

# Submission

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Food Standards Australia New Zealand (FSANZ)  
*Application A1269 – Cultured Quail as a Novel Food*  
(Vow Group Pty Ltd)

## Authored by:



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## 1. Executive summary

Cellular Agriculture Australia (CAA) is pleased to provide comment on FSANZ's assessment of the first application for a cultivated meat product in Australia-New Zealand.

Vow Group Pty Ltd's (Vow) application *A1269 Cultured Quail as a Novel Food* (A1269) represents a landmark in the development of the cellular agriculture sector in Australia. The assessment of this product also contributes to creating the regulatory pathway for more applications and a future where cellular agriculture products are no longer assessed as novel foods, a key focus for CAA.

CAA is pleased to note the findings of the Hazard and Risk Assessment:

1. The assessment concluded that the cell line is genetically stable, and microbiological risks associated with cell line sourcing are very low.<sup>1</sup>
2. Given the aseptic nature of cell proliferation/biomass production stages, the microbiological risk associated with cells at the point of harvest was very low.<sup>2</sup>
3. No toxicological concerns were associated with the cell media or inputs used in the production process at the estimated consumption levels.<sup>3</sup>
4. No nutritional safety concerns were identified from the consumption of the harvested cells containing the levels of nutrients provided in the application.<sup>4</sup>
5. The available information indicated that the harvested cells are unlikely to pose a food allergenicity concern for the general population.<sup>5</sup>

Noting the complexities associated with the first application, CAA commends the rigour and transparency of FSANZ's assessment. However, FSANZ should now consider how streamlining the regulatory process for future applications can occur while maintaining Australia-New Zealand's unimpeachable food safety standards. CAA submits that overregulation may become a barrier to commercialisation if some of the testing and data requirements in A1269 continue to be required.

As a principle, CAA supports the development of a cultivated meat approvals pathway rather than assessment under the novel foods standard. To progress this pathway, FSANZ has advised CAA that amendments to the Food Standards Code can only be made via an application. Therefore, CAA submits that there may be opportunities in this assessment to

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<sup>1</sup> Food Standards Australia New Zealand (FSANZ) "Hazard and risk assessment – Application A1269 Cultured quail as a novel food" Supporting document 1, December 2023, S 2.2.2, p14

<sup>2</sup> Ibid S 4.1, p3

<sup>3</sup> Ibid S 2.2.3.1, p14

<sup>4</sup> Ibid S 4.2 p3

<sup>5</sup> Ibid S 2.2.3.2, p17

start the development of such a framework through more explicit guidance around basal media inputs, allergen testing, genetic drift, and contamination testing.

CAA notes FSANZ's proposal to prepare a draft variation to the Code for the second round of consultation, which would include a new definition for cell-cultured food. CAA has considered how a definition could provide clarity to the broader food sector while capturing the possible combinations of technologies and products for which companies may seek food safety approval. Therefore, CAA submits the following definition for cell-cultured food:

*"Cell-cultured food means a food (whole food or ingredient) that is developed by isolating and cultivating cells from animals, plants or microorganisms, which on their own or in combination with other ingredients, produce new or analogous consumer food products."*

That said, CAA does not support the proposal to mandate a single qualifying term nor FSANZ's preference for the term 'cell-cultured' for either the food name or the statement of ingredients. CAA acknowledges the future potential benefit of mandating specific qualifiers in the Code, but we do not believe the mandating of a specific term should be used as a preemptive measure. CAA supports the term 'cultivated' for products developed using cellular agriculture but submits that an interim measure should be implemented and 'cultivated,' 'cell-cultivated,' 'cultured,' and 'cell-cultured' should all be deemed acceptable.

Based on our reading of the assessment and supporting documentation, CAA is pleased to support FSANZ's finding:

*"The assessment concluded that no public health and safety concerns are associated with permitting harvested quail cells as a novel food ingredient."*<sup>6</sup>

CAA also notes that based on the assessment, FSANZ's proposed approach is "to permit the sale of cultured quail cells as a novel food ingredient."<sup>7</sup> while confirming that "no specific nutrition risk management measures are required".<sup>8</sup>

Therefore, CAA submits there are no scientifically valid food safety reasons to reject A1269 *Cultured Quail as a Novel Food*.

