SUBMISSION GUIDE

Food Standards Australia New Zealand (FSANZ)

Application A1269 - Cultured Quail as a Novel Food

Introduction

The following document has been developed as a guide for interested stakeholders to respond to Food Standards Australia New Zealand's (FSANZ) first of two consultation rounds in relation to 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.

FSANZ is now calling for submissions to assist further consideration of the application, as per the requirements of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

Background

Vow Group Pty Ltd

Vow Group Pty Ltd (Vow) is an Australian company based in Sydney, NSW. Its website states its mission is to make unique, delicious meat directly from animal cells that are nutritious and sustainable. Vow is seeking food safety approval for its first product; cell-cultured quail as a food ingredient.

You can learn more about Vow on their website - https://www.vowfood.com/

Food Standards Australia New Zealand (FSANZ)

Food Standards Australia New Zealand (FSANZ) is an independent statutory agency established by the FSANZ Act and is part of the Australian Government's Health portfolio.

FSANZ develops food standards for Australia and New Zealand that enable a wide variety of safe foods to be available to consumers.

FSANZ develops and administers the Australia New Zealand Food Standards Code. The Code regulates the use of food ingredients, processing aids, colourings, additives, vitamins and minerals. It covers the composition of foods such as dairy, meat and beverages, as well as regulating novel foods and food technologies like genetic modification. The Code also sets requirements for labelling for both packaged and unpackaged food, including mandatory warnings or advisory labels for things like allergens.

You can learn more about FSANZ on their website - https://www.foodstandards.gov.au/

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.

Novel foods are non-traditional foods that require assessment by FSANZ to establish their safety before they are added to the food supply. 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.

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.

Application details:

Application number:	A1269
Application type:	Amendment to the Australia New Zealand Food Standards Code
Category:	Novel Food
Assessment:	Major Procedure
Organisation:	Vow Group Pty Ltd
Date application received:	20 January 2023 (updated 24 October 2023)
Consultation opening date	11 December 2023
Consultation closing date:	6pm (AEST) 5 February 2024
Supporting Document links:	Call for Submissions Supporting document 1 - Hazard and Risk Assessment Supporting document 2 - Consumer Literature Review Supporting document 3 - Consumer Insights Tracker Supporting document 4 - Labelling Application A1269 from Vow Foods Pty Ltd
Submissions to:	Online via the Consultation Hub In writing to: Food Standards Australia New Zealand PO Box 5423 KINGSTON ACT 2604 AUSTRALIA Tel +61 2 6271 2222 Food Standards Australia New Zealand PO Box 10559 WELLINGTON 6140 NEW ZEALAND Tel +64 4 978 5630
Contact:	submissions@foodstandards.gov.au

Consultation Process
FSANZ has undertaken a Hazard and Risk Assessment of the application and now welcomes submissions to assist further consideration of the application.

All submissions will be published on the Consultation Hub. FSANZ will not publish material that is accepted 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.

You can submit your application online via the Consultation Hub. FSANZ also accepts submissions in hard copy to 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 Consultation Hub.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 5 February 2024

SUMMARY OF FINDINGS

The following is a summary of FSANZ's assessment considerations and key findings, including on safety, hazards, nutrition, product definition and labelling.

No food safety concerns were identified.
The Hazard and Risk Assessment addressed microbiology, biotechnology, toxicology, allergenicity, nutrition and dietary intake/exposure considerations of Vow's application.

FSANZ referenced the FAO/WHO publication "Food Safety Aspects of Cell-Based Food" as the foundation for structuring their assessment, which considers potential hazards in the four stages of cell-based food production:
1) cell-sourcing;
2) cell growth and production;
3) cell harvesting; and
4) food processing.

FSANZ's hazard and risk assessment focussed on the first three stages and considered:

- 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, which includes collection, packaging and freezing (harvested cells).

No safety concerns were identified in the biotechnology, toxicology and allergenicity evaluations based on the information available as part of the Vow application.

The high-level findings of the assessment are:

- 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.

Two potential food safety hazards were identified in the assessment, but they are not considered unique to Vow's cultured quail application.

1. Microbiological hazard - *Listeria monocytogenes* is ubiquitous in the environment and can become established in food processing environments. Therefore, FSANZ suggested there may be a contamination risk during harvesting and processing of cell biomass. Vow advised the final product will need to be cooked, but FSANZ' assessment did not consider a processed product.

2. Other hazards - Foodborne pathogens, including faecal associated pathogens such as *Salmonella* and *E. coli* are potential hazards that could contaminate the cell biomass during further processing either from personnel or other ingredients.

Some nutritional issues were highlighted, but no specific nutrition risk management measures are required.

Harvested cells contain higher concentrations of iron and sodium than chicken breast. However, at the highest reported baseline levels of iron intake, no age/sex groups assessed in Australia and New Zealand exceed their respective Upper Limits (ULs).

