Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives (Text with EEA relevance)

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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, Article 30(1) and Article 30(5) thereof,

Whereas:

(1) Regulation (EC) No 1333/2008 provides for the establishment of a Union list of food additives approved for use in foods and their conditions of use.

(2) Food additives which are currently permitted for use in foods under European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs[(2)], European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs[(3)] and European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners[(4)], should be included in Annex II to Regulation (EC) No 1333/2008 after a review of their compliance with Articles 6, 7 and 8 thereof. The review should not include a new risk assessment by the European Food Safety Authority (hereinafter 'the Authority'). Food additives and uses which are no longer needed shall not be entered in Annex II to that Regulation.

(3) Only food additives included in the Union list set out in Annex II to Regulation (EC) No 1333/2008 may be placed on the market and used in foods under the conditions of use specified therein. The additives should be listed on the basis of the categories of food to which they may be added. In order to facilitate the transfer and to enhance transparency of the authorisation procedure, it is appropriate to develop a new food categorisation system which will form the basis of Annex II.

(4) The established Codex Alimentarius General Standard for Food Additives[(5)], food category system has been used as a starting point for developing the Union system. However, that system needs to be adapted to take into account the specificity of the existing food additive authorisations in the Union. Current sector specific Union

provisions on foods have been taken into account. The categories are created with the sole purpose of listing the authorised additives and their conditions of use.

(5) For reasons of clarity it is necessary to list food additives in groups of additives for authorisation for certain foods. Guidance should be provided to describe the different categories in order to ensure uniform interpretation. When necessary, interpretation decisions can be adopted in accordance with Article 19 of Regulation (EC) No 1333/2008 in order to clarify whether or not a particular food belongs to a certain category of food.

(6) Nitrites (E 249–250) are needed as a preservative in meat products to control the possible growth of harmful bacteria, in particular *Clostridium botulinum*. The use of nitrites in meat may however lead to formation of nitrosamines which are carcinogenic substances. The current authorisation of nitrites as food additives makes a balance between these effects, taking into account the scientific opinion of the Authority and the need to maintain certain traditional foods on the market. For some traditionally manufactured meat products maximum residual limits were set out in Annex III to Directive 95/2/EC. Those limits should be maintained in adequately specified and identified products; however it should be clarified that the limits apply at the end of the production process. In addition, the Commission will consult Member States, the stakeholders and the Authority to discuss the possibility to reduce the current maximum limits in all meat products and to further simplify the rules for the traditionally manufactured products. Depending on the outcome of such consultation, the Commission will consider whether it is appropriate to propose an adaptation to the maximum levels of nitrites that may be added to certain meat products.

(7) For prepared table water covered by category 14.1.1, the only permitted additives should be phosphoric acid and phosphates. Taking into account that Annex II to Regulation (EC) No 1333/2008 is intended to further harmonise the use of food additives in foods in the Union and to ensure the effective functioning of the internal market, mineral salts which are added to prepared waters for standardisation purposes should not be considered as additives and, therefore, should not fall within the scope of this Regulation.

(8) All currently authorised food additives are subject to a re-evaluation by the Authority in accordance with Commission Regulation (EU) No 257/2010[(6)] that sets up a programme for the re-evaluation of approved food additives. The re-evaluation of food additives is being carried out in accordance with the priorities laid down in that Regulation.

(9) In January 2008, the Authority adopted an opinion on lycopene[(7)] in which it derived an acceptable daily intake (ADI) of 0,5 mg/kg bw/day for lycopene (E 160d) from all sources and that the potential intake might exceed the ADI, particularly for children. The use of lycopene as a food colour should therefore be restricted.

(10) In September 2009, the Authority adopted scientific opinions on sunset yellow FCF (E 110)[(8)], quinoline yellow (E 104)[(9)] and ponceau 4R (E 124)[(10)]. Based on the dietary exposure assessment in the scientific opinions, the Authority concluded that, in the case of quinoline yellow and ponceau 4R at the maximum levels of use, intake estimates at the mean and the high percentiles are generally above the ADI. Also for sunset

yellow exposure may be too high in particular for 1- to 10-year-old children. The intake estimates are calculated based on the use levels provided by the food industry in 2009. The Commission is revising the current authorised uses and use levels in order to verify that the exposure to these substances is safe for the consumer and it plans to prepare a new proposal with the revised levels by July 2011.

(11) In its opinion on the safety of aluminium from dietary intake adopted on 22 May 2008 the Authority concluded that the exposure might be too high in a significant part of the European population. The Authority could not conclude on the specific sources contributing to the aluminium content of a particular food, such as the amount inherently present, the contributions from use of food additives, and the amounts released to the food during processing and storage from aluminium-containing foils, containers, or utensils. In order to reduce exposure to aluminium the use of certain aluminium containing food additives should be restricted. The Commission is preparing measures to limit exposure to aluminium containing additives and intend to prepare a proposal with revised levels by September 2011.

(12) The stakeholders were requested to provide information about the use and the need to use the food colours as listed in Annex V to Directive 94/36/EC. Some of those food colours are currently not used in some of the food categories listed in that Annex. However, some of those authorised colours should be maintained on the list as they may be needed to replace or partly replace colours that might raise concern to the Authority during re-evaluation. At this stage the number of authorised food colours can be reduced in the following food categories: flavoured processed cheese, preserves of red fruit, fish paste and crustacean paste, precooked crustacean and smoked fish.

(13) Food colour ethyl ester of beta-apo-8'-carotenoic acid (C 30) (E 160f) is not offered anymore by the manufacturer and re-evaluation of this substance by the Authority is no longer supported by the business operators. Therefore, this additive should not be included in the Union list.