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<sup>6</sup> FSANZ (2023) "Call for submissions – Application A1269 Cultured quail as a novel food" pg 16

<sup>7</sup> Ibid pg 15

<sup>8</sup> Ibid pg 14

## 2. Introduction

Cellular Agriculture Australia is pleased to provide this submission to the Food Standards Australia-New Zealand (FSANZ) Call for Submissions (CFS) on the hazard and risk assessment of *A1269 Cultured Quail as a Novel Food* (A1269).

CAA notes Vow's application is for a cultured-quail product. However, CAA will use the term 'cultivated meat' as a descriptor throughout this submission. This term is consistent with the Memorandum of Understanding<sup>9</sup> CAA signed with more than 30 other APAC stakeholders in 2022 that aligned the region on the term 'cultivated' as the preferred English-language descriptor for food products grown directly from animal cells.

This application for a cultivated meat product is a landmark in the development of the cellular agriculture sector in Australia-New Zealand, and we commend FSANZ on the rigour and transparency of the assessment process.

In preparing this submission, CAA considered the following documents on the FSANZ consultation hub website:<sup>10</sup>

[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](#)

CAA has prepared this submission with input and support from cellular agriculture stakeholders and sought specific technical advice from James Ryall, PhD, Life Sciences and Biotech Consultant, and former Chief Scientific Officer at Vow (2019–2023).

We note FSANZ is assessing this application as a Major Procedure that requires two rounds of public consultation. This first 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, with a second CFS to seek feedback on the draft Code due in the first half of 2024.

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<sup>9</sup> Good Food Institute Asia Pacific (GFI-APAC) (2022) Memorandum of Understanding (<https://gfi-apac.org/leading-apac-cellular-agriculture-stakeholders-announce-historic-agreement-in-singapore/>) accessed 27 January 2024

<sup>10</sup>

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

### 3. About Cellular Agriculture Australia

[Cellular Agriculture Australia](https://www.cellularagricultureaustralia.org/)<sup>11</sup> (CAA) is a registered Australian not-for-profit dedicated to advancing Australia's cellular agriculture sector.

Our mission is to build the ecosystem to position Australia as a leader in cellular agriculture. These technologies – particularly cell cultivation and precision fermentation – have the potential to play a critical role in diversifying food production, strengthening food security, and helping to meet the growing global demand for protein and other products sustainably.

We work across Australia's entire cellular agriculture sector, convening conversations to identify and work on common, non-competitive priorities. We are inclusive and participatory in our approach and engage with a broad range of stakeholders on key thematic areas, including navigating regulation, policy and advocacy, sector-building, targeted communications and awareness-raising, and accountability.

Working to create the regulatory environment to support cellular agriculture products to scale is one of CAA's key pillars. In June 2023, we convened a [Food Safety Regulation Workshop](#)<sup>12</sup> in Sydney and established an [Industry Working Group \(Regulation\)](#)<sup>13</sup> to progress the sector's priorities. The working group consists of company representatives and academia, with a focus on supporting the sector's engagement with domestic and global regulation. CAA has also recently published a [suite of resources](#)<sup>14</sup> to assist companies in navigating the Australia-New Zealand food safety system, including template dossiers for use when engaging with FSANZ.

CAA is also a Member of the [APAC Regulatory Coordination Forum](#)<sup>15</sup>, established in 2023 by the APAC Society for Cellular Agriculture and the Good Food Institute (APAC). The purpose of the Forum is to unify efforts to advance regulations for cellular agriculture in the APAC region and beyond.

Common language and understanding are critical to establishing a new industry. In 2023, CAA developed a clear foundation of language relating to cellular agriculture in collaboration with the sector. This involved multiple phases, including secondary research and two rounds of consultation with academic and industry stakeholders. The subsequent

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<sup>11</sup> <https://www.cellularagricultureaustralia.org/>

<sup>12</sup>

[https://assets-global.website-files.com/641400f02d9306cbd4fb3f94/64b77343a11ce89af0fd3ee\\_Food%20Safety%20Regulation%20Workshop%20Report%20-14%20June%202023.pdf](https://assets-global.website-files.com/641400f02d9306cbd4fb3f94/64b77343a11ce89af0fd3ee_Food%20Safety%20Regulation%20Workshop%20Report%20-14%20June%202023.pdf)

<sup>13</sup> <https://www.cellularagricultureaustralia.org/projects/industry-working-group-regulation>

<sup>14</sup> <https://www.cellularagricultureaustralia.org/resources/food-safety-regulation>

<sup>15</sup> <https://www.cellagforum.info/>

[Language Guide](#)<sup>16</sup> aims to reflect as accurately as possible the collectively preferred terms and language of the cellular agriculture sector in Australia, noting that consensus was not always possible.

