

## **SFA LIST OF APPROVED NOVEL FOODS**

*(As at 17 March 2026)*

This document provides a list of novel foods that Singapore Food Agency (SFA) has approved for the import and sale in Singapore. For each approved novel food, the following information are listed:

- a) SFA's decision date,
- b) Name of novel food,
- c) Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable
- d) Brief description of genetic modifications made to the production strain, if applicable
- e) Description of growth media and inputs used
- f) Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)
- g) Specifications of the novel food

## LIST OF APPROVED NOVEL FOODS

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## 1. *Chlamydomonas reinhardtii* (green) strain THN6 algae biomass

<b>Name of the novel food</b>	<i>Chlamydomonas reinhardtii</i> (green) (strain THN 6)
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	21 May 2019
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Chlamydomonas reinhardtii</i> strain THN 6
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A.
<b>Description of growth media and inputs used</b>	Food grade growth substrates that meet acceptable standards for use in food processing
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	<p>Manufacturing process of <i>Chlamydomonas reinhardtii</i> involves fermentation of pure <i>C. reinhardtii</i> THN6 under aseptic conditions in a controlled environment, centrifugation to remove water, and spray-drying.</p> <p>Critical control point includes testing all batches of <i>C. reinhardtii</i> THN6 culture for presence of pathogens, yeast and mold as well as chemical contaminants before seed fermentation and on the final product before product release.</p>
<b>Specifications</b>	See table copied below

<b>Parameter</b>	<b>Specification</b>
Appearance	Green powder
Moisture	≤ 10%
Protein (crude)	30–70%
Fat (crude)	≤ 10%
Fiber (analyzed using acid detergent)	1–25%
Ash	≤ 5%
Chlorophyll	≤ 25%
Arsenic	≤ 0.2 ppm
Cadmium	≤ 0.2 ppm
Lead	≤ 0.2 ppm
Mercury	≤ 0.2 ppm
Total Aerobic Microbial	≤ 1000 CFU/g
Total Yeast & Mold	≤ 1000 CFU/g
Total Coliforms	≤ 100 CFU/g
<i>E. coli</i>	Negative (absent/1 g)
<i>Salmonella</i>	Negative (absent/25 g)
<i>Staphylococcus aureus</i>	Negative (absent/1 g)

## 2. Cultured chicken cells derived from UMNSAH/DF1 cells

<b>Name of the novel food</b>	Cultured chicken cells
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	26 November 2020
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	Cultured chicken cells (derived from UMNSAH/DF1 (ATCC CRL12203))
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A.
<b>Description of growth media and inputs used</b>	Growth media consisting of a basal media (DMEM/F12) comprising amino acids, vitamins, inorganic salts and other components supplemented with FBS as described in the applicant's submission
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	The manufacturing process is conducted under aseptic and controlled conditions, and involves cell immortalization in culture media, cell growth in culture media, harvesting of cells, concentration of cells using centrifugation, washing steps, and frozen storage at -20°C. Safety and purity tests are conducted throughout the manufacturing process to ensure that there is no contamination from viruses, pathogens and chemical substances.
<b>Specifications</b>	See table copied below

<b>Parameter</b>	<b>Specification</b>
Moisture content	85 – 95 %
Protein content	5 – 10 %
Fat content	0.5 – 2 %
Ash content	0 – 2 %
Carbohydrate content	0 – 2 %
Arsenic	< 1 ppm
Lead	< 2 ppm
Mercury	< 0.05 ppm
Cadmium	< 0.2 ppm
Chromium	< 2 ppm
Aerobic plate count	< 10,000 CFU/g (Target) < 30,000 CFU/g (Rejection limit)
Coliforms	< 24 MPN/g or < 100 CFU/g
<i>Escherichia coli</i>	< 3 MPN/g or < 10 CFU/g
Enterococci	< 100 CFU/g
Yeast	< 100 CFU/g
Mold	< 100 CFU/g
Salmonella	Not detected/25g

