11 December 2023
273-23

Call for submissions – Application A1269

Cultured quail as a novel food

FSANZ has assessed an application made by Vow Group Pty Ltd to permit the use of cultured quail cells made with embryonic fibroblasts originating from *Coturnix japonica* (Japanese quail), as a novel food ingredient in food products to be marketed and sold in Australia and New Zealand. Pursuant to section 44 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the application.

Submissions need to be made using the FSANZ Consultation Hub (https://consultations.foodstandards.gov.au). As a trial, FSANZ is consulting on this application by using the Consultation Hub, built on the Citizen Space platform.

All submissions on this application 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 as soon as possible after the end of the submission period.

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 a hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 5 February 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.
Questions about making a submission can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Supporting documents

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

SD1 Hazard and risk assessment
SD2 Consumer literature review
SD3 Consumer Insights Tracker
SD4 Labelling

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Vow Group Pty Ltd (Vow) requesting an amendment to the Australia New Zealand Food Standards Code (the Code) to allow the use of cultured quail made with embryonic fibroblasts from *Coturnix japonica* (Japanese quail), as a novel food.

FSANZ is assessing this application under its Major Procedure which requires two rounds of public consultation. This first call for submissions (CFS) seeks views on FSANZ's hazard and risk assessment and proposed regulatory requirements to inform its decision on developing a measure to amend the Code.

The risk assessment for cultured quail cells evaluated: (1) hazards associated with the embryonic fibroblast cell line from Japanese quail; (2) the production process including any relevant inputs used to grow and propagate the Japanese quail cells; and (3) the cells at the point of harvest which includes collection, packaging and freezing.

The assessment concluded that the cell line is genetically stable and any microbiological risks associated with cell line sourcing are very low. Given the aseptic nature of cell proliferation/biomass production stages, the microbiological risk associated with cells at the point of harvest was very low. 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 consumption of the harvested cells containing the levels of nutrients provided in the application. The available information indicated the harvested cells are unlikely to pose a food allergenicity concern for the general population.

FSANZ prepared 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. 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

FSANZ has reviewed existing, generic labelling requirements in Part 1.2 (Labelling and other information requirements) of the Code to determine how they apply to the applicant's cultured quail cells as a novel food ingredient, and whether additional labelling measures would be warranted. Based on the assessment, food for sale that contains the applicant's cultured quail cells as a novel food ingredient would require the statement 'cell-cultured' in labelling for food identification purposes.

FSANZ's proposed approach is to prepare a draft variation to the Code which will allow the sale of cultured quail cells as a novel food. All submissions received during this 1st CFS will be considered in preparing the draft variation which would seek to amend the following sections of the Code:

- Section 1.1.2—3 to include a new definition for cell-cultured food
- Section S25—2, to list cultured quail as a permitted novel food and prescribe conditions of use, including:
    - that the food be mixed with other ingredients to form products such as, but not limited to, logs, rolls and patties
    - a specified name to identify Vow's cultured quail cells e.g. "Cultured quail (*Coturnix japonica*) fibroblasts" (or similar)
    - food must be produced under a food safety program in accordance with Standard 3.2.1 of the Code

- Schedule 3, to include a specification for cultured quail cells

Production under a documented food safety program pursuant to Standard 3.2.1, supported by good practices will support safe cell biomass production.

FSANZ seeks submissions on all aspects of the assessment of Vow's application, as set out in this first CFS and four supporting documents, and the proposed risk management measures.

1 Introduction

1.1 The applicant

Vow Group Pty Ltd (Vow) is a biotechnology company that uses cell culture to grow cells externally from animals. They are based in Sydney, Australia.

1.2 The application

Vow has requested an amendment to the Australia New Zealand Food Standards Code (the Code) to allow the use of cultured quail made with embryonic fibroblasts from *Coturnix japonica* (Japanese quail), as a novel food ingredient in food products. FSANZ's pre-market hazard and risk assessment focusses on the quail cells up to the point of harvest. These cells will then be mixed with other ingredients to form products such as, but not limited to, logs, rolls and patties. Vow is proposing to market these foods to caterers for use in high end restaurants.

