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**Information Document on the COMMISSION DIRECTIVE 2009/10/EC
of 13 February 2009 amending Directive 2008/84/EC laying down specific purity
criteria on food additives other than colours and sweeteners**

Scope

Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners sets out the purity criteria for the additives mentioned in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners.

The European Food Safety Authority (hereinafter EFSA) concluded in its opinion of 20 October 2006 that nisin produced through a modified production process using a sugar-based medium is equivalent with respect to health protection to the one produced by the original milk-based medium process. On the basis of that opinion, the existing specifications for E234 nisin should be amended in order to adapt the definition and the purity criteria set out for that additive.

Formaldehyde is used as a preservative during the manufacture of alginic acid, alginate salts and esters of alginic acid. It has been reported that residual formaldehyde, up to 50 mg/kg, may be present in the final gelling additives. At the request of the Commission, EFSA assessed the safety in use of formaldehyde as a preservative during the manufacture and preparation of food additives. EFSA in its opinion of 30 November 2006 concluded that the estimated exposure to gelling additives containing residual formaldehyde at the level of 50 mg/kg of additive would be of no safety concern. Therefore the existing purity criteria for E400 alginic acid, E401 sodium alginate, E402 potassium alginate, E403 ammonium alginate,

E404 calcium alginate, and E405 propane-1,2-diol alginate should be amended in such a way that the maximum level of formaldehyde is set at 50 mg/kg.

Formaldehyde is not currently used in the processing of seaweeds for the production of E407 carrageenan and E407a processed eucheuma seaweed. However, it may be naturally occurring in marine algae and be consequently present as an impurity in the finished product. It is therefore appropriate to fix a maximum level of adventitious presence of the above substance in those food additives.

Guar gum is authorised as a food additive for use in foodstuffs by Directive 95/2/EC. In particular, it is used as thickener, emulsifier, and stabiliser. A request to use a partially depolymerised guar gum as a food additive, produced from native guar gum by one of the three manufacturing processes consisting of heat treatment, acid hydrolysis or alkaline oxidation, was submitted to the Commission. EFSA assessed the safety in use of that additive and, in its opinion of 4 July 2007, estimated that partially depolymerised guar gum has been shown to be very similar to native guar gum with respect to the composition of the final product. It also concluded that partially depolymerised guar gum is of no safety concern for its use as thickener, emulsifier or stabiliser. However, in the same opinion, EFSA recommended that the specifications for E412 guar gum should be adjusted to take into account the increased level of salts and the possible presence of undesirable byproducts that may result from the manufacturing process. On the basis of the recommendations issued by EFSA, the specifications of guar gum should be amended.

It is necessary to adopt specifications for E504(i) magnesium carbonate authorised as a food additive for use in foodstuffs through Directive 95/2/EC.

On the basis of data provided by the European Lime Association, it appears that the manufacturing of lime products from available raw materials does not permit them to comply with the existing purity criteria set for E526 calcium hydroxide and E529 calcium oxide, as regards the level of magnesium and alkali salts. Taking into account that magnesium salts are of no safety concern and the specifications as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (hereafter JECFA), it is appropriate to adjust the levels of magnesium and alkali salts for E526 calcium hydroxide and E529 calcium oxide to the lowest achievable values, which remain lower or equal to the levels set by JECFA.

In addition, it is necessary to take into account the specifications as set out in the Codex Alimentarius drafted by JECFA with regard to the level of lead for E526 calcium hydroxide and E529 calcium oxide. However, due to the natural high background of lead contained in the raw material (calcium carbonate) extracted in some Member States, and from which those additives are derived, it appears difficult to align the level of lead contained in those food additives with the upper limit of lead set by JECFA. Therefore the current level of lead should be reduced to the lowest achievable threshold.

E 901 beeswax is authorised as a food additive in Directive 95/2/EC. EFSA in its opinion of 27 November 2007 confirmed the safety in use of this food additive. However, it also indicated that the presence of lead should be restricted to the lowest possible level. Taking into account the

revised specifications for beeswax as set out in the Codex Alimentarius as drafted by JECFA, it is appropriate to amend the existing purity criteria for E901 beeswax in order to lower the maximum permitted level of lead.