### 3. Mycelial biomass derived from *Fusarium* strain *flavolapis*

<b>Name of the novel food</b>	<i>Fusarium</i> strain <i>flavolapis</i> mycelial biomass in food
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	6 Aug 2021
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Fusarium</i> strain <i>flavolapis</i>
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A.
<b>Description of growth media and inputs used</b>	Food grade growth substrates that meet acceptable standards for use in food processing
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	<p>Manufacturing of <i>Fusarium flavolapis</i> involves fermentation of pure culture of <i>F.</i> strain <i>flavolapis</i> under controlled conditions until the mycelial biomass is formed. The biomass is harvested, and the fungal cells are inactivated by heat treatment. Water is removed by mechanical pressing to obtain the final <i>Fusarium</i> protein product, and the product may be further dried and ground to produce flour.</p> <p>Critical control points include pH control, heat inactivation and freezing are in place throughout the manufacturing process and all batches are tested for microorganisms and contaminants using internationally recognized testing methods.</p>
<b>Specifications</b>	See table copied below

<b>Parameter</b>	<b>Specification</b>
<b>Water content</b>	70 - 80%
<b>Protein</b>	> 45% (Essential amino acids make up 20 - 24% of the total dry weight and the total amino acids make up 40 - 50% of the total dry weight. Branched chain amino acids, leucine, isoleucine, and valine make up 10 - 15% of the dry weight and 20 - 25% of the total protein content)
Total sugars	< 0.5%
Glycerol	< 4.0%
<b>Total dietary fiber</b>	25 - 35%
Insoluble	None
Soluble	None
<b>Non-Fiber Carbohydrate</b>	5 - 15%
<b>Total fat</b>	4 - 10%
Saturated	0 - 3%
Monounsaturated	0 - 3%
Polyunsaturated	2 - 6%
Trans	< 1%
<b>Vitamins</b> a) Vitamin B1 (Thiamine) b) Vitamin B5 (Pantothenic acid) c) Vitamin B6 d) Vitamin B12 e) Vitamin C f) Vitamin D g) Vitamin E	a) 0.3 mg/100 g b) 0.9 mg/100 g c) 0.1 mg/100 g d) < 0.440 µg/100 g e) < 0.440 µg/100 g f) < 4 IU/ 100g g) < 0.2 mg/100 g
<b>Minerals</b> a) Potassium b) Calcium c) Sodium d) Chloride e) Magnesium f) Phosphorus g) Iron	a) 5,000 - 6,500 ppm b) 1,000 - 2,000 ppm c) 25 - 300 ppm d) < 600 ppm e) 300 - 450 ppm f) 7,000 - 9,000 ppm g) 15 - 40 ppm
<b>Ash</b>	< 5%
<b>RNA</b>	< 2.0%

**4. Protein Powder from *Xanthobacter* sp. SOF1**

<b>Name of the novel food</b>	Protein Powder from <i>Xanthobacter</i>
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	29 September 2022
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Xanthobacter</i> sp. SOF1
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A
<b>Description of growth media and inputs used</b>	Food grade growth substrates, nitrogen sources that meet acceptable standards for use in food processing
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	<p>Manufacturing process of “Solein” involves fermentation of pure culture of <i>Xanthobacter</i> sp. SOF1 in growth substrates in the bioreactor, heat deactivation of production organism, centrifugation and filtration to separate the biomass and water.</p> <p>pH is actively monitored during the growth phase of the process. The heat treatment step is designated as a critical control point monitoring that sufficient holding time and temperature are reached in order to kill the organism.</p> <p>Additional quality assurance measures include in-house microbial plating and laboratory-based analytical testing. All batches are tested for the presence of total aerobic bacteria, pathogenic bacteria, mold, and yeast.</p>
<b>Specifications</b>	See table copied below

