7 April 2025
336-25

Approval report – Application A1269

Cultured quail as a novel food

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Vow Group Pty Ltd to permit the use of cultured quail cells as a novel food ingredient in food products to be marketed and sold in Australia and New Zealand.

FSANZ completed a first round of statutory public consultation in February 2024 in which it received 40 submissions and one late comment. Following consideration of submitter feedback and a review of the best available evidence, FSANZ undertook a second round of statutory public consultation between 12 November 2024 and 12 January 2025. FSANZ sought submissions on two new draft standards, one new draft schedule and draft consequential variations to other provisions of the Australia New Zealand Food Standards Code and published an associated report. FSANZ received 22 submissions.

FSANZ approved the draft standards, schedule and other variations on 26 March 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 7 April 2025.

This report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

Table of contents

Supporting documents

The following documents which informed the assessment of this application are available on the FSANZ website:

Supporting Document 1	Risk assessment revised after the 2nd CFS (SD1)
Supporting Document 2	Labelling requirements at 2nd CFS (SD2)
Supporting Document 3	University of Adelaide consumer literature review (SD3)
Supporting Document 4	Production and processing requirements revised after the 2nd CFS (SD4)

Executive summary

In February 2023, Food Standards Australia New Zealand (FSANZ) received an application from Vow Group Pty Ltd seeking an amendment to the Australia New Zealand Food Standards Code (the Code) to permit the use of cultured quail cells, derived from embryonic fibroblasts of Japanese quail, as a novel food ingredient.

The application was assessed under FSANZ's major procedure, with two rounds of public consultation.

FSANZ's assessment concluded that:

- The quail embryonic fibroblast cell line is genetically stable and the microbiological risks associated with sourcing this cell line were minimal.
- Effective management of microbiological risks in cell-cultured food production necessitates a comprehensive Hazard Analysis Critical Control Points (HACCP)-based approach, supported by good practices. This is particularly crucial during the cell expansion phase to minimize potential contamination.
- At the estimated consumption levels, there were no toxicological concerns related to the cell media or inputs used in the production process.
- The nutrient content of the harvested cells did not raise any nutritional safety concerns.
- The harvested cells were unlikely to pose a food allergenicity risk to the general population.

The 1st statutory Call for Submissions (CFS) was issued in December 2023 and the 2nd CFS was issued in December 2024. The 2nd CFS included two draft standards, a draft schedule and draft consequential variations to the Code, and an associated report, detailing 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.

For the reasons set out in this report, FSANZ approved the draft standards, draft schedule and consequential variations with some amendments.

The approved draft standards are:

- Standard 1.5.4 – Cell-cultured foods. This standard provides the permissions and sets general requirements for cell-cultured foods including labelling requirements such as the use of the statement 'cell-cultured' or 'cell-cultivated' for food identification purposes. The standard also stipulates a cell-cultured food must not be added to special purpose foods covered by Part 2.9 of the Code.
- Standard 3.4.1 – Food safety requirements for processing of cell-cultured food. This standard establishes production and processing requirements for cell-cultured foods produced in Australia, relating to inputs, premises and equipment, processing protocols, monitoring and verification. Standard 3.4.1 also covers the sourcing of cells from a donor animal through to the production of the final food for sale.
- Schedule 25A – Permitted cell-cultured foods. This schedule lists specific conditions for sale and labelling of cell-cultured quail. Any cell-cultured foods permitted in the future will be included in Schedule 25A.
- Consequential variations to other Code provisions, including an amendment to Standard 1.1.1 to provide that a food for sale must not be, or have as an ingredient or a component, a cell-cultured food unless expressly permitted by the Code

The amendments made to the draft measures prior to their approval included:

- Removing a proposed requirement that cell line suppliers have a food safety program in accordance with Standard 3.2.1. Cell line suppliers already operate according to good laboratory practices (GLP) and good cell-culturing practices (GCCP) to manage risks. In addition, the approved draft regulatory measures will require each cell line to be assessed and approved by FSANZ before it may be used in production of cell-cultured- food. The overall food safety risk is very low for cell lines. Therefore, a food safety program in accordance with Standard 3.2.1 is not required.
- For the same reasons, not expressly requiring cell line suppliers to ensure that inputs do not make cell-cultured food unsafe or unsuitable. This is not required as cell line suppliers operate according to GLP and GCCP standards and FSANZ will assess and approve each cell line.
- Schedule 27 was amended to set microbiological safety criteria for two pathogens, *Salmonella* spp. and *Listeria monocytogenes*, in cell-cultured food. However, these criteria do not apply to cell lines.

The approved draft measures will manage risks with cell-cultured food production and processing for cultured quail and other cell-cultured food products and ensure that cell-cultured food is safe for consumers.

1 Introduction

In February 2023, Food Standards Australia New Zealand (FSANZ) received an application from Vow Group Pty Ltd (the applicant) requesting an amendment to the Australia New Zealand Food Standards Code (the Code) to permit the use of cultured quail cells, derived from embryonic fibroblasts of Japanese quail, as a novel food ingredient.

FSANZ assessed the application under its Major Procedure, requiring two rounds of public consultation. The first call for submissions (CFS) invited feedback on FSANZ's assessment of the application and the proposed regulatory approach to guide the development of draft amendments to the Code. FSANZ received 40 submissions and one late comment in response to the 1st CFS.

A 2nd CFS was subsequently prepared, outlining FSANZ's responses to those submissions and seeking further submissions on, among other things, proposed draft variations to the Code prepared by FSANZ. FSANZ received 22 submissions in response to the 2nd CFS.

Submissions received in response to the 2nd CFS have informed FSANZ's decision on whether to approve, amend or reject the proposed draft regulatory measures. Approved draft regulatory measures must be referred to the Food Ministers' Meeting for ministerial consideration.

There are four supporting documents to this report:

- Supporting Document 1 Risk assessment revised after the 2nd CFS (SD1)
- Supporting Document 2 Labelling requirements at 2nd CFS (SD2)
- Supporting Document 3 University of Adelaide consumer literature review (SD3)
- Supporting Document 4 Production and processing requirements revised after the 2nd CFS (SD4)

1.1 The applicant

Vow Group Pty Ltd is a biotechnology company based in Sydney, Australia, which grows animal cells in culture for food use.

1.2 The application

The applicant requested amendments to the Code to permit the use of cultured quail cells as a novel food ingredient. Cultured quail cells will be combined with other ingredients to create various products, including but not limited to logs, rolls and patties. The applicant advised these products will be cooked before consumption. The applicant initially plans to market these foods through high-end restaurants.

1.3 Relevant standards

Australian and New Zealand food laws require food for sale and food businesses to comply with relevant requirements in the Code. At present, the Code regulates cell-cultured food as novel foods, the provisions for which are outlined below. For this reason, the applicant requested their cultured quail cells be assessed as a novel food.

As explained in this report, FSANZ decided to regulate cell-cultured foods as a separate category of novel food and has approved two draft standards and one draft schedule for this purpose. This means that the Code's novel food provisions will not apply to cell-cultured- food once the approved draft standards and schedule take effect.

1.3.1 Novel foods

Standards 1.1.1 and 1.5.3 of the Code regulate novel foods. Section 1.1.2—8 describes which foods are novel foods for the purposes of the Code. It defines a 'novel food' as a 'non-traditional food' that requires an assessment of public health and safety considerations having regard to:

(a) the potential for adverse effects in humans; or
(b) the composition or structure of the food; or
(c) the process by which the food has been prepared; or
(d) the source from which it is derived; or
(e) patterns and levels of consumption of the food; or
(f) any other relevant matters.

A 'non-traditional' food is defined in the Code as, among other things, a food that does not have a history of human consumption in Australia or New Zealand.

Paragraphs 1.1.1—10(5)(b) and 1.1.1—10(6)(f) of the Code provide that, unless expressly permitted by the Code, a food offered for retail sale must not be a novel food or have a novel food as an ingredient.

Section 1.5.1—3 provides that a novel food, or food containing a novel food as an ingredient, may be offered for retail sale if the novel food is listed in the table to section S25—2 and any conditions of use specified in that table are complied with.

The table to section S25—2 lists permitted novel foods together with conditions for use including use levels, restrictions for use and labelling. Novel foods must undergo pre-market assessment and approval by FSANZ before they can be listed in that table.

1.3.2 Identity and purity requirements

Section 1.1.1—15 of the Code requires that, when added to food in accordance with this Code, or sold for use in food, a substance that is a novel food must comply with any relevant identity and purity specifications set out in Schedule 3 of the Code.

Schedule 3 sets specifications by listing a relevant specification in that schedule itself or by applying a specification included in an international publication listed in sections S3—2 and S3—3 of that schedule.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food.

Standard 1.2.1 sets requirements for applying labelling and information to food for sale that is packaged, unpackaged or not required to bear a label. Food for sale includes retail sales, food sold to a caterer and other sales of food.

Standard 1.2.2 sets information requirements for food identification, including requirements for the name of a food.

Standard 1.2.4 generally requires food for sale to be labelled with a statement of ingredients. Section 1.2.4—4 requires ingredients to be listed by a common, descriptive or generic name (if any). Permitted generic names of ingredients are listed in section S10—2 of Schedule 10.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition, health and related claims made about food.

Standard 1.2.8 generally requires food products to be labelled with nutrition information.

Standard 1.2.10 sets information requirements for the declaration of characterising ingredients and components of food.

Section 1.5.1—3 allows the retail sale of a permitted novel food if any conditions of use, including in some instances the use of a specific name, are met.

1.3.4 Code definitions

Standard 1.1.2 contains definitions applying across the Code. It currently does not contain a definition for cell-cultured food.

Section 1.1.2—3 of the Code sets out what constitutes 'meat' or 'meat flesh' for its purposes. The term ***meat*** is defined to mean 'the whole or part of the carcass of any of the following animals, if slaughtered other than in a wild state: buffalo, camel, cattle, deer, goat, hare, pig, poultry, rabbit or sheep; any other animal permitted for human consumption under a law of a State, Territory or New Zealand'. The definition also provides that 'meat' does not include fish; avian eggs; or foetuses or part of foetuses.

The term ***meat*** flesh is defined to mean meat that consists of skeletal muscle and any attached: animal rind; fat; connective tissue; nerve; blood; blood vessels; or skin (in the case of poultry).

These defined terms do not apply to cultured quail cells. Cultured quail cells are derived from embryo tissue, which is excluded from the definition of 'meat'. Furthermore, cultured quail cells are not the whole or part of a poultry carcass that has undergone slaughter, nor are they derived from skeletal muscle.

1.3.5 Microbiological limits for food lots

Section 1.1.1—11 of the Code requires that a 'lot' of a food must not have an unacceptable level of microorganisms. Standard 1.6.1 sets out how to determine whether a specific lot of food has an unacceptable level of microorganisms. Schedule 27 sets maximum permissible limits for particular microorganisms in different food groups for the purposes of Standard 1.6.1.

1.3.6 Food safety standards

State and Territory food laws and section 1.1.1—14 of the Code require food businesses in Australia to comply with the food safety standards in Chapter 3 of the Code. These include general food safety requirements for people, premises, equipment and processes. A food business may also be required to develop and implement a documented food safety program as required under Standard 3.2.1 to demonstrate how they will manage food safety risks. Chapter 3 standards do not apply in New Zealand.

1.3.7 Primary production and processing standards

State and Territory food laws and sections 1.1.1—3 and 1.1.1—14 of the Code require primary producers and processors of certain commodities (seafood, poultry, meat, dairy, eggs, sprouts, berries, leafy vegetables and melons) to meet relevant requirements in Chapter 4 of the Code. These standards aim to strengthen food safety and traceability

throughout the food supply chain, from paddock to plate. Businesses may need to develop and implement a food safety program or a food safety management statement to demonstrate how they manage food safety risks. Chapter 4 standards do not apply in New Zealand.

1.4 International situation

The FAO/WHO (2023) analysis of global developments in the regulation and risk assessment of cell-based foods indicated that, in most countries, these foods are likely to be assessed under existing novel food regulations.

In December 2020, the Singapore Food Agency approved the first cultured meat product, a cultured chicken, under its novel food regulations. The US Food and Drug Administration (FDA) completed two premarket consultations of foods made with cultured chicken cell material (FAO/WHO, 2023) (Human Food Made with Cultured Animal Cells Inventory (fda.gov)). These were subsequently approved by the US Department of Agriculture Food Safety and Inspection Service (FSIS) (refer to 1st CFS, section 1.4).

More recently, the Ministry of Health National Food Services in Israel approved a cell-cultured- beef product. The product, which was approved in January 2024, originates from bovine cells and is manufactured and sold by Aleph Farms under the name 'Cultivated Petit Steak'.

In March 2024, the Singapore Food Agency approved the applicant's cell-cultured quail product under its novel food regulations. In addition, in November 2024, the applicant expanded sales of 'Forged Parfait' and its latest cell-cultured quail product 'Forged Gras' into Hong Kong. No specific regulations govern the production or sale of cultured meat in Hong Kong, however, the product satisfied the safety assessment requirements of its Centre for Food Safety (CFS), drawing on the regulatory approval granted by the Singapore Food Agency.

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of food regulatory measures.

1.6 Procedure for assessment

The application was assessed under the Major Procedure, which requires two rounds of public consultation.

1.7 Decision

As explained, in December 2024, FSANZ sought public submissions on four draft regulatory measures: draft Standard 1.5.4, draft Standard 3.4.1, draft Schedule 25A and the draft *Food Standards (Application A1269 – Cultured quail as a novel food Consequential Amendments) Variation*.

For the reasons listed in this report, including the Supporting Documents, FSANZ approved these four regulatory measures with amendments. These amendments are outlined in Attachment A.

The approved draft regulatory measures are:

- 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
- The *Food Standards (Application A1269 – Cultured quail as a novel food Consequential Amendments) Variation*, which makes consequential variations to standards 1.1.1, 1.1.2, 1.2.1 and 3.1.1.

An amendment to Standard 1.1.1 will prohibit a cell-cultured food from being a food for sale or an ingredient or a component of a food for sale, unless expressly permitted by the Code.

Standard 1.5.4 will provide the permissions for the purposes of the above-mentioned prohibition, and set general requirements for cell-cultured foods, including labelling requirements.

Schedule 25A will list permitted cell-cultured foods for the purposes of Standard 1.5.4. The Schedule will list the applicant's cell-cultured- quail as a permitted cell-cultured food and set specific conditions for its sale and labelling.

Standard 3.4.1 will set production and processing requirements for cell-cultured foods produced in Australia.

Complete details of the regulatory approach are provided in section 2.5 below.

The approved draft regulatory measures, as amended after consideration of submissions in response to the 2nd CFS, are at Attachment B and will take effect on gazettal.

Each related explanatory statement is at Attachment C. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The versions of the draft regulatory measures on which submissions were sought are at Attachment D.

2 Summary of submissions to the 2nd CFS

2.1 Summary of issues raised in submissions

FSANZ released the 2nd CFS on 12 November 2024, with a nine-week public consultation period that closed on 12 January 2025. In total, 22 submissions were received (refer to Table 1).

For the 2nd CFS, FSANZ included six survey questions aimed at gathering submitter views on specific areas of interest. A summary of these responses, categorised by stakeholder group, can be found in Appendix 1, Table A2.

The submissions reflect a variety of perspectives and highlight numerous issues, some of which were previously addressed by FSANZ in and following the 1st CFS. Key concerns raised by submitters included the sourcing and safety of the cell line, production inputs like media and growth factors, microbiological safety of the harvested cells and overall food safety requirements.

A detailed summary of submitters' comments and FSANZ's responses is provided at Appendix 1, Table A3 – Summary of submissions, with key specific issues also addressed in sections 2.2 and 2.3 below. Submitter comments relating to production and processing are also discussed in SD4 to this report.

Table 1: Number of submissions received by submitter groups

Submitter group	Total
Government	7
Industry / peak bodies	9
Industry advocacy groups	2
Public interest advocacy	1
Individuals	3
Total	**22**

2.2 Submissions related to risk assessment

FSANZ conducted a risk assessment of the applicant's cell-cultured quail, the conclusions of which are summarised in section 2.4 of this report. The full details are available in SD1 to this report. The 1st and 2nd CFS published and sought submissions on the risk assessment and its conclusions.

Risk assessment issues raised in response to the 2nd CFS related primarily to:

- primary cell isolation and cell bank storage
- cell immortalisation
- vertical transmission of microbiological hazards
- genetic stability
- allergenicity
- safety of basal and media inputs
- production and processing requirements
- production scale up
- microbiological safety of cells particularly at harvest
- nutrition
- dietary intake/exposure assessment

- consumer evidence.

No new scientific studies or data were received in the submissions that would warrant a change to the risk assessment conclusions on the safety of the cell-cultured quail or other cell-cultured foods. FSANZ is not aware of any other additional or new evidence that would warrant a change to those conclusions. Detailed responses to individual issues raised in submissions are provided in Appendix 1, Table A3.

2.3 Submissions related to the regulation of cultured quail, including production and processing requirements

The regulatory approach for all cell-cultured foods is set out in section 2.5. This includes the approved draft standards and the approved draft schedule.

Standard 1.1.1 will be amended to state that a food for sale must not contain, as an ingredient or component, any cell-cultured food unless explicitly permitted by the Code. All future cell-cultured foods will be regulated accordingly, with cell-cultured quail being the first to fall under this new regulatory approach.

This section sets out the main issues raised in submitters' feedback on the proposed regulatory approach and FSANZ's responses, including any amendments made to the draft variations as a result of that feedback. Detailed responses to all issues raised in submissions are set out in Appendix 1, Table A3.

2.3.1 Support for the regulatory approach

Submitters broadly supported FSANZ's proposed regulation of cell-cultured foods, particularly emphasising its potential to ensure safe food handling and provide clear labelling to support informed consumer choice.

2.3.1.1 Food industry/peak bodies and industry advocacy groups

'Industry, including peak bodies and advocacy groups, supported the new regulatory approach rather than regulating these foods as novel foods. The restriction on processing of only those cell lines assessed by FSANZ was also supported. Industry submitters emphasised the need for a regulatory approach for cell-cultured foods that would ensure safety, provide certainty and maintain public trust and transparency.

Specifically, industry submitters noted:

- *Regulatory certainty:* The proposed approach of introducing two new standards and one new schedule would offer clear guidelines and regulatory certainty for industry, regulators and consumers. Compared to regulation as a novel food (as proposed at the 1st CFS), this approach would provide greater clarity and certainty.

- *Food safety*: The proposed food safety requirements would provide outcome-based measures that would appropriately manage risks associated with cell lines sourcing, production and consumption.
- *Consumer information and transparency:* Support was split by industry submitters on use of either of the terms 'cell-cultured' or 'cell-cultivated' to ensure transparency and information to support consumer choice.

- *Innovation:* The proposed approach would support innovation while still providing the required level of protection of public health and safety. There was also a request to accept overseas assessment outcomes, where a cell line has been approved as safe in one jurisdiction to reduce the compliance burden on applicants and FSANZ.

Industry submitters supported mandatory pre-market assessment of cell-cultured foods and endorsed requirements for cell lines assessed and approved by FSANZ before they could be used in food production. The proposed approach was considered adequately future-proofed, enabling cell lines intended for use in food production to be assessed and approved by application and on a case-by-case basis.

2.3.1.2 Government

Government submitters supported FSANZ's proposed approach, noting it would provide for safety and regulatory oversight. They acknowledged the increased regulatory clarity and certainty it provides compared to the approach suggested at the 1st CFS.

The proposed approach was also considered adequately future-proofed, ensuring all future applications for cell-cultured food would be assessed and approved on a case-by-case basis and production would be subject to ongoing monitoring based on the proposed food safety program requirements.

Points made in government submissions included:

- *Support for safe food handling and production:* The safe food handling and production requirements outlined in SD4 to the 2nd CFS were supported by Government submitters. The proposed microbiological specifications for cell-cultured food which require applicants to implement measures addressing the identified microbiological hazards, irrespective of production scale were also supported.

- *Regulatory oversight:* The proposed Standard 3.4.1 would ensure appropriate and ongoing regulatory oversight of the production process, including microbiological risk mitigation measures. Any modifications to the applicant's production process would be addressed through the requirement to operate and maintain a food safety program.

- *Support for restricted processing:* The submitter supported the approach of restricting processing to assessed cell lines listed in Schedule 25A for the production of cell-cultured food. This would enable any food produced using an unassessed cell line to be removed from the market, as such foods would be non-compliant. The requirement for cell lines to be listed in Schedule 25A was seen by Government submitters as linking the requirements for pre-market safety assessment and permission to sell as food with the food processing requirements. These measures would effectively safeguard public health and safety.

- *Support for labelling requirements:* The proposed labelling requirements were generally supported by most submitters. A regulatory approach that includes the requirement for a statement (e.g. 'cell-cultured' or 'cell-cultivated') was viewed as balancing flexibility for industry while facilitating informed consumer choice, evidence-based and easy to implement and enforce.

2.3.1.3 Public interest advocacy group

One submitter expressed broad support for the revised approach to establish a new regulatory approach for all cell-cultured products, distinct from that for novel foods.

The submitter highlighted that the cellular agriculture industry already has some global investment, facilities, marketing and regulatory momentum. Therefore, a robust general regulatory approach would be preferred to safeguard the safety, health and wellbeing of all Australians and New Zealanders.

2.3.1.4 Individuals

Individual submitters supported the new regulatory approach and the development of cell-cultured foods in general, noting such foods can offer consumers a sustainable and ethical alternative to conventional meat. Individual submitters noted the introduction of cell-cultured foods could help reduce the increasing land and climate pressures on food production, potentially leading to positive impacts on farming practices and food security.

2.3.2 Regulatory requirements (other than production and processing requirements)

2.3.2.1 Definition of cell-cultured food

SA Health suggested the definition for cell-cultured food in subsection 1.1.2—2(3) be amended to include the words '*in vitro'*, to better reflect the definition provided for cell-cultured quail in section S25A—4.

FSANZ response:

Cell culture involves growing isolated cells away from the living tissue or organism from which they were derived. FSANZ does not consider that the definition should refer to '*in vitro* cultivation of cells'. By its very nature, the culturing of cells occurs *in vitro*. In the context of the definition for cell-cultured food, the term *in vitro* is therefore considered unnecessary. Amending the definition in this way would also mean that any food produced by cell culturing other than in vitro will not be captured by the definition and would not be regulated as a cell-cultured food. Any such food would possibly remain subject to the novel food standard, but without a production standard associated with it.

2.3.2.2 Prohibition on use in foods standardised by Part 2.9 of the Code

Vow sought clarification on the rationale for the prohibition of cell-cultured quail as an ingredient in all special purpose foods, noting that no safety concerns were identified in FSANZ's safety assessment. NSW Food Authority requested clarity from FSANZ in the approval report on how an application to seek permission to use cell-cultured food in/as special purpose food would be progressed.

FSANZ response

FSANZ considers that cell-cultured foods should not be permitted in special purpose foods without additional pre-market assessment. Part 2.9 of the Code contains food standards that prescribe specific requirements for foods processed or manufactured for physiologically vulnerable individuals and population sub-groups. Pre-market assessment is required to evaluate consumption of cell-cultured foods in relation to the specific requirements of these vulnerable population groups.

For any new permission for special purpose foods, FSANZ must have regard to Ministerial Policy Guidelines including the Policy guideline on the intent of Part 2.9 of the Food Standards Code – Special purpose foods and for infant formula products, the Policy guideline on infant formula products. The guideline for special purpose foods includes the specific policy principles that the composition of these foods should be consistent with the intended purpose and the maintenance of a clear distinction between special purpose foods and other foods regulated elsewhere in the Code.

