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COMMISSION REGULATION (EU) No 257/2010

of 25 March 2010

setting up a programme 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

(Text with EEA relevance)

(OJ L 80, 26.3.2010, p. 19)

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Article 1

Subject matter and scope

1. This Regulation sets up a programme for the re-evaluation by the European Food Safety Authority (hereinafter referred to as 'EFSA') of approved food additives, as provided for in Article 32 of Regulation (EC) No 1333/2008.

2. Approved food additives, for which the re-evaluation by EFSA is already completed at the time of the adoption of this Regulation, shall not be re-evaluated again. Those food additives are listed in Annex I.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'approved food additive' means a food additive authorised before 20 January 2009 and listed in Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs ([1]), Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs ([2]) or in Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ([3]);

(b) 'business operator' means any natural or legal person responsible for ensuring that the requirements of Regulation (EC) No 1333/2008 are met within the food business under its control;

(c) 'interested business operator' means a business operator interested in the continuity of the authorisation of one or more approved food additives;

(d) 'original dossier' means a dossier on the basis of which the food additive was evaluated and permitted for use in food before 20 January 2009.

Article 3

Priorities for the re-evaluation of approved food additives

1. Approved food additives shall be re-evaluated in the following order and within the following deadlines:

([1]) OJ L 237, 10.9.1994, p. 3.
([2]) OJ L 237, 10.9.1994, p. 13.
([3]) OJ L 61, 18.3.1995, p. 1.

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(a) the re-evaluation of all approved food colours listed in Directive 94/36/EC shall be completed by 31 December 2015;

(b) the re-evaluation of all approved food additives other than colours and sweeteners listed in Directive 95/2/EC shall be completed by 31 December 2018;

(c) the re-evaluation of all approved sweeteners listed in Directive 94/35/EC shall be completed by 31 December 2020.

2. For certain food additives within the functional classes referred to in paragraph 1 more specific deadlines are set out in Annex II to this Regulation. Those food additives shall be evaluated first among the other food additives of the same functional class.

3. By way of derogation from paragraphs 1 and 2, EFSA may at any moment start the re-evaluation of a food additive or a group of food additives with priority, on a request from the Commission or on its own initiative, if new scientific evidence emerges that

(a) indicates a possible risk for human health or

(b) may in any way affect the safety assessment of that food additive or group of food additives.

Article 4

Re-evaluation procedure

When re-evaluating an approved food additive, EFSA shall:

(a) examine the original opinion and the working documents of the Scientific Committee on Food ('SCF') or EFSA;

(b) examine, where available, the original dossier;

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(c) examine the data submitted by the interested business operator(s) and/or any other interested party in accordance with Articles 5, 6 and 7 of this Regulation;

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(d) examine any data made available by the Commission and Member States;

(e) identify any relevant literature published since the last evaluation of each food additive.

Article 5

Call for data

1. In order to acquire the data from the interested business operators and/or other interested parties, EFSA shall make open call(s) for data for the food additives under re-evaluation. In specifying the timetable for data submission, EFSA shall allow a reasonable time period after the entry into force of this Regulation, to allow the interested business operator and/or any other interested party to meet this duty.

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2. The data referred to in paragraph 1 may comprise among others:

(a) study reports from the original dossier as evaluated by the SCF or EFSA or the Joint FAO/WHO Expert Committee on Food Additives (JECFA),

(b) information on the data on the safety of the food additive concerned not previously reviewed by the SCF or the JECFA,

(c) information on the specifications of the food additives presently in use, including information on particle size and relevant physico-chemical characteristics and properties,

(d) information on the manufacturing process,

(e) information on analytical methods available for determination in food,

(f) information on the human exposure to the food additives from food (e.g. consumption pattern and uses, actual use levels and maximum use levels, frequency of consumption and other factors influencing exposure),

(g) reaction and fate in food.

