Schedule 3 Identity and purity

***Note 1*** This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Standard 1.1.1 relates to introductory matters and standards that apply to all foods. Section 1.1.1—15 and S26 require certain substances to comply with relevant specifications. This Standard sets out the relevant specifications.

***Note 2*** The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014* (NZ). See also section 1.1.1—3.

S3—1 Name

This Standard is *Australia New Zealand Food Standards Code* – Schedule 3 – Identity and purity.

***Note*** Commencement:This Standard commences on 1 March 2016, being the date specified as the commencement date in notices in the *Gazette* and the New Zealand Gazette under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

S3—2 Substances with specifications in primary sources

(1) For subsection 1.1.1—15(2), the specifications are:

(a) any relevant provision listed in the table to subsection (2); or

(b) Combined Compendium of Food Additive Specifications, FAO JECFA Monographs 1 (2005), Food and Agriculture Organisation of the United Nations, Rome, as superseded by specifications published in any of the following:

(i) FAO JECFA Monographs 3 (2006);

(ii) FAO JECFA Monographs 4 (2007);

(iii) FAO JECFA Monographs 5 (2008);

(iv) FAO JECFA Monographs 7 (2009);

(v) FAO JECFA Monographs 10 (2010);

(vi) FAO JECFA Monographs 11 (2011);

(vii) FAO JECFA Monographs 13 (2012);

(viii) FAO JECFA Monographs 14 (2013);

(ix) FAO JECFA Monographs 16 (2014);

(x) FAO JECFA Monographs 17 (2015);

(xi) FAO JECFA Monographs 19 (2016);

(xii)     FAO JECFA Monographs 20 (2017);

(xiii)    FAO JECFA Monographs 22 (2018);

(xiv) FAO JECFA Monographs 23 (2019);

(xv) FAO JECFA Monographs 25 (2020);

(xvi) FAO JECFA Monographs 26 (2021); or

(c)United States Pharmacopeial Convention (2022) Food chemicals codex. 13th ed, United States Pharmacopeial Convention, Rockville, MD; or

(d) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives.

(2) The table to this subsection is:

Relevant provisions

| Substance | Provision |
| --- | --- |
| advantame | section S3—5 |
| amine agarose ion exchange resin | section S3—6 |
| bentonite | section S3—7 |
| Bovine lactoferrin | Section S3—46 |
| bromo-chloro-dimethylhydantoin | section S3—8 |
| carboxymethyl cellulose ion exchange resin | section S3—9 |
| dibromo-dimethylhydantoin | section S3—10 |
| diethyl aminoethyl cellulose ion exchange resin | section S3—11 |
| dimethyl ether | section S3—12 |
| dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA) | section S3—13 |
| 2*′-*fucosyllactose sourced from *Escherichia coli*BL21 | section S3—45 |
| 2*′-*fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from either *Heliobacter enhydrae, Helicobacter pylori* or *Bacteroides vulgatus* | section S3—40 |

|  |  |
| --- | --- |
| 2′-fucosyllactose and difucosyllactose sourced from *Escherichia coli K-12* | section S3—47 |
| lacto-N-tetraose sourced from *Escherichia coli* K-12 | section S3—48 |
| 6′-sialyllactose sodium salt sourced from *Escherichia coli* K-12 | section S3—49 |
| 3′-sialyllactose sodium salt sourced from *Escherichia coli* K-12 | section S3—50 |

|  |  |
| --- | --- |
| ice structuring protein type III HPLC 12 preparation | section S3—14 |
| isomalto-oligosaccharide | section S3—37 |
| Isomaltulose | section S3—15 |
| lacto-N-neotetraose | section S3—41 |
| L-arginine acetate | section S3—38 |
| *Listeria* phage P100  Nicotinamide riboside chloride | section S3—16  section S3—44 |
| nucleotides | sections S3—17 and S3—18 |
| oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695) | section S3—36 |
| oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA) | section S3—21 |
| oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA) | section S3—22 |
| oil derived from the algae *Crypthecodinium cohnii* rich in docosahexaenoic acid (DHA) | section S3—19 |
| oil derived from the fungus *Mortierella alpina* rich in arachidonic acid (ARA) | section S3—20 |
| oxidised polyethylene | section S3—23 |
| phytosterols, phytostanols and their esters | section S3—24 |
| quaternary amine cellulose ion exchange resin | section S3—25 |
| rapeseed protein isolate | section S3—39(A) |
| resistant maltodextrins | section S3—26 |
| *Salmonella* phage preparation (S16 and FO1a) | section S3—33 |
| steviol glycosides from fermentation | section S3—39 |
| steviol glycosides produced by enzymatic conversion | section S3—35 |
| soy leghemoglobin preparation | section S3—42 |
| sulphonate agarose ion exchange resin  Sweet osmanthus ear glycolipids | section S3—34  section S3—43 |
| tall oil phytosterol esters | section S3—27 |
| yeast—enriched selenium | section S3—28 |
| yeast—high chromium | section S3—29 |
| yeast—high molybdenum | section S3—30 |

S3—3 Substances with specifications in secondary sources

If there is no relevant specification under section S3—2, the specification is a specification listed in one of the following:

(a) British Pharmacopoeia Commission (2014) British Pharmacopoeia 2014. TSO, Norwich;

(b) United States Pharmacopeial Convention (2020) United States Pharmacopeia (43) and the National Formulary (38), (USP 43-NF 38). United States Pharmacopeial Convention, Rockville, MD;

(c) Royal Pharmaceutical Society of Great Britain. Lund W (1994) Pharmaceutical codex: principles and practice of pharmaceutics, 12th ed, Pharmaceutical Press, London;

(d) Sweetman SC (2011) Martindale: the complete drug reference. 37th ed, Pharmaceutical Press, London;

(e) the European Pharmacopoeia 8th Edition, Council of Europe, Strasbourg (2014);

(f) the International Pharmacopoeia 4th Edition, World Health Organization, Geneva (2006 and 2008 supplement);

(g) the Merck Index, 15th Edition, (2013);

(h) the Code of Federal Regulations;

(i) the Specifications and Standards for Food Additives, 9th Edition (2018)’, Ministry of Health and Welfare (Japan); or

(j) the International Oenological Codex (2022), Organisation Internationale de la Vigne et du Vin (OIV).

S3—4 Additional and supplementary requirements

If there is no relevant specification under section S3—2 or S3—3, or if the monographs referred to in those sections do not contain a specification for identity and purity of a substance relating to arsenic or heavy metals, the specification is that the substance must not contain on a dry weight basis more than:

(a) 2 mg/kg of lead; or

(b) 1 mg/kg of arsenic; or

(c) 1 mg/kg of cadmium; or

(d) 1 mg/kg of mercury.

S3—5 Specifications for advantame

For advantame, the specifications are:

(a) purity, using the analytical methodology indicated:

(i) assay:

(A) specification—not less than 97.0% and not more than 102.0% on anhydrous basis; and

(B) analytical methodology—high pressure liquid chromatography; and

(ii) specific rotation [α] 20 D:

(A) specification—between -45° and -38°; and

(B) analytical methodology—Japanese Pharmacopeia; and

(iii) advantame-acid:

(A) specification—not more than 1.0%; and

(B) analytical methodology—HPLC; and

(iv) total other related substances:

(A) specification—not more than 1.5%; and

(B) analytical methodology—HPLC; and

(v) water:

(A) specification—not more than 5.0%; and

(B) analytical methodology—Karl Fischer coulometric titration; and

(vi) residue on ignition:

(A) specification—no more than 0.2%; and

(B) analytical methodology—Japanese Pharmacopeia; and

(b) residual solvents, using gas chromatography:

(i) methyl acetate—no more than 500 mg/kg; and

(ii) isopropyl acetate—no more than 2 000 mg/kg; and

(iii) methanol—no more than 500 mg/kg; and

(iv) 2-Propanol—no more than 500 mg/kg.

S3—6 Specification for amine agarose ion exchange resin

(1) This specification relates to agarose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then derivatised with tertiary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting amount of agarose.

(2) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

S3—7 Specification for bentonite

Bentonite must comply with a monograph specification in section S3—2 or section S3—3, except that the pH determination for a bentonite dispersion must be no less than 4.5 and no more than 10.5.

S3—8 Specification for bromo-chloro-dimethylhydantoin

(1) In this section:

***bromo-chloro-dimethylhydantoin*** (CAS Number: 126-06-7) is the chemical with:

(a) the formula C5H6BrClN2O2; and

(b) the formula weight 241.5.

