Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (Text with EEA relevance)

COMMISSION REGULATION (EU) No 231/2012

of 9 March 2012

laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council

(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 Articles 14 and 30(4) thereof, and Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings[(2)], and in particular Article 7(5) thereof,

Whereas:

(1) Specifications relating to origin, purity criteria and any other necessary information should be adopted for food additives listed in the Union lists in Annex II and III to Regulation (EC) No 1333/2008.

(2) To that end, specifications previously developed for food additives in Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs[(3)], Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners[(4)] and Commission Directive 2008/60/EC of 17 June 2008 laying down specific purity criteria concerning sweeteners for use in foodstuffs[(5)] should be updated and taken over to this Regulation. As a consequence, those Directives should be repealed.

(3) It is necessary to take into account the specifications and analytical techniques as set out in the Codex Alimentarius drafted by the Joint FAO/WHO Expert Committee on Food Additives (hereafter JECFA).

(4) The European Food Safety Authority (hereinafter 'the Authority') expressed its opinion on the safety of basic methacrylate copolymer[(6)] as a glazing agent. That food additive has subsequently been authorised on the basis of specific uses and has been allocated the number E 1205. Therefore specifications should be adopted for that food additive.

(5) Food colours ethyl ester of beta-apo-8'-carotenic acid (E 160 f), and brown FK (E 154), as well as the aluminium containing carrier bentonite (E 558) are not used any

more according to information submitted by food manufacturers. Therefore, current specifications for those food additives should not be taken over to this Regulation.

(6) On 10 February 2010 the Authority expressed an opinion on the safety of sucrose esters of fatty acids (E 473) prepared from vinyl esters of fatty acids[7]. Current specifications should be adapted accordingly in particular by reducing maximum limits for impurities of safety concern.

(7) Specific purity criteria currently applicable should be adapted by reducing maximum limits for individual heavy metals of interest where feasible and where the JECFA limits are lower than those currently in force. Pursuant to that approach maximum limits for the contaminant 4-methylimidazole in ammonia caramel (E 150 c), sulphated ash in beta-carotene (E 160 a (i)), and magnesium and alkali salts in calcium carbonate (E 170), should be lowered. That approach should be departed from only for additives trisodium citrate (E 331 (iii)) (lead content), carrageenan (E 407) and processed euchema seaweed (E407 a) (cadmium content), as manufacturers have declared that compliance with stricter Union provisions, reflecting JECFA limits, would not be technically feasible. The contribution to the total intake of those two contaminants (lead and cadmium) in those three individual food additives is not considered to be significant. On the contrary for phosphates (E 338-E 341 and E 450-E 452) new significantly lower values, compared to the ones indicated by JECFA, should be established due to new developments of the manufacturing processes, by taking into account the recent recommendations of the Authority on a reduction of the intake of arsenic, especially in the inorganic form[8]. In addition, a new provision on arsenic for glutamic acid (E 620) should be introduced for safety reasons. The total balance of those adaptations benefits the consumers as maximum limits for heavy metals are becoming stricter in general and in most of the food additives. Detailed information on the production process and starting materials of a food additive should be included in the specifications to facilitate any future decision pursuant to Article 12 of Regulation (EC) No 1333/2008.

(8) Specifications should not make reference to organoleptic tests related to the taste as it cannot be expected by the control authorities to take the risk to taste a chemical substance.

(9) Specifications should not make reference to classes as there is no added value in this reference.

(10) Specifications should not make reference to the general parameter ‘Heavy metals’ as this parameter does not relate with toxicity, but rather with a generic analytical method. Parameters related to individual heavy metals are toxicity related and are included in the specifications.

(11) Some food additives are currently listed under various names (carboxy methyl cellulose (E 466), cross-linked sodium carboxymethylcellulose (E 468), enzymatically hydrolised carboxymethylcellulose (E 469) and beeswax, white and yellow (E 901)) in various provisions of Directive 95/2/EC of the European Parliament and of the Council[9]. Therefore the specifications established by this Regulation should refer to those various names.

(12) Current provisions on Polycyclic Aromatic Hydrocarbons (PAHs) are too generic and not relevant to safety and should be replaced by maximum limits for individual PAHs of concern for food additives vegetable carbon (E 153) and microcrystalline wax (E 905). Similar maximum limits should be established for formaldehyde in carageenan (E 407) and processed euchema seaweed (E 407 a), for particular microbiological criteria in agar (E 406) and for *Salmonella* spp. content in mannitol (E 421 (ii)) manufactured by fermentation.