## **4. A1269 Cultured Quail as a Novel Food**

FSANZ has assessed an application made by Vow Group Pty Ltd (Vow) 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.

The application is seeking approval for the use of harvested cells as a main ingredient to be mixed with other permitted food ingredients (e.g., calcium chloride, microbial transglutaminase, oil, textured vegetable protein) to produce a final mixed food product such as a log, roll or patty and served at a maximum of 300 g of the harvested cells per serve per day.

### **4.1 Proposed changes to the Australia New Zealand Food Standards Code**

CAA notes that the submissions received in this consultation round will inform the development of proposed amendments to the Australia New Zealand Food Standards Code (the Code), which will be the subject of the next round of consultation.

#### **4.1.1 A cultivated meat approvals pathway**

As a principle, CAA supports the development of a cultivated meat approvals pathway rather than assessment under a novel food standard. Beyond nomenclature and definitions, CAA notes this assessment does not appear to be building a framework in the Code whereby regulatory requirements and eligibility start to evolve. CAA is not currently seeking a separate standard for cultivated meat, as it is too early in the sector's development to advance requirements that could be overly prescriptive, particularly as the technologies and products evolve. However, as FSANZ has stated, changes to the Code can only be made through an application; there appear to be some areas that could be considered in the draft Code, including:

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<sup>16</sup> <https://www.cellularagricultureaustralia.org/resources/key-terms>

- The development of relevant thresholds for an acceptable rate of genetic drift, including a clear indication of how FSANZ will assess the data for consumer safety.
- Refining requests for data to ensure they are directed at ensuring the safety of consumers. For example, if the focus is on the potential for allergens to arise from mutations, insertions or deletions, then the requirement should shift towards targeted sequencing of these areas.
- Consideration of phenotypic monitoring as a key indicator of contamination to provide real-time data rather than testing (noting Vow's dual approach) at various times in the production process
- Refining requirements around allergen testing, noting Vow performed sequence homology testing to all known allergens (including soy and peanuts), and this was not deemed useful by FSANZ.
- Unless the basal media inputs not being inserted into the Code are proprietary, consider permissions for these media.
- Consider permissions for an amino acid or carbohydrate to be included in the Code in a concentration deemed safe.

#### **4.1.2 A new definition for cell-cultured food**

CAA notes that the type of food under assessment does not meet the current definition of 'meat' in Section 1.1.2 of the Code, where '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) fetuses or part of fetuses.<sup>17</sup>*

CAA notes that a definition of cell-cultured food will not be mandated on pack but rather inserted into Standard 1.1.2 of the Code.<sup>18</sup> To provide certainty in determining a definition, CAA agrees with FSANZ that any definition should cover not only the food under

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<sup>17</sup> Australian Government (1991) [Food Standards Australia New Zealand Act 1991](#)

"Food Standards Code" (version July 2023) S1.1.2 <https://www.legislation.gov.au/F2015L00385/latest/text> (accessed 27 January 2024)

<sup>18</sup> Labelling is considered separately, in section 6.1 of this submission.



assessment but other subsequent foods of a similar nature. Noting these foods may be certain types of cells, or a combination of cell types, with or without additional components such as fats or scaffold (plant-based and/or muscle, connective tissue, or purified animal proteins such as collagen).

CAA submits that the definition should provide for a wide range of technologies and end products to be considered relevant under the definition. Therefore, CAA proposes:

*“Cell-cultured food means a food (whole food or ingredient) that is developed by isolating and cultivating cells from animals, plants or microorganisms, which on their own or in combination with other ingredients, produce new or analogous consumer food products.”*

#### **4.1.3 Prescribed uses of cultured quail as a novel food**

CAA notes and agrees to FSANZ’s proposal to list cultured quail as a permitted novel food and prescribe conditions for use in Section S25-2, namely:

- 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 (e.g., HACCP) in accordance with Standard 3.2.1 of the Code.<sup>19</sup>

## **5. Hazard and Risk Assessment**

As the first cultivated meat application in Australia, CAA notes and supports the approach by FSANZ in undertaking the Hazard and Risk Assessment, namely:

- Referring to the FAO and WHO publication “Food Safety Aspects of Cell-Based Food,” which outlined 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.
- CAA notes that FSANZ’s hazard and risk assessment focussed on the first three stages and considered the following:
  - 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)

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<sup>19</sup> FSANZ (2023) “Call for submissions – Application A1269 Cultured quail as a novel food” pg 12

- and those cells at the point of harvest, which includes collection, packaging, and freezing of harvested cells.