(2) For bromo-chloro-dimethylhydantoin, the chemical specifications are the following:

(a) appearance—solid or free flowing granules;

(b) colour—white:

(c) odour—faint halogenous odour;

(d) melting point—163–164ºC;

(e) specific gravity—1.8–2;

(f) solubility in water—0.2 g/100 g at 25ºC;

(g) stability—stable when dry and uncontaminated.

(3) Bromo-chloro-dimethylhydantoin must be manufactured in accordance with the following process:

(a) solid dimethylhydantoin (DMH) must be dissolved in water with bromine and chlorine;

(b) the reaction must be 0.5 mole bromine and 1.5 mole chlorine for one mole DMH;

(c) during the reaction the pH must be kept basic by the addition of caustic soda;

(d) the wet product must be transferred to a drier where it is dried to a powder at low temperature;

(e) the powder may then be tableted or granulated.

(4) Bromo-chloro-dimethylhydantoin may be assayed in accordance with various analytical methods, including GLC, HPLC, UV and NMR.

***Note*** HPLC offers the best sensitivity.

S3—9 Specification for carboxymethyl cellulose ion exchange resin

(1) This specification relates to regenerated cellulose that has been cross-linked and alkylated with epichlorohydrin and propylene oxide, then derivatised with carboxymethyl groups, as a result of which the amount of epichlorohydrin plus propylene oxide is no more than 70% by weight of the starting amount of cellulose.

(2) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

S3—10 Specification for dibromo-dimethylhydantoin

(1) In this section:

***dibromo-dimethylhydantoin*** means the chemical with CAS Number 77-48-5 and formula C5H6Br2N2O2.

(2) For dibromo-dimethylhydantoin, the specifications (which relate to purity) are the following:

(a) dibromo-dimethylhydantoin—no less than 97%;

(b) sodium bromide—no more than 2%;

(c) water—no more than 1%.

S3—11 Specification for diethyl aminoethyl cellulose ion exchange resin

(1) This specification relates to:

(a) regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then derivatised with tertiary amine groups whereby the amount of epichlorohydrin plus propylene oxide is no more than 70% by weight of the starting amount of cellulose; and

(b) regenerated cellulose, cross-linked and alkylated with epichlorohydrin then derivatised with tertiary amine groups whereby the amount of epichlorohydrin is no more than 10% by weight of the starting amount of cellulose.

(2) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

S3—12 Specification for dimethyl ether

For dimethyl ether, the specifications are the following:

(a) purity—minimum of 99.8%;

(b) methanol—not greater than 200 mg/kg.

S3—13 Specification for dried marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)

For docosahexaenoic acid (DHA)-rich dried marine micro-algae (*Schizochytrium* sp.), the specifications are the following:

(a) full chemical name—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3 DHA);

(b) solids (%)—minimum 95.0;

(c) DHA (%)—minimum 15.0;

(d) lead (mg/kg)—maximum 0.5;

(e) arsenic (mg/kg)—maximum 0.5.

S3—14 Specification for ice structuring protein type III HPLC 12 preparation

(1) In this section:

***ice structuring protein type III HPLC 12 preparation*** means the protein excreted from the fermentation of a genetically modified yeast (*Saccharomyces cerevisiae*) to which a synthetic gene encoding for the protein has been inserted into the yeast’s genome.

(2) For ice structuring protein type III HPLC 12 preparation, the specifications are the following:

(a) assay—not less than 5 g/L active ice structuring protein type III HPLC 12;

(b) pH—3.0+/-0.5;

(c) ash—not more than 2%;

(d) appearance—light brown aqueous preparation;

(e) heavy metals—not more than 2 mg/L;

(f) microbial limits:

(i) total microbial count—<3 000/g; and

(ii) coliforms—<10/g; and

(iii) yeast and mould count—<100/g; and

(iv) *Listeria* sp.—absent in 25 g; and

(v) *Salmonella* sp.—absent in 25 g; and

(vi) *Bacillus cereus*—<100/g.

S3—15 Specification for isomaltulose

For isomaltulose, the specifications are the following:

(a) chemical name—6-O-α-D-glucopyranosyl-D-fructofuranose:

(b) description—white or colourless, crystalline, sweet substance, faint isomaltulose specific odour;

(c) isomaltulose (%)—not less than 98% on a dry weight basis;

(d) water—maximum 6%;

(e) other saccharides—maximum 2% on a dry weight basis;

(f) ash—maximum 0.01% on a dry weight basis;

(g) lead—maximum 0.1 ppm on a dry weight basis.

S3—16 Specification for *Listeria* phage P100

For *Listeria* phage P100, the biological classification is the following:

(a) order—*Caudovirales*;

(b) family—*Myoviridae*;

(c) subfamily—*Spounaviridae*;

(d) genus—twort-like;

(e) species—*Listeria* phage P100;

(f) GenBank Accession Number—DQ004855.

S3—17 Descriptions and physical constraints for nucleotides

Uridine-5′-monophosphate disodium salt (UMP)

(1) For uridine-5′-monophosphate disodium salt (UMP), the specifications are the following:

(a) empirical chemical formula—C9 H11N2 O9PNa2;

(b) the compound must be of the 5 species, with the disodium monophosphate structure attached to the fifth carbon in the central structure;

(c) molecular weight—368.15;

(d) structure or physical character—occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste;

(e) solubility—freely soluble in water; very slightly soluble in alcohol.

Adenosine-5′-monophosphate (AMP)

(2) For adenosine-5′-monophosphate (AMP), the specifications are the following:

(a) empirical chemical formula—C10H14N5O7P;

(b) the compound must be of the 5 species, with the monophosphate structure attached to the fifth carbon in the central structure;

(c) molecular weight—347.22;

(d) structure or physical character—occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic acidic taste;

(e) solubility—very slightly soluble in water; practically insoluble in alcohol.

Cytidine-5′-monophosphate (CMP)

(3) For cytidine-5′-monophosphate (CMP), the specifications are the following:

(a) empirical chemical formula—C9H14N3O8P;

(b) the compound must be of the 5 species, with the monophosphate structure attached to the fifth carbon in the central structure;

(c) molecular weight—323.20;

(d) structure or physical character—occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic slightly acidic taste;

(e) solubility—very slightly soluble in water; practically insoluble in alcohol.

S3—18 Testing requirements for nucleotides

The testing requirements for nucleotides are as follows:

(a) physical inspection—white crystals or crystalline powder;

(b) identification:

(i) ultraviolet absorbance: a 1 in 12 500 solution of the powder in 0.01N hydrochloric acid exhibits an absorbance maximum at an absorbance of:

(A) for inosine-5′-monophosphate disodium salt—250 ± 2nm; and

(B) for uridine-5′-monophosphate disodium salt—260 ± 2nm; and

(C) for adenosine-5′-monophosphate—257 ± 2nm; and

(D) for cytidine-5′-monophosphate (CMP)—280 ± 2nm; and

(E) guanosine-5′-monophosphate disodium salt (gMP)—256 ± 2nm; and

(ii) IMP, UMP and gMP must test positive for sodium phosphate; and

(iii) IMP, UMP, AMP, CMP and gMP must test positive for organic phosphate;

(c) assay (HPLC)—optimum of not less than 96% (corrected for moisture content);

(d) IMP and gMP have a pH of a 1 in 20 solution: between 7.0 and 8.5;

(e) clarity and colour of solution:

(i) 500 mg/10 mL H2O for IMP: is colourless and shows only a trace of turbidity; and

(ii) 100 mg/10 mL H2O for gMP: is colourless and shows only a trace of turbidity;

(f) moisture:

(i) for inosine-5′-monophosphate disodium salt—not more than 28.5%: Karl Fischer; and

(ii) for uridine-5′-monophosphate disodium salt—not more than 26.0%: Karl Fischer; and

(iii) guanosine-5′-monophosphate disodium salt (gMP)—loss in drying of not more than 25% (4 hrs @ 120ºC); and

(iv) for cytidine-5′-monophosphate (CMP)—loss in drying of not more than 6.0% (4 hrs @ 120ºC); and

(v) adenosine-5′-monophosphate—loss in drying of not more than 6.0% (4 hrs @ 120ºC);

(g) impurities—all nucleotides:

(i) for IMP, gMP—amino acids: negative; and

(ii) for IMP, gMP—ammonium salts: negative; and

(iii) for IMP, UMP, AMP, CMP, gMP—arsenic: not more than 2 ppm; and

(iv) for IMP, UMP, AMP, CMP, gMP—heavy metals: not more than 10 ppm;

(h) related foreign substances:

(i) for IMP—only 5′-inosinic acid is detected by thin layer chromatography; and

(ii) for gMP—only 5′-guanylic acid is detected by thin layer chromatography;

(i) bacteriological profile:

(i) \*SPC—not more than 1 000/g, test per current FDA/BAM procedures; and

(ii) coliforms—negative by test; test per current FDA/BAM procedures; and

(iii) yeast and mould—not more than 300/g, test per current FDA/BAM procedures; and

(iv) *Salmonella*—negative, test per current FDA/BAM procedures.

