

## **EXPLANATORY STATEMENT**

### *Food Standards Australia New Zealand Act 1991*

#### ***Australia New Zealand Food Standards Code – Schedule 25A – Permitted cell-cultured foods***

##### **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 - Schedule 25A – Permitted cell-cultured foods* (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](http://www.legislation.gov.au)).

This instrument is not subject to the disallowance or sunset 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 sunset 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 sunset 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 list cell-cultured foods that are permitted for the purposes of the Code and to set specific requirements for permitted cell-cultured foods. The Standard lists the cell-cultured quail referred to in Application A1269 as a permitted cell-cultured food and sets specific conditions for the sale and labelling of that cell-cultured food.

### **4. Documents incorporated 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](http://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 *Legislation Act 2003*.

### **7. The Standard**

Schedule 25A is a new Standard incorporated into the Code. The purpose of each provision in that Standard is explained below.

The Standard is introduced by three notes providing information about the place of the Standard within the Code and the application of that Standard in New Zealand.

The first note in the Standard explains the instrument is a standard under the FSANZ Act and the Standard and the other standards together make up the Code. The first note also refers to section 1.1.1—3 of the Code. That section provides that unless otherwise provided, the Standard and the other provisions of the Code apply to food that is sold, processed or handled for sale in Australia or New Zealand; or imported into Australia or New Zealand.

The second note explains that the provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014* (NZ). The second note also refers to section 1.1.1—3 of the Code, a note to which lists the provisions of the Code that have not been incorporated in, or adopted under that Act.

The third note explains that Division 3 of the Standard applies in Australia only. It does not apply in New Zealand.

## **Division 1 – Preliminary**

Division 1 of the Standard contains sections S25A—1 to S25A—3.

**Section S25A—1** provides that the name of the Standard is the *Australia New Zealand Food Standards Code – Schedule 25A – Permitted cell-cultured foods*.

The note to section S25A—1 explains that the 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 in accordance with sections 92 and 93 of the FSANZ Act.

**Section S25A—2** provides or refers to definitions for terms used in the Standard. It provides that a reference in the Standard to *cell-cultured quail* means ‘quail cells obtained from culturing embryonic fibroblast cells sourced from *Coturnix japonica*’.

**Section S25A—3** lists permitted cell-cultured foods and their conditions of use for the purposes of section 1.5.4—3 of the Code. Section S25A—3 lists the permitted cell-cultured foods and their conditions of use in a table to the section. Permitted cell-cultured foods are listed in Column 1 of the table. The conditions of use, if any, for each permitted cell-cultured food is listed in the corresponding row in Column 2 of the table.

Item 1 of the table to section S25A—3 lists in Column 1 of the table the following as a permitted cell-cultured food: cell-cultured quail derived from the cell line 221523Fib-Quail and detailed in application A1269. Section S25A—2 provides that the reference to ‘cell-cultured quail’ in that Item 1 is a reference to ‘quail cells obtained from culturing embryonic fibroblast cells sourced from *Coturnix japonica*’.

The corresponding entry in Column 2 of the table to section S25A—3 for the above permitted cell-cultured food refers to Division 2 of the Standard. This reflects that the sections that comprise Division 2 of the Standard set specific requirements for the sale and labelling of the cell-cultured quail listed in Item 1 of the table to section S25A—3.

## **Division 2**

Division 2 is comprised of section S25A—4 and section S25A—5.

**Section S25A—4** sets conditions on and for sale for the ‘cell-cultured quail’ referred to in Item 1 of the table to section S25A—3. Subsection S25A—4(1) provides that cell-cultured

quail must not be a food for retail sale. Subsection S25A—4(1) provides that a food for retail sale may have cell-cultured quail as an ingredient.

**Section S25A—5** sets labelling conditions for a food for retail sale that has cell-cultured quail as an ingredient.

Subsection S25A—5(1) provides the requirements set by section S25A—5 apply only to a food for retail sale that has cell-cultured quail as an ingredient.

Subsection S25A—5(2) provides that the package of a food for retail sale that has cell-cultured quail as an ingredient must not contain the phrase ‘poultry meat’.

Subsection S25A—5(3) provides that the labelling for a food for retail sale that has cell-cultured quail as an ingredient must not contain the word ‘meat’ except when used in conjunction with the statement required by section 1.5.4—5 or a statement required by section 1.5.4—6. Section 1.5.4—5 requires the use - in accordance with the Code’s labelling provisions - of the statement ‘cell-cultured’ or ‘cell-cultivated’ in conjunction with the name of the ingredient that is a cell-cultured food. If section 1.5.4—6 applies to the food for sale, that section would require the same statement (i.e. either ‘cell-cultured’ or ‘cell-cultivated’) that is used to comply with section 1.5.4—5 to be used in conjunction with the name of the food for sale.

Subsection S25A—5(4) provides that subparagraph 1.2.4—4(b)(iii) of the Code does not apply to a food for retail sale that has cell-cultured quail as an ingredient. 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’.

The note to subsection S25A—5(4) explains subparagraph 1.2.4—4(b)(iii).

### **Division 3 – Assessed cell lines**

Division 3 consists of section S25A—6.

**Section S25A—6** lists assessed cell lines for the purposes of the definition of *assessed cell line* in section 3.4.1—2 of the Code. The definition provides that an *assessed cell line* is a cell line listed in section S25A—6. Section 3.4.1—9 provides that a cell culturing food business must only use an assessed cell line for cell proliferation.

Section S25A—6 lists assessed cell lines in a table to that section. Item 1 of the table provides that cell line 221523-Fib-Quail is an assessed cell line.