

## **EXPLANATORY STATEMENT**

*Food Standards Australia New Zealand Act 1991*

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

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

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

#### **2. Variation is a legislative instrument**

The variation 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.

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 Variation to amend Standards 1.1.1, 1.1.2, 1.2.1, 1.2.10, 3.1.1; and Schedules 3 and 27. These amendments are required as a consequence of FSANZ approving the following regulatory measures:

- Standard 1.5.4 – Cell-cultured foods,
- Standard 3.4.1 – Food Safety requirements for processing of cell-cultured food,
- Schedule 25A – Permitted cell-cultured foods.

The purpose of all of the amendments is to provide for the regulation of sale and use of cell-cultured food.

### **4. Documents incorporated by reference**

The Variation 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 1<sup>st</sup> 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 2<sup>nd</sup> 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 2<sup>nd</sup> 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)<sup>1</sup>. 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. Variation

**Clause 1** provides that the name of the Variation is the *Food Standards (Application A1269 – Cultured quail as a novel food – Consequential Amendments) Variation*.

**Clause 2** provides that the Code is amended by the Schedule to the Variation.

**Clause 3** provides that the Variation commences immediately after Standard 1.5.4 takes effect.

### ***The Schedule***

The Schedule to the Variation amends the Code.

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

**Items [1] – [6]** of the Schedule amend Standard 1.1.1 of the Code.

**Item [1]** of the Schedule amends subsection 1.1.1—2(2) to include in that subsection a reference to Standard 1.5.4. Subsection 1.1.1—2(2) lists all the standards of the Code arranged into Chapters, Parts and a set of Schedules. The list does not currently contain a reference to Standard 1.5.4.

The effect of the amendment, if Standard 1.5.4 and the Variation are both approved, is that Standard 1.5.4 will be listed in subsection 1.1.1—2(2) immediately after the reference in that subsection to Standard 1.5.3.

**Item [2]** of the Schedule amends subsection 1.1.1—2(2) to include in that subsection a reference to Standard 3.4.1.

**Item [3]** of the Schedule amends subsection 1.1.1—2(2) to include in that subsection a reference to Schedule 25A.

**Item [4]** amends subsection 1.1.1—10(5) by inserting paragraph 1.1.1—10(5)(ba), which refers to ‘a cell-cultured food’. The effect of this amendment is to ensure that unless expressly permitted by the Code, a cell-cultured food (as defined by the Code) cannot be sold as food.

**Item [5]** amends subsection 1.1.1—10(6) by inserting paragraph 1.1.1—10(6)(fa), which refers to ‘a cell-cultured food’. The effect of this amendment is to ensure that unless expressly permitted by the Code, a cell-cultured food (as defined by the Code) cannot be used as an ingredient or component in a food for sale.

**Item [6]** amends subsection 1.1.1—15(1) by inserting paragraph 1.1.1—15(1)(e), which refers to ‘a cell-cultured food’. The effect of this amendment is to require a cell-cultured food to comply with any relevant specifications set out in Schedule 3, when added to food in accordance with the Code, or sold for use in food.

#### **Standard 1.1.2—Definitions used throughout the Code**

**Items [7] and [8]** of the Schedule amend Standard 1.1.2 of the Code.

**Items [7]** inserts the following new definition into subsection 1.1.2—2(3):

**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.

The effect of this amendment is to define the term *cell-cultured food* for the purposes of the Code.

**Item [8]** amends subsection 1.1.2—8(1) by adding paragraph (d) to the definition of ‘non-traditional food’. A food must be a ‘non-traditional food’ in order to be ‘a novel food’ for Code purposes. New paragraph (d) will provide that a ‘non-traditional food’ does not include a cell-cultured food.

The effect of this amendment is that a food regulated by the Code as a cell-cultured food would not be a novel food for Code purposes.

### **Standard 1.2.1—Requirements to have labels or otherwise provide information**

**Items [9] to [11]** of the Schedule amend Standard 1.2.1 of the Code.

**Item [9]** adds paragraph 1.2.1—8(1)(la) to subsection 1.2.1—8(1). The new paragraph states ‘information relating to cell-cultured food (see sections 1.5.4—5 and 1.5.4—6)’. Subsection 1.2.1—8(1) lists the information that section 1.2.1—6 of the Code provides must be on the label of a food for sale that is in a package. The effect of this amendment is that section 1.2.1—6 requires the label of a food for sale that is in a package to include the information relating to cell-cultured food in accordance with sections 1.5.4—5 and 1.5.4—6.

**Item [10]** adds paragraph 1.2.1—9(3)(baa) to subsection 1.2.1—9(3). The new paragraph states ‘information relating to cell-cultured food (see sections 1.5.4—5)’. Subsection 1.2.1—9(3) lists the information that subsections 1.2.1—9(1) and (2) provide must accompany or be displayed in connection with a food for sale that is not required by section 1.2.1—6 to bear a label. The effect of this amendment is that accompanying or displayed information must include information relating to cell-cultured food in accordance with sections 1.5.4—5.

**Item [11]** adds paragraph 1.2.1—15(h) to section 1.2.1—15. The new paragraph states ‘information relating to cell-cultured food (see section 1.5.4—7)’. Section 1.2.1—15 lists the information that must be stated in the labelling required for food sold to a caterer. The effect of this amendment is that the labelling required for food sold to a caterer must include information relating to cell-cultured food in accordance with section 1.5.4—7.

### **Standard 3.1.1—Interpretation and Application**

**Items [12] and [13]** of the Schedule amend Standard 3.1.1 of the Code.

**Item [12]** adds the following definitions to clause 1 of Standard 3.1.1:

**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.

The effect of this amendment is to apply the new definitions of *cell culturing food business* and *cell line supplier*, as set out in new Standard 3.4.1—2, to the whole of Chapter 3 of the Code.

**Item [13]** would repeal and replace the definition of **food business** in clause 1 of Standard 3.1.1. The new definition would provide as follows

**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.

If approved, the effect of this amendment would be to add both a *cell culturing food business* and a *cell line supplier* (as defined in new section 3.4.1—2 of the Code) in the definition of a ‘food business’ for the purposes of Chapter 3 of the Code.

### **Schedule 3—Identity and purity**

**Items [14] and [15]** of the Schedule amend Schedule 3 of the Code.

**Item [14]** inserts the following entry into the table to subsection S3—2(2), after the table item dealing with ‘carboxymethyl cellulose ion exchange resin’:

cell-cultured quail	section S3—54
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**Item [15]** inserts new section S3—54 after section S3—53.

New section S3—54 provides a specification for cell-cultured quail.

Section 1.1.1—15 requires certain substances when added to food or sold for use in food to comply any relevant specification set out in Schedule 3. Section 1.1.1—15 is amended to also apply to cell-cultured food.

New section S3—54(1) will provide that cell-cultured quail for the purposes of the specification means and therefore applies to ‘quail cells obtained from culturing embryonic fibroblast cells (cell line 221523-Fib-Quail) sourced from *Coturnix japonica*’.

New section S3—54(2) sets specifications for cell-cultured quail in relation to protein, moisture, ash, fat and carbohydrates.

### **Schedule 27— Microbiological limits in food**

**Item [16]** of the Schedule amend Schedule 27 of the Code.

**Item [16]** amends the table to section S27—4 to set microbiological limits for both *salmonella spp* and *Listeria monocytogenes* in cell-cultured food. The Item will insert the following entry into the table.

**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