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Draft

COMMISSION REGULATION (EU) No .../..

of [...]

setting the programme for the re-evaluation of approved food additives in application of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives

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 additives¹, and in particular Article 32 thereof,

Whereas:

- (1) The Commission should, after consultation with European Food Safety Authority (hereinafter referred to as EFSA), set up an evaluation programme for the re-evaluation by EFSA of the safety of the food additives that were already permitted in the Community before 20 January 2009. That programme should define the needs and the order of priorities according to which the approved food additives are to be examined.
- (2) The order of priorities for the re-evaluation of the approved food additives should be set on the basis of certain criteria such as the time since the last evaluation of a food additive, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the 2001 Commission report² on food additive dietary intake at EU level and its subsequent follow up. A report entitled “Food additives in Europe 2000³” was submitted by the Nordic Council of Ministers to the Commission, provides also additional information for the prioritisation of additives for re-evaluation.
- (3) It is important for this re-evaluation to be effective, that EFSA acquires from interested parties all data relevant to the re-evaluation of food additives and that interested parties are informed on the time when additional data is necessary for the completion of the re-evaluation of a food additive.
- (4) A procedure should therefore be established in which the relationship between the parties interested in the re-evaluated food additives, EFSA, the Member States and the

¹ OJ L 354, 31.12.2008, p. 16.

² COM(2001) 542 final

³ Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002:560.

Commission and the obligations of each of the parties for the implementation of the procedure should be laid down.

- (5) Business operators interested in the continuity of the approval of a food additive under re-evaluation should submit any data relevant to the re-evaluation of the food additive. Business operators can take steps to submit information collectively.
- (6) EFSA will make public one or more open calls for data on all food additives to be re-evaluated. Any technical and scientific information about a food additive which is necessary for its evaluation, in particular toxicological data and data relevant for the estimation of the human exposure to the relevant food additive, should be submitted by the interested parties to EFSA within the relevant time limits and to the extent possible in accordance with the applicable guidance on submissions for food additive evaluations (currently the guidance established by the Scientific Committee on Food (hereinafter referred to as 'SCF') on 11 July 2001⁴).
- (7) The information submitted should include existing data on which the previous evaluation of a food additive was based and any new data relevant to the food additive made available since its last evaluation by the SCF. This information should be as comprehensive as possible in order to allow EFSA to complete its re-evaluation and form an up-to-date opinion.
- (8) Where necessary EFSA may require additional information in order to complete the re-evaluation of a food additive. In this case EFSA should request the necessary data in good time either by an open call for data or by contacting the parties that submitted data on the food additive. The interested parties should submit the requested information within a time period that is set by EFSA having considered, where relevant, the views of interested parties of the time required.
- (9) Food additives must be safe when used, there must be a technological need for their use and their use must not mislead the consumer and must be of benefit to the consumer. The approval of food additives should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors. Therefore, at any time including during the re-evaluation of food additives interested parties should inform the Commission and EFSA of any information available relevant to any environmental risks from the production, use or waste of the food additive.
- (10) The re-evaluation procedure of food additives must fulfil transparency and public information requirements while guaranteeing the confidentiality of certain information.
- (11) The re-evaluation of food colours has already been started with priority, since these food additives have the oldest evaluations by the SCF. The re-evaluation of certain colours namely of E102 Tartrazine, E104 Quinoline Yellow, E110 Sunset Yellow FCF, E124 Ponceau 4R, E129 Allura Red AC and E 122 Carmoisine, as well as of E160d lycopene from all sources is therefore already completed at the time this re-evaluation programme is established. In addition, some food additives such as E 234

⁴ Guidance on submissions for food additive evaluations by the Scientific Committee on Food. Opinion expressed on 11 July 2001. SCF/CS/ADD/GEN/26 Final

Nisin and E214–219 Para-hydroxybenzoates have been re-evaluated in recent years when new scientific data had been requested or became otherwise available. In 2007, the Commission presented a report to the European Parliament and the Council on the progress of the re-evaluation of food additives⁵. That report provides a summary of the recent additive re-evaluations undertaken by the SCF and EFSA and describes the related actions taken by the European Commission on the basis of the scientific opinions. Overall, sweeteners have the most recent evaluations and therefore are to be re-evaluated the last.