Highly refined waxes deriving from synthetic hydrocarbon feedstock (synthetic waxes) and from petroleum based feedstock were jointly evaluated by the Scientific Committee on Food (hereinafter SCF) (3) and an opinion on mineral and synthetic hydrocarbons was issued on 22 September 1995. The SCF considered that sufficient data had been provided to allocate a full group ADI (acceptable daily intake), covering both types of waxes, i.e. waxes deriving from petroleum based or synthetic hydrocarbon feed stocks. When purity criteria for E905 microcrystalline wax were established, the synthetic hydrocarbon waxes were omitted and not included in the specifications. The Commission considers it therefore necessary to amend the purity criteria for E905 microcrystalline wax in order to also cover waxes derived from synthetic hydrocarbon feedstocks.

E230 (biphenyl) and E233 (thiabendazole) are no longer permitted as food additives in the EU legislation. These substances have been removed respectively by Directive 2003/114/EC and Directive 98/72/EC. Consequently, the Annex I to Directive 2008/84/EC should be updated accordingly and the specifications to E230 and E233 should be withdrawn.

It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius drafted by the JECFA. In particular where appropriate, the specific purity criteria need to be adapted to reflect the limits for individual heavy metals of interest.

Directive 2008/84/EC should therefore be amended accordingly.

Permitted Food Additives (Amendment) Regulations, 2010

It is proposed to implement the requirements of this Directive as follows:

- 1. Substitutes regulation 6.1 of the principal regulations**
- 2. Substitutes the Seventh Schedule to the principal regulations**

The Commission's website on Food may be found at:

http://ec.europa.eu/enterprise/food/index_en.htm

Who would be interested

All operators dealing with food. This includes manufacturers, importers, distributors, retailers and catering establishments.

Comments

Your comments re this consultation document and accompanying document (also attached to email) are kindly being requested.

Comments are to reach the Regulatory Affairs Directorate in writing or via email by **Thursday, 21st January, 2010**

Should any further information be required kindly contact the *Foodstuffs, Chemicals, Pesticides & Cosmetics Unit* (Regulatory Affairs Directorate) of the Malta Standards Authority using the following contact details:

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L.N. of 2010

**FOOD SAFETY ACT
(CAP. 449)**

Permitted Food Additives (Amendment) Regulations, 2010

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister for Social Policy has made the following regulations:-

Citation and commencement

L.N. 54 of 2005.

1. (1) The title of these regulations is the Permitted Food Additives (Amendment) Regulations, 2010, and they shall be read and construed as one with the Permitted Food Additives Regulations, 2005, hereinafter referred to as “the principal regulations”.
- (2) These regulations shall enter into force on the 13th February, 2010.

Scope

- 2 (1) These regulations implement the provisions of Commission Directive 2009/10/EC amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners.

Substitutes regulation 6.1 of the principal regulations

3. For regulation 6.1 of the principal regulations there shall be substituted the following:-

“6.1 The additives permitted for use by these regulations must satisfy the purity criteria laid down by Commission Directive 2008/84/EC, as amended by Commission Directive 2009/10/EC. A list of the food additives for which purity criteria have been established is given in the Seventh Schedule.”.

Substitutes the Seventh Schedule to the principal regulations

4. For the Seventh Schedule to the principal regulations, there shall be substituted the following:-

“SEVENTH SCHEDULE

Purity Criteria

Purity criteria for the following additives are prescribed in Annex I of Commission Directive 2008/84/EC (OJ L 253, 20.9.2008, p. 1-175), as amended by Commission Directive 2009/10/EC (OJ L 44, 14.2.2009, p. 62-78).

