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Specifications, FAO JECFA Monographs 1 (2005), Food and Agriculture Organisation of the United Nations, Rome, as superseded by specifications published in any of the following: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

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Substance	***Provision***
Bovine lactoferrin	Section S3—46
Bovine milk fat globule membrane-enriched whey protein concentrate	section S3—53
bromo-chloro-dimethylhydantoin	section S3—8
carboxymethyl cellulose ion exchange resin	section S3—9
cell-cultured quail	section S3—54
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 *Corynebacterium glutamicum*	section S3—51
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
2′-fucosyllactose sourced from *Escherichia coli* W	section S3—54(A)
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	section S3—16
2-Methyloxolane	section S3—52
mushroom (*Agaricus bisporus*) chitosan	section S3—55
Nicotinamide riboside chloride	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

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Substance	*Provision*
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	section S3—34
Sweet osmanthus ear glycolipids	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

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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 $[\alpha]^{20}$ 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.

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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 $C_5H_6BrClN_2O_2$; 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 $C_5H_6Br_2N_2O_2$.

(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:

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(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:

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(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—$C_9\ H_{11}N_2\ O_9PNa_2$;

(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—$C_{10}H_{14}N_5O_7P$;

(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—$C_9H_{14}N_3O_8P$;

(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;

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(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 H_2O for IMP: is colourless and shows only a trace of turbidity; and

(ii) 100 mg/10 mL H_2O 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

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(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;

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(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/cm^3 (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.

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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

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(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

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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 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 an 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;

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(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 an 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 enzymes:

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

(ii) UDP-glucosyltransferase sourced from *Escherichia coli* K-12; and

(iii) 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 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;

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(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—$C_8H_{18}N_4O_4$;

(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.

(2) 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;

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(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—$C_{18}H_{32}O_{15}$;

(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;

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(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:

(i) aerobic mesophilic bacteria total count—not more than 3,000 cfu/g;

(ii) yeasts—not more than 100 cfu/g;

(iii) moulds—not more than 100 cfu/g;

(iv) 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——$C_{26}H_{45}NO_{21}$

(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:

(a) soy leghemoglobin protein—maximum 9.0%;

(b) soy leghemoglobin protein purity—minimum 65%;

(c) appearance—dark red concentrated liquid;

(d) solids— maximum 26%;

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(e) fat—maximum 2.0%;
(f) carbohydrate—maximum 6.0%;
(g) pH—5-10;
(h) moisture—maximum 90%;
(i) ash—maximum 4.0%;
(j) lead—maximum 0.4 mg/kg;
(k) arsenic—maximum 0.05 mg/kg;
(l) mercury—maximum 0.05 mg/kg;
(m) cadmium—maximum 0.2 mg/kg;
(n) 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:

(a) the chemical name Pyridinium, 3-(aminocarbonyl)-1-β-D-ribofuranosyl-, chloride (1:1);
(b) the formula $C_{11}H_{15}N_2O_5 \cdot Cl$;
(c) the formula weight 290.7 g/mol.

(2) For Nicotinamide riboside chloride, the specifications are the following:

(a) description—a white to light brown powder;
(b) solubility—freely soluble in water;
(c) assay—not less than 90.0 w/w % and not more than 103 w/w %;

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(d) water—not more than 2.0 w/w %;

(e) residual solvents:

(i) acetone—not more than 5000 ppm; and

(ii) methanol—not more than 1000 ppm; and

(iii) acetonitrile—not more than 50 ppm; and

(iv) methyl tert-butyl ether—not more than 500 ppm;

(f) reaction by-products:

(i) methyl acetate—not more than 1000 ppm; and

(ii) acetamide—not more than 27 ppm; and

(iii) acetic acid—not more than 5000 ppm;

(g) arsenic and heavy metals:

(i) arsenic—not more than 1 ppm; and

(ii) mercury—not more than 1 ppm; and

(iii) cadmium—not more than 1 ppm; and

(iv) lead—not more than 0.5 ppm;

(h) microbial limits:

(i) *SPC—maximum 1000 cfu/g; and

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

(iii) *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—$C_{18}H_{32}O_{15}$

(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

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(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—$C_{18}H_{32}O_{15}$;

(ii) for DFL—$C_{24}H_{42}O_{19}$;

(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);

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(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—$C_{26}H_{45}NO_{21}$;

(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;

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(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—$C_{23}H_{38}NO_{19}Na$;

(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—$C_{23}H_{38}NO_{19}Na$;

(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);

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(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.