The approved draft regulatory measures will prohibit the addition of cell-cultured food to special purpose food standardised by Part 2.9 of the Code (e.g. infant formula products, food for special medical purposes, formulated meal replacements). The prohibition does not preclude FSANZ from considering future applications for cell-cultured quail or other cell-cultured foods to be permitted for use in special purpose foods.

2.3.3 Production and processing requirements

Most submitters supported FSANZ's proposed approach at 2nd CFS to consider cell culturing as food handling under Chapter 3 and mandating food safety programs to apply Hazard Analysis Critical Control Points (HACCP) principles to its production.

Several submitters were concerned about unintended capture of and impeding research and development (R&D) activity or non-food uses of cultured cells such as pharmaceutical production. It was noted these business may have good cell culturing practices (GCCP) but not food safety programs in place, or they may not be using 'assessed cell lines'.

The Code will only apply to and regulate cell lines when used or are intended for use in food production. See the definition of 'cell line' in proposed section 3.4.1—2. Non-food uses of cell lines such as R&D activities or pharmaceutical production are not regulated by the Code.

One submitter was concerned a business could not produce cell-cultured food for export until it had the cell line assessed and cell-cultured food approved by FSANZ. If the business only produces cell-cultured food for export, they need to discuss what requirements apply, with their state or territory government regulator and the Australian Government Department of Agriculture, Fisheries and Forestry.

Several submitters did not agree the processing standard (Standard 3.4.1) proposed by FSANZ at 2nd CFS would effectively support the assessment of safe food products or provide clear guidance on maintaining adequate process control. Closer alignment with how meat is regulated was suggested.

FSANZ is confident the proposed approach, which was based on the best available scientific evidence, will provide for effective food safety assessment and management of these foods. FSANZ is also developing guidance material to support application of Standard 3.4.1, including guidance on maintaining process control and other requirements for cell-cultured food, which will be published on the FSANZ website.

Several submitters commented on the definition of a cell line needing further clarification and amendment to improve its description. Concern was expressed that the definition is unclear when a cell line requires regulation under a food safety program. FSANZ reviewed part (c) of the definition and considered 'intended for use' was appropriate for when the definition applies.

There was a suggestion to move the definition to Standard 1.1.2 as the word cell line occurs in Standard 1.5.4-3 and Schedule 25A. FSANZ does not consider it necessary to relocate the cell line definition to Standard 1.1.2. Its location in Standard 3.4.1 is sufficient for regulatory

purposes. The only references to cell line other than in Standard 3.4.1 will be: to 'the cell-line 221523 Fib-Quail' (such as in section S3—54 and S25A—3); in section S25A—6 which lists each assessed cell line for the purposes of section 3.4.1—2; to 'cell line supplier' in Standard 3.1.1 for definition of food business and links to Standard 3.4.1; and the one reference in the entry in section S27—4 for cell-cultured food (i.e., 'excluding a cell line'). In each case, the context and meaning is clear. Each reference should be read in light of Standard 3.4.1 and the regime it establishes.

Submissions commented the cell line definition was too simplistic as cell lines are quite complex and cells within a cell line may be similar but not uniform. FSANZ reviewed the definition, including consideration of definitions developed and published by Good Food Institute Brazil, United Kingdom Food Standards Agency, World Health Organisation and Good Food Institute – APAC. FSANZ decided the reference to 'uniform composition' in the proposed definition is a more appropriate phrase as the definition is in reference to a stored cell line in freezers/cell banks.

FSANZ has decided to retain the cell line definition from the 2nd CFS.

2.3.3.1 Food safety program for a cell line supplier

Five submitters comprising both industry and government, raised concerns about requiring a cell line supplier (CLS) to have a food safety program compliant with Standard 3.2.1. It was noted that cell line suppliers already follow good cell culturing practices (GCCP) and good laboratory practices (GLP) or quality assurance processes, which are considered equivalent to the requirements of Standard 3.2.1. To avoid unnecessary duplication of requirements, this equivalence should be recognised within Standard 3.4.1.

FSANZ response

The approved draft regulatory measures will require a relevant cell line to be independently assessed and approved before it can be used to produce food. In assessing each cell line intended for use in cell biomass production, FSANZ will consider the cell line sourcing and development process used by the CLS. Once developed, a cell line is typically banked and not subject to ongoing processing activities by the supplier. In these circumstances, FSANZ considers a food safety program is unnecessary in the standard as the food safety risks are lower than those of the cell culturing food business and will be considered by FSANZ in its pre-market assessment. Consequently, this requirement has been removed from Standard 3.4.1.

A CLS will be a food business and subject to Standards 3.2.2, 3.2.3 and 3.4.1. The approved draft Standard 3.4.1 contains the cell line food safety requirements and traceability requirements for a CLS.

2.3.3.2 Inputs requirement for cell line supplier

Three submitters, one government and two industry, raised concern with how 'inputs' used by the CLS were drafted in Standard 3.4.1. One submitter suggested the drafting implied a 'fixed list' of inputs, which may not capture future inputs. Two submissions noted inputs used at this stage of production will be subject to significant dilution during expansion and subsequent processing and pose a very low risk. A separate standalone requirement for inputs is not necessary or supported given the low risk. The risks associated with a cell line are managed under GCCPs and GLP.

FSANZ response

After consideration of submissions, FSANZ agrees inputs used by a CLS to develop and store a cell line are low risk in the final food for consumption. Further, FSANZ will also assess each cell line as part of the pre-market assessment process for each cell-cultured food. Inputs will be considered and assessed as part of that assessment. For these reasons, FSANZ amended draft Standard 3.4.1 to remove the named 'inputs' requirement for a CLS.

2.3.3.3 Traceability requirements for cell line

Two submitters raised concerns with the proposed wording for traceability requirements applying to a CLS. Cell lines are developed for a number of uses and may be stored in cell banks for long periods. The requirement to trace back to a specific donor animal may be challenging in some situations.

FSANZ response

FSANZ considered the issues raised but decided that no changes were necessary. GCCPs require the source of cells to be known and cells to be screened and well characterised, to determine the 'health', features and identity of the cell line. Using a risk assessment approach, safety and identity of the cell line can be demonstrated (and periodically re-confirmed) through relevant analytical testing to verify freedom from contamination and cell line identity. The CLS can and should provide this information to customers, for example through certificates of analysis.

2.3.3.4 Food safety program for a cell-culturing food business

Two submitters sought clarification on what was meant by the term 'a cell culture' in paragraph3.4.1—7(2)(c), as that term is not defined and is unclear on what is required.

FSANZ response

FSANZ has amended paragraph 3.4.1—7(2)(c) to replace the reference to 'a cell culture' with the term 'cell proliferation'. The term 'cell proliferation' is defined in section 3.4.1—2. The Section 3.4.1—7, as amended, will require the food safety program for the cell-culturing food business (CCFB) to detail how the CCFB will identify when a cell proliferation is non-conforming.

2.3.3.5 Existing food safety and hygiene requirements

One submitter raised concern that cell-cultured food will not be held to the same food safety standards as products like beef. The submission requested an equivalence assessment of the proposed Standard 3.4.1 against the established criteria and production process monitoring for red meat and meat products. The submitter did not agree the approach outlined in the CFS effectively supports the assessment of safe food products, providing clear guidance on maintaining adequate process control.

FSANZ response

FSANZ's assessment is the Code's current food safety and hygiene requirements that apply to all food businesses, when supplemented by measures unique to cell-cultured food production, would manage risks with cell-cultured food production and processing. FSANZ agrees there is a need for guidance material to support Standard 3.4.1 and is currently preparing this material which will include guidance on maintaining process control.

2.3.3.6 Schedule 27 – Microbiological limits in food

FSANZ received several comments from submitters on the microbiological criteria for cell-cultured food.

One submitter suggested the microbiological criteria should be included in a specification in Schedule 3, which is the usual approach for approved novel foods.

Another submitter queried including criteria for cell-cultured food for *Salmonella* spp and not other pathogens. They considered there was no need for a separate *Listeria monocytogenes* standard as Schedule 27 already had a standard for ready-to-eat foods. The submitter noted the applicant indicated the cell-cultured quail will be subject to cooking prior to consumption, which would mitigate the food safety risk due to *Salmonella* spp and *Listeria monocytogenes*.

FSANZ response

FSANZ considers, at this time, it is suitable to incorporate food safety microbiological criteria for cell-cultured food into Schedule 27 and guidance on microbiological indicators of hygienic production in the Compendium of Microbiological Criteria for Food (FSANZ 2022).

Cell-cultured food represents a new type of food and a new production process and is considered a potentially hazardous food, as defined in Standard 3.2.2. Although the applicant indicated risk mitigation during further processing of the cell biomass includes a cooking step, this was not assessed. There is no prior history of food preparation in food service or at home by consumers. FSANZ has therefore taken an initially conservative approach to manage the potential microbial risk associated with cell-cultured food. This will be reviewed as cell-cultured foods are developed and consumed more widely in Australia and New Zealand.

The approved draft consequential variation includes criteria for *Salmonella* spp. and *L. monocytogenes* in Schedule 27 - Microbiological *indicators* of hygiene control will be updated in the guidance document, Compendium of Microbiological Criteria for Food (FSANZ 2022).

2.3.3.7 Transitional arrangements

There was general support from NZFS for implementing the Code amendments without a transition period. NZFGC suggest that a transitional arrangement could be required in New Zealand before Vow could manufacture cultured quail in New Zealand.

FSANZ response

The support for not implementing a transitional period from NZFS was noted. The production of cell-cultured food in New Zealand is out of scope and remains a matter for the New Zealand Government. The need or otherwise for transitional arrangements in New Zealand is also a matter for the New Zealand Government.

2.3.4 Labelling

The regulatory approach for labelling of cell-cultured foods is described in FSANZ's assessment at 2nd CFS. The regulatory approach sets requirements for cell-cultured foods as a distinct category of food in the Code (new Standard 1.5.4) and specific labelling requirements that will apply to cell-cultured quail in the new Schedule 25A (see SD2 Labelling requirements at 2nd CFS, accompanying this report). In summary, this approach sets requirements for food identification (terminology, name of ingredient, name of the food, use of the term 'meat', prohibition of the phrase 'poultry meat'), food for sale that is not

required to bear a label and food sold to a caterer.

After considering submitter comments to the 2nd CFS, FSANZ has revised the approach for characterising ingredient information. The following section provides discussion on this issue.

2.3.4.1 Characterising ingredients

A government submitter considered that, based on the consumer evidence and inconsistency with existing requirements in the Code for other food ingredients (including food produced using gene technology and irradiated foods), the characterising ingredient information requirements (also referred to as 'percentage labelling') proposed for cell-cultured food were not justified. They were also concerned that applying these requirements to food containing a cell-cultured ingredient, where that food for retail sale is not required to bear a label, was inconsistent with existing requirements.

Additionally, not applying existing labelling exemptions from characterising ingredient requirements for prepared filled rolls, sandwiches, bagels or similar foods (paragraph 1.2.10—3(3)(a)) and food that is sold at a fund-raising event (paragraph 1.2.10—3(3)(b)) was viewed as problematic because such foods were often made by hand and the amounts of ingredients would vary per food item. The proposed requirement for percentage labelling was therefore considered to be unenforceable (see Table A3 in Appendix 1).

FSANZ response

After considering the submission, FSANZ decided to amend the draft consequential variation at 2nd CFS to remove the proposed characterising information requirements for cell-cultured food when it is used as an ingredient in a food for sale that is not required to bear a label.

The reasons for this decision are outlined below:

- FSANZ agrees there is no evidence of consumer expectations for percentage labelling of the cell-cultured food ingredient to be provided for these types of sale scenarios (e.g. food sold in an assisted service display cabinet).

- FSANZ agrees the proposed requirements at 2nd CFS would be inconsistent with the approach for food produced using gene technology and irradiated foods. Further, the proposed approach would be inconsistent with more generic food ingredients (e.g. for a cell-cultured quail and mushroom patty, the percentage amount of cell-cultured quail would be declared, but not the percentage amount of mushroom).

- FSANZ notes the government submitter's comment that variation in the amount of ingredients in food that is made by hand would make compliance and enforcement difficult for suppliers and enforcement agencies, respectively.

FSANZ has therefore removed the proposed information requirements in items [11], [13] and [14] of the draft consequential variation at 2nd CFS.

Existing requirements for characterising ingredient information will apply to food containing cell-cultured food as an ingredient (paragraph 1.2.1—9(7)(e) of the Code). The general provision applies to food that is not required to bear a label because it is not in a package and food that is made and packaged on the premises from which it is sold. The Code currently requires characterising ingredient information to be displayed in connection with the display of the food or provided to the purchaser on request (subsection 1.2.1—9(6)). This provision is intended to provide flexibility to suppliers whilst still providing consumers access to characterising ingredient information at the point of sale.

Existing labelling exemptions for prepared filled rolls, sandwiches, bagels or similar foods (paragraph 1.2.10—3(3)(a)) and a food for sale that is sold at a fund-raising event (paragraph 1.2.10—3(3)(b)) will apply to a food containing cell-cultured food as an ingredient, as for any other food.

FSANZ notes that characterising ingredient labelling requirements will apply to packaged food for sale containing cell-cultured food as an ingredient, if labelling requirements for the name of the food for sale apply (section 1.5.4—6 of Standard 1.5.4 Cell-cultured foods).

As noted in section 2.5 below, the proposed requirement for information relating to cell-cultured- food (i.e. the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the ingredient name) applies to all retail sales, including foods for sale which are not required to bear a label. This will assist consumers to make informed choices and minimise the potential for them being misled.

2.4 Risk assessment

The risk assessment for cultured quail cells evaluated the:

- hazards associated with the embryonic fibroblast cell line from Japanese quail
- production process including any relevant inputs used to grow and propagate the Japanese quail cells
- cells at the point of harvest which includes collection, packaging and freezing.

In summary, the assessment concluded the following:

- The cell line (221523-Fib-Quail) is genetically stable and any microbiological risks associated with cell line sourcing are very low.
- The management of microbiological risks requires a through-chain, HACCP-based approach to cell-cultured food production supported by good practices. This will limit potential contamination if implemented effectively, particularly during the cell expansion phase.
- There are no toxicological concerns associated with the cell media or inputs used in the production process at the estimated consumption levels.
- No nutritional safety concerns were identified from the nutrient content of the harvested cells.
- The harvested cells are unlikely to pose a food allergenicity concern for the general population.

Full details of the hazard and risk assessment are available in SD1 to this report.

FSANZ has considered the best available scientific evidence on consumers' awareness, understanding and perceptions of cell-cultured meat. Collectively, the evidence found terms that incorporate the word 'cell' such as 'cell-cultured', 'cell-cultivated' and 'cell-based' best enabled consumers to correctly identify the true nature of the product and were perceived as being the most descriptive by consumers.

2.5 Risk management

Following assessment and consideration of submissions, and for the reasons set out in this report, FSANZ has decided to retain the regulatory approach proposed in the 2nd CFS to regulate the sale and production of cell-cultured food in Australia.

The new regulatory approach was approved to effectively manage risks associated with sourcing, production, and consumption of cell-cultured food, ensuring its safety and suitability and provide regulatory certainty for industry, regulators, and consumers.

The new approach also ensures consumers are well-informed and have clear choices by requiring the terms 'cell-cultured' or 'cell-cultivated' to be used for these food products.

Consultation with Australia's cell-cultured food sector indicated that the proposed regulatory measures would have minimal impact on them. The proposed regulatory approach is proportionate to the risks involved. Further, FSANZ has removed the requirement for cell line suppliers to become a ‘food business’ and to have a food safety program. Instead, FSANZ considers GLP or GCCP are adequate to ensure the safety of cell lines. Additionally, the use of cell-cultured quail ingredients and other cell-cultured foods would be voluntary.

The proposed food regulatory measures are expected to provide direct and indirect benefits that likely outweigh the associated costs. Additionally, there are no alternative measures, whether available to FSANZ or not, that would be more cost-effective.

The approved draft regulatory measures are at Attachment B. They include two new standards and a new schedule:

- 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 approved draft regulatory measures, if approved, will amend the Code as follows.

Standard 1.1.1 will be amended to provide that a food for sale must not be, or have as an ingredient or component, a cell-cultured food unless expressly permitted by the Code.

Standard 1.5.4 will provide the permissions and set general requirements for cell-cultured foods.

Standard 1.5.4 will provide that a food for sale may be, or have as an ingredient or component, a cell-cultured food if the cell-cultured food is listed in Schedule 25A and any corresponding conditions listed in Schedule 25A are complied with.

Standard 1.5.4 will require information relating to a permitted cell-cultured food to be included in the food for sale’s labelling to inform consumers. For all retail food sales, the required information is the use of either ‘cell-cultured’ or ‘cell-cultivated’ in conjunction with the name of the cell-cultured food ingredient. This requirement will apply to packaged food, unpackaged food and food for sale that is not required to bear a label. If a packaged food for retail sale is represented as being from the animal from which the cell-cultured ingredient was sourced, the same statement and name of the cell-cultured ingredient must also be in the name of the food.

For cell-cultured food sold to a caterer as an ingredient in another food, or separate as a food, the statement ‘cell-cultured’ or ‘cell-cultivated’ in conjunction with the name of the cell-cultured food must be provided.

To manage the microbiological risks identified in the risk assessment, Standard 3.4.1 will establish general processing and production requirements for cell-cultured foods produced in Australia (refer to SD4 of this approval report). These relate to inputs, premises and equipment, processing protocols, monitoring and verification. They provide for regulation of cell-cultured food throughout the supply chain, from development of a cell line through to manufacturing of the final food for sale. Since culturing cells for food is more akin to food processing than primary production, FSANZ included the processing standard in Chapter 3. This was supported by state and territory governments.

A CLS must comply with food safety and traceability requirements. A CCFB must have a food safety program that complies with Standard 3.2.1 to minimise the risk of foodborne pathogens entering cell culture production phases. A CLS and a CCFB will be a 'food business' for the purposes of Chapter 3 of the Code and relevant food laws. The generic food safety requirements listed in Chapter 3 (Standards 3.1.1, 3.2.2 and 3.2.3) of the Code would also apply to a CLS and CCFB.

Schedule 27 would be amended to set microbiological criteria for two pathogens, *Salmonella* spp. and *Listeria monocytogenes*, in cell-cultured food (excluding cell lines).

Approved draft Schedule 25A lists the applicant's cell-cultured quail as a permitted cell-cultured food and set specific conditions for its sale and labelling. For the purposes of the above permission and conditions, section S25A—2 would define *cell-cultured quail* to mean quail cells obtained from culturing embryonic fibroblast cells (cell line 221523-Fib-Quail) sourced from *Coturnix japonica*.

Section S25A—4 provides that the applicant's cultured quail cells must not be a food for retail sale. That is, the cultured quail cells cannot be sold directly to consumers.

Section S25A—5 imposes labelling requirements for food for retail sale that contain the applicant's cultured quail cells as an ingredient. The section restricts use of the word 'meat' so that it may only be used in conjunction with the statement required for the ingredient name and a statement required for the name of the food. The phrase 'poultry meat' is not permitted to be used as a generic ingredient name or elsewhere on the label.

The approved draft consequential variation will amend Standards 1.1.1, 1.1.2, 1.2.1 and 3.1.1 and Schedule 3 and 27 of the Code to implement the above:

- Standard 1.1.2 will include a definition for 'a cell-cultured food' and 'a cell-cultured food producer', confirm that cell-cultured foods are not a non-traditional food and include information requirements for cell-cultured foods.
- Standard 1.2.1 will include general requirements for retail sales and sales to caterers of cell-cultured foods.
- Standard 3.1.1 will include a 'cell line supplier' and a 'cell culturing food business' as defined by proposed Standard 3.4.1 in the definition of a 'food business'.

The approved draft regulatory measures are premised on cell lines and a cell biomass each being declared to be a *food* for the purposes of the Code and the food laws that apply the Code. This would provide the certainty required for regulation.

The effect of these proposed measures will be that:

- Food for sale in Australia and New Zealand cannot be or have as an ingredient a cell-cultured food (as defined) unless expressly permitted by the Code. That is, cell-cultured food must undergo pre-market assessment and have pre-market approval.
- Permitted cell-cultured foods will be subject to labelling, compositional and other requirements, including restrictions on sale for some permitted foods.

- The production of cell-cultured food in Australia will be subject to food safety requirements under Chapter 3. These requirements will apply to CLS and CCFB whose product is for food use. Both will be 'food businesses' for the purposes of Chapter 3. Food manufacturers who use products supplied by CCFBs would also be subject to Chapter 3 standards as 'food businesses'.

To support Standard 3.4.1, FSANZ will work collaboratively with Implementation Subcommittee for Food Regulation (ISFR) to develop best practice guidance, that will explain the intent of the requirements and provide additional technical background on cell-culturing for food.

2.5.2 Transitional arrangements

In preparing the 2nd CFS, FSANZ considered a range of factors in relation to whether or not transitional arrangements should apply. These included whether any businesses are currently producing and marketing cell-cultured food in Australia and New Zealand and the impact on the applicant, who would, in effect, be unable to sell cell-cultured quail until the transition period is ended if this was in place (see section 2.4.2 of the 2nd CFS).

Following consideration of relevant factors and submitter comments (section 2.3.3.8 above), FSANZ confirms there will be no transitional arrangements for the new regulatory approach, which will take effect immediately upon gazettal. This approach encourages industry innovation by allowing the sale of cell-cultured quail in Australia without delay.

2.6 Risk communication

2.6.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ assessed this application under its Major Procedure which required two rounds of public consultation. FSANZ completed its first round of statutory public consultation in early February 2024. The 1st CFS sought views on FSANZ's risk assessment and proposed regulatory approach. Submitters' comments in response to the first round of consultation informed FSANZ's decision to prepare draft variations to the Code.

FSANZ completed a second round of consultation in January 2025. FSANZ sought submissions on two new draft standards, one new draft schedule and draft consequential variations to other provisions of the Code, as detailed in the 2nd CFS and accompanying supporting documents.

Submissions received in response to each round of public consultation are published on the FSANZ website[2].

FSANZ prepared a communication strategy for this application. Subscribers and interested parties were notified about calls for submissions via the FSANZ Notification Circular, media releases, FSANZ's digital channels and Food Standards News. As part of this strategy, FSANZ maintained a regular dialogue with state and territory governments, the New Zealand Ministry for Primary Industries (NZ MPI) and the Department of Agriculture, Fisheries and Forestry (DAFF) in relation to food safety/food production requirements for cell-cultured food products.

[2] https://www.foodstandards.gov.au/food-standards-code/applications/A1269-Cultured-Quail-as-a-Novel-Food

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions are called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals, organisations and government agencies to consider this application. All comments are valued and contributed to the rigour of the assessment.

The draft variations were considered for approval by the FSANZ Board having regard to all submissions received.

2.6.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

The amendments to the Code, which include various regulatory measures to classify cell-cultured foods as a distinct category for Code purposes, may impact international trade – for instance, the specific labelling requirement that either 'cell-cultured' or 'cell-cultivated' be stated with the name of the food. The approved draft Standard 3.4.1 also sets minimum generic processing requirements for cell-cultured food. Additionally, FSANZ has introduced microbiological criteria for cell-cultured food in Schedule 27, which will apply to domestically produced and imported products. Therefore, FSANZ made a notification to the WTO for this application in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade. No WTO member nation provided comment in response to the notification.