Article 6

Submission of data

1. The interested business operator(s) and any other interested party shall submit the data related to the re-evaluation of a food additive as referred to in Article 5(2), within the period set by EFSA in its call for data. In the submission the interested business operator and the other interested parties shall include the data requested by EFSA by following, to the extent possible, the applicable guidance on submissions for food additive evaluations ([1]).

2. Where there are several interested business operators they may, when possible, submit the data collectively.

3. If during the re-evaluation additional information considered to be relevant for the re-evaluation of a particular food additive is needed, EFSA shall request from the interested business operators, and shall invite other interested parties, to submit this information by an open call for data. It shall set a deadline within which that information shall be submitted having considered, where relevant, the interested business operator's and/or other interested parties' view of the time required. In such cases, EFSA shall make the request for the additional information well in advance so that the overall deadlines for the re-evaluation as set out in Article 3(1) and in Annex II are not affected.

([1]) Currently the Opinion expressed by the SCF on 11 July 2001. SCF/CS/ADD/GEN/26 Final.

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4. Information which has not been submitted within the deadline set by EFSA shall not be taken into account in the re-evaluation. However, in exceptional cases, EFSA may decide with the agreement of the Commission to take into account information submitted after the deadline, if that information is significant for the re-evaluation of a food additive.

5. Where the requested information has not been submitted to EFSA within the set deadlines, the food additive may be removed from the Union list in accordance with the procedure laid down in Article 10.3 of Regulation (EC) No 1333/2008 ([1]).

Article 7

Other information

In the framework of the re-evaluation of a food additive, the interested business operator(s) or any other interested party shall inform EFSA and the Commission of any information available in relation to any environment risks from the production, use or waste of that food additive.

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Article 7a

Follow-up of EFSA opinions

1. Where, on the basis of the information referred to in Article 4, EFSA cannot confirm the safety of a food additive, of its uses or levels of use or recommend changes to the specifications, the Commission may take or request EFSA to take further steps, including the organisation of calls for data, in order to complete the safety assessment.

2. Where the data and information requested in accordance with paragraph 1 has not been submitted or where it does not allow to confirm the safety of the food additive, of its uses or levels of use or specifications, the food additive may be removed from the Union list in accordance with the procedure referred to in Article 10(3) of Regulation (EC) No 1333/2008.

Article 7b

Pre-submission advice

Where EFSA is required or requested to deliver an opinion in accordance with this Regulation, the staff of EFSA shall, at the request of interested business operator(s) or any other interested, party provide advice on the rules applicable to, and the content required for the submission of information pursuant to Articles 4 to 7a. Such advice shall be provided in accordance with Article 32a of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([2]), which shall apply *mutatis mutandis*.

([1]) OJ L 354, 31.12.2008, p. 16.

([2]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

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Article 7c

Notification of studies

Interested business operators and other interested parties shall, without delay, notify EFSA of the title and the scope of any study commissioned or carried out by them to support the re-evaluation of an approved food additive in accordance with Articles 4 to 7a of this Regulation, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.

Laboratories and other testing facilities located in the Union shall also, without delay, notify the Authority of the title and the scope of any study commissioned by business operators and other interested parties, carried out by such laboratories or other testing facilities to support the re-evaluation of an approved food additive in accordance with Articles 4 to 7a of this Regulation, its starting and planned completion dates, as well as the name of the business operators or interested parties who commissioned such a study.

Studies notified in accordance with this article shall be included by EFSA in the database referred to in Article 32b(1) of Regulation (EC) No 178/2002.

Article 7d

Format of submissions

Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, data submitted in accordance with this Regulation shall be submitted in an electronic format allowing for the downloading, printing and searching of documents. After the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, data shall be submitted in accordance with those standard data formats.

Article 7e

Transparency

Where EFSA is required or requested to deliver an opinion in accordance with this Regulation, it shall consult stakeholders and the public on the basis of the non-confidential version of the data submitted pursuant to this Regulation, in accordance with Article 32c(2), of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.

