12 November 2024
317-24

2nd Call for submissions – 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, and has prepared draft food regulatory measures. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measures.

Submissions on this application should be made through the FSANZ Consultation Hub (https://consultations.foodstandards.gov.au/).

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the Consultation Hub.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 24 December 2024

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters. For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission. Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

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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 1st CFS (SD1)
Supporting Document 2	Labelling requirements (SD2)
Supporting Document 3	University of Adelaide consumer literature review (SD3)
Supporting Document 4	Production and processing requirements (SD4)

Executive summary

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

This application is being assessed under FSANZ's major procedure, which requires two rounds of statutory public consultation. FSANZ completed a first round of statutory public consultation in December 2023. FSANZ received 40 submissions and one late comment in response. Each was considered and informed our decision to prepare proposed draft variations to the Code to regulate the sale and production of cell-cultured foods, including the applicant's cultured quail cells. This second call for submissions (CFS) outlines FSANZ's responses to submissions received, FSANZ's proposed regulatory approach for cell-cultured foods and reasons for preparing the proposed draft variations to the Code.

No new scientific evidence was received in submissions that would warrant a change to the conclusions of the FSANZ risk assessment at the 1st CFS. FSANZ concluded that:

- The cell line (221523-Fib-Quail) was genetically stable and any microbiological risks associated with cell line sourcing were very low.
- Management of microbiological risks requires a through-chain, Hazard Analysis Critical Control Points (HACCP)-based approach for cell-cultured food production supported by good practices. This will limit potential contamination if implemented effectively, particularly during the cell expansion phase.
- There were 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 were unlikely to pose a food allergenicity risk for the general population.

FSANZ evaluated a new systematic review conducted by the University of Adelaide to assess consumers understanding of cell-cultured meats (SD 3). The findings were consistent with those of FSANZ's initial review which found terms that incorporate the word 'cell' (e.g. '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.

For the reasons outlined in this CFS, FSANZ prepared two draft Standards, a draft Schedule and consequential variations to other provisions of the Code. The draft standards are Standard 1.5.4 – Cell-cultured foods and Standard 3.4.1 – Food safety requirements for processing of cell-cultured food. The draft schedule is Schedule 25A – Permitted cell-cultured foods.

It is proposed 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.

Standard 1.5.4 would provide the permissions and set general requirements for cell-cultured foods, including labelling requirements. These would require use of the statement 'cell--cultured' or 'cell-cultivated' for food identification purposes. Permitted cell-cultured foods must be listed in Schedule 25A and comply with any conditions listed in that Schedule. Schedule 25A would 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 would establish general production and processing requirements for cell-cultured foods produced in Australia. These would relate to inputs, premises and equipment, processing protocols, monitoring, and verification. They would cover the sourcing of cells from a donor animal through to the production of the final food for sale. Entities engaging in these activities would be a 'food business' for the purposes of Chapter 3 of the Code and relevant food laws. A food safety program that complies with Standard 3.2.1 would be required to minimise the risk of foodborne pathogens entering cell culture production phases. Chapter 3's generic food safety requirements would also apply. Schedule 27 would be amended to set microbiological safety criteria for two pathogens, *Salmonella* spp. and *Listeria monocytogenes*, in cell-cultured food.

FSANZ's assessment is that the Code's current food safety and hygiene requirements, when supplemented by measures unique to cell-cultured food production such as the above, would manage risks with cell-cultured food production and processing.

FSANZ proposes to work with the jurisdictions to develop guidance to support implementation of the above.

FSANZ now seeks submissions to inform its decision whether its proposed regulatory approach and the proposed draft variations should be approved, amended or rejected.

1 Introduction

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

FSANZ is assessing this application under its Major Procedure, which requires two rounds of public consultation. The 1st 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.

This 2nd CFS outlines FSANZ's responses to those submissions and seeks submissions on, among other things, proposed draft variations to the Code prepared by FSANZ. Submissions received in response to the 2nd CFS will inform FSANZ's decision whether to approve, amend or reject the proposed draft variations. If approved by FSANZ, the draft variations must then be referred to the Food Ministers' Meeting for ministerial consideration.

There are four supporting documents to the CFS:

- SD1 Risk assessment revised after the 1st CFS
- SD2 Labelling requirements
- SD3 University of Adelaide consumer literature review
- SD4 Production and processing requirements.

1.1 The applicant

Vow Group Pty Ltd is a biotechnology company based in Sydney, Australia, which uses cell culturing to grow animal-derived cells for food use.

1.2 The application

The applicant has 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. These products will be cooked before consumption. Initially, the applicant plans to market these foods to caterers for 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. Currently the Code regulates cell-cultured food as novel foods, the provisions for which are outlined below.

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 1.2.2 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 have not undergone slaughter and are not part of the carcass (poultry or other) or derived from skeletal muscle.

1.3.5 Microbiological limits for food

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

Section 1.1.1—14 of the Code and State and Territory food laws 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.

1.3.7 Primary production and processing standards

Primary producers and processors of certain commodities (seafood, poultry, meat, dairy, eggs, sprouts, berries, leafy vegetables and melons) must meet relevant requirements in Chapter 4 of the Code under section 1.1.1—3. 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.

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).

Since the 1st CFS, the Singapore Food Agency has approved the applicant's cell-cultured quail product under its novel food regulations. The approval was granted in March 2024. The Ministry of Health National Food Services in Israel approved a cell-cultured beef product in January 2024. The product, originating from bovine cells, is manufactured by Aleph Farms and is sold under the name 'Cultivated Petit Steak'.

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.

2 Summary of the assessment

2.1 Submissions received

FSANZ released the 1st CFS on 11 December 2023, with a nine-week public consultation period that closed on 5 February 2024. In total, 40 submissions were received, along with one late comment (refer to Table 1).

Key issues raised by submitters included the sourcing and safety of the cell line, production inputs such as 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 – Summary of submissions, with some specific issues also addressed in sections 2.2 and 2.3 below. Submitter comments relating to labelling, and production and processing, are also discussed in SD2 and SD4, respectively.

Table 1: Number of submissions received by submitter groups

Submitter group	Total
Private individuals	21
Industry / peak bodies	4
Industry advocacy groups	4
Government	7
Consumer / animal rights groups	5
Total	**41**

2.2 Submissions related to risk assessment and consumer evidence

FSANZ conducted a risk assessment of the applicant's cell-cultured quail during the 1st CFS. The conclusions from this assessment are summarized below, with the full details available in SD1 of this 2nd CFS.

In summary:

- The cell line (221523-Fib-Quail) was genetically stable and any microbiological risks associated with cell line sourcing were very low.
- Management of microbiological risks requires a through-chain, Hazard Analysis Critical Control Points (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 were 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 were unlikely to pose a food allergenicity concern for the general population.

Risk assessment issues raised in submissions 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.

No new scientific studies 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. Nor is FSANZ 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 2.

2.2.1 Consumer evidence

FSANZ has considered the best available scientific evidence on consumers' awareness, understanding, and perceptions of cell-cultured meat. This evidence ensures that risk management decisions take into account consumers' existing knowledge base, as well as the effect that potential risk management measures (such as specific nomenclature) are likely to have on consumers' perceptions and understanding of cell-cultured meat.

FSANZ undertook a rapid systematic evidence review on consumers' understanding, preference and acceptance of different terminologies for cell-cultured meats, as well as consumers' perceptions of cell-cultured meat relative to conventional meat. The key findings of the review were summarised in the 1st CFS and the full literature review report was provided in SD2 of the 1st CFS.

At the same time, FSANZ commissioned the University of Adelaide to conduct a more comprehensive systematic literature review that also examined consumers' levels of awareness, understanding, perceived risks and benefits, and prospective behaviour regarding alternative proteins, including cell-cultured meats. The final report was not available at the time of release of the 1st CFS, but was subsequently provided to FSANZ in December 2023 (see SD3 for the full literature review report).

The University of Adelaide's systematic literature review aligns closely with FSANZ's rapid review of consumer evidence conducted for the section 29 assessment at the 1st CFS. The key findings from the University's review, relevant to the assessment of A1269, are summarised below and organised by research question. A comparison of these findings with the evidence available during the initial assessment published at the 1st CFS is also provided.

Submissions received in relation to consumer evidence have also been considered and responded to in Appendix 1, Table 2.

2.2.1.1 Research question: What are consumers' levels of awareness and knowledge of cell-cultured meat?

The systematic review found evidence from seven studies that there is wide variation in the percentage of consumers who have heard of specific cell-cultured meat terms, or the concept of cell-cultured meat (percentages ranged from 18% to 66% across studies). However, familiarity and knowledge about cell-cultured meat was consistently low across studies (50-88% report no or low familiarity, and 5-21% of consumers consider themselves very knowledgeable about cell-cultured meat).

Consumers' awareness and knowledge of cell-cultured meat was not examined in FSANZ's rapid review. However, FSANZ's Consumer Insights Tracker (CIT) was able to address this issue (see SD3 of the 1st CFS). The CIT found that knowledge about cell-cultured meat is generally low (65% had at least heard of cell-cultured meat, and 6% knew enough that they could explain it to a friend). These findings are consistent with the findings of the University of Adelaide's literature review.

2.2.1.2 Research question: Do consumers want a specific term to differentiate between cell-cultured meat and conventional meat? What terminologies are best for consumer understanding?

The systematic review found evidence from ten studies indicating terminology that includes the word 'cell' (e.g. 'cultivated from the cells of ___', 'grown directly from the cells of ___', 'cell-based' or 'cell-cultured') are best understood by consumers when differentiating cell-cultured products from conventional meat and fish. The term 'lab-grown' performed similarly, as did descriptive phrases (e.g. 'grown from [animal] cells', 'not farmed [or fished]'). However, all had less consumer appeal compared to the terms 'cultured' and 'cultivated'. In addition, 'lab-grown' had a lower level of perceived safety compared to other terms. Overall, no terminologies achieved 100% correct identification that the cell-cultured meat product is neither wild caught nor farm raised.

These findings are consistent with FSANZ's initial rapid review of the evidence. However, in contrast to FSANZ's rapid review, the University of Adelaide's literature review did not describe how consumer understanding of perceived allergenicity compared across the terms that performed best for accurate product identification (e.g. 'cell-based 'versus 'cell-cultured'), as this was not a direct research question.

2.2.1.3 Research question: Do consumers expect information about the true nature of a cell-cultured meat product to be available when food is not required to bear a label (e.g. food sold for immediate consumption in a restaurant)?

The systematic review found no studies that specifically assessed whether consumers expect information to be available indicating that a food is cell-cultured when the food is not required to bear a label (e.g. food sold for immediate consumption in a restaurant). However, limited evidence indicates that, in general, consumers expect to see labelling information that identifies a cell-cultured meat product.

This research question was not examined in FSANZ's rapid review.

2.2.1.4 Research question: Do consumers perceive cell-cultured meat as the same or different to conventional meat? Are they perceived as being as healthy as, and/or nutritionally equivalent (e.g. levels of protein/fat)?

The systematic review found that consumer perceptions of the healthiness and nutritional quality of cell-cultured meat compared to traditional meat are mixed. While some studies suggest that consumers perceive cell-cultured meat as being less healthy or nutritious compared to conventional meat, other studies suggest that consumers perceive the two products as being equally healthy and nutritious.

The systematic review found that it is not possible to provide a definitive conclusion regarding consumers' perceptions of the healthiness and nutritional quality of cell-cultured meat because research participants were often primed with positive information about cell-cultured meat across studies, which may have influenced their perceptions.

This conclusion is broadly consistent with FSANZ's rapid review, where it was acknowledged that consumer perceptions of cell-cultured meat are likely to be highly malleable depending on the type of information (neutral vs. biased descriptions) that consumers receive about the product and the types of products compared (e.g. whether the study examined cell-cultured chicken vs conventional chicken or cell-cultured chicken nuggets vs conventional chicken nuggets).

2.2.1.5 Research question: Are consumers willing to consume cell-cultured meat? Are they willing to incorporate cell-cultured meat into their diet?

The systematic review found evidence from twenty studies that consumers are either unsure or somewhat willing to consume cell-cultured meat as a partial replacement for conventional meat.

The systematic review found that it is not possible to provide a definitive conclusion regarding the percentage of consumers willing to consume cell-cultured meat due to inconsistency in the evidence and concerns related to bias in the cell-cultured meat definition provided across studies.

Consumers' consumption intentions regarding cell-cultured meat was not examined in FSANZ's rapid review. However, FSANZ's CIT was able to address this issue (see SD3 of the 1st CFS). The CIT found that 23.6% of consumers were willing to include cell-cultured foods in their diet, assuming that the product was a similar price to meat and/or meat alternatives, while 28.7% were unsure. 47.7% of consumers were not willing. Of those consumers who were willing to include cell-cultured meat in their diet, most said they would use it as a partial replacement for traditional meat. These findings are broadly consistent with the findings of the University of Adelaide's literature review, and were incorporated into the section 29 assessment that was published with the 1st CFS.

2.3 Submissions related to the regulation of cultured quail as a novel food, and production and processing requirements

At the 1st CFS, FSANZ invited feedback on a proposed approach to regulate cultured quail cells as a novel food. Feedback was also requested on requiring culturing quail cells to be processed under a documented food safety program pursuant to Standard 3.2.1, supported by good practices. A food safety program would support safe cell biomass production, noting the Code would require amendment for Standard 3.2.1 to apply.

This section sets out the main issues raised in submitters' feedback on the proposed regulatory approach and FSANZ's responses. Detailed responses to all issues raised in submissions are set out in Appendix 1, Table 2.

The revised regulatory approach for all cell-cultured foods is set out in section 2.4. This includes new draft standards, which are Standard 1.5.4 – Cell-cultured foods and Standard 3.4.1 – Food safety requirements for processing of cell-cultured food. The draft schedule is Schedule 25A – Permitted cell-cultured foods.

It is also proposed 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. All future cell-cultured foods will be regulated in this manner. Cell-cultured quail will be the first food, if permitted, to come under this new regulatory approach.

2.3.1 Regulation of cultured quail cells as a novel food

No specific objections were raised by submitters regarding FSANZ's proposed approach to regulate cultured quail cells as a novel food.

2.3.1.1 Media inputs/processing aids

Some submitters requested media inputs, including growth factors, be specifically regulated as processing aids. FSANZ understands this to mean that those submitters would like each of the media substances to be assessed separately under Standard 1.3.1 and, if approved, listed in Schedule 18 of the Code.

<u>FSANZ response</u>:

FSANZ does not propose 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

FSANZ has however, assessed the safety of all media inputs used to support the growth of the quail cells during culture and concluded that the media inputs do not pose a health and safety concern.

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.

2.3.1.2 Food for retail sale

Some submitters requested an express prohibition on cultured quail itself being a food for retail sale to a consumer.

FSANZ response:

The applicant's cultured quail will not be able to be sold as a food for retail sale to consumers. Division 2 of proposed Schedule 25A will set specific requirements for 'cell-cultured quail' as a permitted cell-cultured food. These will state expressly that cell-cultured quail must not be a food for retail sale (see subsection S25A—4(1)).

Non-retail sales will be permitted and be subject to labelling requirements; for example, food sold to a caterer or a manufacturer that is either a food containing cell-cultured quail as an ingredient or cell-cultured quail sold as a single ingredient food (see proposed sections 1.5.4—5 and 1.5.4—7).

Requirements for other cell-cultured foods will depend on the nature of the food and be assessed on a case-by-case basis. It is proposed 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.

2.3.1.3 Specifications

Some submitters noted that the 1st CFS did not contain detailed information regarding the proposed specifications for this food, such as the species name, cell type, allergen detection limits, and criteria to prevent food fraud.

FSANZ response:

FSANZ proposes to add a specification for cultured quail cells to Schedule 3 of the Code. This specification will include a definition for cell-cultured quail, detailing the species name and cell type. The assessed cell line will require a unique identifier to ensure only the assessed cell-cultured food can be produced from it. The assessed cell line unique identifier will be listed in Schedule 3 and in the table to section S25A—6. This will be a requirement for all new cell-cultured foods. Additionally, compositional specifications are proposed, based on the parameters outlined in section 4.4.2 of SD1.

The proposed inclusions to Schedule 3 are as follows:

- 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.*

- Composition
  - protein %—not less than 4
  - moisture %—not less than 80
  - ash %—not more than 1.5
  - fat %—not less than 0.5 and not more than 3.0
  - carbohydrates %—not more than 1.

No allergens were detected in the cell-cultured quail, therefore the inclusion of potential allergens in the Schedule 3 specification is not required. The specification will not include limits for heavy metals because analyses of the harvested cells showed levels well below the maximum levels specified in section S3—4 of the Code.

Amendments to subsection 1.1.1—15(1) to include a reference to 'cell-cultured food' will ensure that permitted cell-cultured foods must comply with the relevant specifications in Schedule 3.

2.3.1.4 Definition of cell-cultured food

In general, submitters supported the inclusion of a new definition in the Code to provide clarity and underpin other requirements for cell-cultured food.

There was a suggestion that the definition incorporate that cell-cultured food is a novel food in the Code, so that it is clear subsections 1.1.1—10(5) and (6) apply. Another suggestion was that the definition not exclude any components found in conventional animal meat, as defined by the Code. Submitters queried whether or not the definition would include foods produced from cultured cells where the cells are not the final food, and foods produced using precision fermentation.

In contrast to other submitters, one industry submitter suggested it would be premature to assume that the proposed definition will cover all subsequent foods and, as such, recommended it be applicable to the product currently under assessment only.

Submitters also noted there should be scope to modify/expand the definition in a timely manner to include broader cell types as the category evolves.

<u>FSANZ response:</u>

FSANZ proposes to insert the following definition for 'cell-cultured food' into subsection 1.1.2—2(3) of the Code to provide certainty to industry and other stakeholders and clarity for regulatory purposes:

'*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.'

FSANZ is of the view the proposed definition is appropriate for the purposes of this application and the new standards being proposed. The definition can be amended as required in the future to accommodate future cell-cultured foods.

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.

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

The draft variations will prohibit the addition of a cell-cultured food to a food standardised by Part 2.9 of this Code (for example, infant formula products).

2.3.2 Production and processing requirements

Most stakeholders supported FSANZ's approach to consider cell culturing as food handling under Chapter 3 and mandate food safety programs that would apply HACCP principles to its production.

However some regulators did not support the mechanism proposed for mandating food safety programs under Schedule 25 (refer to Appendix 1, Table 2). Jurisdictions raised the need to establish baseline food safety requirements or a specific processing standard for cell-cultured food products to support their safe production and certain regulatory status. Such a standard should include measures similar to those in primary production and processing (PPP) standards.

In response, FSANZ reviewed current food safety and hygiene requirements in Chapter 3 - Food safety standards and Chapter 4 – Primary production and processing requirements, their application to, and adequacy in, managing food safety risks unique to cell-cultured food This is discussed in detail in SD 4.

2.3.2.1 Requirement for a food safety program

FSANZ retains the requirement in the 1st CFS that cell-cultured food be produced under a food safety program in accordance with Standard 3.2.1. Proposed Standard 3.4.1 establishes production and processing requirements for cell-cultured food in Australia; it requires an identified business to have a food safety program in line with Standard 3.2.1 (refer SD4, section 4). Proposed Standard 3.4.1 will also set additional requirements within the food safety program that relate specifically to cell-cultured food.

2.3.2.2 Existing food safety and hygiene requirements

FSANZ's assessment is that the Code's current food safety and hygiene requirements, when supplemented by measures unique to cell-cultured food production such as the above, would manage risks with cell-cultured food production and processing.

FSANZ's proposed regulatory approach is premised on cells, cell lines and the cell biomass each being declared to be a *food* for the purposes of the Code and the food laws that apply the Code. FSANZ's understanding is that this would provide the certainty required for regulation.

2.3.2.3 Schedule 27 – Microbiological limits in food

The applicant proposed several microbiological criteria to be included in a specification for Schedule 3.

FSANZ considers it is more suitable to incorporate *food safety* microbiological criteria for cell-cultured food into Schedule 27. Cell-cultured food represents a new type of food and a new production process and it is considered potentially hazardous. Although the risk mitigation steps during further processing of the cell biomass were not assessed, the applicant indicated it includes a cooking step. FSANZ proposes to include criteria for *Salmonella* spp. and *L. monocytogenes* in Schedule 27 (refer to SD4).Microbiological *indicators* of hygiene control will also be updated in the *Compendium of Microbiological Criteria for Food*.

2.3.2.4 Finalising food safety measures

FSANZ considered four options in developing processing requirements for cell-cultured food (refer to SD4). As the activity is closer to food processing than it is to primary production, the preferred option is based on and aligns with Chapter 3 standards.