<b>Parameter</b>	<b>Specification</b>
Protein (% Dry weight)	≥ 73%
Total dietary fiber (% Dry weight)	≤ 32.0%
Carbohydrates (% by computation or analysis)	≤ 10.0%
Total fat (% Dry weight)	≤ 11.5 %
Saturated	≤ 3.2%
Trans	≤ 0.5%
Ash (% Dry weight)	≤ 6.3%
Moisture	≤ 8.0%
Iron	≤ 1500 mg/kg
Nickel	≤ 4 mg/kg
Arsenic	≤ 0.02 mg/kg
Lead	≤ 0.02 mg/kg
Cadmium	≤ 0.02 mg/kg
Mercury	≤ 0.02 mg/kg
Coagulase-positive staphylococci	≤ 100 cfu/g
Enterobacteriaceae	≤ 100 cfu/g
<i>E. coli</i>	≤ 100 cfu/g
<i>Salmonella</i>	Negative in 25g
<i>Listeria</i>	Negative in 25g
<i>Clostridium perfringens</i>	≤ 100 cfu/g
Yeast	≤ 100 cfu/g
Mould	≤ 100 cfu/g
Endotoxin	≤ 540 EU/g

## 5. *Chlamydomonas reinhardtii* (red) strain TAI114 algae biomass

<b>Name of the novel food</b>	<i>Chlamydomonas reinhardtii</i> (red) (strain TAI114)
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	19 Oct 2022
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Chlamydomonas reinhardtii</i> strain TAI114
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A.
<b>Description of growth media and inputs used</b>	Food grade growth substrates that meet acceptable standards for use in food processing
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	<p>Manufacturing process of <i>Chlamydomonas reinhardtii</i> involves fermentation of pure <i>C. reinhardtii</i> TAI114 under aseptic conditions in a controlled environment, centrifugation to remove water, and spray-drying.</p> <p>Critical control point includes testing all batches of <i>C. reinhardtii</i> TAI114 culture for presence of pathogens, yeast and mold as well as chemical contaminants before seed fermentation and on the final product before product release.</p>
<b>Specifications</b>	See table copied below

<b>Parameter</b>	<b>Specification</b>
Appearance	Red powder
Moisture	≤ 10%
Protoporphyrin IX Assay	3–7%
Protein (crude)	30–70%
Fat (crude)	≤ 10%
Fiber (acid detergent)	0–25%
Starch	≤ 55%
Ash	≤ 5%
Arsenic	≤ 1 ppm
Cadmium	≤ 1 ppm
Lead	≤ 1 ppm
Mercury	≤ 0.04 ppm
Total Aerobic Microbial	≤ 10,000 CFU/g
Total Yeast & Mold	≤ 100 CFU/g
Total Coliforms	≤ 100 CFU/g
<i>Escherichia coli</i>	Negative/1 g
<i>Salmonella spp.</i>	Negative/25 g
<i>Staphylococcus aureus</i>	≤ 100 CFU/g

**6. Cultured chicken cells derived from UMNSAH/DF1 cells (produced using serum-free media)**

<b>Name of the novel food</b>	Cultured chicken cells
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	11 January 2023
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	Cultured chicken cells (derived from UMNSAH/DF1 (ATCC CRL12203))
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A.
<b>Description of growth media and inputs used</b>	Growth media consisting of a basal media (DMEM/F12) comprising amino acids, vitamins, inorganic salts and other components as described in the applicant's submission.
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	The manufacturing process is conducted under aseptic and controlled conditions, and involves cell immortalization in culture media, cell growth in culture media, harvesting of cells, concentration of cells using centrifugation, washing steps, and frozen storage at -20°C. Safety and purity tests are conducted throughout the manufacturing process to ensure that there is no contamination from viruses, pathogens and chemical substances.
<b>Specifications</b>	See table copied below

<b>Proximate analysis</b>	<b>Specifications</b>
Moisture content	85 – 95 %
Protein content	5 – 10 %
Fat content	0.5 – 2 %
Ash content	0 – 2 %
Carbohydrate content	0 – 2 %
<b>Metals</b>	<b>Specifications</b>
Arsenic	< 1 ppm
Lead	< 2 ppm
Mercury	< 0.05 ppm
Cadmium	< 0.2 ppm
Chromium	< 2 ppm
<b>Microbiological analysis</b>	<b>Specifications</b>
Aerobic plate count	< 10,000 CFU/g (Target) < 30,000 CFU/g (Rejection limit)
Coliforms	< 24 MPN/g or < 100 CFU/g
<i>Escherichia coli</i>	< 3 MPN/g or < 10 CFU/g
Enterococci	< 100 CFU/g
Yeast	< 100 CFU/g
Mold	< 100 CFU/g
Salmonella	Not detected/25g