CAA is pleased to note FSANZ's findings:

1. The assessment concluded that the cell line is genetically stable, and microbiological risks associated with cell line sourcing are very low. (SD1, Section 2.2.2)
2. Given the aseptic nature of cell proliferation/biomass production stages, the microbiological risk associated with cells at the point of harvest was very low. (SD1, Section 4.1)
3. No toxicological concerns were associated with the cell media or inputs used in the production process at the estimated consumption levels. (SD1, Section 2.2.3.1)
4. No nutritional safety concerns were identified from the consumption of the harvested cells containing the levels of nutrients provided in the application. (SD1, Section 4.2)
5. The available information indicated that the harvested cells are unlikely to pose a food allergenicity concern for the general population. (SD1, Section 2.2.3.2)

CAA notes the complexities associated with assessing the first application for cultivated meat in Australia–New Zealand and appreciates the need for regulators to become familiar with these new technologies. It is also essential for confidence in the cellular agriculture sector for a comprehensive and rigorous assessment covering a range of biotechnology, toxicology, and allergenicity questions. Therefore, CAA is pleased to note the detailed and considered assessment by FSANZ.

However, CAA recommends that FSANZ consider how streamlining the regulatory process for future applications can occur while maintaining Australia–New Zealand's unimpeachable food safety standards. CAA submits that overregulation may become a barrier to commercialisation if some of the testing and data requirements in A1269 continue to be required. FSANZ took eleven months to assess the application before opening the first consultation phase. We expect this timing will decrease as the regulator becomes more familiar with these products, updates the Code, and refines the data requirements.

Some observations and recommendations are provided in the following sections.

## **5.1 Cell line**

CAA notes FSANZ's focus on identifying hazards associated with the development of the cell line and its proliferation in culture is appropriate, namely;

- the vertical transmission of microbiological hazards
- cell line stability
- and any known hazards specifically associated with quail.

Firstly, CAA commends Vow for providing evidence that the source farm for the quail cells was under an official monitoring regime and that tests for specific avian pathogenic bacteria, viruses, and mycoplasma were negative.

CAA agrees with FSANZ's finding that the potential microbiological risk posed during the initial cell isolation steps is very low. Because Vow isolated primary avian cells as embryonic cells, there is less risk than if taken from an adult bird. Only pathogenic organisms that can be vertically transmitted from the layer hen to the egg are of concern from a public health perspective. Therefore, a viral contaminant (avian influenza) risk would be extremely low. Plus, airborne particles and faecal matter typically spread avian influenza, so any potential risk is further reduced through the use of embryonic fibroblasts.

While the risk of avian flu is likely reduced, mycoplasma poses a significant risk. Therefore, the negative PCR tests for mycoplasma by both the cell supplier and Vow (where a second enzymatic assay – MycoAlert – was also negative) are essential for regulator confidence. Further, we note that Vow's dual approach to testing for mycoplasma at various stages of the production process and in production runs is more testing than performed by both GOODmeat and Upside Foods in their FDA (US) approved notices.

CAA submits that as the sector matures and products are assessed on a cultivated meat pathway rather than as a novel food, it is worth considering phenotypic monitoring as a key indicator of contamination. Cells contaminated with microorganisms such as yeast or mycoplasma show rapid changes in growth rates and the surrounding pH and oxygen consumption rates. Therefore, monitoring phenotypic changes will likely be more informative and provide a real-time indicator of potential contamination.

We note FSANZ's interest in 'genetic drift' and Vow's provision of results from whole genome sequencing (WGS) that found an acceptable level of genetic drift. If WGS is an ongoing requirement, FSANZ must develop and publish relevant thresholds for an acceptable rate of genetic drift, including a clear indication of how the data should be assessed for consumer safety. WGS generates significant amounts of data across the production lifespan of a cell line. We acknowledge the learning curve associated with assessing the first cultivated meat application, but we expect FSANZ to refine its requests for data to ensure they are directed at ensuring the safety of consumers. For example, if the focus is on the potential for allergens to arise from mutations, insertions or deletions, then the requirement should shift towards targeted sequencing of these areas.

On allergenicity, CAA notes FSANZ's assessment that reported cases of (traditional) quail meat allergens are rare. However, egg allergens are prevalent. While Vow's cell line consists of embryonic fibroblasts, these cells are not responsible for producing allergenic proteins such as ovalbumin. We also submit that while embryonic fibroblasts contain a complete set of DNA (including that which encodes for ovalbumin), this is true of every cell. The majority of genes are quickly silenced (never to be expressed again) as cells become specialised during development. Therefore, while CAA commends the thoroughness of FSANZ's assessment of the cell line's allergen risks, there needs to be a baseline acceptance of the risk margin when seeking data from applicants.

It is unclear from the application whether Vow voluntarily performed sequence homology testing on all known allergens or whether this was a request made by FSANZ. In either case, the following statement suggests that these tests are not useful and should not be required in the future to eliminate over-regulation: *"This additional analysis is of limited value for risk assessment purposes."*<sup>20</sup> We submit that comparing sequence homology in quail to peanuts and soybeans (among others) is not useful.

Finally, CAA is pleased to note that Vow did not use antibiotics in the production of the cells, noting the supplier's use of antibiotics was limited to the first two passages, a welcome benefit arising from cultivated meat production processes.

CAA notes FSANZ's conclusion that:

"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."<sup>21</sup>

## **5.1 Method of Production**

CAA notes there are no independent microbiological data or specifications to assess the hazards of these foods, and no criteria have been established internationally. Therefore, CAA notes the process FSANZ adopted for assessing any food safety risks in the production process, including cell proliferation, media, and other inputs and their suitability for use in food. The assessment confirmed 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. CAA also notes that the detected levels of all growth factors fell within the levels usually found within other regularly consumed avian

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<sup>20</sup> FSANZ (2023) "Hazard and risk assessment – Application A1269 Cultured quail as a novel food" Supporting document 1, December 2023, pg 16

<sup>21</sup> *ibid* pg 17

meat and that there were no concerns with the use of cryoprotectants, anti-foaming agents, or cleaning products.

CAA notes that cell biomass production is managed through Vow's food safety system, which includes a HACCP-based food safety plan supported by GHP, cGMP, and GCCP and was found to be supported by good practices. CAA agrees with FSANZ's requirement that all novel foods must be produced under a HACCP-based food safety plan, supported by GHP, cGMP, and GCCP with evidence of good practice.

Surveillance of the production of these foods, under a HACCP-based food safety plan, as they scale, should be undertaken by State food regulatory agencies, consistent with their current enforcement of food manufacturing standards.

CAA notes FSANZ's finding that there are no safety concerns arising from the presence of the basal media and inputs in the harvested cells. This safety finding should be emphasised as Vow took a very conservative approach, assuming that 100% of each ingredient in the liquid media is taken up and stored by the cell. This assumption almost certainly overestimates the amount of each ingredient likely to be consumed, providing an extremely high margin of safety.

FSANZ assessed numerous inputs in the basal media used for production that were considered low risk and therefore not considered processing aids – i.e., they do not perform a technological purpose during processing. Therefore, FSANZ does not intend to insert these inputs into the Code, noting "the majority" of inputs in the basal media are "permitted in the Code as amino acids, vitamins or minerals, processing aids or food additives."<sup>22</sup> CAA seeks to understand if the products not inserted into the Code are proprietary, and if not, request that in the interests of streamlining future applications, permissions be considered for these media in the Code. Further, FSANZ should consider whether permissions for an amino acid or carbohydrate to a concentration deemed safe could be added to the Code, thus providing for streamlined assessments in the future.

There is some uncertainty about FSANZ's approach to approvals as these technologies scale. FSANZ states that any significant 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."<sup>23</sup> CAA seeks clarification on the use of the term "such as scale up" in this context. CAA understands that if A1269 is approved, it creates the approved specifications for production, and Vow must ensure they meet these specifications as they

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<sup>22</sup> FSANZ (2023) "Call for submissions – Application A1269 Cultured quail as a novel food" pg 10

<sup>23</sup> Ibid pg 12

scale. The advent of new and improved technologies may allow for more efficient approaches as products scale, and this, combined with FSANZ’s limited resourcing, suggests a revised approach could be considered. Scale up activities shouldn’t automatically necessitate regulatory activity and if a manufacturer continues to meet specifications under scaled-up operations, then no regulatory intervention should be required.