FSANZ has prepared a proposed new generic standard under Chapter 3 (Standard 3.4.1 – Food safety requirements for processing of cell-cultured food). New microbiological criteria for this food group are proposed to be added to Schedule 27. To support regulatory capture of the two newly identified cell culture producers (i.e. cell line supplier and cell culturing food business), the Code's definition of *food business* in Standard 3.1.1 will be amended. Measures will apply to both businesses whose product is for food purposes (i.e. it is not intended to capture businesses culturing cells for non-food purposes). All stages of cell-cultured food production would be captured, starting with the sourcing of cells through to further processed product for retail sale. A food safety program in line with Standard 3.2.1 would be mandated for both businesses.

FSANZ considers management measures used to mitigate risks in cell-cultured quail production can serve as a model for other cell-cultured foods. This is due to the similarities in bioreactor production settings, media usage, and cell line establishment phases. By incorporating these measures into a horizontal processing standard, FSANZ aims to ensure clarity of, and transparency on, the requirements for all cell-cultured foods, both now and in the future. Establishing a clear regulatory approach for the production of cell-cultured foods instils confidence these foods can be produced safely and are suitable for consumption, while supporting innovation.

2.3.3 Labelling

SD2 to this report summarises:

- the regulatory approach for labelling of cultured quail cells proposed at 1st CFS
- submitters' responses to that proposal
- FSANZ's further assessment after consideration of those responses and
- a revised regulatory approach for labelling of cell-cultured food.

For the 1st CFS and for this CFS, the proposed approach was underpinned by a labelling risk management framework, comprising of risk management principles based on FSANZ's priority order statutory objectives (see section 2 in SD4 of the 1st CFS) and informed by:

- a risk assessment for harvested cultured quail cells (SD1 to the 1st CFS)
- the findings of a rapid systematic review on consumer understanding, preferences and acceptance of different cell-cultured meat terminologies, and perceptions of cell-cultured meat relative to conventional meat (SD2 to the 1st CFS).

The assessment completed at 2nd CFS has been further informed by:

- submitter comments to the 1st CFS (see Appendix 1, Table 2), and
- the findings of a full systematic literature review undertaken by the University of Adelaide examining consumers' levels of awareness, understanding, perceived risks and benefits, and prospective behaviour regarding alternative proteins, including cell-cultured meats (see section 2.2.1 and SD3 to this CFS).

For the reasons set out in SD2 to this report, FSANZ now proposes the following labelling requirements. These reflect the revised regulatory approach which is for the Code to regulate cell-cultured foods as a distinct category of food, as opposed to regulate one food product only – cell-cultured quail. Certain labelling requirements will apply to cell-cultured quail.

2.3.3.1 Labelling requirements – food for retail sale

The following requirements are proposed for a food that contains a permitted cell-cultured food as an ingredient and that is sold at retail sale or as suitable for retail sale without any further processing, packaging or labelling:

- to apply the Code's existing ingredient name requirements, and:
  - also require either the statement 'cell-cultured' or 'cell-cultivated' (*the statement*) to appear in conjunction with the name of the cell-cultured ingredient in the statement of ingredients
- to apply existing food name requirements if the packaged food for sale is not represented as being from the animal from which the cell-cultured ingredient was sourced (e.g. quail in the case of a food for sale containing cell-cultured quail as an ingredient)
- for a packaged food that is represented as being from the animal from which the cell-cultured ingredient was sourced — in addition to generic food name requirements, the same statement and the name of the cell-cultured ingredient to must also be in the name of the food.
- to apply characterising ingredient declaration requirements, including for the following foods which will not be exempt: prepared filled rolls, sandwiches, bagels or similar products; and for a food for sale that is sold at a fund raising event
- if the food is not required to bear a label or is unpackaged—require the statement in conjunction with the name of the cell-cultured ingredient.

Division 2 of proposed Schedule 25A will set additional labelling requirements for a food for retail sale that contains cell-cultured quail as an ingredient:

- prohibit use of the generic ingredient name 'poultry meat' in the statement of ingredients and the words 'poultry meat' elsewhere on the label, and
- the word 'meat' can only be used under the following circumstances:
  - in conjunction with the statement and the name of the cell-cultured quail ingredient
  - if the packaged food for sale is represented as a quail food product—in the name of the food in conjunction with the statement and the name of the cell-cultured quail ingredient.

2.3.3.2 Labelling requirements – food sold to a caterer and other types of sale

For cell-cultured food sold to a caterer, FSANZ proposes to require the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured food to be stated:

- if the food is packaged—in the label on the package
- if the food is unpackaged—in labelling that must be provided to the caterer with the food.

This requirement will apply whether the cell-cultured food is an ingredient in a food sold to a caterer or is sold to a caterer separately as a food.

For other food sales, FSANZ proposes to require the information necessary to comply with the labelling requirement and this information must be provided in writing if requested or required.

2.3.3.3 Generic labelling requirements

FSANZ is proposing to maintain the preferred approach at 1st CFS (see SD4 to the 1st CFS) and apply the following generic labelling requirements to food that contains a cell-cultured food for:

- mandatory declaration for certain foods (allergens)
- date marking
- directions for use and storage
- nutrition information, and
- nutrition content and health claims.

2.4 Proposed regulatory approach

At the 1st CFS, FSANZ invited feedback on a proposed approach to regulate cultured quail cells as a novel food. Feedback was also requested on requiring cultured quail cells to be processed under a documented food safety program pursuant to Standard 3.2.1, supported by good practices.

FSANZ has considered the feedback provided in submissions to the 1st CFS and, for the reasons set out in this report, revised its regulatory approach to regulate all cell-cultured food including cell-cultured quail. FSANZ prepared draft regulatory measures to implement this revised approach to expressly permit cell-cultured foods and has drafted two new standards and one schedule. The key regulatory elements are:

- Standard 1.1.1 will be updated to mandate explicit permission in the Code for all cell-cultured foods, and
- Standard 1.5.4 – Cell-cultured foods [NEW], and
- Standard 3.4.1 – Food safety requirements for processing of cell-cultured food [NEW], and
- Schedule 25A – Permitted cell-cultured foods [NEW].

It is proposed 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. Subsection 1.1.2—2(3) would include a new definition ‘for cell-cultured food’

Standard 1.5.4 would provide the permissions and set general requirements for cell-cultured foods, including labelling requirements. These would require use of the statement ‘cell-cultured’ or ‘cell-cultivated’ for food identification purposes.

As explained in this report, FSANZ’s assessment is that the new standard, specifically for cell-cultured foods, will provide greater clarity and regulatory certainty compared to regulation as a novel food under Standard 1.5.1, without imposing additional requirements or costs to industry. The sale of cell-cultured foods that have undergone pre-market assessment would be permitted, in this case, the applicant’s cultured quail cells, if approved.

Standard 3.4.1 would establish general processing and production requirements for cell-cultured foods produced in Australia (refer to SD 4 for detailed requirements). These would relate to inputs, premises and equipment, processing protocols, monitoring, and verification. They would cover the sourcing of cells from a donor animal through to the production of the final food for sale. Entities engaging in these activities would be a ‘food business’ for the purposes of Chapter 3 of the Code and relevant food laws. A food safety program that complies with Standard 3.2.1 would be required to minimise the risk of foodborne pathogens entering cell culture production phases. Chapter 3’s generic food safety requirements would also apply. Schedule 27 would be amended to set microbiological

safety criteria for two pathogens, *Salmonella* spp. and *L. monocytogenes*, in cell-cultured food.

Permitted cell-cultured foods must be listed in Schedule 25A and comply with any conditions listed in that schedule. Schedule 25A would list the applicant's cell-cultured quail as a permitted cell-cultured food and set specific conditions for its sale and labelling.

If approved, the applicant's cell-cultured quail would be listed in the schedule as a permitted cell-cultured food with specific conditions for its sale and labelling. The proposed permission would provide that the applicant's cultured quail cells themselves cannot be sold directly to consumers.

For the purposes of the above permission and conditions, proposed section S25A—2 would define *cell-cultured quail* to mean quail cells obtained from in vitro culturing of embryonic fibroblast cells (cell line 221523-Fib-Quail) sourced from *Coturnix japonica*.

- Schedule 3 will be amended to include a specification for cell-cultured quail.
- Schedule 27 will include microbiological limits for *L. monocytogenes* and *Salmonella* spp. in cell-cultured food, including cell-cultured quail.

2.4.1 Consequential changes to the Code

In addition to amendment of Standard 1.1.1 (see above) consequential amendments would be made to Standards 1.1.2, 1.2.1, 1.2.10 and 3.1.1 to implement the above conditions for cell-cultured food – including cell-cultured quail – as follows:

- Standard 1.1.2 would 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 would include general and additional requirements for retail sales of cell-cultured foods.
- Standard 1.2.10 would provide information requirements for cell-cultured foods in relation to characterising ingredients and components of that food.
- Standard 3.1.1 would include an amendment to the definition of a 'food business' to include a 'cell-cultured food producer' (i.e. a 'cell line supplier' and a 'cell culturing food business' as defined by proposed Standard 3.4.1).

Each of the above proposed draft regulatory measures are at Attachment A.

The above proposed measures are also premised on cells, cell lines and the cell biomass – when used as or for food – each being declared to be a *food* for the purposes of the Code and the food laws that apply the Code.

The effect of these proposed measures will be as follows:

- Food for sale in Australia and New Zealand cannot be or have as an ingredient or component 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 of the Code. These requirements will apply to cell line suppliers and cell culturing food businesses whose product is for food use. Both will be 'food businesses' for the purposes of Chapter 3 of the Code. Food manufacturers who

use products supplied by cell culturing food businesses would also be subject to Chapter 3 standards as 'food businesses'. Production of cell lines and cell biomass must be done under a food safety program.

2.4.2 Transitional arrangements

FSANZ considered the following factors in relation to whether or not there was a need for transitional arrangements:

- FSANZ is not aware of any food cell line suppliers in Australia. If any exist, they would likely already possess the necessary data required by FSANZ to ensure the food safety of their cell lines. Having no transition period means food cell line suppliers supplying cells must comply with the requirements of proposed Standard 3.4.1 from date of gazettal.
- FSANZ is not aware of any businesses producing and marketing cell-cultured food in Australia, in which case the impact on the industry could be negligible.
- Each new cell-cultured food must undergo a pre-market safety assessment; thus the regulatory pathway remains unchanged whether the proposed amendments and new standard for cell-cultured food (including an amendment to Standard 1.1.1 and Standard 1.5.4) takes effect or not (i.e. it would be assessed as a novel food if the new standard does not take effect).
- A transition period would provide time for industry to amend their systems, where necessary, to comply with the new standards, and enable jurisdictions to consider their regulatory approach and resources to regulate this new food sector.
- A transition period would also mean that the cell-cultured quail could not be sold in Australia or New Zealand until the end of the transition period.
- As there are currently no products in the market, there are no implications for labelling of these foods.

FSANZ has proposed that there be no transitional arrangements for the new amendments, standards, and Schedule 25A. This means they will take effect immediately upon gazettal. This approach encourages industry innovation by allowing the sale of cell-cultured quail in Australia without delay, provided the amendments are approved. It also establishes a regulatory approach for all other cell-cultured foods to apply for pre-market assessment.

2.5 Risk communication

2.5.1 Consultation

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

FSANZ is assessing this application under its Major Procedure which requires 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. Submissions received in response to this 1st CFS are published in redacted form to the following webpage[1] with this 2nd CFS. Submitters' comments informed FSANZ's decision to prepare the proposed food regulatory measures outlined above.

FSANZ has prepared a communication strategy for this application. As with the 1st CFS, subscribers and interested parties have been notified about this 2nd CFS via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News. As part of this strategy, FSANZ has maintained regular dialogue with state and

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

territory governments and the Department of Agriculture, Fisheries and Forestry (DAFF) in relation to food safety/food production requirements for cell-cultured food products.

FSANZ acknowledges the time taken by individuals, organisations and other government agencies to consider this application. All comments are valued and contribute to the rigour of the assessment.

For this 2nd CFS, FSANZ has provided consultation questions in this document to guide submissions. A consolidated list of consultation questions is at section 2.7. Submitters will be guided through these questions when submitting through the FSANZ Consultation Hub.

2.5.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

FSANZ acknowledges that the proposed 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, FSANZ is suggesting specific labelling requirements, such as using the terms '*cell-cultured'* or '*cell-cultivated'* for food identification. The new 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 imported products. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade has been made to enable other WTO members to comment on the proposed measures.

2.6 FSANZ Act assessment requirements

In preparing the above proposed food regulatory measures, FSANZ has had regard to the following matters in section 29 of the FSANZ Act.

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

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 a Consultation Regulation Impact Statement (CRIS) is not 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 is based on the assumption that the proposed changes are not likely to create significant impacts.

Regardless of whether or not a RIS is required, 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 is 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 considers the potential costs and benefits from the following:

- Standard 1.1.1 will be updated to mandate explicit permission in the Code for all cell-cultured foods
- 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 currently is of the view no other realistic food regulatory measures exist in a broad sense, however information received following consultation may result in FSANZ arriving at a different conclusion. Specifically, FSANZ would welcome any views on how the production of safe products could be achieved with alternative regulatory arrangements that may be more efficient and effective.

The consideration of the costs and benefits in this section is 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.

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

This sections 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 sub-section 2.6.1.1.2.

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.

It is assumed 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 are deregulatory in the sense in that they create a pathway to allow cell-cultured food to be sold for human consumption which is currently prohibited. so

FSANZ's consultation to date with cell-cultured stakeholders in Australia has suggested 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 best available evidence
- managing potential risks associated with cell-cultured food and its production processes that cause foodborne illnesses.

Given uncertainty about how markets for cell-cultured foods will grow in future, it is not currently possible to predict impacts on food availability, sustainability, affordability or equity of regulatory measures that relate to cell-cultured foods, all of which fall outside FSANZ's statutory remit. Comments received from the 1st CFS about such aspects are addressed in Appendix 1, Table 2.

Government
In response to the application for cultured quail as a novel food, jurisdictions raised a number of issues relevant to cell-cultured foods generally. Those concerns are about the need for processing requirements, measures providing for regulatory coverage, consistency, understanding and implementation. The proposed new standards and consequential amendments seek to address those concerns. There would be presently unquantified additional costs to regulators of upskilling and implementing the new standards.

2.6.1.1.2 Costs and benefits of permitting the use of the 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 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. Granting permission for the applicant's proprietary 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.

Consumers
If this application is approved, and depending on the commercial success of final mixed foods containing this cell-cultured novel food 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 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 the proprietary cell culturing process is not expected to have any significant impacts for government.

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

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

- cell-cultured foods are in their infancy with uncertain market growth and
- 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 to date with the cell-cultured food sector in Australia has suggested that the impact on them would be minimal
  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 current assessment is that the direct and indirect benefits that would arise from the proposed food regulatory measures would most likely outweigh the associated costs.

2.6.1.2 Other measures

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.

2.6.1.3 Any relevant New Zealand standards

The proposed new Standard 1.5.4 and the related proposed 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.

The requirements proposed under Standard 3.4.1 and Chapter 3 apply only in Australia. New Zealand has separate requirements for a risk management plan operating under either the *Food Act 2014* (NZ) or the *Animal Products Act 1999* (NZ).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*.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.6.2.1 Protection of public health and safety

The new regulatory approach for cell-cultured foods will protect public health and safety through the following:

- An amendment to 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 will 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, including labelling requirements. These would require use of the statement 'cell-cultured' or 'cell-cultivated' to enable consumer choice.

- Permitted cell-cultured foods will be required to be listed in Schedule 25A and comply with any conditions listed in that Schedule. Schedule 25A would list all future cell-cultured foods and set specific conditions for their sale and labelling.

- Standard 3.4.1 will establish general production and processing requirements for cell-cultured foods produced in Australia to ensure their safety.
    - These would relate to inputs, premises and equipment, processing protocols, monitoring, and verification.
    - The production requirements would cover the sourcing of cells from a donor animal through to the production of the final food for sale.
    - Entities engaging in these activities would be a 'food business' for the purposes of Chapter 3 of the Code and relevant food laws.
    - A food safety program that complies with Standard 3.2.1 would be required to minimise the risk of foodborne pathogens entering cell culture production phases.
    - Chapter 3's generic food safety requirements would also apply.
    - Schedule 27 would be amended to set microbiological safety criteria for two pathogens, *Salmonella* spp. and *L.monocytogenes*, in cell-cultured food.

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

FSANZ assessed the available evidence and information on food safety risks and risk management measures in Chapter 3 that would apply to cell-cultured foods, once assessed. As cell-cultured food is a new food category, with limited scientific data available on food safety at commercial production scale, reliance on Standards 3.2.2 and 3.2.3 alone would not provide the necessary assurance to address food safety risks and protect public health and safety. Production of cell-cultured food requires a HACCP-based, through chain approach.

FSANZ concluded that food cell line suppliers and cell culturing food businesses must have a food safety program that has assessed the hazards, identified appropriate control measures and implemented a system to manage food safety. As cell-cultured food production uses techniques and equipment that are relatively 'new' to food regulation, a specific processing standard has been prepared to ensure relevant requirements are applied to production of cell-cultured food.

The FSANZ risk assessment (SD1) concluded there are no public health and safety concerns associated with permitting cell-cultured quail.

2.6.2.2 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 2.3.3 and SD2 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.

2.6.2.3 The prevention of misleading or deceptive conduct

The proposed labelling requirements as outlined in section 2.3.3 and SD2 of this report, will provide information to identify all permitted future cell-cultured foods. This will minimise the likelihood of consumers being misled including in relation to cell-cultured quail, if permitted.

2.6.3 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. All applicants for cell-cultured foods will 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 considered the international guideline developed by the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO), *Food safety aspects of cell-based food*.

In addition, in relation to consumer behaviour, FSANZ undertook and commissioned the following reviews that informed the assessment:

  - FSANZ rapid consumer literature review (SD2, 1st CFS)
  - University of Adelaide consumer literature review (SD3)

- **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 for these foods. FSANZ, through its network of global regulatory partners, will seek to be involved in setting Codex food standards when they are required.

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

FSANZ has proposed a regulatory approach that categorises all cell-cultured foods, including the applicant's cultured quail cells, as a distinct food category. This strategy aims to foster innovation and support the emerging market sector, positioning the food industry at the forefront of this new technology on an international scale. While several other cell-cultured foods have been approved overseas, this specific cell-cultured quail cell product has only received approval in Singapore.

- **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 assessment in SD1 (risk assessment) and SD2 (labelling), and the assessment above of FSANZ Act requirements, FSANZ considers the proposed permission and labelling requirements are consistent with policy guidance.

2.7 Consultation questions

In addition to general comments on the proposed regulatory approach, FSANZ is also seeking specific feedback on the following questions.

Consultation question 1. Regulation of cell-cultured foods

FSANZ proposes two draft standards and one draft schedule to regulate the production and sale of cell-cultured foods in Australia and New Zealand. This differs from FSANZ's proposed approach at the 1st CFS, which suggested regulating the sale of these foods as novel foods. FSANZ considers this approach will deliver enhanced regulatory clarity, ensuring protection of public health and safety whilst supporting innovation in producing cell-cultured food.

1. 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 2nd CFS?

Consultation question 2. Safe food handling and production requirements (refer to SD4)

FSANZ proposes to establish microbiological criteria for food safety and as indicators of process hygiene and handling. These are based on established criteria for other foods and production process monitoring as well as the applicant's proposed criteria which included specifications for *Salmonella* spp. and hygiene indicator organisms: SPC, Enterobacteriaceae and *E. coli*. FSANZ proposes the below:

- criteria for *L. monocytogenes* and *Salmonella spp.* in Schedule 27 (i.e. food safety criteria for cell-cultured food); and

- cell culturing process hygiene indicators (SPC, Enterobacteriaceae, *E. coli*, yeasts and moulds and coagulase-positive staphylococci) in the *Compendium of Microbiological Criteria for Foods*.

2. Do you agree the approach outlined above effectively supports the assessment of safe food products and provides clear guidance on maintaining adequate process control?

Consultation question 3. Assessed cell line

The proposed processing standard for cell-cultured food restricts processing to only those cell lines assessed by FSANZ.

3a. Do you agree with this approach?

3b. 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?

Consultation question 4. Proposed definition for 'cell-cultured food'

FSANZ proposes the following definition for 'cell-cultured food':

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.

4. Does the proposed new definition for 'cell-cultured food' provide regulatory certainty and clarity for industry, enforcement agencies and other stakeholders?

Consultation question 5. Labelling

FSANZ proposes a revised labelling approach for cell-cultured food in relation to food identification and food sold to a caterer (see section 2.3.3 of the 2nd CFS document and SD2 to that document).

5a. Do you have any comments or additional evidence to inform the proposed labelling approach?

5b. Do you agree with this approach?

Consultation question 6. Costs and barriers

6. 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?

3 Draft variations

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

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Appendix 1

Summary of submitter comments and FSANZ response.

Attachments

A. Draft variations to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Appendix 1 – Summary of submissions

Table 1 provides a list of submitters to the 1st CFS, other than private individuals whose identity will remain undisclosed, together with the abbreviation used in the summary of submissions provided in Table 2.

