote (81):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

17) in category 07.2 (Fine bakery wares), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(ii)	Annatto norbixin	10'		
--	------------	------------------	-----	--	--

18) Category 08.2 (Meat preparations as defined by Regulation (EC) No 853/2004) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 150a-d (Caramels):

	E 160b(i)	Annatto bixin	20	(94)	only <i>breakfast sausages</i> with a minimum cereal content of 6 % and burger meat with a minimum vegetable and/or cereal content of 4 % mixed within the meat; In these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance
	E 160b(ii)	Annatto norbixin	20	(94)	only <i>breakfast sausages</i> with a minimum cereal content of 6 % and burger meat with a minimum vegetable and/or cereal content of 4 % mixed within the meat; In these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance'

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

19) Category 08.3.1 (Non-heat-treated meat products) is amended as follows:

(i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	20	(94)	only <i>chorizo sausage, salchichon, pasturmas</i> and <i>sobrasada</i>
	E 160b(ii)	Annatto norbixin	20	(94)	only <i>chorizo sausage, salchichon, pasturmas</i> and <i>sobrasada</i> '

(ii) the following footnote (94) is added after footnote (66):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

20) Category 08.3.2 (Heat-treated meat products) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 160a (Carotenes):

	E 160b(i)	Annatto bixin	20	(94)	only sausages, pâtés, terrines and <i>luncheon meat</i>
	E 160b(ii)	Annatto norbixin	20	(94)	only sausages, pâtés, terrines and <i>luncheon meat</i>

- (ii) the following footnote (94) is added after footnote (66):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

21) Category 08.3.3 (Casings and coatings and decorations for meat) is amended as follows:

- (i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	E 160b(i)	Annatto bixin	50	(94)	
	E 160b(ii)	Annatto norbixin	50	(94)	

- (ii) the following footnote (94) is added after footnote (89):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

22) Category 09.2 (Processed fish and fishery products including molluscs and crustaceans) is amended as follows:

- (i) the entry for E 160b (Annatto, Bixin, Norbixin) concerning ‘only smoked fish’ is replaced by the following new entries for Annatto bixin and Annatto norbixin, respectively for ‘only smoked fish’ and for ‘only surimi and similar products and salmon substitutes’:

	E 160b(i)	Annatto bixin	10	(94)	only smoked fish
	E 160b(i)	Annatto bixin	30	(94)	only surimi and similar products and salmon substitutes
	E 160b(ii)	Annatto norbixin	10	(94)	only smoked fish
	E 160b(ii)	Annatto norbixin	30	(94)	only surimi and similar products and salmon substitutes’

- (ii) the following footnote (94) is added after footnote (85):

‘(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.’

23) Category 12.5 (Soups and broths) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for Group III (Colours with combined maximum limit):

	'E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	10	(94)	

- (ii) the following footnote (94) is added after footnote (60):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

24) Category 12.6 (Sauces) is amended as follows:

- (i) the following new entries for E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are inserted after the entry for E 110 (Sunset Yellow FCF/Orange Yellow S):

	'E 160b(i)	Annatto bixin	30	(94)	including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces
	E 160b(ii)	Annatto norbixin	30	(94)	including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces'

- (ii) the following footnote (94) is added after footnote (65):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

25) in category 14.1.4 (Flavoured drinks), the following new entry for E 160b(i) (Annatto bixin) is inserted after the entry for E 124 (Ponceau 4R, Cochineal Red A):

	'E 160b(i)	Annatto bixin	20'		
--	------------	---------------	-----	--	--

26) in category 14.2.6 (Spirit drinks as defined in Regulation (EC) No 110/2008), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	10		only liqueurs'
--	------------	---------------	----	--	----------------

27) in category 14.2.8 (Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol), the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(ii)	Annatto norbixin	10		only alcoholic drinks with less than 15 % of alcohol'
--	-------------	------------------	----	--	---

28) Category 15.1 (Potato-, cereal-, flour- or starch-based snacks) is amended as follows:

(i) the two entries for E 160b (Annatto, Bixin, Norbixin) are replaced by the following:

	'E 160b(i)	Annatto bixin	20	(94)	
	E 160b(ii)	Annatto norbixin	20	(94)	

(ii) the following footnote (94) is added after footnote (71):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

29) Category 15.2 (Processed nuts) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	10	(94)	
	E 160b(ii)	Annatto norbixin	10	(94)	

(ii) the following footnote (94) is added after footnote (60):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

30) Category 16 (Desserts excluding products covered in category 1, 3 and 4) is amended as follows:

(i) the entry for E 160b (Annatto, Bixin, Norbixin) is replaced by the following:

	'E 160b(i)	Annatto bixin	15	(94)	
	E 160b(ii)	Annatto norbixin	7,5	(94)	

(ii) the following footnote (94) is added after footnote (74):

'(94): When E 160b(i) (Annatto bixin) and E 160b(ii) (Annatto norbixin) are added in combination, the higher individual maximum level applies to the sum, but the individual maximum levels shall not be exceeded.'