CAA notes FSANZ's conclusion that:

*“There are no safety concerns arising from the presence of the basal media and inputs in the harvested cells.”* <sup>24</sup>

**5.3 Harvested cells**

CAA notes that the microbiological, nutrition, and dietary exposure assessments and specifications apply to the harvested cells, not the final mixed food. The harvested cells are a homogenous cell biomass, where potential microbiological hazards from ingredients, personnel, equipment, and the environment may contaminate the product during additional processing, including the final shaping and packaging.

CAA notes FSANZ's assertion that any microorganisms present are likely to be evenly distributed throughout the product, thus requiring cooking to ensure microorganisms, if present, are adequately mitigated. CAA notes that Vow intends for the final product to be cooked.

CAA accepts that the final harvested cell biomass should be considered a potentially hazardous food (PHF) as defined in Standard 3.2.2.

*Harvested cultured quail cell specifications*

As part of the application process, Vow defined microbiological standards it must meet. These standards are described in table form below and compared to the specifications proposed by GOODmeat and Upside Foods.

**Table 1. Microbiological standards (and results) comparison between Vow, GOODmeat and Upside Foods.**

Test	Vow (spec)	Vow (measured)	GOODmeat (spec)	GOODmeat (measured)	Upside Foods (measured)
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<sup>24</sup> FSANZ (2023) “Hazard and risk assessment – Application A1269 Cultured quail as a novel food” Supporting document 1, December 2023, S 3.1.1, pg 19

Standard Plate Count (CFU/g)	<10 <sup>4</sup>	<10	<10 <sup>4</sup>	<10	<100
Coliforms (CFU/g)	<100	<10	<24MPN/g	<3MPN/g	<10
E.Coli (MPN/g)	<3	<3	<3	<3	<10CFU/g
Enterobacteriaceae (CFU/g)	<100	<10	NA	NA	<10

\*CFU = colony forming units; MPN = most probable number

It is worth noting that both GOODmeat and Upside Foods also present data on yeast (CFU/g) and mould (CFU/g); however, yeast and mould contamination would likely be detected through phenotypic changes to oxygen consumption and pH.

CAA notes two potential food safety hazards were identified in the assessment but that are not unique to cellular agriculture products

- Microbiological hazard - *Listeria monocytogenes* is ubiquitous in the environment and can become established in food processing environments. Therefore, there may be a contamination risk during the harvesting and processing of cell biomass. CAA notes this risk is present for most uncooked/processed meat, vegetables and unpasteurised milk and cheese. FSANZ presented no evidence to suggest that the risk of *Listeria* is higher in cellular agriculture products. Importantly, the risk of *Listeria* is significantly reduced upon cooking, which is the intent with cultured quail.
- 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. CAA notes 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. CAA notes Vow demonstrated they have implemented a HACCP-based approach to producing the cultured quail harvested cells.

CAA notes FSANZ's conclusion that:

*The harvested cells are unlikely to pose a food allergenicity concern for the general population.*<sup>25</sup>

<sup>25</sup> FSANZ (2023) "Call for submissions – Application A1269 Cultured quail as a novel food" pg 8

## 5.4 Nutrition

CAA notes the objectives of the nutrition risk assessment were to compare the composition of the harvested cells to comparison foods, evaluate whether the consumption of the harvested cells would cause a nutritional imbalance in the diet, and determine the effect of the harvested cells on the absorption of other nutrients.

CAA notes that 40 nutrients – macronutrients, vitamins, and minerals – were examined, making it a comprehensive assessment. Vow has provided the most in-depth examination of vitamins for a cell-cultured product (nine vitamins in total, compared to the five reported by GOODmeat and Upside Foods). While some nutritional issues were highlighted, no specific nutrition risk management measures are required.

Again, Vow should be commended for taking a highly conservative approach to their food safety assessment, with a modelled consumption rate of cultured quail of 300g/day when the likely frequency of consumption would not be more than 300g/week. This overestimation of consumption rates should be considered when evaluating all nutritional information. It also provides a long-term horizon for nutritional safety approvals.

It is noted that Vow's cell-cultured quail was found to have ~50% of the protein found in conventional quail meat and a higher overall moisture content. The same is true for the cultivated chicken products produced by GOODmeat and Upside Foods, perhaps reflecting the use of embryonic fibroblasts rather than tissue.

The 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 exceeded 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. CAA notes that cultivated chicken from GOODmeat and Upside Foods also reported elevated sodium levels. Upside Foods reported a sodium level more than double that of Vow's cultured quail (up to 263mg/100g compared to 119mg/100g). While GOODmeat didn't directly report sodium levels in the harvested cell mass, they did detect sodium at a concentration of 1.7% of total dry weight.

CAA notes that cultured quail is high in Vitamin B12 (cobalamin), but no upper limit is placed on cobalamin consumption. CAA notes that cultured quail is high in Vitamin B7 (biotin), but there is no upper limit for biotin consumption.



CAA notes cultured quail is high in Vitamin B9 (folate), 217–268µg/100g (measured as total folate, which includes both natural folate and folic acid). There is no upper limit for natural folate, but folic acid has a sliding scale upper limit based on age and sex. It is unlikely that 100% of the detected folate is folic acid. If so, a 300g serving of cultured quail would exceed the recommended upper limits for anyone aged under 19 only. GOODmeat has also detected elevated total folate levels in their cultivated chicken (91µg/100g), but folic acid accounted for less than 10µg.

FSANZ found 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.

**Table 2. Nutritional standards (and results) comparison between Vow, GOODmeat and Upside Foods.**

Component (%)	Vow (spec)	Vow (measured)	GOODmeat (spec)	GOODmeat (measured)	Upside Foods (spec)	Upside Foods (measured)
Protein	>4	10	5–10	8	>12	14
Moisture	>80	87	85–95	89	>70	81
Ash	<1.5	1.00	0–2	0.86	NA	0.89
Fat	0.5–3.0	1.50	0.5–2.0	1.36	NA	1.51
Carbohydrates	<1	1	0–2	<0.23	NA	2.18

CAA notes FSANZ’s conclusion that:

*“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.”<sup>26</sup>*

## 6. Proposed Regulatory Provisions

### 6.1 Labelling

CAA agrees with FSANZ that labelling is an important mechanism to build trust and confidence in future foods, by providing clear and transparent information to consumers. However, CAA’s views diverge from FSANZ on the mandating of terms, and the term itself.

CAA supports FSANZ’s position that:

<sup>26</sup> FSANZ (2023) “Hazard and risk assessment – Application A1269 Cultured quail as a novel food” Supporting document 1, December 2023, S 5.2, pg 50

- If the food for sale *is not* represented as a quail food product—apply the existing food name requirements.
- If the food for sale *is* represented as a quail food product—in addition to generic food name requirements, that a qualifying term be required. (CAA interprets this as applying to the food name and front-of-pack labelling).

Similarly, CAA supports the proposal to require a qualifying term for identification purposes in the *statement of ingredients*. Further, we believe that any term used in the qualification of an *ingredient* must match that used in a *food name* to avoid potential confusion.

CAA agrees that as per Section 3.4 of Supporting Document 4 – Labelling, the term ‘meat’ should be permitted in product labelling, for use on the label of the food, either in the name of the food or as part of the ingredient name, when accompanied by a qualifying statement.

However, CAA does not support the proposal to mandate any qualifying term/s, nor FSANZ’s preference for the term ‘cell-cultured’, with regards to the *food name* or the *statement of ingredients* at this stage.

We believe that the inclusion of a single mandatory qualifier is premature given the nascency of the sector and the current global divergence in language. It should be sufficient for FSANZ that the product be described using descriptors that accurately reflect “the true nature of the food” as per the requirement of the Code.<sup>27</sup>

In its assessment, FSANZ notes that Singapore is the only country to establish labelling requirements for cell-cultured food, requiring pre-packaged alternative proteins to be labelled with suitable qualifying terms such as ‘cultured’ or ‘cell-based’ to indicate their true nature.<sup>28</sup> Notably, Singapore provides guidance regarding qualifying descriptors without mandating any specific terms. CAA notes in this assessment that FSANZ has taken a view contrary to that of a more advanced jurisdiction by proposing to mandate a single term for labelling these products.

CAA also notes that FSANZ has previously signalled its willingness to work with other jurisdictions to achieve global consistency, where possible, in relation to regulatory

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<sup>27</sup> Australian Government (1991) [Food Standards Australia New Zealand Act 1991](#)  
 “Food Standards Code” (version July 2023) S1.1.2 <https://www.legislation.gov.au/F2015L00385/latest/text>  
 (accessed 27 January 2024)– S 1.2.2-2 Name of the Food

<sup>28</sup> FSANZ (2023) “Labelling – Application A1269 Cultured quail as a novel food” Supporting document 4, December 2023, p6

matters for cellular agriculture products. Mandating 'cell-cultured' as the single required qualifier does not support this.