Table 1: Submitters to the 1st CFS

Submitter	Abbreviation
Industry / peak bodies	
Australian Food and Grocery Council	AFGC
Australian Institute of Food Science and Technology	AIFST
Allergen Bureau	-
Opo Bio	Opo
Industry advocacy groups	
Alternative Proteins Council	APC
Cellular Agriculture Australia	CAA
Good Food Institute APAC and APAC Society for Cellular Agriculture	GFI & APAC-SCA
Food Frontier	-
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	-
South Australia Health	SA Health
Victorian Department of Health and the Victorian Department of Energy, Environment and Climate Action	DOH-VIC & VIC DoEECA
Consumer / animal rights groups	
Animal Justice Party	-
Community Voice Australia	-
GE Free New Zealand	GE Free NZ
GeneEthics	-
WePlanet Australia	WePlanet

Table 2: Summary of submissions and FSANZ response

Submission viewpoint	Raised by	FSANZ response
Risk assessment		
Cell line – Primary cell isolation and cell bank storage		
Raised concerns around the official monitoring of the source farm for the quail eggs and whether this was indicative of an issue with that specific farm.	Individual	Noted. In line with FAO/WHO guidance (2023), it is expected the health of a source animal and environmental conditions in which the animals are held, are inspected by suitably qualified personnel for signs of infection and/or disease prior to cell collection. This extends to any other health information (e.g. animal/flock management, vaccination, and any microbiological test data) relevant to status of the animal. This practice is in line with routine pre- and post-slaughter checks of livestock animals. The draft variations would require traceability from a cell line supplier to identify and track cells from 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 to whom a cell line was supplied. There will also be a condition that a cell line supplier must not collect tissue from a donor animal that is diseased. Refer to Division 2 of draft Standard 3.4.1 providing requirements for the cell line supplier.
The microbiological analyses provided by the applicant (section B.4.1 of the dossier) – including for *Mycoplasma* and viruses – appear to be appropriate, and a reasonable analogue to veterinary health checks for animals to be slaughtered for meat.	WePlanet	Noted.
Queried whether there had been one original cell line received from the cell supplier or are there multiple cell lines (noting microbiological examination of the eggs from the packing station was provided from 2018.)	SA Health	There is only one unique origin cell line that has been characterised and is the subject of this application. FSANZ considers each cell sourcing event is unique given it involves independent cell isolation (potentially from a different donor animal) and immortalisation steps. The health status of the donor animal would be assessed on a case-by-case basis.
Raised concerns regarding the storage of the cell line, the potential for cross contamination between cell lines including transfer of pathogens and misidentification of cell lines.	DOH-WA, DAFF (Late comment)	Cell lines should be maintained as per Good Cell Culturing Practice (GCCP) requirements which, if implemented appropriately, would manage the risk of cross contamination and misidentification of the cell line. The applicant has advised that the cells are stored in cryovials in freezing

Submission viewpoint	Raised by	FSANZ response
		medium, placed in liquid or vapour phase nitrogen. FSANZ notes the issue raised regarding use of cryopreservation bags as detailed by Ong et al. (2021). Cryopreservation bags cited were specifically used for storage of human fusion (blood) products in the 1990s. Most if not all cell line storage banks use specialised screw-capped vials designed for storage of cells at temperatures below -180°C (<77K), in racks that can either hold the vials in the head space above or in the liquid nitrogen. FSANZ agrees there are risks that require management associated with the activities of a cell line supplier. The draft standard has proposed requirements for cell line suppliers to manage these risks. Refer to Division 2 of draft Standard 3.4.1, in particular sections 3.4.1—4 and 3.4.1—5.
Requested further information be provided regarding how many antibiotic-free passages occurred within the 12-month period that cells were cultured in the absence of antibiotics before being sourced by the applicant.	NZFS	The number of passages of cells by the cell supplier is not known, however the applicant advised they cultured cells for more than 12 months without antibiotics before the production of the vMCB (section B.4.2.2 of the non-CCI application - here[2]). The applicant advised antibiotics were used by the cell supplier during the initial cell culture isolation stage of quail embryo cells for the first two passages of the primary culture. For passage 3, media did not contain any antibiotics (section B.4.2.2). No antibiotic residues were detected in the cultured quail cells after harvest.
Cell line – safety and immortalisation		
FSANZ should require rigorous, large and compelling evidence on immortalised cell line safety and efficacy.	GeneEthics	The applicant provided an extensive data package in accordance with FSANZ data requirements (Guidelines 3.1.1 and 3.5.2 of the FSANZ Application Handbook[3]). FSANZ considered the data, and other available information from the latest scientific literature, and undertook a safety assessment on the immortalised cell line (SD1). This included: • DNA barcoding data to confirm the species of the cell line • microbiological testing to assess any vertical transmission of microbiological hazards

[2]://www.foodstandards.gov.au/sites/default/files/2023-12/Application - Cultured Quail as a Novel Food.docx_0.pdf
[3] https://www.foodstandards.gov.au/food-standards-code/consultation/applicationshandbook

Submission viewpoint	Raised by	FSANZ response
		• whole genome sequencing (WGS) analysis to characterise the cell line and determine its genetic stability • a review of adverse health effects resulting from quail consumption • bioinformatic analysis to compare amino sequences from *Coturnix japonica* to those of known food allergens and • an enzyme-linked immunosorbent assay to examine for the presence of allergens. FSANZ is satisfied there are no specific food safety concerns associated with the immortalised cell line.
Raised concerns about the genetic variation arising from the immortalisation process, specifically that: • based on the HeLa cell line, spontaneous immortalisation often results in a number of random genetic mutations that have the potential to cause unintended effects • spontaneous mutation is the *in vitro* equivalent of cancer.	Individual	FSANZ notes these concerns. The cell line risk assessment did not identify any safety concerns associated with the genetic variation that occurred during the immortalisation process. Cells become immortal when they lose their ability to stop cell division. While this is a characteristic of both cancerous cells and immortal cell lines, not all immortal cell lines are cancerous. This includes the applicant's quail cell line. In relation to the submitter's reference to the HeLa cell line, FSANZ notes that cell line was derived from a human cervical cancer sample (Landry et al. 2013). This means HeLa cells have a cancer origin and had already lost their ability to stop cell division before they were cultured. It is therefore not an appropriate comparator for the cell line used by the applicant, which is derived from a healthy quail embryo and immortalised by spontaneous mutation. Spontaneous mutation in and of itself is not a food safety concern. Spontaneous mutation occurs frequently in nature and is one means by which genetic variation occurs (Alonso-Blanco et al. 2009). Such genetic variation is frequently exploited for animal and plant breeding. The occurrence of random genetic variation also occurs in conventional breeding, and does not necessarily alter the phenotype of organisms or lead to changes in the characteristics of derived food products or its safety profile.

Submission viewpoint	Raised by	FSANZ response
		There is no evidence to indicate the spontaneous mutations that occurred in the immortalisation of the quail cells have resulted in changes that would raise any food safety concerns.
Queried what risk analysis was done by FSANZ and what information FSANZ relied on in its consideration of the cell line being in a pre-cancerous or cancerous state. There are concerns about the long-term consequences of human consumption of cells that have the characteristics of stem / cancer / immortalised cells which more easily proliferate.	Community Voice Australia, Individuals	FSANZ's assessment of the cell line focussed on the identification of any hazards resulting from the immortalisation and subsequent cell culturing process. This included examining whether there was any significant genetic instability (e.g. during immortalisation and subsequent cell culture) and, if so, whether this would impact food safety. For this assessment, FSANZ considered the data submitted by the applicant plus other information from the scientific literature. While cancerous cells and immortal cell lines share characteristics, the applicant's quail cells are not cancerous. FSANZ notes: • Bioinformatic analysis was used to classify genomic variants in the cultured quail cell genome according to their molecular function, cellular component or biological process. This analysis did not reveal any association between genomic variants and cancer development. For example, the genomic variants did not affect DNA replication or repair pathways, which are typically associated with cancer development. • While the immortalised cell line has the ability to proliferate indefinitely, its growth is restricted by chemical and biological inputs added to the bioreactor (e.g. media, media components), as well as physical properties found in the bioreactor (e.g. oxygen, pH). Once removed from the controlled environment of the bioreactor, the quail cell line is expected to lose its ability to proliferate. • In the absence of any new or altered hazards, the risk from consumption of the cell line is no different to that from consuming other animal cells found in meat products already in the food supply, including in the long-term.
Cell line – vertical transmission of microbiological hazards		
Recommended revisions to SD1 as follows: 1. Removal of the following sentence in section 2.2.1 of SD1: *'DAFF also administer the Imported Food Control Act, which checks*	DAFF (Late comment)	Noted and amended or removed.

Submission viewpoint	Raised by	FSANZ response
imported food for compliance with the Code and public health and safety.' Whilst correct, it does not relate to the vertical transmission of microbiological hazards. Unless a company is looking to import the cell-cultured product, the Act does not apply. *2.* Revision of the following paragraph in section 2.2.1.2 to be specific to the vMCB and vWCB, thus ensuring consistency with the previous paragraph: '*No animal-derived components or antibiotics are utilised by Vow during initial cell line establishment nor during cell expansion. Negative Mycoplasma tests using MycoAlert and PCR methods were reported for cell samples when the cell banks were established by Vow, minimising the likelihood that Mycoplasma were present.'* 3. Inclusion of a reference to the use of vMSB and wMSB and the associated cGMP in the following sentence in section 3.3.1: *'The prevention of infections at this stage will be reliant on the use of well characterised cell lines and consistent and robust aseptic process.'*		
Cell line – genetic stability and safety		
Raised issues relating to the random accumulation of genetic variation while the cells are in culture: • Risks from genetic and epigenetic drift have not been scientifically assessed. • Submitters want to see evidence that the genetic variations and any phenotypic drift that may occur do not raise any specific food safety concerns.	Individual, GeneEthics, GE Free NZ, CAA, DoH WA, DOH-VIC & VIC DoEECA, DAFF (Late comment)	The degree of genetic variation as a result of cell culture was considered as part of the genetic stability analysis in SD1 (section 2.2.2.1). In response to the specific points raised by the submitters, FSANZ notes the following: • Genetic and epigenetic variation is not unique to cells grown *in vitro*. It occurs in all organisms used for food and does not necessarily equate to phenotypic variation, including variation that would raise any food safety concerns.

Submission viewpoint	Raised by	FSANZ response
• FSANZ must develop, validate and publish methods and relevant thresholds for an acceptable rate of genetic drift, including a clear indication of how [WGS] data should be assessed for consumer safety. • Creating an open-access database could be useful to track genetic drift in cultured meat-relevant cell lines (Ong et al. 2023). • There is no history of safe use of cell-culture for food development. What may or may not be safe and normal in animal cell-culture does not necessarily extrapolate directly to food production.		• FSANZ considers that quantifying the degree of genetic variation is of limited value for directly assessing food safety, nor would it be meaningful from a safety perspective for FSANZ to specify an acceptable level of genetic variation. It is the impact of genetic variation on the phenotype that is important for safety, not the overall quantum of change to the genome. This is exemplified through animal and plant breeding where significant changes to genomes have occurred without adversely impacting food safety. • FSANZ assessed phenotypic stability, specifically, the expression of proteins that are relevant to the safety of the food or that may have an impact on the whole diet. For cell-cultured food, identifying proteins of interest would be dependent on the animal origin of the specific cell line. An analysis of allergen residues can be found in SD1. FSANZ is satisfied there are no specific food safety concerns. • The production of cultured quail cells is supported by GCCP which will limit the potential of the cell line to deviate significantly from its genetic and phenotypic nature assessed in this application. • The degree of random accumulation of genetic variation is limited by the length of the production run. Following a complete cell harvest, the applicant will use new cells from cell banks to start a new production run. This will 'reset' the cells to the genetic and phenotypic baseline assessed in this application. • The creation of an open-access database to track the random accumulation of genetic variation is beyond the scope of this application. FSANZ notes that the permission sought for cell-cultured quail is specific to the applicant. • Although there is no history of animal cell culture for food development in Australia and New Zealand, FSANZ is satisfied the safety of the cell-cultured quail in this application has been established.
There is no clear indication the rate of genetic drift or data from whole genome sequencing (WGS) is instructive for assessing consumer safety. Phenotypic variation should be an appropriate data requirement to ensure consumer safety in lieu of gene sequencing – with specific exceptions as	GFI & APAC-SCA	FSANZ agrees with the submitter that quantifying the degree of genetic variation, based on the results of WGS, is of limited value in assessing safety. The WGS data in the current application contributed to the weight of evidence for cell line stability. That is, it provided evidence that the degree of genetic variation was what would be expected for a cell line grown in

Submission viewpoint	Raised by	FSANZ response
noted in the next entry below.		culture, and was not indicative of any genetic instability. FSANZ's primary focus, however, was on identifying any changes to phenotype that may raise food safety concerns. In its assessment, FSANZ concluded the only risk that could potentially arise should the cells lose their identity in culture or become dysregulated was ectopic expression of egg allergens. FSANZ noted however that this was a theoretical and highly unlikely possibility. ELISA testing across multiple batches of cultured quail cells did not detect egg allergen expression.
Commented that targeted sequencing is a more appropriate data requirement compared to WGS in areas where insertions, deletions, or mutations are known to hold the potential to impact consumer safety on a case-by-case basis, such as allergenicity.	GFI & APAC-SCA, CAA	Noted. FSANZ advises applicants submitting cell-cultured food applications to provide information on the genetic and phenotypic nature of the cell line, including any potential hazards associated with the species of origin or that could arise during the culturing process. FSANZ notes there are different approaches to demonstrate genetic and phenotypic stability. FSANZ will assess their adequacy and suitability on a case-by-case basis.
Clarity was requested on whether WGS extend to analysis [of] polyploidy in either the csMSB or vMCB.	DAFF (Late comment)	As described in SD1, the WGS analysis focused on single nucleotide variants. The analysis did not extend to polyploidy. FSANZ is not aware of any evidence to suggest that polyploidy represents a hazard from a food safety perspective. FSANZ also notes that polyploidy (either naturally occurring or artificially induced) occurs in many plants and some animals (e.g. species of fish) that are safely consumed (Zhou & Gui 2017; Heslop-Harrison et al. 2023).
Cell line – allergenicity		
Raised questions regarding the potential presence of gluten from barley, and the adequacy of the testing done by the applicant to determine whether gluten may be present in the final food. If FSANZ is satisfied the process will deliver a gluten result below the limit of detection, then Schedule 9 of the Code should be amended to include an exemption for declaration of	GE Free NZ, Allergen Bureau, DOH-VIC & VIC DoEECA, SA Health	The applicant has not sought an exemption from the mandatory declaration requirement for gluten for cultured quail cells. If FSANZ was to consider an exemption, it would require relevant data to assess the safety of such an exemption. As noted in SD4 to the 1st CFS, if gluten from barley is present in a food product for sale containing cultured quail cells, gluten and barley would need to be declared.

Submission viewpoint	Raised by	FSANZ response
barley/gluten for cell-cultured quail produced per the approved process.		
It is unclear from the application whether the applicant voluntarily performed sequence homology testing on all known allergens or whether this was a request made by FSANZ. Sequence homology testing on all allergens is not useful and should not be a requirement in the future.	CAA	FSANZ assessed this application under Guideline 3.5.2 Novel foods of the FSANZ Application Handbook. The Handbook specifies that potential allergenicity should be addressed in a safety assessment for this type of food. The Handbook does not however prescribe the approach, the studies undertaken, or methods used as this will vary depending on the nature of the food under assessment. FSANZ considers the totality of the information provided by the applicant, along with other available information from the scientific literature, to reach a conclusion about the potential allergenicity of the food being assessed.
The application often conflates the history of conventional quail meat and egg consumption as support for the consumption of cultured quail meat, yet the two are far from comparable.	Individual	Section 2.2.3 (Allergenic and toxicological hazards associated with quail) of SD1 acknowledges that quail embryonic fibroblasts grown in culture do not have a history of human consumption in Australia or New Zealand. However, the identity of the cell line is confirmed as Japanese quail (*Coturnix japonica*), therefore FSANZ's knowledge of conventional quail and its safety as a food can provide valuable insights into potential hazards associated with consuming cell-cultured quail – in particular, any potential toxigenic or allergenic factors that would also be relevant to fibroblasts derived from a quail embryo.
Method of production – basal media and inputs		
Media additives Expressed concerns about the safety of media additives. Specifically, whether the components of the culture media have been assessed for safety, noting it is not clear if the applicant is using ingredients and processes with a long history of safe use in food production. Scientific literature suggests substances used in the harvest stage like food additives, pH buffer and washing media may contain allergens. An assessment of whether there are any novel allergens in the final product should be seen as a matter of importance.	Individual, GE Free NZ, DOH-VIC & VIC DoEECA, DOH-WA, NSWFA	FSANZ conducted a detailed assessment of the safety of all substances used in the production of cultured quail cells. This included information on all of the components of the basal media, media additives, growth factors, cryoprotectant and cleaning agents. For confidentiality reasons FSANZ was not able to include a detailed description in SD1. The majority of substances used in the media inputs have a long history of consumption from quail or other dietary sources (e.g. vitamins, minerals and the growth factors), or are produced endogenously in the human body (e.g. growth factors, amino acids). The following approach was used: • Substances listed in the Code, in particular those permitted for addition to food at levels consistent with GMP, were generally considered not

Submission viewpoint	Raised by	FSANZ response
Given basal media inputs may be present within the cells at harvest, submitters thought it important to assess the safety in more detail.		to be of concern, with estimated levels of exposure also taken into account. • Some substances such as vitamins, minerals and amino acids were evaluated in the nutrition risk assessment. • For other inputs, consideration was given to the identity, source and any hazards associated with these substances as set out below. • The review considered toxicological information and/or risk assessments of the substances by overseas agencies, as well as information on exposure from other sources. • Exposures to the inputs were estimated based on analytical measurements of the substance in cultured quail cells, or by assuming the entire amount of a particular component in the growth media would be taken up by the cells. • Exposure estimates assumed that 300 g of cultured quail cells would be consumed every day, which is considered likely to be an overestimate. • Estimated exposures were compared to dietary exposures from other sources, endogenous exposures, health-based guidance values (HBGVs) or no observed adverse effect levels (NOAELs) from toxicological studies in laboratory animals. • When estimated exposures were compared with NOAELs, a margin of exposure (MOE) was calculated. • For substances which are not genotoxic and carcinogenic, an MOE > 100 is generally considered to indicate a low health concern. No substances that are genotoxic or carcinogenic are used in the production of cell-cultured quail. • Potential allergenicity of the media inputs was also evaluated. Using the above approach, no safety concerns arising from the presence of the components of the basal media and other inputs in the harvested cells were identified, including in relation to allergenicity. The proposed amendments to the Code and two new standards and one schedule establish a regulatory approach that requires pre-market assessment of cell-cultured food, and that the cell line supplier and cell culturing food business have adequate measures in place to manage food

Submission viewpoint	Raised by	FSANZ response
		safety. Standard 3.4.1 requires the business to assess and ensure all inputs do not make the food unsafe or unsuitable (refer section 3.4.1—5 of Standard 3.4.1)
Media additives Noted the apparent dismissive nature of concerning elements, for example, in section C.6.3.1.2 – Media additives (page 51 of the application) 'All of the additives have a MOE > 100, and are already naturally found in food or are present in the human body. Therefore, use of these additives do not pose a food safety risk in cultured quail.' By this logic cyanogenic glycosides found in raw apricot kernels are also safe.	Individual	The submitter has referred to a statement in the application by the applicant, however FSANZ's assessment did not simply consider presence in food or the human body, but took additional considerations into account following international best practice for risk assessment of chemicals in food. Importantly, FSANZ considered whether the estimated levels of exposure to these substances was of concern, by comparing these with normal dietary intakes, levels of endogenous production in the body or with toxicological reference values (e.g. NOAELs or HBGVs). In all cases the estimated levels of exposure did not raise safety concerns. See section 3.1.2 of SD1.
Media additives The MOE for media additives is calculated from animal toxicity studies and the anticipated exposure level (dose). The applicant has set this at 300 g per serve per day elsewhere in the application so the MOE > 100 is not static.	Individual	MOEs were calculated using a consumption value of 300 g cultured quail cells per day. This is considered to be an overestimation of serving size, with a larger serving size considered highly unlikely. Consumption of a smaller amount would result in even larger MOEs which do not suggest a health concern.
Media additives Requested FSANZ clarify if food additives used during the production process are permitted at GMP. Page 18 of SD1 indicates use of permitted food additives. Page 26 of the application states 'cells may be mixed with food-grade additives'. Submitters also commented that the basal media inputs could be considered processing aids.	NSWFA, DOH-VIC & VIC DoEECA, CAA	These comments appear to refer to two separate issues: use of food additives during cell culture; and use of food additives in the final food product. As noted on page 18 of SD1, some substances used during the cell culture process have permissions in the Code as food additives. However, FSANZ is of the view that the use of these substances, and other basal media inputs during the cell culture process is not use as a food additive or processing aid. The substances are being used to support the growth of the cells during culture and do not perform a technical function during food processing or in the final food. Page 26 of the application states the applicant may combine the cultured quail cells with food additives following harvest. However, FSANZ has received confirmation from the applicant that the statement on page 26 of the application refers to 'food grade ingredients' rather than 'food additives'

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		as defined by the Code. No permission for addition of food additives has been requested in this application.
Media additives Noted there were no studies on the cumulative effect of synthetic end-to-end processes on the human body, and also queried what is the cumulative effect of consuming synthetic additives.	Community Voice Australia	The substances added to the cell culture media were assessed in line with international best practice for risk assessment of chemicals in food (FAO/WHO 2009). As mentioned in the first entry listed under this sub-heading above, the majority of substances used in the cell culture process have a long history of consumption from quail or other dietary sources (e.g. vitamins, minerals and the growth factors), or are produced endogenously in the human body (e.g. amino acids and growth factors). The safety profile of synthetic forms of these substances is expected to be the same as those of their naturally occurring forms. For those media inputs not normally present in food (e.g. the antifoaming agent), toxicological information was reviewed and estimated exposures from cultured quail cells were compared with HBGVs or NOAELs from toxicological studies to confirm their safety.
Cryoprotectant Recommended expanding section 3.1.4 Cryoprotectant of SD1 to ensure clarity on whether the cryoprotectant includes animal derived material (i.e. Foetal Bovine Serum or Bovine Serum Albumin).	DAFF (Late comment)	FSANZ does not consider it necessary to add this clarification to SD1, as this information is not directly relevant to the safety assessment of the cryoprotectant used by the applicant. However, FSANZ can confirm that the cryoprotectant does not contain animal-derived material.
Other factors found in the media Raised concerns regarding horizontal gene transfer between microorganisms found in culture media in a laboratory environment and the safety of recombinant DNA in the final product.	GE Free NZ	Quail cells are grown under aseptic conditions, and as such microorganisms are not present in the cell culture media. Consequently, DNA uptake from the media or horizontal gene transfer between microorganisms cannot occur and is therefore not a concern. DNA has always been present in food, and recombinant DNA is chemically no different to other DNA (non-recombinant DNA) found in food. The overwhelming scientific consensus is that the presence of recombinant DNA in food does not pose any human health or safety concerns.

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Genetic modification Concerned about the use of 'genetic engineering'. In particular, they questioned whether the cell-cultured quail is not a genetically modified organism as it was made using recombinant DNA.	Community Voice Australia, Individuals	Recombinant DNA techniques were not used to alter the heritable genetic material of the quail cells and there is no recombinant DNA present in the quail genome. As such, the quail cells are not genetically modified. Recombinant growth factors (GFs) were used to support the growth of cells during culture. As discussed in the entries that follow, FSANZ assessed the safety of the GFs and is satisfied there are no safety concerns.
Growth factors Requested clarity on the origin of the growth factors. Has the barley been genetically modified?	Individual	FSANZ can confirm the GFs are derived from barley and *E. coli* which have been genetically modified using DNA from porcine and bovine sources. Full details of their production cannot be disclosed as they are deemed CCI *under the Food Standards Australia New Zealand Act 1991* (the Act).
Growth factors Concerns raised regarding the thoroughness of the approach used to assess the GFs. The risks and hazards inherent in the recombinant growth factors derived from genetically modified (GM) organisms have not been assessed by FSANZ. Specific concerns were raised regarding the use of growth factors: • growth factors engineered into barley or *E. coli* have not been assessed for safety from zoonotic infectious diseases or microbial contamination and associated anti-microbial resistance genes • they may have a function in tumour growth regulation and progression • they may have unforeseen effects on the cells of consumers • they are frequently involved in evolvement of resistance to therapeutic regimens for cancer • each growth factor has a different mode of action in the cell.	Individuals, Community Voice Australia, GeneEthics, GE Free NZ	FSANZ has undertaken a detailed safety assessment of the recombinant GFs using data provided by the applicant and other available information. This assessment considered the nature of the genetic modification, the methods used in the genetic modification of the source organism, potential toxicity and allergenicity, bioactivity, and a comparison of levels of exposure from cell-cultured quail with background levels of exposure from the diet or endogenous production of similar growth factors in humans. Based on this assessment, FSANZ is satisfied there are no safety concerns with the presence of these GFs in the cell-cultured quail. In response to the specific concerns raised by submitters, FSANZ notes the following: • In its assessment of the GFs, FSANZ examined the GM production method. Contamination of the GFs with zoonotic infectious diseases, *Bacillus* and *E. coli* strains and associated anti-microbial resistance genes is highly unlikely. The risk of contamination of recombinant GF during production would be similar to the production of non-GM derived substances, both of which require good laboratory practice and quality checks. FSANZ also notes that the recombinant GF are purified, which will reduce the likelihood of contamination. The GM production method does not result in any new or altered hazards and

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From this arises the possibility of a cytokine storm effect in the consumer, that could trigger anaphylactic shock, possibly leading to death.		FSANZ is satisfied there are no safety concerns with these GFs being derived from GM organisms. • Consumers are exposed to a wide range of GFs through the consumption of animal-derived foods such as meat and dairy products. • The same type of GFs used for cell-cultured quail production are found in a range of commonly consumed foods. Their levels in the harvested quail cells are similar to or lower than those found in other meats such as quail, chicken, beef and pork, other commonly consumed foods or the amount produced daily by humans. • In addition, human forms of the GFs used by the applicant are produced endogenously in the human body. • The GFs used are not cytokines. In addition, they will be degraded through cooking as well as digestion in the gastrointestinal tract, which would destroy any residual bioactivity that might result in a cytokine storm. • With respect to the development of resistance to cancer therapeutics, this relates to the production of growth factors by cells within the tumour microenvironment, such as tumour-associated macrophages and cancer-associated fibroblasts (Khan et al. 2024; Wang et al. 2019), rather than growth factor exposure from dietary sources. • As exposures to these GFs are not higher than those from normal background exposures, their use in production of cultured quail cells does not raise safety concerns.
Growth factors Data was collected from only three independent batches to assess the amount of growth factor in the applicant's final cultured quail via ELISA and Western Blots. This is not a great sample size for such an important quantification.	Individual	The results of the GF quantification were generally consistent across batches. Given this, testing of additional batches was considered unnecessary. In addition, when calculating estimated exposures to the GFs, FSANZ adopted a worst case scenario approach where it was assumed that all the GFs present in the cell culture medium would be taken up into a serving of cell-cultured quail. Even using this highly conservative approach, estimated exposures to the GFs from consuming cell-cultured quail are similar to those from conventional foods, and substantially lower than the total amount produced endogenously in humans.
Growth factors Questioned whether the GFs would be considered 'food produced using gene technology' and could:	NZFS, NSWFA, GE Free NZ, Individual	FSANZ does not consider it necessary or practical to separately and individually regulate the GFs as '*food produced using gene technology*'. This matter will be clarified under Proposal P1055 – Definitions for gene

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• be processed, similar to the use of new enzymes produced via precision fermentation • attract provisions of the Code relevant to food produced using gene technology if there were detectable levels in food for sale. The comment was also made that the recombinant growth factors present in the cell culture media have not been approved for food consumption.		technology and new breeding techniques, where such media components are intended to be excluded from the proposed new definition for 'genetically modified food'. FSANZ also does not consider the GFs to be processing aids or food additives as they are not performing a technological function during the course of food processing nor are they performing a technological function in the final food. The sole purpose for adding GFs is to support the growth of cells during the culturing process. As a result of this use, GFs, along with other media components, may be carried over to the harvested cells. As described in other responses above, FSANZ has assessed the GFs and determined their presence does not raise any safety concerns.
Growth factors Concern was expressed regarding the possible presence of bioactive molecules in the final product, and whether certain proteins may trigger an autoimmune response after consumption by sensitive populations, such as infants (Ong et al. 2023).	DOH–WA	The presence of bioactive molecules in cell-cultured foods is a theoretical concern raised in the review paper cited by the submitter. The potential risk of any bioactive substances (should they be present), would need to be assessed on a case-by-case basis. For this assessment, FSANZ evaluated information on each of the inputs used in the production of cell-cultured quail, including bioactivity of the growth factors used in cell culture, and concluded there are no safety concerns associated with their presence.
Growth factors The growth factors used should be identified, including whether they are hormones, cytokines, or chemokines.	GE Free NZ, Individual	As specified in the application and FSANZ's SD1, only two GFs are added to the basal media to support the growth of the quail cells. FSANZ is unable to publicly identify these GFs as this information is considered CCI under the Act.
Pathogenic mutations There has been no assessment of the possibility of pathogenic mutations resulting from the uptake of the cell media components by recombinant molecules.	GE Free NZ	As noted below, FSANZ has assessed the safety of all cell media components. None of these substances were found to be mutagenic.
Residual presence of media inputs Concern that residues from various substances (e.g. additives, processing aids, microcarriers, metals, agricultural chemicals and environmental contaminants), as well as fragments of scaffold	DOH-WA	As noted below, the safety of all media inputs was assessed by FSANZ and no concerns were identified. No scaffold materials are used in the production of the cultured quail cells, which are cultured in suspension.

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materials, could be carried over from the manufacturing process and be present in the final product. Careful selection of novel inputs that are well characterised and safe would be essential. In addition, businesses should develop and validate their own analytical tests to identify such residues, and there should be future research investigating the sensitivity and adequacy of testing.		The proposed amendments to the Code and two new standards and one schedule establish a regulatory approach that requires pre-market assessment of cell-cultured food, and that the cell line supplier and cell culturing food business have adequate measures in place to manage food safety. Standard 3.4.1 requires the business to assess their activities and hazards associated with those activities and ensure they implement adequate controls to ensure the food produced is safe and suitable (refer Divisions 2 and 3 of Standard 3.4.1)
Regulation of media inputs There is a need to consider possible ways to regulate cell culture inputs to provide clarity to the manufacturers and for enforcement purposes. This may be achieved on an internationally recognised basis as is the approach with packaging materials and food flavours for example. One submitter noted regulating inputs via the Code could help streamline future applications (suggesting permissions for an amino acid or carbohydrate be included in the Code in a concentration deemed safe). Concerned FSANZ is not proposing to regulate the substances used in the cell culture medium, particularly when the cells are not washed, and some of the culture medium remains in the final harvested cell product. There are many substances in the cell culture medium and the complexity of their assessment is acknowledged. However, risk based principles could possibly be applied to those that may present health and safety risks. The issue appears to be analogous to the regulation of processing aids prior to introduction of processing aid requirements, where industry was provided time to declare the processing aids they used, which were then mostly grandfathered into	NZFS, Queensland Health, GFI & APAC-SCA, CAA	FSANZ has assessed all the media inputs for the current application and concluded that there are no safety concerns. The proposed approval in the Code is specific to the applicant's product that has been assessed a part of this application. The proposed amendments to the Code and two new standards and one schedule establish a regulatory approach that requires pre-market assessment of cell-cultured food, and that the cell line supplier and cell culturing food business have adequate measures in place to manage food safety. Standard 3.4.1 requires the business to assess and ensure all inputs do not make the food unsafe or unsuitable (refer section 3.4.1—5 of Standard 3.4.1)

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the Code.		
Production scale-up		
Raised concerns regarding process changes including 'production scale-up', ingredient substitution and addition of new ingredients and sought clarification on what would trigger a new health and safety assessment; thresholds and criteria.	GFI & APAC-SCA, AFGC, NSWFA	It is the legal responsibility of those who sell food, including producers and processors, to ensure their food complies with relevant provisions of the Code, including those relating to pre-market approval and to production. The proposed amendments to the Code include a new processing standard, Standard 3.4.1. This standard requires the business to comply with Standard 3.2.1, which is development of a HACCP-based approach to managing food safety for all their activities in handling the food. This requires all changes to processes to be reviewed under the business's HACCP plan and under the oversight of the relevant jurisdiction. Food businesses, including the applicant, must validate and then verify on an ongoing basis, that changes to production, including any increased production scale, does not impact the hazard assessment and/or their controls, and monitoring programs remain effective. Standard 3.4.1 requires the business to assess and ensure all inputs do not make the food unsafe or unsuitable (refer section 3.4.1—5 and section 3.4.1—8 of Standard 3.4.1). The business must assess all changes to inputs used during production of cell-cultured food.
Sought clarification whether risk assessment outcomes are transferable to all production scales and how any changes in scale would impact the microbiological hazard assessment. One submitter sought assessment of the final product from a scaled up production. One submitter considered that there should be a further application once production scale up reached large commercial quantities. If scale up requires another application and assessment, this needs to be identified in the Code. Submitters queried how this would be done within the Code to ensure food regulators could comply with this requirement.	SA Health, DOH-WA, DOH-VIC & VIC DoEECA, NSWFA, Individual, GeneEthics, APC	FSANZ does not expect production changes relating to scale to impact the *nature* of the microbiological hazards identified in the current assessment but it may impact *process controls* to manage them. This would be a similar issue for any food business as it upscales production; all changes to processes, inputs, equipment etc. should be re-evaluated by the business as part of their HACCP-based approach and validated to ensure hazards continue to be managed. Businesses are encouraged to discuss major changes to their food safety program with the jurisdictional food regulator. To achieve this, the draft processing standard for cell-cultured food (Standard 3.4.1) contains a range of requirements, including compliance with a food safety program as required by Standard 3.2.1.

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A submitter considered despite scale, risks would be addressed by good production practices, food safety systems and a cooking control step, as intended, before consumption**.**		FSANZ notes there is limited history of production or use of cell-cultured food on which to rely. The sampling program is relevant to the current scale of production. With increased production, Standard 3.4.1 will require the business to assess the hazards associated with scale-up and to implement controls to ensure the food is safe and suitable. This requires the business to collect data to validate safety at different scales of production (i.e. different sized bioreactor) and/or from different stages during production and this will need to be verified on an ongoing basis to demonstrate control of production. Refer to section 3.4.1—7 for process control requirements for the cell culturing food business.
Harvested cells – microbiological assessment		
Supported the use of a risk-based approach, such as a HACCP-based system, supported by GCCP, GMP and GHP as a way to reduce microbial risk during production.	NZFS, CAA	Noted.
Raised concerns regarding: 1. cooling and cooking specifications of harvested cells (with reference to *L. monocytogenes)* 2. decontamination/cleaning/CIP management following a microbial pathogen contamination event 3. disposal of microbially contaminated cell culture waste. One submitter proposed that, given there is no microbiological data to assist the safety risk and hazards of the cell-based quail, a trial study be undertaken by the applicant to establish there are no detrimental effects on human health.	DOH-VIC & VIC DoEECA, WePlanet, Community Voice Australia, GeneEthics	As part of the hazard identification and characterisation, FSANZ reviewed CCI data on the cooling time/temperature of the harvested cells prepared under current processing procedures. Under the specified parameters, this would minimise the growth of any microbiological contaminants. While these details were not part of the application, the applicant advised the food product will be sold to restaurants and is intended to be cooked. The applicant intends to provide cooking instructions, which would be sufficient to mitigate any microbial contaminants that may be present due to subsequent handling and preparation prior to consumption. The proposed processing standard, Standard 3.4.1, has a temperature control requirement for the harvested cell biomass, as this is a potentially hazardous food (PHF) (refer section 3.4.1—10). As the standard has made clear it is a PHF, the temperature requirements applicable to PHF in Standard 3.2.2 will then apply and must be complied with. As a food business, the cell culturing food business must comply with Standards 3.2.2 and 3.2.3 which address good hygiene practices, good manufacturing practices and design of equipment. In addition, the proposed processing standard has introduced a specific requirement in

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		sections 3.4.1—4 and 3.4.1—7 for the cleaning and sterilisation of all relevant equipment. Decontamination and disposal, response and investigation procedures following detection of a microbial pathogen either in food or in the environment will be detailed in the applicant's HACCP or food safety program and will be managed in a similar manner as any other food business. The HACCP plan can be verified by competent authorities as required. This is a requirement of the proposed processing standard. Refer to Division 3 of Standard 3.4.1 for the requirements applicable to the cell culturing food business.
Cell harvest has multiple options that includes partial harvest or seeding of cells into a second bioreactor. The risk assessment does not specify if this is an aseptic technique to prevent contamination of the biomass.	SA Health	FSANZ notes partial or complete harvest of the bioreactor is unlikely to alter the identified hazards associated with harvesting processes. These processes, which are part of a closed or sealed production system, should prevent contamination of both the cell mass and residual cell culture. This will be detailed in the applicant's HACCP plan supported by good practices, which will cover maintenance of aseptic cell culturing during draw down procedures. Refer to proposed Standard 3.4.1, section 3.4.1—7(2) for the cell culturing specific requirements to be included under the food safety program.
Noted there are potential hazards that could contaminate the cell biomass at- and post-harvest, and recommended the cell biomass should undergo a recognised microbiological control step before consumption.	NZFS	Noted. The applicant has advised the final food is intended to be cooked and will be providing cooking instructions. FSANZ agrees that there are risks of contamination once the cell biomass has been removed from the bioreactors. Proposed amendments to Schedule 27 to include *Salmonella* spp. and *L. monocytgenes* microbiological criteria will apply to cell-cultured food. Amendments will also be made to the *Compendium of Microbiological Criteria for Food* to provide guidance to cell culturing food businesses on relevant process hygiene indicators for the harvested cell biomass and on appropriate environmental monitoring to assist with managing the risk of environmental contamination. The proposed processing standard also identifies the cell biomass as a potential hazardous food (PHF) (refer section 3.4.1—10) which gives effect to the temperature control requirements in Standard 3.2.2 for PHF.
Concerned some microbiological hazards identified	NSWFA	As part of the assessment, FSANZ determined which of the generic

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in Appendix IV of SD1 did not appear to have been addressed by the proposed risk management measures.		hazards listed by FAO/WHO (2023) were appropriate for this application and these were addressed. For completeness and to demonstrate FSANZ considered all identified potential hazards for cell culture processes identified by FAO/WHO (and other regulatory agencies), the relevant parts of the tables were included in SD1, including FSANZ comments as to whether or not they were considered in the final assessment.
The identification of unintentional agents that may be responsible for microbial contamination would also be useful.	DOH-WA	Noted. The proposed processing standard (Standard 3.4.1) will require the business to assess all hazards associated with their activities (refer section 3.4.1—4 and 3.4.1—7 by requiring compliance with Standard 3.2.1). In addition, such information may also be relevant for guidance material, similar to that provided in Safe Food Australia[4], for cell-cultured food products. Such guidance could include coverage of identification of sources and types of microbial contamination that could occur during production.
Suggested that as more information becomes available regarding cell-cultured foods, phenotypic characterisation of the expansion phase may be an appropriate method for real-time monitoring for microbial contamination.	CAA	Noted. FSANZ supports development of guidance, similar to that provided in Safe Food Australia, that will assist businesses and regulators determine the product is safe. FSANZ welcomes additional information that will assist in guidance development.
Suggested that there was no higher risk of *L. monocytogenes* contamination for cell-cultured foods as compared to other foods and it would be significantly reduced by appropriate cooking of the product.	CAA	FSANZ agrees there is no evidence to suggest the risk of contamination by *L. monocytogenes* is greater in cell-cultured food products than in other 'like' foods. However, as it is a concern for many food processors, *L. monocytogenes* has been identified as a potential hazard during activities such as cell harvest and post-harvest product handling. As neither the final food or its risk mitigation measures (e.g. cooking) were assessed, conclusions regarding microbial risks could not be made. FSANZ acknowledges proper cooking of the final food will mitigate the risk of *L. monocytogenes*. There is no history of consumption in Australia of cell-cultured food and limited experience in preparing cell-cultured food for consumption. As cell-cultured food is a potentially hazardous food, supporting the growth of microbial pathogens, FSANZ has proposed amendments to Schedule 27 to include microbiological criteria for *Salmonella* spp. and

[4] https://www.foodstandards.gov.au/publications/safefoodaustralia

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		L. monocytogenes in cell-cultured food.
Requested further explanation and definition on what cell biomass described as 'microbiologically sterile' means. Called for challenge studies with surrogates for foodborne pathogens, as described in SD1, to predate approval (page 22 of SD1).	NSWFA, GeneEthics	The bioreactor phase where the main cell expansion occurs is under hygienic controls to limit the potential ingress of foodborne pathogens during production. Therefore the cells are contained in a controlled environment within the bioreactor and, using good practices, should remain microbiologically sterile. However, once harvested, the cell biomass can be microbiologically contaminated from the environment or handling. FSANZ assessed microbiological data (which is CCI) on the shelf-life of harvested cells. FSANZ considers this data equivalent to challenge studies. The FSANZ assessment concluded the harvested cell biomass (and likely the final food) to be a potentially hazardous food as it supports microbial growth.
Nutrition risk assessment		
Asked FSANZ to clarify the source of folate in the harvested cells. One of the submitters suggested to undertake dietary modelling to consider the potential upper intake amounts in parallel with other dietary sources of folic acid.	NZFS, DOH-VIC & VIC DoEECA	The applicant provided data on the total folate content but did not specify the relative contribution of folic acid and natural folate. It is expected that folic acid would be added during growth and natural folate would be from the cells. Natural folate is 50-60% bioavailable and upper levels (ULs) are not set for it. Folic acid is synthetic, it is approximately 85% bioavailable and therefore ULs have been set. FSANZ used a conservative (worst case scenario) approach to estimate dietary intake, and assumed that the total folate content specified by the applicant was made up entirely of folic acid. Calculations were made using the applicant's suggested serving size of 300 g of harvested cells, which is an amount that is consistent with that for a high chicken/meat consumer. As the harvested cells are intended to be mixed with other permitted foods ingredients, the final serving size would be greater than 300 g which is considered to be unlikely, based on the estimated consumption at the 95th percentile for several meats in Australia of 300-330 g (Table 4 of SD1). At a 300 g serving size of harvested cells, the UL would only be exceeded for boys and girls aged 14-18 if all the folate in the final food was present as folic acid. However, a UL is the highest average daily intake level likely to pose no adverse health effects to almost all individuals in the general population. ULs are established on a long-term or chronic basis and

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		occasional exceedances are not likely to be of concern. Therefore no nutritional risk was identified due to the total folate content of harvested cells. Furthermore, the longer term high consumption (90th percentile or P90) amount of chicken for Australian males and females aged 14-18 years was estimated to be approximately 185 g per day (Table A3.2 of SD1) which is well below the suggested serving size (300 g per day). It is noted that the estimated P90 chicken consumption amount for New Zealand males aged 15-18 years (approximately 370 g per day) is higher than the respective population groups in Australia, however it is based on one day of food consumption data and thus does not reflect longer term estimates of consumption.
The protein specification is >4 g/100 g but the average protein content reported in the food ingredient was 9 g/100 g. This difference could have implications for the dietary exposure assessment.	DOH-VIC & VIC DoEECA	The average protein content of harvested cells was 9 g/100 g which was determined by external validated laboratory analysis and indicates the expected protein content. The lower protein specification of >4 g/100 g was requested by the applicant to reflect the alternative quantification method they routinely use in-house.
Noted that a comparison of amino acid content between media 1 and media 2 shows highly significant differences for all amino acids tested with the exception of Lysine, Methionine and Tryptophan. The applicant chose to present the media 1 values in the table at section C.6.2.3-1 of the application as the typical results, presumably because these are the closest to conventional quail meat.	Individual	FSANZ noted the lower essential amino acid content of harvested cells when grown in media 2 (section 4.2.3.1 of SD1) however the amino acid content was not of concern due to the lack of nutrient reference values for individual amino acids; the adequate protein intake of the majority of Australian and New Zealand populations; and the expectation that harvested cells will not be consumed regularly.
The concentration of biotin and cobalamin are higher than what is found naturally in food and would be unlikely to be permitted through conventional fortification. The conclusions of the nutrition risk assessment should not be influenced by the assumption that intake will be infrequent, since future patterns of consumption may change if	NZFS, Queensland Health, Community Voice Australia (second statement only)	FSANZ notes that requirements for fortification with biotin and cobalamin would not be met however the application was not being assessed on that basis. This application was assessed under the FSANZ Application Handbook guidelines as a novel food. When determining the nutritional risk of a novel food FSANZ considers estimated consumption levels, as per international best practice, using the Codex Risk Analysis framework[5]. Sub-section 1.1.2—8(e) of the Code requires the assessment of a novel

[5] https://www.foodstandards.gov.au/publications/riskanalysisfoodregulation

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cell-cultured products become widely accepted and accessible.		food to have regard to patterns and levels of consumption of the food. The nutrition risk assessment concluded that based on the likely infrequent consumption of cultured cells no safety concerns were raised due to the biotin and cobalamin content of cultured cells.
The complexity and nutritional value of synthetic nutrients in harvested cells is inferior to those found naturally in food.	Community Voice Australia, GE Free NZ, Individuals	The nutrition assessment was undertaken on the harvested cells and did not distinguish between nutrients that were synthesised by the cells and those that may have been added during the production process that may have been chemically synthesised. The scientific literature indicates that synthetic vitamins are at least nutritionally equivalent to nutrients derived from food (Herrero-Barbudo et al. 2006; Winkels et al. 2007; Carr et al. 2013; Lindschinger et al. 2020).
Noted the cell-cultured quail has not been served as food, and they are unaware of any trials looking at the health effects following consumption. As such, they query how there can be literature regarding the effects of eating it.	Community Voice Australia	Limited literature is available on potential adverse effects from the consumption of cell-cultured food as very few products have been developed and brought forward for regulatory approval. Much of the information that is available is therefore theoretical or speculative, i.e. not based on empirical evidence. However, FSANZ has undertaken an independent comprehensive nutrition risk assessment of the cell-cultured quail as outlined in SD1 and did not identify any nutritional concerns.
Called for FSANZ to produce evidence that a serving size of 300 g is an overestimate and that consumption levels of cultured quail will be low. This was in noting a recent study indicates that 42% of Australians' energy intake is from ultra processed foods, with cultured quail falling in this category, according to the submitter.	GeneEthics	The applicant suggested a serving size of harvested cells of 300 g, that would then be mixed with other ingredients for a final serving size of greater than 300 g. The assessment of the proposed serving size of harvested cells is detailed in section 4.3.5.2 of SD1. It indicates that for the Australian population aged 2 years and over, only 5% of respondents consume 300 g or more of meat (including chicken, beef, lamb, mutton and pork) per day, with similar results in New Zealand, for respondents aged 15 years and above, with the exception of beef. For the small number of respondents in the Australian 2011-12 nutrition survey who reported consuming quail, the mean consumption amount was 38 g/day. In addition, the findings of the 2023 FSANZ Consumer Insights Tracker, an online survey of 1237 Australian and 810 New Zealand consumers aged 18+ years (see SD3 from the 1st CFS for details), reported that 23.6% of consumers said they would include cell-cultured meat in their diet. A consumers' perception survey conducted in New Zealand reported that out of 572 respondents aged 25–55 years who were meat consumers, 30%

Submission viewpoint	Raised by	FSANZ response
		were willing to purchase cell-cultured meat (Giezenaar et al. 2023). The assessment of the likely consumption of harvested cells does not relate to the overall consumption of processed foods in the Australian or New Zealand diet. Harvested cells are likely to be a niche product that will be sold in restaurants and therefore are not likely to become a widely consumed product.
Junk food eaters may be more at risk from the high levels of cobalamin and biotin when eating synthetic cell-based substances.	GeneEthics	The National Health and Medical Research Council (NHMRC), New Zealand Ministry of Health and other agencies or bodies including the European Food Safety Authority, United States Food and Nutrition Board and Health Canada have not set upper levels of intake for cobalamin (vitamin B12) or biotin due to a lack of reports of adverse effects from cobalamin or biotin intake in humans or animals. Therefore FSANZ does not have concerns regarding the level of cobalamin or biotin in harvested cells.
Cultured quail would be adding to the availability of ultra processed junk food for sale which, according to a large body of evidence, is responsible for a range of chronic conditions.	GeneEthics	The current assessment considered the safety and nutritional quality of harvested cells as per the requirements of the FSANZ Application Handbook. Consideration of the broader issue of ultra processed foods is beyond the scope of the assessment.
There is potential that cell-cultured meat will be considered ultra processed food and avoided as governments look to enforce policy that minimises the consumption of ultra processed foods.	DOH-WA	Noted.
Dietary intake/ exposure assessment		
The nutrition or dietary exposure/intake assessment results should be applicable to the applicant's product, regardless of scale. In addition, it was suggested that to fully appreciate potential future dietary scenarios, modelling should be conducted for high consumers based on current upper levels of meat consumed (as opposed to chicken only).	NSWFA, DOH-VIC & VIC DoEECA	The worst case scenario was considered for the dietary intake/exposure assessments, i.e. consumers choose to consume the harvested cells at a high serve size of 300 g/day, as proposed by the applicant. This was in addition to conventional meat including chicken which represents a potential future worst case dietary exposure/intake scenario (section 4.3.4.1 of SD1). According to the assessment conducted on the proposed serving size compared to conventional meat consumption data (including beef, lamb, pork and chicken), the results indicated that a 300 g serving size predominantly corresponds to the 95th percentile of chicken consumption. and other meat types for the Australian population (300-330 g) and the 95th percentile chicken consumption for the New Zealand adult population (282 g) (section 4.3.5.2 of SD1). Thus, the dietary

Submission viewpoint	Raised by	FSANZ response
		intake/exposure assessments conducted reflect high consumption of other meats (e.g. beef, lamb and pork). It is noted that the higher 95th percentile consumption amounts of beef for New Zealand children and adults, in comparison to the Australian population, were estimated. This is attributed to the consumption data distributions as a result of needing to report the New Zealand children (aged 5-14 years) and adults (aged 15 years and above) separately based on separate dietary surveys, as opposed to the Australian population (aged 2 years and above) as a whole. As well, it is noted that the harvested cells will be mixed with other permitted food ingredients to form the final mixed food products (e.g. log, roll or patty) that may reduce actual consumption amounts of the harvested cells in the final food than the estimated amounts in its own right.
Consumer evidence		
The FSANZ literature review appears to indicate that whilst the term 'lab-grown' assists consumers to correctly identify these products, it has lower levels of perceived safety. The submitter queries why, in choosing the mandated statement, FSANZ appears to have given greater consideration to consumer perception (and the malleability of perceptions) rather than consumers' ability to correctly identify the product. Specifically, the submitter queries how does this lie within the scope of FSANZ's responsibilities.	Community Voice Australia	FSANZ has undertaken a comprehensive safety assessment of cell-cultured quail to ensure it is safe for human consumption. 'Lab-grown' or another term that leads consumers to perceive the product as less safe would be inaccurate and misleading. The FSANZ literature review found that in addition to enabling consumers to understand the nature of the food, the terms 'cell-cultured' and 'cell-cultivated' were also the best performing terms in relation to consumer understanding of allergenicity and their ability to correctly identify that the product was not safe to consume for those with an allergy to the traditional counterpart food.
Commented the studies cited in the FSANZ literature review to support the use of terms do not appear to represent a broad section of the communities in which they were conducted.	AIFST	The limitations associated with the existing literature were acknowledged by FSANZ in its review. However, the studies that examined consumers' objective understanding of cell-cultured meat terms involved large, nationally representative samples in the USA. Studies that examined perceived understanding involved smaller but still nationally representative studies in the USA, UK, and Brazil.
Urged FSANZ to consider wider industry research and experiences showing that consumers are able to adapt to the use of a range of qualifiers, formats	Animal Justice Party, Food Frontier	As stated above, in conducting its literature review, FSANZ examined the available evidence on consumers' understanding, preference and acceptance of different terminologies for cell-cultured meats. This included

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and utility terms on labelling to accurately describe the product. Presented additional information and references examining consumer awareness of cell-cultured meat, perceptions of safety, and consumption intentions as follows: • ProVeg (UK 2023) found: – limited consumer understanding of the term 'cultured meat' and cellular agriculture – approximately one third of respondents would definitely or probably try meat hybrid burger. • A UK online study found that meat eaters perceived cultured meat products as equally or more healthy, but more disgusting than conventional meat products (Vural et al. 2023). • A 2019 study (Bryant and Barnett 2019) found consumption intentions could be partly dependent on how the product is framed, with 'clean meat' and 'animal free meat' eliciting more positive attitudes towards cell-based meat. One submitter referred to consumer research looking at the knowledge and perceptions of cultured-meat consumers in China, Japan, Singapore, South Korea and Thailand (Heizen 2022). When asked which of a variety of product names would most prompt them to buy a meat product grown directly from animal cells, the results revealed a range of views. However, in Singapore where cultivated meat is available for purchase and where the highest consumer awareness responses were recorded, 'cultivated' was the preferred term, followed closely by 'cell-cultured' meat.		unpublished literature, such as market research, where it met the inclusion criteria. Studies that examined the effect of different terminologies on consumer acceptance, but not on consumer understanding (i.e. Bryant and Barnett 2019) were excluded. This ensured a clearer picture of which terminology achieved a balance between consumer acceptance and understanding. FSANZ notes the findings of the ProVeg (UK 2023) study. The finding that consumers have a limited understanding of the term 'cultured meat' is consistent with the findings of FSANZ's rapid review and the University of Adelaide's systematic review. The finding that approximately one third of UK consumers would be willing to try a plant-based/cultivated meat hybrid burger is also broadly consistent with the findings of FSANZ's Consumer Insights Tracker (CIT), where a minority (approx. 24%) reported that they would be willing to try cell-based meat. Results from the CIT are nationally representative of the Australian and New Zealand population and were incorporated into the risk assessment that was provided with the 1st CFS. The study by Vural et al. (2023) was incorporated into FSANZ's literature review that was released with the 1st CFS. As concluded in FSANZ's literature review, consumer perceptions of the healthiness of cell-cultured meat relative to traditional meat is mixed across studies and appears highly malleable depending on the type of information received about cell-cultured meat and product categories compared. This conclusion is consistent with the findings of the University of Adelaide's literature review. FSANZ notes the Heizen (2022) finding that Singaporean consumers prefer the term 'cultivated'. This finding is consistent with the findings of FSANZ's rapid review and the University of Adelaide's systematic review that the terms 'cultivated' and 'cultured' are more appealing to consumers than other terms. FSANZ must consider evidence supporting terminology that assists consumers to accurately identify cell-cultured food from conventional food, thus enabling informed choice and ensuring they are not being misled. Consumer acceptance is not a primary concern for setting labelling

Submission viewpoint	Raised by	FSANZ response
		regulations.
Noted that a more comprehensive literature review was being undertaken by the University of Adelaide and looked forward to its results. An individual submitter raised that this review, which FSANZ commissioned, is not standard practice for applications, and will increase the cost of the application.	NZFS, NSWFA, Food Frontier, Individual	FSANZ independently commissioned this research to inform a broader consideration of consumer attitudes to cell-cultured food beyond the current application.
Noted the level of consumer understanding of the nutritional difference between cell-cultured meat and conventional meat is unclear and was hopeful that the full systematic literature review would provide greater clarity in this area.	NSWFA	FSANZ's rapid review (SD2 of the 1st CFS) found that consumer perceptions of the healthfulness or nutritional value of cell-cultured meats were varied, depending upon the way in which cell-cultured meat was described and the product categories compared. The full systematic review commissioned from the University of Adelaide (available as SD3 of this 2nd CFS) also found that there were mixed perceptions regarding the healthiness and nutritional quality of cell-based meat compared to traditional meat.
One submitter noted the results from the FSANZ Consumer Insights Tracker (CIT), which found that most consumers reported they would not be confident in the safety of cell-cultured meat if it became available for sale in Australia/New Zealand. The submitter noted that the lack of faith in the food regulatory system to ensure safe and suitable food is a concern. Another submitter referenced the CIT and noted the vast majority of the public is unaware of lab meat and what it entails, and this is not assisted by how it was represented in Figure 1 of SD4 at the 1st CFS.	SA Health, Community Voice Australia	Consumer levels of trust in the food regulation system more broadly are also measured in the CIT. Full results are available on FSANZ's website at: https://www.foodstandards.gov.au/science-data/social-science. In response to the other comment, it is important to note FSANZ did not represent cell-based meat using the graphic included in Figure 1 of SD4. Instead – as articulated in the caption of the figure in SD4 – the figure in SD4 was an 'Example narrative targeted to consumers' developed by industry.
Queried how there can be literature on public responses to cell-based meat, given that there are low levels of consumer awareness and knowledge due to it not being in the marketplace.	Community Voice Australia	FSANZ undertook its own rapid review (SD2 of the 1st CFS) to examine existing evidence around consumer understanding, preference, and acceptance of different terminologies for cell-cultured meat, and consumer perceptions of the nutritional value of cell-cultured meat relative to conventional meat. Twenty-six studies were included in this review.

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		This was supplemented by data from FSANZ's inaugural CIT, which asked respondents about their awareness and understanding of cell-cultured meat, as well as their consumption intentions. FSANZ also commissioned a full systematic review from the University of Adelaide, which examined consumers' awareness, level of knowledge, perceived risks and benefits, terminology preferences, and behavioural intentions and motivations (see SD3 of this 2nd CFS). As cell-cultured meat is not currently available on the market (except for, as understood by FSANZ, some limited availability in Singapore), the self-reported and prospective nature of these studies is a known limitation. However, it is the best available evidence regarding consumers' potential responses were it to be introduced into the market in Australia and New Zealand.
One submitter proposed research and education as follows: • conduct focus groups comprising both meat eaters and non-meat eaters to help ascertain the best way to describe cell-based meat to Australian people • undertake research to determine the most positive terms to use when introducing cell-based meat in both Australia and overseas • conduct a government education campaign on cultured meat products. In addition, another submitter suggested that, if further consumer testing is undertaken, a potential area to explore is whether the use of meat-related terms (e.g. sausage, patties) for cell-cultured foods will be clear to consumers.	Animal Justice Party, NSWFA	FSANZ notes these suggestions.
Supported FSANZ measuring and monitoring consumer understanding of cell-cultivated meat, including via the more comprehensive systematic literature review underway.	Food Frontier, WePlanet	FSANZ notes these comments. FSANZ considers its evidence-based approach to labelling requirements will promote consumer understanding and familiarity and, as such, remain relevant over time, even as the technology evolves. The full systematic literature review commissioned by

Submission viewpoint	Raised by	FSANZ response
		FSANZ from the University of Adelaide is provided at SD3 of this 2nd CFS.
Noted single ingredient meat products are exempt from the requirement to display a NIP. As such, consumer awareness of the relative difference in sodium levels between single ingredient meat products and the cell-cultured product (which has relatively higher levels), and the dietary implications may be an issue. Therefore, educational material may be beneficial to support consumer understanding. Consideration of broader contextual labelling measures may also be helpful, although it is recognised this is outside the scope of the application.	DOH-VIC & VIC DoEECA	The applicant has provided information on the nutrient composition of the new food ingredient i.e. the cell-cultured quail. The cell-cultured biomass is intended to be mixed with other ingredients to form products such as, but not limited to, logs, rolls and patties. As such, a comparison of the sodium levels in the mixed quail product available for sale against a single ingredient meat product would be of limited use. Rather, a comparison of sodium values against similar mixed food products made with conventional quail (or other conventional poultry meat or meat alternatives) would provide more valuable information enabling the consumer to make an informed choice about their sodium intake. Regarding educational material, FSANZ acknowledged in section 3.4 in SD4 of the 1st CFS that consumer education about cell culturing techniques is necessary to assist consumer awareness and understanding of this new technology.
Comments regarding proposed regulatory provisions		
Production/processing requirements – food safety		
Support was expressed for mandating Standard 3.2.1 Food safety programs, but submitters raised there is a need for processing/production requirements similar to those in production standards (i.e. using a systems based approach). Submitters also raised that guidance was needed on what must be included in the food safety program to manage food safety.	Queensland Health, DOH-WA, NSWFA, DOH-VIC & VIC DoEECA, DAFF (Late comment)	FSANZ has proposed a production and processing standard: Standard 3.4.1 – Food safety requirements for processing of cell-cultured food, with requirements specific to cell-cultured food (refer to sections 3.4.1—3, 3.4.1—5, 3.4.1—8 and 3.4.1—10 as examples. See proposed section 3.4.1—10. The FSANZ assessment concluded the harvested cell biomass (and likely the final food) to be a potentially hazardous food as it supports microbial growth. Its production requires handling measures during sourcing, cell line development, cell expansion, harvest, packing, storage and further processing stages. Refer to SD4 for more information on the processing standard, Standard 3.4.1.
Queried: • At what point in the production are the cells considered a food. • When is it food handling?	Queensland Health, SA Health, DAFF (Late comment)	FSANZ reviewed relevant definitions and whether amendments are required to provide clarity on application of the Code to the production of cell-cultured foods. FSANZ prepared a new draft standard, (Standard 3.4.1), with new and amended definitions to address these issues. These

Submission viewpoint	Raised by	FSANZ response
• Does the definition of primary production apply? These issues would need to be clarified to apply Standard 3.2.1.		are included at Attachment A of this report. As the definitions of food, food handling and food business are interlinked in Chapter 3 definitions, amendments are proposed to ensure cell-cultured food (at all stages of production), the handling/production activities and the food business are able to be regulated by jurisdictions as *food* under Chapter 3. These proposed Code amendments are in Attachment A for comment. An amendment is proposed for the definition of a food business within Standard 3.1.1 to clarify a cell-cultured food producer is a food business. As noted above, the proposed regulatory measures are premised on cells, cell lines and the cell biomass each being declared to be a *food* for the purposes of the Code and the food laws that apply the Code. FSANZ's understanding is that this would provide the certainty required for regulation.
Noted that section 2.5.3 in the 1st CFS refers to the business having to comply with *Chapter 3 standards, including validation of the safety of the final food.* Recognising New Zealand's food safety provisions differ, this submitter suggested that the New Zealand requirements are also represented in this 2nd CFS.	APC	The proposed requirements under proposed Standard 3.4.1 and Chapter 3 will apply only in Australia. New Zealand has their own requirements for a risk management plan operating under either the *Food Act 2014* (NZ) or the *Animal Products Act 1999 (*NZ*)*.The food safety standards that comprise Chapter 3 of the Code do not form part of the joint Australian New Zealand Food Standards system.
Requested a FSANZ and jurisdictional working group be established to work through the many issues associated with regulating these new foods for food safety (to include issues such as auditor competency, what must be included in HACCP, audit and enforcement tools).	Queensland Health, SA Health, DOH-WA	Noted. FSANZ and the jurisdictions, including New Zealand Food Safety have formed such a working group.
Noted the applicant's fermentation facility is operating in advance of receiving any approval by FSANZ. This raises questions about adherence to regulatory processes.	Individual	A food cannot be sold before it has had a pre-market safety assessment and FSANZ notes that the food is not being sold in Australia or New Zealand at this time.
Imported product Clarification was sought on whether the assessment is dependent on the product being manufactured in	Queensland Health, DAFF (Late comment)	The applicant is based in, and advises this food will be produced in, Australia.

Submission viewpoint	Raised by	FSANZ response
Australia or whether it could be manufactured elsewhere and imported (in which case it would be subject to the *Imported Food Control Act 1992)*. Noted there needs to be consideration of imported cell-cultured food. FSANZ will be requested to provide an imported food risk statement for cell-cultured food.		The proposed amendments will prohibit all cell-cultured food (CCF) as a food for sale or an ingredient /component in a food for sale unless expressly permitted by the Code. This applies to imported CCF.
Imported product The importation of the cell line for cultured quail production or cultured quail products into New Zealand, must meet the import health standard (IHS) requirements under the Biosecurity Act 1993. Biosecurity requirements would also apply at manufacturing/ production sites. There are also applicable animal welfare requirements when removing tissue from live animals. Documents outlining the policy and regulatory positions for trading animal cell-cultured products in New Zealand are currently in-draft.	NZFS	Noted.
Nutrition risk management		
Suggests setting a maximum level for vitamins and minerals in a new category in Schedule 17 of the Code.	NSWFA	Standard 1.3.2 and Schedule 17 of the Code relate to vitamins and minerals added to foods for a nutritive purpose. Schedule 17 provides maximum claim amounts, and maximum permitted amounts of vitamins and minerals per reference quantity for various product categories, including analogues of meat. In the case of harvested cells, vitamins and minerals are present as a result of the production process and are not considered to be used as a nutritive substance. As discussed in SD1, FSANZ did not identify any nutritional risks with consumption of harvested cells containing the levels of vitamins and minerals provided in the application. FSANZ therefore is not proposing to set maximum limits of vitamins and minerals for cell-cultured quail.
Definition		
Supported the inclusion of a new definition for 'cell-cultured food' in the Code to provide clarity and	APC, WePlanet, DOH-VIC & VIC DoEECA,	FSANZ's response to submissions, including the reasons for its approach, is provided in section 2.3.1.4 of this report.

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underpin other requirements. Comments included:
• The definition should include that cell-cultured food is a novel food in the Code. This would clarify that subsections 1.1.1—10(5) and (6) apply to cell-cultured food and, as such, prohibit the use of cell-cultured food as food for sale or as an ingredient or component of food for sale unless explicitly permitted in the Code.
• In addition to what FSANZ proposes, the definition should not exclude any components found in conventional animal meat or meat flesh, as defined by the Code.
• It should be clear from the definition whether it includes foods produced:
  ○ from cultured cells where the cells are not the final food (such as cultured mammalian cells producing milk)
  ○ using precision fermentation (noting these are derived from bacterial or fungal cell culture).
• Conversely, one submitter contended it would be premature to assume that the proposed definition will cover all subsequent foods and, as such, recommended it be applicable to the product currently under assessment.
• There should be scope to modify/expand the definition in a timely manner to include broader cell types as the category evolves.
	Queensland Health, DAFF (Late comment), AFGC	

Specification – microbiological criteria		
Concerned the proposed microbiological specifications are not sufficient to provide adequate safety assurance of the food product, particularly given the high moisture content and the unknown potential for growth of pathogens. This includes the absence of a specification for coagulase-positive staphylococci and *L. monocytogenes*, in the	DOH-VIC & VIC DoEECA, DOH- WA, SA Health, Queensland Health, NSWFA, Individual	FSANZ's response to submissions, including the reasons for its approach, is stated in section 2.3.2.3 of this report. Amendments to Schedule 27 are proposed to include microbiological criteria for cell-cultured food for two pathogens – *Salmonella* spp. and *L. monocytogenes*.

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proposed final product testing by the applicant. Recommended including specifications in Schedule 27 linking to section 1.1.1—11 of the Code and Standard 1.6.1 as well as Standard 1.2.6 for directions of use. One submitter suggested a drafting approach per Application A1186 (soy leghemoglobin). Future work including shelf-life studies and microbial assessment method validation was recommended.		See section 3.4.1—10 of the proposed processing standard, where the cell biomass is identified as a potentially hazardous food requiring temperature control.
Requested that *L. monocytogenes* be included in final product specification, in addition to routine environmental testing. They noted that SPC, *E. coli* and Enterobacteriaceae are not reliable indicators of contamination, particularly *Listeria.* They note that *Listeria* is a significant microbiological hazard.	SA Health, NSWFA	FSANZ's response to submissions, including the reasons for its approach, is stated in section 2.3.6.2 of this report. Amendments to Schedule 27 are proposed to include microbiological criteria for cell-cultured food for two pathogens – *Salmonella* spp. and *L. monocytogenes.*
Specification – other		
Noted a lack of information regarding specifications for the cultured quail, also in regard to detection limits for allergens. It was assumed the specification at point of harvest would include the animal species (*Coturnix japonica*) and cell type (fibroblasts), noting that specifying the animal species may be important for enforcement purposes. A specification for purity or other criteria to provide protection against food fraud has not been proposed. Appropriate risk management options should be considered in relation to food fraud for the current application and more broadly (e.g. other foods produced by novel cell culturing and precision fermentation technologies). This to ensure the Code is future proofed in relation to these risks.	Individuals, GeneEthics, Queensland Health	FSANZ's response to submissions, including the reasons for its approach, is stated in section 2.3.1.3 and 2.3.2.3 of this report. Amendments to Schedule 27 are proposed to include microbiological criteria for cell-cultured food for two pathogens – *Salmonella* spp. and *L. monocytogenes*.

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A submitter noted that section 1.1.1—15 of the Code states that Schedule 3 specifications only apply to novel foods *'added to food in accordance with this Code, or sold for use in food'.* While the applicant's harvested cells are intended to be mixed with other foods prior to sale, FSANZ may need to consider amending section 1.1.1—15 to ensure specifications for novel foods apply both when the whole novel food is consumed and when added to other foods. This is to cover off any future applications of novel foods that may be consumed in their own right (or included in Proposal P1024 – Revision of the regulation of nutritive substances & novel foods[6]).		
Conditions of use		
Comments regarding conditions of use were: • a specified name be used to ensure the permissions are unique to the applicant's product • it is not clear why the application included a condition the cell-cultured quail be mixed with other foods (noting this is how the product is intended to be offered) • the conditions of use '…mixed with other ingredients to form … logs, rolls and patties' needs more refinement in that by effect the proposed condition would mean the product by itself cannot be sold as food for sale; it has to be used as an ingredient of food for sale. This needs to be appropriately captured in Schedule 25 • the conditions of use must include that the product must not be added to infant formula	NSWFA, Queensland Health, DOH-VIC & VIC DoEECA, WePlanet	FSANZ's response to submissions, including the reasons for its approach, is stated in section 2.3.1 of this report.

[6] https://www.foodstandards.gov.au/food-standards-code/proposals/P1024

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products (assuming this application will be finalised before transitional provisions associated with Proposal P1028 – Infant formula[7] expire, which include prohibitions on novel foods being included in IFP). A comment relating specifically to Schedule 25 was that the listing of permitted cell-cultured food should comprise a product-by-product positive list (similar to FDA[8]), with conditions to include specific regulatory limitations (e.g. naming conventions).		
Noted they cannot use the 'conditions of use' per Schedule 25 to mandate compliance with processing requirements (Standard 3.2.1 – how you make the product). Conditions of use applies to the 'end product' and how it is used, not how it is made. As such, this would not be legally enforceable for jurisdictions. Noted that food businesses in Australia must comply with the Food safety standards in Chapter 3 of the Code, including general food safety requirements and the requirement to develop and implement a food safety program. Therefore, the requirement for the proposed condition of use 'food must be produced under a food safety program in accordance with Standard 3.2.1 of the Code' is unnecessary duplication.	Queensland Health, NSWFA, AIFST	FSANZ has drafted a new standard: Standard 3.4.1 – Food safety requirements for processing of cell-cultured food, which mandates a food safety program as per Standard 3.2.1 which must include additional measures unique to culturing cells for food purposes. Refer to the proposed Code amendments at Attachment A (see sections 3.4.1—4 and 3.4.1—7 of the proposed processing standard). Standard 3.2.1 is not mandatory for all food businesses. It is applied to businesses under the Food Acts depending on the food safety risks associated with the activities and food being handled. FSANZ's risk assessment identified that to manage microbiological hazards, cell-cultured food should be produced under a HACCP-based approach.
Cost and benefit considerations		

[7] https://www.foodstandards.gov.au/food-standards-code/proposals/P1028
[8] https://www.fda.gov/food/human-food-made-cultured-animal-cells/inventory-completed-pre-market-consultations-human-food-made-cultured-animal-cells

Submission viewpoint	Raised by	FSANZ response
Noted the following statements in section 2.5.1 of the 1st CFS, commenting that the absence of proof is not proof of absence: • 'The risk assessment did not identify any safety concerns that could not be adequately managed from permitting this cultured quail cells ingredient.' • 'Use of the foods derived from cultured quail cells would be voluntary and this application is deregulatory.' Queried whether FSANZ's conclusion that benefits arising from permitting cultured quail cells would most likely outweigh the associated costs took into account the University of Adelaide literature review examining consumers' levels of awareness and understanding.	Individual	The statement 'The risk assessment did not identify any safety concerns that could not be adequately managed from permitting this cultured quail cells ingredient' is based on the risk assessment findings as described in SD1 of this report. Regarding the second statement, FSANZ re-confirms that the application is for an additional permission for voluntary use of foods derived from cultured quail cells. Any additional permission is deregulatory by definition. In response to the submitter's query, FSANZ received the full systematic review commissioned from the University of Adelaide in December 2023 (available as SD3 in this 2nd CFS). Its findings have informed this 2nd CFS, including FSANZ's consideration of costs and benefits.
Approval of lab-based foods raises issues of equity in terms of who can afford non-synthetic food and who have no choice but to eat synthetic food. Conversely, there are studies that indicate lab-based foods will never be able to reach a cost point where it is possible to feed the global population[9].	Community Voice Australia	Costs and benefits were considered for this application alone. FSANZ cannot currently predict any long-term market impacts of this application, including any market concentration among certain producers. However, under this scenario all consumers would be better off, all other things being equal. Some consumers would just be preferencing other areas for spending. Likewise, under this scenario, some consumers could be getting access to a relatively affordable protein source for the first time.
The consideration of costs and benefits understates the benefits to society of making cell-cultured foods available. Development of these foods sits firmly in the realm of public benefit due to: • reduction in animal suffering • reduction in agricultural land use • increase in food diversity	WePlanet	There is currently a large amount of uncertainty about how much markets would grow for mixed foods derived from cultured quail cells or for cell-cultured foods generally. Internationally, such foods are generally starting at higher prices than conventional food substitutes, relatively small quantities, and have not yet reached a production scale for certainty about any wider costs or benefits. Therefore, it is not currently possible to speculate on any longer-term

[9] https://thecounter.org/lab-grown-cultivated-meat-cost-at-scale/

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• expected reduction in greenhouse gas emissions • expected reduction in zoonotic diseases • expected reduction in foodborne diseases • expected increase in food security. The 1st CFS stated that consumers may have marginally increased choice of foods. However, the submitter notes that while the application relates to a single product, it belongs to a new food category. Development of this category represents a significant expansion in consumer choice. The 1st CFS understates the benefits to industry. The submitter is of the view there are significant economic opportunities for the market, which are dependent on regulation that enables innovation.		implications for food availability, the environment, consumer choice, or industry benefits, particularly from this application alone. FSANZ notes that based on current knowledge it is not possible to determine if these are likely outcomes in terms of reduction of zoonotic diseases and foodborne disease reduction.
Labelling		
Food identification: terminology		
Did not support mandating any specific term or statement for food identification because: • mandating terms is premature because the sector is new • a range of terms are currently used by industry, academia and the media internationally, as demonstrated by the FAO/WHO publication (2023) • it could impede global trade as it is not consistent with other international regulatory authorities. A less prescriptive approach similar to Singapore's regulatory approach would enable: • adoption of nomenclature that is already in use in international markets (in particular 'cell-	CAA, APC, AIFST, Food Frontier, GFI & APAC-SCA, AFGC, WePlanet	Consumer evidence indicates the use of clear and consistent terms assist consumer understanding (section 3.1.5.4 of SD4 to the 1st CFS). Noting evidence indicates that both 'cell-cultured' and 'cell-cultivated' perform equally well in terms of consumer understanding and use, FSANZ has revised its proposed approach to require either 'cell-cultured' or 'cell-cultivated' in conjunction with the name used for cell-cultured quail, which will provide flexibility and facilitate international harmonisation in the future. See section 2 in SD2.

Submission viewpoint	Raised by	FSANZ response
cultivated'), which would support trade facilitation while maintaining sufficient consumer information • the development of new technologies without the need to update the Code to keep pace with a developing international landscape and market. Suggest 'cultivated', 'cell-cultivated', 'cultured', and 'cell-based' are acceptable qualifying terms.		
Did not support the proposed statement 'cell-cultured' because it was viewed as misleading, misrepresentative, uninformative, unappealing and/or confusing for consumers. Specific comments included: • the word 'cultured' is often associated with traditionally fermented products e.g. kefir and yogurt • common understanding is such that cell cultures are of whole organisms and not of a single cell line from a multicellular organism • the term does not fully capture the essence of the process and the environmental and ethical advantages.	Individuals, CAA, GFI & APAC-SCA	Consumer evidence indicates terms that incorporate the word 'cell' (e.g. 'cell-cultured') best enable consumers to correctly identify the true nature of the product and are perceived as being the most descriptive by consumers (see section 3.1.1 in SD4 of the 1st CFS). This finding is supported by a literature review (see SD3 to this report). No evidence was provided to support the view that consumers commonly understand cell cultures are of whole organisms. FSANZ's systematic review and the University of Adelaide consumer literature review found the term 'cell-cultured' enabled consumers to accurately identify a cell-cultured food from a conventional counterpart food, indicating it is appropriate for food identification purposes. FSANZ notes that issues regarding consumer understanding of the technology may be better addressed through education. See section 2 of SD2 for further discussion regarding terminology.
Preferred the term 'cultivated' for the following reasons: • provides consumer clarity and supports informed consumer choice • has higher levels of consumer appeal/acceptance than 'cultured' terminology • the term aligns with consumers' growing preference for environmentally responsible and ethically produced food options	Food Frontier, WePlanet, CAA, AIFST, GFI & APAC-SCA, NZFS	As noted above, FSANZ has revised the labelling approach to require either the statement 'cell-cultured' or 'cell-cultivated' to be used in conjunction with the name of the cell-cultured food. See response above and section 2 in SD2 for discussion on this issue.

Submission viewpoint	Raised by	FSANZ response
• indicates the product is grown from cells in a controlled environment, distinguishing it from traditional meat products • is consistent with global trends and regulations • consumers would become accustomed to the term before cell-cultivated seafood becomes commercially available (i.e. would mitigate any potential for consumers misidentifying cultivated seafood as being from conventional aquafarming • describes future production processes involving post-harvest cell-mixing and 3D printing, noting that where 3D printing is used, bioreactors will likely still be used due to their efficiency, as a large amount of culture dishes and manual labour would otherwise be required for 3D printing. Supported the term 'cell-cultivated', although for most submitters it was in the context of not mandating a qualifying descriptor. Suggested FSANZ considers the pros and cons of 'cell-cultured' and 'cell-cultivated' in relation to implications on trade, consumer understanding, and technical correctness, before finalising the prescribed statement.		
Considered the term 'lab-grown' was more appropriate than 'cell-cultured' because it would provide clear information about how such products were made and enable informed choice.	Individuals, GE Free NZ	As discussed in SD4 to the 1st CFS, consumer evidence indicates that terms such as 'lab-grown meat' do not consistently perform well in relation to accurate product identification, differentiation, preferences and/or acceptance. As noted above consumer evidence indicates terms that incorporate the word 'cell' (e.g. 'cell-cultured') best enable consumers to correctly identify the true nature of the product and are perceived as being the most descriptive by consumers (see section 3.1.1 in SD4 of the 1st CFS).

Submission viewpoint	Raised by	FSANZ response
Food identification: name of the food		
Commented any term used in the qualification of an ingredient should match that used in a food name, noting this would avoid potential confusion and indicate allergenicity.	CAA, APC	FSANZ has included in the draft variation a requirement for the same statement to be used in the ingredient name and the name of the food (if that food is represented as a cell-cultured food product). See section 4 of SD2 for discussion on this issue.
Recommended the statement 'cell-cultured' be positioned in close proximity to the name of the food, as opposed to being included in the name of the food.	APC	After consideration of submissions, FSANZ considers this approach could be less clear and insufficient to alert consumers to the true nature of the food. Requiring the statement to be part of the name of the food will ensure consumers can make an informed choice and not be misled. The proposed draft variations maintain the approach at 1st CFS for the required statement and name of the cell-cultured food to be used in the name of the food for sale.
Food identification: use of the term 'meat'		
A submitter considered the term 'meat' should be prohibited for use in the name of the product to avoid misleading consumers because the ingredient consists of quail fibroblasts and no skeletal muscle tissue. In contrast, a submitter supported the use of the term 'meat' in the name of the food or as part of the ingredient name, provided it is accompanied by a qualifying term to identify the true nature of the product. Another submitter commented the proposed approach suggests cell-cultured products derived from meat flesh (which may be the subject of future applications), may be labelled as 'meat'.	Queensland Health, APC, Opo	At 2nd CFS FSANZ is maintaining the proposed approach as at 1st CFS (see section 3.4 in SD4). See section 5 in SD2 for FSANZ's response. In respect to future cell-cultured products derived from meat flesh being labelled as 'meat', based on the current definitions for 'meat' and 'meat flesh' in subsection 1.1.2—3(2) of the Code, using the term 'meat' in isolation for a food product containing cultured cells, even if muscle-derived, would be inaccurate and misleading for consumers and would result in regulatory uncertainty for enforcement agencies. In contrast to the Code definition for 'meat', the cell culture has not undergone slaughter, nor is it part of an animal carcass.
Food identification: other labelling information		
For clarity and to avoid misleading consumers, called for a consensus in nomenclature across species (including livestock, poultry, fish, and	Individuals, Opo	Based on the existing requirements in the Code for ingredient names and food names (see sections 3 and 4 in SD2), FSANZ considers mandating the species name to accompany the statement is unnecessary.

Submission viewpoint	Raised by	FSANZ response
shellfish) and cell type (e.g. embryo-derived, muscle-derived or, fat-derived). For example, for the food product containing cultured quail cells, the food name 'cultured quail made with embryonic fibroblasts' was suggested.		FSANZ expects food businesses will likely want to feature the name of the species and therefore additional mandatory requirements may be unnecessarily burdensome and give food businesses less flexibility around the labelling of their product. In regard to the cell type (e.g. whether it is derived from embryos, muscle or fat), there is no evidence from the FSANZ literature review on whether consumers would find this level of detail useful or relevant for making an informed decision. As the technology is new it is likely that a statement that assists them in identifying a cell-cultured food from its conventional counterpart would be the most meaningful. FSANZ also notes that requiring the species name and cell type (source), as suggested, would be unnecessarily restrictive compared to current international and overseas regulations, potentially impacting harmonisation.
Commented that the cell source (e.g. 'Japanese Quail – sustainable cell-based food') should be declared, stating that consumers would need to know this information for the following reasons: • the term 'cell-cultured' is not informative or appealing • the proposed term 'cell-cultured' should not prejudice such a remarkable innovation in food production as cell-based food.	Individual	Based on the consumer evidence (see section 3.1.1 in SD4 of the 1st CFS; and SD3 to this report), FSANZ considers the terms 'cell-cultured' and 'cell-cultivated' are informative because they would enable consumers to accurately identify cell-cultured food products as distinct from conventional counterpart food products. FSANZ notes generic food and ingredient name requirements will apply to cell-cultured food, including the requirement for a name that reflects the true nature of that food or ingredient. The use of 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the ingredient (and the name of the food for sale if it is represented as a quail food product) would inform consumers that the cell-based food ingredient is from quail. Regarding whether the terms 'cell-cultured' or 'cell-cultivated' are not appealing, FSANZ has stated that consumer acceptance is not part of FSANZ's consideration of food identification requirements (section 2 in SD4 of the 1st CFS). The same applies to the issue of consumer appeal. However, industry can voluntarily include information about the cell-source.

Submission viewpoint	Raised by	FSANZ response
Commented proposed labelling requirements did not seem to inform the consumer of the immortalisation method used. They viewed this as a safety concern, noting that each method of immortalisation carries unique real and perceived risks.	Individual	As noted earlier in this table (see FSANZ's response under *Cell line – safety and immortalisation*), FSANZ has undertaken a comprehensive safety assessment on the immortalised cell line (SD1) and is satisfied that there are no specific food safety concerns. Therefore, FSANZ is of the view that mandating this type of additional information could confuse the majority of consumers and would not assist informed choice. It would also pose a greater impost on industry to compile and provide additional information.
Sought clarification on whether it would be a requirement that the ingredient list (i.e. statement of ingredients) list media components still present in the product. Commented that the recombinant growth factors used should be labelled for clarity purposes.	SA Health, Individual	The cell-cultured biomass is intended to be mixed with other ingredients to form products such as, but not limited to, logs, rolls and patties. FSANZ does not intend to require the ingredient list of those final products to include any media components that are still present in the cell-cultured biomass. This is consistent with the approach taken for foods produced using precision fermentation. Recombinant growth factors were used to support the growth of cells during culture. However FSANZ does not consider these growth factors to be 'food produced using gene technology' (see FSANZ's response above relating to 'growth factors'). Labelling for GM food would therefore not apply to these recombinant growth factors.
Food identification: hybrid food products		
Sought clarity on the labelling requirements that would be applicable to a product represented as a quail product that contains both cell-cultured quail and conventional quail meat.	NSWFA	If a permitted cell-cultured food is used as an ingredient in a food for retail sale in addition to a conventional counterpart ingredient, the proposed labelling requirements for cell-cultured food would still apply to that food for retail sale. If the food for retail sale is packaged, and the food is represented in words, images or both as being from the animal from which the cell-cultured food was sourced, the label would: • require one of the following statements 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured food ingredient, in the statement of ingredients. Conventional counterpart food would also need to be declared as an ingredient • the same statement used in the statement of ingredients and name of the cell-cultured food would be required in the name of the food for retail sale

Submission viewpoint	Raised by	FSANZ response
		• representations will automatically trigger characterising ingredient information about the cell-cultured food in the statement of ingredients, which would enable consumers to identify the amount of cell-cultured food present • if the mixed food contained cell-cultured quail as an ingredient either with or without conventional quail, the phrase 'poultry meat' would be prohibited in the statement of ingredients and elsewhere on the label, and • general food name requirements will also apply, where the food must have a name or description sufficient to indicate the true nature of the food. For food for retail sale that is not required to bear a label or is unpackaged, the requirement for the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured food ingredient would apply as indicated in section 7 of SD2 to this report.
Statement of ingredients		
Stated the presence of artificial vitamins, colours and flavours in food containing cultured quail cells should be labelled in the statement of ingredients, as would be for any highly processed food.	Individual	Packaged food products containing cultured quail cells as an ingredient would be subject to generic ingredient labelling requirements, including for food additives.
Mandatory declaration of certain foods		
Commented that barley, or any other food allergen added into the cell culture as an ingredient, should be declared on the label in accordance with Code requirements, because their presence in the cultured quail cells cannot reasonably be foreseen by a consumer.	DOH-VIC & VIC DoEECA	As noted in section 4.1 of SD4 of the 1st CFS, existing allergen declaration requirements would apply to food products containing cultured quail cells. If gluten from barley is present in a food for sale containing cultured quail cells, gluten and barley would need to be declared. Barley is not required to be declared unless gluten is present.
Directions for use and storage		
A new direction for use may be needed in Standard 1.2.6 to specify the cell-cultured product must be cooked before consumption. Without the requirement, it would be up to the business to determine if a microbiological control step such as cooking is required and this creates a risk that the information may not be provided, including when	Queensland Health	FSANZ is maintaining its approach for existing labelling requirements for directions for use and storage in the Code to apply to food for sale containing a cell-cultured food (see section 4.3 of SD4, 1st CFS). Existing requirements require storage conditions and directions for use to be provided on labelling for a food sold to a caterer (paragraph 1.2.1—15(e)). The information is required on the label of a packaged food in

Submission viewpoint	Raised by	FSANZ response
the product is sold to caterers or supplied to manufacturers. Noted there may be a regulatory gap regarding the provision of information because it appears the requirements of Standard 1.2.6 do not apply to sales to manufacturers (unless requested under 1.2.1—21) because the requirements for directions for use in Standard 1.2.1 only apply to retail sales [1.2.1—8(1)(g)] or sales to caterers [1.2.1—9(4)].		accordance with section 1.2.1—12 or in labelling that is provided to the caterer with the food (section 1.2.1—13). Existing requirements would also apply to food containing a cell-cultured food as an ingredient that is sold to a manufacturer (section 1.2.1—21 in the Code). The onus is on the manufacturer to request information relating to directions for use or storage from the supplier of the food and it is in both parties' best interests to ensure all necessary information is supplied. This approach is consistent with the sale of other foods that may require cooking to ensure the food is safe for consumption (e.g. frozen chicken patties made with raw chicken mince). 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 directly.
Nutrition content and health claims		
Provided comments relating to nutrition content and health claims about foods containing cell-cultured quail: • Queried whether it was appropriate for cell-cultured quail food to make nutrition content claims (including 'good source' claims) for biotin, vitamin B12 and folate, when meat analogues either cannot claim or are limited to a maximum claim. • Noted pre-approved high level and general level health claims about folic acid and folate (depending on folic acid content), may also be permitted. • Queried whether claims (including comparative claims) that are based on nutritional differences between conventional quail meat and cell-	NZFS, DOH-WA, NSWFA	FSANZ considers it is appropriate to permit the use of nutrition content and health claims about the mixed food containing cultured quail cells, providing the requirements set out in Standard 1.2.7 and Schedule 4 of the Code are met. This includes the use of comparative claims made about nutrients other than vitamins or minerals. The nutrition risk assessment indicates folate, vitamin B12 and biotin are present in the harvested cells at relatively high levels, having been introduced during the production process and with levels dependent on the growth media used (see SD1 of the 1st CFS). However whilst levels of these vitamins and minerals may be considered relatively high in the harvested cells, they are likely to be lower in the mixed food that contain the cultured quail cells as an ingredient. Consistent with other foods, mixed foods containing cultured quail cells will need to meet the requirements in Standard 1.2.7 to make nutrition and health claims including those about folate, vitamin B12 and biotin.

Submission viewpoint	Raised by	FSANZ response
cultured quail food products should be permitted. For example, is it appropriate to permit comparative nutrition content claims with conventional meat e.g. 'reduced' energy, fat and fatty acids and vice versa. Noted: • there are maximum claimable amounts per reference quantity for vitamins and minerals in section S17—4, but for naturally occurring vitamins and minerals there is only a minimum content requirement • the concentrations of folate, biotin and Vitamin B12 (cobalamin) significantly exceed the amounts permitted in meat analogues • folate and magnesium claims made about plant-based meat analogues are prohibited • as it is the growth media that is the source of the vitamin and mineral content, specific requirements may be needed for vitamins and minerals sourced from the growth media, since they are neither naturally occurring nor used as a nutritive substance • no existing food category in section S17—4 would be appropriate for the applicant's product. One option would be to include a new food category in S17—4 for cell-cultured food.		For meat analogues the Code contains permissions for the addition of certain vitamins and minerals for nutritional equivalency with their conventional counterparts. In contrast, the specific micronutrients in cultured quail cells are not fortificants added for a nutritive purpose. Their presence is inherent in the harvested cells due to the growth media. FSANZ is proposing to regulate cell-cultured food under a separate standard (Standard 1.5.4 – Cell-cultured foods). Under this regulatory approach, assessments would consider the nutrient composition of the cell-cultured food and specific risk management measures would be considered if warranted. Therefore, the regulatory approach does not fit the risk management framework for the addition of vitamins and minerals to analogue foods using maximum claimable amounts. In regard to comparative nutrition content claims (e.g. in relation to macronutrient and fatty acid content), FSANZ notes the nutrient content of the harvested quail cells was compared with that of conventional quail and chicken breast (see section 4.2 in SD1 to the 2nd CFS). Therefore, the differences in energy, protein, fat and saturated fat between these foods are likely to be lower in the mixed food containing the cultured quail cells as an ingredient. As noted above, FSANZ's proposed approach for comparative nutrition content claims was based on a mixed food containing cultured quail cells as being a suitable dietary substitute for a mixed food containing conventional quail meat (section 4.5 in SD4 of the 1st CFS). However, FSANZ notes part (b) of the definition of 'reference food' relies upon the definition of 'food group' in which 'meat' is the comparator. The application of part (b) of the definition was incorrect and part (a) of the definition of 'reference food' would apply i.e. 'a food that is of the same type as the food for which the claim is made and has not been further processed, formulated, reformulated or modified to increase or decrease the energy value or the amount of the nutrient for which the claim is made'. This provision reflects the intent of comparing 'like for like'.
Characterising ingredients		

Submission viewpoint	Raised by	FSANZ response
Noted that characterising ingredients declarations for prepared filled rolls, sandwiches, bagels or similar products, and for foods sold at a fund-raising event would not apply.	Individuals, GeneEthics	FSANZ notes the intention is for characterising ingredient labelling requirements to apply to certain foods that would otherwise be exempt. This means percentage labelling information for characterising ingredients will be required for prepared rolls, sandwiches, bagels or similar products; and for foods sold at fund raising events. See section 6 in SD2 for discussion on this issue.
Recommended applying characterising ingredient information requirements in paragraph 1.2.10—8(1)(a) to a food for sale that is represented as a cell-cultured food (without mention of quail).	NSWFA	FSANZ notes recommendation but considers this is unnecessary for the following reasons: • it would be inconsistent with Code requirements for characterising ingredients, which apply to specific ingredients rather than to a food for sale. Paragraph 1.1.2—4(2)(b) of the Code specifies that an ingredient or category of ingredients that comprises the whole of the food is not a characterising ingredient. FSANZ does not consider a food represented as a cell-cultured food (without mention of the animal source) is referring to a specific ingredient. • use of cell-cultured food as an ingredient in any food for sale would trigger the requirement to use either 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured food (e.g. 'cell-cultured quail'). • if the food for retail sale is packaged, the information would be required in the statement of ingredients. Subsection 1.2.4—5(1) of the Code requires most packaged foods to provide a statement of ingredients, listing in descending order of ingoing weight of ingredients present in a food. Therefore, the position of the cell-cultured food in the statement of ingredients would indicate to consumers its amount relative to the other ingredients present in the food.
Information requirements for food for sale not required to bear a label		
Emphasised the importance of clear labelling for food sold in restaurants to avoid consumer confusion between a food product containing cultured quail cells and one containing conventional quail meat, and to ensure informed choice/consent. Sought clarity on whether, with respect to restaurant sales, the statement 'cell-cultured' would be	Individuals, Queensland Health	Food that is not required to bear a label, including food sold in a restaurant setting, will be required to provide the statement in conjunction with the name of the cell-cultured food. For further discussion on this issue, and responses to submitter comments, see section 7 of SD2.

Submission viewpoint	Raised by	FSANZ response
required with the name of the food printed on menus.		
Food sold to a caterer and other sales of food		
Commented that, for food sold to a caterer and for other sales of food, the onus should not be on the caterer to request information about the food. The onus must be on the supplier to provide labelling information to caterers and, for other food sales, other purchasers.	SA Health	FSANZ has revised its approach for food sold to a caterer and is requiring the information relating to a cell-cultured food to be provided in labelling. The approach for the provision of this information in other food sales has been maintained. See section 8 in SD2 for discussion on this issue.
Other labelling issues raised		
Labelling requirements should ensure consumers can make an informed choice when considering purchasing cell-cultured products, consistent with Australian Consumer Law and the Code. An individual submitter viewed existing food labelling as confusing and considered permitting more novel foods could further confuse Australian consumers.	DAFF (Late comment), Individual	Noted. FSANZ's assessment indicates the proposed labelling approach will ensure there is adequate information for informed choice and reduce the likelihood of consumers being misled. This is consistent with FSANZ's priority objectives for standard development as set by section 18 of the FSANZ Act
Commented that labelling requirements for cell-cultured products should: • evolve over time as consumers become more familiar with the technology • be research and industry-led due to the nascency of the sector.	CAA, Food Frontier	In undertaking its assessment of labelling requirements, FSANZ has had regard to the risk assessment, international and overseas regulations, consumer evidence (including a rapid systematic literature review and, subsequently, a full systematic literature review of the consumer evidence conducted by the University of Adelaide) and industry perspectives on nomenclature, amongst other elements. FSANZ's assessment indicates that, whilst the technology is expected to evolve over time, the labelling requirements, including mandating specific statements will ensure labelling consistency across products and this will promote consumer understanding and familiarity over time.
Sought clarification on how labelling requirements would apply to other cell-based products, for example, those developed through precision fermentation, noting these are derived from bacterial or fungal cell culture.	DOH-VIC & VIC DoEECA	FSANZ has clarified how labelling requirements for a product that is represented as a quail product are intended to apply (see section 4 of SD2). Food substances made using precision fermentation are already regulated in the Code (for example, as food produced using gene technology under Standard 1.5.1). FSANZ has been assessing applications for products of

Submission viewpoint	Raised by	FSANZ response
		precision fermentation for decades (e.g. processing aids, additives, nutritive substances).
Sought clarification on whether proposed additional labelling requirements as a result of this application would apply for any subsequent cell-cultured food application.	Queensland Health	The labelling approach developed through the assessment of A1269 is expected to apply to future applications seeking approval of cell-cultured food. However, consistent with the FSANZ Act requirements, FSANZ will consider each future application it receives on a case-by-case basis. As part of its assessment of an application FSANZ may propose additional labelling requirements if warranted.
Commented that organisations such as CAA and the APC have a role in assessing the appropriateness and accuracy of qualifying terms and facilitating the establishment of labelling guidelines with stakeholders from across the sector, including FSANZ and state regulatory agencies. They noted work in this area has commenced and that the CAA Language Guide contains collectively preferred terms/language used in the sector in Australia that support clarity and consistency. The Guide is being developed with input from industry stakeholders throughout the Asia-Pacific region and could be used to underpin a future labelling guide/supporting information. The APC recommended FSANZ develops a user guide to complement the regulatory changes in the Code and recognise the supporting industry led, self-regulatory labelling guidance.	CAA, Food Frontier, AFGC, APC	FSANZ intends developing communication messages relating to the proposed regulatory approach, if and when approved. FSANZ considers the proposed labelling requirements in the Standard provide clarity such as to negate the need for specific guidance.
Noted existing labelling and marketing practices will enable the appropriation of meat category branding for such foods, with the potential to increase consumer confusion.	Individual	The intent of the proposed regulatory labelling approach is to ensure consumers are not misled and can make informed choices. The requirement for use of either ‘cell-cultured’ or ‘cell-cultivated’ in conjunction with the ingredient name, the name of the food (if the food is represented as a quail food product) and the term ‘meat’ (if used) will assist consumers to correctly identify the true nature of the food.
Requested FSANZ considers whether 'antibiotic free' claims should be permitted. This is in noting FSANZ’s findings in section 2.2 in SD1 of the 1st	NSWFA	The regulation of representations such as ‘antibiotic free’ are subject to consumer protection legislation in Australia and New Zealand, which provides that they must not mislead, deceive or be false. These

Submission viewpoint	Raised by	FSANZ response
CFS.		representations generally fall under the purview of the Australian Competition and Consumer Commission (ACCC) and the New Zealand Commerce Commission (NZCC).
Noted that this and other such products will be marketed to vegan consumers. This would be false advertising, considering the source of the cells.	Individual	Noting cell-cultured quail is made with embryonic fibroblasts sourced from an animal i.e. *Coturnix japonica* (Japanese quail), vegan-oriented representations about food containing cell-cultured quail as an ingredient would likely be misleading. It is also unlikely suppliers would use these types of representations to promote a food containing a cell-cultured quail ingredient. It is more likely suppliers will seek to market products to non-vegan/vegetarian consumers who are seeking more sustainable and novel alternatives to traditional meats. Vegan claims are a type of representation that is not regulated by the Code. Refer to the response above relating to antibiotic free claims.
Proposed a 'climate' rating be presented alongside the health star rating on food packaging to motivate consumers to modify food choices and empower decision making.	Animal Justice Party	'Climate' ratings as proposed by the submitter are a type of representation that is not regulated by the Code. This type of representation falls outside FSANZ's remit. Refer to the response above relating to antibiotic free claims.
Other issues		
Lack of transparency (including CCI)		
Raised concerns regarding the lack of transparency associated with large amounts of information, including safety data and reports marked as Confidential Commercial Information (CCI). For example: • The cell culture media contains substances that have not been publicly divulged, with the assessment indicating that many of the components are similar and mimic the natural environment. This does not give confidence in the expertise of the assessment. • The public does not have access to the process whereby the applicant keeps the quail cells in a spontaneous immortalisation state.	Individuals, Community Voice Australia, GeneEthics, GE Free NZ	Noted. FSANZ is required by law to protect and not disclose CCI. As explained in this 2nd CFS, FSANZ conducted an independent, evidence based assessment of the application in accordance with the FSANZ Act.

Submission viewpoint	Raised by	FSANZ response
Stated that keeping details from the public is unethical. It is not possible for members of the public to have genuine input into FSANZ's assessment without having access to all relevant information. Nor is it possible for there to be independent expert evaluation. Therefore all CCI information should be published. There is also a lack of clarity on Exclusive Capturable Commercial Benefits (ECCB). The application suggests ECCB without providing details about the proprietary cell culturing process, raising doubts about the uniqueness of the process and, as such, the validity of the ECCB claim.		
Scientific uncertainty and lack of evidence		
A range of comments were received relating to scientific uncertainty, lack of evidence and associated issues, as follows: • The FAO/WHO report (2023) notes several unresolved scientific uncertainties confronting regulators. This suggests potential risks that regulators may not fully understand or address. • There is a notable absence of studies on the consumption of cell-cultured quail meat (animal or human trials, including rat studies). This is a significant evidence gap and raises concerns about the safety of the cell culture media and/or the immortalised cell meat. Given the lack of comprehensive studies the application relies on the absence of proof as proof of absence. • There is insufficient data about lasting effects of consumption of lab-grown meat. • Regarding endogenous retroviruses, it appears the assessment is conflating the whole organism with an isolated cell culture.	Individuals, GeneEthics, GE Free NZ	FSANZ is familiar with the content of the FAO/WHO report. FSANZ is required to undertake a pre-market safety assessment utilising many sources of information, the FAO/WHO report being only one of those sources. FSANZ has evaluated the safety of each individual component of the basal media and other inputs, including the growth factors, following the approach outlined in SD1. In addition, there is a long history of consumption of quail meat and eggs. FSANZ's assessment did not identify any short- or long-term safety concerns. Therefore additional testing by way of animal or human studies was not considered necessary. The applicant's microbiological testing of the vMCB included a number of species-specific viruses, including a test for endogenous retroviruses. FSANZ's hazard determination, as detailed in SD1, determined that these particular types of avian viruses are not a foodborne hazard. FSANZ has assessed this application in accordance with the requirements of the FSANZ Act – with the primary objective being the protection of

Submission viewpoint	Raised by	FSANZ response
• Appendix IV of SD1 dismisses serious data vacuums with comments such as 'Not assessed', 'Not tested' or 'Data not supplied' etc. Gaps in the evidence for such a novel food product are not acceptable. • FSANZ repeatedly uses unquantifiable terms such as 'similar', 'unlikely', and 'likely', which may evoke an emotional response without providing concrete evidence. In light of the lack of the comprehensive studies, concerns are raised about the perceived 'rush to market'.		public health and safety.
Concerns about the application and cell-cultured food generally		
Comments included: • The application should be abandoned, at least until all the deficiencies in documentation and processes are resolved. • The Code should not be amended to permit more novel food ingredients in Australian food products. • Given individuals' concerns about cell-cultured meat, use of the precautionary principle is suggested when assessing the application. • The science is too young with too many unknowns to allow a company to profit from it. • Australian consumers want real food from real vegetable and/or animal sources, not fake food created in a laboratory. • Food products should be produced using a clean and green approach. • The focus should be shifted to growing and monitoring low risk foods, encouraging people to decrease meat consumption in favour of plant-based foods, and limit population growth.	Individuals, Community Voice Australia, GeneEthics	FSANZ thanks those individuals and groups for taking the time to make submissions on the application, and notes their opposition to cell-cultured food. FSANZ has conducted a thorough risk analysis based on the best available scientific evidence. 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.