S3—19 Specification for oil derived from the algae *Crypthecodinium cohnii* rich in docosahexaenoic acid (DHA)

For oil derived from the algae *Crypthecodinium cohnii* rich in docosahexaenoic acid (DHA), the specifications are the following:

(a) full chemical name for DHA—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3);

(b) DHA (%)—minimum 35;

(c) \*trans fatty acids (%)—maximum 2.0;

(d) lead (mg/kg)—maximum 0.1;

(e) arsenic (mg/kg)—maximum 0.1;

(f) mercury (mg/kg)—maximum 0.1;

(g) hexane (mg/kg)—maximum 0.3.

S3—20 Specification for oil derived from the fungus *Mortierella alpina* rich in arachidonic acid (ARA)

For oil derived from the fungus *Mortierella alpina* rich in arachidonic acid (ARA), the specifications are the following:

(a) full chemical name for ARA—5,8,11,14-eicosatetraenoic acid (20:4n-6 ARA);

(b) ARA (%)—minimum 35;

(c) \*trans fatty acids (%)—maximum 2.0;

(d) lead (mg/kg)—maximum 0.1;

(e) arsenic (mg/kg)—maximum 0.1;

(f) mercury (mg/kg)—maximum 0.1;

(g) hexane (mg/kg)—maximum 0.3.

S3—21 Specification for oil derived from marine micro-algae (*Schizochytrium* sp*.*) rich in docosahexaenoic acid (DHA)

For oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA), the specifications are the following:

(a) full chemical name—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3 DHA);

(b) DHA (%)—minimum 32;

(c) \*trans fatty acids (%)—maximum 2.0;

(d) lead (mg/kg)—maximum 0.1;

(e) arsenic (mg/kg)—maximum 0.1;

(f) mercury (mg/kg)—maximum 0.1;

(g) hexane (mg/kg)—maximum 0.3.

S3—22 Specification for oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA)

For oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA), the specifications are the following:

(a) full chemical name for DHA—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3 DHA);

(b) DHA (%)—minimum 32;

(c) \*trans fatty acids (%)—maximum 2.0;

(d) lead (mg/kg)—maximum 0.2;

(e) arsenic (mg/kg)—maximum 0.2;

(f) mercury (mg/kg)—maximum 0.2;

(g) hexane (mg/kg)—maximum 10.

S3—23 Specification for oxidised polyethylene

(1) In this section:

***ASTM*** refers to standard test methods prepared by the American Society for Testing and Materials.

***CAS*** means the Chemical Abstracts Service (CAS) Registry Number.

***oxidised polyethylene*** (CAS 68441-17-8) is the polymer produced by the mild air oxidation of polyethylene.

(2) For oxidised polyethylene, the specifications are the following:

(a) average molecular weight—min 1200 (osmometric);

(b) viscosity at 125°C—min 200cP;

(c) oxygen content—max 9.1%;

(d) acid value—max 70 mgKOH/g (ASTM D 1386);

(e) drop point—min 95°C (ASTM D 566);

(f) density (20°C)—0.93-1.05 g/cm3 (ASTM D 1298, D 1505);

(g) extractable constituents:

(i) in water—maximum 1.5%; and

(ii) in 10% ethanol—max 2.3%; and

(iii) in 3% acetic acid—max 1.8%; and

(iv) in n-pentane—max 26.0%.

***Note*** Extraction of oxidised polyethylene—25.0 g of finely ground oxidised polyethylene powder (particle size 300–1 000 μm) is extracted for 5 hours in the Soxhlet apparatus with 350 mL of solvent. The solvent is then distilled off and the distillation residue is dried in a vacuum oven at 80–90°C. After weighing the obtained residue, the components soluble in the solvent are calculated in % weight (based on the initial weight used).

S3—24 Specification for phytosterols, phytostanols and their esters

(1) Subject to subsections (2) and (3), \*phytosterols, phytostanols and their esters must comply with a monograph specification in section S3—2 or section S3—3.

(2) However, for a mixture which contains no less than 950 g/kg of phytosterol and phytostanols, the concentration of hexane, isopropanol, ethanol, methanol or methyl ethyl ketone either singly or in combination must be no more than 2 g/kg.

(3) The \*total plant sterol equivalents content must contain no less than 95% des-methyl sterols.

S3—25 Specification for quaternary amine cellulose ion exchange resin

(1) This specification relates to regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then derivatised with quaternary amine groups whereby the amount of epichlorohydrin plus propylene oxide is no more than 250% by weight of the starting amount of cellulose.

(2) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

S3—26 Specification for resistant maltodextrins

For resistant maltodextrins, the specifications are the following:

(a) chemical structure—glucopyranose linked by α(1-4), α(1-6), α/β(1-2), and α/β(1-3) glucosidic bonds; and contains levoglucosan;

(b) dextrose equivalent—8-12;

(c) appearance—free-flowing fine powder;

(d) colour—white;

(e) taste/odour—slightly sweet/odourless;

(f) solution—clear;

(g) pH (in 10% solution)—4-6;

(h) moisture (%)—maximum 5;

(i) ash (%)—maximum 0.2;

(j) arsenic (ppm)—maximum 1;

(k) heavy metals (ppm)—maximum 5;

(l) microbiological:

(i) \*SPC (cfu/g)—maximum 300;

(ii) yeast and mould (cfu/g)—maximum 100;

(iii) *Salmonella*—negative to test;

(iv) coliforms—negative to test.

S3—27 Specification for tall oil phytosterol esters

(1) In this section:

***tall oil phytosterol esters*** are phytosterols derived from tall oil pitch esterified with long-chain fatty acids derived from edible vegetable oils

(2) For tall oil phytosterol esters, the specifications are the following:

(a) phytosterol content:

(i) phytosterol esters plus free phytosterols—no less than 97%; and

(ii) free phytosterols after saponification—no less than 59%; and

(iii) free phytosterols—no more than 6%; and

(iv) steradienes—no more than 0.3%;

(b) sterol profile based on input sterols:

(i) campesterol—no less than 4.0% and no more than 25.0%; and

(ii) campesterol—no more than 14.0%; and

(iii) B-sitosterol—no less than 36.0% and no more than 79.0%; and

(iv) B-sitostanol—no less than 6.0% and no more than 34%; and

(v) fatty acid methylester—no more than 0.5%; and

(vi) moisture—no more than 0.1%; and

(vii) solvents—no more than 50 mg/kg; and

(viii) residue on ignition—no more than 0.1%;

(c) heavy metals:

(i) iron—no more than 1.0 mg/kg; and

(ii) copper—no more than 0.5 mg/kg; and

(iii) arsenic—no more than 3 mg/kg; and

(iv) lead—no more than 0.1 mg/kg;

(d) microbiological:

(i) total aerobic count—no more than 10 000 cfu/g; and

(ii) combined moulds and yeasts—no more than 100 cfu/g; and

(iii) coliforms—negative; and

(iv) *Escherichia coli*—negative; and

(v) *Salmonella*—negative.

S3—28 Specification for yeast—selenium-enriched

(1) Selenium-enriched yeasts are produced by culture in the presence of sodium selenite as a source of selenium.

(2) These yeasts must contain selenium according to the following criteria:

(a) total selenium content—no more than 2.5 mg/g of the dried form as marketed;

(b) levels of organic selenium (% total as extracted selenium):

(i) selenomethionine—no less than 60% and no more than 85%; and

(ii) other organic selenium compounds (including selenocysteine)—no more than 10%;

(c) levels of inorganic selenium (% total extracted selenium)—no more than 1%.