S3—51 Specification 2′-fucosyllactose sourced from *Corynebacterium glutamicum*

For 2′-fucosyllactose (2′-FL) sourced from *Corynebacterium glutamicum*, the specifications are the following:

(a) chemical name—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;
(b) chemical formula—$C_{18}H_{32}O_{15;}$
(c) molecular weight—488.44 g/mol;
(d) CAS number—41263-94-9;
(e) description—white to off-white/ivory powder;
(f) 2′-FL—not less than 94% (water free);
(g) D-lactose—not more than 3.0% (water free);
(h) L-fucose—not more than 3.0% (water free);
(i) 3-fucosyllactose—not more than 3.0% (water free);
(j) difucosyl-D-lactose—not more than 2.0% (water free);
(k) glucose—not more than 3.0% (water free);
(l) galactose—not more than 3.0% (water free);
(m) water—not more than 9.0%;
(n) ash, sulphated—not more than 0.5%;
(o) ethanol—not more than 1,000 mg/kg (for crystallised product from solvent only);
(p) residual proteins—not more than 0.005%;
(q) lead—not more than 0.02 mg/kg;
(r) arsenic—not more than 0.03 mg/kg;
(s) cadmium—not more than 0.01 mg/kg;
(t) mercury—not more than 0.05 mg/kg;
(u) microbiological:
  (i) total plate count—not more than 500 cfu/g;
  (ii) coliforms—not more than 10 cfu/g;
  (iii) yeasts and moulds—not more than 100 cfu/g;
  (iv) aflatoxin M1—not more than 0.025 µg/kg;
  (v) residual endotoxins—not more than 10 EU/mg

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S3—52 Specification for 2-Methyloxolane

For 2-Methyloxolane, the specifications are the following:

(a) chemical name—2-Methyloxolane;

(b) chemical formula—$C_5H_{10}O$;

(c) CAS Number—96-47-9;

(d) purity (on a dry weight basis)—not less than 99.9%;

(e) ethanol (on a dry weight basis)—not more than 450 mg/kg;

(f) furan (on a dry weight basis)—not more than 50 mg/kg;

(g) 2-methylfuran (on a dry weight basis)—not more than 500 mg/kg.

S3—53 Specification for bovine milk fat globule membrane-enriched whey protein concentrate

(1) In this section, bovine milk fat globule membrane-enriched whey protein concentrate is a preparation of cow's milk consisting of lipids and proteins.

(2) For bovine milk fat globule membrane-enriched whey protein concentrate, the specifications are the following:

(a) description—off white powder;

(b) total protein—not less than 69.0% and not more than 76.0%;

(c) lactose—not more than 2.0%;

(d) fat—not less than 16.0% and not more than 22.0%;

(e) phospholipids—not less than 6.0% and not more than 10.0%;

(f) sphingomyelin—not less than 1.3% and not more than 2.3%;

(g) ash—not more than 3.0%;

(h) moisture—not more than 5.0%;

(i) arsenic—not more than 0.2 mg/kg;

(j) cadmium—not more than 0.1 mg/kg;

(k) lead—not more than 0.05 mg/kg;

(l) mercury—not more than 0.02 mg/kg;

(m) microbial limits:

(i) total plate count (30°C)—not more than 10000 cfu/g;

(ii) total plate count (55°C)—not more than 1000 cfu/g;

(iii) *Bacillus cereus*—not more than 50 cfu/g;

(iv) Sulphite-reducing *Clostridia*—not more than 10 cfu/g;

(v) *Enterobacteriaceae*—not more than 10 cfu/g;

(vi) Coagulase-positive *staphylococci*—absent in 1 g;

(vii) Yeast and moulds—not more than 10 cfu/g.

S3—54(A) Specification for 2′-fucosyllactose sourced from *Escherichia coli* W

For 2′-fucosyllactose (2′-FL) sourced from *Escherichia coli* W containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter mustelae*, the specifications are the following:

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

(b) chemical formula—$C_{18}H_{32}O_{15}$;

(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 82% (water free);

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(g) D-lactose—not more than 5.0% (water free);
(h) L-fucose—not more than 1.0% (water free);
(i) fucosylgalactose—not more than 3.0% (water free);
(j) difucosyllactose (difucosyl-d-lactose)—not more than 3.0% (water free);
(k) glucose and galactose—not more than 1.0% (water free);
(l) water—not more than 9.0%;
(m) ash, sulphated—not more than 0.5%;
(n) residual proteins—not more than 0.01%;
(o) lead—not more than 0.1 mg/kg;
(p) arsenic—not more than 0.1 mg/kg;
(q) cadmium—not more than 0.1 mg/kg;
(r) mercury—not more than 0.1 mg/kg;
(s) microbiological:
  (i) aerobic mesophilic bacteria total count—not more than 1,000 cfu/g;
  (ii) yeasts and moulds—not more than 100 cfu/g;
  (iii) *Enterobacteriaceae*—absent in 10 g;
  (iv) residual endotoxins—not more than 10 EU/g.

S3—54 Specification for cell-cultured quail

(1) For the purposes of this specification, ***cell-cultured quail*** means quail cells obtained from culturing embryonic fibroblast cells (cell line 221523-Fib-Quail) sourced from *Coturnix japonica.*

(2) For cell-cultured quail, the specifications are the following:

(a) protein—not less than 4%;
(b) moisture—not less than 80%;
(c) ash—not more than 1.5%;
(d) fat—not less than 0.5% and not more than 3.0%;
(e) carbohydrates—not more than 1%.