1.3 Relevant standards

Currently there are no regulations covering cell-cultured foods in Australia or New Zealand. FSANZ considers that cell-cultured food, the subject of this application, will be regulated within the following existing standards in the Code.

1.3.1 Novel food permission

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 Schedule 25—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 the table to section S25—2.

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. Any cell-cultured foods would be inserted in Schedule 3.

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. Subsection 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

Section 1.1.2—3 states that ***meat:***

a) means the whole or part of the carcass of any of the following animals, if slaughtered other than in a wild state:
    i. buffalo, camel, cattle, deer, goat, hare, pig, poultry, rabbit or sheep;
    ii. any other animal permitted for human consumption under a law of a State, Territory or New Zealand; and
b) does not include:
    i. fish; or
    ii. avian eggs; or
    iii. foetuses or part of foetuses.

meat flesh means meat that consists of skeletal muscle and any attached:

(a) animal rind; or
(b) fat; or
(c) connective tissue; or
(d) nerve; or
(e) blood; or
(f) blood vessels; or
(g) skin, in the case of poultry.

Based on the current definitions above for meat and meat flesh, using these terms in relation to food products made using cultured quail cells would be inaccurate and misleading for enforcement purposes and for consumers. The quail cells have been derived from embryo tissue which is excluded from the definition of meat. Furthermore, it has not undergone slaughter and is not part of the carcass (poultry or other) or derived of or from skeletal muscle. The proposed approach to a definition and labelling is detailed at sections 2.2.5 and 2.2.8 below.

1.3.5 Food safety standards

Food businesses in Australia must 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 to demonstrate how they will manage food safety risks (see Standard 3.2.1).

The proposed approach to production requirements is detailed at sections 2.2.1 and 2.2.3 below.

1.4 International situation

The regulatory frameworks for cell-based foods are still being developed in many countries (WHO 2023).

In December 2020, the Singapore Food Agency approved the first cultured meat product, a cultured chicken, under its novel food regulations.

The US Department of Agriculture Food Safety and Inspection Service (FSIS) and US Food and Drug Administration (FDA) have established an agreement for regulating human food products made using animal cell culture technology to ensure that such products brought to market are safe, unadulterated and truthfully labelled. Under the agreement, FDA will oversee cell collection, growth, and differentiation of cells. FDA will transfer oversight at the cell harvest stage to FSIS. FSIS will then oversee the cell harvest, processing, packaging, and labelling of products. FDA has completed two premarket consultations of foods made with cultured chicken cell material (WHO, 2023). (Human Food Made with Cultured Animal Cells Inventory (fda.gov)). The FSIS has subsequently approved these two products with Grants of Inspection over the course of the FSANZ assessment of A1269.

While no cultured meat product has passed through the Canadian novel food procedure yet, these products appear to fall within the novel food classification. In China, cell based food would be defined as new food materials referring to items which are not of traditional eating habits in China and require premarket assessment. The preamble of the Novel Food Regulation (European Union) No. 2015/2283 explicitly mentions that its scope includes food from the culture of cells or tissues from animals, plants or microorganisms.

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

An objective of the FSANZ Act is the establishment of common rules for Australia and New Zealand and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

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 a food regulatory measure.

1.6 Procedure for assessment

The application is being assessed under the Major Procedure which requires two rounds of public consultation.

2 Summary of the assessment

2.1 Hazard and risk assessment

FSANZ's hazard and risk assessment focussed on the first three stages of cell-based food production (cell line, method of production, harvested cells). Consideration was given to any potential hazards associated with the cell line, the novel production process (limited to Vow's current scale of production and including any relevant inputs used to grow and propagate the cultured quail cells), and those cells at the point of harvest (referred to as 'harvested cells').

The harvested cells are the main ingredient that will be mixed with other permitted food ingredients to produce a final mixed food product and served at a maximum of 300 g of the harvested cells per serve per day. Other than a nutritional assessment, the further processing of the harvested cells was not assessed as part of this application. It is Vow's responsibility to ensure that any additional ingredients used in the formulation of the final mixed food and any further handling activities comply with any relevant requirements in the Code.

