Commission Regulation (EU) 2015/647 of 24 April 2015 amending and correcting Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of certain food additives (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/647

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(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 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, flavourings, nutrients and their conditions of use.

(3) Those lists 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.

(4) The Union list of food additives was established based on food additives permitted for use in foods in accordance with Directives of the European Parliament and of the Council 94/35/EC[(3)], 94/36/EC[(4)], and 95/2/EC[(5)] and after reviewing their compliance with Articles 6, 7 and 8 of Regulation (EC) No 1333/2008. The Union list includes food additives on the basis of the categories of food to which those additives may be added to.

(5) Due to the difficulties encountered during the transfer of food additives to the new categorisation system provided in Annex II to Regulation (EC) No 1333/2008, certain errors have been detected and should be corrected, other provisions need to be further clarified.

(6) Annex II does not list the different forms under which a food additive can be used, e.g. Sorbitols (E 420) exist in the form of Sorbitol (E 420 (i)) or Sorbitol syrup (E 420 (ii)); Sodium citrates (E 331) exist in the form of Monosodium citrate (E 331 (i)), Disodium citrate (E 331 (ii)) and Trisodium citrate (E 331 (iii)). These forms are specified in Commission Regulation (EU) No 231/2012[(6)]. It should be clarified that those different forms of the authorised food additives can be used.

(7) Canthaxanthin (E 161g) should not be sold directly to the consumer. Therefore, Annex II of Regulation (EC) No 1333/2008, part A, Section 2, point 5 should be amended.

(8) Konjac (E 425) should not be used to produce dehydrated foods intended to be rehydrated upon ingestion. Therefore, in Annex II, Part C, Section 1, Group I, the entry for E 425 the footnote (2) should be introduced.

(9) In food categories 01.7.2: 'Ripened cheese' and 01.7.6 'Cheese products (excluding products falling in category 16)', it should be clarified that Natamycin (E 235) may only be used for external treatment of uncut cheeses and uncut cheese products.

(10) A consistent approach should be taken as regards the wording of the footnotes referring to maximum limits for aluminium coming from aluminium lakes introduced by Commission Regulation (EU) No 380/2012[7]. A sentence 'No other aluminium lakes may be used' should be included in all footnotes referring to specific food additives in the categories: 01.7.3: 'Edible cheese rind', 01.7.5: 'Processed cheese', 04.2.5.2: 'Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC', 08.2: 'Meat preparations as defined by Regulation (EC) No 853/2004', 08.3.1: 'Non-heat-treated meat products', 08.3.2 'Heat-treated meat products', 08.3.3 'Casings and coatings and decorations for meat' and 09.3: 'Fish roe'.

(11) In category 02.1: 'Fats and oils essentially free from water (excluding anhydrous milkfat)', certain additives should not be used in virgin oils and olive oil.

(12) In category 04.2.3: 'Canned or bottled fruit and vegetables', the use of Sulphur dioxide — sulphites (E 220-228) should be permitted in processed mushrooms.

(13) In food category 05.2: 'Other confectionery including breath freshening microsweets' and in food category 05.4: 'Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4', the maximum level of Neotame (E 961) used as flavour enhancer in starch-based confectionery should be set at 3 mg/kg.

(14) In food category 05.4: 'Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4', the use of Cyclamic acid and its Na and Ca salts (E 952) should be permitted in flavoured cream spray cans.

(15) In food category 06.4.4: 'Potato Gnocchi', the use of additives in fresh refrigerated potato Gnocchi should be restricted to a limited number of additives that belong to Group I.

(16) In food category 07.2: 'Fine bakery wares', the use of Sulphur dioxide — sulphites (E 220-228) should be clarified.

(17) In food category 08.2: 'Meat preparations as defined by Regulation (EC) No 853/2004', the entry for Potassium acetate (E 261) should be corrected to Potassium acetates.

(18) In food category 08.3.1: 'Non-heat-treated meat products', the double entries for Erythorbic acid (E 315) and Sodium erythorbate (E 316) should be removed.

(19) In food categories 08.2: 'Meat preparations as defined by Regulation (EC) No 853/2004', 08.3.1: 'Non-heat-treated meat products', 08.3.2: 'Heat-treated meat products' and 08.3.4: 'Traditionally cured meat products with specific provisions

concerning nitrites and nitrates', the expression of the maximum levels of Nitrites (E 249-250) and/or Nitrates (E 251-252) should be clarified.