S3—29 Specification for yeast—high chromium

For high chromium yeast:

(a) the physical specifications are the following:

(i) appearance—fine, free-flowing powder;

(ii) colour—light off-white or light tan;

(iii) odour—slight yeast aroma;

(iv) particle size—minimum 90% through a #100 USS screen; and

(b) the chemical specifications are the following:

(i) moisture—maximum 6%;

(ii) chromium—1.8-2.25 g/kg.

S3—30 Specification for yeast—high molybdenum

For high molybdenum yeast:

(a) the physical specifications are the following:

(i) appearance—fine, free-flowing powder;

(ii) colour—light off-white or light tan;

(iii) odour—slight yeast aroma;

(iv) particle size—minimum 85% through a #100 USS screen; and

(b) the chemical specifications are the following:

(i) moisture—maximum 6%;

(ii) molybdenum—1.8–2.25 g/kg.

S3—33 Specifications for *Salmonella* phage preparation (S16 and FO1a)

(1) In this section:

***a preparation*** means a *Salmonella* phage preparation (S16 and FO1a).

**Salmonella *phage preparation (S16 and FO1a)*** means a solution of a 1:1 blend of *Salmonella* phage S16 and *Salmonella* phage FO1a.

(2) *Salmonella* phage S16 in a preparation must comply with the specification in subsection (4).

(3) *Salmonella* phage FO1a in a preparation must comply with the specification in subsection (5).

(4) The biological classification for *Salmonella* phage S16 in a preparation is the following:

(a) order—Caudavirales;

(b) family—Myoviridae;

(c) genus—T4-like;

(d) species—*Salmonella* phage S16;

(e) GenBank Accession Number—HQ331142

(5) The biological classification for *Salmonella* phage FO1a in a preparation is the following:

(a) order—Caudavirales;

(b) family—Myoviridae;

(c) genus—FelixO1-like;

(d) species— *Salmonella* phage FO1a;

(e) GenBank Accession Number—JF461087.

S3—34 Specification for sulphonate agarose ion exchange resin

(1) This specification relates to agarose, cross-linked with epichlorohydrin and reacted with allyl glycidyl ether or propylene oxide, then derivatised with sulphonate groups whereby the amount of epichlorohydrin plus allyl glycidyl ether or propylene oxide does not exceed 250% by weight of the starting quantity of agarose.

(2) When subjected to the extraction regime listed in the 21 CFR § 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

S3—35 Specification for steviol glycosides produced by enzymatic conversion

(1)      In this section:

***prescribed rebaudiosides*** are:

                       (a)      rebaudioside D;

                            (b)      rebaudioside M; and

                            (c)      rebaudioside AM.

***rebaudioside AM*** means the steviol glycoside with the chemical name: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid, 2-O-β-D-glucopyranosyl-3-O-β-D-glucopyranosyl-β-D-glucopyranosyl ester.

                 (1A)   This specification relates to a steviol glycosides preparation obtained from the leaves of the *Stevia rebaudiana* Bertoni plant.

(2) The preparation must be obtained from the leaves of the *Stevia rebaudiana* Bertoni plant by using one of the following processes:

(a) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside M using protein engineered enzymes that:

(i) contain both UDP‑glucosyltransferase and sucrose synthase (EC 2.4.1.13) components; and

(ii) are sourced from both of the following:

(a) a *Pichia pastoris* strain expressing UGT-A;

(b) a *Pichia pastoris* strain expressing both UGT-B1 and UGT-B2;

(b) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside D using a protein engineered enzyme that:

(i) contains both UDP‑glucosyltransferase and sucrose synthase (EC 2.4.1.13) components; and

(ii) is sourced from *Pichia pastoris* strain UGT-A;

(c)        by enzymatic conversion of purified stevia leaf extract to produce one or more prescribed rebaudiosides using a combination of enzymes that contains:

(i) a UDP-glucosyltransferase from *Stevia rebaudiana* sourced from *Escherichia coli*; and

(ii) a UDP-glucosyltransferase from *Solanum lycopersicum* sourced from *Escherichia coli*; and

(iii) a sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli*.

(d) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside E using a protein engineered enzyme that:

(i) contains both of the following components:

(A) UDP‑glucosyltransferase; and

(B) sucrose synthase (EC 2.4.1.13); and

(ii) is sourced from *Pichia pastoris* strain UGT-A;

(e)    by enzymatic conversion of purified stevia leaf extract to produce rebaudioside M using all of the following protein engineered enzymes:

(i) UTP-glucose-1-phosphate uridylyltransferase (EC 2.7.7.9) sourced from *Escherichia coli* K-12; and

1. UDP-glucosyltransferase sourced from *Escherichia coli* K-12; and
2. sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* K-12;

(f)      by enzymatic conversion of purified stevia leaf extract to produce rebaudioside I using both of the following protein engineered enzymes:

(i) UTP-glucose-1-phosphate uridylyltransferase (EC 2.7.7.9) sourced from *Escherichia coli* K-12; and

(ii) sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* K-12.

(2A) The final product may be spray dried.

(3) The preparation may contain different individual steviol glycosides.

(4) The specifications are the following:

(a) Description—white to light yellow powder, approximately 150 to 300 times sweeter than sucrose;

(b) Assay—not less than 95% of steviol glycosides on the dried basis;

(c) Solubility—freely soluble in water;

(d) pH—between 4.5 and 7.0 (1% solution);

(e) Total ash—not more than 1%;

(f) Loss on drying—not more than 6% (105°C, 2 hour);

(g) Residual solvents: Not more than 200 mg/kg methanol

Not more than 5000 mg/kg ethanol

(h) Arsenic—not more than 1 mg/kg;

(i) Lead—not more than 1 mg/kg;

(j) INS number—960.

S3—36 Specification for oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)

For oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695), the specifications are the following:

(a) full chemical name—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3 DHA);

(b) DHA (%)—minimum 35;

(c) EPA (%)—maximum 10;

(d) \*trans fatty acids (%)—maximum 2.0;

(e) lead (mg/kg)—maximum 0.1;

(f) arsenic (mg/kg)—maximum 0.1;

(g) mercury (mg/kg)—maximum 0.1;

(h) hexane (mg/kg)—maximum 0.3.

S3—37 Specification for isomalto-oligosaccharide

For isomalto-oligosaccharide (IMO), the specifications are the following:

(a) chemical structure—IMO is a mixture of glucose oligomers with α 1→6 glycosidic linkages that include isomaltose, panose, isomaltotriose, isomaltopentaose and various branched oligosaccharides;

(b) description—a white crystalline powder or transparent clear pale yellow coloured syrup;

(c) IMO content (dry weight)—not less than 90% (powder) and not less than 75% (syrup);

(d) oligosaccharides—not less than 55% with a degree of polymerisation of 3 or more;

(e) glucose (dry weight)—not more than 5%;

(f) moisture—not more than 5% for the powder, not applicable for syrup;

(g) ash (dry weight)—not more than 0.3%.

S3—38 Specification for L-arginine acetate

For L-arginine acetate, the specifications are the following:

(a) full chemical name—(2S)-2-amino-5-(diaminomethylideneamino) pentanoic acid acetate;

(b) description—white crystalline powder;

(c) chemical formula—C8H18N4O4;

(d) CAS number—71173-62-1;

(e) purity (assay, on dried basis)—98.0-101.0%;

(f) loss on drying—maximum 0.5%;

(g) lead—maximum 0.4 mg/kg;

(h) arsenic—maximum 1 mg/kg;

(i) cadmium—maximum 0.2 mg/kg;

(j) mercury—maximum 0.4 mg/kg.

**S3—39 Specification for steviol glycosides from fermentation**

(1) This specification relates to a steviol glycosides preparation that:

(a) is obtained from fermentation;

(b) is not obtained from the leaves of the *Stevia rebaudiana* Bertoni plant; and

(c) contains steviol glycosides that are only derived from one of the following:

(i) *Saccharomyces cerevisiae* strain CD15407 containing novel genes for the production of steviol glycosides;

(ii) *Saccharomyces cerevisiae* strain Y63348 containing novel genes for the production of steviol glycosides;

(iii) *Yarrowia lipolytica* strain VRM0014 containing novel genes for the production of steviol glycosides.