- (12) The prioritisation of the re-evaluation of the particular food additives is done on the basis of the criteria set in this Regulation. For efficiency and practical purposes, the re-evaluation will, as far as possible, be conducted by group of food additives according to the main functional class to which they belong. However, when necessary these priorities may change and on request from the Commission or on its own initiative EFSA, after the agreement of the Commission, may commence the re-evaluation of a food additive or a group of food additives with higher priority, if new scientific evidence emerges that indicates a possible risk for human health or which in any way may affect the assessment of the safety of a food additive.
- (13) Where the requested information which is necessary for the re-evaluation of a food additive is not provided and as a result EFSA can not conclude on the safety of a particular food additive, a measure may be adopted to change the conditions of use or remove the food additive from the Community list of approved food additives.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1
Scope

1. This Regulation lays down the criteria, the procedure and the order of priorities for a new risk assessment (here in after referred to as "re-evaluation") by EFSA of food additives which were permitted 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 foodstuffs⁶, Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs⁷ and in Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners⁸ (here in after referred to as "currently approved additives").
2. By the time of publication of this Regulation, the Commission shall make available to the public a list of the currently approved food additives under consideration in the re-evaluation together with the date of their latest evaluation by the SCF or EFSA.

⁵ COM(2007) 418 final

⁶ OJ L 237, 10.9.1994, p. 3.

⁷ OJ L 237, 10.9.1994, p. 13.

⁸ OJ L 61, 18.3.1995, p. 1.

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

Article 2
Definitions

For the purposes of this Regulation:

- (a) 'Business operator' means the natural or legal persons responsible for ensuring that the requirements of Regulation (EC) No 1333/2008 and of this Regulation are met within the food business under their control;
- (b) 'Original dossier', in relation to a food additive, means the dossier on the basis of which the food additive was evaluated and permitted for use in food before 20 January 2009.

Article 3
Criteria for setting priorities in the re-evaluation programme of currently approved food additives

1. The order of priority under which currently approved food additives will be evaluated is set in Article 4 and Annex II on the basis of the following criteria:
 - (a) The time since the last evaluation of a food additive by the SCF, or by EFSA;
 - (b) The existence of new scientific evidence or technical information made available since the last evaluation which may affect the assessment of the safety of a food additive;
 - (c) The extent of the use of a group of food additives or a particular food additive in foods and concerns over the human exposure to the specific food additive(s);
 - (d) The case where for a food additive an Acceptable Daily Intake (ADI) could not be established or a temporary ADI was established by the SCF or the basis for the ADI established by the SCF was unclear;
 - (e) The existence of diverging views on the risk assessment of the same food additive between SCF and Joint FAO/WHO Expert Committee on Food Additives (hereinafter referred to as JECFA), leading for example to the setting of different ADIs;
 - (f) The search for efficiency of the re-evaluation process and the need, for practical reasons, for a food additive to be re-evaluated at the same time as others belonging to the same functional group.

Article 4
Priorities for the re-evaluation of currently approved food additives

1. Food additives shall be re-evaluated with the following order and within the following deadlines taking also into account the specific deadlines as referred to in paragraph 2:
 - The re-evaluation of all currently approved food colours listed in Directive 94/36/EC shall be completed by 30.06.2011.

- The re-evaluation of all currently approved food additives other than colours and sweeteners listed in Directive 95/2/EC shall be completed by 31.12.2018
 - The re-evaluation of all currently approved sweeteners listed in Directive 94/35/EC shall be completed by 31.12.2020
2. For certain food additives within the functional classes of food additives referred to in paragraph 1 more specific deadlines are set in Annex II to this Regulation on the basis of the criteria set in Article 3. Those food additives shall be evaluated first among the other food additives of the same functional class of food additives referred to in paragraph 1 and within the specific deadlines set in Annex II.
 3. By way of derogation from paragraphs 1 and 2, EFSA may at any moment, on the request from the Commission or on its own initiative, commence the re-evaluation of a food additive or a group of food additives with priority, if new scientific evidence emerges that indicates a possible risk for human health or which in any way may affect the assessment of the safety of a food additive. In duly justified cases and only when such re-evaluation may delay substantially the re-evaluation of other food additives, the deadlines laid down under paragraph 1 and in Annex II of this Regulation may be revised accordingly.
 4. The Commission may establish more specific deadlines within those laid down under paragraph 1 and in Annex II, for individual food additives or groups of food additives, in order to allow the smooth running of the re-evaluation process or in case of emerging concern.