(20) In food category, 08.3.2: 'Heat-treated meat products' the use of Gallates, TBHQ and BHA (E 310-320) should be permitted in dehydrated meat.

(21) In food category 08.3.3: 'Casings and coatings and decorations for meat', the number of footnote (80) should be corrected to (89).

(22) In food category 08.3.4.2: 'Traditional dry cured products', the maximum level for nitrites (E 249-250) should be reintroduced for *jamón curado, paleta curada, lomo embuchado* and *cecina* and similar products.

(23) In food categories 09.1.2: 'Unprocessed molluscs and crustaceans' and 09.2: 'Processed fish and fishery products including molluscs and crustaceans', it should be clarified that the units according to which the maximum limits for Sulphur dioxide and Sulphites (E 220-228) depend are expressed per kilogram, and the footnote related to 4-Hexylresorcinol (E 586) should be clarified and corrected.

(24) In food category 09.2: 'Processed fish and fishery products including molluscs and crustaceans', the use of Titanium dioxide (E 171) and Iron oxides and hydroxides (E 172) should be restricted to smoked fish.

(25) In food category 09.2: 'Processed fish and fishery products including molluscs and crustaceans', it should be clarified that the maximum level for Sorbic acid — sorbates; Benzoic acid — benzoates (E 200-213), applies to the additives individually or in combination and to the sum and that the levels are expressed as the free acid.

(26) In category 10.2: 'Processed eggs and egg products', the maximum level for Triethyl citrate (E 1505) should apply only to dried egg white.

(27) In food categories 14.2.7.1: 'Aromatised wines' and 14.2.7.2: 'Aromatised wine-based drinks', the use of colours belonging to Group II and Group III should be corrected according to the uses of colours that were permitted in Directive 94/36/EC.

(28) In food category 17.1: 'Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms', the number of footnote (79) should be changed and introduced in the entry for the food additive Dimethyl polysiloxane (E 900).

(29) In Annex III to Regulation (EC) No 1333/2008, in Part 4, 'Food additives including carriers in food flavourings', the maximum limits for Octenyl succinic acid modified gum arabic (E 423) should apply to the final food. In Part 6, 'Definitions of groups of food additives for the purposes of Parts 1 to 5', in Table 7 'Alginic acid — alginates', Calcium alginate (E 404) should be included.

(30) 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. Since the Union list is amended in order to include uses of additives already permitted

in accordance with Directive 94/35/EC, Directive 94/36/EC and Directive 95/2/EC, it constitutes an update of that list which is not liable to have an effect on human health. Therefore, it is not necessary to seek the opinion of the Authority.

(31) Annexes II and III to Regulation (EC) No 1333/2008 should therefore be amended and corrected accordingly.

(32) 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 II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

Annex III to Regulation (EC) No 1333/2008 is amended in accordance with Annex II to this Regulation.

Article 3

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, 24 April 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2015/647. (See end of Document for details)*

ANNEX I

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

I. Part A is amended as follows:

(1) In Section 1, the first indent is replaced by the following:

— the name of the food additive and its E-number; as an alternative more specific E-numbers and names listed in Commission Regulation (EU) No 231/2012[8] may be used, excluding synonyms, if the named food additives have indeed been added to a certain food.

(2) In Section 2, point 1 is replaced by the following:

1. Only the substances listed in Part B, as specified by Regulation (EU) No 231/2012, may be used as additives in foods, unless more specifically provided for in Part E.

(3) In Section 2, point 5 is replaced by the following:

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

II. In Part C, Section 1 — Group I, the entry for E 425 is replaced by the following:

E 425	Konjac (i) Konjac gum (ii) Konjac glucomannane		10 g/kg, individually or in combination ([1]) ([2]) ([3])

III. Part E is amended as follows:

(1) In category 01.7.2 — ‘Ripened cheese’, the entry for E 235 is amended as follows:

(a) the entry for E 235 is replaced by the following:

	E 235	Natamycin	1 mg/dm^2 surface (not present at a depth of 5 mm)		only for the external treatment of uncut hard, semi-hard and semi-soft cheese

(b) footnote 8 is deleted.

(2) In category 01.7.3 — ‘Edible cheese rind’, footnote 67 is replaced by the following:

(67) : Maximum limit for aluminium coming from aluminium lakes of