1. The specifications are the following:

(a) Description—white to light yellow powder, approximately 200 to 300 times sweeter than sucrose;

(b) Assay—not less than 95% of steviol glycosides on the dried basis;

(c) Solubility—freely soluble in water;

(d) pH—between 4.5 and 7.0 (1% solution);

(e) Total ash—not more than 1%;

(f) Loss on drying—not more than 6% (105°C, 2 hour);

(g) Residual solvents—not more than 200 mg/kg methanol and not more than 5000 mg/kg ethanol;

(h) Arsenic—not more than 1 mg/kg;

(i) Lead—not more than 1 mg/kg;

(j) Cadmium—not more than 1 mg/kg;

(k) Mercury—not more than 1 mg/kg;

(l) The final product may be spray dried.

S3—39(A) Specification for rapeseed protein isolate

For rapeseed protein isolate, the specifications are the following:

(a) Composition:

(i) Total protein (%) – no less than 90; and

(ii) Carbohydrates (%) – no more than 7; and

(iii) Fat (%) – no more than 5; and

(iv) Ash (%) – no more than 5; and

(v) Moisture (%) – no more than 7;

(b) Purity:

(i) Glucosinolates (μmol/g) – no more than 1;

(ii) Erucic acid (%) – no more than 0.005;

(iii) Phytates (% w/w) – no more than 1.5;

(c) Metals:

(i) Lead (mg/kg) – no more than 0.5;

(d) Microbiological:

(i) Total plate count (cfu/g) no more than 10,000; and

(ii) *Escherichia coli* (cfu/10g) absent; and

(iii) *Salmonella* spp. (cfu/25g) absent; and

(iv) Yeasts and moulds (cfu/g) less than 100.

S3—40 Specification for 2′-fucosyllactose sourced from *Escherichia coli* K-12

For 2′-fucosyllactose (2′-FL) sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from either *Heliobacter enhydrae,* *Helicobacter pylori* or *Bacteroides vulgatus,* the specifications are the following:

(a) chemical name—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;

(b) chemical formula—C18H32O15;

(c) molecular weight—488.44 g/mol;

(d) CAS number—41263-94-9;

(e) description— white to off-white powder

(f) 2′-FL—not less than 83%;

(g) D-lactose—not more than 10.0%;

(h) L-fucose—not more than 2.0%;

(i) difucosyl-D-lactose—not more than 5.0 %;

(j) 2′-fucosyl-D-lactulose—not more than 1.5 %;

(k) sum of saccharides (2′-FL, D-lactose, L-fucose, difucosyl-D-lactose, 2′-fucosyl-D-lactulose)—not less than 90%;

(l) pH (20°C, 5% solution)—3.0-7.5;

(m) water—not more than 9.0%;

(n) ash, sulphated—not more than 2.0%;

(o) acetic acid—not more than 1.0%;

(p) residual proteins—not more than 0.01%;

(q) microbiological:

1. aerobic mesophilic bacteria total count—not more than 3,000 cfu/g;
2. yeasts—not more than 100 cfu/g;
3. moulds—not more than 100 cfu/g;
4. endotoxins—not more than 10 EU/mg.

S3—41 Specification for lacto-N-neotetraose

For lacto-N-neotetraose (LNnT), the specifications are the following:

(a) chemical name—–β-D-galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose

(b) chemical formula—–C26H45NO21

(c) CAS number—–13007-32-4

(d) description—–white to off white powder or agglomerates

(e) assay (water free) for sum of LNnT, lactose, lacto-N-triose II, and *para*-lacto-N-hexaose—–not less than 95.0%

(f) assay (water free) LNnT—–not less than 92.0%

(g) D-lactose—–not more than 3.0%

(h) lacto-N-triose II—–not more than 3.0%

(i) *para*-lacto-N-neohexaose—–not more than 3.0%

(j) LNnT fructose isomer—–not more than 1.0%

(k) pH (20°C, 5% solution) —–4.0 to 7.0

(l) water—–not more than 9.0%

(m) ash, sulphated—–not more than 1.5%

(n) methanol—–not more than 100 mg/kg

(o) residual proteins—–not more than 0.01%

(p) lead—–not more than 0.1 mg/kg

(q) microbiological:

(i) *Salmonella*—–absent in 25 g

(ii) total plate count—–not more than 500 cfu/g

(iii) *Enterobacteriaceae*—–absent in 10 g

(iv) *Cronobacter (Enterobacter) sakazakii*—–absent in 10 g

(v) *Listeria monocytogenes*—–absent in 25 g

(vi) *Bacillus cereus*—–not more than 50 cfu/g

(vii) yeasts—–not more than 10 cfu/g

(viii) moulds—–not more than 10 cfu/g

(ix) residual endotoxins—–not more than 10 EU/mg

S3—42 Specification for a soy leghemoglobin preparation

***Note*** Subsections S26—3(5) and (7) require a soy leghemoglobin preparation to comply with the specifications set out in this section.

For a soy leghemoglobin preparation, the specifications are the following:

1. soy leghemoglobin protein—maximum 9.0%;
2. soy leghemoglobin protein purity—minimum 65%;
3. appearance—dark red concentrated liquid;
4. solids— maximum 26%;
5. fat—maximum 2.0%;
6. carbohydrate—maximum 6.0%;
7. pH—5-10;
8. moisture—maximum 90%;
9. ash—maximum 4.0%;
10. lead—maximum 0.4 mg/kg;
11. arsenic—maximum 0.05 mg/kg;
12. mercury—maximum 0.05 mg/kg;
13. cadmium—maximum 0.2 mg/kg;
14. microbiological:

(i) *Escherichia coli*—negative to test;

(ii) *Salmonella spp*.—negative to test;

(iii) *Listeria monocytogenes*—negative to test.

S3—43 Specification for sweet osmanthus ear glycolipids

For sweet osmanthus ear glycolipids, the specifications are the following:

(a) CAS number—2205009-17-0;

(b) chemical structure—a mixture of long-chain glycolipids obtained from the fermentation and filtration of the non-GMO *Dacryopinax spathularia* strain MUCL 53181;

(c) description—off-white to ivory powder;

(d) pH—between 5.0 and 7.0 (1% aqueous solution);

(e) water—less than 5%;

(f) protein—less than 3%;

(g) fat—less than 2%;

(h) total glycolipid content on a dry weight basis for the powder—no less than 93%;

(i) lead—not more than 2 mg/kg;

(j) arsenic—not more than 1 mg/kg;

(k) cadmium— not more than 1 mg/kg;

(l) mercury— not more than 1 mg/kg;

(m) microbial limits:

(i) total aerobic microbial count—not more than 100 cfu/g;

(ii) total yeast and mould count—not more than 10 cfu/g;

(iii) coliforms—not more than 3 MPN/g;

(iv) *Escherichia coli*—not more than 3 MPN/g.

**S3—44 Specification for Nicotinamide riboside chloride**

1. In this section,

***Nicotinamide riboside chloride*** (CAS Number 23111-00-4) is the chemical with:

1. the chemical name Pyridinium, 3-(aminocarbonyl)-1-β-D-ribofuranosyl-, chloride (1:1);
2. the formula C11H15N2O5·Cl;
3. the formula weight 290.7 g/mol.
4. For Nicotinamide riboside chloride, the specifications are the following:
5. description—a white to light brown powder;
6. solubility—freely soluble in water;
7. assay—not less than 90.0 w/w % and not more than 103 w/w %;
8. water—not more than 2.0 w/w %;
9. residual solvents:
   1. acetone—not more than 5000 ppm; and
   2. methanol—not more than 1000 ppm; and
   3. acetonitrile—not more than 50 ppm; and
   4. methyl tert-butyl ether—not more than 500 ppm;
10. reaction by-products:
    1. methyl acetate—not more than 1000 ppm; and
    2. acetamide—not more than 27 ppm; and
    3. acetic acid—not more than 5000 ppm;
11. arsenic and heavy metals:
    1. arsenic—not more than 1 ppm; and
    2. mercury—not more than 1 ppm; and
    3. cadmium—not more than 1 ppm; and
    4. lead—not more than 0.5 ppm;
12. microbial limits:
    1. \*SPC—maximum 1000 cfu/g; and
    2. yeast and mould—maximum 100 cfu/g; and
    3. *Escherichia coli*—absent in 10 g

**S3—45                Specification for 2′*-*fucosyllactose sourced from *Escherichia coli*BL21**

          For 2′-fucosyllactose (2′-FL) sourced from *Escherichia coli* BL21, the specifications are the following:

(a)        chemical name—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose

(b)        chemical formula—C18H32O15

(c)        CAS number—41263-94-9

(d)        description—either a white to ivory powder, or a colourless to slightly yellow liquid

(e)        2′-FL—not less than 90.0%

(f)         D-lactose—not more than 5.0%

(g)        L-fucose—not more than 3.0%

(h)        3-fucosyllactose—not more than 5.0%

(i)         difucosyllactose—not more than 5.0%

(j)         fucosyl-galactose—not more than 3.0%

(k)        glucose—not more than 3.0%

(l)         galactose—not more than 3.0%

(m)       water—not more than 9.0% for powder, not applicable for liquid

(n)        solids—45% w/v (± 5%) dry matter in water, not applicable for powder

(o)        ash, sulphated—not more than 0.5%

(p)        residual proteins—not more than 0.01%

(q)        lead—not more than 0.02 mg/kg

(r)         arsenic—not more than 0.2 mg/kg

(s)        cadmium—not more than 0.1 mg/kg

(t)         mercury—not more than 0.5 mg/kg

(u)        microbiological:

(i)         *Salmonella*—absent in 100 g for powder, absent in 200 mL for liquid

(ii)        total plate count—not more than 10000 cfu/g for powder, not more than 5000 cfu/g for liquid

(iii)       coliform/Enterobacteriaceae—absent in 11 g for powder, absent in 22 mL for liquid

(iv)       *Cronobacter sakazakii*—absent in 100 g for powder, absent in 200 mL for liquid

(v)        yeast and mould—not more than 100 cfu/g for powder, not more than 50 cfu/g for liquid

(vi)       aflatoxin M1—not more than 0.025 μg/kg

(vii)      endotoxins—not more than 10 EU/mg

(viii)     GMO detection—not detected.

S3—46 Specification for bovine lactoferrin

1. In this section, bovine lactoferrin is a protein derived from cow’s milk and consisting of a single polypeptide chain of 689 amino acids.

(2) For bovine lactoferrin, the specifications are the following:

(a) description—a pink to reddish brown coloured, free-flowing powder;

(b) protein (N x 6.38)—more than 93.0%;

(c) purity—more than 95.0%;

(d) moisture—less than 4.5 g/100 g;

(e) ash—not more than 1.5 g/100 g;

(f) iron—not more than 35 mg/100 g;

(g) pH (2% solution)—5.2 to 7.2;

(h) solubility transmittance (2% solution, 20°C)—transparent;

(i) lead—not more than 1 mg/kg;

(j) microbial limits:

(i) *Salmonella* spp.—absent in 25 g;

(ii) *Listeria monocytogenes*—–absent in 25 g;

(iii) *Cronobacter* spp.—–absent in 10 g.

**S3—47 Specification for a combination of 2′-fucosyllactose and difucosyllactose sourced from *Escherichia coli K-12***

For a mixture of 2′-fucosyllactose (2′-FL) and difucosyllactose (DFL) sourced from *Escherichia coli K-12* containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*, the specifications are the following:

(a) chemical names:

(i) for 2′-FL––α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;

(ii) for DFL––α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-[α-L-fucopyranosyl-(1→3)]-D-glucose;

(b) chemical formulas:

(i) for 2′-FL––C18H32O15;

(ii) for DFL––C24H42O19;

(c) molecular weights:

(i) for 2′-FL––488.44 g/mol;

(ii) for DFL––634.58 g/mol;

(d) CAS numbers:

(i) for 2′-FL––41263-94-9;

(ii) for DFL––20768-11-0;

(e) description––white, white to off-white, or off-white powder, agglomerates, or powder with agglomerates;

(f) 2′-FL––not less than 75.0% (water free);

(g) DFL––not less than 5.0% (water free);

(h) sum of 2′-FL and DFL––not less than 85.0% (water free);

(i) sum of human identical milk saccharides: 2′-FL, DFL, D-lactose, L-fucose, 3-fucosyllactose ––not less than 92.0% (water free);

(j) D-lactose––not more than 10%;

(k) L-fucose––not more than 1.0%;

(l) 2'-fucosyl-D-lactulose––not more than 2.0%;

(m) pH (20°C, 5% solution)––4.0-6.0;

(n) water––not more than 6.0%;

(o) ash, sulphated––not more than 0.8%;

(p) residual protein––not more than 0.01%;

(q) lead––not more than 0.1 mg/kg;

(r) microbiological:

(i) aerobic mesophilic bacteria total count––not more than 1,000 cfu/g;

(ii) *Enterobacteriaceae*––absent in 10 g;

(iii) yeasts––not more than 100 cfu/g;

(iv) moulds––not more than 100 cfu/g;

(v) residual endotoxins––not more than 10 EU/mg.

**S3—48 Specification for lacto-N-tetraose sourced from *Escherichia coli K-12***

For lacto-N-tetraose (LNT) sourced from *Escherichia coli K-12* containing the gene for beta-1,3-N-acetylglucosaminyltransferase from *Neisseria meningitides* and the gene for beta-1.3-galactosyltransferase from *Helicobacter pylori*, the specifications are the following:

(a) chemical name––β-D-galactopyranosyl-(1→3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucose;

(b) chemical formula––C26H45NO21;

(c) molecular weight––707.63 g/mol;

(d) CAS number––14116-68-8;

(e) description––white, white to off-white, or off-white powder, agglomerates, or powder with agglomerates;

(f) LNT––not less than 70.0% (water free);

(g) sum of human identical milk saccharides: LNT, D-lactose, lacto-N-triose II––not less than 90.0% (water free);

(h) D-lactose––not more than 12.0%;

(i) lacto-N-triose II––not more than 10.0%;

(j) *para*-lacto-N-hexaose-2––not more than 3.5%;

(k) β-D-Galactopyranosyl-(1→3)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-fructose (LNT fructose isomer)––not more than 1.0%;

(l) pH (20°C, 5% solution)––4.0-6.0;

(m) water––not more than 6.0%;

(n) residual protein––not more than 0.01%;

(o) ash, sulphated––not more than 0.5%;

(p) lead––not more than 0.1 mg/kg;

(q) microbiological:

(i) aerobic mesophilic bacteria total count––not more than 1,000 cfu/g;

(ii) *Enterobacteriaceae*––absent in 10 g;

(iii) yeasts––not more than 100 cfu/g;

(iv) moulds––not more than 100 cfu/g;

(v) residual endotoxins––not more than 10 EU/mg.

**S3—49 Specification for 6′-sialyllactose sodium salt sourced from *Escherichia coli K-12***

For 6′-sialyllactose (6′-SL) sodium salt sourced from *Escherichia coli K-12* containing the gene for alpha-2,6-sialyltransferase from *Photobacterium damsela* and CMP-Neu5Ac synthetase, Neu5Ac synthetase, *N-*acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*, the specifications are the following:

(a) chemical name––N-acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt;

(b) chemical formula––C23H38NO19Na;

(c) molecular weight––655.53 g/mol;

(d) CAS number––157574-76-0;

(e) description––white, white to off-white, or off-white powder, agglomerates, or powder with agglomerates;

(f) 6′-SL sodium salt––not less than 90.0% (water free);

(g) sum of human identical milk saccharides: 6′-SL sodium salt, D-lactose, sialic acid––not less than 94.0% (water free);

(h) D-lactose––not more than 5.0%;

(i) sialic acid––not more than 2.0%;

(j) sialyl-lactulose––6’- isomer––not more than 3.0%;

(k) sodium––2.5-4.5%;

(l) chloride––not more than 1.0%;

(m) pH (20°C, 5% solution)––4.5-6.0;

(n) water––not more than 6.0%;

(o) residual protein––not more than 0.01%;

(p) lead––not more than 0.1 mg/kg;

(q) microbiological:

(i) aerobic mesophilic total plate count––not more than 1,000 cfu/g;

(ii) *Enterobacteriaceae*––absent in 10 g;

(iii) yeasts––not more than 100 cfu/g;

(iv) moulds––not more than 100 cfu/g;

(v) residual endotoxins––not more than 10 EU/mg.