## 7. Mycoprotein from *Neurospora crassa* Bstr 26 produced by biomass fermentation

<b>Name of the novel food</b>	Mycoprotein from <i>Neurospora crassa</i> Bstr 26 (“Rhiza”)
<b>Date that SFA allowed the GM food / novel food to be used as food</b>	15 Oct 2024
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Neurospora crassa</i> Bstr 26
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A.
<b>Description of growth media and inputs used</b>	Food grade carbon, nitrogen, and mineral sources Antifoam that a history of use in food processing
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	Manufacturing process of “Rhiza” involves thermal sterilization of the growth substrate, inoculation of <i>Neurospora crassa</i> Bstr 26 in food grade liquid media, fermentation in a controlled bioreactor, harvesting by removing the media, thermal dehydration of the biomass, thermal devitalization to inactivate further growth, detection of any metal residues in the biomass, and weighing and labelling.  Critical control points during the manufacturing process include thermal sterilization of the growth substrate, thermal dehydration, thermal devitalization, and detection of potential metal parts.
<b>Specifications</b>	See table copied below

<b>Parameter</b>	<b>Specification</b>
Ash	< 10 %
Moisture	< 11 % in dry form
Protein	> 40 %
Total coliforms	< 10 CFU/g
<i>Escherichia coli</i>	< 10 CFU/g
Enterobacteriaceae	< 10 CFU/g
<i>Listeria monocytogenes</i>	Negative in 25 g
Mould	<10 CFU/g
<i>Salmonella</i> spp.	Negative in 25 g
Yeasts	<10 CFU/g
Arsenic	< 0.1 ppm
Lead	< 0.1 ppm
Mercury	< 0.05 ppm
Cadmium	< 0.1 ppm

## 8. “Fermotein”, *Rhizomucor pusillus* fungal biomass

<b>Name of the novel food</b>	“Fermotein”, <i>Rhizomucor pusillus</i> fungal biomass in food
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	14 Mar 2024
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Rhizomucor pusillus</i>
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A.
<b>Description of growth media and inputs used</b>	Food grade growth substrates that meet acceptable standards for use in food processing
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	<p>Manufacturing of <i>Rhizomucor pusillus</i> involves fermentation of pure culture of <i>Rh. pusillus</i> under controlled conditions until the mycelial biomass is formed. The biomass is sieved, pasteurized, washed, compressed and dried to obtain a powder product.</p> <p>Critical control point includes metal detection. All batches are tested for microorganisms and contaminants using internationally recognized testing methods.</p>
<b>Specifications</b>	See table copied below

<b>Parameter</b>	<b>Specifications</b>
Moisture	3 - 10%
Crude protein	44 - 68%
Total fat	4 - 8%
Total dietary fiber	25 - 39%
Total digestible carbohydrate	≤ 3%
Ash	≤ 6%
Arsenic	< 1 ppm
Cadmium	< 0.2 ppm
Lead	< 2 ppm
Mercury	< 0.05 ppm
Total Aerobic Count	< 100,000 CFU/g
Yeast	< 500 CFU/g
Mould	< 500 CFU/g
Enterobacteriaceae	< 300 CFU/g
<i>Escherichia coli</i>	<10 CFU/g
<i>Salmonella spp.</i>	Absent in 25g
<i>Staphylococcus aureus</i>	< 50 CFU/g
<i>Bacillus cereus</i>	< 100 CFU/g
<i>Listeria monocytogenes</i>	Absent in 25 g
<i>Clostridium perfringens</i>	< 100 CFU/g

## 9. Cultured Japanese quail fibroblast

<b>Name of the novel food</b>	Cultured Japanese quail cells
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	22 March 2024
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	Japanese quail ( <i>Coturnix japonica</i> ) embryonic fibroblasts
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A.
<b>Description of growth media and inputs used</b>	Proprietary growth media with media additives as described in the applicant's submission
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	<p>The manufacturing process involves cell expansion in culture flasks, which are further expanded in a stirred tank bioreactors ranging from 200 – 20,000L under aseptic conditions. The cells may be either completely or partially harvested upon reaching the target culture volume and density (minimum of 30 g/L) and the cells will be frozen immediately after harvest.</p> <p>Processing conditions are designed for food production following HACCP principles, commercial production will be in compliance with Good Cell Culture Practice (GCCP) and that all equipment will undergo routine cleaning and maintenance.</p>
<b>Specifications</b>	See table copied below