2.7 FSANZ Act assessment requirements

2.7.1 Section 29

2.7.1.1 Consideration of costs and benefits

The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise (paragraph 29(2)(a)). The purpose of this consideration was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considered the potential costs and benefits from the following:

- Standard 1.1.1 will be amended to provide that a food for sale must not be, or have as an ingredient or component, a cell-cultured food unless expressly permitted by the Code
- a new Standard 1.5.4
- a new Standard 3.4.1
- a new Schedule 25A
- the specific permission for use of cultured quail cells as a novel food ingredient to enable the sale and use of a mixed food derived from the cell-cultured quail
- consequential variations to other provisions as previously outlined.

FSANZ is of the view no more cost – effective measures are available.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the

status quo.

Note that changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA). Impact analysis is no longer required to be finalised with the OIA. Under the new approach, FSANZ's assessment is that neither a Consultation Regulation Impact Statement (CRIS) nor a Decision Regulation Impact Statement (DRIS) are required for the proposed food regulatory measures of Standards 1.5.4 and 3.4.1, Schedule 25A and the specific permission for use of cultured quail cells as a novel food ingredient. This assumes the proposed changes are not likely to create significant impacts.

2.7.1.1.1 Costs and benefits of the new standards to regulate the permissions, production and processing requirements and general requirements for cell-cultured foods

This section sets out the potential costs and benefits of the proposed new standards and consequential amendments to the Code for cell-cultured foods in general. Potential costs and benefits of specifically permitting the sale and use of a mixed food derived from the cell-cultured quail ingredient are outlined in the next subsection 2.7.1.1.2.

Industry
It is expected that proposed new standards and consequential amendments would provide a pathway for assessing and permitting the sale of different cell-cultured foods that is clear to industry participants.

After consultation, it is expected that the new standards would not unduly restrict or impose significant costs on the small number of existing cell cultivating activities or other businesses. These changes create a pathway to allow cell-cultured food to be sold for human consumption which is currently prohibited.

It is anticipated that establishing a clearer pathway for assessing and permitting the safe innovation of cell-cultured foods will yield net benefits for the industry through potential new business opportunities, as well as net benefits for consumers (see below). While cell-cultured foods might displace some future demand for substitute products, including traditional proteins, such impacts remain uncertain due to the current unpredictability of future growth and consumption patterns of cell-cultured foods.

Consultations by FSANZ with stakeholders in the cell-cultured food sector in Australia have indicated that the impact on them would be minimal.

Consumers
The new standards would allow additional products to enter the market that a number of consumers may find desirable. They provide assurance of consumer safety by:

- creating a clear pathway to assess the safety of new cell-cultured foods before they are permitted, based on latest available evidence
- managing potential risks associated with cell-cultured food and its production processes that could potentially cause foodborne illnesses.

Due to the uncertainty surrounding the future growth of markets for cell-cultured foods, it is currently not possible to predict the impacts on food availability, sustainability, affordability or equity of regulatory measures related to these foods. These aspects fall outside FSANZ's statutory remit. Comments received from the 1st CFS about such aspects are addressed in Appendix 1, Table A2 of the 2nd CFS.

Government
In response to the application for cultured quail as a novel food, jurisdictions raised several issues pertinent to cell-cultured foods in general. These concerns include the need for processing requirements, regulatory coverage, consistency and the understanding and implementation of these measures. The approved draft regulatory measures address these concerns. There are likely to be additional costs to regulators of upskilling staff and other implementation costs. These costs have not been quantified.

2.7.1.1.2 Costs and benefits of permitting cultured quail ingredient

Industry
Due to the voluntary nature of the permission, industry would only use foods derived from the cell-cultured quail ingredient where they believe a net benefit exists for them.

Granting a permission to the applicant for their unique cell-culturing process, linked to the assessed cell-line, will prevent other businesses from producing this food in the same manner. That is unless the applicant permits other businesses to do so under a licencing or other commercial agreement. Granting permission for the applicant's cell culturing process described in the application does not preclude any other business from applying to amend the Code in relation to similar and competing foods, including those using the same cell line, after pre-market safety assessment. FSANZ would assess other applicants' cell-culturing processes on a case-by-case basis, including any new cell-lines not already assessed.

Consumers
If this application is approved and depending on the commercial success of final mixed foods containing this cell-cultured ingredient, consumers may have marginally increased choice of foods. Some consumers may view a range of potential benefits from an ethical and environmental point of view, subject to individuals' dietary, nutritional and other considerations.

Granting a permission to the applicant for the applicant's proprietary cell culturing process described in the application may create a short-term barrier to allowing competition between suppliers to reduce prices paid by consumers for foods that contain cell-cultured quail ingredients.

Government
The approval of cultured quail may result in a small but likely inconsequential cost to government in terms of an addition to the potential range of cell-cultured foods which are monitored for compliance. Granting a permission to the applicant for their cell culturing process is not expected to have any significant impacts for government.

2.7.1.1.3 Conclusions from cost benefit considerations of the proposed new standards and the specific permission for use of the cultured quail ingredient

FSANZ is of the view that the proposed food regulatory measures are, risk-proportionate and not likely to create significant impacts to markets, industry, consumers or government. That is because:

- Cell-cultured foods are in early development with uncertain market growth.
- The proposed measures are designed to ensure safety and suitability of cell-cultured food and achieve greater regulatory clarity for food businesses and jurisdictional food regulators.
- FSANZ's consultation with Australia's cell-cultured food sector indicated that the proposed regulatory measures would have minimal impact on them
- The risk assessment did not identify any safety concerns.

- Use of foods derived from the specific cultured quail ingredient and other cell-cultured foods would be voluntary.
- Industry would only use mixed foods derived from cell-cultured quail or other future permitted cell-cultured foods covered by the standards where they believe a net benefit exists for them.

Therefore, FSANZ's assessment is that the direct and indirect benefits that would arise from the proposed food regulatory measures would most likely outweigh the associated costs.

2.7.1.2 Other measures

For the reasons set out in this report, FSANZ's assessment is that there are no other measures (whether available to FSANZ or not) that would be more cost-effective than the proposed draft regulatory measures.

2.7.1.3 Any relevant New Zealand standards

Approved draft Standard 1.5.4 and the related approved draft measures relating to sale, labelling, composition etc. of cell-cultured foods will apply in both Australia and New Zealand. There are no relevant New Zealand only standards in this regard.

Approved draft Standard 3.4.1 and Chapter 3 apply only in Australia. In New Zealand, the production of cell-cultured foods is regulated by an independently evaluated risk management programme under the *Animal Products Act 1999* and/or an independently evaluated food control plan under the *Food Act 2014*. The food safety standards that comprise Chapter 3 of the Code do not form part of the joint Australian New Zealand Food Standards system established by the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System*.

2.7.1.4 Any other relevant matters

Other relevant matters are considered below.

2.7.2 Subsection 18(1)

FSANZ considered the three objectives in subsection 18(1) of the FSANZ Act in its assessment.

2.7.2.1 Protection of public health and safety

The new regulatory approach for cell-cultured foods implemented by the approved draft regulatory measures will protect public health and safety through the following:

- Standard 1.1.1 will provide that a food for sale must not be, or have as an ingredient or a component, a cell-cultured food unless expressly permitted by the Code. This will ensure no cell-cultured foods can enter the market without a pre-market safety assessment.
- Standard 1.5.4 will provide the permissions and set general requirements for cell-cultured foods. It will provide that cell-cultured foods must not be added to a food standardised by Part 2.9 of the Code.
- Permitted cell-cultured foods must be listed in Schedule 25A and must comply with any specific conditions listed in that Schedule relating to their sale and labelling.
- Standard 3.4.1 will set general production and processing requirements for cell-cultured foods produced in Australia to ensure their safety (refer to part 2.3.3 for information on the production and processing standard).

These approved draft regulatory measures, which support the production of a safe and suitable product, will be applicable to all cell-cultured foods.

The FSANZ risk assessment (SD1 to this report) concluded there are no public health and safety concerns associated with permitting the applicant's cell-cultured quail.

2.7.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Application of generic labelling requirements along with the proposed additional labelling requirements as outlined in section 2.5 of this report will provide information about all future cell-cultured foods. This enables consumers to make informed choices and is relevant to foods including those relating to cell-cultured quail.

2.7.2.3 The prevention of misleading or deceptive conduct

The proposed labelling requirements outlined in section 2.5 of this report will provide information to identify all permitted future cell-cultured foods, minimising the likelihood of consumer confusion.

2.7.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis for this application on cultured quail cells. This included several literature reviews of the evidence on consumer behaviour (SD1 and SD3 to this report).

All future applicants for cell-cultured foods will also be required to submit a dossier of information and scientific literature. These dossiers, together with other relevant technical and scientific information, will be considered by FSANZ in assessing any application.

FSANZ also had regard to the publication by the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) on *Food safety aspects of cell-based food*.

- **the promotion of consistency between domestic and international food standards**

As culturing cells to be used as food is an emerging technology globally, there are not yet Codex food standards or guidelines for these foods.

- **the desirability of an efficient and internationally competitive food industry**

The approved draft regulatory measures will regulate cell-cultured foods, including the applicant's cultured quail cells, as a distinct food category. This decision will support the emerging market sector internationally.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

FSANZ has had regard to high order and specific policy principles in the Ministerial Policy Guideline on Novel foods (MPG 2003) and the Ministerial Policy Guideline on the Labelling of Foods Produced or Processed Using New Technologies (MPG 2014). The former was of relevance in the preparation of the 1st CFS, which occurred prior to FSANZ's decision to prepare new standards and regulate this new product as a cell-cultured food, rather than as a novel food under the existing Standard 1.5.1.

Noting the risk assessment and assessment of the labelling approach (SD1 and SD2 Labelling requirements at 2nd CFS, accompanying this report, respectively), together with the assessment above of FSANZ Act requirements, FSANZ considers the proposed permission and labelling requirements are consistent with policy guidance.

3 References

FAO/WHO. Food safety aspects of cell-based food. 2023. Rome. https://doi.org/10.4060/cc4855en%20 Accessed September 2023.

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MPG 2003. Ministerial policy guideline on novel foods. Food Regulation Secretariat. https://www.foodregulation.gov.au/resources/collections/ministerial-policy-guidelines

MPG 2014. Ministerial policy guideline on the labelling of food produced or processed using new technologies. Food Regulation Secretariat. https://www.foodregulation.gov.au/resources/collections/ministerial-policy-guidelines.

Attachments

A. Amendments made to the draft regulatory measures proposed in the 2nd CFS
B. Approved draft variations to the Australia New Zealand Food Standards Code
C. Explanatory Statements
D. Draft variations to the *Australia New Zealand Food Standards Code* (2nd call for submissions)

Appendix 1 – Summary of submissions

Table A1 provides a list of submitters to the 2nd CFS (sorted by stakeholder group) together with the abbreviation used in the summary of submissions provided in Table A3.

Table A1: Submitters to the 2nd CFS

Submitter	Abbreviation
Government	
Department of Agriculture, Fisheries and Forestry	DAFF
Department of Health Western Australia	DOH-WA
New South Wales Food Authority	NSWFA
New Zealand Food Safety	NZFS
Queensland Health	Qld Health
South Australia Health	SA Health
Victorian Department of Health and the Victorian Department of Energy, Environment and Climate Action	DOH-VIC & VIC DoEECA
Total	7
Industry / peak bodies	
Vow Group Pty Ltd	Vow
Australian Food and Grocery Council	AFGC
New Zealand Food and Grocery Council	NZFGC
Australian Chicken Meat Federation	ACMF
Australian Meat Industry Council	AMIC
Cattle Australia	CA
Red Meat Advisory Council	RMAC
Australian Pork Limited	APL
Opo Bio	Opo
Total	9
Industry advocacy groups	
Alternative Proteins Council, Cellular Agriculture Australia, Food Frontier	APC/CAA/FF
Good Food Institute APAC and APAC Society for Cellular Agriculture	GFI & APAC-SCA
Total	2
Public interest advocacy	
GeneEthics	GE
Total	1
Individuals	
Initials only provided to ensure privacy	EG, PS, MM
Total	3
Total	**22**

Table A2: Responses to multiple choice survey questions (broken down by stakeholder group) at 2nd CFS

Survey questions		Government	Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals	Government	I Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals	Government	Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals	Government	Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals
N.	Question	Yes, I agree					No, I do not agree					I neither agree nor disagree					I have no feedback for this question				
Q1	**Regulatory approach:** Do you agree with FSANZ's approach to regulating cell-cultured foods, which involves developing two draft standards and one draft schedule, as outlined in section 2.4 of the second call for submissions?	4	4	2				2			1	1			1		1		2		2
Q2	**Safe food handling and production requirements:** Do you agree the approach outlined (which is to establish microbiological criteria for food safety and as indicators of process hygiene and handling) effectively supports the assessment of safe food products and provides clear guidance on maintaining adequate process control?	4	2			1		3	1		1	1	2	1	1		1		1		1
Q3a	**Assessed cell line:** The proposed processing standard for cell-cultured food restricts processing to only those cell lines assessed by FSANZ. Do you agree with this approach?	5	5	2		1		1			1		2		1		1				1

Survey questions		Government	Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals	Government	I Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals	Government	Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals	Government	Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals
N.	Question	Yes					No					Unsure					I have no feedback for this question				
Q3b	**Assessed cell line:** Do the requirements in Standard 3.4.1, when considered alongside Standard 1.5.4 and Schedule 25A, effectively achieve the intended outcome where cell lines for use in producing food are subject to pre-market assessment?	2	2				1	2	1	1	1	3	3	1				1			2
Q4	**Definition of 'cell-cultured food':** Does the proposed definition provide regulatory certainty and clarity for industry, enforcement agencies and other stakeholders?	2	3	1		1	1	2	1	1	2	1	2				2	1			
N.	Question	Yes					No														
Q5a	**Labelling:** Do you have any comments or additional evidence to inform the proposed labelling approach?	2	4	2	1	2	4	4			1										
N.	Question	Yes, I agree					No, I do not agree					I neither agree nor disagree					I have no feedback for this question				
Q5b	**Labelling:** Do you agree with the proposed labelling approach?	5	1	2				3			2	1	2		1	1		2			

Survey questions		Government	Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals	Government	I Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals	Government	Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals	Government	Industry / peak bodies	Industry advocacy	Public interest advocacy	Individuals
N.	Question	Yes					No					Unsure					I have no feedback for this question				
Q6	**Costs and barriers:** Would proposed Standards 1.5.4 and 3.4.1 restrict or impose significant costs or barriers to the production of cell-cultured foods? Can you please provide specifically, the potential costs to your business?	1	1	1	1		1					1	3		1	1	3	4			2

Table A3: Summary of submissions (2nd CFS) and FSANZ response

Submission viewpoint	Raised by	FSANZ response
Cell line – safety and immortalisation		
This submitter noted Figure B.5.1-1 in the application dossier, particularly the production process step 'Single-cell cloning and expansion' and queried whether this meant that food directly from cloned animal cells would enter the food supply.	Individual (PS)	'Single-cell cloning and expansion' refers to a technique used in cell culture that involves the isolation of an individual cell from a heterogenous population and its expansion (through cell division) into a homogenous population. It does not mean the cells are sourced from a cloned animal. FSANZ notes that food from cloned animals does not require premarket approval before it may enter the food supply. Further information about food from cloned animals can be found on the following webpage.
The submitter expressed concern that the genetic changes in immortalised cell lines parallel those found in cancers, including the activation of protooncogenes, the inactivation of tumour suppressor genes and chromosomal abnormality.	GE	Concerns about the genetic variation in immortalised cell lines causing indefinite cellular proliferation and that this parallels cancer, were raised at the 1st CFS. FSANZ responded to this issue in the 2nd CFS report (pages 34-35). Briefly, the cell line safety assessment did not identify any safety concerns associated with the genetic changes that occurred during the immortalisation process. In the absence of any new or altered hazards, the risk is no different to the consumption other animal cells found in meat products already in the food supply.
Cell line – vertical transmission of microbiological hazards		
Noted FSANZ's consideration of 'relevant avian viruses' in relation to the quail cell line and, in particular, that only avian influenza and Newcastle Disease were tested for in the cell line. One other significant disease of concern to Australia, from a biosecurity and production perspective, is Infectious Bursal Disease Virus. Submitter considered this a significant gap in the risk assessment methodology to be reviewed and rectified.	ACMF	A full assessment of the cell line is carried out by FSANZ to mitigate any such risks, whether imported or locally sourced.
Basal media and inputs		
Disclosure and assessment Stated that information about the media inputs need to be fully disclosed as they have remaining questions about the growth factors	Individual (MM)	FSANZ notes the submitter concerns regarding the limited amount of publicly available information on the media inputs.

Submission viewpoint	Raised by	FSANZ response
and other substances, including antibiotics, used during the cell culture process.		Such information was accepted as Confidential Commercial Information (CCI). FSANZ is required by law to protect and not disclose CCI. FSANZ conducted a full and independent evidence-based assessment of all media inputs and was satisfied their use and/or presence did not raise any safety concerns.
Submitter expressed a desire for strong, independent assessment and regulation of the substances and processes used in cell-cultured food production.	GE	Noted. All cell-cultured foods will require pre-market safety assessment by FSANZ before they can be sold in Australia and New Zealand. This assessment will include consideration of the media and other inputs as well as the production process. Cell-culturing food businesses must also comply with the proposed Standard 3.4.1
Requested rigorous data collection on the identity and amount of all substances used in every stage of production – especially new and emerging processing aids and additives.	GE	FSANZ agrees that it is important to consider the safety of substances used in cell-cultured food production. FSANZ reviewed information on the identity and amount of all substances used in the production of cell-cultured quail as part of its safety assessment. This will continue for all future applications for this type of food.
Requested periodic reporting of substances used during cell-cultured food production to food safety authorities in relevant jurisdictions.	GE	As covered above, cell lines used to produce food and cell-cultured foods will require premarket safety assessment by FSANZ. Substances used during cell-cultured food production will be assessed on a case-by-case basis. Existing arrangements allow for swift action to be taken in the event that a food product on the market may be identified as unsafe or unsuitable.
Media inputs as processing aids Questioned the rationale for FSANZ not to 'regulate media inputs as processing aids having regard to the definition of 'used as a processing aid' in section 1.1.2—13 of the Code. These inputs are used to support cell growth during culture and do not serve a technological function during food processing or in the final product.' Some/ all of these substances would likely be used for all products, so they have a 'technological function' and must be assessed and monitored for safety, as such.	GE	FSANZ does not agree that the use of media inputs to support cell growth during culture makes those inputs processing aids for Code purposes. See the definition of 'used as a processing aid' in section 1.1.2—13 of the Code. Media inputs do not have a technological function during the course of processing a food or in the final food for sale. FSANZ evaluated the safety of all media inputs used to support the growth of quail cells during culture. FSANZ will follow the same evaluation process for future cell-

Submission viewpoint	Raised by	FSANZ response
		cultured food applications. Media inputs used in the production of a CCF will be subject to premarket assessment that will ensure they do not pose health and safety concerns.
Nutrition risk assessment		
Concern in relation to the high levels of some nutrients. Specific issue raised in relation to vitamin B12 where FSANZ had stated there was insufficient data to derive an UL and that current levels of intake from foods and supplements did not represent a health risk. Submitter noted concentrations of vitamin B12 in the harvested cells are much higher than those naturally present in foods, conventional fortification and supplements currently on the market in Australia and New Zealand. They noted that in New Zealand, the maximum daily limit for vitamin B12 in dietary supplements is 50 µg (Dietary Supplements Regulations, 1985).	NZFS, Individual (MM)	The nutrition risk assessment (Supporting Document 1) focussed on vitamin B12 (cobalamin), biotin and folate due to their relatively high levels in the harvested cells compared to other foods. It was concluded that these levels are not likely to pose a nutritional risk to humans in terms of overexposure of the recommended daily allowance. As stated in the risk assessment, no dosage limits for vitamin B12 supplements have been set by the Australian Therapeutic Goods Administration and 1000 µg cobalamin supplements for daily use are currently available in Australia. FSANZ concluded there are no concerns regarding the level of vitamin B12 in harvested cells. Further, FSANZ considers that cell-cultured- quail will be sold as a niche product and therefore is not likely to be widely or frequently consumed.
Stated ultra-processed foods (UPFs) should be considered within the scope of this and future similar applications. Concern in relation to the commercialisation of cell-cultured foods, the increased volume of UPFs available and the significant contribution this will have on adverse health outcomes.	GE	The nutrition risk assessment considered the macronutrient and micronutrient content of harvested cells including components introduced during the production process and found no nutritional concerns. Future applications will be assessed on a case-by-case basis. The issue of the inclusion of UPFs in the food supply is beyond the scope of this application.
Stated that having 'regard' to the FAO/WHO (2023) report on 'whether the protein content/profile of cell-based meats is the same as traditional meat' is insufficient.	GE	FSANZ undertook an assessment of the protein content and amino acid profile of harvested cells compared to conventional quail and chicken breast (Section 4.2.3.1 SD1). A serving of harvested cells has a slightly lower protein content than conventional quail however the majority of Australian and New Zealand consumers eat the Estimated Average Requirement (EAR) for protein. No consistent pattern was observed between the essential amino

Submission viewpoint	Raised by	FSANZ response
		acid content of harvested cells compared to quail and chicken meat (Appendix 1 of SD1), with the content higher in cells grown with media 1. No EARs have been set for individual amino acids and cultured quail cells are not expected to be consumed regularly, therefore the amino acid content of harvested cells did not raise a nutritional concern. Should cell-cultured quail products be sold more broadly in the future as a packaged food, consumers could refer to the nutrition information panel (NIP) to determine whether the product fulfils their individual protein content requirements.
Production and processing requirements – food safety		
Production and processing requirements (SD4) Raised concerns the processing standard and SD4 are not based on science. There is no reference to the evidence base used by FSANZ to demonstrate proposed regulatory measures will manage food safety.	GE	FSANZ does not agree. In developing the production and processing requirements, FSANZ has completed a safety assessment using the best available scientific evidence as detailed in SD1 to this report as well as drawing on production practices relevant to this production environment. The assessment is based on evidence drawn from scientific literature as well as data from the applicant.
Scope of standard and application of assessed cell line prohibition Submitters raised concerns of unintended capture of research and development organisations and pharmaceutical production by the definition of cell line supplier. Also raised concern research and development on new cell lines for producing new cell-cultured food would be prohibited. Submitters were also concerned the standard would impede cell-cultured- food production for export markets where it is already approved for sale.	Vow GFI & APAC-SCA APC/CAA/FF NSWFA AFGC	Refer to section 2.3.3 of this report.
FSANZ Act Section 6 declaration that cells, cell lines and cell-culture are food To enable the proposed approach, it will be necessary to provide certainty that the activities being undertaken by these businesses are capable of being regulated under food legislation. This will be assisted by declaring cell lines, cell banks and cell biomasses as food.	DOH-VIC & VIC DoEECA Qld Health	Noted. Declarations made under section 6 of the FSANZ Act are not a matter for FSANZ, this matter has been referred to the relevant Australian Government agency for consideration.