(14) The use of food colour canthaxanthin (E 161g) is authorised only in ‘Saucisses de Strasbourg’. The Commission was informed that this food colour is no longer used. Therefore, the authorisation of use of this additive in Saucisses de Strasbourg should not be included in the Union list. However Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products[(11)] lays down that Member States shall not authorise, for the colouring of medicinal products for human and veterinary use any colouring matters other than those covered by Annex I to Directive 94/36/EC. Canthaxanthin is currently being used in some medicinal products. The additive should therefore remain on the list of authorised additives.

(15) Commission Regulation (EC) No 884/2007 of 26 July 2007 on emergency measures suspending the use of Red 2G (E 128) as food colour[(12)] suspended the use of the colour and the placing on the market of foods containing this colour. Therefore, Red 2G (E 128) should not be included in the Union list.

(16) During the re-evaluation by the Authority it appeared that the food colour, brown FK (E 154) only authorised in kippers, is no longer used. During its re-evaluation, the

Authority could not conclude on the safety of this substance due to the deficiencies in the available toxicity data[13]. Therefore, this additive should not be included in the Union list.

(17) The anti-caking agent silicon dioxide (E 551) is currently authorised under Directive 95/2/EC for a variety of uses. This food additive has been allocated an acceptable daily intake (ADI) 'not specified' by the Scientific Committee on Food in its opinion of 18 May 1990[14]. There is a technological need to extend its uses to a higher level than is currently authorised for salt substitutes. Such use would benefit the consumer by providing anti-caking salt substitutes for sale in hot and humid European countries, since currently caking effects result in an inconvenient and often impossible usage of salt substitutes. Therefore, it is appropriate to authorise an increased maximum limit for salt substitutes.

(18) The Authority assessed the information on the safety of basic methacrylate copolymer as a glazing agent/coating agent in solid food supplements. In its opinion of 10 February 2010, the Authority concluded that this uses is of no safety concern, since basic methacrylate copolymer is virtually not absorbed from the gastrointestinal tract after oral administration. The additive is expected to play a technological role by moisture protection and taste masking of various nutrients in combination with a fast release of the nutrient in the stomach. Therefore, it is appropriate to authorise the use of basic methacrylate copolymer as a glazing agent/coating agent in solid food supplements as defined in Article 2 of Directive 2002/46/EC of the European Parliament and of the Council[15] at a level of 100 000 mg/kg. This new food additive should be assigned the E number E 1205.

(19) It is necessary to regulate the use of additives in table-top sweeteners as defined in point (g) of Article 3(2) of Regulation (EC) No 1333/2008. Those preparations containing permitted sweeteners are intended for sale to the final consumer as a substitute for sugar. The need for additives may be different depending on the different forms in which they are presented: liquid, powder and tablet form.

(20) The transfer of food additives to Annex II of Regulation (EC) No 1333/2008 should be considered as complete in accordance with Article 34 of that Regulation from the date of application of amendments introduced by this Regulation. Until then, the provisions of Article 2(1), (2) and (4) of Directive 94/35/EC, Article 2(1) to (6) and (8) to (10) of Directive 94/36/EC and Articles 2 and 4 of Directive 95/2/EC and Annexes to these Directives should continue to apply.

(21) The current uses of additives covered by Articles 6, 7 and 8 of Regulation (EC) No 1333/2008, should not be affected by their transfer to the Union list. However, a transitional period should be provided in order to allow business operators to comply with the provisions of this Regulation.

(22) It is necessary to clarify the exception to the carry-over principle in a compound food other than as referred to in Annex II as laid down in point (a) of Article 18(1) of Regulation (EC) No 1333/2008. In Article 3 of Directive 95/2/EC and Article 3 of Directive 94/36/EC this exception applied to the foods that are now listed in Tables 1

and 2 respectively. In other compound foods belonging to the categories listed in part E (such as soups, sauces, salads etc) the carry over principle should continue to apply.

(23) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee of the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EC) No 1333/2008

Annex II to Regulation (EC) No 1333/2008 is replaced by the text of the Annex to this Regulation.

Article 2

Transitional provisions

1 Annex II to Regulation (EC) No 1333/2008, as amended by this Regulation, shall apply from 1 June 2013.

2 By derogation to paragraph 1, the following entries in Annex II to Regulation (EC) No 1333/2008, as amended by this Regulation, shall apply from the date of entry into force of this Regulation:

a in point 3 of part B, the entry concerning basic methacrylate copolymer (E 1205);

b in point 12.1.2 of Part E, the entry concerning the use of silicon dioxide (E 551) in salt substitutes;

c in point 17.1 of Part E, the entry concerning the use of basic methacrylate copolymer (E 1205) in food supplements supplied in solid form.

3 Article 2(1), (2) and (4) of Directive 94/35/EC, Article 2(1) to (6), (8), (9) and (10) of Directive 94/36/EC and Articles 2 and 4 of Directive 95/2/EC and the Annexes to those Directives shall cease to apply from 1 June 2013.

4 By derogation to paragraph 3, the entry in Annex IV to Directive 95/2/EC concerning of use of silicon dioxide (E 551) in salt substitutes shall cease to apply from the date of entry into force of this Regulation.

5 Foods that have been lawfully placed on the market before 1 June 2013, but do not comply with this regulation, may continue to be marketed until their date of minimal durability or use-by-date.

Article 3

Regulation (EC) No 884/2007 is repealed as from 1 June 2013.

Article 4

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.