Category	Characteristic	Specification
Microbiological analysis	Total Plate Count	< 10 <sup>4</sup> cfu/g
	Coliforms	< 100 cfu/g
	Enterobacteriaceae	< 100 cfu/g
	E. Coli spp.	< 3 MPN/g
	Salmonella	Not detected in 25g
Proximate analysis	Protein content	> 4%
	Moisture content	> 80%
	Ash content	< 1.5%
	Fat content	0.5 - 3%
	Carbohydrate content	< 1.5%
	pH	> 4.5

## 10. Urolithin A derived from chemical synthesis

<b>Name of the novel food</b>	Urolithin A derived from chemical synthesis
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	13 March 2025
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	N.A.
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A.
<b>Description of growth media and inputs used</b>	2-bromo-5-hydroxybenzoic acid, resorcinol, sodium hydroxide, copper sulphate pentahydrate, acetic acid
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	<p>The product is manufactured by reacting 2-bromo-5-hydroxybenzoic acid with resorcinol, in the presence of copper sulphate and sodium hydroxide, followed by purification through trituration with acetic acid, filtration, washing, and drying.</p> <p>Urolithin A is manufactured in compliance with current Good Manufacturing Practice (cGMP).</p>
<b>Specifications</b>	See table copied below

Parameter		Specification
Appearance		Solid / Powder
Color		Beige to Yellow
Infra-Red Spectrum		Conforms to reference
Assay (HPLC area %)		NLT 98%
Purity (HPLC area %)		NLT 98.5 %
Total Impurities		Target: 0.7%
Individual Organic Impurities	AZX-1	NMT 0.3%
	RRT 1.05 – 1.06	NMT 0.20%
	Any other individual impurities	NMT 0.1%
Water Content (K.F.)		NMT 0.5%
Residual Solvents	Acetic Acid	NMT 5000 ppm
Residue on Ignition		NMT 0.5%
Inorganic Impurities	Cd	NMT 0.2 ppm
	Pb	NMT 0.1 ppm
	As	NMT 0.1 ppm
	Hg	NMT 0.05 ppm
	Other heavy metals (ICP-MS screening)	Report each NLT 1 ppm
	Cu	NMT 50 ppm
	Al	NMT 5 ppm
Microbial Enumeration Test	Total aerobic microbial count (TAMC)	NMT 10 <sup>3</sup> CFU/g
	Total combined yeast and mould count (TYMC)	NMT 10 <sup>2</sup> CFU/g
Test for microorganisms	Escherichia coli	Absent in 1g
Particle size dimensions	D <sub>90</sub> µm	NMT 30 µm
	D <sub>50</sub> µm	NMT 20 µm

**11. 3'-sialyllactose (3'-SL) sodium salt produced using precision fermentation of a genetically modified (GM) *Escherichia coli* BL21(DE3) JBT-3SL**

<b>Name of the novel food</b>	3'-sialyllactose (3'-SL) sodium salt
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	18 June 2025
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Escherichia coli</i> BL21(DE3) JBT-3SL
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	<i>E. coli</i> BL21(DE3) JBT-3SL is derived from the non-pathogenic <i>E. coli</i> BL21(DE3) through insertion of genes that allow for production and secretion of 3'-SL.
<b>Description of growth media and inputs used</b>	Sucrose, glucose, lactose, and glycerol as starting materials in fermentation medium. Food or pharmaceutical grade chemicals, solvents, and processing aids (e.g., ion exchange resins, activated carbon and filtration membranes) are used in the manufacture of 3'-SL.
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	<p>Production strains are grown in media containing glycerol and lactose to make 3'-SL. The production strain biomass is removed via centrifugation and ultrafiltration, leaving the desired 3'-SL.</p> <p>Degradation strain (JBT-SL-DS) is used to reduce the levels of saccharide by-products, such as <i>N</i>-acetylglucosamine and lactose, that may occur during the fermentation process. The 3'-SL undergo further downstream chromatographic purification and filtration steps to increase their purity and further remove residual biomass from the production strains. Finally, the 3'-SL are spray-dried.</p>
<b>Specifications</b>	See table copied below