Submission viewpoint	Raised by	FSANZ response
Imported cell lines and cell-cultured food Several submitters raised issues with regulation of imported cell lines and imported CCF, to verify compliance with Australia's requirements for these foods. One submitter also asked about how the *Trans-Tasman Mutual Recognition Act 1997* (TTMRA) may be applied to these foods imported from New Zealand.	DOH-VIC & VIC DoEECA SA Health NSWFA OpoBio DAFF	The *Imported Food Control Act 1992* (IFC Act) requires all food imported into Australia to be safe. Importers are legally responsible for ensuring the foods they import comply with the standards that apply to their products and do not pose a risk to human health and comply with applicable Australian standards. DAFF administers that IFC Act and the Imported Food Inspection Scheme established by it. FSANZ provides risk advice to DAFF on imported food for the purposes of the Scheme. The IFC Act and the Scheme will apply to cell-cultured food and cell lines imported into Australia The operation of the TTRMA is a matter for the Australian and New Zealand governments.
Regulatory implementation considerations Several submitters raised a range of regulatory implementation considerations associated with preparing for implementation and then administering the new standards for these new food businesses.	DOH-VIC & VIC DoEECA, SA Health, Qld Health, NSWFA, DAFF	Noted. Refer to section 2.3.3.7 of this report.
Novel food processing techniques Submitter advised these are still novel processes to produce food and should remain novel foods, subject to pre-market assessment by FSANZ until the industry is more established.	WA Health	Cell-cultured food (CCF) is a subset of novel food and will be managed in a similar way by the approved draft regulatory measures. A pre-market assessment will be required for each new CCF and cell line used for cell proliferation to produce food.
Defining CLS as a food business Additional burden for cell line suppliers given systems in place to manage risks associated with developing and storing cell lines. Unintended capture of non-food cell line businesses.	OpoBio	Chapter 3 standards apply only in Australia and therefore only to businesses in Australia. FSANZ considers it important to capture CLS as a food business when the cells will be for use in food. Where the cell line is not intended to produce food for sale in Australia, it is not captured. Refer Section 2.3.3 of the Approval Report While currently many businesses supply for non-food purposes,

Submission viewpoint	Raised by	FSANZ response
		this may change as businesses emerge for the specific purpose of developing cell lines purely for food purposes. As FSANZ will assess each cell line intended for use in making cell-cultured food, these businesses will be identified prior to the food being offered for sale in Australia.
Cell biomass definition Requested definition include reference to 'in the production of a CCF', not production of a food. Concerned about capturing precision fermentation.	NSWFA	Noted. Precision fermentation is already excluded as cell-cultured food as food derived from culturing cells from specific animals. No microorganisms are listed in the definition as a permitted source.
Definition of cell line Submitter expressed concern that Part (c) of definition is unclear when a cell line requires regulation under a food safety program. As cell line is referenced in Standard 1.5.4-3 and Schedule 25A, one submitter suggested relocating the definition to Standard 1.1.2 so it applies to whole of Code. Several submitters commented that the proposed definition is too simplistic. A cell line contains cells at different stages of cell cycle with unique protein compositions; cells will be similar but not uniform. Suggested reference to 'same broad cell type' rather than 'uniform composition'.	NSWFA CAA Opo Bio	Part (c) of the definition of 'cell line' requires that the relevant collection of cells be or are *intended for use in the production of a cell biomass*. Other Code provisions use or set similar requirements using the same language. FSANZ is not aware of evidence of a problem in this regard. If the intent is not to use the cell line for that purpose (i.e. for food use), requirements will not apply. FSANZ does not consider it necessary to relocate the cell line definition to Standard 1.1.2. Its location in Standard 3.4.1 is sufficient for regulatory purposes. The only references to cell line other than in Standard 3.4.1 will be: to 'the cell-line 221523Fib-Quail' (such as in section S3—54 and S25A—3); in section S25A—6 which lists each assessed cell line for the purposes of section 3.4.1—2; to 'cell line supplier' in Standard 3.1.1 for definition of food business and links to Standard 3.4.1; and the one reference in the entry in section S27—4 for cell-cultured food (i.e. 'excluding a cell line'). In each case, the context and meaning is clear. Each reference has to be read in light of Standard 3.4.1 and the regime it establishes. FSANZ reviewed the definition, including consideration of definitions developed and published by Good Food Institute Brazil, United Kingdom Food Standards Agency, World Health Organisation and Good Food Institute – APAC. FSANZ decided

Submission viewpoint	Raised by	FSANZ response
		the reference to 'uniform composition' in the proposed definition is a more appropriate phrase as the definition is in reference to a stored cell line in freezers/cell banks. These cells will be of uniform composition as they are all derived from the same batch.
Cell line supplier requirements in Standard 3.4.1 Consider allowing an equivalent to Standard 3.2.1 such as good laboratory practices (GLP)/good cell-culturing practices (GCCP) otherwise it is duplicative and may not outweigh the costs to industry. For CLS, the proposed requirement for inputs is a fixed list, so it may not capture other inputs. Suggest FSANZ consider broadening the requirement to any inputs used. CLS will use non-food approved substances to develop a cell line and store cell lines. But given subsequent cell expansion and processing by the cell-culturing food business, it will not affect safety of the final cell biomass. Suggest the inputs requirement requires amendment to acknowledge the low risk associated with these inputs by the cell line supplier.	CAA GFI & APAC-SCA DOH-VIC & VIC DoEECA SA Health Vow	Refer to section 2.3.3.1 of this report for consideration of equivalence to Standard 3.2.1. Refer to section 2.3.3.2 of this report for consideration of inputs for a cell line supplier.
Cell line donor animal health Source animal not known in many cell collections as were not originally developed for use in cell-culture food production. More detail needed to explain how disease status may be established (such as for wild caught fish).	Opo Bio CAA GFI APAC/SCA	FSANZ reviewed these requirements against the principles for good cell-culturing practices (GCCP) and noted that knowing the disease status or confirming risk status of the cell line is required. Evidence provided to FSANZ confirms that cell line suppliers are already operating according to GCCP in order to manage risks. See section 2.3.3.1. GCCP requires animal health and lineage to be recorded. These records are available to purchasers of cell lines. The standard is drafted as an outcomes based standard, allowing flexibility for how the health status may be verified. Animal health can be determined via animal & farm site or processor documentation and/or via adequate screening of the cell line for pathogens and viruses. FSANZ considers no change to the drafting is required. These are

Submission viewpoint	Raised by	FSANZ response
		outcomes based requirements, so business will need to demonstrate to the satisfaction of a regulator the requirement has been met. FSANZ will work collaboratively with the Implementation Sub-committee for Food Regulation to develop guidance to assist with compliance.
Cell line traceability As this industry is still emerging, currently available cell lines were developed for other purposes and industries or research and are unlikely to have full traceability to donor animals at times.	CAA GFI APAC/SCA	The business will need to demonstrate that there is traceability for the origin of the cell line. In those situations where the cell line supplier sources a cell line from another entity (i.e. they did not source the cells from the donor animal), traceability to the entity providing the cell line must be retained.
Non-conforming cell culture Concern that the reference to 'a cell culture' is not defined and unclear in sub-section 3.4.1—7(2)(c), where the wording makes reference to 'a cell culture is non-conforming'.	NSWFA CAA	Agreed. The reference to 'a cell culture' in paragraph 3.4.1—7(2)(c) has been changed to 'cell proliferation' (NOTE: is section 3.4.1-5(2)(c) in approved draft). The amended requirement is that the food safety program must identify how the business will identify when cell proliferation (as defined) is non-conforming. This amendment clarifies that the business must be able to identify when a cell proliferation is non-conforming, prior to or immediately following extraction of the biomass from a bioreactor.
Inputs used by a cell-culturing food business Concerned the standard does not sufficiently manage use of substances as inputs for proliferation in bioreactors by the cell-culturing food business. Example provided of residues of antimicrobial compounds in cell biomass and resulting final food.	Qld Health	Refer to response below on media inputs. In relation to the presence of residues of antimicrobial compounds, FSANZ notes that cell-cultured food must comply with all requirements of the Code, including those in Chapter 1 of the Code. This includes general requirement there must be no detectable residues of antimicrobials in food for sale unless there is a permission in the Code (Std 1.4.2).
Regulation of media inputs The submitter noted the regulation of cell-cultured foods is relatively new internationally. They suggested it may be necessary to review FSANZ's proposed approach to the regulation of media inputs in the future, given current international initiatives to develop guidelines and regulatory frameworks specific to cell culture media and inputs, or if	NZFS	FSANZ will consider the suitability of international guidelines or standards for media inputs should they be developed in the future.

Submission viewpoint	Raised by	FSANZ response
safety concerns arise.		
Australia only standard These submitters acknowledged requirements under Chapter 3 of the Code apply in Australia only. In New Zealand, the production of cell-cultured foods would be regulated by an independently evaluated risk management programme under the *Animal Products Act 1999* and/or an independently evaluated food control plan under the *Food Act 2014*. FSANZ was asked to note Section 2.6.1.3 of the 2nd CFS is incorrect in this regard. NZFS considered that New Zealand's food safety legislation can effectively be amended which, together with the proposed changes to the Code, would achieve the safe provision of cell-cultured foods. The submitters also commented in addition to food safety requirements, the importation of cell-cultured food products or cell lines for food production into New Zealand must meet the requirements of an import health standard (IHS) under the Biosecurity Act 1993. Biosecurity requirements would also apply at manufacturing/production sites. NZFGC commented due to the lack of specific regulation/ standard/ notice established in New Zealand under the *Food Act 2014* or *APA 1999*, the submitter queries whether a transitional arrangement would be required in New Zealand before the applicant could manufacture cultured quail in New Zealand.	NZFS NZFGC	Noted. See section 2.7.1.3 of this report. The reference to there being 'no relevant New Zealand only standards' relates only to Standard 1.5.4. FSANZ is not aware of any New Zealand only cell-cultured- food standards that are akin to Standard 1.5.4. The production of cell-cultured food in New Zealand is out of scope and remains a matter for the New Zealand Government. The need or otherwise for transitional arrangements in New Zealand is also a matter for the New Zealand Government.
Cell-cultured food and cell lines Consider more clarity required that only assessed cell lines, producing approved cell-culture foods are permitted for sale.	DOH-VIC & VIC DoEECA	The proposed Code amendments, when read together, mean only approved cell-cultured foods, made from assessed cell lines, can be sold as food in Australia. FSANZ considers further clarity can be provided in guidance material. If an assessed cell line is used but new inputs have been added to produce a new CCF, that food is not permitted to be sold unless this new CCF has been explicitly approved.
The proposed approach does not support assessment of safe food products	CA GE	FSANZ's evidence based risk assessment, using the best available scientific evidence, concluded the applicant's CCQ did

Submission viewpoint	Raised by	FSANZ response
Submitters did not agree that the approach outlined by FSANZ effectively supports the assessment of safe food products and provides clear guidance on maintaining adequate process control.		not pose a public health and safety risk and the regulatory approach implemented through the approved draft regulatory measures will protect public health and safety. FSANZ is not aware of any evidence provided by submitters to the contrary FSANZ is developing guidance material to support application of Standard 3.4.1..
Specification – microbiological criteria		
<u>*Microbiological criteria applied to CCF*</u> Submitters asked why did FSANZ choose *Salmonella* spp and *Listeria monocytogenes* and not other food pathogens. One submission suggested given this is a new food, caution should be taken and all the micro criteria proposed for the Compendium should be placed into S27. The micro criteria in S27 should be in S3 as a specification to align with other international approaches.	Opo Bio NZFS GE ACMF AFGC AMIC MM Vow	The application sought microbiological criteria for *Salmonella* spp. FSANZ's assessment concluded that these were warranted. FSANZ's assessment also concluded that microbiological criteria for *Listeria monocytogenes* were warranted as it poses a hazard at biomass harvest and during subsequent handling. *Salmonella* spp. and Listeria monocytogenes are the pathogens of primary concern and relevance, having regard to the application and noting both can be introduced from environment/food handlers. FSANZ disagree with incorporating all microbiological criteria into S27 as process hygiene criteria are not appropriate for S27. FSANZ disagree. FSANZ considered use of S3 for pathogens in a potentially hazardous food is not consistent with how Australia applies microbiological criteria. While this application is for the cell biomass that will be an ingredient in a final food, other future CCF may be the final food.

Submission viewpoint	Raised by	FSANZ response
Several submitters expressed concern the risk assessment only considered quail, there may be other microbiological criteria for other CCFs in future.	DOH WA GE	CCF are a prohibited food until assessed and approved by FSANZ. Each new CCF will be assessed by FSANZ. The proposed Code amendments are a result of the assessment of the current application and drawing on other relevant information about managing hazards in similar production settings. Further Code amendments, including changes to microbiological criteria, may occur as more applications are submitted for other CCF.

Submission viewpoint	Raised by	FSANZ response
One submitter commented that as bioreactor is a sterile environment, FSANZ should consider lowering the SPC standard to reflect loss of control.	DOH-VIC & VIC DoEECA	Noted. The SPC criteria is captured in the *Compendium of Microbiological Criteria for Food* (the Compendium) which is guidance. FSANZ agrees levels of bacteria should be low given the closed bioreactor system. FSANZ will not make any change at this point but will review after several applications or 3-5 years.
Testing requirements Testing should only be required for the final cell biomass. However, unclear to which product the Schedule 27 microbiological criteria apply to.	APC/CAA/FF GFI APAC/SCA	FSANZ agrees the proposed microbiological criteria should apply to cell-cultured food except cell lines. As part of GCCPs, sterility and viral screening of master cell lines are used to demonstrate freedom from hazards. *Salmonella* and *Listeria monocytogenes* testing/screening is not required unless the cell line fails screening tests (noting GCCPs are that cells should not be further used if fail screening tests). This applies to both master cell lines, that is: • by CLS as part of cell line development; and • by CCFB as part of incoming verification and confirmation their CCFB master cell line is free of pathogens/viruses. FSANZ has amended Schedule 27 to exclude cell lines from this requirement. Further processed cell-cultured food or a food containing CCF, if ready-to-eat, will be subject to *Listeria monocytogenes* limits listed in Schedule S27. The Compendium of Microbiological Criteria for Food (FSANZ 2022) will be updated to provide guidance for CCFB on the application of process hygiene criteria as part of their HACCP based food safety program.

Submission viewpoint	Raised by	FSANZ response
Potential for thermophile contamination In light of dangerous thermophile contamination, temperature control requirements throughout the process from sourcing the quail cells from the supplier right through to serving on the plate is required.	Individual (MM)	Section 3.4.1-5 will require the CCFB to have a food safety program. The CCFB must be able to identify when a cell proliferation is non-conforming. Once the cell biomass has been extracted, Section 3.4.1-8 identifies the cell biomass as a potentially hazardous food requiring temperature control and subject to those requirements in Standard 3.2.2. FSANZ proposes to include process hygiene criteria in the Compendium.
Specification – other		
Safety criteria for nutrients Submitter supported proposed approach for the two pathogenic microbial species, however suggested food safety criteria also for nutrient content as a result of the growth medium used. This is due to the potential for carry over of nutrients from the growth medium into the cell-cultured food, resulting in levels significantly different to the source cell product.	NZFGC	The suggestion is noted, however FSANZ does not consider specific criteria for nutrient content are warranted. FSANZ conducted a thorough safety assessment of all substances used in the production of cultured quail cells, including vitamins, minerals and amino acids. The nutrition risk assessment found no risk associated with the consumption of this food. The nutrient profile of new cell-cultured foods will vary based on several factors, such as media inputs, whether the cells are washed, the percentage of cell biomass incorporated into the final food and other ingredients in the final food, all of which affect overall dietary exposure/intake. Each new cell-cultured food will be assessed on a case-by-case basis to determine if any nutritional risks are present.
Specification for protein Per the submitter's response to the 1st CFS, the proposed specification in Schedule 3 for protein (not less than 4%) does not provide a useful control measure given analytical testing found the actual protein content of the proposed cell-cultured quail to be significantly higher (average of 9 g/ 100 g). The applicant's request for 4% reflects an alternative in-house quantification method. However, such variation in testing method results raises questions about the suitability of the testing method rather than validating such a wide specification. Concerned the lower specification could allow lower protein products to be produced which may impact FSANZ's assessment. For example,	DOH-VIC & VIC DoEECA	The specification in Schedule 3 for protein is not and cannot be a criterion for determining whether a food qualifies as 'meat'. The purpose of the 4% protein specification in Schedule 3 is to set a specification that will apply to the Applicant's product (CCQ) when sold for use a food ingredient or when added to food. If the food is sold at retail with a higher protein level (9%), the seller must ensure the nutritional panel accurately reflects the nutritional content and maintain records to confirm this. The requirements for claiming a food is a 'Good Source' or being 'Increased' in protein in Schedule 4 of the Code remain unchanged and must be met by any food manufacturer, whether the food is

Submission viewpoint	Raised by	FSANZ response
certain cell-cultured food might be able to use the word 'meat' (which is generally strongly associated with being high protein by consumers), when the product may not qualify to make a protein source claim under Schedule 4. For these reasons, the protein specification in Schedule 3 should be reconsidered with FSANZ working with the applicant to determine more appropriate criteria which balances product identity and analytical feasibility.		cell-cultured or otherwise. FSANZ has discussed the varying protein levels with the applicant, agreeing on 4% for production purposes and 9% for retail, should the product be sold at retail level.
Specifications for other substances FSANZ's risk assessment report does not include information that is sufficient to determine whether further prescriptions in the food safety standards are necessary to formalise food safety criteria for other potentially relevant hazards such as: chemicals, enzymes, antibiotics, heavy metals, growth factors, metabolites, allergens and chemicals/compounds used for scaffolds. Submitter considered that additional criteria in the standards are required to address these various hazards.	DOH-WA	Since this particular food does not contain many of the listed substances or a scaffold, regulation for these substances is not currently required. Future assessments of cell-cultured foods using these substances will ensure they are captured, allowing for informed enforcement and consumer safety and visibility. FSANZ considers the heavy metal limits set by section S3—4 to be adequate for this cell-cultured food. Allergens specified by the Code must be declared in accordance with the provisions in the Code for all foods.
Concerned about the lack of full disclosure regarding the chemicals, enzymes and other substances used during production. The proposed approach is unclear on what regulatory mechanisms are in place for chemicals and substances that will be used in cell-cultured food manufacturing that are not explicitly permitted under Schedules 15 to 19. Though the safety of the chemicals and substances that will be used by the applicant has been assessed, the proposed approach limits FSANZ's assessment up to the initial production of cell-lines only. Any non-permitted substances (and their by-products) that are used/present from that point on might potentially make the final product non-compliant.	DOH-WA	FSANZ conducted an independent evidence based assessment that was informed by the best available scientific evidence. That assessment included a review of all inputs and concluded they were safe and did not pose public health and safety risk. The applicant adds other ingredients to the cell biomass to create the final mixed food. FSANZ's assessment concluded that none of these additions require regulation under Schedules 15 to 19. As the sector grows, it is anticipated that food additive-type inputs will be used and appropriate regulations can be established within those standards. FSANZ considers the approach implemented by the approved draft regulatory measures is appropriate to regulate such foods and is consistent with how novel foods are regulated under the Code.
It is untenable that 'A published specification is not available for cultured quail. Vow proposes specifications that establish the qualitative and quantitative parameters for each	GE	Food Regulators will monitor and enforce the new cell-cultured food standards relating to the production process and specifications for the final food.

Submission viewpoint	Raised by	FSANZ response
batch of cultured quail.' (A1269 application, page 26). Regulators are bound to monitor batch production case-by-case, as consistent, reliable and sound data is necessary to assess and approve such products.		
Not all states and jurisdictions possess the technical expertise required to assess the safety of cell lines used in the production of cell-cultured food. Centralising the assessment of cell lines within FSANZ would ensure that the process is conducted consistently and by a team of technical experts.	DOH-WA	Noted.
Restricting processing to assessed cell lines Processing should be limited to cell lines that have undergone FSANZ's pre-market assessment for safety, genetic stability and reliability. This minimises risks such as contamination, allergenicity and genetic instability, while ensuring clear regulatory guidance to uphold the safety of food products.	AMIC	Noted.
Assessed cell line – positive list Accepted that the proposed draft processing standard refers to those cell lines assessed by FSANZ. However, the proposal to link the cell lines to final food products for sale, underpinned by a FSANZ risk assessment, effectively creates a table of products rather than cell lines. Alternative suggested, whereby cell lines are listed in the schedule. This could streamline the regulatory process, foster innovation in the cell-cultured food industry and maintain FSANZ's commitment to public health and safety.	APC/CAA/FF	FSANZ disagrees the proposed approach effectively creates a table of final food products. The intent is to link and therefore limit the *production and processing of cell-cultured food* only to assessed cell lines.
Assessed cell line – stage-gated process A list of assessed cell lines suggests the future ability for cell lines to undergo pre-market approval (thereby becoming an 'assessed cell line') in a stage-gated process. Assessed cell lines could thus be treated as 'food ingredients', whereby they could be included in food product dossiers without significant additional assessment by FSANZ. It was unclear to submitter: - if this is FSANZ's intention - if there will be additional mechanisms/manufacturing standards for cell lines to be 'approved' in a Standard in the absence of an end food safety product dossier,	Opo	The FSANZ assessment is specific to each new cell-cultured food and includes an assessment of the cell line. The intent is that once a cell-cultured food has been assessed and listed in S25A, it can be made and sold for use as an ingredient in food in Australia, subject to any conditions prescribed in S25A.

Submission viewpoint	Raised by	FSANZ response
- what the benefits of having an approved cell line list are to the industry. In the case a cell line can be assessed and receive a stage-gated pre-market approval (thereby becoming an 'assessed cell line') as an individual food ingredient to a manufacturing standard (with the implication being fewer future steps to that cell line being included in an end product), then the submitter agreed in principle with this approach. However, if the cell line can only be pre-approved as part of a complete novel food dossier, then the submitter would disagree with this mechanism as it is not fit for purpose. It would not streamline the approvals process or allow new assessed cell lines to be used as an ingredient in food manufacturing. The proposed definitions and framework do not provide a mechanism or process for the former to occur. If cell lines can only be assessed and approved as part of a consumer product, the application of this proposed change has minimal benefit to FSANZ or the industry.		
Assessed cell line – acceptance of international assessments The requirement for cell line assessment in multiple jurisdictions creates a significant barrier to the viability of the nascent cellular agriculture industry, as well as a significant compliance burden on FSANZ. As such and, as a means of future-proofing, FSANZ's approach should be to accept safety assessments of cell lines undertaken by aligned jurisdictions, for example the Singapore Food Agency, European Food Safety Authority or Health Canada. Submitters noted that acceptance of overseas assessment outcomes is currently under consideration as part of the review of the FSANZ Act.	APC/CAA/FF, GFI & APAC-SCA	FSANZ will endeavour to align its risk assessment practices and data requirements with overseas jurisdictions to the extent possible. This includes using assessment reports where they are fit-for-purpose as part of the scientific weight of evidence; this is the current practice for all applications. There is currently no statutory mechanism to adopt approvals from overseas jurisdictions.
Need for randomised controlled trials (RCTs) The submitter argued that cell-culture quail is new globally and FSANZ's safety assessment is insufficient. The submitter calls for FSANZ to commission independent RCTs for cell-cultured quail (similar to the introduction of new drugs) and all other novel creations	Individual (MM)	FSANZ does not require the submission of RCTs consistent with requirements of food agencies globally. The risk context of food is different to that of drugs.