The mean and high usual intake of sodium at baseline exceeded the ULs or Suggested Dietary Target (SDTs) for all of the population subgroups assessed for Australia and New Zealand, except the mean usual intake for females aged 51 years and older.

Overall, considering the evidence FSANZ found there were no nutritional risks identified from the consumption of the harvested cells containing the levels of nutrients provided in the application, particularly given the likely infrequent consumption of the harvested cells.

FSANZ will include a new definition for cell-cultured food in the Food Standards Code.

The Call for Submissions states that 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 defined in subsection 1.1.2—3(2) of the Code (see section 1.3.4 of the 1st CFS).

FSANZ considers a new definition should cover not only Vow's product, 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.

FSANZ proposes to require that these products must be labelled "cell cultured".

Currently, the Code does not include specific labelling requirements for cell-cultured food. Along with generic labelling requirements (including ingredients, date marking and directions for use etc), in the Labelling Guidance provided as part of the CFS, FSANZ proposes to require the statement 'cell-cultured' in labelling for food identification purposes.

For food for sale that contains the applicant's cultured quail cells as a novel food ingredient, FSANZ's proposed approach, currently, 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 naming requirements.
- If the food for sale is represented as a quail food product—in addition to existing food naming 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 Nutritional 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.
    - if 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.

FSANZ considers that mandating a specific statement would ensure labelling consistency across products and promote consumer understanding and familiarity over time, while noting this may not be the most flexible approach for industry.

Underpinning their proposed approach to the term "cell-cultured" is evidence from available consumer literature, highlighted in the FSANZ assessment:

- Terms incorporating the word 'cell' (eg 'cell-cultured', 'cell-cultivated' and 'cell-based') perform the best for consumers to correctly identify the true nature of the product.
- These terms were viewed as being the most descriptive based on objective and perceived levels of understanding and enabled consumers to best differentiate the product from conventional meat and plant-based meat alternatives.

- Consumer acceptance of these terms was lower than for terms ‘cultured’ and ‘cultivated’ but FSANZ notes consumer acceptance is less important from a regulatory perspective and is not a consideration under the labelling risk management principles.
- Consumer understanding of allergenicity of cell-cultured meat/seafood is not high, even for the best performing terms for accurate product identification (‘cell-cultured’, ‘cell-cultivated’), as only up to 66% of consumers correctly identified that the product was not safe to consume for those with an allergy to the traditional counterpart.
- Terms such as ‘lab-grown meat’, ‘artificial’, ‘clean meat’, ‘slaughter free meat’ and ‘in vitro meat’ were also examined but did not consistently perform well in relation to accurate product identification, differentiation, preferences and/or acceptance.
- FSANZ considers the term ‘cell-cultured’ more accurately describes the production process. For example, ‘cultured’ or ‘culturing’ means growing cells outside their natural environment under controlled conditions and involves the use of culture media. ‘Cultivated’ is less specific, as it can relate to a ‘cultivator’ (bioreactor) or relate to its use in agriculture to describe crops.
- FSANZ also notes the technology is expected to evolve beyond the production of a cell biomass made up from a single cell type, such as fibroblasts in Application A1269. In the future, different cell types (eg muscle and fat cells) may be mixed together for organoleptic properties. Cell mixing may occur post-harvest or as part of the cell production process to form meats intended to mimic the taste and appearance of conventional meats. FSANZ considers the term ‘cell-cultured’ would remain relevant for these scenarios (including post-harvest when cells are mixed outside the bioreactor).
- Cell mixing could involve the formation of structured meats, for example, a 3D printed whole cut meat-like tissue, or the cells could be grown onto a 3D printed biodegradable scaffold. In these examples, the tissue or cells (either from a single cell type or different cell types) would still be cultured (kept alive in a culture dish with media) but not cultivated in the industry description sense, because a bioreactor is not involved in the assembly of the final product.

When considering labelling of product, FSANZ is proposing to require the statement ‘cell-cultured’ to be used in conjunction with the name of the novel food ingredient in the statement of ingredients, for example, “cell-cultured quail patties.”

FSANZ has also determined the term “meat” cannot be used in isolation to describe a food containing, in this case, cultured quail cells, for example “quail meat patties’, or as the ingredient (“quail meat”). The term meat could still be used in conjunction with the qualifier cell-cultured.

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SUBMISSION GUIDE

FSANZ has not provided specific requests for information or questions for consideration as part of the consultation process. Instead, a submission is an opportunity to provide comments on its findings and raise any additional information you think FSANZ should take into consideration as part of this consultation.

FSANZ has indicated that submissions received in this round of consultation will be considered in preparing the draft variation to the Code, making this a valuable opportunity for stakeholders to shape how cell-cultured food products will be assessed, approved and labelled in the future. The draft variation to the Code will form the basis of the second consultation period, due in the first half of 2024.