2.1.1 Cell line

The cells used by Vow were originally isolated from a Japanese quail embryo and immortalised as an embryonic fibroblast cell line. Immortalisation ensures the cells can proliferate indefinitely under appropriate culture conditions. Contamination by foodborne pathogens associated directly with the embryonic fibroblast isolation procedure or quail hens is likely to be very low. Vow provided evidence to confirm the species of the cells as well as the genetic stability of the cell line during the production process. Some genetic variation arising from the immortalisation and culturing process was identified but is consistent with what would be expected for cultured cells and does not itself raise any specific food safety concerns.

2.1.2 Method of production

Vow demonstrated that all materials used in the production process meet the requirements for food grade or pharmaceutical grade ingredients with a purity and quality suitable for their intended use in food. The production process in this application consists of preparation and maintenance of cell banks (master and working), cell expansion (seed train) and cell harvesting. Production under a HACCP-based system supported by Good Cell Culturing Practice (GCCP), Good Manufacturing Practice (GMP) and Good Hygienic Practice (GHP) for the production of the cell biomass as a food, will limit the potential for ingress of foodborne pathogens during the cell expansion phase.

2.1.3 Harvested cells

While there is no history of consumption of cultured quail cells as food there is a long history of safe consumption of quail meat and eggs. Evaluation of the cell media and other inputs used during the production process demonstrated there are no safety concerns from exposure to these substances from consumption of the harvested cells. The available information indicates the harvested cells are unlikely to pose a food allergenicity concern for the general population. Vow analysed for the presence of gluten in the harvested cells due to potential carry over of barley proteins from the cell culture medium. Levels were below the limit of detection of the assay used.

Vow has undertaken a preliminary microbiological analysis of the harvested cells which has formed the basis for the microbiological hazard assessment. The main food-associated risk would occur post-harvest where the harvested cells are exposed to the food production environment and any foodborne pathogens, particularly *Listeria monocytogenes*. Given that there are no microbiological controls applied during production of the cell biomass, food products containing the harvested cells should undergo a recognised microbiological control step (e.g. cooking) before consumption, particularly as a safeguard for vulnerable persons.

2.1.4 Nutrition

A nutrition assessment and dietary intake assessment were conducted to determine if the consumption of the harvested cells would cause a nutritional imbalance in the diet. No nutritional issues were identified for the majority of nutrients assessed. More detailed evaluations were undertaken for some specific nutrients found to be present at high levels. These were cobalamin (vitamin B12), biotin, folate, iron and sodium. The levels of cobalamin and biotin in the harvested cells resulted in intakes that were up to 929 times the estimated average requirement (EAR) and 9 times the adequate intake (AI) respectively per serving, however no upper levels (UL) have been set for these vitamins and no adverse effects have been reported from their high consumption. Similarly, a folic acid content per 300 g serving of harvested cells may exceed the UL in individuals aged 14-18 years, if total folate is present as folic acid. However, this is not expected to be of concern based on the likely overestimation of serving size and expected infrequent consumption of harvested cells.

The concentrations of iron and sodium in the harvested cells were higher than chicken breast. The total high intake of iron did not exceed the UL for all the Australian and New Zealand population subgroups assessed, even if consumers eat 300 g of the harvested cells daily in addition to other conventional meats. At this consumption level of harvested cells, the increase in the dietary intake of sodium, compared to high baseline usual intake, ranged from 8% to 19% for the Australian population aged 2-3 years, however a 300 g serving size is likely to be an overestimation for this age group.

2.1.5 Conclusions

FSANZ has undertaken a hazard and risk assessment of cultured quail cells, taking into account microbiology, biotechnology, toxicology, nutrition and dietary intake/exposure considerations.

The cell line is genetically stable and microbiological hazards associated with cell line sourcing are very low. There are no safety concerns from exposure to the substances used in the production process at the estimated consumption levels.

The harvested cells are unlikely to pose a food allergenicity concern for the general population. Vow analysed for the presence of gluten in the harvested cells due to potential carry over of barley proteins from the cell culture medium. Levels were below the limit of detection.

Given the aseptic nature of cell proliferation/biomass production stages, the main microbiological process-associated risk is post-harvest where the harvested cells are exposed to the food production environment and any foodborne pathogens therein. Given this, food products containing the harvested cells should undergo a recognised microbiological control step (e.g. cooking) before consumption. The likelihood of microbiological hazards entering the cell biomass has been assessed at the current scale of production and this would change if production is scaled up.