Submission viewpoint	Raised by	FSANZ response
prior to public consumption. This is to protect public health, the company's and FSANZ's reputation and the industry at large. The submitter also suggests RCTs are required to examine how this novel product behaves when combined with other ingredients.		With respect to ingredients, cell-cultured quail will be combined with food-grade ingredients that are known to be safe to eat. There is no reason to expect that the combination of such ingredients with cell-cultured quail will affect its safety profile like any other mixed food.
Nutrition risk management		
Prohibition on use in special purpose foods Submitter expressed concern regarding proposed drafting for section 1.5.4—4 prohibiting addition of cell-cultured food to a food standardised by Part 2.9, given the potential safety and suitability of cell-cultured ingredients and sought clarity on the rationale. The proposed prohibition may stifle innovation or prevent future applications for cell-cultured food that could serve consumers with specific needs.	Vow	This application did not request or provide evidence to support the use of cell-cultured quail in special purpose foods. FSANZ's safety assessment considered consumption of cell-cultured quail for the general population only, not for use in special purpose foods. The rationale for the prohibition for use of cell-cultured foods in special purpose is explained in section 2.3.2.2 of this report.
The rationale for the proposed prohibition on use of an approved cell-cultured food in special purpose foods (Standard 1.5.4—4) was requested, for example, in the Approval Report, for completeness and clarity.	NZFS	Please refer to section 2.3.2.2 of this report.
Generally supportive of the proposed prohibition on the use of cell-cultured food in/as Part 2.9 Special purpose foods, however requested clarity in the Approval report on how an application to seek permission to use cell-cultured food in/as special purpose food would be progressed e.g. as a novel food? This is in noting the recent amendment in the Ministerial Policy Guideline on the Regulation of Infant Formula Products to clarify cell-based human milk products should follow the same principles as traditional infant formula products. Submitter recommended FSANZ explore how to regulate such products in line with the revised Ministerial Policy Guideline. Also, now that Standard 2.9.1 applies in Australia only, there was concern about the implications for future innovation for cell-based human milk products in New Zealand.	NSWFA	For this current application, FSANZ's assessment did not consider use of cell-cultured foods in special purpose foods. FSANZ will consider any future applications for use of cell-cultured foods in special purpose foods on a case-by-case basis and with regard to the intended purpose of addition, including consideration of use as a novel food or nutritive substance, and any relevant Ministerial Policy Guidelines. The proposed definition for a *cell-cultured food* does not capture cell-based human milk products. Pre-market assessment via an application to FSANZ would be required which would include assessment of the intended purpose of addition, appropriate pathway for regulation and any relevant Ministerial Policy Guidelines. Future applicants are encouraged to discuss the

Submission viewpoint	Raised by	FSANZ response
		requirements of an application with FSANZ prior to submission. As Standard 2.9.1, as currently in-force in the Code, does not apply in New Zealand, the use of cell-based human milk products in New Zealand infant formula products is a matter for the New Zealand Ministry for Primary Industries. Consideration of such imports into Australia is a matter for the Australian Department of Agriculture, Fisheries and Forestry.
Definition of 'cell-cultured food'		
Definition of cell-cultured food not future proof The proposed definition does not reflect the current scope of cellular agriculture products in development (e.g. cultivated coffee, cocoa or cell-based milks) so is therefore not future-proof. Proposed an alternative definition per the 1st CFS, but without microorganisms: 'Cell-cultured food means a food (whole food or ingredient) that is developed by isolating and cultivating cells from animals or plants, which on their own or in combination with other ingredients, produce new or analogous consumer food products.' On reflection, inclusion of microorganisms had the potential to create confusion with precision fermentation-derived ingredients or products. Alternatively, if FSANZ's intent is to propose a standard for meat products at this time, then definition should be amended to 'cell-cultured meat' to provide clarity. Otherwise, requested FSANZ to provide advice on the pathway for non-meat cell-cultured foods, including seafood.	APC/CAA/FF	The proposed definition '*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*' is not intended to be a fixed or definitive list of sources. As the cell-cultured food category develops, the definition can be amended to include foods from other sources. FSANZ has made the decision to exclude 'microorganisms' from the definition. Products of microbial fermentation are adequately regulated by other standards in the Code.
Whilst the proposed definition is appropriate for the purposes of A1269 it does not provide enough regulatory certainty for future cell-cultured foods. More clarity requested in the Approval report on what products will and will not be captured as cell-cultured food. Also, further commentary was requested in the Approval report as to what regulatory pathway should be followed if a product is not captured by the proposed definition of a cell-cultured food. For example:	NSWFA	Other food categories in the Code - such as the genetically modified food or the novel food provisions - can apply to a product not captured by the proposed definition of a cell-cultured food. If an application is received for a cell-cultured food that does not come within the scope of the current CCF definition (e.g. because it is not derived from any of the listed cell sources) FSANZ also has the option of expanding the CCF definition to include the new cell

Submission viewpoint	Raised by	FSANZ response
- Precision fermentation products – submitter supported the view such products should be out of scope of cell-cultured food. However, the proposed drafting does not clearly exclude these; the rationale for exclusion provided in the 2nd CFS is not sufficient to remove doubt. Recommended including commentary as below in the Explanatory Statement to clarify the intent: 'Precision fermentation is a well-established technique that utilises bacterial or fungal cell cultures to produce various food substances and specific ingredients, such as proteins, enzymes and other compounds, through controlled fermentation processes. FSANZ has assessed numerous applications for precision fermentation products over the years. These products have been regulated under the Code as foods produced using gene technology (Standard 1.5.2) and, depending on their intended use in food, as processing aids, food additives, or nutritive substances. Consequently, they fall outside the scope of the proposed definition for 'cell-cultured food' and this application more broadly.' (CFS report page 14) - Food produced using cell culture from other sources – submitter supported limiting the sources for cell-cultured food to cells obtained from animals with a history of human consumption. Recommended close alignment between the source species for cell-cultured food and the range of animal species that have a safe history of human consumption in Australia or New Zealand (e.g. dairy, meat, seafood). Food produced using cell culture from cell sources other than abovementioned ones should be considered a novel food, because such food would meet the definition of non-traditional food and would require an assessment of the public health and safety consideration having regard to the novel production process, composition of the food, potential food allergenicity risk etc. Recommended more clarity in the Approval report so that future applicants are adequately informed. FSANZ should provide clear guidance that any food for sale produced using cell culture is subject to pre-market assessment. This is consistent with the Food Ministers' expectation (FMM 2022).		source. Products of microbial fermentation are not captured by the definition of cell-cultured food as the definition does not list any microorganisms as a source of cells. See responses above. FSANZ agrees that the Code's novel food provisions may apply to require premarket assessment of food products not captured by the proposed definition of a cell-cultured food and that are produced using cell culture from sources other than animal species that have a safe history of human consumption in Australia or New Zealand.
Submitter queried whether the proposed definition for 'cell-cultured	GE	See responses above. The definition, including its list of sources,

Submission viewpoint	Raised by	FSANZ response
food' provides regulatory certainty and clarity for industry, enforcement agencies and other stakeholders. Submitter also noted: -Proposed definition is too narrow and not sufficiently future proofed. Cells derived from many other organisms may be future candidates for cell-culturing. - The definition of 'cell-cultured food' must include the word 'synthetic'.		is not fixed. It can be updated if necessary as new food sources are developed. The definition also refers to 'cell-cultured food' in general and is not limited to foods derived from animal cells. FSANZ does not consider the addition of the term "synthetic" to the definition is appropriate because it inaccurately describes the nature of the quail cells, which have not been created or synthesized per se.
Definition restricts cell sources to specific animal categories, which may unnecessarily limit technological innovation in food production. Recommended FSANZ create a more flexible framework that can accommodate emerging cell-culturing technologies. Revised definition was suggested as follows: 'Any food product derived from the *in vitro* cultivation of cells isolated from animals. It specifies *in vitro* cultivation and broadens the sourcing permissions to all animal sources. This is more open to future product development and does not restrict innovation.	SA Health	See responses above. The definition, including its list of sources, can be updated, if necessary, as new food sources are developed. Cell culture, by its nature, can only ever be an *in vitro* technique and therefore there is no need to specify the term 'in vitro' in the description.
Submitter noted that products that meet the proposed definition for cell-cultured food can be regulated as food under the *Victorian Food Act 1984*. This will be facilitated by declaring cell lines, cell banks and cell biomasses as food. However, for greater flexibility and to future proof the definition, consideration should be given to expanding it to include cells beyond animal sources and plant sources.	DOH-VIC & VIC DoEECA	Please see responses above.
Definition of cell-cultured food adequately future proof Submitter of the view that the proposed new definition for cell-cultured food provides regulatory certainty and clarity. Cell sources can be expanded in the future in response to new applications for cell-cultured food obtained by culturing cells isolated from sources not listed in the proposed definition.	NZFS	Noted.
A clear and concise definition for cell-cultured food is needed to	RMAC	The definition covers the source listed by this submitter. The

Submission viewpoint	Raised by	FSANZ response
ensure clarity, consistency and certainty to industry and consumers. Cell-cultured foods need to be clearly defined as products derived from cultured cells of livestock, poultry, seafood, eggs, game, or embryos for regulatory purposes.		definition can be amended in the future if cells are sourced from species other than those commonly found in traditional farming practices Consumers are unlikely to refer to or rely on the Code definition itself. Instead, the labelling requirements set by the approved draft regulatory measures for cell-cultured food will be of more relevance to and for consumers and in promoting consumer understanding and assist them to make informed choices. See SD2.
A clear definition for cell-cultured food is vital for regulatory certainty and consistency. Defining these products as derived from cultured cells of livestock, poultry, game, seafood, eggs, or embryos helps industry and consumers understand their nature and regulatory framework.	AMIC	Please see responses above.
Definition – lack of clarity Whilst definition is clear with regard to meat protein produced from cell-culture, it was not clear if this definition is intended to cover milk/protein produced by mammalian cells. If not, why not? The CFS also indicates that the definition can be altered in the future if necessary. While this is true, given the consultation requirements, this could be a lengthy process. Therefore, submitter considered it best to ensure the definition is expansive enough now to ensure alterations are not required for some time.	NZFGC	Please See responses above. The definition, including the listed sources is not fixed. fixed It can be updated as new food sources are developed. Other food categories in the Code - such as the genetically modified food or the novel food provisions – can still operate to capture products not covered by the definition. An all-encompassing definition of 'cell-cultured food' is not required or warranted at this point. Developing an all-encompassing definition before relevant food products are developed is likely to be challenging. The definition refers to 'cell-cultured *food*' in general. It is not limited to meat proteins.
It was unclear to the submitter what species of animals are captured as ‘game’ in the definition and more clarity was requested in the Approval Report on this aspect, including those species capable of being a source animal of cell-cultured food (as defined).	NSWFA	In this context, "game" as defined, refers to the flesh of any wild animal or bird in its ordinary sense. The new regulatory approach is prohibitive, meaning it is prohibited unless explicitly allowed. The necessary FSANZ premarket assessment will ensure that game is

Submission viewpoint	Raised by	FSANZ response
To clarify that a source animal for cell-cultured food has a history of safe human consumption, FSANZ was requested to consider parity with conventional animal-derived food in the Code in the relevant Standards (e.g. Standard 2.2.1 Meat and meat products, Standard 2.2.2 Egg and egg products, Standard 2.2.3 Fish and fish products, Standard 2.5.1 Milk).		safe and suitable when used as a source of cells for these types of food. Since only specific types of cells are sourced from animals, including game and a comprehensive safety assessment of the cell line is conducted, the history of safe human consumption does not apply as it does for other foods, such as novel foods. All cell lines will be evaluated for presence of micro-organisms, viruses or prions, and allergenicity. Consequently, the source animal is of lesser importance.
Clarification requested on the particular sources of cells included in the definition to ensure they are consistent with other parts of the Code (e.g. seafood, livestock). This also applies to the proposed definition of 'animal' in section 3.4.1—2.	AFGC	Please see responses above. The definition, including the list of sources, is not fixed. It can be updated as new food sources are developed. Since each cell line undergoes its own safety assessment, foods sourced from other cell lines can be assessed and permitted on a case-by-case basis.
It was unclear whether the definition applied to the harvested cells only or a finished product containing cultured cells. (This comment also relates to this submitter's comments in response to question 2 regarding microbiological criteria and scope of the assessment.)	AFGC	In this case, the cell biomass was assessed up to the point of harvest. However, new cell-cultured foods may come in different formats.
The definition includes terms e.g. 'livestock', 'game', 'poultry' that lack precise legal definitions in the Code. In addition, there is no specific definition for 'embryo' in the Code. Recommended more explicit definitions for these terms if the broader definition to reference all animals is not acceptable.	SA Health	FSANZ does not agree that prescriptive definitions of 'livestock', 'game', 'poultry' etc are required. These terms will have their ordinary and commonly understood meaning. FSANZ is not aware of any evidence of a problem to date with this approach.
As there is no definition for 'livestock' in the Code, submitter suggested it be included or, alternatively, cells from the specific animals that are permitted be listed.	Qld Health	Please see responses above.
The Standard name is 'Standard 1.5.4 - Cell-Cultured Foods' while the definition is for 'Cell-cultured food'. Suggested the singular form is used for consistency.	SA Health	Not supported. This approach is used elsewhere in the Code (for example see novel food standard and definition) and FSANZ is not aware of any evidence of a problem in this regard.
Current definition (section 1.5.4—2) is overly broad, potentially creating interpretation challenges for manufacturers and regulators	SA Health	Please see responses above.
Submitter sought clarification on whether this definition included plants, insects, fungi, or other organisms. A future-proof standard is favoured, which is sufficiently flexible to accommodate all other food-like substances that may be cell-cultivated in future.	GE	Please see responses above. The definition excludes plants, insects, fungi, and other organisms. However, it can be amended if applications for cell-cultured foods

Submission viewpoint	Raised by	FSANZ response
		from these sources are submitted in the future.
<u>*Definition – alter to be consistent with proposed labelling statements*</u> Noted that proposed statements for labelling are 'cell-cultured' or 'cell-cultivated'. As such, industry and consumers would benefit from the inclusion of 'cell-cultivated food' in the proposed definition: 'Cell-cultured food, or cell-cultivated 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.'	GFI & APAC-SCA	Please see responses above. 'Cell-cultured food' is a defined term. The purpose of the definition is to identify the foods that will be subject to regulation by Standard 1.5.4 as a cell-cultured food. The Standard includes separate labelling requirements in sections 1.5.4—5, 6 and 7 that apply to approved cell-cultured foods that meet this definition. FSANZ notes there is precedence in the Code where the term identifying the food category differs from the labelling statement (e.g. a food that meets the definition of 'food produced using gene technology' is captured for assessment, whereas the labelling requirement for an approved food produced using gene technology is the statement 'genetically modified'.
Definition of 'meat'		
From section 1.3.4 of the 2nd CFS, noted the applicant's cell-cultured quail does not meet the definition of meat as it is derived from embryo tissue and the animal has not undergone slaughter. If cells are derived from a slaughtered animal (considering future applications), the question emerges as to whether or not the definition of meat would be met in this circumstance. To address this issue, submitter recommended definition for meat at section 1.1.2—3(b) be amended to include the following, to clarify that meat does not include cell lines derived from animals regardless of whether they come from a carcass or live animal: (iv) cell-lines derived from animals	SA Health	The term 'meat' is defined by reference to a 'carcass from an animal slaughtered other than in a wild state'. That is the dead body of an animal that has been *slaughtered other than in a wild state*. FSANZ consider that cells taken from live animal embryos do not fall within the definition of meat and this change will not be made. See section 1.3.4 above.
Schedule 25A permissions		
<u>*Specificity of the proposed permission*</u> The drafting is unclear on the level of specificity in the proposed permission for cell-cultured quail as a permitted cell-cultured food. The draft Explanatory Statement for section S25A—3 states: 'Item 1 of the table 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 manufactured by Vow Group Pty Ltd (ABN 49 632 680*	NSWFA	The inclusion of '*and manufactured by Vow Group Pty Ltd (ABN 49 632 680 472)*' in the Explanatory Statement for section S25A—3 was an error and has now been corrected. Stating *'detailed in application A1269*' ensures that only the specified cell line, 221523Fib-Quail can be used to manufacture the approved food (Vow's quail cell biomass).

Submission viewpoint	Raised by	FSANZ response
472)'. Whilst this would offer some guidance on interpretation, submitter requested more clarity on the regulatory intent of '*detailed in application A1269*' in section S25A—3. This is in noting the following the 2nd CFS report: - 'FSANZ is proposing to regulate these foods as products such that all cell media and inputs will be assessed for safety as a part of approval of future cell-cultured foods.' (page 12) - 'Granting a permission to the applicant for the proprietary cell culturing process described in the application will prevent other businesses from producing this food in the same manner. That is unless the applicant permits other businesses to do so.' (page 23) Supported the regulatory intent as above that a permission for cell-cultured food would be granted on a product-by-product basis. However, was unclear whether this intent is achieved with the drafting as proposed, including *'detailed in application A1269'* in section S25A—3. Submitter recommended clarifying that the permission granted through A1269 is limited to the applicant's product as assessed by FSANZ. One way to achieve this may be a reference to the applicant in the listing of permitted cell-cultured food in section S25A—3.		
Food additive permissions		
The scope of A1269 is much wider now and, as such, submitter recommended the proposed standard provide appropriate food additive and processing aid permissions, for cell-cultured food, particularly in processed products like sausages and fermented smallgoods, similar to that of meat, fish, poultry, game etc. Comprehensive guidance on food additives allowed should also be provided. Submitter gave example of a cell-cultured food made as an ingredient in a sausage/fermented sausage and queried whether there was the permission to use these additives, noting it would seem probably that the manufacturers would need to use them. Failure to provide permissions is considered restrictive to innovation and fair trade,	SA Health	FSANZ thanks SA Health for this suggestion. The use of food additives is not relevant to this particular application. FSANZ advised the applicant that food additives require specific permissions in foods and the applicant confirmed they do not intend to add food additives to this food. Future applications for cell-cultured foods requesting permission for food additives can be addressed through the appropriate process. Where permissions for adding food additives to sausages or fermented sausages exist, they apply to that food class. If cultured

Submission viewpoint	Raised by	FSANZ response
noting the proposed new standard captures cell-cultured food not limited to quail. Submitter listed range of preservatives permitted in meat products as part of their submission.		quail is added as an ingredient, to sausages or fermented sausages the existing permissions for that food would apply. If a cell-cultured food is a standalone product and food additives are requested, a specific food class can be inserted into the Code.
LABELLING		
Terminology		
Considered that allowing both 'cell-cultured' and 'cell-cultivated' may create consumer confusion. The submitter recommended standardising with single, clear terminology. Noted that other terms for cell-cultivated food may be used by the seller, but these do not have to be defined in the Standard.	SA Health	FSANZ's evidence based decision is to maintain the approach at 2nd CFS that either statement 'cell-cultured' or 'cell-cultivated' must be used, for the reasons previously stated (see section 2 in SD2 Labelling requirements at 2nd CFS, accompanying this report). In particular, consumer evidence indicates both terms perform equally in relation to consumers' objective understanding, descriptiveness of the food and perceived allergenicity. FSANZ considers consistency on pack for the same statement to be used in the statement of ingredients and name of the food (if other representations warrant the statement) will reduce the potential for consumer confusion.
Commented the statements 'cell-cultured' or 'cell-cultivated' are unlikely to be understood by the majority of consumers, given the Australian population has limited familiarity with cell-cultured meat. The submitter noted this is a new way of producing food and may require additional work to ensure consumers understand these products and can make informed decisions.	DAFF	Based on our assessment of the evidence (which indicates these terms performed best in relation to consumer's objective understanding, descriptiveness of the food and perceived allergenicity), submitter feedback and noting terminology used by overseas regulatory counterparts, FSANZ is proceeding with the proposed labelling approach. As with any new food technology, it will be incumbent on suppliers of cell-cultured food to educate consumers about the features and benefits of such foods. Once cell-cultured foods are available in the marketplace, consumer understanding and familiarity will increase over time.
Considered it essential that 'synthetic' appears with the name 'cell-cultured food'.	GE	FSANZ notes the submitter provided no evidence to support mandating the use of this term in this way. FSANZ's proposed approach is based on evidence that terms including the word 'cell-'(e.g. 'cell-cultured' or 'cell-cultivated') perform best in consumer understanding and ability to identify a cell-cultured food from its conventional counterpart.
Name of food		

Submission viewpoint	Raised by	FSANZ response
Considered that section 1.5.4—6 of the primary draft variation could be improved to support informed choice. The submitter suggested the use of either statement in the name of the food for sale, irrespective of whether the product is represented as being from the animal or not. Noted that under this drafting, foods that do not specify an animal source (e.g. sausage rolls and meat pies) would be required to identify ingredients as cell-cultured in the ingredients list but not be required to be identified as cell-cultured in the product name. Also, as cell culture technology advances and non-animal cell sources are commercialised, such products would similarly not be identified as cell-cultured in product naming. It is expected consumers will desire transparency in relation to products using this novel technology. As such, further consideration of labelling requirements is recommended to ensure clear communication e.g., requiring a statement that a product is produced using cell culture similar to that currently required for food produced using gene technology.	DOH-VIC & VIC DoEECA	Noted. After consideration of submissions, FSANZ decided to maintain the approach for food identification requirements at the 2nd CFS (see SD2 Labelling requirements at 2nd CFS, accompanying this report). FSANZ considers it is not appropriate to apply proposed food name requirements to a mixed food that is not represented as being from the animal for the following reasons: • Mandating this requirement would be more onerous for food suppliers than for existing GM food requirements. The 'genetically modified' labelling statement is required in conjunction with the name of the GM food (subsection 1.5.2—4(2) of the Code), but this information is not required in the name of a mixed food for sale that contains a GM ingredient. • Information relating to cell-cultured food will always be provided in the statement of ingredients to assist consumers to make informed choices. The proposed labelling approach to require the information relating to cell-cultured food in the statement of ingredients is also more stringent than for GM ingredients, which may be included in the statement of ingredients (subsection 1.5.2—4(3) of the Code) or elsewhere on the label. • Food for sale such as sausage rolls and meat pies would require a name or description to indicate the true nature of the food. 'Sausage' and 'meat pie' are defined terms that rely on the definition of 'meat' and have specific compositional requirements relating to their sale. FSANZ has restricted the use of the word 'meat' to food identification requirements in sections 1.5.4—5 and 6 of the primary variation. Unpackaged foods and foods not required to bear a label must provide information relating to cell-cultured food in labelling or displayed in connection with the display of the food. FSANZ notes that future cell-cultured foods may warrant additional labelling measures (e.g. if the cell-cultured food is a food for sale in

Submission viewpoint	Raised by	FSANZ response
		its own right or is derived from a non-animal source). FSANZ will consider the implications for labelling of such foods as they arise.
Use of the word 'meat'		
Sought clarity regarding whether use of certain terms containing 'meat' (e.g. 'meatball', 'meatloaf') would also be captured by the proposed prohibition.	NSWFA	Subsection S25A—5(3) will prohibit the word 'meat' in labelling unless it is used in the statement of ingredients or name of the food in conjunction with information relating to cell-cultured food (i.e. either statement 'cell-cultured' or 'cell-cultivated' and the ingredient name). Terms such as 'meat ball' and 'meat loaf' would only be permitted as part of the name of the food in accordance with section 1.5.4—6.
Suggested a future scenario where the use of the term 'meat' is complicated if only cell-cultured fat is present in a product.	GFI & APAC-SCA	Similar to our response noted above, FSANZ would consider the applicability of the proposed labelling requirements as part of the assessment of a relevant application.
Commented that the word 'meat' should not be used in isolation with these products. By definition meat is 'the flesh of an animal, typically a mammal or bird, as food.'	RMAC	The word 'meat' will not be permitted to be used in isolation (see SD2 Labelling requirements at 2nd CFS, accompanying this report and subsection S25A—5(3) of the primary variation). After consideration of submissions, FSANZ decided to permit the use of the word 'meat' in the statement of ingredients and in the name of the food, if other requirements are met (e.g. with the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the ingredient name).
The word 'meat' must not appear anywhere on the label of any synthetic cell-cultured product. Such uses of 'meat' would be false, misleading and deceptive. The proposed exceptions are therefore rejected.	GE	Noted. However, after considering all submissions, FSANZ decided to maintain the approach for the reasons stated in section 5 of SD2 Labelling requirements at 2nd CFS, accompanying this report. The proposed approach to permit the word 'meat' in conjunction with the information relating to cell-cultured food is supported by consumer evidence.
Use of the phrase 'poultry meat'		
Queried the rationale for prohibiting the use of 'poultry meat' elsewhere on the label (outside of the statement of ingredients and name of the food), noting the requirement for the statement to be used in conjunction with the term 'meat' and provided the cell-cultured quail ingredient is clearly labelled as such in the ingredients list and/or the name of the food.	NZFS	As previously noted, FSANZ considers the generic ingredient name 'poultry meat' by itself is not appropriate for cultured quail cells as an ingredient because consumers would not be informed of the true nature of the ingredient. For example, the ingredient name 'cell-cultured poultry meat' may mislead consumers that other poultry species are produced using cell-culturing techniques (see section 3.3 of SD4 to the 1st CFS). It is unlikely that food

Submission viewpoint	Raised by	FSANZ response
It is understood from the drafting that if 'meat' is to be used on the label it would always have to be stated as 'cell-cultured/cultivated meat', therefore if 'poultry meat' was used elsewhere on the label that too would be required to be stated as 'cell-cultured/cultivated poultry meat'.		suppliers would refer to 'cell-cultured quail poultry meat' in the statement of ingredients when they can refer to 'cell-cultured quail meat'. While the evidence indicates use of the word 'meat' in conjunction with the name of the ingredient or food name is unlikely to be misleading (e.g. 'cell-cultured quail meatballs'), FSANZ considers it would be misleading to permit the phrase 'poultry meat' in the name of the food (without also requiring the name of the conventional source animal) as its inclusion would wrongly suggest the food itself is poultry meat. 'Poultry meat' is a non-specific term. In the case of cell-cultured quail, it will not be permitted as a food for retail sale. The approved draft regulatory measures will only permit the word 'meat' in the name of the ingredient in the statement of ingredients and in the name of the food, if other conditions are met. The word 'meat' would not be permitted elsewhere on the label. Therefore, the prohibition for use of the phrase 'poultry meat' elsewhere on the label on the package of food is consistent with this approach. The intent is to make it easier for consumers to distinguish between foods containing cell-cultured- quail and foods containing conventional quail.
Noted the labelling approach prohibits the phrase 'poultry meat' in the statement of ingredients (as a generic ingredient name) and elsewhere on the label. The submitter noted that Standard 4.2.2 defines the term 'poultry' and sought clarification on whether the use of this word by itself on a label or in association with cell-cultured quail would also be prohibited. Submitter sought clarification on the use of the word 'poultry' by itself and whether if used in association with cell-cultured quail will also be prohibited.	DOH-WA	The definition of 'poultry' in subsection 4.2.2—1(3) applies only to Standard 4.2.2 Primary Production and Processing Standard for Poultry Meat (Australia only). It has no application for labelling purposes. The word 'poultry' is a non-specific term describing a range of domesticated birds used for food. FSANZ considers a specific prohibition of the word is unwarranted because it is highly unlikely that it would be used as part of an ingredient name or name of the food to identify accurately the nature of the food. Similarly, it is highly unlikely that it would appear elsewhere on the label in product marketing.