- E 170 (i) Calcium carbonate
- E 200 Sorbic acid
- E 202 Potassium sorbate
- E 203 Calcium sorbate
- E 210 Benzoic acid
- E 211 Sodium benzoate
- E 212 Potassium benzoate
- E 213 Calcium benzoate
- E 214 Ethyl p-Hydroxybenzoate
- E 215 Sodium ethyl p-hydroxybenzoate
- E 218 Methyl p-Hydroxybenzoate
- E 219 Sodium Methyl p-Hydroxybenzoate
- E 220 Sulphur dioxide
- E 221 Sodium sulphite
- E 222 Sodium bisulphate
- E 223 Sodium metabisulphite
- E 224 Potassium metabisulphite
- E 226 Calcium sulphite
- E 227 Calcium bisulphite
- E 228 Potassium bisulphite
- E 231 Ortophenylphenol
- E 232 Sodium ortophenylphenol
- E 234 Nisin
- E 235 Natamycin
- E 239 Hexamethylene tetramine
- E 242 Dimethyl dicarbonate
- E 249 Potassium nitrite
- E 250 Sodium nitrite
- E 251 Sodium nitrate
 - 1. Solid sodium nitrate
 - 2. Liquid sodium nitrate
- E 252 Potassium nitrate
- E 260 Acetic acid
- E 261 Potassium acetate
- E 262 (i) Sodium acetate
- E 262 (ii) Sodium diacetate
- E 263 Calcium acetate

- E 270 Lactic acid
- E 280 Propionic acid
- E 281 Sodium propionate
- E 282 Calcium propionate
- E 283 Potassium propionate
- E 284 Boric acid
- E 285 Sodium tetraborate (borax)
- E 290 Carbon dioxide
- E 296 Malic acid
- E 297 Fumaric acid
- E 300 Ascorbic acid
- E 301 Sodium ascorbate
- E 302 Calcium ascorbate
- E 304 (i) Ascorbyl palmitate
- E 304 (ii) Ascorbyl stearate
- E 306 Tocopherol-rich extract
- E 307 Alpha-tocopherol
- E 308 Gamma-tocopherol
- E 309 Delta-tocopherol
- E 310 Propyl gallate
- E 311 Octyl gallate
- E 312 Dodecyl gallate
- E 315 Erythorbic acid
- E 316 Sodium erythorbate
- E 319 Tertiary-butylhydroquinone (TBHQ)
- E 320 Butylated hydroxyanisole (BHA)
- E 321 Butylated hydroxytoluene (BHT)
- E 322 Lecithins
- E 325 Sodium lactate
- E 326 Potassium lactate
- E 327 Calcium lactate
- E 330 Citric acid
- E 331 (i) Monosodium citrate
- E 331 (ii) Disodium citrate
- E 331 (iii) Trisodium citrate
- E 332 (i) Monopotassium citrate
- E 332 (ii) Tripotassium citrate
- E 333 (i) Monocalcium citrate
- E 333 (ii) Dicalcium citrate
- E 333 (iii) Tricalcium citrate
- E 334 L (+) – Tartaric acid
- E 335 (i) Monosodium tartrate
- E 335 (ii) Disodium tartrate
- E 336 (i) Monopotassium tartrate
- E 336 (ii) Dipotassium tartrate
- E 337 Potassium sodium tartrate

E 338 Phosphoric acid
E 339 (i) Monosodium phosphate
E 339 (ii) Disodium phosphate
E 340 (i) Monopotassium phosphate
E 340 (ii) Dipotassium phosphate
E 340 (iii) Tripotassium phosphate
E 341 (i) Monocalcium phosphate
E 341 (ii) Dicalcium phosphate
E 341 (iii) Tricalcium phosphate
E 343 (i) Monomagnesium phosphate
E 343 (ii) Dimagnesium phosphate
E 350 (i) Sodium malate
E 350 (ii) Sodium hydrogen malate
E 351 Potassium malate
E 352 (i) Calcium malate
E 352 (ii) Calcium hydrogen malate
E 353 Metatartaric acid
E 354 Calcium tartrate
E 355 Adipic acid
E 356 Sodium adipate
E 357 Potassium adipate
E 363 Succinic acid
E 380 Triammonium citrate
E 385 Calcium disodium ethylenediaminetetraacetate
E 400 Alginic acid
E 401 Sodium alginate
E 402 Potassium alginate
E 403 Ammonium alginate
E 404 Calcium alginate
E 405 Propane-1,2-diol alginate
E 406 Agar
E 407 Carrageenan
E 407a Processed eucheuma seaweed
E 410 Locust bean gum
E 412 Guar gum
E 413 Tragacanth
E 414 Acacia gum
E 415 Xanthan gum
E 416 Karaya-gum
E 417 Tara gum
E 418 Gellan gum
E 420 (i) Sorbitol
E 420 (ii) Sorbitol syrup
E 421 Mannitol
E 422 Glycerol
E 425 (i) Konjac gum