S3—55 Specification for mushroom (*Agaricus bisporus*) chitosan

For mushroom (*Agaricus bisporus*) chitosan, the specifications are the following:

(a) chemical structure—a natural co-polymer and comprises a chitin moiety (N-acetyl-d-glucosamine units) covalently linked to a beta-glucans moiety (glucose units);
(b) source–*Agaricus bisporus*.
(c) description—white to beige, odourless and flavourless powder, almost completely insoluble in aqueous or organic medium;
(d) average molecular weight—10 to 400 kDa;
(e) degree of deacetylation—70.0 to 95.0 mol%;
(f) water—less than 5.0%;
(g) total chitosan content on a dry weight basis—not less than 95.0%;
(h) total beta-glucan content on a dry weight basis—not more than 5.0%.

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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. 32 of Schedule 3 as in force on **16 September 2025** (up to Amendment No. 244). It includes any commenced amendment affecting the compilation to that date.

Prepared by Food Standards Australia New Zealand on **16 September 2025**.

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
C[x] = Compilation No. x
exp = expired or ceased to have effect
rs = repealed and substituted
am = amended
ed = editorial change
rep = repealed

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).

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Section affected	A'ment No.	FRL registration Gazette	Commencement (Cessation)	How affected	Description of amendment
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).

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Section affected	A'ment No.	FRL registration Gazette	Commencement (Cessation)	How affected	Description of amendment
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

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Section affected	A'ment No.	FRL registration Gazette	Commencement (Cessation)	How affected	Description of amendment
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

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Section affected	A'ment No.	FRL registration Gazette	Commencement (Cessation)	How affected	Description of amendment
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 Nov 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 Nov 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*
S3-2(2)	230	F2024L00989 12 August 2024 FSC 170 15 August 2024	15 August 2024	ad	Insert into table 2′-fucosyllactose sourced from *Corynebacterium glutamicum*

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Section affected	A'ment No.	FRL registration Gazette	Commencement (Cessation)	How affected	Description of amendment
S3-51	230	F2024L00989 12 August 2024 FSC 170 15 August 2024	15 August 2024	ad	Insert Specification for 2′-fucosyllactose sourced from *Corynebacterium glutamicum*
S3—2(2)	234	F2025L00012 8 January 2025 FSC 174 13 January 2025	13 January 2025	ad	Insert 2-Methyloxolane into S3—2(2) table.
S3—52	234	F2025L00012 8 January 2025 FSC 174 13 January 2025	13 January 2025	ad	Insert Section S3—52, Specification for 2-Methyloxolane
S3—2(2)	239	F2025L00689 18 June 2025 FSC 179 18 June 2025	18 June 2025	am	Insert cell-cultured quail into S3—2(2) table
S3—54	239	F2025L00689 18 June 2025 FSC 179 18 June 2025	18 June 2025	ad ed C29	Insert Section S3—54, Specification for cell-cultured quail Section S3—54 was inserted after section S3—52
S3—2(2)	240	F2025L00857 18 July 2025 FSC 180 22 July 2025	22 July 2025	ad	Insert Bovine milk fat globule membrane-enriched whey protein concentrate into S3—2(2) table
S3—53	240	F2025L00857 18 July 2025 FSC 180 22 July 2025	22 July 2025	ad	Insert Section S3—53, Specification for bovine milk fat globule membrane-enriched whey protein concentrate
S3—2(2)	240	F2025L00858 18 July 2025 FSC 180 22 July 2025	22 July 2025	ad ed C30	Insert 2′-fucosyllactose sourced from *Escherichia coli* W into S3—2(2) table Editorial change to update a provision cross-reference
S3—54(A)	240	F2025L00858 18 July 2025 FSC 180 22 July 2025	22 July 2025	ad ed C30	Insert Section S3—54(A), Specification for 2′-fucosyllactose sourced from *Escherichia coli* W Editorial change to renumber section S3—54 (first occurring) as section S3—54(A)
S3—35(2)	243	F2025L00988 26 August 2025 FSC 183 2 Sept 2025	2 September 2025	rs	Replace *protein engineered enzymes* with *enzymes*
S3—35(2)	243	F2025L00988 26 August 2025 FSC 183 2 Sept 2025	2 September 2025	rs	Replace *a protein engineered enzyme* with *an enzyme*
S3—2(2)	244	F2025L01081 11 Sep 2025 FSC 184 16 Sep 2025	16 September 2025	am	Insert *mushroom (Agaricus bisporus) chitosan* into S3—2(2) table
S3—55	244	F2025L01081 11 Sep 2025 FSC 184 16 Sep 2025	16 September 2025	ad	Insert Section S3—55 *Specification for mushroom (Agaricus bisporus) chitosan*

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