(2) In Part 2 of Annex III to Regulation (EC) No 1333/2008, the entry for E 900 (Dimethyl polysiloxane) is replaced by the following:

'E 900	Dimethyl polysiloxane	200 mg/kg in the preparation, 0,2 mg/l in final food	Colour preparations of E 160a carotenes, E 160b(i) annatto bixin, E 160b(ii) annatto norbixin, E 160c paprika extract, capsanthin, capsorubin, E 160d lycopene and E 160e beta-apo-8'-carotenal'
--------	-----------------------	---	--

ANNEX II

In the Annex to Regulation (EU) No 231/2012, the respective entries for E 160b Annatto, Bixin, Norbixin: (i) Solvent-extracted bixin and norbixin, (ii) alkali extracted annatto and (iii) oil extracted annatto are replaced by the following:

E 160 b (i) ANNATTO BIXIN

(I) SOLVENT-EXTRACTED BIXIN

Synonyms	Annatto B, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	<p>Solvent-extracted bixin is obtained by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide. The resulting preparation may be acidified, followed by the removal of the solvent, drying and milling.</p> <p>Solvent-extracted bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	230-248-7
Chemical name	cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo- Ψ,Ψ -carotenedioate
Chemical formula	cis-Bixin: C ₂₅ H ₃₀ O ₄
Molecular weight	394,5
Assay	<p>Not less than 85 % colouring matter (expressed as bixin)</p> <p>E¹_{1cm} 3090 at ca. 487 nm in tetrahydrofuran and acetone</p>
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Insoluble in water, slightly soluble in ethanol
Spectrometry	The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm
Purity	
Norbixin	Not more than 5 % of total colouring matters

Residual Solvents	Acetone: Not more than 30 mg/kg	
	Methanol: Not more than 50 mg/kg	
	Hexane: Not more than 25 mg/kg	
	Ethanol:	not more than 50 mg/kg, singly or in combination
	Isopropyl alcohol:	
	Ethyl acetate:	
Arsenic	Not more than 2 mg/kg	
Lead	Not more than 1 mg/kg	
Mercury	Not more than 1 mg/kg	
Cadmium	Not more than 0,5 mg/kg	

(II) AQUEOUS-PROCESSED BIXIN

Synonyms	Annatto E, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	<p>Aqueous-processed bixin is prepared by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) by abrading the seeds in the presence of cold, mildly-alkaline water. The resultant preparation is acidified to precipitate bixin which is then filtered, dried and milled.</p> <p>Aqueous-processed bixin contains several coloured components; the major colouring principle is cis-bixin, a minor colouring principle is trans-bixin; thermal degradation products of bixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	230-248-7
Chemical name	cis-Bixin: Methyl (9-cis)-hydrogen-6,6'-diapo- Ψ,Ψ -carotenedioate
Chemical formula	cis-Bixin: $C_{25}H_{30}O_4$
Molecular weight	394,5
Assay	<p>Not less than 25 % colouring matter (expressed as bixin)</p> <p>$E_{1\text{cm}}^{1\%}$ 3090 at ca. 487 nm in tetrahydrofuran and acetone</p>
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Insoluble in water, slightly soluble in ethanol

Spectrometry	The sample in acetone shows absorbance maxima at about 425, 457 and 487 nm
Purity	
Norbixin	Not more than 7 % of total colouring matters
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

E 160 b (ii) ANNATTO NORBIXIN

(I) SOLVENT-EXTRACTED NORBIXIN

Synonyms	Annatto C, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	<p>Solvent-extracted norbixin is obtained from the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) by washing with one or more of the following food grade solvents: acetone, methanol, hexane, ethanol, isopropyl alcohol, ethyl acetate, alkaline alcohol or supercritical carbon dioxide followed by solvent removal, crystallization and drying. Aqueous alkali is added to the resultant powder, which is then heated to hydrolyse the colouring matter and cooled. The aqueous solution is filtered, and acidified to precipitate the norbixin. The precipitate is filtered, washed, dried and milled, to give a granular powder.</p> <p>Solvent-extracted norbixin contains several coloured components; the major colouring principle is <i>cis</i>-norbixin, a minor colouring principle is <i>trans</i>-norbixin; thermal degradation products of norbixin may also be present as a result of processing.</p>
Colour Index No	75120
Einecs	208-810-8
Chemical name	<p><i>cis</i>-Norbixin: 6,6'-Diapo-Ψ,Ψ-carotenedioic acid</p> <p><i>cis</i>-Norbixin dipotassium salt: Dipotassium 6,6'-diapo-Ψ,Ψ-carotenedioate</p> <p><i>cis</i>-Norbixin disodium salt: Disodium 6,6'-diapo-Ψ,Ψ-carotenedioate</p>
Chemical formula	<p><i>cis</i>-Norbixin: C₂₄H₂₈O₄</p> <p><i>cis</i>-Norbixin dipotassium salt: C₂₄H₂₆K₂O₄</p> <p><i>cis</i>-Norbixin disodium salt: C₂₄H₂₆Na₂O₄</p>

Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)	
Assay	Not less than 85 % colouring matter (expressed as norbixin) $E_{1\text{cm}}^{1\%}$ 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution	
Description	Dark red-brown to red-purple powder	
Identification		
Solubility	Soluble in alkaline water, slightly soluble in ethanol	
Spectrometry	The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm	
Purity		
Residual Solvents	Acetone: Not more than 30 mg/kg	
	Methanol: Not more than 50 mg/kg	
	Hexane: Not more than 25 mg/kg	
	Ethanol: Isopropyl alcohol: Ethyl acetate:	not more than 50 mg/kg, singly or in combination
Arsenic	Not more than 2 mg/kg	
Lead	Not more than 1 mg/kg	
Mercury	Not more than 1 mg/kg	
Cadmium	Not more than 0,5 mg/kg	

(II) ALKALI-PROCESSED NORBIXIN, ACID-PRECIPITATED

Synonyms	Annatto F, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	<p>Alkali-processed norbixin (acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution and is acidified to precipitate the norbixin. The precipitate is filtered, dried and milled to give a granular powder.</p> <p>Alkali-processed norbixin contains several coloured components; the major colouring principle is <i>cis</i>-norbixin, a minor colouring principle is <i>trans</i>-norbixin; thermal degradation products of norbixin may also be present as a result of processing.</p>

Colour Index No	75120
Einecs	208-810-8
Chemical name	cis-Norbixin: 6,6'-Diapo- Ψ,Ψ -carotenedioic acid cis-Norbixin dipotassium salt: Dipotassium 6,6'-diapo- Ψ,Ψ -carotenedioate cis-Norbixin disodium salt: Disodium 6,6'-diapo- Ψ,Ψ -carotenedioate
Chemical formula	cis-Norbixin: $C_{24}H_{28}O_4$ cis-Norbixin dipotassium salt: $C_{24}H_{26}K_2O_4$ cis-Norbixin disodium salt: $C_{24}H_{26}Na_2O_4$
Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)
Assay	Not less than 35 % colouring matter (expressed as norbixin) $E_{1\text{cm}}^{1\%}$ 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Soluble in alkaline water, slightly soluble in ethanol
Spectrometry	The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm
Purity	
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg

(III) ALKALI-PROCESSED NORBIXIN, NOT ACID-PRECIPIATED

Synonyms	Annatto G, Orlean, Terre orellana, L. Orange, CI Natural Orange 4
Definition	Alkali-processed norbixin (not acid-precipitated) is prepared by the extraction of the outer coating of the seeds of the annatto tree (<i>Bixa orellana</i> L.) with aqueous alkali. The bixin is hydrolysed to norbixin in hot alkaline solution. The precipitate is filtered, dried and milled to give a granular powder. Extracts contain mainly the potassium or sodium salt of norbixin as the major colouring matter.

	Alkali-processed norbixin (not acid-precipitated) contains several coloured components; the major colouring principle is <i>cis</i> -norbixin, a minor colouring principle is <i>trans</i> -norbixin; thermal degradation products of norbixin may also be present as a result of processing.
Colour Index No	75120
Einecs	208-810-8
Chemical name	<i>cis</i> -Norbixin: 6,6'-Diapo- Ψ , Ψ -carotenedioic acid <i>cis</i> -Norbixin dipotassium salt: Dipotassium 6,6'-diapo- Ψ , Ψ -carotenedioate <i>cis</i> -Norbixin disodium salt: Disodium 6,6'-diapo- Ψ , Ψ -carotenedioate
Chemical formula	<i>cis</i> -Norbixin: C ₂₄ H ₂₈ O ₄ <i>cis</i> -Norbixin dipotassium salt: C ₂₄ H ₂₆ K ₂ O ₄ <i>cis</i> -Norbixin disodium salt: C ₂₄ H ₂₆ Na ₂ O ₄
Molecular weight	380,5 (acid), 456,7 (dipotassium salt), 424,5 (disodium salt)
Assay	Not less than 15 % colouring matter (expressed as norbixin) E ¹ _{%1cm} 2870 at ca. 482 nm in 0,5 % potassium hydroxide solution
Description	Dark red-brown to red-purple powder
Identification	
Solubility	Soluble in alkaline water, slightly soluble in ethanol
Spectrometry	The sample in 0,5 % potassium hydroxide solution shows absorbance maxima at about 453 nm and 482 nm
Purity	
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 0,5 mg/kg'