- E 425 (ii) Konjac glucomannan
- E 426 Soybean hemicellulose
- E 431 Polyoxyethylene (40) stearate
- E 432 Polyoxyethylene sorbitan monolaurate (polysorbate 20)
- E 433 Polyoxyethylene sorbitan monooleate (polysorbate 80)
- E 434 Polyoxyethylene sorbitan monopalmitate (polysorbate 40)
- E 435 Polyoxyethylene sorbitan monostearate (polysorbate 60)
- E 436 Polyoxyethylene sorbitan tristearate (polysorbate 65)
- E 440 (i) Pectin
- E 440 (ii) Amidated pectin
- E 442 Ammonium phosphatides
- E 444 Sucrose acetate isobutyrate
- E 445 Glycerol esters of wood rosin
- E 450 (i) Disodium diphosphate
- E 450 (ii) Trisodium diphosphate
- E 450 (iii) Tetrasodium diphosphate
- E 450 (v) Tetrapotassium diphosphate
- E 450 (vi) Dicalcium diphosphate
- E 450 (vii) Calcium dihydrogen diphosphate
- E 451 (i) Pentasodium triphosphate
- E 451 (ii) Pentapotassium triphosphate
- E 452 (i) Sodium polyphosphate
 - 1. Soluble polyphosphate
 - 2. Insoluble polyphosphate
- E 452 (ii) Potassium polyphosphate
- E 452 (iii) Sodium calcium polyphosphate
- E 452 (iv) Calcium polyphosphate
- E 459 Beta-cyclodextrin
- E 460 (i) Microcrystalline cellulose
- E 460 (ii) Powdered cellulose
- E 461 Methyl cellulose
- E 462 Ethyl cellulose
- E 463 Hydroxypropyl cellulose
- E 464 Hydroxypropyl methyl cellulose
- E 465 Ethyl methyl cellulose
- E 466 Sodium carboxy methyl cellulose
- E 468 Cross-linked sodium carboxymethylcellulose
- E 469 Enzymatically hydrolysed carboxymethylcellulose
- E 470a Sodium, Potassium and Calcium salts of fatty acids
- E 470b Magnesium salts of fatty acids
- E 471 Mono- and diglycerides of fatty acids
- E 472a Acetic acid esters of mono- and diglycerides of fatty acids
- E 472b Lactic acid esters of mono- and diglycerides of fatty acids
- E 472c Citric acid esters of mono- and diglycerides of fatty acids
- E 472d Tartaric acid esters of mono- and diglycerides of fatty acids
- E 472e Mono- and diacetyltartaric acid esters of mono- and diglycerides of fatty acids

E 472f Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids
E 473 Sucrose esters of fatty acids
E 474 Sucroglycerides
E 475 Polyglycerol esters of fatty acids
E 476 Polyglycerol polyricinoleate
E 477 Propane-1,2-diol esters of fatty acids
E 479b Thermally oxidized soya bean oil interacted with mono- and diglycerides of fatty acids
E 481 Sodium stearoyl-2-lactylate
E 482 Calcium stearoyl-2-lactylate
E 483 Stearyl tartrate
E 491 Sorbitan monostearate
E 492 Sorbitan tristearate
E 493 Sorbitan monolaurate
E 494 Sorbitan monooleate
E 495 Sorbitan monopalmitate
E 500 (i) Sodium carbonate
E 500 (iii) Sodium sequeicarbonate
E 501 (i) Potassium carbonate
E 501 (ii) Potassium hydrogen carbonate
E 503 (i) Ammonium carbonate
E 503 (ii) Ammonium hydrogen carbonate
E 504 (i) Magnesium carbonate
E 504 (ii) Magnesium hydroxide carbonate
E 507 Hydrochloric acid
E 508 Potassium chloride
E 509 Calcium chloride
E 511 Magnesium chloride
E 512 Stannous chloride
E 513 Sulphuric acid
E 514 (i) Sodium sulphate
E 514 (ii) Sodium hydrogen sulphate
E 515 (i) Potassium sulphate
E 515 (ii) Potassium hydrogen sulphate
E 516 Calcium sulphate
E 517 Ammonium sulphate
E 520 Aluminium sulphate
E 521 Aluminium sodium sulphate
E 522 Aluminium potassium sulphate
E 523 Aluminium ammonium sulphate
E 524 Sodium hydroxide
E 525 Potassium hydroxide
E 526 Calcium hydroxide
E 527 Ammonium hydroxide
E 528 Magnesium hydroxide
E 529 Calcium oxide