**S3—50 Specification for 3′-sialyllactose sodium salt sourced from *Escherichia coli K-12***

For 3′-sialyllactose (3′-SL) sodium salt sourced from *Escherichia coli K-12* containing the gene for alpha-2,3-sialyltransferase from *Neisseria meningitides* and CMP-Neu5Ac synthetase, Neu5ac synthase, *N-*acetylglucosamine-6-phosphatase epimerase from *Campylobacter jejuni*, the specifications are the following:

(a) chemical name––N-acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt;

(b) chemical formula––C23H38NO19Na;

(c) molecular weight––655.53 g/mol;

(d) CAS number––128596-80-5;

(e) description––white, white to off-white, or off-white powder, agglomerates, or powder with agglomerates;

(f) 3′-SL sodium salt––not less than 88.0% (water free);

(g) sum of human identical milk saccharides: 3′-SL sodium salt, D-lactose, sialic acid––not less than 90.0% (water free);

(h) D-lactose––not more than 5.0%;

(i) sialic acid––not more than 1.5%;

(j) sialyl-lactulose-3′-isomer––not more than 5.0%;

(k) sodium––2.5-4.5%;

(l) chloride––not more than 1.0%;

(m) pH (20°C, 5% solution)––4.5-6.0;

(n) water––not more than 8.0%;

(o) residual protein––not more than 0.01%;

(p) lead––not more than 0.1 mg/kg;

(q) microbiological:

(i) aerobic mesophilic total plate count––not more than 1,000 cfu/g;

(ii) *Enterobacteriaceae*––absent in 10 g;

(iii) yeasts––not more than 100 cfu/g;

(iv) moulds––not more than 100 cfu/g;

(v) residual endotoxins––not more than 10 EU/mg.

Amendment History

The Amendment History provides information about each amendment to the Schedule. The information includes commencement or cessation information for relevant amendments.

These amendments are made under section 92 of the *Food Standards Australia New Zealand Act 1991* unless otherwise indicated. Amendments do not have a specific date for cessation unless indicated as such.

**About this compilation**

This is compilation No. 26 of Schedule 3 as in force on **31 May 2024** (up to Amendment No. 228). It includes any commenced amendment affecting the compilation to that date.

Prepared by Food Standards Australia New Zealand on **31 May 2024**.

**Uncommenced amendments or provisions ceasing to have effect.**

To assist stakeholders, the effect of any uncommenced amendments or provisions which will cease to have effect, may be reflected in the Schedule as shaded boxed text with the relevant commencement or cessation date. These amendments will be reflected in a compilation registered on the Federal Register of Legislation including or omitting those amendments and provided in the Amendment History once the date is passed.

The following abbreviations may be used in the table below:

ad = added or inserted am = amended

C[x] = Compilation No. x ed = editorial change

exp = expired or ceased to have effect rep = repealed

rs = repealed and substituted

**Schedule 3** was published in the Food Standards Gazette No. FSC96 on 10 April 2015 as part of Amendment 154 (F2015L00493 –- 2 April 2015) and has since been amended as follows:

| Section affected | A’ment No. | FRL registration  Gazette | Commencement  (Cessation) | How affected | Description of amendment |
| --- | --- | --- | --- | --- | --- |
| S3—2(1) | 168 | F2017L00414  11 April 2017  FSC110  13 April 2017 | 13 April 2017 | am | Update list of references. |
| S3—2(1)(b) | 172 | F2017L01142  6 Sept 2017  FSC114  7 Sept 2017 | 7 Sept 2017 | am | Update list of references. |
| table to S3—2(2) | 163 | F2016L00787  12 May 2016  FSC105  19 May 2016 | 19 May 2016 | ad | Provision for *Salmonella* phage preparation (S16 and FO1a). |
| table to S3—2(2) | 164 | F2016L01204  21 July 2016  FSC106  21 July 2016 | 21 July 2016 | am | Reference to agarose ion exchange resin replaced with amine agarose ion exchange resin. |
| table to S3—2(2) | 164 | F2016L01204  21 July 2016  FSC106  21 July 2016 | 21 July 2016 | ad | Entry for sulphonate agarose ion exchange resin. |
| table to S3—2(2) | 168 | F2017L00409  10 April 2017  FSC110  13 April 2017 | 13 April 2017 | ad | Entry for steviol glycosides from *Stevia rebaudiana* Bertoni. |
| table to S3—2(2) | 170 | F2017L00586  23 May 2017  FSC112  25 May 2017 | 25 May 2017 | ad | Entry for oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695). |
| table to S3—2(2) | 171 | F2017L00915  11 July 2017  FSC113  13 July 2017 | 13 July 2017 | ad | Entry for isomalto-oligosaccharide. |
| table to S3—2(2) | 173 | F2017L01176  13 Sept 2017  FSANZ Notification Circular 24-17 (Urgent Proposal)  14 Sept 2017 | 14 Sept 2017 | ad | Entry for L-arginine acetate. |
| S3—3 | 168 | F2017L00414  11 April 2017  FSC110  13 April 2017 | 13 April 2017 | am | Update reference in paragraph (j). |
| S3—3 | 172 | F2017L01142  6 Sept 2017  FSC114  7 Sept 2017 | 7 Sept 2017 | am | Update reference in paragraph (j). |
| S3—6 | 164 | F2016L01204  21 July 2016  FSC106  21 July 2016 | 21 July 2016 | am | Reference to agarose ion exchange resin replaced with amine agarose ion exchange resin. |
| S3—6(2), (3) | 168 | F2017L00414  11 April 2017  FSC110  13 April 2017 | 13 April 2017 | rs | Specification updated to be consistent with a more recent specification. |
| S3—9(2), (3) | 168 | F2017L00414  11 April 2017  FSC110  13 April 2017 | 13 April 2017 | rs | Specification updated to be consistent with a more recent specification. |
| S3—11(2), (3) | 168 | F2017L00414  11 April 2017  FSC110  13 April 2017 | 13 April 2017 | rs | Specification updated to be consistent with a more recent specification. |
| S3—25(2), (3) | 168 | F2017L00414  11 April 2017  FSC110  13 April 2017 | 13 April 2017 | rs | Specification updated to be consistent with a more recent specification. |
| S3—27(2) | 157 | F2015L01374  1 Sept 2015  FSC99  3 Sept 2015 | 1 March 2016 | am | Correction of typographical error in subparagraph (b)(ii). |
| S3—27(2) | 161 | F2016L00120  18 Feb 2016  FSC103  22 Feb 2016 | 1 March 2016 | am | Correction to typographical error in units for total aerobic count. |
| S3—31 | 160 | F2016L00041  12 Jan 2016  FSC102  14 Jan 2016 | 1 March 2016 | ad | Specification for rebaudioside M. |
| S3—32 | 160 | F2016L00041  12 Jan 2016  FSC102  14 Jan 2016 | 1 March 2016 | ad | Specification for steviol glycoside mixture including rebaudioside M. |
| S3—33 | 163 | F2016L00787  12 May 2016  FSC105  19 May 2016 | 19 May 2016 | ad | Specification for *Salmonella* phage preparation (S16 and FO1a). |
| S3—34 | 164 | F2016L01204  21 July 2016  FSC106  21 July 2016 | 21 July 2016 | ad | Specification for sulphonate agarose ion exchange resin. |
| S3—35 | 168 | F2017L00409  10 April 2017  FSC110  13 April 2017 | 13 April 2017 | ad | Specification for steviol glycosides from *Stevia rebaudiana* Bertoni. |
| S3—36 | 170 | F2017L00586  23 May 2017  FSC112  25 May 2017 | 25 May 2017 | ad | Specification for oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695). |
| S3—37 | 171 | F2017L00915  11 July 2017  FSC113  13 July 2017 | 13 July 2017 | ad | Specification for isomalto-oligosaccharide. |
| S3—38 | 173 | F2017L01176  13 Sept 2017  FSANZ Notification Circular 24-17 (Urgent Proposal)  14 Sept 2017 | 14 Sept 2017 | ad | Specification for L-arginine acetate. |
| S3—2(1)(b) | 182 | F2018L01594  23 Nov 2018  FSC123  29 Nov 2018 | 29 November 2018 | am | Update international references |
| S3—2(1)(c) | 182 | F2018L01594  23 Nov 2018  FSC123  29 Nov 2018 | 29 November 2018 | am | Update international references |
| S3—28(2)(a) | 182 | F2018L01594  23 Nov 2018  FSC123  29 Nov 2018 | 29 November 2018 | am | Correction typographical error |
| S3—35(2) | 183 | F2019L00039  11 Jan 2019  FSC124  23 Jan 2019 | 23 January 2019 | am | Specification for *Stevia rebaudiana* Bertoni plant. |
| S3—2(2) | 187 | F2019L01135  28 Aug 2019  FSC128  5 Sept 2019 | 5 September 2019 | ad | Specification for steviol glycosides from fermentation; specification for Rebaudioside MD |
| S3—35(2)(b) | 187 | F2019L01136  28 Aug 2019  FSC128  5 Sept 2019 | 5 September 2019 | am | Specification for Rebaudioside D |
| S3—35(1) | 191 | F2020L00153  20 Feb 2020  FSC132  26 Feb 2020 | 26 February 2020 | am | Specification for steviol glycosides obtained from the leaves of the *Stevia rebaudiana* Bertoni plant |
| S3—35(2)(d) | 191 | F2020L00153  20 Feb 2020  FSC132  26 Feb 2020 | 26 February 2020 | ad | Specification to produce one or more prescribed rebaudiosides by enzymatic conversion of purified stevia leaf extract |
| S3—35(4)(a) | 191 | F2020L00153  20 Feb 2020  FSC132  26 Feb 2020 | 26 February 2020 | am | Specification of description |
| S3—35(2)(d) | 193 | F2020L00937  23 July 2020  FSC134  28 July 2020 | 28 July 2020 | am | Specification to produce rebaudioside E from enzymatic conversion of purified stevia leaf extract |
| S3—2(2) | 198 | F2021L00332  25 March 2021  FSC 139  26 March 2021 | 26 March 2021 | ad | Specification for 2*′-*O-fucosyllactose and lacto-N-neotetraose |
| S3—42 | 198 | F2021L00326  25 March 2021  FSC 139  26 March 2021 | 26 March 2021 | ad | Specification for a soy leghemoglobin preparation |
| S3—2(2) | 198 | F2021L00327  25 March 2021  FSC 139  26 March 2021 | 26 March 2021 | ad | Specification for Sweet osmanthus ear glycolipids |
| S3—2(1)(b) | 200 | F2021L00684  2 June 2021  FSC 141  3 June 2021 | 3 June 2021 | am | Update international references (xii), (xiii) and (xiv) |
| S3—2(1)(c) | 200 | F2021L00684  2 June 2021  FSC 141  3 June 2021 | 3 June 2021 | rs | Update international references |
| S3—2(2) | 200 | F2021L00684  2 June 2021  FSC 141  3 June 2021 | 3 June 2021 | am | Entries for resistant maltoextrins, *Salmonella* phage preparation (S16 and FO1a), steviol glycosides from fermentation, steviol glycosides produced by enzymatic conversion |
| S3—3(b) | 200 | F2021L00684  2 June 2021  FSC 141  3 June 2021 | 3 June 2021 | rs | Update international references |
| S3—3(i) | 200 | F2021L00684  2 June 2021  FSC 141  3 June 2021 | 3 June 2021 | am | Update international references |
| S3—31 | 200 | F2021L00684  2 June 2021  FSC 141  3 June 2021 | 3 June 2021 | rep | Repeal section S3—31 |
| S3—32 | 200 | F2021L00684  2 June 2021  FSC 141  3 June 2021 | 3 June 2021 | rep | Repeal section S3—32 |
| S3—35 | 200 | F2021L00684  2 June 2021  FSC 141  3 June 2021 | 3 June 2021 | am | Specification for steviol glycosides produced by enzymatic conversion |
| S3—35(2) | 200 | F2021L00684  2 June 2021  FSC 141  3 June 2021 | 3 June 2021 | rs | Specification for steviol glycosides produced by enzymatic conversion |
| table to S3—2(2) | 198 | F2021L00324  24 March 2021  FSC 139  26 March 2021 | 30 June 2021 | ad  ed C16 | Entry for rapeseed protein isolate  Editorial change to update a provision cross-reference |
| S3—39(A) | 198 | F2021L00324  24 March 2021  FSC 139  26 March 2021 | 30 June 2021 | ad  ed C16 | Specification for rapeseed protein isolate  Section S3—40 (first occurring) was renumbered as section S3—39(A) by editorial change |
| table to S3 —39(2) | 201 | F2021L00985  14 Jul 2021  FSC 142  22 July 2021 | 22 July 2021 | Ad | Entry for Rebaudioside M |
| table to S3 —39(2) | 203 | F2021L01431  14 October 2021  FSC 144  21 October 2021 | 21 October 2021 | Ad | Entry for Nicotinamide riboside chloride |
| S3—44 | 203 | F2021L01431  14 October 2021  FSC 144  21 October 2021 | 21 October 2021 | Ad | Specification for Nicotinamide riboside chloride |
| S3—39(1) and (2) | 204 | F2021L01690  2 Dec 2021  FSC 145  6 Dec 2021 | 6 December 2021 | am | Specification for steviol glycoside preparation |
| table to S3—2(2) | 205 | F2022L00038  18 Jan 2022  FSC 146  20 Jan 22 | 20 January 2022 | am | 2*′-*O-fucosyllactose to 2*′-*fucosyllactose sourced from *Escherichia coli*K-12 |
| table to S3—2(2) | 205 | F2022L00038  18 Jan 2022  FSC 146  20 Jan 22 | 20 January 2022 | Ad | 2*′-*fucosyllactose sourced from *Escherichia coli*BL21 |
| S3—40 | 205 | F2022L00038  18 Jan 2022  FSC 146  20 Jan 22 | 20 January 2022 | am | 2*′-*O-fucosyllactose to 2*′-*fucosyllactose sourced from *Escherichia coli*K-12 |
| S3—45 | 205 | F2022L00038  18 Jan 2022  FSC 146  20 Jan 22 | 20 January 2022 | Ad | Specification for 2*′-*fucosyllactose sourced from *Escherichia coli*BL21 |
| S3-2(2) | 209 | F2022L00964  11 July 2022  FSC 149  15 July 2022 | 15 July 2022 | am | Entry for 2′-fucosyllactose sourced from *Escherichia coli* K-12) |
| S3—40 | 209 | F2022L00964  11 July 2022  FSC 149  15 July 2022 | 15 July 2022 | am | Specification for 2’--fucosyllactose sourced from *Escherichia coli* K-12  containing the gene for alpha-1,2-fucosyltransferase from either *Helicobacter pylor*i or *Bacteroides vulgatus* |
| table to S3—2(2) | 217 | F2023L00452  19 April 2023  FSC157  21 April 2023 | 21 April 2023 | ad | Entry for bovine lactoferrin |
| S3—46 | 217 | F2023L00452  19 April 2023  FSC157  21 April 2023 | 21 April 2023 | ad | Specification for bovine lactoferrin |
| S3—2(1) and S3-3 | 220 | F2023L01004  11 July 2023  FSC160  19 July 2023 | 19 July 2023 | rs | Repeal and substitute updated references |
| S3—14, 18, 26, 27, 39, 39(A), 41, 42, 43, 44 | 220 | F2023L01004  11 July 2023  FSC160  19 July 2023 | 19 July 2023 | rs | Repeal and substitute formatting (capitialisations, italics, acronym, bullets and numbering) |
| S3—2(2) | 223 | F2023L01561  27 November 2023  FSC163  30 November 2023 | 30 November 2023 | ad | Insert entries for each of the following,  2′-fucosyllactose and difucosyllactose sourced from Escherichia coli K-12,  lacto-N-tetraose sourced from Escherichia coli K-12,  6′-sialyllactose sodium salt sourced from Escherichia coli K-12,  3′-sialyllactose sodium salt sourced from Escherichia coli K-12 |
| S3 | 223 | F2023L01561  27 November 2023  FSC163  30 November 2023 | 30 November 2023 | ad | Insert specifications after S3-46 for each of the following,  2′-fucosyllactose and difucosyllactose sourced from Escherichia coli K-12,  lacto-N-tetraose sourced from Escherichia coli K-12,  6′-sialyllactose sodium salt sourced from Escherichia coli K-12,  3′-sialyllactose sodium salt sourced from Escherichia coli K-12 |
| S3-35(2) | 225 | F2024L00079  17 January 2024  FSC165  19 January 2024 | 19 January 2024 | rs | Omit and substitute the S3-35 Specification for steviol glycosides produced by enzymatic conversion |
| S3-2(2), 40 | 228 | F2024L00587  29 May 2024  FSC168  31 May 2024 | 31 May 2024 | rs | Omit and substitute entry for 2′-fucosyllactose to include *Heliobacter enhydrae* |