Article 5

Data gathering and submission

1. Business operators, or their representatives, interested in the continuity of the authorisation of one or more currently approved food additives after the re-evaluation process, shall make the necessary effort to gather and submit the data referred to in Article 6(2) which are necessary for the re-evaluation of these food additive(s). Such a business operator, or representative, is hereinafter referred to as 'the submitter'.
2. Data shall be submitted following the procedure laid down in Article 6.
3. Where the requested information which is necessary for the re-evaluation of a food additive has not been submitted to EFSA within the set deadlines referred to in Article 6 (4) and 6 (6) and as a result EFSA cannot conclude on the safety of a particular food additive, a measure may be adopted to change the conditions of use or remove the food additive from the Community list in accordance with the procedure laid down in Regulation (EC) No 1331/2008⁹

Article 6

Re-evaluation procedure

1. In re-evaluating each food additive EFSA shall:

⁹ OJ L354, 31.12.2008, p.1

- Examine the original SCF opinion and SCF working documents;
- Examine, where available, the original dossier;
- Examine the data provided by the submitters or other interested parties as referred to in paragraph 4;
- Examine any data made available by the Commission and Member States;
- Identify any relevant literature published since the last evaluation of each food additive.

2. In order to acquire data from submitters and other interested parties, EFSA shall make one or more open calls for data for the food additives under re-evaluation. These data may comprise among others:

- study reports from the original dossier as evaluated by the SCF or EFSA and JECFA,
- information on data on the safety of the food additives concerned not previously reviewed in the scientific opinions by SCF and JECFA,
- Information on the specifications of the food additives presently in use, including information on particle size and relevant physicochemical characteristics and properties,
- Information on the manufacturing process,
- Information on analytical methods available for determination in food,
- Information on the human exposure to the food additive from food (e.g. consumption pattern and uses, actual use levels and maximum use levels, frequency and other factors influencing exposure).
- Reaction and fate in the food

3. The submitter(s) or any other interested party shall submit data related to the re-evaluation of a food additive within the submission period defined by EFSA in its call for data. In the submission the submitter shall include the data requested by EFSA as referred to in paragraph 2 by following, to the extent possible, the applicable guidance document on submissions for food additive evaluations. The guidance document applicable at the time of entry into force of this Regulation is the guidance on submissions for food additive evaluations by the Scientific Committee on Food¹⁰.

4. Where for a food additive there are several submitter(s) they shall take all reasonable steps to submit the data collectively. In specifying the timetable for data submission, EFSA shall allow a reasonable period of time following publication of this Regulation, to allow submitters to meet this duty.

5. During the re-evaluation, EFSA may request from the submitter(s) and/or by an open call for data additional information considered to be relevant for the re-evaluation of a particular

¹⁰ Opinion expressed on 11 July 2001. SCF/CS/ADD/GEN/26 Final

food additive setting a time limit within which this information shall be provided having considered, where relevant, the submitter's view of the time required. In those cases, EFSA shall make the request for the additional information in good time so that the overall deadlines set for the re-evaluation in Article 4(1) and in Annex II are not affected.

6. Information which has not been submitted within the period 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 original period, if this information is significant for the re-evaluation of a food additive.

Article 7 **Other information**

During the re-evaluation of a food additive, the submitter(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 the food additive.

Article 8 **Confidentiality**

1. Confidential treatment may be given to information the disclosure of which might significantly harm the competitive position of business operators or other interested parties,

Information relating to the following shall not, in any circumstances, be regarded as confidential:

- (a) the name and address of the submitter;
- (b) the name and a clear description of the substance;
- (c) information for the use of the substance in or on specific foodstuffs or food categories;
- (d) information that is relevant to the assessment of the safety of the substance;
- (e) where applicable, the analysis method(s).

2. For the purposes of implementing paragraph 1, the submitter(s) shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases.

3. EFSA shall decide after consulting the submitter(s) which information can remain confidential and shall notify them the Commission and the Member States accordingly.

4. The Commission, EFSA and the Member States shall, in accordance with Regulation (EC) No 1049/2001¹¹, take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

¹¹ OJ L 145, 31.5.2001, p. 43.

5. The implementation of paragraphs 1 to 4 shall not affect the circulation of information between the Commission, EFSA and the Member States.

Article 9
Monitoring progress

Every year on the date of entry into force of this Regulation, EFSA shall inform the Commission and the Member States on progress with the re-evaluation programme.

Article 10
Entry into force

This Regulation shall enter into force on the 20th 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, [...]