Article 8

Confidentiality

Upon submission of data in accordance with this Regulation, the interested business operator or other interested party may submit a request to treat certain parts of the information or data as confidential. Such request shall be accompanied by verifiable justification. Such confidentiality requests shall be assessed in accordance with Article 12 of Regulation (EC) No 1331/2008, which shall apply *mutatis mutandis*.

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Article 9

Monitoring progress

Every year in December, EFSA shall inform the Commission and the Member States on the progress of the re-evaluation programme.

Article 10

Entry into force

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.

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ANNEX I

A list of approved food additives which were approved before 20 January 2009 and for which the re-evaluation by EFSA is completed at the time of adoption of this Regulation

E No	Substance	Year of latest evaluation by SCF or EFSA	Status of re-evaluation by EFSA
E 102	Tartrazine	2009	Re-evaluation completed on 23 September 2009
E 104	Quinoline Yellow	2009	Re-evaluation completed on 23 September 2009
E 110	Sunset yellow FCF, Orange Yellow S	2009	Re-evaluation completed on 24 September 2009
E 122	Azorubine, Carmoisine	2009	Re-evaluation completed on 24 September 2009
E 124	Ponceau 4R, Cochineal Red A	2009	Re-evaluation completed on 23 September 2009
E 129	Allura Red AC	2009	Re-evaluation completed on 23 September 2009
E 160d	Lycopene	2008	Re-evaluation completed on 30 January 2008
E 234	Nisin	2006	Re-evaluation completed on 26 January 2006
E 173	Aluminium	2008	Re-evaluation completed on 22 May 2008
E 214	Ethyl p-hydroxybenzoate	2004	Re-evaluation completed on 13 July 2004
E 215	Sodium ethyl p-hydroxybenzoate	2004	Re-evaluation completed on 13 July 2004
E 218	Methyl p-hydroxybenzoate	2004	Re-evaluation completed on 13 July 2004
E 219	Sodium methyl p-hydroxybenzoate	2004	Re-evaluation completed on 13 July 2004
E 235	Natamycin	2009	Re-evaluation completed on 26 November 2009
E 473	Sucrose esters of fatty acids	2006	Re-evaluation completed on 23 November 2004; revised on 26 January 2006
E 474	Sucroglycerides	2006	Re-evaluation completed on 23 November 2004; revised on 26 January 2006
E 901	Beeswax, white and yellow	2007	Re-evaluation completed on 27 November 2007

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ANNEX II

Specific priorities for certain food additives within the functional classes of food additives as referred to in Article 3(1) and (2)

PART I: FOOD COLOURS

Within the overall deadline of 31.12.2015 set for the re-evaluation of food colours in Article 3(1) the following specific deadlines are set for the following food colours:

1. **The following food colours shall be evaluated by 15.4.2010**

E 123 Amaranth,

E 151 Brilliant Black BN, Black PN

E 154 Brown FK,

E 155 Brown HT and

E 180 Litholrubine BK

2. **The following food colours shall be evaluated by 31.12.2010**

E 100 Curcumin,

E 127 Erythrosine,

E 131 Patent Blue V,

E 132 Indigotine, Indigo carmine

E 133 Brilliant Blue FCF,

E 142 Green S,

E 150a Plain caramel,

E 150b Caustic sulphite caramel,

E 150c Ammonia caramel,

E 150d Sulphite ammonia caramel,

E 161b Lutein,

E 161g Canthaxanthin,

E 170 Calcium carbonate,

3. **The following food colours shall be evaluated by 31.12.2015**

E 101 (i) Riboflavin (ii) Riboflavin-5'-phosphate,

E 120 Cochineal, Carminic acid, Carmines

E 140 Chlorophylls and Chlorophyllins: (i) Chlorophylls (ii) Chlorophyllins,

E 141 Copper complexes of Chlorophylls and Chlorophyllins: (i) Copper complexes of chlorophylls (ii) Copper complexes of chlorophyllins,

