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

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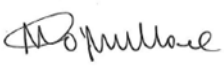
The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on gazettal.

Dated 10 June 2025



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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.