E 530 Magnesium oxide
E 535 Sodium ferrocyanide
E 536 Potassium ferrocyanide
E 538 Calcium ferrocyanide
E 541 Sodium aluminium phosphate, acidic
E 551 Silicon dioxide
E 553a (i) Magnesium silicate
E 553a (ii) Magnesium trisilicate
E 553b Talc
E 554 Sodium aluminium silicate
E 555 Potassium aluminium silicate
E 556 Calcium aluminium silicate
E 558 Bentonite
E 559 Aluminium silicate (Kaolin)
E 570 Fatty acids
E 574 Glucono-delta-lactone
E 576 Sodium gluconate
E 577 Potassium gluconate
E 578 Calcium gluconate
E 579 Ferrous gluconate
E 585 Ferrous lactate
E 586 4-Hexylresorcinol
E 620 Glutamic acid
E 621 Monosodium glutamate
E 622 Monopotassium glutamate
E 623 Calcium diglutamate
E 624 Monoammonium glutamate
E 625 Magnesium diglutamate
E 626 Guanylic acid
E 627 Disodium guanylate
E 628 Dipotassium guanylate
E 629 Calcium guanylate
E 630 Inosinic acid
E 631 Disodium inosinate
E 632 Dipotassium inosinate
E 633 Calcium inosinate
E 634 Calcium 5'-ribonucleotide
E 635 Disodium 5'-ribonucleotide
E 640 Glycine and its sodium salt
E 650 Zinc acetate
E 900 Dimethyl polysiloxane
E 901 Beeswax
E 902 Candelilla wax
E 903 Carnauba wax
E 904 Shellac
E 905 Microcrystalline wax

E 907 Hydrogenated poly-1-decene
E 912 Montan acid esters
E 914 Oxidised polyethylene wax
E 920 L-cysteine
E 927b Carbamide
E 938 Argon
E 939 Helium
E 941 Nitrogen
E 942 Nitrous oxide
E 943a Butane
E 943b Isobutane
E 944 Propane
E 948 Oxygen
E 949 Hydrogen
E 950 Acesulfame K
E 951 Aspartame
E 953 Isomalt
E 957 Thaumatin
E 959 Neohesperidine dihydrochalcone
E 965(i) Maltitol
E 965(ii) Maltitol syrup
E 966 Lactitol
E 967 Xylitol
E 999 Quillaia extract
E 1103 Invertase
E 1105 Lysozyme
E 1200 Polydextrose
E 1201 Polyvinylpyrrolidone
E 1202 Polyvinylpolypyrrolidone
E 1204 Pullulan
E 1404 Oxidised starch
E 1410 Monostarch phosphate
E 1410 Monostarch phosphate
E 1412 Distarch phosphate
E 1413 Phosphated distarch phosphate
E 1414 Acetylated distarch phosphate
E 1420 Acetylated starch
E 1422 Acetylated distarch adipate
E 1440 Hydroxypropyl starch
E 1442 Hydroxypropyl distarch phosphate
E 1450 Starch sodium octenyl succinate
E 1451 Acetylated oxidized starch
E 1452 Starch aluminium octenyl succinate
E 1505 Triethyl citrate
E 1517 Glyceryl diacetate
E 1518 Glyceryl triacetate

E 1519 Benzyl alcohol
E 1520 Propane-1,2-diol
Polyethylene glycol 6000.”.

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