There were no nutritional risks identified from the consumption of the harvested cells containing the levels of nutrients provided in the application, particularly given consumption is likely to be infrequent.

2.1.6 Consumer evidence

FSANZ prepared 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.

FSANZ has also commissioned the University of Adelaide to conduct a more comprehensive systematic literature review that also examines consumers' levels of awareness, understanding, perceived risks and benefits, and prospective behaviour regarding alternative proteins, including cell-cultured meats. The findings of this literature review will inform the 2nd CFS.

The key findings of FSANZ's rapid systematic evidence review are summarised below, grouped by research question (see Supporting Document 2 (SD2) for the full literature review report).

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

Terms that incorporate the word 'cell' (e.g. 'cell-cultured', 'cell-cultivated' and 'cell-based') best enable consumers to correctly identify the true nature of the product and are perceived as being the most descriptive by consumers, but may decrease consumer appeal compared to 'cultured' or 'cultivated'.

The terms 'cultured' and 'cultivated' produce low levels of consumer understanding. This is the case for both seafood and chicken/beef, but is more pronounced for seafood. The term 'artificial' meat/seafood also produces low levels of consumer understanding. Although the term 'lab-grown' enabled consumers to correctly identify the product, it has lower levels of perceived safety than other terms.

Consumer understanding of allergenicity of cell-cultured meat/seafood is not high, even for the best performing terms ('cell-cultured', 'cell-cultivated'). Up to 66% of consumers correctly identified that the product was not safe to consume for those with an allergy to the traditional counterpart. The term 'cell-based' produced low levels of perceived allergenicity for beef products in particular, with only 38% of consumers identifying an allergenicity concern. Regardless, the overall findings suggest that terminology alone cannot sufficiently convey allergen information to consumers.

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)?

When provided with a neutral description of cell-cultured meat, consumers consistently perceived it as less healthy and/or nutritious than conventional meat, regardless of the terminology employed. One study suggests this may be because consumers do not see cell-cultured meat as compositionally the same as conventional meat.

However, consumer perceptions of the healthfulness/nutritional value of cell-cultured meats appear to be highly malleable depending on the information received (neutral vs. biased descriptions) and product categories compared (chicken/beef vs. chicken nuggets/beef burgers).

Qualitative findings also suggest that levels of trust in scientists/experts and/or cell-cultured meat companies may impact perceptions of healthfulness of cell-cultured meat, in both positive and negative directions.

2.2 Proposed regulatory provisions

FSANZ proposes that Vow cultured quail cells would be a novel food according to the provisions of the Code and in line with international regulations (WHO 2023). If permitted, a draft variation will be made to the Code for the use of Vow's cultured quail cells as a novel food. All submissions to this CFS will be considered in finalising the draft variation, which will be provided at the 2nd CFS.

The risk management response to matters raised by the risk assessment are as follows.

2.2.1 Safety considerations

The hazard and risk assessment of the cell line, exposure to the substances used in the production process and the estimated consumption levels of harvested cells are unlikely to pose a food allergenicity concern for the general population. Analysis for the presence of gluten in the harvested cells found that levels were below the limit of detection.

Post-harvest is where the cells are exposed to the food production environment and any potential foodborne pathogens therein. Production under a documented food safety program pursuant to Standard 3.2.1, supported by good practices will support safe cell biomass production. As there are no microbiological controls applied during production of the cell biomass, the final food products containing the cells should undergo a recognised microbiological control step (e.g. cooking) before consumption. FSANZ note that microbiological hazards have been assessed at Vow's current scale of production and these hazards will need to be managed by the manufacturer at scale-up to ensure the risks remain low and do not compromise the conclusion of this pre-market hazard and risk assessment.

2.2.2 Production inputs

Whilst there are numerous inputs contained in the basal media used for production, FSANZ considers them low risk and after having regard to the definition of "used as a processing aid" in 1.1.2—13, does not consider them processing aids. That is, they do not perform a technological purpose in the course of processing. This consideration aligns with our assessments of food enzymes and other specialty foods where the basal media inputs are not deemed processing aids. Whilst not intending to insert these inputs into the Code in this instance, FSANZ has assessed each input to ensure their safety (section 3.1 of SD1). The majority of inputs in the basal media are permitted in the Code as amino acids, vitamins or minerals, processing aids or food additives.

2.2.3 Safe food handling and production requirements

Food processing activities in Australia must comply with general requirements for people, premises, equipment and processing for safe food handling (as set out in Standards 3.2.2 and 3.2.3). A food business producing cultured cells should also implement a documented food safety program to demonstrate how they will manage the food safety risks (Standard 3.2.1).

As there is no step in the production of cultured quail cells to eliminate or reduce microbiological contaminants, control measures must focus on prevention of contamination entering the production process and reduction of microbial hazards if present. Food safety controls therefore must include initial cell sourcing, expansion stage, harvest and freezing of the harvested cells. Specific points during production must be identified where microbial hazards could occur. Appropriate control points in a HACCP-based system to minimise the risk should be identified and supported using good practices (GCCP, GHP, GMP), including validation of processes and proposed shelf life. Vow have implemented a HACCP-based approach to producing the cultured quail harvested cells.

Further processing of the harvested cells into the final food product was not assessed in this application but would be subject to the food safety standards in Chapter 3 of the Code. If the cell biomass is supplied to an Australian food manufacturer or food service business for further processing, these businesses would also need to comply with the Chapter 3 standards, including validation of the safety of the final food.

2.2.4 Nutrition

To determine the potential nutritional impact of harvested cells in the diet, the risk assessment compared the nutrient content of a 300 g serve of harvested cells (refer to section 4.3.5.2 of SD1) to the Australian and New Zealand Nutrient Reference Values (NHMRC and MoH 2006), along with typical serving size of conventional quail (180 g) and chicken breast (142 g). Nutrient composition per 100 g was also compared, and the nutrient content for the two culture media formulations was considered (refer section 4.2 of SD1).

The application stated that products containing harvested cells will be served in restaurants at limited serving sizes, are intended to serve as a new food available to consumers and are not anticipated to serve as a substantial substitute for any food group or type of protein. The FSANZ Consumer Insights Tracker (CIT) online survey (refer SD3) found only 23.6% of consumers would be willing to include cell-cultured foods in their diet, assuming that the product was a similar price to meat and/or meat alternatives. Of those consumers who are willing to include cell cultured food in their diet, most said they would use it as a partial replacement for traditional meat. While this data only represents a snapshot in time, it does suggest that products containing cultured quail cells are unlikely to fully replace conventional quail or other meats in the diet. Consumers' consumption intentions could, however, change as they become more familiar and therefore possibly more accepting of cell cultured foods.

As noted in section 2.1 of this report, the nutrition risk assessment concluded there are no nutritional risks from the consumption of harvested cells, particularly given the expected infrequent consumption levels. FSANZ therefore does not consider any specific nutrition risk management measures are warranted.

2.2.5 Proposed definition

A new definition for cell-cultured foods will be added to the Code, as these types of foods do not meet the current definition of 'meat' as indicated in section 1.3.4 above. FSANZ considers such a definition should cover not only this food, but other subsequent foods of a similar nature. These foods may be certain types of cells, or a combination of cell types, with or without other components such as fats or scaffold. The definitional name will not be mandated on pack, but rather inserted into Standard 1.1.2 of the Code to provide certainty to industry and other stakeholders and clarity for enforcement purposes. Labelling requirements are considered separately in SD4. FSANZ proposes to require the label of a food for sale to include the statement 'cell-cultured' for food identification purposes (see section 2.2.8 below).

2.2.6 Specification

Subsection 1.1.1—15(2) requires that a novel food, when added to food in accordance with the Code, or sold for use in food, must comply with any relevant specification set out in Schedule 3. A specification for the cultured quail cells at the point of harvest will be included in Schedule 3, based on parameters included in sections 4.4.1 and 4.4.2 of SD1.

FSANZ notes that the specification and novel food permission are relevant to our assessment of the harvested quail cells at the time of assessment. Any major changes to the production process, such as substitution of, or addition of new ingredients, or a change in the production process, such as scale up, which may affect the conclusions of this health and safety assessment would require a new assessment.

