# Commission Regulation (EU) 2018/1481 of 4 October 2018 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 octyl gallate (E 311) and dodecyl gallate (E 312) (Text with EEA relevance)

## COMMISSION REGULATION (EU) 2018/1481

## of 4 October 2018

## 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 octyl gallate (E 311) and dodecyl gallate (E 312)

## (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) Octyl gallate (E 311) and dodecyl gallate (E 312) are substances authorised as antioxidants in a variety of foods, as well as in food flavourings, in accordance with Annexes II and III to Regulation (EC) No 1333/2008.

(5) 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').

(6) For that purpose, a program for the re-evaluation of food additives is laid down in Commission Regulation (EU) No 257/2010[(3)]. Pursuant to Regulation (EU) No 257/2010 the re-evaluation of antioxidants had to be completed by 31 December 2015.

(7) On 5 May 2015 the Authority delivered a Scientific Opinion on the re-evaluation of dodecyl gallate (E 312) as a food additive[(4)]. The opinion stated that there was a lack of adequate toxicological data on dodecyl gallate. Consequently the Authority was not able to confirm the safety of dodecyl gallate as a food additive and concluded that the

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Regulation (EU) 2018/1481. (See end of Document for details)*

present group Acceptable Daily Intake (ADI) for propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) should no longer be valid. The opinion stated that a sufficient toxicological database would be required for an adequate assessment of the safety of dodecyl gallate as a food additive.

(8) On 1 October 2015 the Authority delivered a Scientific Opinion on the re-evaluation of octyl gallate (E 311) as a food additive[5]. The opinion stated that there was a lack of adequate toxicological data on octyl gallate. Consequently the Authority was not able to confirm the safety of octyl gallate as a food additive and concluded that the present group ADI for propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312) should no longer be valid. The opinion stated that a sufficient toxicological database would be required for an adequate assessment of the safety of octyl gallate as a food additive.

(9) On 30 May 2017 the Commission launched a public call for scientific and technological data on propyl gallate (E 310), octyl gallate (E 311) and dodecyl gallate (E 312)[6], targeting the data needs identified in the Scientific Opinions on the re-evaluation of those substances as food additives. However, no business operator committed to providing the requested toxicological data for octyl gallate (E 311) and dodecyl gallate (E 312). Without those data the Authority cannot complete the re-evaluation of the safety of octyl gallate and dodecyl gallate as food additives and consequently it cannot be determined whether those substances still fulfil the conditions pursuant to Article 6(1) of Regulation (EC) No 1333/2008 for inclusion in the Union list of approved food additives.

(10) It is therefore appropriate to remove octyl gallate (E 311) and dodecyl gallate (E 312) from the Union list of approved food additives.

(11) Pursuant to Article 10(3) of Regulation (EC) No 1333/2008, the Union list of approved food additives shall be amended in accordance with the procedure referred to in Regulation (EC) No 1331/2008 of the European Parliament and of the Council[7].

(12) Article 3(1) of Regulation (EC) No 1331/2008 provides that the Union list of food additives may be updated either on the initiative of the Commission or following an application.

(13) Therefore, Annexes II and III to Regulation (EC) No 1333/2008 and the Annex to Regulation (EU) No 231/2012 should be amended by deleting octyl gallate (E 311) and dodecyl gallate (E 312) from the Union list of authorised food additives since due to the absence of appropriate toxicological data their inclusion in the list can no longer be justified.

(14) It is appropriate to provide for a transitional period during which foods containing octyl gallate (E 311) and/or dodecyl gallate (E 312) that have been lawfully placed on the market before the entry in force of this Regulation may continue to be marketed.

(15) 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) 2018/1481. (See end of Document for details)*

*Article 1*

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

*Article 2*

In the Annex to Regulation (EU) No 231/2012, the entries for food additives octyl gallate (E 311) and dodecyl gallate (E 312) are deleted.

*Article 3*

Foods containing octyl gallate (E 311) and/or dodecyl gallate (E 312) that have been lawfully placed on the market before the entry into force of this Regulation may continue to be marketed until 25 April 2019.

*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, 4 October 2018.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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ANNEX

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

(a) in Part B, in Table 3: Additives other than colours and sweeteners, the entries for the food additives E 311 octyl gallate and E 312 dodecyl gallate are deleted;

(b) in Part C, in Table 5: Other additives that may be regulated combined, point (k) 'E 310-320: Gallates, TBHQ and BHA' is replaced by the following:

(k) E 310–320: Propyl gallate, TBHQ and BHA

| **E-number** | **Name** |
|---|---|
| E 310 | Propyl gallate |
| E 319 | Tertiary-butyl hydroquinone (TBHQ) |
| E 320 | Butylated hydroxyanisole (BHA) |

(c) Part E is amended as follows:

1. In category 01.5 (Dehydrated milk as defined by Directive 2001/114/EC), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA) is replaced by the following:

| | | | | | |
|---|---|---|---|---|---|
| | E 310-320 | Propyl gallate, TBHQ and BHA | 200 | (1) | only milk powder for vending machines |

2. In category 02.1 (Fats and oils essentially free from water (excluding anhydrous milkfat)), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA, individually or in combination) is replaced by the following:

| | | | | | |
|---|---|---|---|---|---|
| | E 310-320 | Propyl gallate, TBHQ and BHA | 200 | (1) (41) | only fats and oils for the professional manufacture of heat-treated foods; frying oil and frying fat (excluding olive pomace oil) and |

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| | | | | | |
|---|---|---|---|---|---|
| | | | | | lard, fish oil, beef, poultry and sheep fat |

3. 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 concerning food additives E 310-320 (Gallates, TBHQ and BHA, individually or in combination) is replaced by the following:

| | | | | | |
|---|---|---|---|---|---|
| | E 310-320 | Propyl gallate, TBHQ and BHA | 200 | (1) (2) | only frying fat |

4. In category 04.2.5.4 (Nut butters and nut spreads), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA) is replaced by the following:

| | | | | | |
|---|---|---|---|---|---|
| | E 310-320 | Propyl gallate, TBHQ and BHA | 200 | (1) (41) | only processed nuts |

5. In category 04.2.6 (Processed potato products), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA) is replaced by the following:

| | | | | | |
|---|---|---|---|---|---|
| | E 310-320 | Propyl gallate, TBHQ and BHA | 25 | (1) | only dehydrated potatoes |

6. In category 05.3 (Chewing gum), the entry concerning food additives E 310-321 (Gallates, TBHQ, BHA and BHT) is replaced by the following:

| | | | | | |
|---|---|---|---|---|---|
| | E 310-321 | Propyl gallate, TBHQ, BHA and BHT | 400 | (1) | |

7. In category 06.3 (Breakfast cereals), the entry concerning food additives E 310-320 (Gallates, TBHQ and BHA) is replaced by the following: