



Amendment No. 239

The following instruments are separate instruments in the Federal Register of Legislation and are known collectively in the Food Standards Gazette as Amendment No. 239

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Standard 1.5.4 – Cell-cultured foods

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date of gazettal.

Dated 10 June 2025



Matthew O'Mullane, General Manager, Food Safety
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC 179 on 18 June 2025. This means that this date is the gazettal date for the purposes of the above notice.

Standard 1.5.4 Cell-cultured foods

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.

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.

Division 1 Preliminary

1.5.4—1 Name

This Standard is *Australia New Zealand Food Standards Code – Standard 1.5.4 – Cell-cultured foods*.

Note Commencement:
This Standard commences on the date of gazettal, 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.

1.5.4—2 Definitions

Note In this Code (see sections 1.1.2—2):

a **cell-cultured food** means a food obtained by culturing cells isolated from any of the following sources: livestock; poultry; game; seafood (including fish); an egg or an embryo of any of the former.'

Division 2 General requirements

1.5.4—3 When a cell-cultured food is permitted for sale

A food for sale may be, or have as an ingredient, a *cell-cultured food if:

- (a) the cell-cultured food is listed in Schedule 25A; and
- (b) any corresponding conditions listed in that Schedule are complied with.

1.5.4—4 Prohibition on use in special purpose foods

A *cell-cultured food must not be added to a food standardised by Part 2.9 of this Code.

1.5.4—5 Labelling requirement – name of the ingredient in a food for sale

- (1) This section applies to a food for sale that has a *cell-cultured food as an ingredient.
- (2) For the labelling provisions, the information relating to *cell-cultured food is the use of one of the following statements in conjunction with the name of the ingredient that is a *cell-cultured food:
 - (a) 'cell-cultured';
 - (b) 'cell-cultivated'.

Note The labelling provisions are set out in Standard 1.2.1. Labelling provisions apply to both packaged and unpackaged food.

Example The label on a packaged food for sale that contains a *cell-cultured food as an ingredient, must use the statement *cell-cultured* or *cell-cultivated* in conjunction with the name of that ingredient in a statement of ingredients required by Standard 1.2.1 and 1.2.4.

1.5.4—6 Labelling requirement – name of the food for sale – retail sale

- (1) This section applies to a food for sale that:
 - (a) is one of the following:
 - (i) for retail sale; or

- (ii) suitable for retail sale without any further processing, packaging or labelling; and
 - (b) is packaged; and
 - (c) has a *cell-cultured food as an ingredient (**the ingredient**); and
 - (d) is represented in words, images or both as being from the animal from which the *cell-cultured food was sourced.
- (2) Paragraph (1)(d) does not apply to a reference in a statement of ingredients to the animal from which the *cell-cultured food was sourced.
- (3) For the labelling provisions, the information relating to *cell-cultured food is the use in the name of the food for sale of the same statement that is used in conjunction with the name of the ingredient in accordance with section 1.5.4—5.

Note The labelling provisions are set out in Standard 1.2.1

Example The label on a packaged food for sale that contains a *cell-cultured food as an ingredient and that uses the statement *cell-cultured* in relation to that ingredient in the statement of ingredients in accordance with section 1.5.4—5, must also include the statement *cell-cultured-* in the name of the food if the food for sale is represented in words, images or both as being from the animal from which the *cell-cultured food is sourced (e.g. 'made from cell-cultured [animal name]' or 'cell-cultured [animal name] patties').

A packaged food for sale that contains a *cell-cultured food as an ingredient and that has no representations in words, images or both on its label of being from the animal from which the food is sourced, would not be subject to labelling requirements relating to the food for sale in section 1.5.4—6. Standard 1.2.2 would apply to require the use of a name or description in relation to that food that is sufficient to indicate the true nature of that food.

1.5.4—7

Labelling requirement – name of the food for sale – non-retail sale

- (1) This section applies to a food for sale that is:
- (a) a *cell-cultured food; and
 - (b) a food for sale to which Division 3 or 4 of Standard 1.2.1 applies.
- (2) For the labelling provisions, the information relating to *cell-cultured food is the use of one of the following statements in conjunction with the name of the *cell-cultured food:
- (a) 'cell-cultured';
 - (b) 'cell-cultivated'.

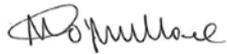
Note The labelling provisions are set out in Standard 1.2.1. Labelling provisions apply to both packaged and unpackaged food.

Example Paragraph 1.2.1—15(a) provides that the labelling of food sold to a caterer must state the name of the food in accordance with section 1.2.2—2 (such as a name or description sufficient to indicate the true nature of the food). A packaged food that is a cell-cultured- food and is sold to a caterer must include the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured food, where that name is the name of the food for sale (e.g. 'cell-cultivated [animal]').

Schedule 25A – Permitted cell-cultured foods

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date of gazettal.

Dated 10 June 2025



Matthew O'Mullane, General Manager, Food Safety
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC 179 on 18 June 2025. This means that this date is the gazettal date for the purposes of the above notice.

Schedule 25A Permitted cell-cultured foods

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.

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.

Note 3 Division 3 of this Standard applies in Australia only.

Division 1 Preliminary

S25A—1 Name

This Standard is *Australia New Zealand Food Standards Code – Schedule 25A – Permitted cell-cultured foods*.

Note Commencement:
This Standard commences on the date of gazettal, 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.

S25A—2 Definitions

In this Schedule,

cell-cultured quail means quail cells obtained from culturing embryonic fibroblast cells sourced from *Coturnix japonica*.

S25A—3 Permitted cell-cultured foods

For section 1.5.4—3, the permitted *cell-cultured foods are:

Permitted cell-cultured foods

<i>Permitted cell-cultured foods</i>	<i>Conditions</i>
1. Cell-cultured quail that is (a) derived from the cell line 221523-Fib-Quail; and (b) detailed in application A1269	See Division 2 of this Standard.

Division 2 Cell-cultured quail

S25A—4 Conditions on sale

- (1) Cell-cultured quail must not be a food for retail sale.
- (2) A food for retail sale may have cell-cultured quail as an ingredient.

S25A—5 Labelling conditions

- (1) This section applies to a food for retail sale that has cell-cultured quail as an ingredient.
- (2) The label on the package of the food must not contain the phrase 'poultry meat'.
- (3) The labelling of the food must not contain the word 'meat' other than in conjunction with the following:
 - (a) the statement required by section 1.5.4—5;
 - (b) a statement required by section 1.5.4—6.
- (4) Subparagraph 1.2.4—4(b)(iii) does not apply to the food.

Note Subparagraph 1.2.4—4(b)(iii) permits the use of generic names specified in Schedule 10 to identify certain ingredients in a statement of ingredients, including the generic names 'meat' and 'poultry meat'.

Division 3 **Assessed cell lines**

S25A—6 **Assessed cell line**

For the definition of **assessed cell line** in section 3.4.1—2, the following cell lines are listed:

Assessed cell lines

Cell line

1. The cell line **221523-Fib-Quail**.

Food Standards (Application A1269 – Cultured quail as a novel food – Consequential Amendments) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated 10 June 2025



Matthew O'Mullane, General Manager, Food Safety
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 179 on 18 June 2025. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Application A1269 – Cultured quail as a novel food – Consequential Amendments) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences immediately after the commencement of Standard 1.5.4.

SCHEDULE

Standard 1.1.1—*Structure of the Code and general provisions*

[1] **Subsection 1.1.1—2(2)**

Insert:

Standard 1.5.4 Cell-cultured foods

[2] **Subsection 1.1.1—2(2)**

Insert:

Standard 3.4.1 Food Safety requirements for processing of cell-cultured food

[3] **Subsection 1.1.1—2(2)**

Insert:

Schedule 25A Permitted cell-cultured foods

[4] **Paragraph 1.1.1—10(5)(b)**

Repeal the paragraph, substitute:

- (b) if the food is for retail sale—a *novel food;
- (ba) a *cell-cultured food;

[5] **Paragraph 1.1.1—10(6)(f)**

Repeal the paragraph, substitute:

- (f) if the food is for retail sale—a *novel food;
- (fa) a *cell-cultured food;

[6] **Paragraph 1.1.1—15(1)(d)**

Repeal the paragraph, substitute:

- (d) a *novel food;
- (e) a *cell-cultured food.

Standard 1.1.2—*Definitions used throughout the Code*

[7] **Subsection 1.1.2—2(3)**

Insert:

cell-cultured food means a food obtained by culturing cells isolated from any of the following sources: livestock; poultry; game; seafood (including fish); an egg or an embryo of any of the former.

[8] Subsection 1.1.2—8(1) (paragraph (c) of the definition of non-traditional food)

Repeal the paragraph, substitute:

- (c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand; and
- (d) does not include a *cell-cultured food.

Standard 1.2.1—Requirements to have labels or otherwise provide information

[9] Paragraph 1.2.1—8(1)(l)

Repeal the paragraph, substitute:

- (l) information relating to irradiated food (see section 1.5.3—9);
- (la) information relating to *cell-cultured food (see sections 1.5.4—5 and 1.5.4—6);

[10] Paragraph 1.2.1—9(3)(ba)

Repeal the paragraph, substitute:

- (ba) for a food referred to in paragraph 1.2.1—6(1)(c)—information relating to foods produced using gene technology (see section 1.5.2—4);
- (baa) information relating to *cell-cultured food (see section 1.5.4—5).

[11] Paragraph 1.2.1—15(g)

Repeal the paragraph, substitute:

- (g) information relating to irradiated food (see section 1.5.3—9);
- (h) information relating to *cell-cultured food (see section 1.5.4—7).

Standard 3.1.1—Interpretation and Application

[12] Clause 1 (Interpretation)

Insert:

cell culturing food business has the meaning given by section 3.4.1—2.

cell line supplier has the meaning given by section 3.4.1—2.

[13] Clause 1 (definition of food business)

Repeal the definition, substitute:

food business means –

- (a) a business, enterprise or activity (other than primary food production) that involves one or both of following:
 - (i) the handling of food intended for sale; or
 - (ii) the sale of food:regardless of whether the business, enterprise or activity concerned is of a commercial, charitable or community nature or whether it involves the handling or sale of food on one occasion only; or
- (b) a cell culturing food business; or
- (c) a cell line supplier.

Schedule 3—Identity and purity

[14] Subsection S3—2(2) (table, after the table item dealing with ‘carboxymethyl cellulose ion exchange resin’)

Insert:

cell-cultured quail

section S3—54

[15] After section S3—53

Insert

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%.

Schedule 27—Microbiological limits in food

[16] Section S27—4 (table, at the end of the table)

Add:

Cell-cultured food (excluding cell lines)

<i>Salmonella</i> spp	5	0	not detected in 25 g
<i>Listeria monocytogenes</i>	5	0	not detected in 25 g

Standard 3.4.1 – Food safety requirements for processing of cell-cultured food

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on gazettal.

Dated 10 June 2025



Matthew O'Mullane, General Manager, Food Safety
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC 179 on 18 June 2025. This means that this date is the gazettal date for the purposes of the above notice.

Standard 3.4.1 Food safety requirements for processing of cell-cultured food

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.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

3.4.1—1 Name

This Standard is *Australia New Zealand Food Standards Code – Standard 3.4.1 – Food safety requirements for processing of cell-cultured food*.

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

3.4.1—2 Definitions

In this Standard:

animal means an animal that is one of the following: livestock; poultry; game; seafood (including fish); and includes an egg or an embryo of such an animal.

assessed cell line means a cell line listed in section S25A—6.

bioreactor means a device in which cell proliferation occurs under closed and controlled conditions.

cell bank means a collection of one or more cell lines.

cell biomass means a mass of cells extracted from a bioreactor and that is intended for use in the production of a food.

cell culturing food business means a business, enterprise or activity that undertakes cell proliferation.

cell differentiation means the process by which cells are induced to differentiate into the final cell type(s) of the cell-cultured food.

cell line means a collection of cells that:

- (a) are derived from a single source that was prepared under specific culture conditions; and
- (b) have a uniform composition; and
- (c) are intended for use in the production of a cell biomass.

cell proliferation means the production of a cell biomass.

cell extraction means one or both of the following processes:

- (a) extraction of a mass of cells from a bioreactor;
- (b) separation of a cell biomass from the media by sedimentation, centrifugation or other action.

cell line supplier means a business, enterprise or activity that involves both of the following:

- (a) sourcing cells for use in creating a cell line;
- (b) creating a cell line.

donor animal means an animal from which cells are sourced to create a cell line.

media means a growth medium used for one or both of the following purposes:

- (a) cell proliferation;
- (b) cell differentiation.

Division 2 Cell line supplier

3.4.1—3 Cell lines – food safety requirements

- (1) A cell line supplier must ensure that a cell line does not contain any of the following.
 - (a) bacteria;
 - (b) fungi;
 - (c) prions;
 - (d) viruses.
- (2) A cell line supplier must identify and record the species of the cells that comprise a cell line.
- (3) A cell line must be sourced from a donor animal that is free of disease.

3.4.1—4 Traceability

A cell line supplier must have in place a system that:

- (a) identifies and tracks cells from collection from a donor animal through to supply of a cell line; and
- (b) identifies the donor animal for the cells used to develop each cell line; and
- (c) identifies to whom a cell line was supplied.

Division 3 Cell culturing food business

3.4.1—5 Food safety program

- (1) A cell culturing food business must comply with Standard 3.2.1.
Note Standard 3.2.1 sets out other requirements for a food safety program.
- (2) The food safety program must also detail each of the following:
 - (a) the indicators of a loss of process control in a bioreactor;
 - (b) the food handling activities related to:
 - (i) cell sourcing, selection and banking; and
 - (ii) cell proliferation, including serial sub-culturing in flasks; and
 - (iii) seeding and proliferation of cells in a bioreactor; and
 - (iv) cell differentiation; and
 - (v) cell extraction;
 - (c) how the business will identify when cell proliferation is non-conforming;
 - (d) how the business will undertake the calibration, cleaning and sterilisation of all relevant equipment.

3.4.1—6 Inputs

A cell culturing food business must ensure that any substance used in or for any of the following does not make *cell-cultured food unsafe or unsuitable:

- (a) cell proliferation;
- (b) cell differentiation;
- (c) cell extraction;
- (d) handling of a cell biomass;

- (e) storage of a cell biomass.

3.4.1—7 Cell line used for cell proliferation

A cell culturing food business must only use an assessed cell line for cell proliferation.

3.4.1—8 Cell biomass – temperature control

A cell biomass is a potentially hazardous food for the purposes of Standard 3.2.2.

3.4.1—9 Traceability

A cell culturing food business must have in place a system that identifies each of the following:

- (a) the cell line used for cell proliferation;
- (b) the supplier of the cell line used for cell proliferation;
- (c) to whom the cell biomass was supplied.