2.2.7 Conditions of use

The table to section S25—2 of the Code includes the name of any approved novel food and conditions of use for that food. FSANZ proposes to impose the following conditions of use (or similar) on cultured quail cells:

- that the food be mixed with other ingredients to form products such as, but not limited to, logs, rolls and patties
- a specified name to identify Vow's cultured quail cells e.g. "Cultured quail (*Coturnix japonica*) fibroblasts"
- food must be produced under a food safety program in accordance with Standard 3.2.1 of the Code.

2.2.8 Labelling

FSANZ has reviewed existing, generic labelling requirements in Part 1.2 (Labelling and other information requirements) of the Code to determine how they apply to the applicant's cultured quail cells as a novel food ingredient, and whether additional labelling measures would be warranted (See SD4).

In developing the proposed approach, FSANZ's assessment has also included consideration of the following elements: a labelling risk management framework (comprising the priority objectives in Section 18 of the FSANZ Act (1991)), relevant Ministerial policy guidelines, international and overseas regulations, a systematic review of available scientific literature on cell-based food terminologies published by the Food and Agriculture Organization of the United Nations (FAO) and WHO, industry perspectives on nomenclature, the risk and technical assessment (SD1) and consumer evidence (SD2).

Based on the assessment, for food for sale that contains the applicant's cultured quail cells as a novel food ingredient, FSANZ's proposed approach is to:

- require the following labelling elements:
  - the statement 'cell-cultured' in labelling for food identification purposes
  - if the food for sale is not represented as a quail food product—apply the existing food name requirement.
  - if the food for sale is represented as a quail food product—in addition to existing food name requirements, require the statement 'cell-cultured' to be included in the name of the food
  - apply existing ingredient naming requirements to packaged food products, except:
    - require the statement 'cell-cultured' to be used in conjunction with the name of the novel food ingredient in the statement of ingredients, and
    - the generic ingredient name 'poultry meat' would not apply
  - apply existing nutrition information requirements to packaged food products, except for the exemption for poultry that comprises a single ingredient or a category of ingredients from the requirement for a nutrition information panel (NIP), which would not apply
  - apply characterising ingredient declaration requirements, except for the exemptions for prepared filled rolls, sandwiches, bagels or similar products and for a food for sale that is sold at a fund raising event, which would not apply
  - for food for sale that is not required to bear a label if:
    - the food is not represented as a quail food product—require the statement 'cell-cultured' in conjunction with the ingredient name
    - the food is represented as a quail food product—require the statement 'cell-cultured' to be included in the name of the food
    - the statement 'cell-cultured' is information that would be required to be stated in labelling that accompanies the food or is displayed in connection with the display of the food.
- apply existing requirements for the following labelling elements:
  - declaration requirements for certain foods (allergens)
  - date marking requirements to packaged food products
  - directions for use and storage
  - nutrition content and health claim requirements
  - information relating to a food sold to a caterer, and for other food sales.

2.3 Proposed regulatory conclusion

FSANZ's proposed approach is to permit the sale of cultured quail cells as a novel food ingredient and prepare a draft variation to the Code, which will be provided at the 2nd CFS. All submissions received during this 1st CFS will be considered in preparing the draft variation which will seek to amend the following sections of the Code:

- Section 1.1.2—3, to include a new definition for cell-cultured food
- Section S25—2, to list cultured quail as a permitted novel food and prescribe conditions of use, including:
    - that the food be mixed with other ingredients to form products such as, but not limited to, logs, rolls and patties
    - a specified name to identify Vow's cultured quail cells e.g. "Cultured quail (*Coturnix japonica*) fibroblasts" (or similar)
    - food must be produced under a food safety program in accordance with Standard 3.2.1 of the Code
- Schedule 3, to include a specification for cultured quail cells

Specific labelling requirements (section 2.2.8 above) to inform consumers that the novel food ingredient is 'cell-cultured' are proposed to apply as conditions of use when cultured quail cells are used as an ingredient in a food for sale.

No specific nutrition risk management measures are required.

2.4 Risk communication

2.4.1 Consultation

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

FSANZ has developed a communication strategy for this application. Subscribers and interested parties have been notified about this call for submissions (CFS) via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News.

FSANZ acknowledges the time taken by individuals and organisations to consider this application. All comments are valued and contribute to the rigour of our assessment. Comments received will be taken into account when deciding whether to develop draft variation(s) at the next stage of assessment.

