EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

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

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1269 which seeks to amend the Code to permit the sale and use of cultured quail cells as a new food. The Authority considered the application in accordance with Division 1 of Part 3 and has approved the following draft regulatory measures:

- Standard 1.5.4 – Cell-cultured- foods;
- Schedule 25A – Permitted cell-cultured foods;
- Standard 3.4.1 – Food Safety requirements for processing of cell-cultured food; and
- *Food Standards (Application A1269 – Cultured quail as a novel food – Consequential Amendments) Variation.*

This explanatory statement relates to *Australia New Zealand Food Standards Code - Standard 3.4.1 – Food safety requirements for processing of cell-cultured food* (the Standard).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the Standard.

2. Standard is a legislative instrument

The Standard is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under

an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority approved the Standard to set food safety requirements for the processing and production of cell-cultured food, including for the cultured quail cells that are the subject of Application A1269. These requirements will apply from the point of collection of cells from a donor animal through to the production of the end product used as an ingredient in a food for sale.

4. Documents incorporate by reference

The Standard does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1269 included two rounds of public consultation. The 1st call for submissions was held from 11 December 2023 to 5 February 2024. The submissions received informed the Authority's decision to prepare the draft Standard and other proposed regulatory measures mentioned above. The 2nd CFS was issued in December 2024 and included two draft standards, a draft schedule and draft consequential variations to the Code, and an associated report. It detailed the rationale for the proposed measures and regulatory approach for cultured quail cells and for future cell-cultured- foods. FSANZ received 22 submissions in response to the 2nd CFS. Each submission received was considered as part of our assessment. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA) [1]. Impact analysis is no longer required to be finalised with the OIA. Under the new approach, FSANZ's assessment is that a Regulation Impact Statement (RIS) is not required for this application, as the proposed variation to the Code are not likely to create significant impacts on the community, government or industry.

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legisla*tion *Act 2003*.

7. The Standard

Standard 3.4.1 is a new Standard incorporated into the Code. The purpose of each provision in the Standard is explained below.

The Standard is introduced by two notes providing information about the place of the

Standard within the Code and the non-application of that Standard in New Zealand.

Note 1 explains that the instrument is a standard under the FSANZ Act and that the Standard and the other standards together make up the Code.

Note 2 explains that the Standard applies only in Australia. It does not apply in New Zealand.

Division 1 – Preliminary

Division 1 of the Standard contains sections 3.4.1—1 and 3.4.1—2.

Section 3.4.1—1 establishes that the name of the instrument is the *Australia New Zealand Food Standards Code – Standard 3.4.1 – Food safety requirements for processing of cell-cultured food*.

The note to section 3.4.1—1 explains that the Standard commences on the date of gazettal, being the date specified in accordance with sections 92 and 93 of the FSANZ Act.

Section 3.4.1—2 sets out the definitions for key words and phrases used in the Standard, or signposts to where those definitions are provided in other standards in the Code.

> **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.
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> **Assessed cell line** means a cell line listed in Schedule 25A—6.
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> **Bioreactor** means ‘a device in which cell proliferation occurs under closed and controlled conditions’. Section 3.4.1—2 also defines the term ‘cell proliferation’ to mean ‘the production of a cell biomass’ and the term ‘cell biomass’ to mean a cell mass that is intended ‘for use in the production of food’. The effect of the latter is that, for the purposes of Standard 3.4.1, the term ‘bioreactor’ can apply only to a device used for the production of food.
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> **Cell bank** means ‘a collection of one or more cell lines’. Section 3.4.1—2 defines the term ‘cell line’ to mean a ‘cell line’ that is intended for use in the production of food (see definition of ‘cell line’ below). This means that, for the purposes of Standard 3.4.1, a ‘cell bank’ is a collection of one or more cell lines that is or are intended for use in the production of food. The term ‘cell bank would also cover both a master cell bank and a working cell bank that a food business may create for their cell lines.
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> **Cell biomass** means a mass of cells extracted from a bioreactor and that is intended for use in the production of a food.
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> **Cell culturing food business** means ‘a business, enterprise or activity that undertakes cell proliferation’. Section 3.4.1—2 also defines the term ‘cell proliferation’ to mean ‘the production of a cell biomass’ and the term ‘cell biomass’ to mean a cell mass that is intended ‘for use in the production of food’. This means that, for the purposes of Standard 3.4.1, a ‘cell culturing food business’ is one that undertakes production of a cell biomass for use in food production.
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> **Cell differentiation** means ‘the process by which cells are induced to differentiate into the final cell type(s) of the cell-cultured food’. The final cell type is the particular type of cell (e.g. muscle cell) that comprises the cell biomass.

Cell line means a collection of cells that meet each of the following criteria: the cells are derived from a single source that was prepared under specific culture conditions; the cells have a uniform composition; and the cells are intended for use in the production of a cell biomass. Section 3.4.1—2 also defines the term 'cell biomass' to mean a cell mass that is intended 'for use in the production of food'. This means that, for the purposes of Standard 3.4.1, a cell line is one that is intended for use in the production of a food. A cell line that is not used or intended for use in production of food is not a cell line for the purposes of Standard 3.4.1.

Cell proliferation means the production of a cell biomass. Section 3.4.1—2 also defines the term 'cell biomass' to mean a cell mass that is intended 'for use in the production of food'. This means that, for the purposes of Standard 3.4.1, cell proliferation is the production (by means of growing or multiplying cells) of a cell mass for use in the production of food.