Below we have included a suggested structure to inform the writing of your own submission. We have also offered suggestions, in italics, on points you may wish to consider and incorporate if you are making your own submission.

Suggested structure:

Introduction

- Address the letter to the Regulator.
- Introduce your company.
- *You may wish to acknowledge the significance of the application assessment and commend FSANZ on their comprehensive assessment of the food safety risks.*
    - *This assessment is a landmark in the development of the cellular agriculture sector in Australia and New Zealand.*
    - *Vow's application is the first cultivated/cultured meat product to be assessed by FSANZ, so represents an important milestone in the development of the sector in Australia – New Zealand. Approving the food safety of these products underpins the development of new food products delivering consumer choice, provides confidence to consumers in their safety, and provides the potential for investment opportunities for domestic and international companies in Australia – New Zealand.*

Food safety assessment

- *Your submission may wish to support the rigorous assessment undertaken by FSANZ, noting the transparent approach and comprehensive data provided by Vow that demonstrates the safety of their product.*

Food safety hazards assessment

- *Your submission could highlight that Listeria is a safety risk in all food processing and production environments and not a risk specific to the production of cultured quail. FSANZ produced no evidence to suggest that the risk of Listeria is higher in cultured quail. The risk of Listeria is significantly reduced upon cooking, which is the intent in relation to Vow's cultured quail product.*
- *Your submission could highlight that adherence to a HACCP-based food safety system that has correctly and accurately identified control points or critical control points, with evidence of good practices, is important in reducing the microbiological risk for cell cultured food production. FSANZ noted that Vow was able to demonstrate they have implemented a HACCP-based approach to producing the cultured quail harvested cells.*

Nutrition

- *Your submission could highlight the need to consider the low likely frequency of consumption of cell cultured quail (initially in food service) as well as a nutritional assessment of 300g/day of cultured quail cells that will be mixed or blended with other ingredients prior to consumption, when evaluating all nutritional information.*

Product definition

Noting the evolving status in defining cell-cultured/cultivated meat (as the application process progresses), FSANZ's determination of 'cell-cultured'' as the industry standard definition would likely have implications for the Australian sector's ability to define and call their products '(cell-) cultivated' moving forward. Depending on your position, you may wish to either:

- *provide your support for FSANZ's proposed product definition, noting the evidence they have considered to reach this determination based on Vow's cultured quail product as the first and only application before FSANZ.*
- *advocate that it is premature to determine product definition applicable to all future products of a similar nature based on Australia's first application, and that the proposed terminology be applied only to this product under assessment, giving industry the opportunity to submit further applications and evidence to inform a standard reflective of the broader sector.*
- *suggest a varied definition including both 'cell-cultivated' and 'cell-cultured,' bypassing the need to seek another variation to the Code in the future, similar to the approach taken in Singapore.*

Labelling

The current proposed labelling requirements would mandate the sector label its products per the proposed standard definition, 'cell-cultured.' The term 'meat' would still be permitted for use in labelling as long as it is used in conjunction with the qualifier 'cell-cultured.'

Looking abroad to the two jurisdictions that have approved these products for sale, FSANZ notes that there is no consistency in the regulatory labelling approaches adopted by Singapore and the USA. Singapore only provides guidance on the qualifying descriptors, whereas in the USA, the specific term 'cell-cultivated' was approved for two companies' cultivated chicken products.

Depending on your position, you may wish to:

- *provide support for FSANZ's proposed labelling requirements as they relate to using the term 'meat' in isolation, noting the importance of accurate product representation and mitigating the potential to mislead consumers about the nature of the product.*
- *provide your support for FSANZ's proposed mandatory labelling requirements as they relate to the proposed definition 'cell-cultured', noting the importance of setting clear industry standards early to ensure consistency.*
- *advocate that it is premature to determine product labelling requirements applicable for all future products of a similar nature based on Australia's first application, in particular given the limited field of academic literature currently available to support robust decision-making. Instead, the proposed requirements should be applied only to the product under assessment, therefore giving the regulator and industry more opportunity to assess and present further evidence to inform a standard.*
- *suggest alternative labelling requirements based on an alternate proposed definition, for instance, 'cell-cultivated,' that could appropriately be applied for the suite of products of a similar nature that may seek regulatory approval in coming years, noting the widespread industry usage of 'cultivated' as a descriptor.*

Conclusion

- Thank FSANZ for the opportunity to provide comment on this landmark assessment for the Australia - New Zealand cellular agriculture sector.
- *You may wish to highlight the scientific rigour, transparency and accountability exhibited both by Vow (the applicant) and FSANZ (the regulator).*
- *You may wish to express your willingness to discuss elements of your submission in further detail, or provide clarification where required.*
- *You may wish to state that you look forward to engaging with FSANZ on the release of the draft Australia New Zealand Food Standard Code as part of the second consultation period for this application.*

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