(13) The use of propan-2-ol (isopropanol, isopropyl alcohol) should be allowed for manufacturing the additives curcumin (E 100) and paprika extract (E 160 c), in line with JECFA specifications, as this particular use has been considered safe by the Authority[10]. The use of ethanol in replacement of propan-2-ol in the manufacturing of gellan gum (E 418) should be permitted where the final product still complies with all other specifications and ethanol is considered to be of less safety concern.

(14) The percentage of the colouring principle in cochineal, carminic acid, carmines (E 120) should be specified, as maximum limits are to apply to quantities of that principle.

(15) The numbering system for subcategories of carotenes (E 160 a) should be updated in order to bring it in line with the Codex Alimentarius numbering system.

(16) The solid form of lactic acid (E 270) should also be included in the specifications, as it can now be manufactured in the solid form and there is no safety concern.

(17) The current temperature value in loss on drying for monosodium citrate (E 331 (i)), anhydrous form should be adjusted as under the currently listed conditions the substance decomposes. Drying conditions for trisodium citrate (E 331 (iii)) should also be adjusted to improve the reproducibility of the method.

(18) The current specific absorption value for alpha-tocopherol (E 307) should be corrected and the sublimation point for sorbic acid (E 200) should be replaced by a ‘solubility test’ as the former is not relevant. The specification of bacterial sources for the manufacturing of nisin (E 234) and natamycin (E 235) should be updated according to the current taxonomic nomenclature.

(19) As new innovative manufacturing techniques resulting in less contaminated food additives are now available, the presence of aluminium in food additives should be restricted. In order to enhance legal certainty and non-discrimination it is appropriate to provide the manufacturers of food additives with a transitional period to adapt gradually to those restrictions.

(20) Maximum limits for aluminium should be established for food additives where relevant, and particularly for calcium phosphates (E 341 (i)-(iii)) intended to be used in food for infants and young children[11], according to the relevant opinion of Scientific Committee on Food expressed on 7 June 1996[12]. In this framework a maximum limit for aluminum in calcium citrate (E 333) should also be established.

(21) The maximum limits for aluminium in calcium phosphates (E 341 (i)-(iii)), disodium diphosphate (E 450 (i)) and calcium dihydrogen diphosphate (E 450 (vii)) should be in accordance with the opinion of the Authority of 22 May 2008[13]. Current limits should

be reduced, where this is technically feasible, and where the contribution to the total aluminium intake is significant. In this framework aluminium lakes of individual food colours should be authorised only if technically needed.

(22) Provisions on maximum limits for aluminium in dicalcium phosphate (E 341 (ii)), tricalcium phosphate (E 341 (iii)) and calcium dihydrogen diphosphate (E 450 (vii)) should not cause any disruption of the market, due to a possible lack of supplies.

(23) According to Commission Regulation (EU) No 258/2010 of 25 March 2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins[(14)], maximum limits should be set for the contaminant pentachlorophenol in guar gum (E 412).

(24) According to recital 48 of Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[(15)] Member States are requested to examine other foodstuffs than the ones included in that Regulation for the occurrence of contaminant 3-MCPD in order to consider the need to set maximum levels for that substance. French authorities have submitted data on high concentrations of 3-MCPD in the food additive glycerol (E 422) and the average use level of this food additive in various food categories. Maximum limits for 3-MCPD in this particular food additive should be set in order to avoid contamination of the final food at a higher than permissible level, taking into account the dilution factor.

(25) Due to the development of analytical methods certain current specifications should be updated. The current limit value ‘not detectable’ is linked to the evolution of analytical methodologies and should be replaced by a specific number for additives acid esters of mono- and diglycerides (E 472 a-f), polyglycerol esters of fatty acids (E 475) and propane-1,2-diol esters of fatty acids (E 477).

(26) Specifications relating to the manufacturing procedure should be updated for citric acid esters of mono- and diglycerides of fatty acids (E 472 c), as the use of alkaline bases is replaced today by the use of their milder acting salts.

(27) The current criterion ‘free fatty acids’ for additives citric acid esters of mono- and diglycerides of fatty acids (E 472 c) and mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids (E 472 e) is not appropriate. It should be replaced by the criterion ‘acid value’ as the latter expresses better the titrimetric estimation of the free acidic groups. This is in accordance with the 71st report on food additives from JECFA[(16)] where such change was adopted for mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids (E 472 e).