<b>Analysis</b>	<b>Specification</b>
Appearance (Colour)	White to ivory
Appearance (Form)	Spray-dried powder
3'-sialyllactose	≥ 88 % dry weight
Other carbohydrates	≤ 12 % dry weight
Lactose	≤ 5 % dry weight
Sialic acid	≤ 10 % dry weight
N-Acetylglucosamine	≤ 5 % dry weight
Protein content	≤ 100 µg/g
Ash	≤ 8.5 %
Moisture	≤ 9.0 %
Sodium	≤ 4.2 %
Endotoxins	≤ 10 EU/mg
Aflatoxin M1	≤ 0.025 µg/kg
GMO residues	Negative
Arsenic	≤ 0.2 mg/kg
Cadmium	≤ 0.1 mg/kg
Lead	≤ 0.02 mg/kg
Mercury	≤ 0.5 mg/kg
Standard plate count	≤ 10000 cfu/g
Yeast and mould	≤ 100 cfu/g
<i>Enterobacteriaceae</i>	≤ 10 cfu/g
<i>Salmonella</i>	Absent/25 g
<i>Cronobacter</i> spp.	Absent/10 g

**12. 6'-sialyllactose (6'-SL) sodium salt produced using precision fermentation of a genetically modified (GM) *Escherichia coli* BL21(DE3) JBT-6SL**

<b>Name of the novel food</b>	6'-sialyllactose (6'-SL) sodium salt
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	18 June 2025
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Escherichia coli</i> BL21(DE3) JBT-6SL
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	<i>E. coli</i> BL21(DE3) JBT-6SL is derived from the non-pathogenic <i>E. coli</i> BL21(DE3) through insertion of genes that allow for production and secretion of 6'-SL.
<b>Description of growth media and inputs used</b>	Sucrose, glucose, lactose, and glycerol as starting materials in fermentation medium. Food or pharmaceutical grade chemicals, solvents, and processing aids (e.g., ion exchange resins, activated carbon and filtration membranes) are used in the manufacture of 6'-SL.
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	Production strains are grown in media containing glycerol and lactose to make 6'-SL. The production strain biomass is removed via centrifugation and ultrafiltration, leaving the desired 6'-SL. Degradation strain (JBT-SL-DS) is used to reduce the levels of saccharide by-products, such as <i>N</i> -acetylglucosamine and lactose, that may occur during the fermentation process. The 6'-SL undergo further downstream chromatographic purification and filtration steps to increase their purity and further remove residual biomass from the production strains. Finally, the 6'-SL are spray-dried.
<b>Specifications</b>	See table copied below

<b>Analysis</b>	<b>Specification</b>
Appearance (Colour)	White to ivory
Appearance (Form)	Spray-dried powder
6'-sialyllactose	≥ 90 % dry weight
Other carbohydrates	≤ 10 % dry weight
Lactose	≤ 5 % dry weight
Sialic acid	≤ 10 % dry weight
N-Acetylglucosamine	≤ 5 % dry weight
Protein content	≤ 100 µg/g
Ash	≤ 8.5 %
Moisture	≤ 9.0 %
Sodium	≤ 4.2 %
Endotoxins	≤ 10 EU/mg
Aflatoxin M1	≤ 0.025 µg/kg
GMO residues	Negative
Arsenic	≤ 0.2 mg/kg
Cadmium	≤ 0.1 mg/kg
Lead	≤ 0.02 mg/kg
Mercury	≤ 0.5 mg/kg
Standard plate count	≤ 10000 cfu/g
Yeast and mould	≤ 100 cfu/g
<i>Enterobacteriaceae</i>	≤ 10 cfu/g
<i>Salmonella</i>	Absent/25 g
<i>Cronobacter</i> spp.	Absent/10 g