Submission viewpoint	Raised by	FSANZ response
• Although referred to as a niche product, if approved, there will be an influx of applications for other types of lab-based foods. The ultimate objective appears to be to replace all natural foods with synthetic alternatives. A ban should be placed on all synthetic foods. • Permitting synthetic food in Australia is likely to result in widespread health issues, leading to diseases and premature deaths. Submitters made references to leaky gut, adverse effects on the gut microbiome, systematic inflammation and chronic diseases. This raised concerns about whether the introduction of such foods might be an intentional measure to reduce population size. • The technology is unnatural. It does not have thousands of years of consumption and research behind it. By the time ill-effects from this man-made product are identified it will be too late. Noting the potential for long-term effects, a submitter sought changes to FSANZ's assessment process for novel foods to require life-cycle assessments including systematic monitoring and reporting on long-term health and well-being.		
Lack of accountability		
Noted accountability is mandatory in the context of a novel synthetic product being placed on the food market, and therefore called for forensic audit trails which can place direct financial and criminal liability on corporations in the supply chain, boards and senior managers. In addition, a licensing regime must apply such that the product is signed off by the relevant board of directors and senior management, with liens on assets, before going to market.	Community Voice Australia, GeneEthics	The proposed variations impose traceability requirements for cell-cultured foods. See, for example, proposed sections 3.4.1—6 and 3.4.1—11. In terms of accountability, it is noted neither FSANZ staff nor the FSANZ Board make the decision on whether to permit the availability of cell-cultured quail in Australia and New Zealand by approving a variation to the Code. That decision is made by the 10 members of the Food Ministers' Meeting (FMM). In addition, as explained in and demonstrated by this 2nd CFS and its

Submission viewpoint	Raised by	FSANZ response
Sought the qualifications, experience and industry connections of those involved in the hazard and risk assessment. There is concern FSANZ staff use regulatory science to make assessments as these methods use assumptions/best guesses to fill data gaps in the evidence. One submitter was of the view the names of members of the FSANZ Novel Food Committee should be provided, in the interests of transparency and accountability.		supporting documents, FSANZ has conducted an independent, evidence based and transparent assessment of the application in accordance with Australian law, including the FSANZ Act. This CFS, the evidence relied on, each proposed measure and the reasoning for those measures are all publicly available for scrutiny and comment. FSANZ Board meeting outcomes are also publicly available from the FSANZ website here[10]. Privacy and other laws prevent the disclosure of personal information of those involved in the assessment of A1269. All involved in the assessment are subject to laws requiring the declaration and management of conflicts of interest. The 'Novel Food Committee' or the Advisory Committee on Novel Foods (ACNF) does not have a role in assessing applications to change the Code. It is not involved in the assessment of A1269. Rather, the ACNF provides advice to external parties enquiring about whether a particular food is novel or not and, if yes, whether a safety assessment needs to be done. Further information about the ACNF is available from the FSANZ website[11].
Level of trust		
Noted that to engender trust in lab-based foods there must be: • long-term trials prior to being released to market • forensic audit trails • available information on chemicals, processes, additives etc. used and appropriate explanations of process • a halt to the use of behavioural modification techniques, in relation to language and framing questions.	Community Voice Australia	In assessing the application and in developing the proposed food regulatory measure, FSANZ has had regard to the best available scientific evidence and the assessment criteria prescribed by the FSANZ Act. These includes the statutory objectives relating to: 1. the protection of public health and safety; and 2. the provision of adequate information relating to food to enable consumers to make informed choices; and 3. the prevention of misleading or deceptive conduct. FSANZ has also had regard to:

[10] https://www.foodstandards.gov.au/about-us/board/meeting-outcomes
[11] https://www.foodstandards.gov.au/business/novel/novelcommittee

Submission viewpoint	Raised by	FSANZ response
		• the need for standards to be based on risk analysis using the best available scientific evidence; • the promotion of consistency between domestic and international food standards; • the desirability of an efficient and internationally competitive food industry; and • the promotion of fair trading in food. The submitter did not provide any new information for FSANZ to assess as a part of their submission.
Review		
Suggested a review of the approval be undertaken, for example, in five years, taking into consideration any more recent information available. This is in line with good Quality Assurance practice, i.e. increased surveillance initially to identify unexpected issues, followed by a relaxation of surveillance as a positive reputation is developed. Such a review should cover areas including technology, regulation and terminology.	AIFST	FSANZ's pre-market risk assessment has not identified any public health and safety concerns that would justify a review of the proposed regulatory measures for cell-cultured quail, if approved.
Future applications		
Suggested other companies could file an amendment to the applicant's approval rather than submitting entirely new applications, to reduce the regulatory burden and support innovation.	GFI & APAC-SCA	The FSANZ Application Handbook requires that an application be specific to the product in question and how it is produced.
Other		
Recommendations to support the cell-cultured meat sector as well as the farming sector Whilst some of the recommendations made by this submitter have been addressed separately in the Labelling section of this table, other recommendations are summarised below: • Provide government subsidies to research and approve other cultured meats.	Animal Justice Party	Noted. These recommendations are not within FSANZ's remit and are outside the scope of this application.

Submission viewpoint	Raised by	FSANZ response
• Remove subsidies from existing intensive animal agriculture and use it to accelerate the production of cultured meat. • Assist farmers (including with financial incentives) to transition to plant based agriculture which can then be used to assist in the growth of cultured meat. Organise and fund focus groups for farmers to educate and assist them in the transition. • Consult with the National Farmers Federation to access their expertise into how best to transition to other means of farming. • Provide psychological support for farmers to help them adapt to major lifestyle changes and to reduce suicide risk. • Employ farmers to become ambassadors for cell-based meat and to reassure their colleagues that this provides an opportunity, rather than taking away their livelihood. • Encourage other Australian companies to develop cell-based meat. • Use the expertise of companies in Australia who have already started on their journey to cell-based meat. • Disallow organisations with conflicts of interest such as the Department of Agriculture from conducting surveys about cell-based meat where bias might affect the interpretation of results. • Provide honest information about the world's resources of food so that people can make informed choices. • Ensure that cell-based meat is tailored to meet optimal health outcomes by tailoring it to be low in fat and high in vitamins and essential amino acids.		

Submission viewpoint	Raised by	FSANZ response
• Adopt the One Health approach which recognises that the health of domestic and wild animals, plants and the wider environment are intrinsically linked and interdependent.		
Food systems and the environment Noted there is no evidence that replacing livestock with lab-grown meat would be the best practice for the environment. Specific comments included: • The 'sustainability' rhetoric appears to contrast lab-grown meat to conventional livestock farming, positioning the former as better for the environment, without considering options like regenerative agriculture. • Long-term effects of lab-meat production could be worse than livestock production, in terms of greenhouse gas emissions and plastics use. • With governments making farming economically unviable worldwide, and with these same governments getting behind the lab-meat industry, the submitter queries whether there is an agenda at work. For example, the transformation of food systems to increasingly synthetic, genetically altered systems. An example of this is the 2020 partnership between the UN FAO and CropLife to deliver sustainable global food systems. • The dominance of the lab-grown food industry by patents threatens to produce monopolies of big corporations squeezing farmers out of the food market. • A better solution to the world's food problem would be to look for more efficient farming methods. The livestock industry is constantly evolving, moving towards reducing their carbon footprint whilst providing good quality and safe meat that is fit for human consumption.	Individuals, Community Voice Australia	Noted. Comments regarding the potential impact of this technology on the environment and global food systems are outside the scope of the application.

Submission viewpoint	Raised by	FSANZ response
Perceived regulatory capture Noted the government backing received by the applicant, suggesting a possible regulatory capture (e.g. major corporations are influencing legislation for their financial gain) and a trend where government regulators may prioritise monetary interests over public health. Those shaping legislation must understand motives, financial interests and ultimate goals of those involved.	Individuals	Noted. As explained in and demonstrated by this 2nd CFS and its supporting documents, FSANZ has conducted an independent, evidence based and transparent assessment of the application in accordance with Australian law, including the FSANZ Act. This CFS, the evidence relied on, each proposed measure and the reasoning for those measures are all publicly available for scrutiny and comment. See also responses above.
Other views Expressed a range of views/concerns as follows: • The slaughter and serving of quail meat is concerning from an animal rights perspective, and the option of plant-based alternatives should be considered instead. • Raised potential human rights violations, where denying access to healthy food raises significant ethical and legal questions. • Technology undermines the spiritual connection humans have with their food and the land. The word 'sustainability' has been hijacked, and there is a shift toward technocratic and digitised food production that disconnects people from the earth. • Those who oppose lab-grown food, especially in the absence of details regarding the manufacturing process, are being unduly labelled as 'neophobic'. • Submitters also expressed criticism over the manipulation of public opinion through advertising.	Individuals, Community Voice Australia	Noted. These issues are not within the scope of the application.
Supportive comments about the application and cell culture technology		
Supportive comments were received as follows: • The application represents a new and innovative food source.	Individuals, AFGC, AIFST, APC, CAA, GFI & APAC-SCA, Animal Justice Party	Noted.

Submission viewpoint	Raised by	FSANZ response
• The technology could potentially address environmental issues associated with traditional livestock production; has the potential to revolutionise the food industry; could enhance food security; help meet the growing demand for alternative protein sources; and could improve animal welfare. • Startups like Vow Group Pty Ltd should have the opportunity to work on unresolved questions surrounding cultured meat and answer them definitively in the long run. • If Australia does not embrace the technology it risks falling behind other countries in this emerging industry. Obstruction and restriction may impede innovation and hinder Australia's progress in the field of cultured meat. • Permitting this novel food is consistent with one of the key Food Regulation Priorities: *Maintaining a strong, robust and agile Food Regulation System.* • FSANZ is commended for the work done to assess this application; the application relates to a developing area of food science globally and is challenging for regulatory bodies around the world, and FSANZ has assessed the application in a robust and transparent manner. • The assessment of this product contributes to the creation of a regulatory pathway for more applications and a future where cellular agriculture products are no longer assessed as novel.		

Attachment A – 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.'

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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

(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 *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:

(a) 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

(b) 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

(1) 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:

(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—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.

Attachment B1 – Draft Explanatory Statement

DRAFT 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 prepared 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 draft explanatory statement relates to draft Standard 1.5.4 (the draft Standard).

2. Variation will be a legislative instrument

If approved, the draft Standard would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be 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 Food Ministers Meeting (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 prepared the draft 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 draft 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 includes two rounds of public consultation. The first 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 second call for submissions (including the three draft Standards and draft consequential variation) will be open for a six-week period.

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 Consultation Regulation Impact Statement (CRIS) is not required for this application, as the proposed changes are not likely to create significant impacts.

6. Statement of compatibility with human rights

If approved, this instrument would be 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 draft Standard

The draft Standard would be 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 draft Standard explains the instrument is a standard under the FSANZ Act, and the draft 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 draft 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 draft Standard contains sections 1.5.4—1 and 1.5.4—2.

Section 1.5.4—1 provides that the name of the draft 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, if approved, the draft Standard would commence 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 draft 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 1 of the draft 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. Proposed amendments to Standard 1.2.1 will 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 would apply 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) would require 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. Proposed amendments to Standard 1.2.1 will 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 B2 – Draft Explanatory Statement

DRAFT 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 prepared 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 draft explanatory statement relates to draft Standard – *Schedule 25A – Permitted cell-cultured foods* (the draft Schedule).

2. Variation will be a legislative instrument

If approved, the draft Schedule would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be 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 Food Ministers Meeting (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 prepared the draft Schedule 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 draft Schedule will list the cell-cultured quail referred to in Application A1269 as a permitted cell-cultured food and set specific conditions for the sale and labelling of that cell-cultured food.

4. Documents incorporated by reference

The draft Schedule 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 includes two rounds of public consultation. The first 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 second call for submissions (including the three draft Standards and draft consequential variation) will be open for a six-week period.

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 Consultation Regulation Impact Statement (CRIS) is not required for this application, as the proposed changes are not likely to create significant impacts.

6. Statement of compatibility with human rights

If approved, this instrument would be 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 draft Standard

The draft Standard would be 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 draft Standard explains the instrument is a standard under the FSANZ Act, and the draft 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 draft 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 draft Standard would apply in Australia only. It would not apply in New Zealand.

Division 1 – Preliminary

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

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

The note to section S25A—1 explains that, if approved, the draft Standard would commence 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 draft Standard**.** It provides that a reference in the draft Standard to *cell-cultured quail* means 'quail cells obtained from in vitro culturing of 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. The section lists the permitted cell-cultured foods and their conditions of use in a table. 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 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 49 632 680 472). Section S25A—2 provides that the reference to **'**cell-cultured quail' in that Item 1 is a reference to 'quail cells obtained from in vitro culturing of embryonic fibroblast cells sourced from Coturnix japonica'.

The corresponding entry in Column 2 of the Table for the above permitted cell-cultured food refers to Division 2 of the draft Standard. This reflects that the sections that comprise Division 2 of the Draft 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—6(1) provides that cell-cultured quail must not be a food for retail sale. Subsection S25A—6(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 2 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. Item 1 of the table provides that cell-line 221523-Fib-Quail is an assessed cell line.

Attachment B3 – Draft Explanatory Statement

DRAFT 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 prepared 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 draft explanatory statement relates to *Food Standards (Application A1269 – Cultured quail as a novel food – Consequential Amendments) Variation* (the draft variation).

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be 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 Food Ministers Meeting (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 has prepared the draft 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 proposed amendments are required as a consequence of the following draft 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 proposed amendments is to provide for the regulation of sale and use of cell-cultured food.

4. Documents incorporated by reference

The draft 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 includes two rounds of public consultation. The first 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 variation and other proposed regulatory measures mentioned above. The second call for submissions (including the three draft Standards and the draft variation) will be open for a six-week period.

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 Consultation Regulation Impact Statement (CRIS) is not required for this application, as the proposed changes are not likely to create significant impacts.

6. Statement of compatibility with human rights

If approved, this instrument would be 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 draft 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 draft variation.

Clause 3 provides that the draft variation will commence immediately after draft Standard 1.5.4 takes effect.

The Schedule

The Schedule to the draft variation amends the Code.

Standard 1.1.1—Structure of the Code and general provisions

Items [1] – [4] 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 the draft Standard 1.5.4 and the draft variation are both approved, will be 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'. If approved, the effect of this amendment would be 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'. If approved, the effect of this amendment would be 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'. If approved, the effect of this amendment would be 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 to the variation 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.

If approved, the effect of this amendment would be 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.

If approved, the effect of this amendment would be 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 [12] 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 Standard 1.5.4)'. 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. -If approved, the effect of this amendment would be that section 1.2.1—6 would require the label of a food for sale that is in a package to include the information relating to cell-cultured food in accordance with Standard 1.5.4.

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 Standard 1.5.4)'. 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. If approved, the effect of this amendment would be that accompanying or displayed information must include information relating to cell-cultured food in accordance with Standard 1.5.4.

Item [11] amends subsection 1.2.1—9(7) by repealing and replacing paragraph 1.2.1—9(7)(e). Paragraph 1.2.1—9(7)(e) lists information that subsections 1.2.1—9(1) and (6) provide must be displayed in connection with or provided on request to the purchaser of a food for sale that is not required by section 1.2.1—6 to bear a label. The new paragraph 1.2.1—9(7)(e) will require display or provision of information about characterising ingredients and characterising components for the following:

- A food for sale that 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)).

- A food for sale 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).

Item [12] adds paragraph 1.2.1—15(h) to section 1.2.1—15. The new paragraph states 'information relating to cell-cultured food (see Standard 1.5.4)'. Section 1.2.1—15 lists the information that must be stated in the labelling required for food sold to a caterer. If approved, the effect of this amendment would be that the labelling required for food sold to a caterer must include information relating to cell-cultured food in accordance with Standard 1.5.4.

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

Items [13] and [14] of the Schedule amend Standard 1.2.10 of the Code.

Item [13] amends subsection 1.2.10—3(1) by inserting the text 'subject to subsection (4),' after the words 'For the labelling provisions,''. This amendment is to account for the amendment made by Item [14].

Item [14] adds subsection 1.2.10—3(4) to section 1.2.1—10. New subsection 1.2.1—10(4) would provide that paragraphs 1.2.10—3(a) and (b) do not apply in relation to a characterising ingredient that is a cell-cultured food. Subsection 1.2.10—3(3) provides that, for the labelling provisions, information about characterising ingredients and characterising components is not required for a food listed in that subsection. New paragraph 1.2.1—10(4) would provide

that this exemption does not apply to a characterising ingredient that is a cell-cultured food and an ingredient in one of the following foods: prepared filled rolls, sandwiches, bagels or similar products; or a food for sale that is sold at a fund-raising event.

Standard 3.1.1—Interpretation and Application

Items [15] and [16] of the Schedule amend Standard 3.1.1 of the Code.

Item [15] 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.

If approved, the effect of this amendment would be 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 [16] 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 [17] and [18] of the Schedule amend Schedule 3 of the Code.

Item [17] 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—52

Item [18] inserts new section S3—54 after section S3—53.

If approved, new section S3—54 will provide 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 will be 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 *in vitro* culturing of embryonic fibroblast cells sourced from *Coturnix japonica’.*

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

Schedule 27— Microbiological limits in food

Items [19] of the Schedule amend Schedule 27 of the Code.

Item [19] 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			
Salmonella spp	5	0	not detected in 25 g
Listeria monocytogenes	5	0	not detected in 25 g

Attachment B4 – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Draft 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 prepared 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 draft explanatory statement relates to draft Standard - *Standard 3.4.1 – Food safety requirements for processing of cell-cultured food* (the draft Standard).

2. Variation will be a legislative instrument

If approved, the draft Standard would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be 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 Food Ministers Meeting (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 prepared the draft 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 draft 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 includes two rounds of public consultation. The first 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 variation and other proposed regulatory measures mentioned above. The second call for submissions (including the three draft Standards and the draft variation) will be open for a six-week period.

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 Consultation Regulation Impact Statement (CRIS) is not required for this application, as the proposed changes are not likely to create significant impacts.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legisla*tion *Act 2003*.

7. The draft Standard

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

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.

Section 3.4.1—1. This section 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 1 explains that the Standard will commence 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. This section sets out the definitions for key words and phrases used in the draft 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—8.

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' as one 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 pre-existing 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 draft Standard contains sections 3.4.1—3 to 3.4.1—6.

Division 2 set 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: 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 a cell line supplier to not collect tissue from a donor animal that is diseased. The reference to 'diseased' would include 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: Subsection 3.4.1—4(1) requires a cell line supplier to comply with Standard 3.2.1 of the Code. Standard 3.2.1 sets requirements for a food safety program based on a hazard analysis and critical control point (HACCP) system. Subsection 3.4.1—4(2) provides that, in addition to any requirements specified in Standard 3.2.1, the food safety program must detail food handling activities undertaken by the business, including: cell sourcing and selection; development of a cell line and development of a cell bank. The food safety program must also detail how the business will undertake cleaning, sterilisation and calibration of all relevant equipment. The purpose of these provisions is to ensure, at a minimum, details of all the key activities of a cell line supplier are included in a documented and implemented HACCP-based food safety program. The reference in paragraph 3.4.1—4(2)(a) to 'cell sourcing and selection' includes the collection and/or selection of cells by the cell line supplier for use in a cell line, irrespective of these cells are sourced by the cell line supplier directly from a donor animal (e.g. by biopsy) or indirectly (e.g. from a pre-existing cell sample).

Section 3.4.1—5: Subsection 3.4.1—5(1) requires a cell line supplier to ensure inputs do not make cell-cultured food unsafe or unsuitable. Subsection 3.4.1—5(2) provides that inputs for this purpose include: anti-microbials (e.g. antibiotics); media; and substances added to cells to facilitate their storage, such as cryoprotectants. The purpose of these provisions to require

a cell line supplier to ensure inputs do not introduce any microorganisms or chemical or physical contaminants into cultured cells used for food production.

Section 3.4.1—6: This section 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 draft Standard contains sections 3.4.1—7 to 3.4.1—11.

Division 3 set requirements that apply to a 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 Division 2 and 3.

Section 3.4.1—7: Subsection 3.4.1—7(1) requires a cell culturing food business to comply with Standard 3.2.1 of the Code. Standard 3.2.1 sets requirements for a food safety program based on a hazard analysis and critical control point (HACCP) system. Subsection 3.4.1—7(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—7(2) also requires the food safety program to specify: how the business will identify when a cell culture 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—8: This section 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—9: This section 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—9 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 25A—8 of the Code) are used by a cell culturing food business for cell proliferation.

Section 3.4.1—10: This section 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—11: This provision 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.