(28) The current erroneous description of additive magnesium oxide (E 530) should be corrected according to information submitted by the manufacturers, in order to bring it in line with the Pharmacopoeia Europea[(17)]. The current maximum value for the reducing matter in additive gluconic acid (E 574) should also be updated as this limit is not technically feasible. For the estimation of the water content of xylitol (E 967) the current method based on ‘loss on drying’, should be replaced by a more appropriate method.

(29) Some current specifications for additive candelilla wax (E 902) should not be taken over to this Regulation since they are erratic. For calcium dihydrogen diphosphate (E 450 (vii)) the current entry concerning P_2O_5 content should be corrected.

(30) In the current entry 'assay' for thaumatin (E 957) a calculation factor should be corrected. That factor is to be used in the Kjeldahl method for the estimation of the total content of the substance based on the measurement of nitrogen. The calculation factor should be updated according to the relevant published literature for thaumatin (E 957).

(31) The Authority evaluated the safety of steviol glycosides, as a sweetener and expressed its opinion of 10 March 2010[(18)]. The use of steviol glycosides, which have been allocated number E 960, has subsequently been permitted on the basis of well defined conditions of use. Therefore specifications should be adopted for this food additive.

(32) Due to a taxonomic change, current specifications for source materials (yeasts) used in the manufacturing of erythritol (E 968) should be updated.

(33) For quillaia extract (E 999) the current specification relating to the pH range should be adjusted in order to bring it in line with JECFA.

(34) The combination of citric acid and phosphoric acid (which are currently both individually authorised for use in the manufacturing of additive polydextrose (E 1200)), should be allowed, where the final product still complies with the purity specifications, as it improves yields and results to more controllable reaction kinetics. There is no safety concern involved in such amendment.

(35) Unlike for small molecules, the molecular mass of a polymer is not one unique value. A given polymer may have a distribution of molecules with different masses. The distribution may depend on the way the polymer is produced. Polymer physical properties and behaviors are related to the mass and to the distribution of molecules with a certain mass in the mixture. A group of mathematical models describe the mixture in different ways in order to clarify the distribution of molecules in the mixture. Among the different models available, it is recommended in scientific literature to use the weight average molecular weight (Mw) to describe polymers. The specifications for polyvinylpyrrolidone (E 1201) should be adjusted accordingly.

(36) The criterion 'Distillation range' referred to in current specifications for propane-1,2 diol (E 1520) leads to contradictory conclusions compared to results from the assay. That criterion should therefore be corrected and renamed into 'Distillation test'.

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

HAS ADOPTED THIS REGULATION:

(**1**) OJ L 354, 31.12.2008, p. 16.

(**2**) OJ L 354, 31.12.2008, p. 1.

(**3**) OJ L 6, 10.1.2009, p. 20.

(**4**) OJ L 253, 20.9.2008, p. 1.

(**5**) OJ L 158, 18.6.2008, p. 17.

(**6**) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of Basic Methacrylate Copolymer as a food additive on request from the European Commission. *EFSA Journal* 2010; 8(2):1513.

(**7**) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the safety of sucrose esters of fatty acids prepared from vinyl esters of fatty acids and on the extension of use of sucrose esters of fatty acids in flavourings on request from the European Commission. *EFSA Journal* 2010; 8(3):1512.

(**8**) EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Arsenic in Food. *EFSA Journal* 2009; 7(10):1351.

(**9**) OJ L 61, 18.3.1995, p. 1.

(**10**) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of curcumin (E 100) as a food additive. *EFSA Journal* 2010; 8(9):1679.

(**11**) As defined in Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (codified version), OJ L 339, 6.12.2006, p. 16.

(**12**) Opinion on Additives in nutrient preparations for use in infant formulae, follow-on formulae and weaning foods. Reports of the Scientific Committee on food (40th Series), p. 13-30, (1997).

(**13**) Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials on a request from European Commission on Safety of aluminium from dietary intake. *EFSA Journal* (2008) 754, 1-34.

(**14**) OJ L 80, 26.3.2010, p. 28.

(**15**) OJ L 364, 20.12.2006, p. 5.

(**16**) WHO Technical Report Series, No 956, 2010.

(**17**) EP 7.0 volume 2, p. 2415-2416.

(**18**) EFSA Panel on Food Additives and Nutrient Sources (ANS); Scientific Opinion on the safety of steviol glycosides for the proposed uses as a food additive. *EFSA Journal* (2010); 8(4):1537.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 231/2012, Introductory Text.