2.4.2 World Trade Organization

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

This issue will be fully considered at the next stage of the assessment. As explained above, FSANZ has yet to decide to prepare a proposed measure. Submissions received in response to this CFS will inform that decision. If FSANZ decides to prepare a proposed measure, public consultation must occur in relation to that measure, once prepared. If necessary, notification will be made at that point in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade (TBT) or Application of Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO members to comment on any proposed amendments.

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act.

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Impact analysis requirements applying to FSANZ were changed in April 2023[1]. As a result, undertaking a Regulation Impact Statement (RIS) in addition to the assessment required under the FSANZ Act is no longer mandated. However, given the nature of the proposed change it is unlikely that a RIS would have been required under the previous arrangements.

Regardless of whether or not a RIS is required, FSANZ has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. FSANZ will also consider further feedback and any further data. 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 from the proposed measure (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, where the status quo is rejecting the application. This analysis considers the costs and benefits of the sale and use of a mixed food derived from cell-cultured quail.

FSANZ is of the view that no other realistic food regulatory measures exist, however information received following consultation may result in FSANZ arriving at a different conclusion.

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 by permitting the use of cell-cultured quail.

Costs and benefits of permitting the use of cultured quail cells

The use of cultured quail cells as a novel food ingredient would be permitted under the Code.

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.

Industry

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

Consumers

If this application is approved, and depending on the commercial success of 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

[1] For more information, refer to the Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies (June 2023)

considerations.

Government

There may be small additional costs of monitoring an extra novel food ingredient for regulators to ensure compliance with the Code requirements, including regulators becoming familiar with the concept of cell-cultured foods.

Conclusions from cost benefit considerations

The risk assessment did not identify any safety concerns that could not be adequately managed from permitting this cultured quail cells ingredient (see sections 2.1 and 2.2 of this CFS). Use of foods derived from cultured quail cells would be voluntary and this application is deregulatory. Industry would only use mixed foods derived from cultured quail cells where they believe a net benefit exists for them.

Therefore, FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of cultured quail cells most likely outweigh the associated costs.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application. FSANZ seeks comments on this assessment to inform its decision on preparation of draft variation.

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ has completed a hazard and risk assessment (SD1) which is summarised in section 2.1 of this report. The assessment concluded that there are no public health and safety concerns associated with permitting harvested quail cells as a novel food ingredient.

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

Existing and proposed labelling requirements in section 2.2.8 of this report would apply to cultured quail cells when added as a novel food ingredient to food products for sale, which would provide information to enable consumers to make an informed choice.

2.5.2.3 The prevention of misleading or deceptive conduct

Proposed labelling requirements in section 2.2.8 of this report would reduce the risk of consumers being misled, by assisting consumers to identify the presence of cultured quail cells as novel food ingredient as distinct from conventional quail.

2.5.3 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. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other relevant technical and scientific information, was considered by FSANZ in assessing the application.

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

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

Whilst there are other cell cultured foods provided permission overseas, this Vow cultured quail cell novel food has only been assessed by FSANZ and in Singapore. Providing permission for the Vow cultured quail cells could help foster continued innovation and improvements in food manufacturing techniques and processes in relation to this type of technology.

- **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 Forum on Food Regulation**

FSANZ has had regard to both high order and specific policy principles in relevant Ministerial Policy Guidelines. Two Ministerial Policy Guidelines specifically applied to this application:

- Regulation of Novel Foods
- Labelling of foods produced or processed using new technologies.

Noting the assessment in SD1 and SD4, and the assessment above of FSANZ Act requirements, FSANZ considers these policy guidelines would be met by the proposed permission and labelling requirements, if approved.

3 References

National Health and Medical Research Council (NHMRC), Australian Government Department of Health and Aging, New Zealand Ministry of Health (MoH) (2006) Nutrient Reference Values for Australia and New Zealand including recommended dietary intake 2006, updated September 2017. Available here: https://www.nhmrc.gov.au/file/3321/download?token=RHlu4kNJ

WHO 2023 Food safety aspects of Cell-based food. World Health Organization & Food and Agriculture Organization of the United Nations. https://www.who.int/publications/i/item/9789240070943