

ANNEX

The Annex I to Directive 2008/84/EC is amended as follows:

- The text concerning E 234 nisin is replaced by the following:

E 234 NISIN

Definition	Nisin consists of several closely related polypeptides produced during the fermentation of a milk or sugar medium by certain natural strains of <i>Lactococcus lactis subsp. lactis</i>
Einecs	215-807-5
Chemical formula	C ₁₄₃ H ₂₃₀ N ₄₂ O ₃₇ S ₇
Molecular weight	3 354,12
Assay	Nisin concentrate contains not less than 900 units per mg in a mixture of non-fat milk proteins or fermented solids and a minimum sodium chloride content of 50 %
Description	White powder
Purity	
Loss on drying	Not more than 3 % when dried to constant weight at 102 °C to 103 °C
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

- The text concerning E 400 alginic acid is replaced by the following:

E 400 ALGINIC ACID

Definition	Linear glycuronoglycan consisting mainly of β -(1-4) linked D-mannuronic and α -(1-4) linked L-guluronic acid units in pyranose ring form. Hydrophilic colloidal carbohydrate extracted by the use of dilute alkali from natural strains of various species of brown seaweeds (<i>Phaeophyceae</i>)
Einecs	232-680-1
Chemical formula	(C ₆ H ₈ O ₆) _n
Molecular weight	10 000-600 000 (typical average)

Status: This is the original version (as it was originally adopted).

Assay	Alginic acid yields, on the anhydrous basis, not less than 20 % and not more than 23 % of carbon dioxide (CO ₂), equivalent to not less than 91 % and not more than 104,5 % of alginic acid (C ₆ H ₈ O ₆) _n (calculated on equivalent weight basis of 200)
Description	Alginic acid occurs in filamentous, grainy, granular and powdered forms. It is a white to yellowish brown and nearly odourless
Identification	
A. Solubility	Insoluble in water and organic solvents, slowly soluble in solutions of sodium carbonate, sodium hydroxide and trisodium phosphate
B. Calcium chloride precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one fifth of its volume of a 2,5 % solution of calcium chloride. A voluminous, gelatinous precipitate is formed. This test distinguishes alginic acid from acacia gum, sodium carboxymethyl cellulose, carboxymethyl starch, carrageenan, gelatin, gum ghatti, karaya gum, locust bean gum, methyl cellulose and tragacanth gum
C. Ammonium sulphate precipitation test	To a 0,5 % solution of the sample in 1 M sodium hydroxide solution, add one half of its volume of a saturated solution of ammonium sulphate. No precipitate is formed. This test distinguishes alginic acid from agar, sodium carboxymethyl cellulose, carrageenan, de-esterified pectin, gelatin, locust bean gum, methyl cellulose and starch
D. Colour reaction	Dissolve as completely as possible 0,01 g of the sample by shaking with 0,15 ml of 0,1 N sodium hydroxide and add 1 ml of acid ferric sulphate solution. Within 5 minutes, a cherry-red colour develops that finally becomes deep purple
Purity	
pH of a 3 % suspension	Between 2,0 and 3,5
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Sulphated ash	Not more than 8 % on the anhydrous basis

Sodium hydroxide (1 M solution)	Not more than 2 % on the anhydrous basis insoluble matter
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g

3. The text concerning E 401 sodium alginate is replaced by the following:

E 401 SODIUM ALGINATE

Definition	
Chemical name	Sodium salt of alginic acid
Chemical formula	$(C_6H_7NaO_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 90,8 % and not more than 106,0 % of sodium alginate (calculated on equivalent weight basis of 222)
Description	Nearly odourless, white to yellowish fibrous or granular powder
Identification	
Positive test for sodium and alginic acid	
Purity	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram

Status: This is the original version (as it was originally adopted).

Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g

4. The text concerning E 402 potassium alginate is replaced by the following:

E 402 POTASSIUM ALGINATE

Definition	
Chemical name	Potassium salt of alginic acid
Chemical formula	$(C_6H_7KO_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 16,5 % and not more than 19,5 % of carbon dioxide corresponding to not less than 89,2 % and not more than 105,5 % of potassium alginate (calculated on an equivalent weight basis of 238)
Description	Nearly odourless, white to yellowish fibrous or granular powder
Identification	
Positive test for potassium and for alginic acid	
Purity	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g

5. The text concerning E 403 ammonium alginate is replaced by the following:

E 403 AMMONIUM ALGINATE

Definition	
Chemical name	Ammonium salt of alginic acid
Chemical formula	$(C_6H_{11}NO_6)_n$
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % of carbon dioxide corresponding to not less than 88,7 % and not more than 103,6 % ammonium alginate (calculated on an equivalent weight basis of 217)
Description	White to yellowish fibrous or granular powder
Identification	
Positive test for ammonium and alginic acid	
Purity	
Loss on drying	Not more than 15 % (105 °C, 4 hours)
Sulphated ash	Not more than 7 % on the dried basis
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g

6. The text concerning E 404 calcium alginate is replaced by the following:

E 404 CALCIUM ALGINATE

Synonyms	Calcium salt of alginate
Definition	
Chemical name	Calcium salt of alginic acid
Chemical formula	$(C_6H_7Ca_{1/2}O_6)_n$

Status: This is the original version (as it was originally adopted).

Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 18 % and not more than 21 % carbon dioxide corresponding to not less than 89,6 % and not more than 104,5 % of calcium alginate (calculated on an equivalent weight basis of 219)
Description	Nearly odourless, white to yellowish fibrous or granular powder
Identification	
Positive test for calcium and alginic acid	
Purity	
Loss on drying	Not more than 15,0 % (105 °C, 4 hours)
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g

7. The text concerning E 405 propane-1,2-diol alginate is replaced by the following:

E 405 PROPANE-1,2-DIOL ALGINATE

Synonyms	Hydroxypropyl alginate 1,2-propanediol ester of alginic acid Propylene glycol alginate
Definition	
Chemical name	Propane-1,2-diol ester of alginic acid; varies in composition according to its degree of esterification and the percentage of free and neutralised carboxyl groups in the molecule
Chemical formula	(C ₉ H ₁₄ O ₇) _n (esterified)
Molecular weight	10 000-600 000 (typical average)
Assay	Yields, on the anhydrous basis, not less than 16 % and not more than 20 % of CO ₂ of carbon dioxide

Description	Nearly odourless, white to yellowish brown fibrous or granular powder
Identification	
Positive test for 1,2-propanediol and alginic acid after hydrolysis	
Purity	
Loss on drying	Not more than 20 % (105 °C, 4 hours)
Total propane-1,2-diol content	Not less than 15 % and not more than 45 %
Free propane-1,2-diol content	Not more than 15 %
Water-insoluble matter	Not more than 2 % on the anhydrous basis
Formaldehyde	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 500 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g

8. The text concerning E 407 carrageenan is replaced by the following:

E 407 CARRAGEENAN

Synonyms	Products of commerce are sold under different names such as: Irish moss gelose Eucheuman (from <i>Eucheuma</i> spp.) Iridophycan (from <i>Iridaea</i> spp.) Hypnean (from <i>Hypnea</i> spp.) Furcellaran or Danish agar (from <i>Furcellaria fastigiata</i>) Carrageenan (from <i>Chondrus</i> and <i>Gigartina</i> spp.)
Definition	Carrageenan is obtained by aqueous extraction of natural strains of seaweeds of <i>Gigartinaceae</i> , <i>Solieriaceae</i> , <i>Hypneaeceae</i> and <i>Furcellariaceae</i> , families of the class <i>Rhodophyceae</i> (red seaweeds). No organic precipitant shall be used other than methanol, ethanol and propane-2-ol. Carrageenan

Status: This is the original version (as it was originally adopted).

	consists chiefly of the potassium, sodium, magnesium and calcium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Carrageenan shall not be hydrolysed or otherwise chemically degraded. Formaldehyde may be present as an adventitious impurity up to a maximum level of 5 mg/kg
Einecs	232-524-2
Description	Yellowish to colourless, coarse to fine powder which is practically odourless
Identification	
Positive tests for galactose, for anhydrogalactose and for sulphate	
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO ₄)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not more than 2 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g

9. The text concerning E 407a processed eucheuma seaweed is replaced by the following:

E 407A PROCESSED EUCHEUMA SEAWEED

Synonyms	PES (acronym for processed eucheuma seaweed)
Definition	Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds <i>Eucheuma cottonii</i> and <i>Eucheuma spinosum</i> , of the class <i>Rhodophyceae</i> (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consist chiefly of the potassium salt of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded. Formaldehyde may be present as an adventitious impurity up to a maximum level of 5 mg/kg.
Description	Tan to yellowish, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
B. Solubility	Forms cloudy viscous suspensions in water. Insoluble in ethanol
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO ₄)

Status: This is the original version (as it was originally adopted).

Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 2 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>E. coli</i>	Absent in 5 g
<i>Salmonella</i> spp.	Absent in 10 g

10. The text concerning E 412 guar gum is replaced by the following:

E 412 GUAR GUM

Synonyms	Gum cyamopsis Guar flour
Definition	Guar gum is the ground endosperm of the seeds of natural strains of the guar plant, <i>Cyamopsis tetragonolobur</i> (L.) Taub. (family <i>Leguminosae</i>). Consists mainly of a high molecular weight hydrocolloidal polysaccharide composed of galactopyranose and mannopyranose units combined through glycosidic linkages, which may be described chemically as a galactomannan. The gum may be partially hydrolysed by either heat treatment, mild acid or alkaline oxidative treatment for viscosity adjustment.
Einecs	232-536-0
Molecular weight	Consists mainly of a high molecular weight hydrocolloidal polysaccharide (50 000-8 000 000)

Assay	Galactomannan content not less than 75 %
Description	A white to yellowish-white, nearly odourless powder
Identification	
A. Positive tests for galactose and for mannose	
B. Solubility	Soluble in cold water
Purity	
Loss on drying	Not more than 15 % (105 °C, 5 hours)
Ash	Not more than 5,5 % determined at 800 °C
Acid-insoluble matter	Not more than 7 %
Protein (N × 6,25)	Not more than 10 %
Starch	Not detectable by the following method: to a 1 in 10 solution of the sample add a few drops of iodine solution (no blue colour is produced)
Organic peroxides	Not more than 0,7 meq active oxygen/kg sample
Furfural	Not more than 1 mg/kg
Lead	Not more than 2 mg/kg
Arsenic	Not more than 3 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg

11. After the entry E 503(ii), the following text concerning E 504(i) is added:

E 504(I) MAGNESIUM CARBONATE

Synonyms	Hydromagnesite
Definition	Magnesium carbonate is a basic hydrated or a monohydrated magnesium carbonate or a mixture of the two
Chemical name	Magnesium carbonate
Chemical formula	MgCO ₃ .nH ₂ O
Einecs	208-915-9
Assay	Not less than 24 % and not more than 26,4 % of Mg

Status: This is the original version (as it was originally adopted).

Description	Odourless, light, white friable masses or as a bulky white powder
Identification	
A. Solubility	Practically insoluble both in water or ethanol
B. Positive tests for magnesium and for carbonate	
Purity	
Acid insoluble matter	Not more than 0,05 %
Water soluble matter	Not more than 1 %
Calcium	Not more than 0,4 %
Arsenic	Not more than 4 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

12. The text concerning E 526 calcium hydroxide is replaced by the following:

E 526 CALCIUM HYDROXIDE

Synonyms	Slaked lime, hydrated lime
Definition	
Chemical name	Calcium hydroxide
Einecs	215-137-3
Chemical formula	Ca(OH) ₂
Molecular weight	74,09
Assay	Content not less than 92 %
Description	White powder
Identification	
A. Positive tests for alkali and for calcium	
B. Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol
Purity	
Acid insoluble ash	Not more than 1,0 %
Magnesium and alkali salts	Not more than 2,7 %
Barium	Not more than 300 mg/kg
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg

Lead	Not more than 6 mg/kg
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13. The text concerning E 529 calcium oxide is replaced by the following:

E 529 CALCIUM OXIDE

Synonyms	Burnt lime
Definition	
Chemical name	Calcium oxide
Einecs	215-138-9
Chemical formula	CaO
Molecular weight	56,08
Assay	Content not less than 95 % on the ignited basis
Description	Odourless, hard, white or greyish white masses of granules, or white to greyish powder
Identification	
A. Positive test for alkali and for calcium	
B. Heat is generated on moistening the sample in water	
C. Solubility	Slightly soluble in water. Insoluble in ethanol. Soluble in glycerol
Purity	
Loss on ignition	Not more than 10 % (ca. 800 °C to constant weight)
Acid insoluble matter	Not more than 1 %
Barium	Not more than 300 mg/kg
Magnesium and alkali salts	Not more than 3,6 %
Fluoride	Not more than 50 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 7 mg/kg

14. The text concerning E 901 beeswax is replaced by the following:

E 901 BEESWAX

Synonyms	White wax, yellow wax
Definition	Yellow beeswax is the wax obtained by melting the walls of the honeycomb

Status: This is the original version (as it was originally adopted).

	made by the honey bee, <i>Apis mellifera</i> L., with hot water and removing foreign matter White beeswax is obtained by bleaching yellow beeswax
Einecs	232-383-7 (beeswax)
Description	Yellowish white (white form) or yellowish to greyish brown (yellow form) pieces or plates with a fine-grained and non-crystalline fracture, having an agreeable, honey-like odour
Identification	
A. Melting range	Between 62 °C and 65 °C
B. Specific gravity	About 0,96
C. Solubility	Insoluble in water Sparingly soluble in alcohol Very soluble in chloroform and ether
Purity	
Acid value	Not less than 17 and not more than 24
Saponification value	87-104
Peroxide value	Not more than 5
Glycerol and other polyols	Not more than 0,5 % (as glycerol)
Ceresin, paraffins and certain other waxes	Absent
Fats, Japan wax, rosin and soaps	Absent
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg

15. The text concerning E 905 microcrystalline wax is replaced by the following:

E 905 MICROCRYSTALLINE WAX

Synonyms	Petroleum wax, hydrocarbon wax, Fischer-Tropsch wax, synthetic wax, synthetic paraffin
Definition	Refined mixtures of solid, saturated hydrocarbons, obtained from petroleum or synthetic feedstocks
Description	White to amber, odourless wax
Identification	

A.	Solubility	Insoluble in water, very slightly soluble in ethanol										
B.	Refractive Index	n_D^{100} 1,434-1,448 Alternative: n_D^{120} 1,426-1,440										
Purity												
	Molecular weight	Average not less than 500										
	Viscosity	Not less than $1,1 \times 10^{-5} \text{ m}^2 \text{ s}^{-1}$ at 100 °C Alternative: Not less than $0,8 \times 10^{-5} \text{ m}^2 \text{ s}^{-1}$ at 120 °C, if solid at 100 °C										
	Residue on ignition	Not more than 0,1 wt %										
	Carbon number at 5 % distillation point	Not more than 5 % of molecules with carbon number less than 25										
	Colour	Passes test										
	Sulphur	Not more than 0,4 wt %										
	Arsenic	Not more than 3 mg/kg										
	Lead	Not more than 3 mg/kg										
	Polycyclic aromatic compounds	The polycyclic aromatic hydrocarbons, obtained by extraction with dimethyl sulfoxide, shall meet the following ultraviolet absorbency limits: <table border="1" data-bbox="858 1240 1340 1541"> <thead> <tr> <th>Nm</th> <th>Maximum absorbance per cm path length</th> </tr> </thead> <tbody> <tr> <td>280-289</td> <td>0,15</td> </tr> <tr> <td>290-299</td> <td>0,12</td> </tr> <tr> <td>300-359</td> <td>0,08</td> </tr> <tr> <td>360-400</td> <td>0,02</td> </tr> </tbody> </table> Alternative, if solid at 100 °C PAC method as per 21 CFR& 175.250; Absorbency at 290 nm in decahydronaphthalene at 88 °C: Not exceeding 0,01	Nm	Maximum absorbance per cm path length	280-289	0,15	290-299	0,12	300-359	0,08	360-400	0,02
Nm	Maximum absorbance per cm path length											
280-289	0,15											
290-299	0,12											
300-359	0,08											
360-400	0,02											

16. The text concerning E 230 and E 233 is deleted.