For the Commission
[...]
The President

ANNEX I

List of food additives which were approved before 20 January 2009 and of which the re-evaluation by EFSA is completed at the time of adoption of this Regulation as referred to in Article 1

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 24 September 2009
E 104	Quinoline Yellow	2009	Re-evaluation completed on 24 September 2009
E 110	Sunset yellow FCF, Orange Yellow S	2009	Re-evaluation completed on 24 September 2009
E 120	Cochineal, Carminic acid, Carmines	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 24 September 2009
E 129	Allura red AC	2009	Re-evaluation completed on 24 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 as part of the opinion on the safety of aluminium from dietary intake
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	1979	ongoing
E 901	Beeswax, white and yellow	2007	Re-evaluation completed on 27 November 2007

ANNEX II

Specific priorities for certain food additives within the functional classes of food additives as referred to in Article 4 (1) and (2)

PART I: FOOD COLOURS

Within the overall deadline of 30.06.2011 set for the re-evaluation of food colours in Article 4(1) the following specific deadlines are set for the following food colours:

1) The following food colours shall be evaluated by 15.04 2010

E123 Amaranth,

E151 Brilliant Black BN

E154 Brown FK,

E155 Brown HT and

E180 Litholrubine BK

2) E160b Annatto, bixin, norbixin shall be evaluated by 31.03. 2010

3) The following food colours shall be evaluated by 31.12.2010

E100 Curcumin ,

E101 (i) Riboflavin (ii) Riboflavin-5'-phosphate,

E127 Erythrosine,

E131 Patent blue V,

E132 Indigotine,

E133 Brilliant blue FCF,

E140 Chlorophylls and chlorophyllins,

E141 Copper complexes of chlorophylls and chlorophyllins

E142 Green S,

E150a Plain caramel,

E150b Caustic sulphite caramel,

E150c Ammonia caramel,

E150d Sulphite ammonia caramel,

E153 Vegetable carbon,

E160a Carotenes (i) mixed carotenes, (ii) beta-carotene,

E160c Paprika extract, capsanthin, capsorubin,

E160e Beta-apo-8'-carotenal (C30),

E160f Ethyl esters of beta-apo-8', -carotenoic acid,

E161b Lutein,
E161g Canthaxanthin,
E162 Beetroot red, betanin,
E163 Anthocyanins,
E170 Calcium carbonate,

4) The following food colours shall be evaluated by 30.06.2011

E171 Titanium dioxide,
E172 Iron oxides and hydroxides,
E174 Silver,
E175 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 4(1), the following specific deadlines are set for certain food additives and groups of food additives:

1) Preservatives and antioxidants E200-203; E210-215, E218-252, E280-285; E300-E321, E586 and E1105 shall be evaluated by 31.12.2013

with higher priority within this group on:

- E310-312 Gallates
- E320 Butylated hydroxyanisole (BHA)
- E321 Butylated hydroxytoluene (BHT)
- E220-228 Sulphur dioxide and sulphites
- E304 Ascorbyl palmitate and stearate
- E200-203 Sorbates
- E 284 Boric acid
- E 285 Sodium tetraborate
- 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 and calcium salts
- E306-309 Tocopherols

2) Emulsifiers, stabilisers, gelling agents E322, E400-E 419; E422-E 495; E1401-E 1451; E1103 shall be evaluated by 31.12.2016

With higher priority within this group on:

- E 483 Stearyl tartrate
- E491-495 Sorbitan esters
- E 431 Polyoxyethylene (40) stearate
- E432-436 Polysorbates
- E 444 Sucrose acetate isobutyrate
- E 481 Sodium stearoyl-2-lactylate
- E 482 Calcium stearoyl-2-lactylate
- E 414 Acacia gum*
- E 410 Locust bean gum (carob bean gum)*
- E417 Tara gum*
- E422 Glycerol
- E475 Polyglycerol esters of fatty acids

* All natural gums E 400-418 and E425 could be evaluated at the same time.

3) E620-625 Glutamates, E1105 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 551 Silicon dioxide
- E 553b Magnesium trisilicate (talc)
- E 558 Bentonite
- E 999 Quillaia extract
- E338-343 Phosphates
- E450-452 Di-, tri- and polyphosphates
- E900 Polydimethylsiloxane
- E 912 Montan acid esters
- E 914 Oxidised polyethylene wax
- E902 Candellila wax
- E904 Shellac
- E626-629 Inosinates
- E634-635 5' Ribonucleotides
- E 507-511 Hydrochloric acid, Potassium chloride, Calcium chloride, Magnesium chloride
- E513 Sulphuric acid