Submission viewpoint	Raised by	FSANZ response
Food identification: other terminology issues		
One submitter commented that either statement 'cell-cultured' or 'cell-cultivated' must be prominently displayed on the label. Two submitters considered these statements must be clearly displayed.	AMIC AMAC RMAC	FSANZ considers the requirement for either statement in conjunction with the name of the cell-cultured ingredient and this information in the name of the food (if other representations warrant it) is sufficient to alert consumers. Further, general legibility requirements in section 1.2.1—24 of the Code, which provides for required statements to be legible and prominent so as to contrast distinctly with the background of the label, will apply. This approach is consistent with the regulatory approach for labelling of genetically modified food.
Directions for use and storage		
Commented the microbiological risk from the product may be lower than conventional meat products (e.g. poultry products). However, as a completely new type of food, users of the product may have very poor understanding of microbiological risks and how to control them. Therefore, it will be important this information is provided on the labelling or any of the associated documentation provided to businesses receiving the product.	Qld Health GE	FSANZ agrees. As previously noted, the onus is on the supplier of the food to provide appropriate directions for use and storage and any storage conditions relating to their food product (see section 4.3 in SD4 to the 1st CFS; and Table 4 in Appendix 1 of the 2nd CFS).
Nutrition information		
Supported the application of existing requirements for nutrition information, however noted the levels of some vitamins in cell-cultured quail differ to conventional quail and chicken. The submitter noted this is a new food and vitamin levels may not appear as part of a product's nutrition information. While it was acknowledged there are no known nutrition issues as a result of these differences, this submitter requested FSANZ consider an approach for the nutrient profile of the product to be accessible to consumers and enable consumers to make informed choices.	NZFS	FSANZ's assessment concluded there is no safety issue that would warrant mandating nutrition information. A requirement to declare vitamin or mineral content in the nutrition information panel (NIP) would be onerous for food suppliers and would have limited value to a consumer if the comparator food (i.e. a mixed food containing conventional quail or chicken) is not required to declare the same information. However, there is nothing to preclude a food supplier from voluntarily declaring this information in the NIP, noting the nutrition information would reflect the average quantity of the nutrient from all ingredient sources in the mixed food product.
Nutrition content and health claims		
Comparative claims	NSWFA	Requirements in section 1.2.7—16 apply to the food for which the

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Disagreed that part (a) of the definition of 'reference food' would apply to justify the comparative claims between food containing cell-cultured quail and food containing conventional quail meat. The submitter commented the application of part (a) in relation to the regulation of comparative claims about dietary substitutes is not consistent with the original intent in P293. They stated it is arguable if food containing conventional quail meat is 'of the same type' as food containing cell-cultured quail and 'that has not been further processed, formulated, reformulated or modified'. The submitter requested a stronger rationale in the Approval report about comparative claims on food containing cell-cultured quail.		claim is made (in this case, the mixed food), rather than any specific ingredient that may be considered more 'processed' or 'formulated' than a conventional counterpart ingredient. Further, comparative claim requirements are limited to macronutrient content from all ingredient sources, which could vary based on the amount of ingredients used. FSANZ considers it remains appropriate for the general requirement for comparative claims between food containing cell-cultured- quail and food containing conventional quail meat. However, it notes the regulatory approach would need to be considered when assessing future cell-cultured food that could be consumed as a whole food, such as cell-cultured steak.
Health claims and nutrition information Stated the health attributes and nutritional value displayed on food products should accurately represent the contents of that product only and not denigrate or unethically appropriate the health assurances or food value of any other food product.	CA	In general, all foods that are packaged for retail sale are required to declare nutrition information in a NIP. The declaration must reflect the nutrient composition of the food. FSANZ notes the cell-cultured- quail will be used as an ingredient in a food for retail sale, meaning the nutrition information will relate to the mixed food. General claim requirements will also apply. This is consistent with the existing regulatory approach for meat analogue products. A mixed food for retail sale containing cell-cultured quail as an ingredient will be subject to nutrition content and health claims requirements and conditions in the Code. Comparative claims about macronutrients (e.g. energy, fat, protein) will be permitted if claim conditions are met. Comparative claims relating to vitamins and minerals are not permitted for any food (see FSANZ response in Table A4 to Appendix 1 in the 2nd CFS).
Characterising ingredients		
Considered that, based on the consumer evidence provided, the proposed changes for characterising ingredients were not justified. That is, there was no evidence that investigated whether consumers expected this information to be provided when a food is not required to bear a label.	NZFS	FSANZ agrees with the submitter's comments that requiring additional characterising ingredient information for food not required to bear a label would be onerous for food suppliers and difficult to enforce. FSANZ now considers that existing generic characterising ingredient requirements should apply to cell-cultured food ingredients for the reasons described in section 2.3.4.1 of this report.

Submission viewpoint	Raised by	FSANZ response
Noted that, in general, the labelling requirements for cell-cultured food and ingredients are proposed to align with existing requirements for irradiated foods and food produced using gene technology. However, this submitter considered the proposed requirements for cell-cultured food in subparagraph 1.2.1—9(7)(e)(i) of the draft primary variation at 2nd CFS go beyond these existing requirements. The following example was provided to illustrate the difference: unclear why a cheese and cell-cultured quail muffin sold from an assisted display cabinet would need to provide information on both the % cheese and % cell-cultured quail, when a cheese and tomato muffin (containing irradiated tomato) sold in the same way does not have to provide either the % cheese or the % tomato. Further, the submitter stated that removing the exemptions for prepared filled rolls, sandwiches, bagels or similar products (paragraph 1.2.10—3(3)(a) and a food for sale that is sold at a fund-raising event (paragraph 1.2.10—3(3)(b) for cell-cultured food ingredients would have the effect of requiring percentage labelling for all characterising ingredients and components of such foods, irrespective of whether the cell-cultured food is itself a characterising ingredient of the food. The submitter noted these exempted foods are often made by hand therefore amounts of ingredients (including characterising ingredients) will vary per item. This manual process makes accurate provision of characterising ingredient information very difficult if not impossible. It would not be possible to enforce this requirement due to the variation in the percentage per item. Noted that removing this exemption requires percentage labelling for all characterising ingredients and components of such foods, irrespective of whether the cell-cultured food is itself a characterising ingredient of the food. There appears to be no clear rationale for why these exemptions should not apply for foods containing cell-cultured foods.		

Submission viewpoint	Raised by	FSANZ response
Sought clarification regarding the application of characterising ingredient information to cell-cultured food. This submitter queried whether the use of either statement 'cell-cultured' or 'cell-cultivated' in the name of the food for sale would trigger the requirement for characterising ingredient information in the statement of ingredients. Another query related to the scenario where the name of a food for sale is 'cell-cultured quail with apples' and apples were represented in the name and/or in an image. The submitter queried if the percentage of the apples would only need to be declared, or the percentage of both ingredients (cell-cultured quail and apples) would be required in the statement of ingredients.	DOH-WA	The characterising ingredient information requirements rely on the definition of 'characterising ingredient', which 'means an ingredient or a category of ingredients of the food that (a) is mentioned in the name of the food; or (b) is usually associated with the name of the food by a consumer; or (c) is emphasised on the label of the food in words, pictures or graphics' (subsection 1.1.2—4(1) of the Code). Paragraphs (a) and (c) are relevant in the case of a packaged food for sale containing a cell-cultured food ingredient. The intent is for characterising ingredient information about the cell-cultured food ingredient to apply if information relating to the cell-cultured food is used in the name of the food. FSANZ considers the presence of the statement and the name of the ingredient in the name of the food (e.g. 'cell-cultured quail patties') would satisfy paragraph (a) of the definition of characterising ingredient. Similarly, the presence of the word 'apple' in the name of the food would satisfy paragraph (a), whereas an image of an apple elsewhere on the label would meet paragraph (c) of the definition of characterising ingredient. Either scenario would trigger percentage labelling of the apple ingredient.
Considered that current requirements (sections 1.5.4—6 and 1.5.4—7) could create complex labelling obligations that could be challenging for manufacturers. Despite significant amendments to labelling of food that is not required to bear a label (Standard 1.2.1), Standard 1.5.4 does not include these requirements. Suggested Standard 1.5.4 includes labelling requirements for the sale of food that is not required to bear a label in relation to characterising ingredients and those foods that would not be exempt (e.g. prepared filled rolls, sandwiches, bagels or similar and food for sale that is sold	SA Health	FSANZ has decided to not apply additional characterising ingredient information to food for sale that contains a cell-cultured food as an ingredient and is not required to bear a label. See response above and section 2.3.4.1 of this report.

Submission viewpoint	Raised by	FSANZ response
at a fund raising event).		
Compound ingredient		
Noted the proposed requirements in sections 1.5.4—5 and 1.5.4—6 apply to food for sale that has a cell-cultured food as an 'ingredient'. Similarly, the proposed section S25A—5 applies to a food for retail sale that has cell-cultured quail as an 'ingredient'. It is unclear how above drafting would apply in the case a food for sale has a cell-cultured food/quail as a compound ingredient, particularly if the cell-cultured food is an ingredient of a compound ingredient that comprises less than 5% of the food for sale, the cell-cultured food/quail would not be required to be listed in the statement of ingredients. Submitter therefore recommends adding food for sale that has a cell-cultured food/quail as a 'component ' in scope of labelling requirements, as well as an ingredient, so that all food containing cell-cultured food/quail would be subject to the labelling requirements.	NSWFA	FSANZ adopted a different approach to that recommended by the submitter for several reasons. In the first instance, FSANZ considers it would be highly unlikely for a cell-cultured ingredient to be present in a food for sale in such a small amount (i.e. as an ingredient of a compound ingredient that is itself less than 5% of the food). In the case of A1269, the proportion of cultured quail cells in food would be much higher due to its intended use to create alternative protein products. Secondly, FSANZ notes that where there is a conflict between specific provisions in subchapter 1.5 standards and general labelling provisions in subchapter 1.2 standards, the specific provisions will prevail. Information relating to cell-cultured food (either statement and the ingredient name) would need to be declared irrespective of whether or not cell-cultured foods are specified in subparagraph 1.2.4—5(6)(b)(i). FSANZ notes it has proposed a specific reference to genetically modified food in that paragraph in the 2nd CFS draft variation for P1055 Definitions for gene technology and new breeding techniques. This proposed variation was made for clarity and accounts for the possibility of small amounts of genetically modified food ingredients present as an ingredient of a compound ingredient in a food for sale. The decision regarding this proposed approach is pending. FSANZ considers a similar provision for cell-cultured food is not warranted under the present application but would reconsider this approach in future assessments of new cell-cultured foods.
Information requirements for food for sale not required to bear a label		
Commented there was no Code requirement to display ingredients of unpackaged food available for retail sale.	NSWFA	At 2nd CFS, FSANZ noted the intent is to ensure consumers have access to information relating to cell-cultured food (comprising both the statement and the ingredient name) in all retail scenarios,

Submission viewpoint	Raised by	FSANZ response
This submitter referred to the Note to subsection 1.5.4—5(2) of the primary draft variation at 2nd CFS that states 'labelling provisions apply to both packaged and unpackaged food'. Clarity was sought regarding the provision of information relating to cell-cultured food as it relates to unpackaged food.		including food for sale that is not required to bear a label and unpackaged food. To achieve this intent, FSANZ proposed adding a new paragraph to require information relating to cell-cultured food for these types of retail sale (see item [10] of the consequential variation at approval). The Note to subsection 1.5.4—5(2) at 2nd CFS provided a signpost to provisions in Standard 1.2.1 for both packaged and unpackaged food (see section 7.4 in SD2 Labelling requirements at 2nd CFS, accompanying this report). The Note is consistent with the approach for GM foods (see the Note to subsection 1.5.2—4(2) of the Code) and irradiated foods (see Note 1 to section 1.5.3—9 of the Code).
Noted that, although the systematic review did not specifically capture evidence of consumer expectations regarding the identification of cell-cultured food sold in a restaurant, it seems sensible to assume from the available evidence that consumers would like to have this information in the restaurant setting.	NZFGC	FSANZ agrees. Consumers should be provided with information relating to cell-cultured food in all retail sale scenarios, including in a restaurant setting, so as to be able to make an informed choice. Food containing a cell-cultured ingredient that is sold in a restaurant or café setting will be subject to labelling requirements for food for retail sale. That is, if a food for sale is not required to bear a label, the information relating to cell-cultured food must be stated in labelling that accompanies the food or is displayed in connection with the display of the food (see section 7 of SD2 Labelling requirements at 2nd CFS, accompanying this report and proposed paragraph 1.2.1—9(3)(baa) and section 1.5.4—5).
--Commented that information requirements for foods containing a cell-cultured ingredient that are not required to bear a label are unclear. Sought clarification about whether customers in a food service setting, such as in a restaurant or café, would know if they are consuming cell-cultured food. One submitter queried what labelling requirements are being proposed regarding menus to ensure consumers can make informed choices.	NZFGC APL RMAC Individual (MM)	As noted above, food containing a cell-cultured ingredient that is sold in a restaurant or café setting will be subject to labelling requirements for food for retail sale. That is, if a food for sale is not required to bear a label, the information relating to cell-cultured food must be stated in labelling that accompanies the food or is displayed in connection with the display of the food (see section 7 in SD2 Labelling requirements at 2nd CFS accompanying this report and see proposed paragraph 1.2.1—9(3)(baa) and section 1.5.4—5).

Submission viewpoint	Raised by	FSANZ response
		The Code does not regulate how information requirements for these types of retail sales must be provided. Subsection 1.2.1—9(3) of the Code provides flexibility to food suppliers regarding how they wish to declare the information. For example, patties displayed in an assisted display cabinet may have a shelf label stating the food contains cell-cultured quail, or a restaurant menu may include either statement and the ingredient name in relation to a particular menu item.
Food sold to a caterer and other sales of food		
Sought clarity regarding how the information relating to cell-cultured food must be provided to caterers if the food is unpackaged. This submitter specifically queried whether stating the information (either 'cell-cultured' or 'cell-cultivated') on accompanying documentation would suffice as being labelling 'in conjunction with' the unpackaged food?	DOH-WA	FSANZ is applying existing requirements for the provision of information about a food sold to a caterer. Section 1.2.1—13 of the Code specifies that labelling containing the information required by section 1.2.1—15 must be provided to the caterer with the food. This provision provides flexibility to suppliers regarding how they provide the information. FSANZ has noted previously that it is common practice for suppliers to provide information to caterers and manufacturers about their food products (e.g. information about the ingredients used, nutrition information, cooking instructions, storage requirements) in a product information form or specification. The information ensures caterers and manufacturers handle and prepare the products correctly. It is also common for suppliers to provide food product details online or when requested (Appendix 1, Table A3 Summary of submissions in the 2nd CFS).
Stated that warning labels about cooking, including temperature requirements, must be included if that is part of the applicant's proposed food handling sanitation necessities.	Individual (MM)	See response above regarding information, including cooking and storage information, that suppliers provide to caterers or manufacturers.
Other labelling issues		
Additional statement Considered the statement 'Embryo Quail Fibroblast Cell Derived Biomass' should be on the label.	Individual (MM)	FSANZ does not agree with the proposed statement for the same reasons noted in relation to the suggested food name 'cultured quail made with embryonic fibroblasts' (see Appendix 1, Table 2 in the 2nd CFS).
Labelling of chemicals Requested every chemical used in the process to obtain and maintain the cells to be included on the label, to enable consumers with certain allergies or sensitivities to be informed prior to purchase and	Individual (MM)	FSANZ's assessment determined there are no safety concerns associated with the consumption of cultured quail cells. Similarly, there are no issues relating to allergenicity in regard to listed food

Submission viewpoint	Raised by	FSANZ response
consumption. Considered this approach would not only protect the applicant or producer, but also the consumer, which in turn protects the company's reputation and future viability.		allergens or potential new allergens of public health concern for consumers (see SD1 to this report).
Senate Inquiry on the definitions of meat and other animal products Commented that the proposed labelling framework gives no indication of how lab-grown fake 'meat' products will be labelled. This submitter considered this framework is in opposition to Senate recommendations to the Australian Government to implement as worded in the Senate report 'Don't mince words: definitions of meat and other animal products'. Noted that urgent action is demanded on alternative protein labels, including cell-cultured goods. Minimum regulated standards are required to prohibit the use of plant or synthetic protein descriptors (including cell-cultured foods) that contain any reference to animal flesh or products made predominately from animal flesh, including but not limited to 'meat', 'beef', 'lamb' and 'goat'. Supported the definition of beef to only include products derived from actual livestock raised by cattle farmers and ranchers and harvested for human consumption. One submitter considered it was imperative that meat category brands are protected from misleading labelling and product denigration from manufactured proteins.	CA RMAC	FSANZ disagrees with the submitters' view that the proposed labelling framework does not indicate how cell-cultured foods will be labelled. FSANZ considers the proposed approach provides an evidence-based labelling mechanism for consumers to accurately identify a cell-cultured food from a conventional comparator food. The approach is based on consumer evidence, which indicates consumers find the use of cell-type terminologies with the term 'meat' to be 'moderately to very differentiating from conventional meat or plant-based descriptors (see SD2 to the 1st CFS). To date, FSANZ has only assessed cultured quail cells and will consider how proposed labelling requirements would apply to other cell-cultured foods (for example, a cell-cultured food grown on a scaffold to mimic a cut of meat) in future assessments. Matters relating to the labelling of plant-based meat or milk alternative products and whether the name of the source animal (e.g. 'beef' or 'lamb') can be used in product names or elsewhere on product labels, are not in scope for A1269. The Code does not define animal names such as 'beef' and this is also not in scope of A1269. FSANZ notes the Government Response to the Senate inquiry on the definitions of meat and other animal products has not been published to date.
Use of imagery and descriptors -Considered that labelling should prevent consumer confusion by providing clear, unambiguous information that the product is derived from cultured cells, rather than from conventional animal sources. There was opposition to the use of images and descriptors associated with protein sourced from livestock production on the labelling of cell-cultured products, plant or synthetic food packaging or marketing materials.	AMIC CA RMAC APL	FSANZ agrees that labelling information should assist consumers to make informed choices and not be misleading. The Code generally does not regulate representations such as images or graphics unless there is a specific public health and safety issue to be addressed (for example, the pregnancy warning pictogram as defined in section 2.7.1—2 of Standard 2.7.1 Labelling of alcoholic beverages and food containing alcohol). Requirements in the Code operate in conjunction with requirements in consumer protection legislation in Australia and

Submission viewpoint	Raised by	FSANZ response
		New Zealand which prohibit misleading or deceptive conduct and false or misleading representations about goods and services. In Australia, the Australian Competition and Consumer Commission (ACCC) enforces the Competition and Consumer Act 2010 (Cth); and states and territories enforce their own consumer protection legislation. In New Zealand, the New Zealand Commerce Commission (NZCC) enforces the Fair Trading Act 1986 (NZ). In previous discussions with the ACCC and NZCC, they stated that they consider whether the overall representation is misleading (section 3.2.6 in the Approval Report for A1186 Soy leghemoglobin in meat analogue products).
Application of Standard 1.2.2 (1)(b)(i) Requested clarification on how the requirement in Standard 1.2.2—2(1)(b)(i) that 'a name or description that is sufficient to indicate the true nature of the food' would be applied to a range of cultivated food products. Two issues were raised: 1. would a minimum % of cell-cultivated ingredient be required to enable the use of cell-cultivated in the name of a food product? 2. how would this standard be applied to the use of a cell-cultivated fat ingredient in a plant-based meat alternative product? Could such a food product use cell-cultured or cell-cultivated in its name, or indeed, would it be required to do so if cell-cultivated fat represents only 5% the weight of a product but this is equivalent to the amount of intramuscular fat found in the animal meat from which the cell-cultured ingredient was sourced?	GFI & APAC-SCA	The general requirement in subparagraph 1.2.2—2(1)(b)(i) for a name or description that is sufficient to indicate the true nature of the food applies to all food for retail sale (except those foods that have a prescribed name). Additionally, subparagraph 1.2.2—2(1)(b)(ii) requires a name or description that includes any additional words required by the Code to be included in the name of the food. This general requirement gives effect to the specific proposed requirement for either statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured food ingredient to be in the name of the food (subsection 1.5.4—6(1) of the draft variation). Although the requirement for the statement 'cell-cultured' or 'cell-cultivated' described above is based on how the food for sale is represented rather than whether a particular amount of the cell-cultured food ingredient is present, the presence of the statement in the name of the food would trigger the requirement for characterising ingredient information in the statement of ingredients (see section 2.3.4.1 of this report). This would inform consumers about the proportion of the cell-cultured ingredient in the food. If a future scenario relating to a cell-cultured fat ingredient arose through an application, FSANZ would consider the applicability of

Submission viewpoint	Raised by	FSANZ response
		the proposed labelling requirements including whether variations to the standard would be warranted.
CONSUMER EVIDENCE		
Evidence for labelling approach Commented that it seems unlikely that any of the reviewed evidence looked at consumer views of specific priority population groups in New Zealand such as Māori and Pacific. This submitter considers this evidence to be a minimum requirement when considering regulatory changes applicable for the New Zealand population.	NZFGC	FSANZ notes these data limitations. As discussed in both the FSANZ rapid review and the University of Adelaide systematic review, there is limited Australian and New Zealand data available. In the systematic review, out of 43 total studies reviewed, four were undertaken in New Zealand and none specifically examined New Zealand's Māori or Pasifika populations. Both reviews included international studies that used representative studies of their total population. FSANZ has based its decision on the best available evidence on consumers' understanding, preference and acceptance of different terminologies for cell-cultured meats at this time.
Noted concerns about the restrictions placed on the consumer research in relation to the use of meat and animal labels being used by the alternative protein sector.	APL	As noted above, matters relating to the use of other meat and animal descriptors for alternative proteins are out of scope of A1269.
Acknowledged FSANZ's rationale for use of 'cell-' in the food name as it allows consumers to identify the true nature of the food more clearly. Noted this was based on the best available evidence provided by the University of Adelaide consumer literature review. However, there are data limitations, in particular the: • limited quality of studies • absence of Australian and New Zealand data on terminology preferences • use of outdated data from 2018-19. As such, submitter recommended that FSANZ increases engagement with the cellular agriculture sector to complement its understanding of the best available evidence-base with the commercial and technical advances being made by industry participants. There is also an apparent need for additional contemporary research with an Australia-New Zealand focus.	APC/CAA/FF	Following essential components of evidence-based practice to provide high-quality evidence, the quality of each study included in the reviews was considered. Additionally, the consistency of findings across studies, the precision and generalisability of the findings, and the strength of the evidence was also considered when synthesising the results of the studies. The overall body of work provides comprehensive insights into the specific topic, and supports robust conclusions. FSANZ has engaged closely with stakeholders, including the cellular agriculture sector, throughout the assessment process and stakeholders have not provided or identified any additional consumer evidence. FSANZ has based its decision on the best available scientific evidence on consumers' understanding, preference and acceptance of different terminologies for cell-cultured meats at this time, alongside other considerations required under the FSANZ Act (see section 2 in SD2 Labelling

Submission viewpoint	Raised by	FSANZ response
In noting the above, submitter supported mandated labelling without the qualifier 'cell-' as more effective in facilitating consumer acceptance and trust in products. This is critical to facilitate the commercial success of this emerging industry. Submitter accepted this is not FSANZ's primary concern but suggested it should be a consideration.		requirements at 2nd CFS, accompanying this report and section 3.1 in SD4 to the 1st CFS). As noted previously, FSANZ has stated that consumer acceptance is not part of its consideration of food identification requirements (Table A3, Appendix 1 to the 2nd CFS; and section 2 in SD4 to the 1st CFS).
Noted the lack of knowledge of the public in relation to cell-based meat (CBM) is demonstrated in the University of Adelaide consumer literature review in the following extract: 'Overall, findings from a single nationally representative survey of Australian consumers which were reported in two separate studies (both of moderate quality), show 69% of Australian consumers had previously heard of at least one of the six CBM terms presented, but only 20% of consumers felt knowledgeable about at least one of the CBM terms.' This submitter stated the lack of knowledge from the average consumer raises concerns about the limited labelling requirements, including that the term 'cell-cultured quail' with an image of a quail could be misleading. It was noted that 'cell-cultured quail' is not a whole organism but an *in-vitro* growth of one type cell from a quail. The following analogy was provided: if something looks like an apple, tastes like an apple, but is not grown on an apple tree, is it an apple? This submitter suggested alternative, more suitable descriptions 'cell-cultured animal derived quail' or 'cell-cultured manufactured quail'.	Individual (PS)	As noted in the previous response, FSANZ has based its decision on, among other things, the best available scientific evidence as required by the FSANZ Act (see section 2 in SD2 Labelling requirements at 2nd CFS, accompanying this report and section 3.1 in SD4 to the 1st CFS). The overall body of work provides comprehensive insights into the specific topic, and supports robust conclusions. As noted in Appendix 1 of the 2nd CFS, no evidence was provided to FSANZ to support the view that consumer understand cell-cultures are of whole organisms. Furthermore, the final food containing the cultured quail cells is distinctly different from conventional quail. FSANZ also considers the mandatory presence of either statement 'cell-cultured' or 'cell-cultivated' will alert consumers that the cell-cultured food ingredient food is sourced via a novel method of production rather than from the conventional animal source. Further, voluntary representations including images of the animal source would provide context regarding that animal source.
Commented it is proven that the use of traditional beef nomenclature on alternative products is confusing to consumers and weakens the value of products derived from actual livestock production (referred to 2021 Pollinate National Consumer Research).	CA	FSANZ acknowledges the reference to the Pollinate Research. Matters/research relating to the labelling of plant-based meat or milk alternative products and whether the name of the source animal (e.g. 'beef' or 'lamb') can be used in product names, are not in scope for A1269. FSANZ notes the Government Response to the Senate inquiry on the definitions of meat and other animal products has not been published.
Commented that spending scarce resources on canvassing public opinion is a much lower priority than beginning to fill data gaps. It	GE	Ensuring public confidence in the food supply is a core part of FSANZ's remit under the Act. As such, where necessary FSANZ may conduct consumer research to inform applications and

Submission viewpoint	Raised by	FSANZ response
smacks of industry promotion which is not FSANZ's role or responsibility.		proposals to change the Code, or to better understand consumer awareness, attitudes and behaviours in relation to food labelling and consumption.
Commented that FSANZ commissioned two opinion studies, at public expense. These confirmed that most people were unaware of cell-fermented foods. They steered participants into selecting preferred names for the new product labels. This did not increase the body of 'best available scientific evidence' for which FSANZ admits there is no long-term evidence of safety. Market acceptance and cool names to assuage public mistrust would benefit ultra processed food industries so they should have funded such surveys, not FSANZ.	GE	FSANZ's rapid review explored consumers' understanding, preference and acceptance of different terminologies for cell-cultured meats and consumers' perceptions of cell-cultured meat relative to conventional meat. The University of Adelaide systematic review explored consumers' understanding, acceptance and behaviours in response to cell-based proteins. These reviews were undertaken to provide evidence to support informed decision-making by consumers. Following essential components of evidence-based practice to provide high-quality evidence, the quality of each study included in the reviews was considered. Additionally, the consistency of findings across studies, the precision and generalisability of the findings, and the strength of the evidence was also considered when synthesising the results of the studies. The overall body of work provides comprehensive insights into the specific topic, and supports robust conclusions.
Cost and benefit considerations		
The proposed regulatory framework would provide clarity on regulatory requirements for cell-cultured food for sale in Australia and New Zealand and for production of these foods in Australia. This would assist future applicants prepare their application to FSANZ. -FSANZ's intent to grant product-by-product permission for cell-cultured food was supported. This approach would require any new cell-cultured food manufacturer to undergo FSANZ's application process regardless of similarity to the existing permitted cell-cultured food listed in Schedule 25A. While it may seem costly and burdensome for future applicants, this approach was supported as the best way to protect public health and safety while the cell-cultured food industry is in its infancy. This would nurture consumer confidence in the safety of cell-cultured food over time and consequently the industry	NSWFA	FSANZ notes these comments.

Submission viewpoint	Raised by	FSANZ response
would see the benefit.		
Omission to cost/benefit analysis Submitter of the view its members who produce traditional animal-protein source foods are likely to be concerned that the costs to traditional protein providers and exporters are not considered in FSANZ's cost/benefit analysis under industry costs. This is a significant omission to FSANZ's cost/benefit analysis and the submitter queried why this omission.	NZFGC	FSANZ's consideration of costs and benefits has now had regard to potential costs to traditional protein providers and exporters. Net overall benefits to industry and consumers are generally implicitly assumed for costs and benefits of permitting all safe innovations.
Submitter of the view the following proposed variations unduly restricted the production and sale of cultivated foods without a requisite food safety justification: - Section 1.5.4—4 prohibiting use in special purpose foods. If cultivated food products are assessed as safe by FSANZ, then this prohibition seems incongruent with the scientific assessment results without any additional justification being provided. FSANZ requested to either remove this provision or justify its inclusion. - S25A—4 has a condition of sale that cell-cultured quail must not be a food for retail sale. The safety of cell-cultivated quail has been determined at the point of harvest without further processing; therefore, there is no justification to prevent it being sold as a food for retail sale except where it is used as an ingredient. Again, FSANZ was requested to remove this requirement or justify its inclusion.	GFI & APAC-SCA	The rationale for the prohibition for use of cell-cultured foods in special purpose is detailed in section 2.3.2.2 of this report. FSANZ assesses applications according to their scope as requested. The applicant did not request that cell-cultured quail be sold for retail as a single ingredient. Other permitted ingredients will be mixed with the cultured quail cells to produce the final food served in food service establishments and not for consuming cell-cultured quail as a single food. Due to the application's scope, dietary exposure and safety has been assessed for the harvested cell-cultured quail cells. This does not prevent other applications for cell-cultured foods to be retailed as a single ingredient.
Requirements specific to Australia and New Zealand that are in addition to those imposed by other jurisdictions will impose additional cost to applicants. FSANZ should indicate whether requirements imposed by other aligned regulators are being considered and, in the case these are concluded to be insufficient, FSANZ should fully outline the human health risk associated with the gap in order to justify the additional cost.	APC/CAA/FF	FSANZ aims to harmonise regulatory requirements with other jurisdictions to the extent possible within the unique requirements of the Act and the policy settings established by the joint Australia New Zealand Food Regulation System.
Costs of compliance for cell line suppliers as food businesses The proposal to regulate cell line suppliers as food businesses may duplicate the documentary requirements of the quality management system (for laboratories) they already operate under (i.e. fully	DOH-VIC & VIC DoEECA	Refer to subsection 2.3.3. of this report for a response to these issues.

Submission viewpoint	Raised by	FSANZ response
documented good laboratory practice (GLP) / good cell culturing practice (GCCP)). Existing quality management systems may adequately manage hazards associated with food production. Consideration should be given to whether the additional benefits of cell line suppliers complying with Standard 3.2.1 and potential duplication with existing GLP/GCCP quality management systems outweigh the costs. Submitter had no information to quantify industry costs.		
Costs associated with ensuring clarity for and acceptance by consumers Any industry 'costs' must be seen as part of the package of introducing this new product into the food supply. If the upfront or additional costs for clarity for consumers helps prevent public rejection of the product, then it is an affordable cost. The same applies for costs associated with doing RCTs to gain social license for a non-vegan foodstuff whereby its production requires more power than free sunlight to grow normal quail meat. Wild quail needs no power, mining or perpetual producing of chemicals that the cell-cultured quail requires. Thus, regulator costs such as these should not be dismissed for these costs are for the consumer and company benefit.	Individual (MM)	FSANZ notes the points in this submission and notes that certain industry costs and regulator costs are necessary to ensure safety and are unlikely to outweigh overall benefits to industry, consumers and government. Costs of power and other inputs to cultivate cell-cultured quail are considered to be costs of normal business.
FSANZ's cost benefit assessment must not be influenced by commercial interests To ensure safety and caution, FSANZ must not modify its regulatory approach to satisfy the commercial interests of synthetic cell-cultured food businesses. Ameliorating the problems of UPF processors are not the province of food regulators who must act with caution in the public interest, not to benefit private enterprises.	GE	FSANZ operates independently within the parameters defined in the Act. FSANZ has considered the range of potential first-order costs and benefits to consumers, industry and government and has not placed greater weight on commercial interests than on other costs or benefits. The protection of public health and safety is the primary statutory objective for FSANZ. The risk assessment, including the dietary exposure assessment, concluded that this product would pose no safety concerns. The broader standards 1.5.4 and 3.4.1 proposed would ensure adequate safety before this food and any other cell-cultured foods are permitted to be sold in Australia or New Zealand.

Submission viewpoint	Raised by	FSANZ response
Commercial, technical and public acceptance hurdles for synthetic cell-cultured foods are recognised, reviewed and discussed in Garrison et al. (2022), which concludes: 'Our economic analysis suggests that cell-cultured meat produced in a large-scale plant can be produced at a cost $63/kg if technology can be developed to produce the hormones at low cost and efficiencies in use of the medium can be reached. This cost estimate may not ever be reached since it will require multiple technological advances to be achieved. In practical terms, for this large-scale production, a kilogram of cell-cultured hamburger meat would cost well over $100/kg at the supermarket and restaurants. The three largest costs of production are the cell-culture media, bioreactors and processing equipment and labour, resulting in a cost of over $55/kg for just those three categories. The cell-cultured meat industry requires innovation in reducing the cost of the media before it can reach the costs estimated here. Cell-cultured meat … will be much more expensive than other meat and protein products. The risk of contamination and any possible liability for damages to consumers was not considered. Each of these limitations provides the opportunity for further economic research efforts.'	GE	The consideration of costs and benefits acknowledges that cell-cultured foods are in their infancy with uncertain market growth. That takes into consideration the currently high production costs and uncertainty of the future speed or extent of technology developments for reducing production costs. Regarding risk of contamination or possible liability for damages to consumers, FSANZ's proposed new safety standards 1.5.4 and 3.4.1 would ensure adequate safety before any cell-cultured foods are permitted to be sold in Australia or New Zealand. In anticipation of those safety standards, the risk assessment for cell-cultured quail, including the dietary exposure assessment, concluded that this product would pose no safety concerns beyond allergens of conventional quail.
Other issues		
Industry and government guidance		
Need for guidance material to support Standard 3.4.1 As a new food, using novel processes, guidance is required to assist auditors and businesses in understanding the hazards and being able to assess safety of changes to production.	DOH-VIC & VIC DoEECA DOH WA NSWFA Qld Health SA Health	FSANZ agrees. ISFR is responsible for development of nationally consistent guidance in relation to food standards. FSANZ has commenced developing guidance material in consultation with jurisdictions.
Ongoing monitoring and enforcement		
Monitoring consumption The application states that cultured quail will be served to patrons in restaurants at limited serving sizes. Submitter queried who would be responsible and accountable for monitoring consumption of the cell-cultured quail meat per patron and how it would be enforced.	Individual (PS)	The small serving sizes are because the cell-cultured quail is intended to be sold in restaurants as a canapé that commands a high price. The small serving size was not a restriction imposed by FSANZ.

Submission viewpoint	Raised by	FSANZ response
		FSANZ has undertaken a comprehensive safety assessment of cell-cultured quail and has established additional risk management measures to ensure derived food products are safe for human consumption. Monitoring and limiting consumption post-approval is unnecessary because the product poses minimal risk.
The submitter considered that life-cycle assessments of all synthetic cell-cultured foods are required, including systematic monitoring to assess any long-term health and wellbeing impacts on families.	GE	FSANZ undertook a comprehensive assessment of the cell-cultured quail including the cell line and all media inputs. The evidence based assessment did not identify any hazards that would indicate an ongoing need to monitor for long-term adverse health outcomes.
Monitoring compliance Further discussions are needed regarding what guarantees are in place to ensure that retailers and caterers disclose the presence of cell-cultured ingredients in their products.	AMIC	The responsibility to disclose the presence of ingredients in mixed foods lies with retailers and caterers. The Code mandates this, specifically through labelling requirements, naming of the food, percentage labelling of characterising ingredients and listing all ingredients. Australian and New Zealand food laws apply these requirements and make noncompliance an offence.
There is potential for fraud and deception in relation to cell-cultured quail – where a seller uses conventional quail meat to resemble cell-cultured quail and applies a label saying it is cell-cultured – a consumer could be deceived it is cell-cultured. The potential for this occurring could be where the cell-cultured quail is at a higher sale price than the conventional quail meat. How would the enforcement agency be able to test?	SA Health	Please see responses above. Fraud can occur with any current food product and is not constrained to, or more likely to occur with cell-cultured foods. A test for any particular cell-type, or the percentage of cells in a mixed food would be very difficult to develop and therefore impractical. Furthermore, it is likely the appearance, texture and flavour of conventional quail meat and cell-cultured quail would be significantly different. FSANZ consider that the usual methods of compliance for mixed foods of this type, such as sausages, would be adequate to ensure compliance.
Maintaining stakeholder engagement		
FSANZ was encouraged to maintain open engagement with stakeholders as the regulatory framework evolves alongside advancements in cell-cultured food technology. AMIC able to contribute further to ensure that industry standards support safety and transparency across the food sector.	AMIC	FSANZ welcomes the opportunity for open engagement to ensure that industry standards support safety and transparency across the food sector.
Given the complexity and potential implications to industry and the limited consultation period for this submission, submitter welcomed an opportunity to further engage with FSANZ on the drafting of the	RMAC	FSANZ has assessed this application under the major procedure, which includes two rounds of public consultation. Each consultation period has been extended beyond the standard six-

Submission viewpoint	Raised by	FSANZ response
standards to ensure they meet the requirements of a transparent, sustainable and safe food sector.		week duration, deemed adequate for the complexity of this application. As the cell-cultured food sector is in its early commercial development phase, FSANZ anticipates further opportunities for engagement either outside of this application, or as more applications are received.
Submitter would appreciate an opportunity for them and other peak industry bodies representing the livestock sectors to engage with FSANZ to better understand the detail of the proposed changes to the standards and the considerations that have led FSANZ to draft the proposed changes to the standards.	APL	Please see above. FSANZ believes the opportunity to comment on this application has been sufficient, and has had regard to all submissions and comments received. However, FSANZ welcomes engagement with APL either outside of this application or before, or once further applications are received.
Future applications		
Application Handbook The Application Handbook should be updated to provide clarity for businesses who would like to seek approval for the use and sale of cell-cultured foods.	NZFS	Noted. FSANZ is currently updating the Application Handbook. FSANZ will consider including requirements for cell-cultured food in the Handbook once the A1269 amendments have been gazetted.
Noted FSANZ's recognition of cultivated food as a distinct food category and looked forward to the Application Handbook guidelines being updated to include information requirements for applications on cultivated foods, once the standards and schedule have been gazetted.	GFI & APAC-SCA	Please see response above.
GM cell-cultured food Requested clarity as to which standard will take precedence – Standard 1.5.2 (GM food) or 1.5.4 (Cell-cultured food), in the event of an application for a GM cell-cultured food (i.e. a food meeting definitions of both a GM food and cell-cultured food in the Code). Also sought clarity on labelling requirements for such food.	NSWFA	GM CCF will be captured as CCF, meaning schedule 25A will list both GM and non-GM CCF. A full pre-market safety assessment will be undertaken, which will include consideration of any GM aspects. Approved GM CCF will be subject to the GM food labelling requirements in Standard 1.5.2.
Consideration should be given to a future scenario of a cell-cultured food produced using a GM cell line and the applicable regulatory pathway i.e. the proposed cell-cultured food standards or GM/novel food standards) – all subject to pre-market assessment.	AFGC	See above.
Page 18 of the 2nd CFS states 'FSANZ prepared draft regulatory measures to implement this revised approach to expressly permit cell-cultured foods.'	GE	To clarify, one of the proposed changes is to amend Standard 1.1.1 to provide that a food for sale must not be, or have as an ingredient or a component, a cell-cultured food unless expressly permitted by the Code. In other words, cell-cultured foods are

Submission viewpoint	Raised by	FSANZ response
Submitter of the view the exact meaning and intention of this was ambiguous. Proposed regulatory measures would be supported only if each process and product appears in the standard following assessment, regulation and approval. The default position must be that a synthetic cell-cultured food is prohibited unless it is approved on a case-by-case basis and listed.		prohibited unless expressly permitted on a case-by-case basis by the Code after a pre-market safety assessment. Please see section 1.7 above
Transitional arrangements		
Agreed transitional arrangements for Standard 1.5.4, Schedule 25A and consequential amendments are not required, as cell-cultured food is a new regulatory food category and the applicant's product would be the first such product approved for sale on the New Zealand and Australian markets.	NZFS	FSANZ notes this
Agreed to no transition period for the Code amendments through A1269. As there is no permitted cell-cultured food in Australia or New Zealand and no cell line supplier or cell culturing food businesses operating in NSW, the Code amendment through A1269 would not result in an immediate ban on any existing food production activities due to non-compliance with Standards 1.5.4 or 3.4.1. Businesses producing non-food products or doing R&D that is not related to food for sale would not be prohibited from continuing activities by the proposed Code changes.	NSWFA	FSANZ notes this
Drafting errors/amendments		
For 1.5.4—5(2)(b) and 1.5.4—7(2)(b), the single quotation marks for 'cell-cultivated' are incomplete.	NZFS	This has been corrected.
[8] The substituted paragraphs for subsection 1.1.2—8(1) definition of non-traditional food should be renumbered from (a) and (b) to (c) and (d) respectively.	NZFS, SA Health	This has been corrected.
[13] refers to 1.2.1—10(1) which is incorrect. It may be referring to 1.2.10—3(3), or 1.2.10—3(1) as this section also starts with the words 'For the labelling provisions'.	NZFS	This change is no longer required. FSANZ has decided the existing exemptions for certain foods from characterising ingredient information requirements will apply to cell-cultured food. See response relating to characterising ingredients above.
[14] refers to 1.2.1—10(3) but should refer to 1.2.10—3(3).	NZFS	No change required. See above response.
Items [9], [10] and [12] include '(see Standard 1.5.4)'. For consistency with other parts of the Code, it was suggested references to the relevant sections of Standard 1.5.4 are also included.	NZFS	This change has been made.
For Section 1.5.4—3, include 'component' in addition to ingredient to	NSWFA	FSANZ consider this is unnecessary noting that the Code prohibits

Submission viewpoint	Raised by	FSANZ response
be consistent with the provision in section 1.1.1—10.		a range of substances (processing aids, food additives, nutritive substances, novel foods etc.) from being present in a food for sale as an ingredient or component. [Component is defined to mean 'a substance that is present as a constituent part of the food for sale (as distinct from an ingredient).] However, rarely does the Code provide a permission for the presence in a food for sale as component of that food. For example , the novel food and GM permissions in 1.5.1—3 and 1.5.2—3. These only provide a permission for presence as an ingredient. Presence in a food for sale of a novel food or a GM food as a component remains prohibited, which is no different from a cell-cultured food.
Regarding Section 1.5.4—4, the general prohibition on use of cell-cultured- food in/as special purpose foods was supported; submitter recommended adding 'used' to clarify that the prohibition is on the use as food for sale as well as ingredient or component of food for sale.	NSWFA	The current application provides for cell-cultured quail to be used as an ingredient in a food for retail sale. Cell-cultured quail itself is not a food for retail sale. The approved draft regulatory measures retain the drafting proposed at the 2nd CFS; that is, a cell-cultured- food must not be added to food standardised by Part 2.9 of the Code.
Other		
Assessment of safety (including over the long term) Considered FSANZ's statement [in SD4 to the 2nd CFS] "*Given the lack of consumption history in Australia and the limited scientific data available, FSANZ will continue to require pre-market assessment"* to be unsettling, as mere assessment is insufficient and much more robust assurances than those are required.	GE	The FSANZ assessment is based on the best available scientific evidence. The submission does not identify what in particular was insufficient in FSANZ's assessment, or provide any further advice on what should be assessed. FSANZ is also consulting with regulatory agencies globally and will continue to monitor the scientific literature for any emerging risks associated with these types of foods.
Submitter asserted that FSANZ was not supplied with essential data so failed to assess many important aspects of the processes and products. It was further stated that FSANZ ignored substances used in post-harvest processing.	GE	The applicant submitted a dossier of quality-assured experimental data that supported the risk analysis of the cell line, processes used during cell culture and the harvested cell biomass. The risk assessment also had regard to other evidence – see section 2.7.3 of this report and each SD. No safety concerns were identified by the risk analysis. The harvested cells may be mixed with other ingredients to form

Submission viewpoint	Raised by	FSANZ response
		products such as, but not limited to, logs, rolls and patties. Such post-harvesting processes fall under Australian and New Zealand food laws that require food for sale and food businesses to comply with relevant requirements in the Code. In Australia, this includes general food safety requirements under Chapter 3 of the Code.
The submitter objected to the statement from the 2nd CFS report: *'The submitters have not provided any scientific evidence to support concerns about adverse long-term health effects, or to justify the need for post-market monitoring. Should such scientific evidence be submitted, FSANZ will assess that information as a part of its risk analysis.'* The submitter was concerned that this statement implies FSANZ is moving the burden of proving the long-term safety and efficacy of cell-cultured foods onto the community.	GE	The onus is on submitters to substantiate any issues or statements that are made with a reasoned scientific argument, information or data. The statement in the CFS was a request for individuals or organisations to provide any additional or new data they may be aware of that may not have already been reviewed by FSANZ. As stated above, FSANZ will continue to monitor the scientific literature and consult with regulatory agencies for any emerging risks associated with these types of foods.
Concern over labelling of lab grown proteins This submitter referred to the 2021 Senate Inquiry into the 'Definitions of Meat and Other Animal Products' and the subsequent Senate recommendations to the Australian Government to implement as worded in the Senate Inquiry report 'Don't mince words: definitions of meat and other animal products'. These recommendations include (amongst other things) a regulatory framework for labelling of plant-based products (applicable to cultured meat products) and qualifiers for named animal-derived commodities in the Code to be prohibited (e.g. 'vegan' is prohibited in relation to 'sausage'). Submitter reiterated the importance of ensuring new technologies, such as lab-grown proteins, are properly vetted by regulatory authorities, to guard against potential risk to consumer and environmental health, or the compromise of consumer trust.	CA	FSANZ considers the proposed labelling approach will assist consumers to accurately identify food containing cell-cultured quail as an ingredient from food containing conventional quail and not be misleading. The proposed approach is underpinned by consumer evidence, overseas regulatory positions and submitter feedback. FSANZ held discussions with representatives from the Australian Consumer and Competition Commission (ACCC) and New Zealand Commerce Commission (NZCC) in 2024 and 2025. These consumer protection agencies were supportive of the proposed labelling approach. As noted above, the Government Response to the Senate Inquiry report referred to by the submitter has yet to be published. FSANZ is not considering specific labelling requirements for plant-based meat or milk alternative products.
Concern over potential for cell line to be GM Submitter was concerned FSANZ may not have independently tested the veracity of the claim by Vow that the cell line is not GM and that such information is not publicly available so that others may test of	GE	FSANZ has comprehensively reviewed the data provided by Vow relating to the immortalisation of the cells and is satisfied the cultured quail cells are not GM. FSANZ's assessment also considered the genetic and phenotypic stability of the cell line post-

Submission viewpoint	Raised by	FSANZ response
confirm this claim. They requested/recommended that: - both FSANZ and the Office of the Gene Technology Regulator (OGTR) further explore the provenance of the cell lines to ensure that the immortalised cell lines are not GM - the OGTR be engaged in assessing all dealings with GM immortalised cell lines and any GM-derived substances proposed to be used during the culturing process - FSANZ review the status of Vow's CCI claim and justify each exemption from publication - Vow publicly disclose the types of mutations from which their cell-lines originate and the implications for safety and efficacy.		immortalisation. This assessment confirmed that following immortalisation the cells remained genetically and phenotypically stable in culture. FSANZ notes the Gene Technology Act 2000 (GT Act) only applies to dealings with live and viable genetically modified organisms (GMOs). Separate authorisation and oversight of the cultured quail cells by the Gene Technology Regulator is therefore not required. Substances derived from GMOs (for example, recombinant growth factors, food additives or processing aids) are also not regulated by the GT Act. Substances such as growth factors and other media inputs were assessed as part of FSANZ's safety assessment. It was concluded their use and/or presence does not raise any safety concerns. In relation to CCI, FSANZ determined that the information in question met the definition of CCI set by the FSANZ Act. As such, disclosure of that information is restricted by and under that Act and other Australian laws. It is a matter for Vow to decide whether to disclose information that has been granted CCI by FSANZ.
Inadequate consultation and responses to submitters The following points were raised: - The timing of consultation could have been reconsidered to foster a genuine opportunity to engage with the Australian livestock sectors. Holding both rounds of public consultation at the end of year/festive period substantially impacts industry peak bodies' ability to prepare detailed submissions, informed by producer consultation. - There is an opportunity for FSANZ to more effectively consult with the Australian livestock and meat production sectors. Specifically, there were a number of opportunities during 2024 when FSANZ could have attended industry meetings where they could have actively engaged with the sector, answered questions and genuinely sought	APL	The FSANZ Act sets deadlines by which the assessment of applications such as A1269 must be completed. These deadlines can create scheduling challenges for our consultation periods. When a consultation period falls near the end or beginning of the year, we provide extra time. Both consultations were extended by several weeks beyond our standard six-week period. Additionally, the second CFS was released in early November, well away from the festive period. -FSANZ would welcome invitations to attend livestock industry meetings and provide updates on the progress of any future cell-

Submission viewpoint	Raised by	FSANZ response
consultation.		cultured food applications. We also welcome any correspondence on these types of food outside of this application.
FSANZ must adopt a less combative and more constructive stance towards its citizen submitters; they are on a par with other stakeholders that have commercial or scientific interests. In addition, FSANZ rebuts and critiques 'submission viewpoints' without compelling evidence or dialogue. FSANZ must acknowledge contributions made to improve its application/proposal processes. Rebutting or dismissing citizens, non-profits and state Health Departments, without celebrating their positive contributions, harms FSANZ's reputation. In response to the comment 'FSANZ thanks those individuals and groups for taking the time to make submissions on the application and notes their opposition to cell-cultured food' submitter stated it insults the many civil society commenters who propose constructive solutions and are not oppositional.	GE	Noted FSANZ appreciates the diverse views and perspectives provided by submitters as these contribute to the overall rigour of our assessments and the decisions that are made.
Data transparency Concerned over gaps in information, issues withheld and/or dismissed areas. It is not in the regulator's or company's interests to be cagey about the details as this will not win favour with the customer.	Individual (MM)	FSANZ does not consider there were any data gaps that prevented completion of the risk assessment. All requisite information was provided in the application pursuant to the data requirements in the Application Handbook. This was supplemented with independent searches of the scientific literature by FSANZ, additional data requested by FSANZ from the applicant and studies commissioned by FSANZ. Certain information submitted in the application that was evaluated by FSANZ is protected from disclosure under the CCI provision in the Act. CCI is defined by Section 4 of the FSANZ as: a. a trade secret relating to food; or b. any other information relating to food that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.
Submitter stated they were relying on the transparency and veracity of relevant statements in the 2nd CFS, although this was difficult with	GE	

Submission viewpoint	Raised by	FSANZ response
most information hidden behind CCI: 'FSANZ has … revised its regulatory approach to regulate all cell-cultured food including cell-cultured quail.' (page 18) This was interpreted to mean that all synthetic cell-cultured edibles (and not only meat), will be subject to all the standard's provisions. Publishing complete and credible information on its proposed processes and products is essential for this application to proceed further. The full specifications for each cell-cultured process and product should be published on a case-by-case basis. CCI status must only be accorded where applicants make a strong, specific and genuinely compelling case for particular information to be CCI.		The statement in question is a reference to the fact explained in the CFS that FSANZ broadened its approach from assessing this food as a novel food, to developing a new regulatory approach for all foods of this type. These may include cells sourced from sources other than traditionally farmed animals. This approval report also explains the new regulatory approach and the intent of the two new standards and new schedule. The approved draft regulatory measures will insert product specifications into Schedule 3. Similar specifications for future products will be considered in the assessment of the relevant assessment. See responses above in relation to CCI.
Reliability of assessment The use of regulatory science makes FSANZ assessments unreliable. Submitter sought evidence that a revolving door does not exist among FSANZ staff, regulators, industry and public service.	GE	Regulatory science is an established, internationally used and robust scientific discipline for assessing the safety and suitability of a variety of substances (e.g. medicines, food, agricultural and veterinary chemicals, industrial chemicals) for regulatory approval. The FSANZ risk analysis framework used to support regulatory decision making is based on the Codex model and aligned to processes adopted by food regulatory bodies across the world. FSANZ is recognised internationally as a leader in regulatory science and makes independent, evidence-based assessments of applications and proposals in accordance with the FSANZ Act.
Regulatory capture Supporting documents (SDs) synthesise applicant viewpoints and advocate applicant proposals. FSANZ is complicit with and captive of food industries (including UPF industries), including those seeking approval for fermented, cell-based foods, when it should be taking responsibility for rigorously assessing and regulating them.	GE	FSANZ makes independent evidence-based assessments of applications and proposals in accordance with the FSANZ Act. FSANZ engages with numerous stakeholders in the food industry as part of the statutory functions. The same is true for other stakeholders, including public health and consumer groups. We welcome any advice from the submitter on aspects of our

Submission viewpoint	Raised by	FSANZ response
		stakeholder engagement that they believe do not meet, or contravene the obligations of the FSANZ Act.
Calls to stop the clock or reject application Submitter recommended FSANZ stop the clock on this application until: - deficiencies in A1269 documentation and processes are resolved - the proposed new standards are enacted. The applicant should be required to re-apply under the new standards.	GE	There were no data gaps or deficiencies in the application that would prevent completion of the risk assessment and therefore no basis to impose the Act's stop clock provisions. As FSANZ's comprehensive risk assessment did not identify any public health and safety concerns there are no grounds to reject the application.
Minimal regulation does not build trust Submitter dissatisfied 'the proposed approach was designed to be the minimal regulation needed to achieve appropriate food safety outcomes for processing cell-cultured food'. They argued such statements would not build public confidence or trust that FSANZ has established a 'safe and healthy system' for the production of cell-cultured food.	GE	Noted. The regulatory approach proposed by FSANZ and developed collaboratively with food regulators is risk proportionate. FSANZ is required by the FSANZ Act and Australian administrative law to be cognisant of regulatory burden when assessing the regulation of new foods. The focus of the assessment is on the safety of the consumer, which is consistent with FSANZ's primary objective under the FSANZ Act. FSANZ is also bound by the The Regulatory Policy, Practice & Performance Framework, which sets out the expectation that Commonwealth entities continuously maintain their regulatory systems throughout the regulatory life cycle and achieve outcomes cost-effectively for Australian consumers and businesses. Consumers have the opportunity to review and provide comment on any FSANZ application for a new food.
Consumer information Develop consumer-friendly guidance on what 'cell-cultured' means in practical terms. Consumers will still continue to use the term 'cell-cultured meat' even if the regulation tries to limit its use.	SA Health	Noted. FSANZ currently has consumer information on its website , relating to cell-cultured foods. This will be updated if and when the regulatory approach for cell-cultured foods is approved.

Attachment A –.Amendments made to the draft regulatory measures proposed in the 2nd CFS

Drafting at 2nd CFS	Revised drafting at approval report (bold font)
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 Standard 1.5.4); [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 Standard 1.5.4). [12] 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 Standard 1.5.4).	[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). [12] 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 1.2.1—Requirements to have labels or otherwise provide information Labelling requirements for characterising ingredients – specifically: [11] Paragraph 1.2.1—9(7)(e) [13] Subsection 1.2.1—10(1) [14] After subsection 1.2.1—10(3)	**Deleted.** Characterising ingredient information requirements will not apply for food not required to bear a label and unpackaged food.
Schedule 27 – Microbiological limits in food [19] Section S27 – 4 Cell-cultured food Salmonella spp 5 0 not detected in 25 g Listeria monocytogenes 5 0 not detected in 25 g	[19] Section S27 – 4 Cell-cultured food **(excluding cell lines)** Salmonella spp 5 0 not detected in 25 g Listeria monocytogenes 5 0 not detected in 25 g
Section 3.4.1—3 Cell lines – food safety requirements (3) A cell line supplier must not collect tissue from a donor animal that is diseased.	**(3)** A cell line supplier must be **sourced from** a donor animal that is **free of disease**.
Section 3.4.1—4 Food safety programs (1) A cell line supplier must comply with Standard 3.2.1.	**Deleted** Section 3.4.1-4 food safety programs.
Section 3.4.1—5 Inputs (1) A cell line supplier must ensure that inputs do not make cell-cultured food unsafe or unsuitable. (2) For the purposes of subsection (1), inputs includes each of the following: (a) anti-microbials;	**Deleted** Section 3.4.1-5 Inputs for cell line supplier.

(b) media; (c) substances added to cells to facilitate their storage (such as cryoprotectants).	
Section 3.4.1—7 Food safety program (2)(c) how the business will identify when a cell culture is non-conforming;	(2)(c) how the business will identify when **cell proliferation** is non-conforming.

Attachment B – Approved draft variations to the Australia New Zealand Food Standards Code

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 [To be completed by the Delegate]

[Name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. 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 [To be completed by the Delegate]

[Name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. 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

Permitted cell-cultured foods		***Conditions***
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

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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 [To be completed by the Delegate]

[Name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. 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)			
Salmonella spp	5	0	not detected in 25 g
Listeria monocytogenes	5	0	not detected in 25 g

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 [To be completed by Delegate]

[Insert Delegate's name]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. 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.

Attachment C1 – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Australia New Zealand Food Standards Code – Standard 1.5.4 – 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 - Standard 1.5.4 – 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).

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 out when a food for sale may be, or have as an ingredient, a cell-cultured food and to set requirements for the use and labelling of permitted cell-cultured foods.

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.

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

Standard 1.5.4 is a new Standard incorporated into the Code. The purpose of each provision in the Standard is explained below.

Standard 1.5.4 is introduced by two 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.

Division 1 – Preliminary

Division 1 of the Standard contains sections 1.5.4—1 and 1.5.4—2.

Section 1.5.4—1 provides that the name of the Standard is the *Australia New Zealand Food Standards Code – Standard 1.5.4 – Cell-cultured foods.*

The note to section 1.5.4—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 1.5.4—2 provides or refers to definitions for terms used in the Standard**.** The note to section 1.5.4—1 refers to the following definition of 'cell-cultured food' in section 1.1.2—2 of the Code: 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

Division 2 of the Standard contains sections 1.5.4—3 to 1.5.4—7.

Section 1.5.4—3 provides that 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.

Section 1.5.4—4 prohibits the addition of a cell-cultured food to a special purpose food. It provides that a cell-cultured food must not be added to a food standardised by Part 2.9 of the Code; for example, an infant formula product.

Section 1.5.4—5 sets labelling requirements for a food for sale that has a cell-cultured food as an ingredient.

Subsection 1.5.4—5(1) provides that section applies to a food for sale that has a cell-cultured food as an ingredient.

Subsection 1.5.4—5(2) provides that, for the labelling provisions, the reference to 'information relating to cell-cultured food' includes or requires the use of the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the ingredient that is a cell-cultured food. The labelling provisions are set out in Standard 1.2.1. Amendments to Standard 1.2.1 require the labelling for certain foods for sale to include 'information relating to cell-cultured food'. Subsection 1.5.4—5(2) sets out what that information includes.

The Note to subsection 1.5.4—5(2) explains the reference in that subsection to the labelling provisions and that the labelling provisions apply to both packaged and unpackaged food.

The Note to subsection 1.5.4—5(2) is followed by an example. The example illustrates how the subsection applies in relation to a statement of ingredients required by Standard 1.2.1 and 1.2.4. That is, if those Standards require a food for sale that has a cell-cultured food as an ingredient to bear a label with a statement of ingredients, subsection 1.5.4—5(2) requires the statement of ingredients to list the ingredient that is the cell-cultured food using 'cell-cultured' or 'cell-cultivated' in conjunction with that ingredient's name.

Section 1.5.4—6 sets out the labelling requirements for a food for retail sale that has a cell-cultured food as an ingredient and that is represented as being from the animal from which the cell-cultured food was sourced.

Subsections 1.5.4—6(1) and (2) set out the foods for sale that the labelling requirement imposed by subsection 1.5.4—6(3) applies to**.** That is, to a food for sale that:

(a) is for retail sale or 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; and
(d) is represented in words, images or both as being from the animal from which the cell-cultured food was sourced.

Subsection 1.5.4—6(2) provides that paragraph 1.5.4—6(1)(d) does not apply to a reference in a statement of ingredients to the animal from which the cell-cultured food was sourced.

Subsection 1.5.4—6(3) provides that, for the labelling provisions, the reference to 'information relating to cell-cultured food' includes or requires 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. The labelling provisions are set out in Standard 1.2.1. Amendments to Standard 1.2.1 require the labelling for certain foods for sale to include 'information relating to cell-cultured food'. Subsection 1.5.4—5(2) sets out what that information includes.

As explained, section 1.5.4—5 requires the use of the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the ingredient that is the cell-cultured food. If, for example, the statement 'cell-cultivated' is used in conjunction with the name of the ingredient for the purposes of section 1.5.4—5, then section 1.5.4—6 would require the same statement – 'cell-cultivated' – to be used in the name of the food for sale if that food for sale meet the criteria set out in subsection 1.5.4—6(1).

The Note to subsection 1.5.4—6(3) explains the reference in that subsection to the labelling provisions.

The Note to subsection 1.5.4—6(3) is followed by an example. The example illustrates how subsection 1.5.4—6(3) would apply to 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. The example explains that, if the food for sale is represented as being from the animal from which the cell-cultured ingredient is sourced (e.g. 'made from cell-cultured [animal name]' or 'cell-cultured [animal name] patties'), subsection 1.5.4—6(3) would require the statement 'cell-cultured' to be included in the name of the food on the label.

The example also covers the situation where a packaged food for sale contains a cell-cultured food as an ingredient, but does not represent on its label that it is from the animal from which the cell-cultured food (the ingredient) is sourced. In this situation, subsection

1.5.4—6(3) does not apply. Standard 1.2.2 would still apply and require the use of a name or description in relation to the food for sale that is sufficient to indicate the true nature of that food.

Section 1.5.4—7 sets out the labelling requirements for a cell-cultured food sold other than by retail sale.

Subsection 1.5.4—7(1) provides that section 1.5.4—7 applies to a cell-cultured food that is a food for sale to which Division 3 or 4 of Standard 1.2.1 applies. Division 3 of Standard 1.2.1 applies to food sold to caterers. Division 4 of Standard 1.2.1 applies to sales of food that are not retail sales, sales to caterers, or intra-company transfers.

-**Subsection 1.5.4—7(2)** provides that, for the labelling provisions, the reference to 'information relating to cell-cultured food' includes or requires the use of the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured food.

The Note to subsection 1.5.4—7(2) refers to the labelling provisions that are set out in Standard 1.2.1 and states that the labelling provisions apply to both packaged and unpackaged food.

The Note to subsection 1.5.4—7(2) is followed by an example. The example illustrates how the subsection would apply in relation to the labelling requirement imposed by paragraph 1.2.1—15(a) of the Code. The paragraph requires the labelling of food sold to a caterer to state the name of the food in accordance with section 1.2.2—2 (which requires the use of a name or description sufficient to indicate the true nature of the food). The example explains that subsection 1.5.4—7(2) would require the use of the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the food for sale required by paragraph 1.2.1—15(a).

Attachment C2 – Explanatory Statement

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).

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 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.

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.

Attachment C3 – Explanatory Statement

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 (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 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 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 *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 c*ell 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

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)

Salmonella spp	5	0	not detected in 25 g
Listeria monocytogenes	5	0	not detected in 25 g

Attachment C4 – Explanatory Statement

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.
>
> **Assessed cell line** means a cell line listed in Schedule 25A—6.
>
> **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.
>
> **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.
>
> **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’. 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.

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.

Attachment D – Draft variation/s to the *Australia New Zealand Food Standards Code* at 2nd call for submissions

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 [To be completed by the Delegate]

[Name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. 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 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

(2) 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 [To be completed by the Delegate]

[Name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. 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 *in vitro* culturing of 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

Permitted cell-cultured foods		***Conditions***
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

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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 [To be completed by the Delegate]

[Name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. 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:

(e) 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

(f) 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 Standard 1.5.4);

[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 Standard 1.5.4).

[11] Paragraphs 1.2.1—9(7)(e)

Repeal the paragraph, substitute:

(e) information about *characterising ingredients and *characterising components (section 1.2.10—3)—if the food:

(i) has a *cell-cultured food as an ingredient and is not required to *bear a label because of section 1.2.1—6 (other than paragraph 1.2.1—6(1)(c)); or

(ii) does not have a *cell-cultured food as an ingredient and is not required to *bear a label because of paragraph 1.2.1—6(1)(a) or subsection 1.2.1—6(4);

[12] 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 Standard 1.5.4).

Standard 1.2.10—Information requirements – characterising ingredients and components of food

[13] Subsection 1.2.1—10(1)

Insert the words ‘subject to subsection (4),’ after the words ‘For the labelling provisions,’’.

[14] After subsection 1.2.1—10(3)

Insert:

(4) Paragraphs 1.2.10—3(a) and (b) do not apply in relation to a *characterising ingredient that is a *cell-cultured food.

Standard 3.1.1—Interpretation and Application

[15] 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.

[16] 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

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

Insert:

cell-cultured quail	section S3—52

[18] After section S3—53

Insert

S3—54 Specification for cell-cultured quail

(2) For the purposes of this specification, ***cell-cultured quail*** means quail cells obtained from *in vitro* culturing of 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

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

Add:

Cell-cultured food			
Salmonella spp	5	0	not detected in 25 g
Listeria monocytogenes	5	0	not detected in 25 g

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 [To be completed by Delegate]

[Insert Delegate's name]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. 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.

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—8.

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 supplier must not collect tissue from a donor animal that is diseased.

3.4.1—4 Food safety programs

(1) A cell line supplier must comply with Standard 3.2.1.

(2) The food safety program must also detail each of the following:

(a) food handling activities undertaken by the business, including:

(i) cell sourcing and selection;

(ii) development of a cell line;

(iii) development of a cell bank;

(b) how the business will undertake each of the following:

(i) cleaning and sterilisation of all relevant equipment;

(ii) calibration of all relevant equipment.

3.4.1—5 Inputs

(1) A cell line supplier must ensure that inputs do not make cell-cultured food unsafe or unsuitable.

(2) For the purposes of subsection (1), ***inputs*** includes each of the following:

(a) anti-microbials;

(b) media;

(c) substances added to cells to facilitate their storage (such as cryoprotectants).

3.4.1—6 Traceability

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

(c) identifies and tracks cells from collection from a donor animal through to supply of a cell line; and

(d) 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—7 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 a cell culture is non-conforming;
(d) how the business will undertake the calibration, cleaning and sterilisation of all relevant equipment.

3.4.1—8 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—9 Cell line used for cell proliferation

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

3.4.1—10 Cell biomass – temperature control

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

3.4.1—11 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.