Moreover, consumer research on the most accurate and accepted terminology is also highly limited. Language in this sector is clearly divergent and evolving, hence it is our view that to mandate a single qualifying statement for a food name or ingredient labelling purposes would be premature and counterproductive at this time.

CAA sees merit in the evolution of labelling requirements over time but that this should be research and industry-led due to the nascency of the sector. It is our view that organisations such as CAA and the Alternative Proteins Council have a role to play 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. CAA has already commenced work in this area through its Language Guide,<sup>29</sup> which includes input from industry stakeholders throughout the Asia-Pacific region, and we believe should underpin future labelling guidance.

However, given the current absence of an informed evidence base and labelling guidelines, CAA believes an interim measure should be implemented and that 'cultivated,' 'cell-cultivated,' 'cultured,' and 'cell-cultured' should all be deemed acceptable (for both the food name and statement of ingredients) for the purposes of this application. Beyond this application, CAA submits that labelling be industry-led, as explained above.

Relating to the interim measure and our disagreement over the proposed use of "cell-cultured", we outline the merits of 'cultivated' (in particular) and (to a lesser extent) 'cell-cultivated' below:

- The majority of Australian industry stakeholders with whom CAA has consulted support the term 'cultivated' over 'cultured' (with Vow being the notable exception) due to higher levels of consumer appeal and acceptance. This is also reflected in the regional 2022 Memorandum of Understanding on the use of the descriptor 'cultivated' signed by 36 signatories. CAA is of the view that nomenclature should be industry, not regulator-led.
- When considering the term most identifiable to consumers that most accurately speaks to the production process, FSANZ's review fails to consider that the term 'cultured' is often associated with traditionally fermented products, particularly dairy products such as kefir and yoghurt. Thus, the use of 'cell-cultured' carries the risk of confusing consumers based on its potential for association with existing

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<sup>29</sup> <https://www.cellularagricultureaustralia.org/resources/key-terms>

product types, which may cause consumer confusion. On the contrary, 'cultivated' or 'cell-cultivated' benefits from increased novelty in the context of food, potentially leading to less confusion.

- CAA disagrees with discounting 'cultivated' based on concerns about future production processes involving post-harvest cell-mixing and 3D printing. CAA sought guidance from cell cultivation experts and confirmed that if 3D printing is used to make final products, it is highly likely that bioreactors will still be used due to their efficiency, as a large amount of culture dishes and manual labour would otherwise be required for 3D printing.
- CAA disagrees with reducing preference for 'cultivated' based on lower consumer identification in relation to seafood products. The research and development of cultivated fish and seafood is considerably behind that of cultivated meat products. Furthermore, no cultivated seafood companies are operational in Australia or New Zealand. The precedence of other meat products will mitigate the potential for product misidentification and confusion when fish and seafood products are finally made available for sale.
- CAA prefers the qualifying term be used without the prefix 'cell-.' FSANZ consumer research found that terms without the prefix 'cell-' perform better from a consumer acceptance standpoint. Consumer acceptance should be a factor in determining terminology, and disregarding it risks stifling the growth of this nascent industry.
- Companies in Singapore and the United States have received approval for the qualifying statements 'cultivated' and 'cell-cultivated' respectively. In January 2024, Aleph Farms received approval from Israel's Ministry of Health for its cultivated beef steaks. At the time of writing, the Ministry of Health had not released its assessment nor provided public advice on any required qualifying terms (CAA understands this information will be released in the coming months). However, Aleph Farms refers to the product in media statements as "cultivated beef steaks" and "cultivated Petit Steak." Hence 'cultivated' and 'cell-cultivated' are clearly valid and preferred terms in other jurisdictions.

Importantly, CAA acknowledges the potential benefit of mandating specific qualifiers in the code to describe both food name and ingredients in the future, if deemed necessary. However, it is important to reiterate that we do not believe the mandating of specific terms in the Code should be used as a preemptive measure.

CAA would also like to note that if FSANZ chooses not to follow these recommendations and instead chooses to mandate a qualifying term/s at this time, we strongly believe that

this should not be limited to the single term 'cell-cultured' but expanded to allow multiple terms including 'cultivated', 'cultured, and 'cell-cultivated'.

Overall, CAA believes that this proposed approach would ensure that any language used not only indicates the true nature of the food and manages any risks to consumers but also builds consumer acceptance and can evolve in parallel with future consumer-research findings and global trends.

## **7. Contact**

Cellular Agriculture Australia prepared this submission with technical input from James Ryall, Ph.D.

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