E 153 Vegetable carbon,

E 160b Annatto, bixin, norbixin

E 160a Carotenes: (i) mixed carotenes, (ii) beta-carotene,

E 160c Paprika extract, capsanthin, capsorubin,

E 160e Beta-apo-8'-carotenal (C30),

E 160f Ethyl ester of beta-apo-8', -carotenoic acid (C30),

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E 162 Beetroot red, betanin,

E 163 Anthocyanins,

E 171 Titanium dioxide,

E 172 Iron oxides and hydroxides,

E 174 Silver,

E 175 Gold

PART II: FOOD ADDITIVES OTHER THAN COLOURS AND SWEETENERS

Within the overall deadline of 31.12.2018 set for the re-evaluation of food additives other than colours and sweeteners in Article 3(1), the following specific deadlines are set for certain food additives and groups of food additives:

1. **Preservatives and antioxidants E 200-203; E 210-215, E 218-252, E 280-285; E 300-E 321 and E 586 shall be evaluated by 31.12.2015**

   with higher priority within this group on:

   E 310-312 Gallates

   E 320 Butylated hydroxyanisole (BHA)

   E 321 Butylated hydroxytoluene (BHT)

   E 220-228 Sulphur dioxide and sulphites

   E 304 Fatty acid esters of ascorbic acid: (i) Ascorbyl palmitate (ii) Ascorbyl stearate

   E 200-203 Sorbic acid and sorbates

   E 284 Boric acid

   E 285 Sodium tetraborate (borax)

   E 239 Hexamethylene tetramine

   E 242 Dimethyl dicarbonate

   E 249 Potassium nitrite

   E 250 Sodium nitrite

   E 251 Sodium nitrate

   E 252 Potassium nitrate

   E 280-283 Propionic acid and its sodium, calcium and potassium salts

   E 306 Tocopherol-rich extract

   E 307 Alpha-tocopherol

   E 308 Gamma-tocopherol

   E 309 Delta-tocopherol

2. **Emulsifiers, stabilisers, gelling agents E 322, E 400-E 419; E 422-E 495; E 1401-E 1451 shall be evaluated by 31.12.2016**

   With higher priority within this group on:

   E 483 Stearyl tartrate

   E 491-495 Sorbitan esters

   E 431 Polyoxyethylene (40) stearate

   E 432-436 Polysorbates

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E 444 Sucrose acetate isobutyrate

E 481 Sodium stearoyl-2-lactylate

E 482 Calcium stearoyl-2-lactylate

E 414 Acacia gum (gum arabic) (*)

E 410 Locust bean gum (*)

E 417 Tara gum (*)

E 422 Glycerol

E 475 Polyglycerol esters of fatty acids

3. **E 551 Silicon dioxide, E 620-625 Glutamates, E 1105 Lysozyme and E 1103 Invertase shall be evaluated by 31.12.2016**

4. **The remaining food additives other than colours and sweeteners shall be evaluated by 31.12.2018**

With higher priority on

E 552 Calcium silicate

E 553a Magnesium silicate and trisilicate

E 553b Talc

E 558 Bentonite

E 999 Quillaia extract

E 338-343 Phosphoric acid and phosphates

E 450-452 Di-, tri- and polyphosphates

E 900 Dimethyl polysiloxane

E 912 Montan acid esters

E 914 Oxidised polyethylene wax

E 902 Candellila wax

E 904 Shellac

E 626-629 Guanylic acid, Disodium guanylate, Dipotassium guanylate and Calcium guanylate

E 630-633 Inosinic acid, Disodium inosinate; Dipotassium inosinate and Calcium inosinate

E 634-635 Calcium 5'-ribonucleotides and Disodium 5'-ribonucleotides

E 507-511 Hydrochloric acid, Potassium chloride, Calcium chloride, Magnesium chloride

E 513 Sulphuric acid

(*) All natural gums E 400-418 and E 425 could be evaluated at the same time.