Cell extraction means one or both of: extraction of a mass of cells from a bioreactor; and separation of a cell biomass from the media by sedimentation, centrifugation or other action. The terms 'bioreactor' and 'cell biomass' are also both defined in section 3.4.1—2. The term 'cell extraction' is intended to cover the removal of cells from the bioreactor as well as the removal of media from extracted cells.

Cell line supplier means a business, enterprise or activity that involves both sourcing cells for use in creating a cell line and the creation of a cell line. As explained above, the terms 'cell line is also defined in section 3.4.1—2 to mean a collection of cells that, among other things, are intended for use in the production of a cell biomass. A cell biomass is a cell mass that is intended 'for use in the production of food'. This means that, for the purposes of Standard 3.4.1, a cell line supplier is a business, enterprise or activity that undertakes both the sourcing and the creation of cell lines intended for use in food production. The reference to 'sourcing cells' includes the direct collection of cells from a donor animal (e.g. by biopsy) as well as indirect sourcing (e.g. from a preexisting cell sample).

Donor animal means an animal from which cells are sourced to create a cell line. As explained above, the terms 'animal' and 'cell line' also defined in section 3.4.1—2.

Media means a growth medium used for the purposes of cell proliferation, cell differentiation or both. As explained above, the terms 'cell proliferation' and 'cell differentiation' are also defined in section 3.4.1—2.

Division 2 – Cell line supplier

Division 2 of the Standard contains sections 3.4.1—3 and 3.4.1—4.

Division 2 sets out requirements that apply to a cell line supplier. Section 3.4.1—2 provides a definition of what is a cell line supplier for the purposes of these requirements.

Section 3.4.1—3 sets out food safety requirements relating to cell lines. Subsection 3.4.1—3(1) requires a cell line supplier to ensure that a cell line does not contain any bacteria, fungi, prions, or viruses. Subsection 3.4.1—3(2) requires a cell line supplier to identify and record the species of the cells that comprise a cell line. Subsection 3.4.1—3(3) requires that a cell line must be sourced from a donor animal that is free of disease. In other words, a cell line supplier must not collect tissue from a donor animal that is diseased, which includes an animal showing signs of an infection, such as the confirmed presence of a pathogenic microorganism in the animal. The purpose of these provisions is to ensure cells used for cell lines are of a confirmed species and are safe and suitable for human food.

Section 3.4.1—4 requires a cell line supplier to have a system in place that can: identify and track cells from initial collection from a donor animal through to supply of a cell line; identify the donor animal for the cells used to develop each cell line; and identify the person, business or enterprise to whom a cell line was supplied. The purpose of the section is ensure that a traceability system is in place that will enable the business to trace cells used for food production in the event that a food safety issue occurs and a product recall is required.

Division 3 – Cell culturing food business

Division 3 of the Standard contains sections 3.4.1—5 to 3.4.1—9.

Division 3 sets out requirements that apply to a cell culturing food business. Section 3.4.1—2 provides a definition of what is a cell culturing food business for the purposes of these requirements.

A cell culturing food business can also be a cell line supplier. In this case, the business must comply with the requirements in both Divisions 2 and 3.

Section 3.4.1—5 sets out requirements relating to a food safety program with which a cell culturing food business must comply. Subsection 3.4.1—5(1) requires a cell culturing food business to comply with Standard 3.2.1 of the Code. Standard 3.2.1 sets out requirements for a food safety program based on a hazard analysis and critical control point (HACCP) system. Subsection 3.4.1—5(2) provides that, in addition to any requirements specified in Standard 3.2.1, the food safety program must detail: the indicators of a loss of process control in a bioreactor (e.g. contamination of the culture); the food handling activities related to cell sourcing, selection and banking; cell proliferation, including serial sub-culturing in flasks; seeding and proliferation of cells in a bioreactor; cell differentiation; and cell extraction. Subsection 3.4.1—5(2) also requires the food safety program to specify: how the business will identify when a cell proliferation is non-conforming (e.g. the cell type or purity is not as expected); how the business will undertake the calibration, cleaning and sterilisation of all relevant equipment.

Section 3.4.1—6 requires a cell culturing food business to ensure that any substance used in or for any of the following does not make cell-cultured food unsafe or unsuitable: cell proliferation; cell differentiation; cell extraction; the handling and/or storage of a cell biomass. The purpose of this section is require the cell culturing food business to ensure that substance used in or for any of these activities do not introduce microorganisms or chemical or physical contaminants into cultured cells.

Section 3.4.1—7 requires a cell culturing food business to only use an assessed cell line for cell proliferation. Section 3.4.1—2 provides a definition of what is an assessed cell line for this purpose. The purpose of section 3.4.1—7 is to ensure that only those cell lines that have been assessed and permitted for use (that is, by being listed in section in section S25A—6 of the Code) are used by a cell culturing food business for cell proliferation.

Section 3.4.1—8 provides that a cell biomass is a potentially hazardous food for the purposes of Standard 3.2.2. The purpose of this section is ensure that the temperature control requirements set by Standard 3.2.2 apply to the handling of the cell biomass, including during its receipt, storage, processing and transport.

Section 3.4.1—9 requires a cell culturing food business to have a system in place that identifies: the cell line used for cell proliferation; the supplier of the cell line used for cell proliferation; and the person or business to whom the cell biomass was supplied. The

purpose of the section is ensure that a traceability system is in place that will enable the business to trace cells used for food production in the event that a food safety issue occurs and a product recall is required.