### 13. Mycelium biomass from *Pleurotus pulmonarius*

<b>Name of the novel food</b>	<i>Pleurotus pulmonarius</i> mushroom mycelium
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	24 Sep 2025
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Pleurotus pulmonarius</i>
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	N.A
<b>Description of growth media and inputs used</b>	Food grade growth substrates that meet acceptable standards for use in food processing.
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	Manufacturing process of <i>Pleurotus pulmonarius</i> mycelial biomass involves cultivation of pure mycelium spawns of <i>Pleurotus pulmonarius</i> in growth substrate in the bioreactor until media is depleted. The biomass is harvested using liquid - solid separated method such as centrifugation, filtration or sieving and subsequently washed to remove culture broth.
<b>Specifications</b>	See table copied below

Analyte	Specification
Composition (g/100g dry weight)	
Protein	≥25
Fiber	≤70
Fat	≤10
Ash	≤10
Heavy Metals (mg/kg)	
Arsenic	<0.2
Cadmium	<0.1
Lead	<0.1
Mercury	<0.05
Microbiology (CFU/g)	
Total Aerobic Count	<5000
Yeast and Molds	<1000
Enterobacteriaceae	<1000
<i>Escherichia coli</i>	<10
<i>Salmonella spp.</i>	Not detected

#### 14. Cultivated chicken biomass

<b>Name of the novel food</b>	Cultivated chicken biomass
<b>Date that SFA/ex-AVA allowed the GM food / novel food to be used as food</b>	17 Oct 2025
<b>Identity of the production strain (e.g., animal cell line / plant / microorganism), if applicable</b>	<i>Chicken (Gallus gallus) embryonic stem cells</i>
<b>Brief description of genetic modifications made to the production strain, if applicable</b>	Not applicable. No genetic modifications have been made to the cell line.
<b>Description of growth media and inputs used</b>	<p>A food safe growth medium, without animal-derived components.</p> <p>The growth medium used for production in the final bioreactor contains sugars, vitamins, amino acids, proteins, minerals, polyamines, vegetable fat and anti-shearing agent.</p>
<b>Brief description of manufacturing process and risk management measures (e.g., based on Critical Control Points)</b>	<p>The manufacturing process begins with thawing a cryovial containing chicken cells sourced from the characterised and qualified cell bank (CCP1) which is free from microbial contamination.</p> <p>The cells are used to establish a seed train, where they are expanded in a stepwise approach until a sufficient volume is reached to inoculate the bioreactor.</p> <p>The stainless-steel bioreactor used to produce the cultivated chicken biomass, undergoes qualified cleaning-in-place (CCP2 and 3) and sterilisation (CCP6) procedures to ensure the absence of chemical, microbial, and physical contaminants.</p> <p>Prior to inoculation, the sealed bioreactor (CCP5) is filled with the food safe growth medium, which is filtered through a sterilising-grade filter (CCP 4) to inhibit microbial contamination. Filter integrity checks are done for all built-in filters of the bioreactor (CCP7). After a visual inspection of the medium (CCP8), the cells are added and proliferate under controlled hygienic conditions for several days.</p> <p>Once the cells reach the desired density, the contents of the bioreactor are harvested, and the cultivated chicken cells are separated from the residual medium. The harvested material is filled into individual containers, each subjected to visual inspection (CCP10), and stored at <math>-20\text{ }^{\circ}\text{C}</math> (CCP11) to ensure microbial and product stability.</p>

	Finally, risks linked to allergen contaminants are controlled through testing done on the regulatory batches (CCP9 and CCP12).
<b>Specifications</b>	See table copied below

<b>Parameter</b>	<b>Specification</b>
Protein	>6 %
Moisture	>70 %
pH	>5
Mercury (mg/kg)	<0.05
Arsenic (mg/kg)	<1
Lead (mg/kg)	<2
Cadmium (mg/kg)	<0.2
Tin (mg/kg)	<250
Antimony (mg/kg)	<1
Enterobacteriaceae	<1000 cfu/g
E. coli $\beta$ -glucuronidase positive	<100 cfu/g
Presumptive Bacillus cereus at 30°C	<200 cfu/g
Clostridium perfringens 37°C	<100 cfu/g
Coagulase-positive Staphylococcus aureus	< 100 cfu/g

## **15. Revision History**

1. 17 March 2026 – Initial Issue